RPM

RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT

RAPID PHARMACEUTICAL MANAGEMENT ASSESSMENT: AN INDICATOR-BASED APPROACH

MSH
MANAGEMENT SCIENCES FOR HEALTH

USAID
U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

SINCE 1820
UNITED STATES PHARMACOPEIA

THIS PUBLICATION WAS MADE POSSIBLE THROUGH SUPPORT PROVIDED BY THE U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT, UNDER THE TERMS OF COOPERATIVE AGREEMENT NUMBERS HRN-5974-A-00-2059-00, AND HRN-0004-A-00-5002-00 (MSH); AND HRN-5974-A-00-2052-00, AND HRN-0004-A-00-5001-00 (USP). THE OPINIONS EXPRESSED HEREIN ARE THOSE OF THE AUTHOR(S) AND DO NOT NECESSARILY REFLECT THE VIEWS OF THE U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT.

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July 1995

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A.7 Practice of generic substitution (C/R/F)

Rationale: While in many countries generic substitution is not explicitly permitted by law, it does often occur. This indicator measures the practical acceptance of this important principle of cost reduction.

Definition: This indicator is defined as the prevalence of generic substitution practices, as described by either: (a) reports on this behavior by informed sources, or (b) observation based on simulated purchases.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH health facility	Pharmacy Dispenser or Pharmacist	Record of generic substitution behavior, or views on practice of generic substitution; direct observation through simulated purchase
20 drug retail outlets	Pharmacy Dispenser or Pharmacist	

Data to substantiate this indicator may be qualitative, gathered through *interviews* with dispensers; or quantitative, gathered through *simulated purchase surveys*. The obvious limitation of interviews is that most developing countries do not have laws explicitly permitting generic substitution, and informants may perceive risk in acknowledging the practice. The result will be under-reporting of this behavior. When interviews are used, it is suggested that questions be posed to both key informants at the central and regional levels, and to dispensers at the health facility or retail pharmacy level. This will provide a cross-check for assessing the probable validity of responses.

The most objective way to measure this indicator is to carry out a sample survey using the *simulated purchase* method. This is described in detail in chapter 4, section E, "Defining Approaches for Collecting Survey Data." To summarize, this requires a data collector, who pretends to be a patient, to visit a sample of dispensing sites, present a prescription for a brand name product, and ask the dispenser if it is possible to substitute a cheaper product for the one prescribed. Willingness to do this may suggest prevalence of generic substitution. In making this determination, however, only those cases wherein the substituted item is chemically equivalent to the one prescribed should be counted. For cases in which a different chemical compound is substituted for the prescribed product, the term which applies is "therapeutic substitution."

The simulated purchase method is best suited for retail settings because the dispensers there normally have several options for making substitutions, and this is often not the case in MOH facilities. In practice, therefore, it may be most feasible to gather data in MOH settings through interview, and gather data in retail settings through simulated purchase.

2

- ***Illegal***, if generic substitution is explicitly prohibited in both public and private sectors

Presentation: In country Y, Congressional Decree #85 was approved in 1991, amending the Public Health Code, and permitting pharmacists practicing in MOH facilities to substitute generic equivalents unless specifically indicated otherwise on the prescription.

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ACKNOWLEDGMENTS

This manual could not have been created, tested and revised without the assistance of a large number of interested professionals. We take pleasure in acknowledging the important contributions made by the following organizations and individuals.

United States Agency for International Development

Two USAID staff members deserve special mention for their roles in this activity. **Nicholas Studzinski** provided instrumental leadership in getting the work started through the Latin America/Caribbean Health and Nutrition Sustainability Project. **Anthony Boni** has provided unfailing support for continued development through the Rational Pharmaceutical Management Project.

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Gill Walt
Krisantha Weerasuriya
Agathe Wehrli
Albert Wertheimer
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Richard Wilson
Alonzo Wind
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EXECUTIVE SUMMARY

A. Purpose

This manual presents an indicator-based approach for rapidly assessing pharmaceutical management systems and programs. Such assessments have a number of potential applications, including:

- Defining the status of the pharmaceutical system, including strengths and weaknesses, for managers and donors
- Designing and planning interventions
- Defining budget or resource requirements
- Monitoring changes in systems and the impact of interventions
- Comparing the performance of different systems, programs, or countries

Rapid assessments may be indicated when the existing management information system is unable to track the performance of the pharmaceutical system, or when urgent drug problems are evident. The assessment should result in an analysis of why the problems that exist have come to pass, which problems can be solved, and what interventions are feasible in terms of cost-effectiveness and sustainability.

B. Scope

The manual presents a set of 46 indicators of performance, grouped under eight topics of pharmaceutical management, which are listed below.

- Policy, Legislation and Regulation
- Formulary/Essential Drug Lists and Drug Information
- Ministry of Health Budget and Finance
- Ministry of Health Pharmaceutical Procurement
- Ministry of Health Pharmaceutical Logistics
- Patient Access and Drug Utilization
- Product Quality Assurance
- Private Sector Pharmaceutical Activity

Each topic is covered by a subset of indicators. Thirty-four of the indicators are quantitative, that is, expressed as numbers. Twelve are qualitative, in that they describe the presence or absence of a policy or management system, and in some cases, the degree of implementation.

Carrying out an assessment that includes all 46 indicators will provide a reasonably complete overview of pharmaceutical systems operations in a given country. It is also valid to use the subsets of indicators selectively, according to need. This approach could be used for focused assessments based on, for example, the indicators for logistics or the indicators for drug utilization.

C. Development Process

In developing this manual, our overall objective has been to produce a concise set of proposed indicators for use in the context of a rapid assessment method that can be carried out in a reasonable period of time by non-specialists. To be useful over the long run, it is necessary that each of the indicators in the set meet the following criteria.

- **Importance** - Each indicator must reflect an important dimension of performance.
- **Measurability** - Indicators must be measurable, within constraints of time and variable quality and availability of data.
- **Reliability** - Each indicator must be reliable over time and with different observers.
- **Validity** - Each indicator must allow a consistent and clear interpretation and have a similar meaning across different environments.

To meet these criteria, we began by soliciting recommendations from a panel of over 150 professionals working internationally in drug management, who subsequently produced a preliminary list of over 200 items. From this list, we distilled a list of 33 indicators for field testing. Next, teams of international and local experts carried out assessments in 11 countries, including Guatemala, Ecuador, El Salvador, Nicaragua, Jamaica, the Organization of Eastern Caribbean States, Ghana, Mozambique, Nepal, Cambodia and Russia. Based on the outcomes of these field tests, we made revisions, added new indicators and produced the current set of 46 indicators presented in this manual. The work was done in close collaboration with PAHO, with a view to harmonizing this set of indicators with data collected by PAHO in a survey of Central American countries.

D. Intended Users of this Manual

Depending on the purpose and context of assessment activities, likely users of this manual include:

- Ministry of Health (MOH) decision makers, health planners, health economists, donor representatives, or experts responsible for project design and evaluation activities

- System managers at the national, regional or local levels wishing to measure the performance of specific systems or activities, such as drug registration, product selection, procurement, stock record keeping or prescribing

- Social scientists, and health project or facility managers who are interested in operational research and management tools

Other potential "users" of this manual are "system participants" who might benefit from the specific findings that an indicator-based assessment produces. For example, indicators measuring the performance of stock record keeping systems or prescribing practices can be usefully reported to staff at warehouses or clinical facilities to give them an idea of how their own performance compares with that of others.

Users have basically three options for gathering data for the indicators study:

- Structured Assessment - Field visits by a dedicated team that makes use of structured survey instruments
- Limited Assessment - Interviews, document review using less formal assessment methods
- Self-Assessment - Informal questionnaires and working groups to determine the nature and extent of the problems

E. Contents

The manual is designed to take users step-by-step through the assessment process, beginning with introducing the concept of indicator-based assessments, and ending with producing an assessment report. There are five chapters in the manual:

I. Introduction: Provides background on the history of indicator-based assessments and the development of this manual.

II. Indicators Description Format: Defines the standard format for presenting the indicators.

III. Detailed Descriptions of the Indicators: Explains, for each indicator, the rationale, definition, data collection, computation, and sample presentations of results.

IV. Guidelines for Study Design: Provides details for survey design and data collection activities.

V. Implementation of an Indicators Study: Covers the practical problems of carrying out an assessment, including logistical arrangements and recruiting and training data collectors.

I. INTRODUCTION

This manual is the result of an ongoing effort to develop and test a rapid assessment method based on a set of process and outcome indicators that can be used to monitor and compare significant aspects of pharmaceutical systems. The work has been done under the auspices of two projects financed by the United States Agency for International Development (USAID).

Initial development and field testing of 33 indicators, and various methods for data collection, were done by a working group led by the Management Sciences for Health Drug Management Program and the Harvard Drug Policy Research Group, with support and guidance from the Latin America/Caribbean Health and Nutrition Sustainability Project (LA/C-HNS), a USAID-funded project managed by University Research Corporation. Input into the first draft list of indicators was also provided by the Ghana and Indonesia Core Groups of the International Network for Rational Use of Drugs (INRUD).

Additional field tests, and revisions of both methods and the manual itself, have been accomplished through country pharmaceutical sector assessments performed by the USAID-financed Rational Pharmaceutical Management Project (RPM), which is composed of cooperative agreements with Management Sciences for Health (MSH) and the United States Pharmacopeial Convention, Inc. (USP). As a result, the original set of indicators has been expanded to 46. This set is given as Table 1 (page 9). As of December 1994, data have been collected in nine countries, and the results are presented in Table 2 (page 11). The method has subsequently been applied in Cambodia and Russia, but the data from these assessments have not yet been incorporated into the comparison matrix.

As a review of these two tables shows, the indicators are grouped under eight topics of drug management:

- Policy, Legislation and Regulation
- Formulary/Essential Drug Lists and Drug Information
- Ministry of Health Budget and Finance
- Ministry of Health Pharmaceutical Procurement
- Ministry of Health Pharmaceutical Logistics
- Patient Access and Drug Utilization
- Product Quality Assurance
- Private Sector Pharmaceutical Activity

In reviewing Table 2, it is important to note that, as the indicator set has undergone testing and revision, a number of indicators have evolved. In general, this evolutionary process has been in the direction of more specificity and focus, based on the data actually available. One consequence of this is that, in some cases, indicator data collected in earlier tests are not complete enough for purposes of expressing the revised indicators. Where this has occurred, the decision has been made to not include the incomplete data in the table. Although this produces gaps in the presentation, it maintains the quality and integrity of the data set.

A. Background

Pharmaceutical supply systems in many developing countries have severe problems, including ineffective procedures in selection, poor quality control, and economically inefficient procurement. This has been documented in numerous reports and publications.[1] Nonetheless, there has been no standard method for measuring the effectiveness of these systems. The LA/C-HNS and RPM work described in this manual builds on and complements other activities directed at developing indicators for pharmaceutical systems and sectors.

Indicators have been used for years in "developed" countries to measure aspects of pharmaceutical systems. Notable examples of organizations that have used indicators in the United States include the U.S. Public Health Service, Division of Health Care Delivery, the Joint Commission on Accreditation of Healthcare Organizations, and the American Society of Hospital Pharmacists. The focus of the indicators developed by these organizations is relatively specific to U.S. institutions.

The World Health Organization, and in particular the WHO Action Programme on Essential Drugs, have recognized the need for formal indicators that would facilitate comparative analyses of developing country pharmaceutical systems. In 1988, WHO published the *World Drug Situation*, which presented an impressive amount of useful information, organized into an indicator format.[2] These indicators were, in most cases, not presented in a quantitative format, but this work stimulated widespread interest in the concept of pharmaceutical system indicators.

In the fall of 1994, the WHO Action Programme on Essential Drugs issued a draft manual, entitled *Model Indicators for Monitoring National Drug Policies*, which proposes a set of 31 background indicators, 50 structural indicators, 38 process indicators, and 10 outcome indicators.[3] These indicators are intended for self use by developing countries to monitor their pharmaceutical systems. The WHO Action Programme on Essential Drugs 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 - Paris, France) to develop these indicators. Field testing is planned for 1995.

The Australian government has recently adapted the WHO indicator format to develop its own set of drug policy indicators for use in Australia.[4] This set has 41 process indicators, 27 impact indicators and 6 outcome indicators. In this model, <u>process indicators</u> are equivalent to WHO structural indicators, and <u>impact indicators</u> are similar to WHO process indicators.

Another group active in developing and testing indicators is the International Network for Rational Use of Drugs (INRUD). INRUD is a network promoting rational drug use in developing countries, involving 10 African and Asian member countries. It is coordinated by MSH, with additional technical support provided by the Harvard Drug Policy Research Group, the Karolinska Institute, the University of Newcastle, and the WHO Action Programme on Essential Drugs. Network sponsors include Danida, WHO, USAID, SIDA, and the Pew Charitable Trusts. INRUD developed and field tested a set of indicators related to drug use review in primary care health facilities. 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*.[5] These indicators also form the core of drug use assessment in this manual.

In addition, the Pan American Health Organization (PAHO) sponsored a multi-country project to develop and test indicators which could be used to measure progress of Essential Drugs Programs in Central America. The data from this work were collated and assembled by the PAHO Essential Drugs Advisor for the subregion. In October 1993 LA/C-HNS, RPM and PAHO technical staff met for the purpose of standardizing terminology and methods. The indicators in this manual were modified according to the recommendations made at this meeting, and, in light of the more advanced stage of development and testing of the MSH indicators and their compatibility with PAHO's previous effort, the Regional Essential Drugs Program discontinued its field work in this area. Subsequently, in August 1994, PAHO technical staff responsible for PAHO/WHO Essential Drugs Programs in Latin America met in Lima, Peru, and agreed that the revised RPM and LA/C-HNS indicators would be used, as required, for purposes of program development and evaluation. PAHO will be collaborating in workshops and other activities to promote the use of the indicators by the managers of national Essential Drugs Programs.

Discussions have also taken place with the WHO Action Programme on Essential Drugs to explore the possibility of harmonizing the terms and methods used in this manual with those used in *Model Indicators for Monitoring National Drug Policies*. The two methods are complementary rather than competitive, in that they have different approaches to data collection. The RPM/LA/C-HNS approach is primarily a rapid assessment method, while the WHO approach relies on self reporting by country officials. It is expected that steps toward harmonization will occur after the WHO Model Indicators are field tested.

B. Objectives

The goal of the LA/C-HNS and RPM indicators development process is to develop an indicator-based rapid assessment methodology that can be used by developing country managers, international agencies, and donors to monitor pharmaceutical systems on a regular basis. This means that the indicator set and assessment methodology should be as concise as possible, so that the data can be collected in a reasonable time frame.

There are four general criteria for useful indicators, which are listed below.

- **Importance** - Each indicator must reflect an important dimension of performance. Certain data may be readily and consistently available, but say nothing important about the system performance.

- **Measurability** - Each indicator must be measurable, within existing constraints of time and variable quality and availability of source data.

- **Reliability** - Each indicator must be reliable over time and with different observers. If one observer reports a certain result from a set of data, it is expected that a second observer will report the same result.

- **Validity** - Each indicator must allow a consistent and clear interpretation and have a similar meaning across different environments.

It is important to recognize that, although the term "indicators" is used for convenience, the indicators proposed are not yet indicators in the truest sense, but rather they are standardized measurements of a local pharmaceutical system. There is not enough data available yet to be able to establish normative ranges for any of the measures, or to determine which of the measures have sufficient diagnostic worth to be regarded as standard indicators. For example, we may be able to say that a country has a national formulary with 400 discrete drug products, 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 well functioning pharmaceutical system.

As more data are gathered using consistent methods, it should become possible to determine to what extent these proposed standard measurements meet the criteria of **importance, measurability, reliability,** and **validity**, and to begin to establish normal ranges of performance for each of the indicators.

C. Cautions

It is important to keep in mind that this list of indicators, like any other, has limitations. When interpreting the data presented in Table 2 (page 11), or indicator data which users of this manual may collect themselves, four important cautions should be observed:

- First, when collecting indicator data, it is essential to systematically collect descriptive background information. Such information is often required for usefully interpreting individual indicators. For example, consider indicator G.3, "Existence of a formal system for reporting product quality complaints." The indicator may be recorded as ***limited***, indicating that such a system formally exists but does not function regularly in practice. Specificity can be added by providing background information, as in the following illustrative example:

  In country Y, the Drug Regulatory Authority is mandated by the health code to monitor and take action on product quality complaints. The status of this system is at best ***limited****, because no standard reporting forms exist, and only one complaint was received during the twelve months preceding the assessment. There was no evidence of follow up action.*

- Second, to place the pharmaceutical indicator data in context, additional information about the local situation may be required. The indicators described here are not intended to stand alone, but rather to be used in conjunction with compilations of social and health indicators such as the World Bank *World Development Report*.

- Third, it should not be assumed that the indicator data must be collected on an all-or-nothing basis. For example, if for some reason the indicators in section H, "Private Sector Pharmaceutical Activity" cannot be collected, it is still worthwhile to collect the indicators covering the public sector system. In fact, one recent application of the indicator set, carried out in Cambodia, demonstrated that selected indicators could be drawn from various sections of the overall set to meet the needs of local decision makers.

- Fourth, not all of the indicators may be reliably compared from country to country and region to region. Indicators for drug prices, drug availability, stock record keeping and drug use may be usefully compared across a spectrum of countries when supplemented with appropriate background information. Financial indicators, however, should be compared with great caution because public and private sector financial contexts are so complex and vary so significantly from country to country, and region to region.

Table 1: List of Pharmaceutical System Indicators

A. POLICY, LEGISLATION AND REGULATION
1. Existence of a national drug policy approved by the government
2. Existence of comprehensive drug control legislation, regulations and enforcement agencies
3. Percentage of unregistered drug products in a sample of private sector drug retail outlets
4. Type of drug registration information system
5. Number of drugs registered
6. Law permitting generic substitution by pharmacists
7. Practice of generic substitution

B. FORMULARY/ESSENTIAL DRUGS LIST AND DRUG INFORMATION
1. Number of unique drug products on the National Drug Formulary List
2. Existence of an official manual, based on the National Drug Formulary List, providing basic drug information to prescribers, revised and published within the last five years
3. Percentage of MOH health facilities visited with the most current edition of an official manual based on the National Drug Formulary List
4. Existence of drug information centers that provide unbiased and current information to public health decision makers, health care providers and consumers

C. MINISTRY OF HEALTH BUDGET AND FINANCE
1. MOH budget or expenditures on pharmaceuticals, US$ per capita
2. Existence of a system for recovering the cost of drugs dispensed in MOH health facilities
3. Percentage of patients who pay a charge for drugs they receive in MOH health facilities
4. Percentage of total government recurrent budget used for Ministry of Health
5. Percentage of total MOH recurrent budget allocated to pharmaceuticals

D. MINISTRY OF HEALTH PHARMACEUTICAL PROCUREMENT
1. Existence of a policy limiting MOH pharmaceutical procurement to drugs on the National Drug Formulary List
2. Percentage by value of MOH drugs purchased through a central procurement system
3. Percentage of average international price paid for last regular procurement of a set of indicator drugs
4. Percentage by value of MOH drugs purchased through competitive tender

E. MINISTRY OF HEALTH PHARMACEUTICAL LOGISTICS
1. Weighted average percentage of inventory variation for a set of indicator drugs in MOH storage and health facilities
2. Average percentage of individual variation for a set of indicator drugs in MOH storage and health facilities
3. Average percentage of stock records that corresponds with physical counts for a set of indicator drugs in MOH storage and health facilities
4. Average percentage of a set of unexpired indicator drugs available in MOH storage and health facilities
5. Average percentage of time out of stock for a set of indicator drugs in MOH storage and health facilities

F. PATIENT ACCESS AND DRUG UTILIZATION

1. Population per functional MOH health facility that dispenses drugs
2. Population per licensed pharmacist or pharmacy technician in the public sector
3. Population per authorized prescriber in the public sector
4. Average number of drugs prescribed per curative outpatient encounter in MOH health facilities
5. Percentage of drugs prescribed by generic name in MOH health facilities
6. Percentage of drugs prescribed from the National Drug Formulary List in MOH health facilities
7. Percentage of outpatients prescribed injections at MOH health facilities
8. Percentage of outpatients prescribed antibiotics at MOH health facilities
9. Percentage of prescribed drugs presented for dispensing that are actually dispensed in MOH health facilities

G. PRODUCT QUALITY ASSURANCE

1. MOH drug product quality laboratory tests during the past year: (a) number of drug products tested, and (b) total number of drug product quality tests performed
2. Use of WHO Certification Scheme
3. Existence of formal systems for reporting: (a) product quality complaints, and (b) adverse drug reactions (ADRs)

H. PRIVATE SECTOR PHARMACEUTICAL ACTIVITY

1. Population per licensed private sector drug retail outlet
2. Number of licensed or registered drug retail outlets per government drug inspector
3. Percentages of drug manufacturers, distributors, and drug retail outlets inspected during a one-year period
4. Total value of private sector retail pharmaceutical sales, US$ per capita
5. Combined value of public sector pharmaceutical expenditures and private sector retail sales, US$ per capita
6. Percentage of products on National Drug Formulary List that are currently manufactured or co-manufactured within the country
7. Average of median private sector drug retail prices as a percentage of MOH acquisition prices for a set of indicator drugs
8. Existence of price controls for drugs in the private sector
9. Percentage of licensed drug retail outlets where an antibiotic was available without a prescription

TABLE 2: PHARMACEUTICAL INDICATORS SET: COMPARISON OF SELECTED COUNTRIES

	MOZAMBIQUE 1993	GHANA 1993	ECUADOR 1992	ECUADOR 1994	EL SALVADOR 1993	GUATEMALA 1992	NICARAGUA (A) 1994	JAMAICA 1992	OECS (B) 1993	NEPAL 1993
A. POLICY, LEGISLATION AND REGULATION										
1. Existence of a national drug policy approved by the government	No	No	Yes	Yes	No	Yes	No		No	No
2. Existence of comprehensive drug control legislation, regulations and enforcement agencies	No	Yes	Yes	Yes	No	Yes			No	Yes
3. % of unregistered drug products in a sample of private sector drug retail outlets	N/A	N/A	0%	N/A	23%	7.3%		21%	100%	
4. Type of drug registration information system	None	Manual	Mixed	Mixed	Manual	Computerized		Manual	None	Manual
5. Number of drugs registered		1,574			19,700	7,006				11,000+
6. Law permitting generic substitution by pharmacists	N/A	No	No	No	No	No	No	No	No	No
7. Practice of generic substitution										
B. FORMULARY/ESSENTIAL DRUGS LIST AND DRUG INFORMATION										
1. Number of unique drug products on National Drug Formulary List	383	222	438	438	284	428	234	1,010	388	261
2. Existence of an official manual, based on the NDFL, providing basic drug information to prescribers, revised and published within last 5 years	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
3. % of MOH health facilities visited with the most current edition of an official manual based on the NDFL	100%	45%	25%	70%	0%	0%	7%	N/A	100%	N/A
4. Existence of drug information centers that provide unbiased and current information to public health decision makers, health care providers and consumers	No	No	No	No	Yes	Yes	Yes		No	No
C. MINISTRY OF HEALTH BUDGET AND FINANCE										
1. MOH budget or expenditures on pharmaceuticals, US$ per capita	$ 0.62	$0.46 (C)	$0.09	$0.25	$4.96	$3.93	$1.13	$1.98	$5.50	
2. Existence of a system for recovering the costs of drugs dispensed in MOH health facilities	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes
3. % of patients who pay a charge for drugs they receive in MOH health facilities					N/A	N/A	0%	N/A		
4. % of total government recurrent budget used for MOH	6%	14%	8%		15%	15%		3%	12%	4%
5. % of total MOH recurrent budget allocated to pharmaceuticals	2%	No budget	1%		4%	26%	16%	8%	6%	

All dollar amounts are in U.S. dollars.
N/A indicates that information was not available despite attempts to collect it.
Blanks indicate that these indicators were not part of the original studies.
Grey shading indicates that the indicator is new or has been changed since the assessment, as a result of field tests. For some indicators, data is available from information already collected.

(A) Nicaragua results are based on data collected for the USAID-funded Decentralized Health Services Project. They include two regional/intermediate medical stores and 20 health facilities. These results may or may not represent the country as a whole.
(B) OECS is the Organization of Eastern Caribbean States. The countries studied included: Dominica, Grenada, Montserrat, St. Kitts and Nevis, St. Lucia, and St. Vincent and the Grenadines.
(C) Ghana CMS purchases only; there were also substantial direct purchases by regional stores and health facilities.

TABLE 2: PHARMACEUTICAL INDICATORS SET: COMPARISON OF SELECTED COUNTRIES

		MOZAMBIQUE	GHANA	ECUADOR	ECUADOR	EL SALVADOR	GUATEMALA	NICARAGUA (A)	JAMAICA	OECS (B)	NEPAL
		1993	1993	1992	1994	1993	1992	1994	1992	1993	1993
D. MINISTRY OF HEALTH PHARMACEUTICAL PROCUREMENT											
1. Existence of a policy limiting MOH pharmaceutical procurement to drugs on NDFL		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. % by value of MOH drugs purchased through a central procurement system		100%	N/A	<50%	<50%	80%	27%		80%	100%	N/A
3. % of average international price paid for last regular procurement of a set of indicator drugs		76-205%	79%	161%		114%	164-371%		145%	147%	63%
4. % by value of MOH drugs purchased through competitive tender		91%	45% (D)	45%	28%	80%	10%		95%	100%	50%
E. MINISTRY OF HEALTH PHARMACEUTICAL LOGISTICS											
1. Weighted average % of inventory variation for a set of indicator drugs in MOH storage and health facilities	Tally:CMS	124%	0%						48%		
	RMS		3%					8%			
	HF		11%					8%			
	Ledger:CMS	159%	15%	3%		0%	5%			19%	
	RMS		5%		5%						
	HF		16%		38%						
2. Average % of individual variation for a set of indicator drugs in MOH storage and health facilities	Tally:CMS										
	RMS										
	HF										
	Ledger:CMS										
	RMS										
	HF										
3. Average % of stock records that corresponds with physical counts for a set of indicator drugs in MOH storage and health facilities	Tally:CMS								0%		
	RMS										
	HF										
	Ledger:CMS						14%				
	RMS				23%						
	HF										
4. Average % of a set of unexpired indicator drugs available in MOH storage and health facilities	CMS	67%	100%	93%		94%	93%		100%	79%	
	RMS	80%	87%	87%	72%	81%		89%		58%	
	HF	59%	60%	38%	46%	78%	60%	72%	95%		
5. Average % of time out of stock for a set of indicator drugs in MOH storage and health facilities	CMS		8%	79%		23%	32%		27%	15%	
	RMS		7%					21%			
	HF		11%		12%			13%			

All dollar amounts are in U.S. dollars.
N/A indicates that information was not available despite attempts to collect it.
Blanks indicate that these indicators were not part of the original studies.
Grey shading indicates that the indicator is new or has been changed since the assessment, as a result of field tests. For some indicators, data is available from information already collected.

(D) 87% of the Ghana central procurement was done competitively; about 52% of drugs purchased by regional stores came through the central agency. Thus, 45% of the MOH drugs were purchased competitively.

TABLE 2: PHARMACEUTICAL INDICATORS SET: COMPARISON OF SELECTED COUNTRIES

	MOZAMBIQUE 1993	GHANA 1993	ECUADOR 1992	ECUADOR 1994	EL SALVADOR 1993	GUATEMALA 1992	NICARAGUA (A) 1994	JAMAICA 1992	OECS (B) 1993	NEPAL 1993	INRUD Avg. (E)
F. PATIENT ACCESS AND DRUG UTILIZATION											
1. Population per functional MOH health facility that dispenses drugs	13,798	35,253	6,310	6,307	14,430	8,529	8,622	5,855	3,945	15,600	
2. Population per licensed pharmacist or pharmacy technician in the public sector											
3. Population per authorized prescriber in the public sector											
4. Average # of drugs prescribed per curative outpatient encounter in MOH health facilities	2.4	4.3	1.3	2.0	2.2	1.4	2.1	2.4	2.0	2.1	2.1
5. % of drugs prescribed by generic name in MOH health facilities	99%	59%	37%	39%	72%	71%	86%	40%	49%	44%	67%
6. % of drugs prescribed from the NDFL in MOH health facilities											
7. % of outpatients prescribed injections at MOH health facilities	20%	56%	17%	19%	7%	13%	10%	4%	2%	5%	25%
8. % of outpatients prescribed antibiotics at MOH health facilities	52%	47%	27%	42%	32%	27%	34%	30%	39%	43%	43%
9. % of prescribed drugs presented for dispensing that are actually dispensed in MOH health facilities	77%	86%					61%	92%	84%	83%	77%
G. PRODUCT QUALITY ASSURANCE											
1. MOH drug product quality laboratory tests during the past year:											
(a) number of drug products tested	N/A	<10	N/A	N/A	N/A	0			43	N/A	
(b) total number of drug product quality tests performed	N/A	N/A	N/A	N/A	3,042	0			N/A	960	
2. Use of WHO Certification Scheme	No		Yes	Yes	No	No	No		No	N/A	
3. Existence of formal systems for reporting:											
(a) product quality complaints	None	None	None	None	None	Limited	None	None	Functional	None	
(b) adverse drug reactions (ADRs)	No	No	No	Yes	Yes	No	No		Yes	No	
H. PRIVATE SECTOR PHARMACEUTICAL ACTIVITY											
1. Population per licensed private sector drug retail outlet	285,156	3,438	3,419	3,569	4,835	4,805		9,720	8,178		
2. Number of licensed or registered drug retail outlets per government drug inspector	19	262	13		no inspectors	947		63	1 Grenada inspect. (F)		
3. %s of drug manufacturers, distributors, and drug retail outlets inspected during a one-year period											
4. Total value of private sector retail pharmaceutical sales, US$ per capita	$ 0.08	N/A	$12.84	$18.98	$11.09	$10.98		$10.29	N/A		
5. Combined value of public sector pharmaceutical expenditures & private sector retail sales, US$ per capita	$ 0.85	N/A	$12.93	$19.23	$16.05	$14.91		$12.27	N/A		
6. % of products on NDFL which are currently manufactured or co-manufactured within the country	1%	70%	50%		50%	71%		15-20%	0%	7%	
7. Average of median private sector drug retail prices as a % of MOH acquisition prices for a set of indicator drugs											
8. Existence of price controls for drugs in the private sector	No	Yes	Yes	Yes			Yes		No		
9. % of licensed drug retail outlets where an antibiotic was available without a prescription		85%	100%	95%	100%	100%			N/A		

All dollar amounts are in U.S. dollars.
N/A indicates that information was not available despite attempts to collect it.
Blanks indicate that these indicators were not part of the original studies.
Grey shading indicates that the indicator is new or has been changed since the assessment, as a result of field tests. For some indicators, data is available from information already collected.

(E) INRUD Average is based on data collected by the International Network for Rational Use of Drugs in eleven countries from 1989 to 1992.
(F) Grenada has one inspector. The other OECS countries do not have any inspectors.

II. INDICATORS DESCRIPTION FORMAT

Chapter 3 presents detailed descriptions of each of the 46 proposed indicators, grouped under the eight topics identified in chapter 1. Each description follows exactly the same format, which is summarized below.

Indicator data can be collected at three different levels of the health care system. Each indicator in the descriptions that follow is coded according to the level at which it is measured, with the code appearing after the indicator title. The level codes used are:

C	Central level - under direct supervision of the central government
R	Regional or district level - acts as the intermediary; provides supplies to the health facilities and not directly to patients
F	Health facility level - provides direct care to the patient population

Indicator Name: The name of the indicator along with the different system levels that may be examined (for example, **C/R/F** signals that the indicator may be applied at the central, regional and health facility levels).

Rationale: The reason that the indicator is important.

Definition: The meaning of the indicator, and the terms used to describe this indicator.

Data Collection: The most likely source(s) of information are summarized in a table indicating *where* the data are to be collected, *who* to ask for assistance, and *what* documents and records to review.

Brief discussions of methods and issues related to data collection.

Citations of the data collection forms to be used, if any. Data for 18 indicators are collected using eight different forms. There is a discussion of how to develop the required forms in chapter 4, and examples given in Annex C.

Computation & Example: Computations, if any, which are needed, accompanied by an example using illustrative data.

Presentation: Brief example of how results may be presented.

Notes: Suggestions for additional information or discussion required to put the indicator in proper context, or to provide more detail.

III. DETAILED DESCRIPTIONS OF THE INDICATORS

A. Policy, Legislation and Regulation

A.1 Existence of a national drug policy approved by the government (C)*

Rationale: National drug legislation should be a guide to action in three areas: providing quality pharmaceuticals to the public, regulating control of pharmaceuticals, and supporting cost-effective management. To be effective, health policies should be based on reliable information. When approved by the appropriate authorities, the government explicitly commits itself to implement and enforce the policy. The health needs and priorities of the population change; therefore, policies need to be reviewed to ensure that they respond to changing needs. This indicator will assess the existence or absence of a document containing the national drug policy (NDP), as recommended by WHO. This is a measure of the government's political commitment to improving the pharmaceutical management in both the public and private sectors.

Definition: A national drug policy is a written document, officially approved by the national government, and used as the basis for current policy in the pharmaceutical sector. It has guidelines pertaining to three areas:

- Control of import, export, manufacture, and pricing of drugs, and of distribution, supply, storage and sale
- Authority for regulation of labelling, information and advertising, drug registration, scheduling of controlled substances, imposition of fees and price controls
- Drug control administration: organization and function, prescribing and dispensing restrictions, mechanisms of appeals against decisions

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Senior administrative official, Chief Pharmacist	Document(s) containing the National Drug Policy
Health Policy and/or Planning Office	Officer in charge	
Drug Regulatory Authority	Officer in charge of registry	
Central Government Registry or National Archives	Officer in charge	
Government official newspaper or gazette	Information Officer	Record of published dissemination of the NDP

This national drug policy should be identified through interviews with key officials and a search of records. A copy should be made available to the assessment team.

*See page 15 for description of codes.

Computation & Example: Record the existence of a national drug policy according to the following categories:

- ***Yes, WHO***, if a national drug policy along WHO guidelines exists (include year approved or revised)
- ***Yes, not WHO***, if a national drug policy exists, but does not follow WHO guidelines (include year approved or revised)
- ***In process***, if a WHO-style national drug policy is in the process of development (include expected date of completion)
- ***No***, if there is no national drug policy

Presentation: In country X, the national drug policy, which follows WHO guidelines, is described within the "Política Nacional del Sector Salud," approved by the National Health Council in 1988 and revised in October 1990. Thus country X is rated *yes, WHO*. The policy addresses issues regarding the supply of drugs and the control of importation and local manufacturing, but does not include the registration of drugs for sale in the country. A copy of the policy is attached in the annex.

Notes: The ideal way to present data for indicators such as this one is to record the rating plus annotation, such as dates. For example: *Yes WHO, 1989*. However, for relatively complex tables which compare data from several countries, such as Table 2 (page 11), this would result in a visually crowded presentation that would be difficult to read. In such cases it is best to present just the rating. When presenting data for just one country, however, it is more feasible to present both rating and annotation.

A.2 Existence of comprehensive drug control legislation, regulations and enforcement agencies (C)

Rationale: Drug control legislation and regulations, and functioning agencies that enforce them, are measures of a government's capacity to implement beneficial policies and practices in pharmaceutical management. If a government does not allocate financial resources or staff to the agencies charged with enforcing legislation and regulation, this suggests a situation where plans for pharmaceutical improvement will exist on paper but are not implemented in reality.

Definition: Comprehensive drug control legislation is defined as written, government-approved legislation and regulation applying to: drug manufacturing, registration, licensing, distribution, prescribing, and sales practices, as well as regulations assigning official responsibility for enforcement of these rules. A functioning drug regulation enforcement agency is one that has sufficient staff and funding to carry out policy mandates. Reports of its activities should be available, and discussions with its staff will indicate the extent of their activities.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Pharmaceutical Services Director/Chief/Secretary	Legislation and regulation documents, name of agency/persons in charge of enforcing them
Drug Regulatory Authority	Officer in charge of registry	
Ministry of Industry	Officer in charge of importation and control, registry of retail pharmacies, and of protection of local industry	Legislation documents, registers, and reports of inspections
Pharmacists Association and Pharmacy Owners Association	Association Executive, Director or Secretary Member pharmacists	Verification of awareness of drug control legislation and compliance with the laws

Through document review and interviews with the Chief Pharmacist in the MOH, the Head of the Drug Regulatory Authority, or other similar agency, determine if legislation exists in areas listed below, and which agency has been assigned responsibility for enforcing these regulations. If possible, check with the pharmacy association about awareness of and enforcement of these laws.

Computation & Example: Record the existence of drug control legislation, regulations and enforcement agencies for drug manufacturing, drug registration, drug distribution, authorization to prescribe drugs, authorization to sell drugs and drug marketing and promotion as follows:

- ***Yes***, if drug control legislation, regulations and enforcement agencies all exist (include relevant dates and titles of legislation, regulations or agency names)
- ***Partial***, if some of these elements are in place but others are not
- ***No***, if there is no drug control legislation, regulation, or enforcement agency

Presentation: In country A, the existence of components of drug control legislation was as follows:

Legislative Area	Legislation in Place	Enforcing Agency in Place
Drug manufacturing	Yes, Food & Drug Act, 1989	Yes, Pharmaceutical Supply Division, MOH (PSD/MOH)
Drug registration	Yes, Food & Drug Act, 1989	Yes, PSD/MOH
Drug distribution	Yes, Food & Drug Act, 1989	Yes, PSD/MOH
Authorization to prescribe drugs	Yes, Medicines Act, 1989	Yes, National Medical Association
Authorization to sell drugs	Yes, Medicines Act, 1989	Yes, National Pharmacy Council
Drug marketing and promotion	Yes, Medicines Act, 1989	YES, PSD/MOH

A.3 Percentage of unregistered drug products in a sample of private sector drug retail outlets (C)

Rationale: The percentage of unregistered drugs available for sale is a measure of the degree to which a government enforces its drug control policies and protects its people from products of uncertified quality and effect. High percentages of unregistered products indicate a regulatory agency that does not function effectively. This may be due to such factors as insufficiency of staff, financial resources or political will.

Definition: This indicator measures how completely drug registration regulations are being implemented. A product is considered officially registered when the drug is listed on an official register of products approved for sale or distribution in the country. Drugs not listed on this official register are considered to be unregistered. The indicator applies to all pharmaceutical drug products identified in national legislation as requiring registration, both legend (prescription required) and non-legend. Products classified as foodstuffs, diagnostics and medical supplies are usually excluded. Vitamins may or may not be included as pharmaceutical drug products.

Note: If drug registration is not required by law, this indicator is not relevant.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Pharmaceutical Services Director/ Chief Pharmacist	List of registered drugs, how often it is updated, purged, date of last entry, waiting list to be registered
Drug Regulatory Authority	Drug Registration Inspector	Review of drug registration information system, reports of sale of unregistered drugs, list of registered drugs
Private drug retail outlets	Pharmacist/Dispenser	Check products on shelf for number of unregistered drugs out of 200 selected brand names

Select a sample of 20 retail drug sales outlets. At each site select from the shelves 10 products, and record the complete name (both brand and generic), and name of manufacturer and/or supplier listed on the product label. If the law requires a product license number on the package, record this number from sample products. This gives a total sample of 200 products.

If working with more than one data collector, duplication can be avoided by assigning each data collector an exclusive range of letters of the alphabet, with instructions to select products within the assigned range. For example, if there are three data collectors (Joe, Mary, and Bob), then Joe selects only products starting with the letters A-H, Mary selects products starting with the letters I-Q, and Bob selects products starting with letters R-Z. Prior to the start of the assessment, all the data collectors should be instructed to carry out this part of the work at the same time.

See the "Drug Registration Data Form" in Annex C, page 139.

Computation & Example:

Compare the sample of 200 product names collected with the most current list or database of registered products. Check to see if any of the names in the sample are *not* registered. Record the number of unregistered products. Compute the percentage of unregistered sample products by dividing the number of unregistered products by the number of products sampled; multiply this quotient by 100 to obtain the percentage.

$$\text{\% of Unregistered Drug Products} = \frac{\text{Number of Unregistered Drug Products}}{\text{Number of Drug Products Sampled}} \times 100$$

$$\text{\% of Unregistered Drug Products} = \frac{14}{200} \times 100 = 7\%$$

Presentation:

In country A, 7% of the drug products, or 14 out of a sample of 200, selected during July 1993 were found to be unregistered.

A.4 Type of drug registration information system (C)

Rationale: The type and characteristics of the drug registration system a country has in place is a measure of the government's ability to collect and retrieve information on drug registration and use it to monitor and evaluate the degree to which policies and regulations are enforced. Computerized systems, when functional, are far more efficient in organizing and recovering information than manual systems. The degree of usefulness of the registration system is measured in terms of the speed, type and amount of information that it can generate to support decision-making and action.

Definition: A drug registration system should record pharmaceutical product information supplied for registration, including the name and contact information of the company which registered the drug, the name of the manufacturing company (if different from the company registering), the country where the product was manufactured, when it was registered, and complete product description (which includes therapeutic effect, dosage, side effects, and shelf life). A drug registration system should not be static. Manufacturers and distributors should periodically register their drugs; therefore, regular reviews ensure that drug information is up-to-date.

Note: If drug registration is not required by law, this indicator is not relevant.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Pharmaceutical Services Director/Chief/Secretary	A demonstration of how the registration system works, information (brand names, strengths and dosages, and companies that registered the drugs) about two or three common drugs selected by INN or generic name
Drug Regulatory Authority	Officer in charge of registry	
Ministry of Industry	Officer in charge of importation and control, and protection of local industry	Description of registration system

Interview personnel who work directly with the drug registration system. Ask them to show how the system works. To determine whether the system is *manual* or *computerized*, ask the following questions for two or three common drug products:

- How many manufacturers or suppliers have registered the drug under the generic name or a brand name?
- What are the strengths and dosage forms available?
- Which companies have registered the drug?

Watch to see if this information is obtained through consultation of files and ledgers (indicating a manual system) or through use of a computer. In some cases, the respondent may consult both manual files and a computerized data base in order to answer the questions; this is termed a *mixed* system.

Computation & Example: Describe the drug registration system as follows:

- ***Manual*** (include date established)
- ***Computerized*** (include date established)
- ***Mixed*** (include dates for establishment of the manual system, and introduction of computerized elements)
- ***None***, if no system is established

Presentation: In country A, the drug registration system is fully computerized. The system was established in 1989. The primary source document is the "Registration Application Form" submitted by the party wishing to register the product. One staff member enters the information from approved applications into the system. The system is menu-driven and designed to produce reports by a range of variables including brand and generic names, number of active ingredients, dosage forms, routes of administration, manufacturers and country of origin.

A.5 Number of drugs registered (C)

Rationale: The number of drugs registered is a rough measure of the functionality of a drug registration system and the degree to which the regulatory authority enforces drug control regulations. A relatively large number of registered products (in excess of 10,000) may indicate that (a) there is no effective effort to make sure only safe and effective products are registered, (b) products are not licensed for a specific time period, and in fact, many of the registered products may not really be marketed, or (c) the system is not being kept up-to-date, and products with expired licenses are not being purged from the records.

Definition: A drug registration system, either manual or computerized, should be able to produce an accurate figure for the total number of drugs registered for import and sale in a country. In order to usefully interpret this indicator it is necessary to gather background information on the contents of drug policies and regulations, as well as the degree to which staff are able to keep the registration information system current and up-to-date.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Pharmaceutical Services Director/Chief/Secretary	Determine terms of registration, number of drugs registered, frequency of license checks
Drug Regulatory Authority	Officer in charge of registry	Number of registered drugs, date of last check, number of drugs delisted
Ministry of Industry	Officer in charge of importation and control and of protection of local industry	Number of patented or registered drugs, duration of registration

The information for this indicator may be collected at the time when interviews are held to determine the type of drug registration information system. Ask for the total number of drugs registered for sale in the country, and verify the source of information and the method of calculating the number of registered products.

Computation & Example: Record the number of registered drugs provided by drug registration staff, obtained from the registration information system or other sources, as well as the source itself.

Presentation: In country A, there are 7,006 registered products, of which 5,898 are brand named and 1,108 are generically named, according to a computerized report produced by staff in the drug registration process upon request. Registration is renewed every five years. If the registration is not renewed, the product is delisted and manufacturer, health facilities and retailers are advised accordingly. Registration checks for expiry are carried out monthly.

A.6 Law permitting generic substitution by pharmacists (C)

Rationale: A generic product is any drug product unprotected by patent. Any manufacturer is therefore entitled to produce it. In the marketplace, drug products sold under generic name are almost always less expensive than brand name products. Generic substitution is the dispensing of a product, with the same active ingredients(s) in the same dosage form and strength, in place of the drug that is prescribed by brand name. The existence of a law or regulation that allows pharmacists to make generic substitutions is a means of promoting the use of relatively low cost, generically named products.

Definition: The written law or regulation must explicitly permit qualified pharmacists, or those practicing in designated settings, to substitute generic drug products for prescribed brand name products, only when the substituted drug is chemically equivalent to the one prescribed.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Pharmaceutical Services Director/Chief/Secretary	Document(s) that regulate generic prescribing or dispensing, views on level of compliance with regulation
Board of Pharmacy	Chairman	
Pharmacy Owners Association, Pharmacists Association	Executive Director, Secretary and/or members	

Use document review and interviews to determine the existence of a law or written regulation that allows generic drug products to be dispensed in place of brand name products. Note which settings are covered by this law or regulation. This indicator scores only the existence of such law(s) or regulation(s), not whether substitution of generic for proprietary drugs is actually practiced. A copy of such a document should be made available to the assessment team and/or as a reference in the MOH.

Computation & Example: Record the existence of a law permitting generic substitution by pharmacists as follows:

- ***Yes public and private***, if a written law or regulation permitting generic substitution in both the public and the private sector (pharmacies) exists (record name of law or regulation and year of enactment)
- ***Yes public***, if a written law or regulation permitting generic substitution only in public settings exists (record name of law or regulation and year of enactment)
- ***Yes private***, if a written law or regulation permitting generic substitution only in the private sector (pharmacies) exists (record name of law or regulation and year of enactment)
- ***No***, if such a law or regulation does not exist

See the "Generic Substitution and Sale of Antibiotics Data Form" in Annex C, page 143.

Computation & Example:

This indicator is recorded as a percentage, calculated as the number of dispensers who either: (a) state that they practice generic substitution; or (b) are observed to practice generic substitution, divided by the total number of dispensers in a sample, and multiplied by 100.

- For data collected through *interview*, the formula is:

$$\text{\% of Dispensers Acknowledging Generic Substitution} = \frac{\text{Number of Acknowledging Practice}}{\text{Total Number Interviewed}} \times 100$$

$$\text{\% of Dispensers Acknowledging Generic Substitution} = \frac{8}{20} \times 100 = 40\%$$

- For data collected through *simulated purchase surveys*, the formula is:

% of Dispensers Observed Practicing Generic Substitution =

$$\frac{\text{Number Making a Generic Substitution}}{\text{Total Number Purchases}} \times 100$$

$$\text{\% of Dispensers Observed Practicing Generic Substitution} = \frac{12}{20} \times 100 = 60\%$$

Presentation:

In country C, 40%, or 8 dispensers interviewed at a sample of 20 MOH clinical facilities, stated that they make generic substitutions when filling prescriptions. At the same time, 60%, or 12 drug sellers from a sample of 20 retail pharmacies, made valid generic substitutions, for brand name products, while 15%, or 3 drug sellers, substituted nonequivalent products.

B. Formulary/Essential Drugs List and Drug Information

B.1 Number of unique drug products on National Drug Formulary List (C)

Rationale: The number of unique drug products on a National Drug Formulary List (NDFL) or National Essential Drugs List (NEDL) is one measure of a country's commitment to rational resource allocation and to containing drug costs by using only essential and cost-effective products in the health care system. Sometimes, however, the term "Essential Drugs List" refers only to a list of products authorized for use in primary health care facilities. It is important, therefore, to understand how the terms related to essential drug lists are used before assuming that they meet the test of being equivalent to an NDFL.

Definition: The term NDFL refers to a listing of all the unique drug products approved for medical practice in MOH facilities in a particular country. Sometimes the NDFL will appear in a manual which contains a description for each product on the list. In countries where the MOH uses the term "National Essential Drug List," this is often the equivalent of an NDFL.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Director of Pharmaceutical and/or Medical Supplies Services	NDFL and/or NEDL
Central Medical Stores	Officer in charge/Director/Mgr.	

Determine whether a NDFL/NEDL exists. If so, study investigators must obtain copies to assess the number of drug products it contains. In order to make an accurate assessment, it is necessary to specify criteria for counting products containing the same active ingredient(s).

Products that are counted as the *same* item include:

- Brand name products that are chemically equivalent to generic products of the same strength and dose form appearing on the list. For example, Bactrim 400/80 mg tablets and co-trimoxazole 400/80 mg tablets are counted as the same product.
- Tablets and capsules of the same product appearing in the same strength. For example, ampicillin 500 mg tablets and ampicillin 500 mg capsules are counted as one product.
- Fixed combination drug products, no matter how many chemicals they contain. For example, a combination product, containing ergometrine and caffeine, is counted as one drug product.

Products that are counted as *different* items include:

- Different strengths of the same chemical entity. For example, tetracycline 250 mg capsules and tetracycline 500 mg capsules are counted as two products.
- Dosage forms for different routes of administration. For example, tablets and capsules (oral), suppositories (rectal), and injectable (IM/IV/SC) should each be counted as different drug products for a particular drug product.
- Different dosage forms for the same route of administration, such as tablets and suspensions. For example, ampicillin 500 mg tablets and ampicillin 50 mg/ml suspension are counted as two different drug products.

Computation & Example: The indicator is recorded as the total number of unique drug products on the National Drug Formulary List. Record the year of the most recent edition of the published NDFL. If no NDFL exists, this indicator would be recorded as *none*.

Presentation: Country A has a National Drug Formulary List with a total of 230 unique drug products listed. It was revised in 1993. There is also an Essential Drugs List for primary health care facilities with 35 unique drug products listed.

B.2 Existence of an official manual, based on the National Drug Formulary List, providing basic drug information to prescribers, revised and published within the last five years (C)

Rationale: The existence of a government produced or sanctioned manual with accurate, unbiased, and reasonably current information for prescribers concerning the drugs on the National Drug Formulary List is a measure of the official awareness of the need for drug information to promote rational use of the drugs available.

Definition: To qualify as an official manual for purposes of this indicator, a document must be intended as a clinical reference for health care providers and present the following information on drug products: pharmacology, chemical components, accepted indications, contraindications, side effects, and recommended dosages.

Any document which provides the information summarized above for the sub-set of drugs authorized for use in a given type of clinical facility meets the definition of manual for this indicator. Such documents might take the form of *formulary manuals (FM)*, which use the drugs on the list as the point of departure, and are organized by therapeutic categories of products. The manual could also be organized as *standard treatment guidelines (STG)*, which use health problems as the point of departure, and discuss the use of NDFL drugs to treat these problems.

In many countries, the drugs presented in the NDFL are classified according to level of use, with the greatest number of drugs authorized for use in hospitals with specialist physicians and the least number authorized for use in facilities staffed by paramedical workers. Accordingly, there may be FMs or STGs which cover subsets of the overall NDFL and which are aimed at particular groups of health care providers, such as paramedical staff working in rural health posts.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Director of Pharmaceutical and/or Medical Supplies Services, Director of Health Services	Most recent copy of manual

Such a manual must officially exist for this indicator to be meaningful. If so, obtain the most recent copy of the manual that has been prepared to provide impartial information about the drugs on the National Drug Formulary List. Evaluate whether or not the information in the manual meets all the following criteria, specified in the definition above:

- The document is intended as a clinical reference for health care providers
- The document presents therapeutic effects, chemical components, indications, contraindications, side effects, and recommended dosages for drug products

Computation & Example: Record the existence of an official manual, based on the NDFL, providing information to prescribers, and revised within the last five years, as follows:

- ***Yes***, if either a formulary manual, or standard treatment guidelines, which meet the definitions given above, exists and has been revised and published within the last five years. Record the type of manual (FM or STG) and the year in which the manual was published.
- ***No***, if:
  - A manual exists, but has not been revised within the past five years.
  - A manual is under production and incomplete.
  - A complete manual exists as an approved draft, but has not been printed or circulated.

Presentation: In country Y, a national formulary manual exists; it was revised in June 1992. The manual is intended for use by physicians, nurses and medical and nursing students. It contains information on indications, dosages and contraindications for 38 drugs. It lacks information on side effects or pediatric dosages.

B.3 Percentage of MOH health facilities visited with the most current edition of an official manual based on the National Drug Formulary List (F)

Rationale: The degree of distribution of a current edition of a manual providing unbiased information on products of the NDFL is a measure of the effort actually being made to effectively promote appropriate use of the drugs on the list.

Definition: This indicator measures the presence of the current edition of an official formulary manual in a given sample of health facilities.

Data Collection:

Where to go	*Who to ask*	*What to get*
20 MOH health facilities	Officer in charge	Most recent copy of manual

A manual, or manuals, covering products on the NDFL/NEDL, must exist in order for this indicator to be meaningful. As noted in the discussion of indicator B.2, such a document may take the form of either formulary manual or standard treatment guidelines. Data for this indicator are collected by survey of a sample of 20 health facilities. At each site, staff are asked to produce a copy of a document appropriate to their type of facility.

If a recent manual (revised within the past five years) does not exist (that is, the answer to indicator B.2 is *No*) then, if possible, record the presence of the most current edition of any manual which meets the definition.

See the "Inventory Data Form" in Annex C, page 147.

Computation & Example: This indicator is a percentage. It is computed as the number of facilities at which an official manual is found, divided by the total number of facilities in the sample; multiply this quotient by 100, to convert the decimal to a percentage.

$$\text{\% of Facilities with Official Manual} = \frac{\text{Number of Facilities with Official Manual}}{\text{Number of Facilities in Sample}} \times 100$$

$$\text{\% of Facilities with Official Manual} = \frac{5}{20} \times 100 = 25\%$$

Presentation: An indicator study carried out in country A revealed that in only 25% of health facilities, or five health facilities out of a sample of 20 surveyed, could staff produce a copy of the 1990 edition of the *Standard Treatment Guidelines*.

B.4 Existence of drug information centers that provide unbiased and current information to public health decision makers, health care providers and consumers (C)

Rationale: The existence of one or more drug information centers that provide unbiased and current information is a measure of the degree of access that exists to the information required for rational selection, procurement, and use of drugs.

Definition: A drug information center should maintain and provide current information for policy makers, prescribers, pharmacists and consumers on such topics as: indications, contraindications, dosage, adverse reactions, costs and sources, storage requirements, drug quality/purity, and actions to take for inadvertent administration and overdoses. The center may or may not be government operated, but to qualify according to this indicator, it should be freely accessible to health care providers of the system being surveyed.

In some countries, there are information centers which exist only to provide information on drug availability, that is, where drugs may be purchased, or otherwise obtained. There may also be centers operated by groups or associations which are intended only for use by members. Cases such as these do not meet the definition for this indicator.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH Drug Regulatory Authority MOH Dept. of Pharmacy Services	Director/Manager Chief Pharmacist	Information on the existence of the center and a description according to criteria listed below
MOH Information, Education, and Communication Department	Health Educator	
Schools of Medicine or Pharmacy	Professors	
Drug information center	Director	Information on services offered, utilization, resources, location, staffing and budget

Interview key informants to identify the drug information centers. Follow up with a brief visit to each site. Collect the following information:

- Location of the center and its affiliation (i.e., university, MOH, etc.)
- Principal users (i.e. Drug Regulatory Authority drug registration staff, hospital staff, medical students or the general public)
- Services offered and frequency of use
- Documented demand/quantity of services provided
- Types of equipment and information resources available, scope and currency
- Numbers and qualifications of staff
- Source of funding

Computation & Example: This indicator is recorded as follows:

- *Yes*, if one or more drug information centers that meet the definition for this indicator exist; record the number of such centers and describe any existing centers by providing the information stated above
- *No*, if no drug information center exists

Presentation: In country Q, there is one drug information center. It is located in the College of Pharmacy, and serves the University, the MOH, and the Board of Pharmacy. The center responds to requests and irregularly publishes a newsletter on new drugs. This center is staffed by one pharmacist, who has no formal training in providing drug information. The center has a typewriter but no computer. The information resources consist of twelve texts; the newest is five years old. Funds for the center are obtained from the MOH, the College of Pharmacy and WHO. Funds for resource acquisition are budgeted, but never spent. No records are kept to document the numbers and types of inquiries received.

C. *Ministry of Health Budget and Finance*

C.1 MOH budget or expenditures on pharmaceuticals, US$ per capita (C)

Rationale: The MOH's per capita budget or expenditures on drugs is a measure of the adequacy of financing for pharmaceuticals in the public sector. Government financing in many developing countries has decreased in recent years due to inflation and increase in population.

Definition: MOH per capita pharmaceutical expenditures are defined as the total amount of money (in US$ at the current rate of exchange) spent on pharmaceuticals by all MOH sources (national, regional and local budgets combined) **for the most recent financial year**, per individual in the population. MOH budget is defined as the budget for pharmaceutical purchases which was approved, not the requested budget. In many countries, only the approved budget figures will be readily available, but whenever possible, it is preferable to use expenditure data for calculating this indicator.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH/MOF	Budget Director, Health Planner	Budget and/or expenditures by budget category for most recent financial year(s), World Bank reports
Donors and NGOs	Health Financing Specialist, Logistics Specialist	
Bureau of Statistics	Census Director	Most recent population census figure, population projections for intercensal period

In most countries, the Ministry of Finance (MOF) publishes an annual report on budgets and expenditures. This source of information should be combined with interviews with relevant government officials and examination of historical documents to obtain a complete-as-possible accounting of total budget or expenditures on pharmaceuticals in the previous fiscal year. Valuation of donated products should be included, if their value was accounted for in the forward planning budget. This estimate must include budget or expenditures from all public sources at the central, regional, and local levels. Finally, obtain a reasonably reliable estimate of the current national population from the Bureau of Statistics or some other official source.

In collecting this data, keep the following points in mind:

- Although the indicator is for the budget or expenditures for the most recent financial year, if possible, the data should be collected for the preceding three to five years. This would give an idea of trends in financing.

- In some countries, there are as many as three budget figures: amount requested, amount sent forward, and amount approved. It is crucial to use the amount approved rather than either of the other two amounts.

- The value of donated drugs should be included in the indicator **only if the value of donations was included as a line item in forward budget planning or actual expenditures**. The practice on this point varies from country to country.

- If reliable current population estimates are not available locally, there are two options. The first is to obtain the last census figure, note the date, and calculate an estimated current population based on estimated annual population growth rates. The second option is to use the figures from the latest edition of the World Bank *World Development Report*.

Computation & Example:

The indicator is computed by dividing the total value of the MOH drug budget or expenditures for the most recent fiscal year (expressed in US$ at the current rate of exchange) by the national population. Be sure to stipulate whether the value represents actual expenditure or budget, and record the fiscal year on which the data are based.

$$\text{MOH Drug Budget Per Capita} = \frac{\text{Total of MOH Drug Budget}}{\text{National Population}}$$

$$\text{MOH Drug Expenditure Per Capita} = \frac{\text{Total of MOH Drug Expenditure}}{\text{National Population}}$$

$$\text{MOH Drug Expenditure Per Capita} = \frac{\$2{,}850{,}000}{3{,}694{,}000} = \$0.77$$

Presentation:

In country A, both budget and actual expenditure data for the most recent financial year were available. These data showed a pharmaceutical budget for fiscal year 1993 of $3,000,000, with actual expenditures being $2,850,000. In the same year, the MOH received $1,050,000 worth of donated drugs, including $500,000 from UNICEF, $500,000 from USAID and $50,000 from WHO. In accordance with local accounting norms, none of the donated drugs figured in budget projections or expenditure estimates.

The most current population estimate was from a census taken in 1990, which gave the figure 3,430,000. The MOH Family Planning Division estimates annual population growth at 2.5%. This gives an estimated population of 3,694,000 in 1993.

Taking into account the norms listed in the **Data Collection** section, the correct financial figure to use is $2,850,000 (that is, expenditure is preferred to budget, and donations are excluded), and the MOH drug expenditure per capita was US$ 0.77 in 1993.

C.2 Existence of a system for recovering the cost of drugs dispensed in MOH health facilities (C)

Rationale: In most countries the funds available through government budgets and donors are not sufficient to meet rising demands for drugs. The existence of a system (or systems) to recover costs of drugs from consumers is a measure of a country's recognition that regular budgetary means require supplementation in order to bridge the gap between supply and demand.

Definition: For purposes of this indicator, a cost recovery system is defined as any system which supports drug supply costs by charging patients for all or part of the drugs dispensed to them. Included within this definition are:

- Systems that charge patients prices intended to recover 100% of acquisition, storage, distribution and dispensing costs
- Systems that charge patients prices intended to recover only part of these cost, for example 50%; such systems are sometimes called *cost sharing* systems
- Systems that charge patients a flat fee, regardless of the types of drugs dispensed or their costs, when all revenues are allocated to buying new drugs; these systems are also sometimes called *cost sharing* systems

Not included in the definition of pharmaceutical cost recovery, for purposes of this indicator, are schemes that charge patients for medical consultations, with no stipulation that the revenues be used for buying new drugs. This exclusion holds even in cases where some of the revenues may be used to purchase drugs.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Health Finance Director	Document that describes the cost recovery program, its objectives, management and accounting systems, etc.
MOF	Revenue Collection/ Planning Director	Records of cost recovery revenues collected by MOH facilities
NGO/Donors	Director or Project Director	Cost recovery program activities, plan and records

Gather information for verifying the existence of cost recovery systems through interviews with key informants. In addition, attempt to gather a range of background information as available:

- Coverage of the cost recovery system, expressed as the percentage of all facilities wherein cost recovery takes place
- Financial objectives, such as full or partial cost recovery, recovery of replacement cost, etc.
- Percentage of costs actually recovered

- Types of fee charged and basis for fee scheme
- Exemption systems which excuse indigent or chronically ill patients from all or part of customary charges
- The year(s) for which all such data collected apply
- Management system and accountability for fees collected: records, reports, joint facility-community bank accounts, etc.

Computation & Example:

Record this indicator as follows:

- *Yes*, if one or more cost recovery systems exits, meeting the definitions listed above
- *No*, if at least one scheme does not exist

Presentation:

In country A, cost recovery schemes operate in all of the MOH's 36 national and regional hospitals, but not in the 122 health centers. There is no documentation of financial objectives concerning average percentage of costs to be recovered, but it is clear that the objective is partial cost recovery, or cost sharing, and not total cost recovery.

Patients are charged flat fees for each different drug product that they receive, but there is a two-tiered fee structure: 10 pesos for *ordinary* drugs and 20 pesos for *expensive* drugs. No figures are available for the total amounts of money collected nationally. Data for the Western Region indicate that for fiscal year 1992, total revenues from drug sales at the six hospitals were P 9,000,000. This represents 25% of the cost of the region's hospital drug purchases, and 15% of MOH's total drug purchases for the region.

Notes:

This indicator has been reduced in scope as a result of field tests of this manual. Originally, the indicator covered such points as *average prices charged* and *revenues collected as a percentage of MOH drug expenditures*. In practice, these data were difficult to obtain in most settings without major study efforts, which were not feasible in the context of the overall indicator assessment. Nevertheless, it is strongly felt that attempts should be made to obtain the types of information listed above, as part of filling in the background for this indicator. *Remember:* This indicator only measures a country's *recognition* of the problem of inadequate finances for drug supply. By itself, it does not tell how active are that country's attempts at using cost recovery to solve the problem. The more background data that is collected, the more usefully this indicator can be interpreted.

Although the indicator does not measure cost recovery systems which are not related to drugs, it is useful to note in the report information on other types of cost sharing/cost recovery programs, including the nature of the charge, amounts charged, scope of the program and results achieved.

C.3 Percentage of patients who pay a charge for drugs they receive in MOH health facilities (F)

Rationale: There is often substantial variation between stated cost recovery policies and actual practice. Ministries of Health may have stated policies of charging for drugs, but in practice do not enforce these policies in health care facilities. Taking a measure of the percentage of patients who actually make some payment gives an indication of whether cost recovery systems exist on paper only, or whether they operate in practice, and how much is actually recovered. This will determine the success of the cost recovery policy in achieving its objectives.

Definition: The definition of *patient who pays a charge* is any observed patient encounter in which the patient pays a charge (no matter how large or small) specifically related to drugs which are dispensed.

Data Collection:

Where to go	*Who to ask*	*What to get*
20 MOH health facilities	Pharmacist/Dispenser	Number of patients that paid a charge out of 30 observations or records

Data for this indicator are collected retrospectively, from dispensing or accounting records, or prospectively as follows: In a sample of 20 health facilities, review records or observe drug dispensing for 30 patients at each facility. This gives a sample of 600 contacts. At each site, record the number of patients who pay a charge explicitly for the drugs they receive, and the number that do not. If a fee is paid for medical services, which includes consultation fees as well as drugs, then these data should not be used for this indicator.

See the "Charge for Drugs Tally Form" in Annex C, page 151.

Computation & Example: The percentage of patients paying a charge is calculated by dividing the total number of patients paying a charge (for pharmaceuticals only), by the total number of patients observed, and multiplying by 100.

$$\text{\% of Patients who Pay A Charge For Drugs} = \frac{\text{Number of Patients Paying a Charge for Drugs}}{\text{Number of Patients Observed}} \times 100$$

$$\text{\% of Patients Who Pay A Charge for Drugs} = \frac{252}{600} \times 100 = 42\%$$

Record the number of health facilities examined and the time period in which the data were collected.

Presentation: In country Q, drug dispensing was observed at a sample of 20 health care facilities. Out of 600 patients observed, 42% paid a charge for the drugs they received during November 1991.

C.4 Percentage of total government recurrent budget used for Ministry of Health (C)

Rationale: The percentage of total government recurrent budget used for the Ministry of Health is a measure of the relative priority which the government gives to public health. The MOH percentage depends on the government's policies in other sectors, such as education, social services, industry subsidies, defense forces, macroeconomic adjustment policies, debt servicing, etc. The impact of decisions in these other sectors will be reflected in the overall state of health of the population as a consequence of budgetary cuts. Trends in the previous years will help show whether or not the health sector has been favored by governmental policies.

Definition: The recurrent budget is the amount of money allocated for routine operating costs. It normally excludes capital costs (and in some cases, excludes donations). This indicator is expressed as the percentage of the total government recurrent budget which is provided as a recurrent budget to the MOH, in the most recent fiscal year for which information is available.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Permanent Secretary, Health Finance Director, Chief Administrative Officer	Budget and expenditure reports for most recent financial year(s), a copy of the most recent budget/expenditure books
MOF	Planning Director	

Normally these data are collected from the most recent report on recurrent expenditures published by the Ministry of Finance. If such a report has not been published, contact senior officials at the MOH and/or the Ministry of Finance to obtain necessary information. If the information is only estimated, stipulate this when recording the data. Be sure to avoid confusion between amounts requested and amounts approved. The amount approved is the relevant number. If information is available for actual expenditures, record information for both allocated budget and expenditures. Attempt to determine whether or not debt servicing is included in the budget figures being used. If so, this should be excluded before making calculations.

Computation & Example: The indicator is recorded as a percentage, calculated as total Ministry of Health recurrent budget divided by total government recurrent budget, and multiplied by 100.

$$\text{\% of Total Government Recurrent Budget for MOH} = \frac{\text{Ministry of Health Recurrent Budget}}{\text{Government Recurrent Budget}} \times 100$$

$$\text{\% of Total Government Recurrent Budget for MOH} = \frac{8{,}190{,}000}{136{,}500{,}000} \times 100 = 6\%$$

Record the year on which data are based.

Presentation: In 1992, country A devoted 6.0% of its total recurrent budget to the Ministry of Health.

C.5 Percentage of total MOH recurrent budget allocated to pharmaceuticals (C)

Rationale: The percentage of total Ministry of Health recurrent budget used for pharmaceuticals is a measure of the degree of priority given to meeting demand for drugs, and also measures the impact on the system of pharmaceutical expense.

Definition: The recurrent MOH budget has been defined in the previous indicator. The amount used for pharmaceuticals is that amount allocated for the purchase of pharmaceuticals in the same budget year. As is the case with the previous indicator, actual expenditures are preferable to budget allocations, if the information is available. It is important that all figures used for deriving the indicator be of the same type, that is, either *expenditure* or *budget*. The two should not be mixed within one calculation.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Chief Administrative Officer, Permanent Secretary, Planning Director, Finance Director, Director of Pharmaceutical and/or Medical Supplies Service	Pharmaceutical budget allocation and expenditures for most recent financial year(s)
MOF	Planning Director	

Normally, this data is collected from the most recent report on recurrent expenditures which is published by the Ministry of Finance. If such a report has not been published, contact senior officials at the MOH and/or the Ministry of Finance to obtain necessary information. If the information is only estimated, stipulate this when recording the data. Be sure to avoid confusion between amounts requested and amounts approved. The amount approved is the relevant number. If information is available for actual expenditures, use this information for comparison with allocations. In some countries, it may be difficult to quantify the drug budget or expenditures because expendable medical supplies and drugs are included together in the same figure. In such cases, the total amount should be recorded, and the assessment team should obtain the most reliable estimates available concerning the relationship between drugs and other supplies. The values of donated drugs should be excluded from this indicator, unless they are included as line items in forward budget planning or actual expenditures.

Computation & Example: The indicator is recorded as a percentage, calculated as the MOH recurrent budget for pharmaceuticals divided by total Ministry of Health Budget, and multiplied by 100.

$$\text{\% of MOH Recurrent Budget Used for Pharmaceuticals} = \frac{\text{MOH Recurrent Budget Used for Pharmaceuticals}}{\text{Total MOH Recurrent Budget}} \times 100$$

$$\text{\% of MOH Recurrent Budget Used for Pharmaceuticals} = \frac{2{,}850{,}000}{8{,}190{,}000} \times 100 = 35\%$$

Record the year on which data are based.

Presentation: In the 1993 fiscal year, country A devoted 35% of its Ministry of Health recurrent budget to pharmaceuticals.

D. Ministry of Health Pharmaceutical Procurement

D.1 Existence of a policy limiting MOH pharmaceutical procurement to drugs on the National Drug Formulary List/National Essential Drugs List (C)

Rationale: The existence of a policy limiting MOH pharmaceutical procurement to products on the NDFL/NEDL is a measure of a country's recognition of the need to contain costs by restricting supplies to those items that have been authorized.

Definition: A written official policy should explicitly restrict MOH procurement to items included on the government-approved national drug list (NDFL/NEDL).

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH Procurement Office	Procurement Officer	Copy of the written policy
CMS	Chief of CMS	

Obtain a copy of a written MOH procurement policy related to the restricted purchase of products on the National Drug Formulary List. The indicator measures only whether such a policy exists, not whether it is actually followed.

Computation & Example: The indicator is recorded as follows:

- ***Yes***, if only drugs on the NDFL/NEDL are eligible for MOH procurement
- ***No***, if an NDFL/NEDL does not exist, or if procurement is not restricted to drugs on the list

Presentation: In country X, an NEDL exists, but the MOH has no requirement that procurements be limited to products on this list. Data show that in 1993 MOH expenditures on drugs from the NEDL accounted for 62% of total drug expenditures, while out-of-formulary drugs accounted for 38%.

D.2 Percentage by value of MOH drugs purchased through a central procurement system (C)

Rationale: Centralized procurement systems, when operated efficiently, have significant potential for containing drug costs by taking advantage of competitive forces in the market and by achieving economies of scale. The presence of centralized procurement systems is a measure of recognition of this potential.

Definition: The "central system" is an officially mandated procurement mechanism via a centralized agency, authority, or ministry office.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH Procurement Office or other government or parastatal agency (Disease Control Programs or facilities, Regional or Provincial governments)	Procurement Officer Tender Board Secretary Chief Pharmacist	Procurement reports for most recent financial year(s), invoices from suppliers, tender documents
Central Medical Stores	Chief of CMS	

Assess whether a centralized procurement system exists, and assess the approximate percentage by value of MOH drugs procured via this system. Data are obtained from procurement records for the most recent year for which they are available. If data on total procurement are not reliable, or in situations where extensive local facility purchases occur, it may be necessary to rely on estimates gathered through interviews. It should be documented, however, when such a method is used. The following data are needed:

- Total value of drugs procured by or for MOH; if more than one agency or institution purchases drugs, provide separate value purchased by each facility or each type of facility
- Value of drugs purchased by central procurement system

If no central procurement system exists, the indicator should be scored as 0%.

Computation & Example: Record the percentage by value of drugs purchased through the central procurement system, computed by dividing the monetary value of drugs centrally procured by the total monetary value of drugs purchased in the MOH, and multiplied by 100.

$$\text{\% by Value of MOH Drugs Purchased through Central Procurement System} = \frac{\text{Value of Drugs Centrally Procured}}{\text{Total Value of Drugs Purchased by MOH}} \times 100$$

$$\text{\% by Value of MOH Drugs Purchased through Central Procurement System} = \frac{2{,}280{,}000}{2{,}850{,}000} \times 100 = 80\%$$

Record the year on which data are based.

Presentation: In country A, central drug procurement is managed by the Central Medical Stores. National and regional hospitals also have separate budgets for emergency procurements. In 1992, 80% by value of total drug purchases was made centrally by the CMS, and a total of 20% by the individual hospitals.

Notes: In some countries each state or region may have a separate central procurement system. In others, health facilities may purchase independently, but there may be a central group purchasing scheme serving one group of facilities. If there are significant variations in procurement practices from region to region, or at different levels of the system, it is important to document these differences, and calculate estimated values for central procurement separately for the regions or facility types.

D.3 Percentage of average international price paid for last regular procurement of a set of indicator drugs (C/R/F)

Rationale: The cost of drugs procured as a percentage of average international prices is a measure of the efficiency of procurement systems. This indicator will help determine the potential savings that could be achieved if the procurement practices are improved, and in this way support changes in the pharmaceutical supply system.

Definition: Average international price is the average free on board (FOB) price from a set of international suppliers. One source of price information is the MSH *International Drug Price Indicator Guide*. The last regular procurement price refers to the cost, insurance, freight (CIF) price paid during the last regular procurement.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH-Procurement Unit	Officer in charge of pharmaceutical purchases	List of most recent prices paid for a set of indicator drugs
Central Medical Store	Manager or Reception Officer	
Regional government administration or Medical Store	Manager	
Health facilities	Pharmacist or Procurement Officer	Tender documents, supplier invoices

A set of indicator drugs for which this indicator will be measured must be developed as one of the preparatory activities for the indicator study (see chapter 4, "Guidelines for Study Design," section C, "Specifying a List of Indicator Drugs"). Examples of indicator drug lists that have been used for assessments in different countries are found in Annex B. Information on CIF prices paid by the MOH for the indicator drugs should apply to the last regular procurement. Any more recent *ad hoc* or emergency procurements that may have taken place should be compared separately to international prices. The average international prices for the indicator drugs may be determined by reference to average international unit prices in the MSH *International Drug Price Indicator Guide*.[6] The average price in this guide is FOB, and should be adjusted upward by 20% to reflect average shipping and insurance costs. Specify the source of international prices and the year of both data sets. If all purchases are not done by one central agency, compile information separately by type of institution, and compute the percentage of international price for each type of purchasing institution (e.g., Regional Medical Stores, hospitals, health centers, etc). Note the date of the most recent regular drug procurement. When making calculations, it may be necessary to convert prices paid in local currencies into U.S. dollars. **It is important to use the exchange rates in effect at the time the purchases were made, and to use the edition of the Price Guide which corresponds with the year in which purchases were made.**

See the "International Price Comparison Form" in Annex C, page 167.

Computation & Example:

The indicator should be presented as an average of the percentages of international prices for the set of indicator drugs. If data are collected from different levels of the system, a separate average should be calculated for each level. The computation involves two steps:

- First, the percentages are calculated for each of the indicator drugs by dividing the purchase cost of the *comparison unit* (e.g., tablet, milliliter, etc.) at the last regular procurement by the average international price of that unit and multiplying the result by 100.

$$\text{\% of Average International Price} = \frac{\text{Comparison Unit Price}}{\text{Average International Unit Price}} \times 100$$

- Second, the average percentage for all indicator drugs is calculated by summing their percentages and dividing by the total number on the list.

$$\text{Average \% of All Indicator Drugs} = \frac{\text{Sum of Percentage of All Indicator Drugs}}{\text{Total Number of Indicator Drugs}}$$

For purposes of illustrating the computation of the result at the CMS, assume an indicator list of three products:

Product	Comparison Unit Price	Adjusted Average International Unit Price*
Tetracycline 250 MG CAP	0.0207	0.0163
ORS 200 ML PKT	0.0677	0.0578
Paracetamol SYR 24 MG/ML	0.0070	0.0051

1. The first step is to calculate the percentage for each product.

For tetracycline, the first product on the list, this is done as follows:

$$\text{\% of Average International Price} = \frac{0.0207}{0.0163} \times 100 = 127\%$$

Using the data in the table, the percentages for ORS and paracetamol are calculated as 117% and 137%, respectively.

2. Next, the average percentage for all three products is calculated as follows:

$$\text{Average \% of All Indicator Drugs} = \frac{127 + 117 + 137}{3} = 127\%$$

* The figures in this column have been adjusted to reflect estimated CIF prices.

Presentation: In country C, comparisons of drug purchase prices with average international prices were made at both the Central Medical Store and at a sample of one national and three regional hospitals. In 1992 the CMS paid 127% of the average international price, while the hospitals paid 206%.

Notes: Where there is a wide range in the average percentages for a list of indicator drugs, this can be reflected in the report by also calculating the standard deviation from the mean for the list. The standard deviation from the mean is a way of indicating an average amount by which the individual percentages are different than the average percentages. All major computer spreadsheet programs have a function which automatically calculates standard deviation.

D.4 Percentage by value of MOH drugs purchased through competitive tender (C/R/F)

Rationale: Competitive tenders are among the best ways to minimize the costs of drug purchases. Even when central purchase mechanisms are in place, they may not result in economical purchases unless competitive tendering is used. The percentage of total purchases made using this method is a measure of commitment and ability to manage purchases in a cost efficient way.

Definition: To be considered a formal competitive tender process, pharmaceuticals must be purchased on the basis of sealed bids submitted in response to government requests to supply drugs. The tender process may be open, such as international competitive bidding (ICB), or closed, and with or without pre-qualification of suppliers.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH-Procurement Unit	Officer in charge of pharmaceutical purchases	Total value of drugs purchased, total value of drugs purchased through competitive tender
Central Medical Store	Manager or Procurement Officer	
Health facilities (if procurement is decentralized)	Procurement Officer/Facility accountant	

For this indicator to be relevant, the MOH must use competitive tenders. Collect data on the total value of all drugs purchased during the last fiscal year, and on the value of drugs purchased through formal competitive tenders. Information may be available from a central purchasing agency. As for D.2, if reliable data is not available, estimates may be used, providing that the source and reliability of estimates are documented.

Computation & Example: The indicator is a percentage, calculated by dividing the total value of drugs purchased through competitive tender (in the previous fiscal year) by the total value of all drugs purchased that year, and multiplying the result by 100.

$$\text{\% of Drugs Purchased through Competitive Tender} = \frac{\text{Total Value of Drugs Purchased through Competitive Tender}}{\text{Total Value of All Drugs Purchased}} \times 100$$

$$\text{\% of Drugs Purchased through Competitive Tender} = \frac{\$1{,}710{,}000}{\$2{,}850{,}000} \times 100 = 60\%$$

Presentation: In country A, in the Financial Year 1990/91, 60% of the drugs (by value) procured by the MOH were purchased through competitive tender.

Notes: As for D.2, it may be necessary to compile percentages of competitive procurement separately for different states, regions, or type of health facility.

E. Ministry of Health Pharmaceutical Logistics

E.1 Weighted average percentage of inventory variation for a set of indicator drugs in MOH storage and health facilities (C/R/F)

Rationale: Stock record keeping systems that are significantly inaccurate are of limited use for monitoring the status of inventory, estimating future needs, and for controlling leakage and wastage of stock. Weighted average percentage of inventory variation measures the degree to which stock record keeping systems reflect the real status of drugs in stock.

Definition: The weighted average percentage of inventory variation is the weighted average percentage difference between recorded stock levels and actual physical counts for a set of indicator drugs. This is also known as average piece variation. As a measure, it indicates the overall correspondence between records and real stock levels.

Data Collection:

Where to go	*Who to ask*	*What to get*
Central Medical Store	Inventory Officer/Storekeeper	Most accurate records of current stock levels for each indicator drug, issues and receipts not entered; method to record stocks; physical count of unexpired stock levels
Regional Medical Store	Manager	
20 MOH health facilities	Dispenser/Pharmacist/Storekeeper	

This indicator is based on the list of 25 to 50 indicator drugs used to treat common health problems (see chapter 4 "Guidelines for Study Design," section C "Specifying a List of Indicator Drugs," and Annex B, which gives examples of indicator drug lists). Visit the CMS (and at least one regional store if they exist in this system), and a sample of 20 health facilities. At each site, carry out the following procedure:

- Ask staff to produce the most accurate records of current stock level for each of the indicator drugs. Ask them to produce their files for any recent (i.e., within the past month) issues or receipt vouchers which have not been entered in their stock level records. If unentered issues and receipts can be adjusted on the spot, this should be done, and the recorded totals should reflect the adjustment. If the records are badly behind (e.g., several weeks or months of issues or receipts have not been entered), use the actual recorded total, and make a note in the report that records are not current.

- Take note of the means used to produce these estimates (computerized system, manual ledgers, bin cards). If bin cards exist, and if they were not used to produce the best estimates, obtain a second set of data from the bin cards. If there are both manual and computerized records, obtain data from both systems.

- Finally, carry out a physical count of the unexpired stock levels for these drugs, and record the number of units for each indicator drug in stock. The expired units should not be counted.

It may be possible to collect three sets of data for a list of indicator drugs at each site in a sample. These sets would include: physical count, stock levels noted in the computerized records or manual ledgers, and stock levels taken by tally from bin cards. This means that this indicator is calculated twice, that is, one calculation based on comparison of the physical count and computer/ledger results, and another based on physical count and the tally or bin card results. If either ledgers or bin cards do not exist, or if one of these systems is in total disarray, it may be possible to make only one comparison. If there is difficulty in collecting data, the comparison between physical count and ledger results should have priority.

For the most ambitious assessment, this indicator would be calculated for both computerized stock records/ledgers and bin cards at the CMS, at the sample Regional or District Medical Stores, and at a sample of health facilities. Whether this is possible for all of these sites, or just some of them, will depend on the state of the record keeping systems. It is important, however, to record the following information for all data collected and all indicators computed: the site visited, and which record keeping systems have been assessed, that is, computerized systems, ledgers or bin cards.

See the "Inventory Data Form" in Annex C, page 147.

Computation & Example:

To calculate the *weighted average percentage of inventory variation*, carry out the following steps:

- First, write down the sum of the adjusted totals of all units of indicator drugs recorded in the computer/ledger and/or on the bin cards.
- Second, record the total of all units of indicator drugs verified by physical count.
- Third, subtract the physical count from the recorded count, and remove any negative signs, thereby creating an absolute value.
- Fourth, divide the result by the total of the physical count, and multiply this quotient by 100 to get the weighted average percentage difference.

$$\text{Weighted Average \% of Inventory Variation} = \frac{\text{Recorded Count - Physical Count}}{\text{Physical Count}} \times 100$$

For purposes of illustrating the computation of this indicator, assume an indicator drug list of three products:

Product	Record	Physical Count
Tetracycline 250 MG CAP	1000	900
ORS 200 ML PKT	400	450
Paracetamol SYR 100 ML BOT	350	100
Total	1750	1450

The weighted average percentage of inventory variation is calculated as follows:

1. Add up the total number of units for each product shown in the record:
   1000 + 400 + 350 = 1750

2. Add up the total number of units verified by physical count:
   900 + 450 + 100 = 1450

3. Subtract the physical count from the recorded amount:
   1750 - 1450 = 300

4. Calculate the weighted average percentage of inventory variation:

$$\text{Weighted Average \% of Inventory Variation} = \frac{300}{1450} \times 100 = 21\%$$

Presentation: After adjusting for issues and receipts not yet entered in the records, at the Central Medical Store in country B, the average percentage of inventory variation between the computerized record keeping system and the physical count was calculated to be 21%.

E.2 Average percentage of individual variation for a set of indicator drugs in MOH storage and health facilities (C/R/F)

Rationale: As noted in the previous indicator, stock record keeping systems that are significantly inaccurate are of limited use for monitoring the status of inventory and for controlling leakage and wastage of stock. Average percentage of individual variation measures the degree to which stock record keeping systems reflect the real status of drugs in stock. As a measure, it indicates the magnitude of discrepancy between records and the real stock levels of individual items.

Definition: The average percentage of individual variation is the weighted average of the absolute differences between recorded stock levels and physical counts for the same list of indicator drugs.

Data Collection:

Where to go	*Who to ask*	*What to get*
Central Medical Store	Inventory Officer/Storekeeper	Most accurate records of current stock levels for each indicator drug, issues and receipts not entered, method to record stocks, physical count of unexpired stock levels
Regional Medical Store	Manager	
20 MOH health facilities	Dispenser/Pharmacist/Storekeeper	

This indicator is based on the list of 25 to 50 indicator drugs used to treat common health problems (see chapter 4 "Guidelines for Study Design," section C "Specifying a List of Indicator Drugs," and Annex B, which gives examples of indicator drug lists). It is calculated based on the same data that was collected for the previous indicator, E.1. Use this data and proceed to calculate the weighted average percentage of individual variation. As was the case with indicator E.1, if there are multiple record systems, the indicator should be calculated for all functioning systems. The data should be presented in separate tables for each type of facility in the sample (CMS, RMS and peripheral health facilities).

See the "Inventory Data Form" in Annex C, page 147.

Computation & Example: To calculate the *average percentage of individual variation*, carry out the following steps:

- For *each* drug on the indicator list, determine the absolute value of individual variation, as follows:
  Subtract the physical count from the recorded quantity (ledger or bin cards).
  Record that result as an absolute value by removing any negative signs. *All results should be expressed as positive numbers.*

Absolute Value of Variation = Recorded Quantity - Physical Count

- Calculate the percentage of variation for each indicator drug as follows: Divide the absolute variation by the recorded quantity, and multiply that quotient by 100 to get the percentage of individual variation.

$$\text{\% of Individual Variation} = \frac{\text{Absolute Value of Variation}}{\text{Recorded Quantity}} \times 100$$

- Determine the average percentage of individual variations by summing all of the percentages of individual variation and dividing by the total number of percentages of variation calculated.

$$\text{Average \% of Individual Variation} = \frac{\text{Sum of Percentages of Individual Variations}}{\text{Total Number of Percentages Calculated}}$$

Once again, this indicator may be calculated for both computerized stock records/ledgers and bin cards at the CMS, at a sample of Regional or District Medical Stores, and at a sample of health facilities. Whether this is possible for all of these sites, or just some of them, will depend on the state of the record keeping systems. It is important, however, to record the following information for all data collected and all indicators computed: the site visited, and which record keeping systems have been assessed, that is, computerized systems, ledgers or bin cards.

Assume the same indicator drug list as for the previous indicator, E.1, for purposes of illustrating the computation of results:

Product	Record	Count
Tetracycline 250 MG CAP	1000	900
ORS 200 ML PKT	400	450
Paracetamol SYR 100 ML BOT	350	100

1. To determine the weighted average percentage of individual variation, the first step is to calculate the percentages of individual variation.

For tetracycline, the first product on the list, this is done as follows:

Absolute Value of Variation: 1000 - 900 = 100

2. Next, percentage of individual variation is calculated:

$$\text{\% of Individual Variation} = \frac{100}{1000} \times 100 = 10\%$$

The percentage of individual variation for ORS is calculated as:

1. 400 - 450 = -50 = 50

2. $\frac{50}{400} \times 100 = 12.5\%$

The percentage of individual variation for paracetamol is:

1. 350 - 100 = 250

2. $\frac{250}{350} \times 100 = 71.4\%$

3. Finally, the average percentage of individual variation for all three products is calculated as follows:

Average % of Individual Variation $= \frac{10 + 12.5 + 71.4}{3} = 31.3\%$

Presentation: After adjusting for issue tickets not yet entered in the records, at the Central Medical Store in country B, the average percentage of individual variation for the set of indicator drugs was calculated as 31.3%.

E.3 Average percentage of stock records that corresponds with physical counts for a set of indicator drugs in MOH storage and health facilities (C/R/F)

Rationale: The average percentage of stock records that corresponds with physical counts is useful for clarifying the quality of the stock record keeping system in cases where average variations and variance are skewed by a small number of items.

Definition: This is the average percentage of in-stock indicator drug inventory records which corresponds exactly with physical stock count for a set of indicator drugs.

Data Collection:

Where to go	*Who to ask*	*What to get*
Central Medical Store	Inventory Officer/Storekeeper	Most accurate records of current stock levels for each indicator drug, issues and receipts not entered, method to record stocks, physical count of unexpired stock levels
Regional Medical Store	Manager	
20 MOH health facilities	Dispenser/Pharmacist/Storekeeper	

This indicator is based on the list of 25 to 50 indicator drugs used to treat common health problems (see chapter 4 "Guidelines for Study Design," section C "Specifying a List of Indicator Drugs," and Annex B, which gives examples of indicator drug lists). Visit the CMS (and at least one regional store if they exist in this system), and a sample of 20 health facilities. At each site, carry out the following procedure:

- Ask staff to produce the most accurate records of current stock level for each of the indicator drugs. Ask them to produce their records for any recent issues or receipts which have not been entered in their stock level records.
- Take note of the means used to produce these estimates (computerized system, manual ledgers, bin cards). If bin cards exist, and if they were not used to produce the best estimates, obtain a second set of data based on bin cards.
- Finally, carry out a physical count of the unexpired stock levels for these drugs, and record the number of units for each indicator drug in stock. The expired units should not be counted. Indicator drugs which are not normally stocked by the facility should be excluded.

See the "Inventory Data Form" in Annex C, page 147.

Computation & Example:

- For the set of indicator drugs calculate the percentage of records checked which corresponds exactly with the physical counts according to the tally and the ledger. To do this, divide the number of records for which no discrepancy was found by the total number of records checked, and multiply this result by 100.

% of Stock Records Corresponding with Physical Counts =

$$\frac{\text{Number of Stock Records with No Discrepancies}}{\text{Total Number of Records Examined}} \times 100$$

- Present the data in separate tables for each type of facility in the sample (CMS, RMS, or peripheral health facilities). For the sample of health facilities, the indicator is calculated as the average of the facility-specific averages:

Average % of Stock Records Corresponding with Physical Counts =

$$\frac{\text{Sum of Average \% for Each Facility}}{\text{Total Number of Facilities in Sample}}$$

For purposes of illustrating this computation, assume an indicator drug list of three products:

Product	Record	Count
Tetracycline 250 MG CAP	10000	10000
ORS 200 ML PKT	1000	990
Paracetamol SYR 100 ML BOT	88	87

To calculate the percentage of stock records that corresponds exactly with physical counts, carry out the following steps:

For one health facility, using the indicator drug list above:

1. The number of records examined = 3

2. The number of records with no discrepancy = 1

$$\text{\% of Stock Records Corresponding with Physical Counts} = \frac{1}{3} \times 100 = 33\%$$

For a sample of 20 health facilities, for which the sum of percentages of stock records that correspond exactly with physical counts is 600%, the average percentage of indicator drugs in stock is calculated as:

$$\text{Average \% of Stock Records Corresponding with Physical Counts} = \frac{600\%}{20} = 30\%$$

Presentation: After adjusting for issue tickets not yet entered in the records at the Central Medical Store in country Q, the percentage of records for 25 indicator drugs that corresponded exactly with physical counts was 33%. The average percentage of health facility records that corresponded exactly with physical counts was 30%, with the range among facilities from 10% to 60%.

E.4 Average percentage of a set of unexpired indicator drugs available in MOH storage and health facilities (C/R/F)

Rationale: The availability of indicator drugs is perhaps the single most important indicator of this entire set. This indicator measures a procurement and distribution system's ultimate effectiveness in fulfilling its basic mission, that is, providing drugs at health facilities.

Definition: A drug is defined as available if even one unit of unexpired product is in stock. Since expired drugs are inappropriate for use in almost all situations, they are not counted as stock available for use.

Data Collection:

Where to go	*Who to ask*	*What to get*
Central Medical Store	Inventory Officer/Storekeeper	Inventory records and stock count for indicator drugs
Regional Medical Store	Manager/Storekeeper	
20 MOH health facilities	Dispenser/Pharmacist/Storekeeper	

This indicator is based on the list, developed by study organizers, of indicator drugs used to treat common health problems (see chapter 4 "Guidelines for Study Design," section C "Specifying a List of Indicator Drugs," and Annex B, which gives examples of indicator drug lists). First, in consultation with staff at the CMS, RMS, and local health facilities, determine which of these products are normally stocked at each level. The figure for drugs *normally stocked* becomes the denominator in calculations. Then, assess whether each of the normally stocked drugs is available. If any of each of the indicator drugs is unexpired and available, record that item as "present" even if it is likely to be out of stock very soon. If all stock for a product on the list is expired, record 0. Do not worry about stock levels for this indicator.

See the "Inventory Data Form" in Annex C, page 147.

Computation & Example:

- The indicator is recorded as a percentage, calculated by dividing the number of specified products found in stock by the total number of drugs for which availability was assessed, and multiplying by 100.

$$\text{\% of Indicator Drug Availability} = \frac{\text{Number of Indicator Drugs with Unexpired Stock}}{\text{Total Number of Indicator Drugs Normally Stocked}} \times 100$$

- Present the data in separate tables for each type of facility (CMS, RMS and peripheral health facilities) visited. For the sample of health facilities, the indicator is calculated as the average of the facility-specific averages:

$$\text{Average \% of Indicator Drug Availability} = \frac{\text{Sum of Average \% for Each Facility}}{\text{Total Number of Facilities in Sample}}$$

To calculate the average percentage of indicator drug availability for the sample of health facilities, carry out the following steps:

1. For one health facility with 11 unexpired indicator drugs in stock, from a list of 19 indicator drugs normally stocked, the calculation is:

$$\text{\% of Indicator Drug Availability} = \frac{11}{19} \times 100 = 58\%$$

2. For a sample of 20 health facilities, for which the sum of percentages of indicator drugs in stock is 960%, the average percentage of indicator drugs in stock is calculated as:

$$\text{Average \% of Indicator Drug Availability} = \frac{960\%}{20} = 48\%$$

Presentation: In a survey of 20 health facilities, where 19 indicator products were confirmed to be normally stocked, an average of 48% of the listed products was found in stock. The range among facilities was 25% to 85%, with the lower end of the range being associated with more peripheral health facilities. The facility-specific averages are listed below.

- Regional medical stores - 85%
- District hospitals - 64%
- Health centers and posts - 48%

E.5 Average percentage of time out of stock for a set of indicator drugs in MOH storage and health facilities (C/R/F)

Rationale: The percentage of time out of stock for a set of indicator drugs gives a measure of a procurement and distribution system's capacity to maintain a constant supply of drugs.

Definition: Time out of stock, or stockout time, is defined as the number of days that a product was not present in a warehouse or health facility over a recent twelve month period (usually the 12 months preceding the one during which the assessment takes place). To be considered a stockout, there must have been none of an unexpired drug in stock. If even small quantities of an unexpired drug were present, the drug should be counted as in stock. Percentage of time out of stock is defined as the percentage of days during a 12 month period that a drug has been out of stock (based on inventory records).

Data Collection:

Where to go	*Who to ask*	*What to get*
Central Medical Store	Inventory Officer/Storekeeper	Drugs that are normally stocked from the list of indicator drugs, number of days these normally stocked drugs were out of stock during the 12 months prior to assessment or previous year
Regional Medical Store	Manager	
20 MOH health facilities	Dispenser/Pharmacist/Storekeeper	

This indicator is based on the list, developed by study organizers, of 25 to 50 indicator drugs used to treat common health problems (see chapter 4 "Guidelines for Study Design," section C "Specifying a List of Indicator Drugs," and Annex B, which gives examples of indicator drug lists). In order to determine stockout duration, it is necessary that there be a reasonably accurate inventory recording system (computer/ledger/bin cards) in place. As in the previous indicator, the first step is to consult with staff at each facility and determine which of the products are normally stocked. It is the number of drugs *normally stocked* that will be used in calculations. To determine average stockout duration, identify which of the normally stocked drugs were out of stock during the last year, and then determine for how many days the product was out of stock during that time. Ideally, this should be determined for the 12 months prior to the month in which the visit occurs. The critical issue is that the same 12-month period should be used for all health facilities and warehouses visited.

See the "Stockout Data Form" in Annex C, page 155.

Computation & Example:

Enter the historical stock data into a table, recording the names of the indicator drugs, and the number of days of stockout in the previous year. To compute this indicator, carry out the following steps:

- First, for each indicator drug on the table, record the number of days out of stock for each of the last 12 months. Then sum the total numbers of days out of stock over the past 12 months for all drugs.

- Second, to record this indicator, compute the *average percentage of time that all indicator drugs were out of stock*, within the 12 month period, by adding all the stockout days for all drugs, dividing by 365 times the number of drugs, and multiplying by 100.

Average % of Time that Indicator Drugs were Out of Stock =

$$\frac{\text{Total Number of Stockout Days for All Indicator Drugs}}{365 \times \text{Total Number of Indicator Drugs Normally Stocked}} \times 100$$

Present this data in tables, and report averages for each type of facility visited (CMS, RMS, and peripheral health facilities).

For purposes of illustrating the computation, assume an indicator drug list of three products:

Product	Total Days Out of Stock
Tetracycline 250 MG CAP	36
ORS 200 ML PKT	64
Paracetamol SYR 100 ML BOT	123

Assume that in a CMS, all three of these indicator drugs are normally stocked.

Average % of Time that Indicator Drugs were Out of Stock =

$$\frac{36 + 64 + 123}{365 \times 3} \times 100 = 20\%$$

Presentation:

In country C, over a 12-month period, the indicator drugs were out of stock an average of 20% of the time at the Central Medical Stores. In the Regional Medical Store, the indicator drugs were out of stock an average of 30% of the time. In the sample of health clinics, the indicator drugs were out of stock an average of 40% of the time.

F. Patient Access and Drug Utilization

F.1 Population per functional MOH health facility that dispenses drugs (C)

Rationale: The ratio of population to functional health facilities that dispense drugs provides a rough measure of access to and availability of pharmaceutical services. The information provided by this indicator will allow health planners and evaluators to assess and monitor strategies to improve distribution and access to pharmaceuticals.

Definition: Any fixed, functional health facility that dispenses drugs to inpatients or outpatients should be included in the total count. This might include hospitals, health centers and rural health posts. It should not include vaccination posts which do not normally dispense drugs.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Chief Pharmacist, Director of Health Services	Most recent list of facilities
Bureau of Statistics	Census Director	Most recent population census figure, population projections for intercensal period

Obtain lists of all functional MOH health facilities that meet the above definition of facilities that dispense drugs. If facilities that are managed completely, or partly, by NGOs, are considered part of the overall MOH system, they should be counted as well. The population estimate should be as current as possible. If an estimate for the current year is not available locally, then the options are the same as those explained in the **Data Collection** section of indicator C.1. That is, either use the estimate provided by the most recent edition of the World Bank's *World Development Report*, or build an estimate using a recent census figure and applying the cumulative annual rate of population growth to bring it up to the current year.

Computation & Example: This indicator is a ratio, calculated by dividing the total national population by the number of functional MOH health facilities which dispense drugs.

$$\text{Ratio} = \frac{\text{National Population}}{\text{Number of Functional MOH Health Facilities which Dispense Drugs}}$$

$$\text{Ratio} = \frac{13{,}000{,}000}{424} = 30{,}660$$

Presentation: In country C, the total number of MOH facilities is reported as 424. This includes national, regional and district hospitals, health posts, and sub health posts, all of which stock and dispense drugs. With a population of 13,000,000 this gives an average of 30,600 persons per health facility that dispenses drugs.

F.2 Population per licensed pharmacist or pharmacy technician in the public sector (C)

Rationale: The unavailability of technically skilled human resources can be an important constraint in developing countries. This indicator provides a rough measure of access to skilled pharmacy personnel. Health care systems with a high ratio of population per pharmacist and trained pharmacy technician should include in their human resource management plan the recruitment, training and development of this important resource in order to bring about improvements in service delivery.

Definition: For purposes of this indicator, *pharmacist* is defined as a person holding a university degree in pharmacy, and *pharmacy technician* is defined as a person who has completed formal course work leading to a certificate or diploma in pharmacy technology. Only these personnel who work full or part-time in the health care system which is surveyed should be counted.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Chief Pharmacist, Director of Personnel or Human Resources	Latest count or registry of pharmacists and pharmacy technicians in the health care system
Drug Regulatory Authority /Professional Associations	Officer in charge of professional and technical registrations	
School of Pharmacy	Faculty members	
Ministry of Planning/Personnel Management	Human Resource Planner	

Use interviews with key informants at any of the sites listed above to obtain lists, tables or other documentation. Sometimes this type of information is available in gazettes or other compendia. If possible, obtain breakdowns of numbers of pharmacists and pharmacy technicians working in the public, NGO and private sectors. It is important that the estimates be as current as possible. Cite the names and dates of sources.

Computation & Example: This indicator is a ratio obtained by dividing the total national population by the combined number of licensed pharmacists and pharmacy technicians who were full or part-time employees in the public sector health system.

$$\text{Ratio} = \frac{\text{National Population}}{\text{Pharmacists} + \text{Pharmacy Technicians}}$$

$$\text{Ratio} = \frac{13{,}000{,}000}{21 + 68} = 146{,}067$$

Presentation: In country C, information on the numbers of licensed pharmacists and pharmacy technicians was obtained from the Human Resources Division of the Ministry of Planning. Breakdowns for both the public and private sector are given in the table below for the year 1993.

Sector	Pharmacists	Pharmacy Technicians
Public (full or part-time)		
Ministry of Health	14	46
Social Security Agency	7	22
Subtotal	21	68
Private (only)		
Manufacturers	19	32
Distributors	3	0
Retail	2	41
Subtotal	24	73
Totals:	45	141

There were 21 pharmacists and 68 pharmacy technicians who worked full or part-time for the MOH in 1993. The estimated population for that year was 13,000,000, which gives a ratio of 146,067 people per licensed pharmacist or pharmacy technician in the MOH health system.

F.3 Population per authorized prescriber in the public sector (C)

Rationale: Adequate numbers of technically qualified staff who are authorized to prescribe medicines are essential to a sound health care system. This indicator provides a rough measure of access to health care providers in the public sector who are authorized to prescribe drugs.

Definition: For purposes of this indicator, an *authorized prescriber* is a practitioner with formal training in primary and/or curative health care, who is legally authorized to prescribe drugs. Physicians, registered nurses, auxiliary nurses and nurse mid-wives are examples of categories of professionals who are authorized to prescribe drugs in many countries. Exclude traditional healers and community based volunteers, even if they have had training and prescribe selected drugs.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Director of Personnel or Human Resources	Latest count or registry of physicians, professional nurses and auxiliary nurses and other paramedical staff (community health workers, health inspectors, health extension officers, etc.) who are authorized to prescribe drugs
Drug Regulatory Authority /Professional Associations	Officer in charge of professional and technical registrations	
Ministry of Planning/Personnel Management	Human Resource Planner	

Use interviews with key informants at any of the sites listed to obtain lists, tables or other documentation. Sometimes this type of information is available in gazettes or other compendia. The indicator is for the health care system being surveyed. If possible, obtain breakdowns for numbers of authorized prescribers working in the public, NGO and private sectors. Keep in mind that one difficulty in interpreting such breakdowns is that, in many countries, practitioners may work in both the public and private sectors. It is important that the estimates be as current as possible. Cite names and dates of sources.

Computation & Example: This indicator is a ratio obtained by dividing the total national population by the combined number of authorized prescribers.

$$\text{Ratio} = \frac{\text{National Population}}{\text{Combined Total of Authorized Prescribers in the Health Care System}}$$

In country C, information on the numbers of authorized prescribers was obtained by first consulting the National Health Code. According to that document, there are three legally established categories of health care providers: physicians, registered nurses and auxiliary nurses. Only the physicians may prescribe the full range of ethical and over-the-counter products. Prescribing practices of nurses and auxiliary nurses are covered by an amendment to the Code, which authorizes them to prescribe selected

drugs on the National Drug Formulary List when working in MOH facilities, or under the direct supervision of a private physician. It was only possible to obtain numbers of physicians practicing in both the public and private sectors. Information on the two categories of nurses was available only for the public sector, though there are thought to be relatively few of them working in the private sector.

Sector	Physicians	Nurses	Auxiliary Nurses
Public (full or part-time)			
Ministry of Health	209	42	612
Social Security Agency	62	15	65
University Hospital	42	20	32
Subtotal	313	77	709
Private (only)	74	N/A	N/A
Totals:	387	77	709

$$\text{Ratio} = \frac{13{,}000{,}000}{313 + 77 + 709} = 11{,}829$$

Presentation: In country C, the population for 1993 was estimated at 13,000,000. Based on the information available, this gives a ratio of 11,829 people per authorized prescriber in the MOH system.

F.4 Average number of drugs prescribed per curative outpatient encounter in MOH health facilities (F)

Rationale: This indicator attempts to describe prescriber behavior, since too high (or too low) an average number prescribed can indicate poor prescribing practices. These practices can be explained by lack of pharmaceutical information and education, or by chronic lack of supplies that force health workers to prescribe what is available. Additional information is necessary to explain the cause of the prescribing practices observed.

Definition: This indicator measures the average number of drugs prescribed per outpatient per curative encounter. Each drug written separately is counted as a separate drug prescribed. Encounters include only visits by patients seeking curative care.

Data Collection:

Where to go	*Who to ask*	*What to get*
20 MOH health facilities	Medical Records Officer/Health Facility Manager/Pharmacist	Determine the number of drugs prescribed for a sample of 30 patients per facility, by consulting daily registers, patient records, prescription slips, or through observation

Select a sample of 30 outpatient encounters at each health facility, and count the number of drugs prescribed to each patient. These data may be gathered either retrospectively from medical records, or prospectively from observation. (See description of sampling methods in chapter 4, section E, "Defining Approaches for Collecting Survey Data.") Include only patients seeking curative care. To count drugs in a uniform way in some settings, guidelines must be established for data collectors on how to count ambiguous prescribing practices. Examples of these include locally compounded multi-drug combination therapies, or certain combined oral/injection therapies, such as a standard treatment of injection followed by oral administration. The methods for collecting these indicators are also described in the manual *How to Investigate Drug Use in Health Facilities*, published by WHO.[7]

See the "Drug Use Data Form" in Annex C, page 159.

Computation & Example: For each health facility in the sample, the indicator is recorded as an average, calculated by dividing the number of different drug products prescribed by the total number of curative outpatient encounters surveyed. Remember to count any curative encounters in which no drug was prescribed. The overall indicator is an average of these facility-specific averages. Along with this overall average, provide the range of highest and lowest facility averages. If different levels of the system are visited (i.e., hospitals, health centers and health posts), tabulate results separately and summarize with averages for each type of facility. Express the results as the number of drugs prescribed per encounter.

$$\text{Average Number of Drugs Prescribed Per Curative Outpatient Encounter} = \frac{\text{Total \# of Drugs Prescribed in All Encounters}}{\text{Total \# of Curative Encounters Studied in All Facilities}}$$

- For example, assume that the data collected for 30 patient encounters at one health facility showed that 51 drugs had been prescribed. Results for that one facility are calculated as follows:

$$\text{Average Number of Drugs Prescribed Per Curative Outpatient Encounter} = \frac{51}{30} = 1.7 \text{ per encounter}$$

- For a sample of 20 health centers surveyed, a total of 1800 drugs were prescribed for 600 patient encounters. The average number of drugs per encounter, for health facilities, is calculated as follows:

$$\text{Average Number of Drugs Prescribed Per Curative Outpatient Encounter} = \frac{1800}{600} = 3 \text{ drugs per encounter}$$

Presentation: An indicator survey covering a sample of 20 health centers in country A found that patients received an average of 3 prescribed drugs per curative encounter. The range among health facilities was 0.9 to 3.8 drugs per facility.

F.5 Percentage of drugs prescribed by generic name in MOH health facilities (F)

Rationale: If health care providers prescribe by generic names instead of brand names, it is easier to control drug costs in the health care system, because generic substitution is not needed.

Definition: This indicator measures the percentage of drugs which are prescribed using their internationally recognized generic names, as identified in the WHO list of international nonproprietary names (INN).[8] The availability of generically named drugs in the market, and the information available to prescribers, will influence the pattern observed. Although the INN is used as the "official" generic name for this indicator, in some countries, generic drugs may be available under INN and other variations such as USAN or BAN. For example, the antihistamine chlorphenamine (INN) may be marked as chlorpheniramine (USAN). Or, only the USAN or BAN generic product may be marketed. In such situations, any of the common generic names may be counted for purposes of this indicator.

Data Collection:

Where to go	*Who to ask*	*What to get*
20 MOH health facilities	Medical Records Officer/Health Facility Manager	Determine the number of generic drugs and total of all drugs prescribed for a sample of 30 patients per facility, by consulting daily registers, patient records, prescription slips, or through observation

Study organizers must develop a list of (or an explicit way of defining) the specific product names to be included as generic drugs; usually the generic names of drugs are identified on the National Drug Formulary List. Select a sample of 30 patient encounters at each health facility. These data may be gathered either retrospectively, from medical records, or prospectively, from observation of patient encounters. Note the way each drug prescribed in the sample is recorded. (See chapter 4, "Guidelines for Study Design," section E, "Defining Approaches for Collecting Survey Data"). Include only patients seeking curative care. Data collectors must be able to observe the actual names used to describe the drugs prescribed, as opposed to having access only to the names of the products dispensed. Thus, the dispensing ledger (if there is one) may not be an accurate source for this indicator.

See the "Drug Use Data Form" in Annex C, page 159.

Computation & Example:

For each facility in the sample, the indicator is recorded as a percentage, computed by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, and multiplying this quotient by 100. The overall indicator is an average of these facility-specific percentages. Along with this average, provide range figures.

$$\text{\% of Drugs Prescribed by Generic Name} = \frac{\text{Total Number of Drugs Prescribed by Generic Name}}{\text{Total Number of All Drugs Prescribed}} \times 100$$

If different levels of the system are included, summarize the results in separate tables for each type of health facility.

- For example, results for one health facility are calculated as follows:

$$\text{\% of Drugs Prescribed by Generic Name} = \frac{41}{51} \times 100 = 80\%$$

- A total of 900 drugs were prescribed at 15 health posts; 324 were prescribed by generic name. The average for this sample would be calculated as follows:

$$\text{\% of Drugs Prescribed by Generic Name for All Facilities} = \frac{324}{900} \times 100 = 36\%$$

Presentation:

In 15 health centers in country A, an average of 36% of drugs was prescribed by generic name, while in 5 hospitals in the same country, 43% of drugs were prescribed using their generic names. The rate among facilities varied from 15% to 80%.

F.6 Percentage of drugs prescribed from the National Drug Formulary List in MOH health facilities (F)

Rationale: In well-managed pharmaceutical systems, health care providers are trained to confine prescribing to those drugs on the NDFL/NEDL which are authorized for the type of facility in which they work; compliance with the NDFL/NEDL is an essential part of cost control. This indicator provides a measure of the extent to which this objective is achieved.

Definition: This indicator measures the percentage of drugs prescribed, by either brand or generic name, which are listed in the current NDFL/NEDL.

Data Collection:

Where to go	*Who to ask*	*What to get*
20 MOH health facilities	Medical Records Officer/Health Facility Manager/Pharmacist	Determine the number of drugs prescribed that are in the NDFL/NEDL, and total number of drugs prescribed in a sample of 30 patients per facility, by consulting daily registers, patient records, prescription slips, or through observation

Before the study, organizers should obtain a copy of the NDFL/NEDL, and if possible, assemble an index of brand and generic names for products on the list. Select a sample of 30 patient encounters from each health facility. These data may be gathered either retrospectively, from medical records, or prospectively, from observation of patient encounters. Record the names of the drugs prescribed exactly the way they are written. (See chapter 4, "Guidelines for Study Design," section E, "Defining Approaches for Collecting Survey Data"). Include only patients seeking curative care. Data collectors must be able to observe the actual names used to describe the drugs prescribed, as opposed to having access only to the names of products dispensed. For drugs written by brand name it may be necessary to determine the generic equivalent, before determining whether or not the product is contained in the NDFL/NEDL. This may be done by consulting relevant indexes. The services of a local pharmacist will also be useful here.

See the "Drug Use Data Form" in Annex C, page 159.

Computation & Example: For each health facility in the sample, the indicator is recorded as a percentage, computed by dividing the number of drugs prescribed which are contained in the NDFL/NEDL by the total number of drugs prescribed, and multiplying by 100. The overall indicator is an average of these facility-specific percentages. Along with this average, provide range figures.

$$\text{\% of Drugs Prescribed From the NDFL/NEDL} = \frac{\text{Total Number of Drugs Prescribed from NDFL/NEDL}}{\text{Total Number of Drugs Prescribed}}$$

If different levels of the system are included, summarize the results in separate tables for each type of health facility.

- For example, results from one health facility are calculated as follows:

$$\text{\% of Drugs Prescribed From the NDFL/NEDL} = \frac{36}{45} \times 100 = 80\%$$

- If, for 20 health facilities, data for a sample of 600 patient encounters showed that a total of 2,280 drugs were prescribed, and that 1664 of these were prescribed by generic name, then the average for all facilities would be calculated as follows:

$$\text{\% of Drugs Prescribed From the NDFL/NEDL for All Facilities} = \frac{1{,}664}{2{,}280} \times 100 = 73\%$$

Presentation: An indicator survey covering a sample of twenty health facilities in country A found that 73% of all drugs prescribed were contained in the NEDL. The range was from 62% to 94%.

F.7 Percentage of outpatients prescribed injections at MOH health facilities (F)
F.8 Percentage of outpatients prescribed antibiotics at MOH health facilities (F)

Rationale: The increasing incidence of AIDS and hepatitis B provides a good reason to assess the extent of injectable therapies and promote their rational use. Injections are essential for some purposes, but overuse, which is common, wastes scarce resources and exposes patients to risks for adverse reactions and disease. Both of these outcomes are less likely with oral therapies.

Antibiotics and injections are costly therapies and are frequently overused. Antibiotic resistance to common infections has rendered some formerly useful drugs ineffective. This is partly caused by indiscriminate, empirical and uninformed prescribing practices and other forms of overuse. This is especially serious when national capacity for laboratory monitoring of antimicrobial sensitivity is limited or nonexistent.

Definition: Injectable drugs are those given intravenously or intramuscularly. For purposes of this indicator, count only injectable drugs prescribed for curative encounters. Do not count EPI vaccinations. All antibacterials, penicillins, anti-infective dermatologicals, ophthalmic anti-infectives, and anti-diarrheal drugs containing antibiotics should be included as antibiotics. Metronidazole and anti-tuberculosis drugs (except streptomycin) would not be considered antibiotics for this indicator. The indicator measures the percentage of outpatient curative encounters for which these therapies are prescribed. The indicator result would be misleading if inpatient and outpatient encounters were mixed.

Data Collection:

Where to go	*Who to ask*	*What to get*
20 MOH health facilities	Medical Records Officer/Health Facility Manager/Pharmacist	Determine the number of outpatients who were prescribed an antibiotic, and number who were prescribed an injection for a sample of 30 patients by consulting daily registers, patient records, prescription slips, or through observation

Before the study, organizers should develop a list of which medications are to be counted as antibiotics to be used as a reference by data collectors. Select a sample of 30 patient encounters from each facility. These data may be gathered either retrospectively, from medical records, or prospectively, from observation. Count the number of injections and/or antibiotics prescribed for each patient. (See description of sampling methods in chapter 4, section E, "Defining Approaches for Collecting Survey Data.") Include only outpatients seeking curative care. Count separately the number of patients who are prescribed one or more antibiotics, or one or more injections. If a patient receives two or more antibiotics, this counts as one instance

for this purpose. If a patient receives two or more injections, this counts as one instance for the indicator.

It is extremely important to avoid, or at least be aware of, factors in the data collecting environment which would bias results. For example, if the patient encounter sample covered one or more days at facilities when most patients who attended were diabetics coming for insulin, the number of injections observed in a sample would be artificially high. Similar problems would occur if the sample was weighted with days when a psychiatric clinic was held and a high proportion of patients came for maintenance antipsychotic injections.

See the "Drug Use Data Form" in Annex C, page 159.

Computation & Example:

For each facility in a sample, both indicators are recorded as percentages, computed by dividing the number of patient encounters during which an antibiotic is prescribed/an injection is given, by the total number of patient encounters surveyed, and multiplying by 100. The overall indicators are the averages of these facility-specific percentages. Along with this average, provide range figures.

$$\text{\% of Patients Prescribed Injections} = \frac{\text{Total Number of Patients Prescribed Injections}}{\text{Total Number of Patient Encounters Surveyed}} \times 100$$

$$\text{\% of Patients Prescribed Antibiotics} = \frac{\text{Total Number of Patients Prescribed Antibiotics}}{\text{Total Number of Patient Encounters Surveyed}} \times 100$$

- For example, results from one health facility are calculated as follows:

$$\text{\% of Patients Prescribed Injections} = \frac{4}{30} \times 100 = 13\%$$

$$\text{\% of Patients Prescribed Antibiotics} = \frac{7}{30} \times 100 = 23\%$$

- If, for 20 health facilities surveyed, data for a sample of 600 patient encounters showed that a total 120 patients received injections, then the average for all facilities would be calculated as follows:

$$\text{\% of Patients Prescribed Injections for All Facilities} = \frac{120}{600} \times 100 = 20\%$$

- For the same 20 health facilities, the same data also showed that 102 patients received antibiotics. Therefore, the average for all facilities would be calculated as follows:

$$\text{\% of Patients Prescribed Antibiotics for All Facilities} = \frac{102}{600} \times 100 = 17\%$$

Presentation: In a survey of 20 health facilities in country Z, an injection was prescribed during 20% of all outpatient encounters, with a range of 0% to 55% among facilities. For the same sample, 17% of encounters resulted in prescription of antibiotics, with a range of 0% to 57% among facilities.

F.9 Percentage of prescribed drugs presented for dispensing that are actually dispensed in MOH health facilities (F)

Rationale: This indicator measures the ability of a sample of health facilities to meet the pharmaceutical needs of their users. It is also a measure of the availability of drugs in the health facilities.

Definition: Drugs that are actually dispensed are defined as drugs that are prescribed and dispensed from the health facility. In this indicator, it is based only on the prescriptions *presented* for dispensing.

Date Collection:

Where to go	*Who to ask*	*What to get*
20 MOH health facilities	Medical Records Officer/Health Facility Manager	Number of drugs dispensed and total number of drugs that were prescribed in a sample of 30 dispensing encounters at each facility

At each of the 20 health facilities, examine 30 dispensing encounters in a given month. Prior to the start of the assessment, all the data collectors should agree on which month or set time period to study these 30 encounters at each health facility. If records document which drugs were not dispensed, this indicator can be collected retrospectively. Otherwise, observe 30 dispensing encounters. (See chapter 4, section E, "Defining Approaches for Collecting Survey Data.") Record the number of prescribed drugs presented for dispensing, and then record the number of drugs actually dispensed from these 30 encounters. Each prescribed drug should be counted separately. If any portion of the prescribed amount is dispensed, count the drug as dispensed.

See the Drug Use Data Form" in Annex C, page 159.

Computation & Example: For each health facility in the sample, indicators are recorded as percentages, computed by dividing the number of drugs actually dispensed by the total number of prescribed drugs which were presented for dispensing, and multiplying this quotient by 100. The overall indicator is an average of these facility-specific percentages. Along with this average, provide the range figures.

% of Prescribed Drugs that are Dispensed =

$$\frac{\text{Number of Drugs Actually Dispensed}}{\text{Number of Prescribed Drugs Presented for Dispensing}} \times 100$$

- The results for one health facility are calculated as follows:

$$\% \text{ of Prescribed Drugs that are Dispensed} = \frac{35}{45} \times 100 = 78\%$$

- If, for 20 health facilities surveyed, data for a sample of 600 patient encounters showed that 438 prescribed drugs were actually dispensed, then the average for all facilities would be calculated as follows:

$$\text{Average \% of Prescribed Drugs that are Dispensed for All Facilities} = \frac{438}{600} \times 100 = 73\%$$

Presentation: In country C, for a sample of 20 health facilities, an average of 73% of prescribed drugs presented for dispensing were actually dispensed, with a range from 50% to 96% among facilities.

G. *Product Quality Assurance*

G.1 MOH drug product quality laboratory tests during the past year: (a) number of drug products tested and (b) total number of drug product quality tests performed (C)

Rationale: This indicator measures how actively the Ministry of Health pursues drug product quality assurance (QA) testing. Typically, Ministries of Health have laboratory analyses conducted on drug samples on such occasions as: receipt of bids from potential suppliers, arrival of new stock at the central warehouse, receipt of complaints concerning specific products, or random sampling in retail pharmacies.

Definition: This indicator measures the number of separate drug products which were submitted by MOH facilities for testing within a recent 12 month period, and the total number of tests for quality which were performed.

Data Collection:

Where to go	*Who to ask*	*What to get*
Drug Regulatory Authority or Quality Control Testing Laboratory	Officer in charge of quality control and drug testing laboratory services	Information on the existence of drug product testing program, its description and performance

Use interviews with key informants to determine and record:

- Whether or not the MOH has an active drug product testing program
- Names and affiliations of the laboratories which actually perform the tests
- Occasions on which testing is carried out
- Number of drug products submitted for testing, from where and why
- Number of drug products actually tested this past year
- Number of tests carried out in the past year, with results of tests
- The year these tests were performed
- Information at the drug testing laboratory concerning staff level and capacity, equipment, record systems, and access to reagents, reference standards and technical information

Computation & Example: This indicator is expressed as:

- Number of drug products tested by the MOH for drug quality.

- Total number of tests carried out by the MOH for drug quality. For example, drugs X and Y were submitted to the MOH for testing. Four separate tests were done on X and only two on Y. Therefore, two drug products were tested and a total of six tests were performed. In addition, present any information which permits breaking down the total number of tests by such criteria as: number initially presented for testing, reasons for testing, numbers of positive and negative results, and locations of testing.

Presentation: Six drugs purchased by the MOH in country Q were submitted for testing to the Regional Drug Testing Laboratory in 1993. At the time of the survey, results had been obtained for three of these items. One (ampicillin) was found to be substandard. A total of eight tests were performed on these three drugs.

G.2 Use of WHO Certification Scheme (C)

Rationale: Developing countries with inadequate pharmaceutical testing facilities may be unable to carry out quality control analyses. The WHO *Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce* is one mechanism to help assure the quality of pharmaceutical products manufactured or purchased in a country.[9] Full participation of the exporting country in the Scheme provides assurance that the drug has been authorized to be sold in the exporting country, that the manufacturing laboratory has been inspected and complied with good manufacturing practices, and facilitates the exchange of drug information between governments.

Definition: This indicator measures the degree to which the WHO *Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce* is used by importing countries for drug registration and for public sector procurement, and by exporting countries to certify quality of exported products.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Director of Pharmaceutical Services	Evidence of membership to and use of WHO Scheme to assure quality of pharmaceuticals in registration, procurement, and/or certification for exports
Central Procurement Agency	Director	
Drug Regulatory Authority	Officers in charge of registration and of certifying good manufacturing practices	

There are four ways for a country to participate in the WHO *Certification Scheme*. A country may:

1. Issue and use certification for drug registration
2. Issue certification for exports
3. Use certification issued by other countries for drug registration
4. Uses certification by other countries for public sector procurement

Visit whatever sites are required for determining whether the country participates in each of these components. Also determine if the country is using the current version of the Scheme, and obtain data on the specific number of instances of use for purposes of procurement, registration and certification of exports. Verbal assurances of participation in and active use of the *Certification Scheme* do not necessarily mean that the Scheme is being used. The study team should ask for documents which verify use.

Computation & Example: Record participation in the *Certification Scheme* as follows:

- ***Total***, if the country is a member and uses the Scheme and for all of the registration, export, and procurement functions
- ***Partial***, if the country is a member and actively uses the Scheme for at least one of the registration, export, and procurement functions
- ***Limited***, if the country is an official member of the Scheme, but there is limited or no evidence that it is active for specific purposes of registration, exports, or procurement
- ***None***, if the country does not participate in the Scheme

Presentation: Country A is a partial participant in the WHO *Certification Scheme of Pharmaceutical Products Moving in International Commerce*. Review of relevant records showed that in 1993, there were six import certifications for drugs purchased by the MOH Central Medical Store. There is no evidence that the Scheme is used for product registration or export certification.

G.3 Existence of formal systems for reporting: (a) product quality complaints, and (b) adverse drug reactions (ADRs) (C)

Rationale: Product quality assurance is most readily assured by a combination of purchases from reliable suppliers and functioning mechanisms through which health care providers report potentially defective products and potential adverse reactions. Effective follow-up on such reports is also critical. This indicator measures a government's ability to monitor drug product quality problems, as well as drug-induced disease.

Definition: Formal mechanisms designed for reporting product quality complaints and adverse drug reactions in patients are programs which have been enacted by legislation, written regulation, or through official notices from the responsible government agency. To be considered functioning, the offices responsible for administering these systems must be able to produce standard forms used for reporting quality complaints or ADRs. In addition, there must be evidence that follow-up investigations occur when reports are submitted.

Data Collection:

Where to go	*Who to ask*	*What to get*
Drug Regulatory Authority	Quality Control Officer	Format for reporting drug quality complaints and ADRs, number of complaints and ADRs reported during previous year, action taken and sample of reporting forms
MOH	Chief Pharmacist	
Adverse Drug Reaction Monitoring Center or Unit	ADR monitoring officer	

Determine, through interviews and review of documents on hand at the office(s) responsible for pharmaceutical quality control and adverse drug reactions, how reports are intended to be processed. Obtain copies of reporting forms. Determine how many product quality complaints or ADR reports have been received during the last year. If it is verified that reports have been received, ask for evidence of any follow-up that took place.

Computation & Example: Each part of this indicator should be scored according to the following criteria:

- ***Functional***, if a formal reporting system is mandated, there are standard reporting forms, there is evidence that reports are submitted, and there is evidence that follow-up investigations take place
- ***Limited***, if a reporting system is mandated, but no standard reporting forms exist, or even if standard reporting forms do exist, reports are rarely or never submitted, and there is no evidence of follow-up investigations
- ***Nonexistent***, if there is no reporting system in place

Presentation: In country Y, the Drug Regulatory Authority is mandated by the Health Code to monitor and take action on product quality complaints. The status of this system is at best **limited**, because no standard reporting forms exist, and only one complaint was received during the 12 months preceding the assessment. There was no evidence of follow-up action.

For adverse drug reactions the situation is similar, with even less evidence of activity. There is no legal mandate for reporting ADRs, but staff at the Drug Regulatory Authority do acknowledge responsibility in this area. There is no standard reporting form, nor is there evidence that reports have ever been submitted. Therefore, the most appropriate rating for an ADR reporting system appears to be **nonexistent** at the national level.

There are, however, two hospitals in the capital city that do have their own ADR reporting systems, both using regular reporting forms: the University Teaching Hospital and the Adventist Hospital. At the University Hospital, an average of two ADRs were reported monthly over the twelve months preceding the assessment, and at the Adventist Hospital a monthly average of one ADR was reported over the same period.

H. Private Sector Pharmaceutical Activity

H.1 Population per licensed private sector drug retail outlet (C)

Rationale: The private pharmaceutical sector is the primary source of medicines consumed in most countries. The extent and impact of this sector on the health status of the population is usually not well documented. This indicator provides one measure of the coverage of the private sector drug system.

Definition: A private sector drug retail outlet is any private drug outlet, pharmacy, or formally organized store that is authorized by the Drug Regulatory Authority to sell ethical and/or over-the-counter pharmaceutical products to the public.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Chief Pharmacist	List of all licensed private sector drug retail outlets
Pharmacy Board	Members	
Drug Regulatory Authority	Director	
Bureau of Statistics	Census Director	Most recent population census figure/population projections for intercensal period

Obtain a list or a count of all licensed private sector drug retail outlets. Obtain official information about the most recent estimate of national population. If the most recent local estimates are not current, extrapolate from the last census figure, the year it was done, and the population growth rate per year (or use the most recent edition of the *World Development Report*).

Computation & Example: This indicator is a ratio, obtained by dividing the national population by the number of licensed private sector drug retail outlets. Express results in terms of persons per drug retail outlet.

$$\text{Population per Licensed Private Sector Drug Retail Outlet} = \frac{\text{National Population}}{\text{Number of Licensed Private Sector Drug Retail Outlets}}$$

$$\text{Population per Licensed Private Sector Drug Retail Outlet} = \frac{10{,}000{,}000}{400} = 25{,}000$$

Presentation: In country X, a total of 400 licensed private sector drug retail outlets were in operation during the year 1993. With a total population of 10,000,000 persons that year, this yields an average of 25,000 persons per licensed private sector drug retail outlet.

H.2 Number of licensed or registered drug retail outlets per government drug inspector (C)

Rationale: Governments need to ensure that the private pharmaceutical sector is an effective partner in sustaining and improving the health status of the population. Active enforcement of the legislation and regulations require adequate numbers of trained inspectors. The number of licensed/registered drug retail outlets per government drug inspector provides an estimate of the government's capacity to monitor the formal drug retail market.

Definition: Only pharmacies and other formally organized stores that are licensed to sell drugs to the public should be counted. Government drug inspectors are those whose primary or secondary responsibility is inspecting drug manufacturers, drug importers, drug warehouses, private pharmacies, and other drug retail outlets. This indicator, however, concerns only drug retail outlets.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Director of Pharmaceutical Services	List of all licensed private sector drug retail outlets, and total number of staff that are officially counted as drug inspectors
Pharmacy Board	Members	
Drug Regulatory Authority	Director	

Obtain the most recent information regarding the number of licensed and/or registered drug retail outlets in a given year. Define the categories of government staff that are officially counted as drug inspectors, and obtain an estimate of the number of such personnel that are currently employed by the government in that given year.

Computation & Example: This indicator is calculated by dividing the number of licensed drug retail outlets by the number of actual drug inspectors. Express the results in terms of outlets per inspector.

$$\text{Number of Licensed Drug Retail Outlets per Drug Inspector} = \frac{\text{Number of Licensed Drug Retail Outlets}}{\text{Number of Drug Inspectors}}$$

$$\text{Number of Licensed Drug Retail Outlets per Drug Inspector} = \frac{900}{12} = 75$$

Presentation: In country X, the Department of Drug Administration has 12 staff members whose full or part time responsibilities include inspecting drug retail outlets of all categories. There are 900 licensed pharmacies. This yields an average of 75 licensed drug retail outlets per inspector.

H.3 Percentages of drug manufacturers, distributors, and drug retail outlets inspected during a one-year period (C)

Rationale: The degree of coverage for inspections of drug manufacturers, distributors, and drug retail outlets provides a rough measure of the enforcement of drug legislation and regulations.

Definition: For this indicator, drug manufacturers are those companies that are licensed to manufacture raw materials, formulate from imported or manufactured raw materials, repackage finished dosage forms and strengths, or any combination thereof. Distributors include companies that distribute pharmaceuticals, as well as other products. See H.1 for a definition of drug retail outlets.

Data Collection:

Where to go	Who to ask	*What to get*
MOH	Director of Pharmaceutical Services	List of all manufacturers, distributors and licensed private sector drug retail outlets, and total number of sites inspected in each category in 12 months prior to the assessment or during the last year
Pharmacy Board	Members	
Drug Regulatory Authority	Director	

Interview key informants and review records to determine:

- Numbers of manufacturers, distributors and retailers
- Numbers of sites in each category that received one or more inspection visits during either the 12-month period preceding the assessment, or the most recent one-year period for which data are available

Computation & Example: For each category, calculate the percentage of total sites receiving one or more inspection visits in the past year, as follows:

$$\text{\% of Sites Inspected} = \frac{\text{Number of Sites Inspected}}{\text{Total Number of Sites}} \times 100$$

H.4 Total value of total private sector retail pharmaceutical sales, US$ per capita (C)

Rationale: The value per capita of private sector retail pharmaceutical sales is one measure of the value of national resources allocated to pharmaceuticals. To allow cross-national comparisons, the value is expressed in US$ per capita.

Definition: Private sector retail pharmaceutical sales are those sales that are made to the public through private drug retail outlets. It excludes sales from distributors to public sector hospitals and outpatient health facilities.

Data Collection:

Where to go	*Who to ask*	*What to get*
Pharmaceutical Manufacturers Association	President and/or members	Total value of retail sales in US$ for most recent calendar or fiscal year
Retail Trade Association	President and/or members	
Customs or Internal Revenue Agency	Registry Director	
Ministry of Finance or Trade	Planning Director	
Bureau of Statistics	Census Director	Most recent population estimate, international data sources such as IMS International Data

After ascertaining what information sources are available, study organizers must determine the most reliable method of obtaining total private sector retail pharmaceutical sales in a recent fiscal or calendar year. Often, the most reliable source for such information is the local association which represents pharmaceutical manufacturers. Sometimes information will be available from the Ministry of Health or the Ministry of Trade (or its equivalent). Obtain a reasonably accurate official estimate of the national population (as described in other indicators) during this fiscal year. Be sure not to double count wholesale and retail sales. If sales data were provided in local currency, and there have been significant changes in the conversion rates, select and report on a method for averaging the exchange rate. Obtain data for the same time period used for MOH pharmaceutical expenditures.

Computation & Example: The indicator is calculated as the total value of private sector retail pharmaceutical sales, in U.S. dollars, divided by the national population.

$$\text{Private Sector Pharmaceutical Sales Per Capita} = \frac{\text{Total Value of Private Sector Retail Drug Sales}}{\text{National Population}}$$

The Office of Inspection provided information summarized in the table below concerning sites inspected during 1993.

Type of Site	Number	Number Inspected	Percent Inspected
Manufacturer	6	4	67%
Distributor	14	6	43%
Drug Retail Outlet	900	84	9%

The example below illustrates the calculation for the drug retail outlets:

$$\text{\% of Sites Inspected} = \frac{84}{900} \times 100 = 9\%$$

Presentation: During a one year period in country X, the percentage of sites inspected, by category, was as follows: 9% of drug retail outlets, 43% of distributors, and 67% of manufacturers.

H.6 Percentage of products on National Drug Formulary List that are currently manufactured or co-manufactured within the country (C)

Rationale: The percentage of products on the NDFL/NEDL which are currently manufactured or co-manufactured within the country measures a country's self sufficiency for supplying the most essential pharmaceutical products.

Definition: For the indicator to be relevant, there must be a National Drug Formulary List in existence, as well as a local drug industry. Drugs from this list are counted as manufactured in-country if they are manufactured either from raw materials or intermediate chemical constituents; drugs which are simply repackaged or relabelled are not counted.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Pharmaceutical Services Director	Total number of drugs in NDFL/NEDL
Local Pharmaceutical Manufacturers Association	President/Members	List of drugs manufactured from raw materials or intermediate chemical constituents

Determine the number of pharmaceutical products listed on the National Drug Formulary List. For each of these products, determine if one or more local manufacturers currently manufactures the product in-country and markets it in either generic or proprietary form. If a product is manufactured by one or more manufacturers, it is recorded as being produced in the country.

Computation & Example: This indicator is recorded as a percentage, calculated by dividing the number of drugs produced in-country, in a given year, on the National Drug Formulary List by the total number of unique, generic drug products on the list, and multiplying by 100.

% NDFL Drugs Manufactured In-country =

$$\frac{\text{Number of Drugs on NDFL that are Manufactured In-country}}{\text{Number of Drugs on NDFL}} \times 100$$

$$\text{\% NDFL Drugs Manufactured In-country} = \frac{120}{284} \times 100 = 42\%$$

Presentation: In 1992, 42% of the drugs on the National Drug Formulary List of country D were manufactured in-country by one or more of the six local producers.

Computation & Example: For the same time period, adjust the public and private sector components, add together, then divide by the estimated national population.

$$\text{Combined Public Drug Purchases and Private Sector Sales Per Capita} = \frac{\text{Public Sector Purchases} + \text{Private Sector Sales}}{\text{National Population}}$$

OR add the values of the indicators C.1 and H.4, assuming the data was collected over the same period of time for both, and there are no other major public sector health systems.

Combined Public Drug Purchases and Private Sector Sales Per Capita =

$$\frac{\$18{,}000{,}000\ (\text{MOH}) + \$8{,}000{,}000\ (\text{Social Security}) + \$58{,}800{,}000(\text{Private})}{14{,}000{,}000} = \$6.06$$

Presentation: In country B, in the previous calendar year, the total value of the drug market was US$ 6.06 per capita ($1.86 by the public sector and $4.20 in the private sector).

H.5 Combined value of public sector pharmaceutical expenditures and private sector retail sales, US$ per capita (C)

Rationale: The combined value of public sector drug purchases and private sector retail pharmaceutical sales is one measure of the value of total national resources allocated to pharmaceuticals. This indicator complements the previous one. Viewed together, they provide a basis for comparing the relative weights of the MOH and private sector in the market.

Definition: Total public sector per capita purchases are defined as the total amount of money (in US$ at the current rate of exchange) spent on purchasing pharmaceuticals by all public sector systems (national, regional and local budgets combined) for the most recent financial year, per individual in the population. The total private sector market is estimated by the value of total pharmaceutical retail (rather than wholesale) sales as described in the previous indicator. The periods (and exchange rates) used for private and public markets should be the same. This value should not include donations for (or from) NGOs and/or PVOs. However, major NGO health systems which purchase drugs in the local market for distribution through their own health systems should be included, if possible.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH and other major public sector health systems	Finance or Budget Director	Total public sector purchases and total value of retail sales in US$ for most recent calendar or fiscal year
Pharmaceutical Manufacturers Association/Retail Trade Association	President and/or members	
College of Pharmacy	President and/or members	
Customs or Internal Revenue Agency	Registry Director	
Ministry of Finance or Trade	Planning Director	
International data sources, such as IMS International Data		
Bureau of Statistics	Census Director	Most recent population estimate

Two major components of this indicator have been collected previously in two other indicators (C.1 and H.4). In order to be able to combine them for this indicator, however, the MOH expenditures and private sector sales figures must be calculated for the same defined period of time. If there are other major public sector health systems, such as Social Security, these estimated or actual purchases must be added to the MOH figure for the same period of time.

$$\text{Private Sector Pharmaceutical Sales Per Capita} = \frac{\$58{,}800{,}000}{14{,}000{,}000} = \$4.20$$

Presentation: In country B, the value of the private pharmaceutical sector sales was approximately $4.20 worth of drugs per capita during 1993.

Computation & Example:

Using the *median retail prices*, this indicator is calculated as follows:

- For each indicator drug, divide the median retail unit price by the MOH acquisition unit price, and multiply by 100.

$$\% \text{ of MOH Acquisition Price} = \frac{\text{Median Retail Unit Price}}{\text{MOH Acquisition Unit Price}} \times 100$$

- For the entire list of indicator drugs, add up the results of the above calculation done for each product, then divide by the total number of indicator drugs.

Average % of MOH Acquisition Price =

$$\frac{\text{Sum of \% of MOH Acquisition Prices for all Indicator Drugs}}{\text{Total Number of Indicator Drugs}}$$

For example, for purposes of illustrating this result, assume an indicator drug list of three products.

Product	Median Retail Unit Price	MOH Acquisition Unit Price
Tetracycline 250 MG CAP	0.112 per CAP	0.014 per CAP
ORS 200 ML PKT	0.36 per PKT	0.04 per PKT
Paracetamol SYR 100 ML BOT	4.30 per ML	0.43 per ML

1. To arrive at the average percentage of MOH acquisition price, the first step is to calculate the percentage of MOH acquisition price for each product. For tetracycline, the first product on the list, this is done as follows:

$$\% \text{ of MOH Acquisition Price} = \frac{0.112}{0.014} \times 100 = 800\%$$

2. Using the data provided in the table, the percentages of MOH acquisition prices for ORS and paracetamol syrup are calculated as 900% and 1000%, respectively.

3. Finally, the average percentage of MOH acquisition price for all three products is calculated as follows:

$$\text{Average \% of MOH Acquisition Price} = \frac{800 + 900 + 1000}{3} = 900\%$$

Presentation:

In country Q, retail prices of 25 indicator drugs were found to be, on average, 900% of MOH acquisition prices, based on retail data collected in July 1993 and MOH acquisition prices paid in March 1993.

H.7 Average of median private sector drug retail prices as a percentage of MOH acquisition prices for a set of indicator drugs (C)

Rationale: The average percentage of median indicator drug prices in private sector drug retail outlets provides a measure of the cost-effectiveness of operating in-house retail pharmacy services in MOH health facilities. Cost-effectiveness increases to the degree that retail prices exceed MOH acquisition prices.

Definition: The average of median private sector retail prices is the average of the median retail prices for a list of 25 to 50 tracer drugs, based on data collected at a sample of 20 drug retail outlets. These data can be collected as part of the sample survey covering both MOH health facilities and drug retail outlets that is required for covering a number of other indicators. (See chapter 4, "Guidelines for Study Design.") The average MOH acquisition prices are the average of CIF prices paid for the same indicator drugs in the most recent MOH procurement.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH Procurement Unit or CMS	Officer in charge	Most recent regular CIF price paid for list of tracer drugs
Sample of drug retail outlets	Pharmacy owner /Dispenser /Pharmacist	Retail price for list of tracer drugs

To collect prices from retail outlets, begin with the list of tracer drugs. Visit the sample of pharmacies or other drug retail outlets, and at each site obtain the current selling price for each of the indicator drugs. If an item is not stocked, skip that drug and go to the next. If more than one brand is stocked, use the price of the least expensive product. Select the *median* price for each indicator drug from the aggregate of prices collected from all sites visited. [The *median* (or middle-most), is used instead of the *mean* (or average) retail price to avoid bias caused by outlying high or low prices for a given drug product.] To determine the median retail price for each product, examine the complete list of 20 prices obtained from all sites, arranged in ascending order, and pick the middle two numbers (**10** and **11**). Add these two numbers and divide by two to obtain the median. If the list contains an odd number of items, simply select the middle-most number as the median. See the following examples:

Ex. 2,3,4,5,6 Median is **4**

Ex. 2,3,4,5,6,7 Median: 4 + 5 = 9 ÷ 2 = **4.5**

The MOH acquisition price is the CIF price paid for the indicator drugs for the most recent regular (non-emergency) procurement. This has already been discussed in indicator D.3.

See the "Price Comparison Data Form" in Annex C, page 163.

- ***Wholesale Only***, if price controls apply only at the wholesale level
- ***Retail Only***, if price controls only apply at the retail level
- ***None***, if there are no official price controls in place

Presentation: In country X, there are regulations that control drug prices at both the wholesale and retail units. The regulations limit markups at the wholesale level to 10%, and at the retail level to 15%. Interviews with MOH officials and the Pharmaceutical Association suggest that controls are not rigorously enforced.

H.8 Existence of price controls for drugs in the private sector (C)

Rationale: Governments often attempt to influence the level of profit the private sector can obtain from drug sales. This indicator will record whether there are policies and regulations controlling the prices of drugs in the private sector.

Definition: Price controls are regulations which govern markups, margins, sales prices or profits for drugs at the manufacturer, importer, wholesale distributor and/or retail sales level.

Data Collection:

Where to go	*Who to ask*	*What to get*
MOH	Director of Pharmaceutical Services	Copy of legislation or regulations controlling prices of drugs in the private sector, list of prices, description of measures to monitor prices charged, sanctions to violators, and number of sites where price checks were carried out in the last 12 months
MOF	Price Control Authority	
Manufacturers, importers, wholesalers	Company Managers	
Retail outlets	Owners	
Professional and industry associations	President	

Interviews and document review are used to determine the presence of price controls at manufacturer, wholesale and retail levels. The type and extent of controls at each level should be obtained. If feasible, price lists from manufacturers and wholesale and retail outlets should be used in combination with interviews, to determine whether controls are enforced. During interviews, request information about programs in place to monitor compliance with price controls, and sanctions which are applied to violators. If possible, obtain quantitative information as to the number of outlets where prices were physically checked in the last 12 months, and the number of exceptions which were found. In addition, collect information on such related points as titles of pertinent laws and regulations, rigor of enforcement and fines or other sanctions for violations.

Computation & Example: This indicator is scored as follows:

- ***Manufacturer, Wholesale and Retail***, if price controls are in force for all three levels
- ***Manufacturer and Wholesale***, if price controls exist at both manufacturer and wholesale levels
- ***Wholesale and Retail***, if price controls exist at both wholesale and retail levels
- ***Manufacturer Only***, if price controls are applicable only to manufacturers

Computation & Example: This indicator is recorded as a percentage, calculated as the number of drug retail outlets where an antibiotic was successfully purchased without a prescription divided by the total number of drug retail outlets where the attempts to purchase were made, and multiplied by 100.

$$\text{\% of Outlets where Antibiotic was Available Without a Prescription} = \frac{\text{\# of Outlets where Antibiotic Available Without a Prescription}}{\text{Total Drug Retail Outlets Visited}} \times 100$$

$$\text{\% of Outlets where Antibiotic was Available Without a Prescription} = \frac{14}{20} \times 100 = 70\%$$

Presentation: When an assessor asked to purchase tetracycline without a prescription, she was successful in 14 out of 20, or 70%, of drug retail outlets during the month of March 1994.

H.9 Percentage of licensed drug retail outlets where an antibiotic was available without a prescription (C/R/F)

Rationale: Antibiotics have precise indications when epidemiological and laboratory evidence confirm or suggest a bacterial infectious agent. In the absence of this evidence, use of antibiotics is not only ineffective and a waste of resources, but it can also result in resistance. Health care system staff should be aware of the detrimental consequences of unjustified use of antibiotics and in countries where policies regulate their sale with a prescription, compliance should be enforced. This indicator will measure the degree to which existing regulations on the sale of antibiotics without a prescription are obeyed in practice. If there are no regulations, this indicator is not relevant.

Definition: For this indicator, a prescription is a document that contains the physician/prescriber's choice of drug treatment for the patient. All antibacterials, penicillins, anti-infective dermatologicals, ophthalmic anti-infectives, and anti-diarrheal drugs containing antibiotics should be included as antibiotics.

Data Collection:

Where to go	*Who to ask*	*What to get*
20 licensed drug retail outlets near the health facilities assessed	Pharmacist or dispenser	Purchase of one or two capsules/tablets of an antibiotic without a prescription

Ascertain whether any regulations exist regarding the sale of antibiotic products without a prescription. If they do, ask which antibiotic drugs might commonly be sold over the counter without a prescription (e.g., tetracycline, ampicillin or co-trimoxazole). Recruit the assistance of local personnel, and have them attempt to purchase 1 or 2 capsules/tablets of the product in question at a randomly selected drug retail outlet near each of the 20 health facilities (see methods described in chapter 4, "Guidelines for Study Design," Section E, "Defining Approaches for Collecting Survey Data"). Count all drug retail outlets where drugs are successfully purchased.

Drugs that are purchased should be retained by the principal investigator. If quality assurance testing facilities exist in the country, products could be tested for quality. The investigator might also be able to determine the number of different suppliers' products which are sold. Once any such activities are completed, properly dispose of any remaining drugs. Prior to the start of any assessment, all data collectors should agree to do this study over the same set period of time (e.g., within the month of July), and to attempt to purchase the same drug product (not necessarily from the same manufacturer).

See the "Generic Substitution and Sale of Antibiotics Data Form" in Annex C, page 143.

Experience in several countries has shown that the most practical way to carry out the pharmaceutical indicators study is to engage two or more expert investigators to work with counterparts over a period of three to six weeks. An ideal combination would include the following people:

- A *pharmaceutical management specialist* to take charge of data collection at the *central* level. For this, familiarity with pharmaceutical policy, system management, procurement, and budget issues would be most useful.

- A *health care provider* such as a physician, pharmacist or nurse to take charge of the surveys to be carried out at the *regional and health facility* levels. For this, familiarity with pharmaceutical products and work routines in health facilities would be an asset.

The rest of this chapter, and the following one, are based on the assumption that the pharmaceutical indicator study will be carried out by two investigators. In order to avoid confusion, one member of the study team should be designated as the team leader. Technical responsibilities should be divided according to the skills and interests of each team member. Data collection at facility level may be handled largely or entirely by data collectors recruited locally. Using local health care system counterparts who are fully committed to participation and who are available full time will expand the technical reach of the assessment substantially. Furthermore, it is essential to have a senior operations official of the local health care system designated as principal counterpart to the assessment team.

One crucial step that cannot be overlooked when planning an assessment is the definition and identification of necessary resources. The financial and human resource requirements depend primarily on the purpose and scope of the assessment, and the number of significant levels in the health care system.

An experienced two person team of experts might be able to manage a survey of public sector pharmaceutical programs in a small-to-medium-sized country in a total of six weeks. The team would spend one week preparing for the assessment, three weeks in-country and two weeks analyzing data and writing the report. This assumes that local officials and counterparts were active supporters and participants, and that the health care system has no more than three levels to be covered, i.e., central, provincial and district.

In the same country, an additional experienced person would be needed to cover the private sector in detail, and a fourth person would be needed if there were additional levels in the public sector system. The cost of these experts is higher both in terms of salary or fee and travel expenses if international consultants are used; costs may be reduced if there are local experts who have the necessary expertise and experience.

In addition to the cost of experts (local or international), which includes salary, all travel and per diem, there are additional costs which must be covered:

- Preparation of data collection forms
- Communications
- Travel and per diem for local counterparts
- Travel and per diem for local data collectors
- Cost of personnel to enter data into computers
- Miscellaneous local costs during the study

IV. GUIDELINES FOR STUDY DESIGN

General Approach

This manual is intended for use in a structured assessment of the pharmaceutical sector. At first glance, gathering data for the 46 indicators described in the preceding chapter may seem complex and intimidating. The complete assessment requires that information be gathered on eight different topics, at three administrative levels, and using seven different methods of data collection. These three dimensions of the indicator study are given below:

Topics	Levels	Methods
Policy, Legislation and Regulation	Central	Structured Interview
Formulary/Essential Drugs List and Drug Information	Regional	Document review
Ministry of Health Budget and Finance	Health facility	Inventory taking and stock record review
Ministry of Health Pharmaceutical Procurement		Clinical record review
Ministry of Health Pharmaceutical Logistics		Observation of clinical encounters
Patient Access and Drug Utilization		Shelf checks
Product Quality Assurance		Simulated purchases
Private Sector Pharmaceutical Activity		

The actual management is not, however, as difficult as it may seem. In practice, the entire set of indicators sorts itself into two groups, which constitute distinct data collection efforts:

- At the *central level*, data are collected for 38 indicators, of which 30 are collected through structured interview and document review, and eight through physical inventory and stock record review.

- At the *regional and health facility levels*, data for 18 indicators are collected through sample surveys, in the course of which techniques such as physical inventory, review of stock records, review of clinical records, shelf checks and simulated purchases are all used. These methods are also supplemented by structured interviews.

These two efforts represent roughly equal amounts of work. Note that data for some of the indicators are collected at multiple levels. Although the central-level effort has the most indicators to cover, all of the required data should be available in the capital city, and most of them may be relatively easy to obtain. The regional/health facility effort covers fewer indicators, but it requires organizing a survey to collect different types of data in 40 or more sites.

- List of sources of drugs flowing through the distribution system, and estimated values for each source. This should include the central and regional budgets, donors and NGOs.
- For each major source of drugs, to the extent possible, list the annual schedules for budgeting, needs estimation, procurement and distribution.
- Tables showing geographical distribution of warehouses and health facilities.
- Delivery schedules for all levels of the system.
- Summary of transport arrangements that link storage and health facilities. This should be as specific as possible, indicating numbers and types of vehicles available by geographic zone. If transport is through contract arrangements with parastatal or commercial agencies, describe those arrangements and indicate the budgets.
- Qualitative descriptions of major problems that affect the movement of drugs through the procurement and distribution system.
- Staffing patterns that reflect numbers and geographic distribution.

In most settings, it will be possible to create all of these items through interviews and document review. Annex A gives examples of charts and tables developed for one recent study.

C. *Specifying a List of Indicator Drugs*

Seven indicators are measured on the basis of a standard list of indicator drugs. These include indicators related to procurement, stock control, drug availability in the public sector, and prices in the private sector. Although it would be ideal to collect data on all drugs flowing through a system, this would usually require too much time and effort. Therefore, data are collected for a standard list of 25 to 50 products, called *indicator drugs*. There is no "universal" indicator drug list. An indicator drug list must be developed locally for each country wherein assessments take place. While developing the list, keep the following points in mind:

- The list of indicator drugs must include drugs that are commonly used and that should be available at warehouses and health facilities. Most of the drugs should be drawn from the national formulary or essential drugs list. However, it may also be useful to include one or more drugs which are not from these lists, but which local team members believe are used in violation of official policies.

- In country settings where record keeping is generally disorganized and incomplete, it is best to have a longer list of about 50 products. This will help to ensure that data for all indicators are collected for a core sample of products, for example, at least 20 to 25.

- It is absolutely essential to involve local experts in the formulation of indicator drug lists. Failure to do so may seriously undermine the credibility of results. For example, co-trimoxazole may be the international expert's drug of choice for treating pneumonia in children, but local experts may know that ampicillin is used most often in practice. In such a case, it would be desirable to have both products on the indicator drug list.

- The indicator drug list should cover a range of therapeutic categories, as well as important individual drugs within each category. If feasible, selection should also be based on drug utilization data and on data concerning values of drugs purchased, such as those provided by ABC analysis. For example, the list probably should include antibiotics, cardiovascular drugs,

These additional costs usually run between US$2,000 and US$10,000 (as of 1995) depending on the actual costs for local travel and support. The total cost of a country-wide structured assessment may vary between US$50,000 and US$150,000 (again, as of 1995) for a medium-sized country with a pharmaceutical sector of average complexity. This assumes that the principal assessment team members are all international consultants. This is indeed a substantial sum, but it must be remembered that a development project based on the assessment might be worth US$100 million.

Before any data are collected, it is first necessary to prepare systematically by carrying out seven tasks:

A. Gather vital statistics on the country and the Ministry of Health
B. Prepare an overview of Ministry of Health pharmaceutical management operations
C. Specify a list of indicator drugs
D. Design a sample survey of health care facilities and drug retail outlets
E. Define approaches for collecting different types of survey data in health facilities and retail pharmacies
F. Develop data collection forms and structured interview questionnaires
G. Define the range of dates which will be used to collect retrospective data

A. Gathering Vital Statistics and Background Information

There are certain vital statistics which are used repeatedly, either to derive specific indicators, or to provide context when presenting the results in a report. When two or more investigators work on a study, it can easily happen, based on interviews with different informants and readings of different documents, that they begin to use and derive different figures, which result in embarrassing divergences in the information presented. To avoid this problem, the following data should be collected, recorded and distributed to all investigators at the very outset of the work:

- The dates covered by the government fiscal year
- Exchange rates of local currency for U.S. dollars for the periods covered by the data to be collected
- Inflation rates for the previous five years
- National and regional population figures
- Rates of population increase
- Prevalence and incidence of major health problems
- Numbers and distribution of MOH health facilities
- Numbers and distribution of drug retail outlets
- Numbers and distribution of drug wholesalers, distributors and manufacturers

B. Preparing an Overview of MOH Pharmaceutical Management Operations

In order to efficiently carry out an indicators study, usefully interpret the results, and make recommendations for system improvement, it is also essential to have an overall picture of current operations. At a minimum, this should include:

- Organigram showing agencies and offices responsible for procurement and distribution. This should include the offices responsible for managing procurement (by both purchase and donation), storage facilities and health facilities.

Three examples may make this more clear:

Example 1: (1) Capital city; (2) Highland agricultural district; (3) Lowland agricultural district; and (4) Arid district

Example 2: (1 and 2) Capital city and one other densely settled urban area; and (3 and 4) Two rural agricultural districts

Example 3: (1) Capital city; (2 and 3) Two rural districts with reasonably good transportation links; and (4) One relatively inaccessible rural district

Second, select the health facility sample:

It is recommended that at least five health facilities in each of the four selected regions (for a total of 20 facilities) be included in the sample. The actual selection of sites should be guided by the following factors:

- The district hospital outpatient unit should always be one of the facilities selected in each study district. Select randomly if there is more than one district hospital in the district.

- For systems organized with only one basic tier of outpatient facilities below the district hospital (for example, rural health centers) select the other four as follows:

  - If geographic distances and transportation logistics are such that all facilities can be visited, and all data can be collected in one day, select four of these second level units at random, from all of those in the district.
  - If transportation is more difficult, select two facilities at random, and then choose two other facilities that are geographically close to them, so that the paired facilities may be visited in one trip.

- For systems with two tiers below the district hospital level (for example, poly-clinics staffed by physicians and lower level health posts staffed by paramedics) select the other four facilities as follows:

  - Choose two second level health facilities at random.
  - For each of those two second level health facilities choose, from among the group of third level facilities that are geographically close, one site. The result is paired sets of second and third tier facilities.

- For systems that are organized in a different way, distribute the five facilities to be studied in each district among the possible types of health facilities, according to such factors as their geographic location or patient load.

The most important principle to remember in each phase of this process is *random selection*. The simplest approach to random selection is to apply the interval method to site lists. Make sure that the site lists are complete and organized alphabetically, and select every n^{th} site, where n is determined by dividing the total number of available sites by the desired sample size. For example, if there are 200 sites available, and 20 are needed for the study, select every tenth site on the list. If there are 40 sites available, select every other site to reach a sample size of 20, and so forth.

analgesics, parenteral solutions, and representatives of therapeutic categories used to treat diseases important in the health care system.

- Normally, all products on the indicator drug list should be authorized for use at all levels of the system of the country where the indicators study is taking place. If exceptions are to be made to this rule, they should be made systematically and with a technical rationale. For example, although anti-hypertensive drugs or antidiabetic drugs may not be available in lower level health facilities, these products may be considered essential for purposes of a given study. If the decision is made to include some drugs not used in all facilities, then as a rule of thumb, at least 80% of the products on the list should be used at all levels.

- Include a range of dosage forms, that is, tablets or capsules, oral liquids, injections, intravenous solutions and topical products. The matter of dosage forms may be a critical issue. For example, if there is a special interest in child survival activities, then it would be important to include available pediatric dosage forms of products for treating such problems as diarrheal disease, malaria and ARI.

- In some surveys it may be useful to include drugs used by vertical programs, such as family planning products, in order to incorporate these vertical distribution systems into the survey.

Annex B provides examples of indicator drug lists developed for indicator studies in different countries.

D. Designing a Survey of Health Facilities and Drug Retail Outlets

First, propose a sample design:

The exercise of constructing the overview of pharmaceutical management operations will often reveal that important variations exist within a pharmaceutical procurement and distribution system. Some features of systems may vary from region to region, facility to facility, and from prescriber to prescriber. These local variations might include such items as access to finances, sources of drug supply, ease of access to facilities, condition of inventory records, or patterns of prescribing practices.

It is important to ensure that facilities representing all significant variants of the overall system are included in the sample. One way to do this is to choose four geographic areas (that is, districts or regions) in which to work, based on an informed division of the country into groupings determined by such variables as geography, socio-economic factors, population density, or key features of the health care system. Some suggestions are offered below.

- The capital city and the main population center (if different) should always be included as one of the study areas.
- If the country is relatively homogeneous, geographically and epidemiologically, simply choose three other districts at random.
- If there are varying conditions in different areas of the country that might be expected to influence the way pharmaceuticals are managed, first organize all districts into groups, based on these characteristics, then select three study districts at random from these groups.

For *retrospective data collection*, the objective is to collect, for each of the six indicators of drug use, data on 30 curative outpatient contacts for each of 20 health facilities, which gives a total sample of 600 contacts. This method can only be used if the facility retains, on site, records documenting drug prescribing and dispensing.

- Begin by extracting, from the facility's patient register, a list of names for the first 60 patients seen during the month preceding the one in which the study takes place. If service levels are too low to yield a list of 60 names for this period, they may be distributed over a number of months, for example five patients per month for 12 months.
- In rare cases, most or all of the data required may be found right in the register. More commonly, however, it is necessary to consult the individual patient records and/or dispensary records.
- In either case, the next step is to fill out the data collection form, recording information until *complete data on all six of the drug use indicators* are collected for 30 curative contacts at each site. (The reason for beginning with the list of 60 names is that very often the records do not contain complete data for every contact, so a certain number of names for which data are incomplete will have to be discarded.)

For *prospective data collection*, the objective is also to collect complete data for 30 curative contacts per site, for each of 20 health facilities.

- One approach is direct observation: data collectors position themselves in drug dispensing areas, and record data for the first 30 patients who come. A potential disadvantage of this approach is that the presence of data collectors may influence the behavior of both prescribers and dispensers, and give non-representative results.
- A second approach is to use the *exit poll* technique, with data collectors positioned outside the facilities. The data collectors approach patients leaving the facility and question them about what drugs have been prescribed. At large facilities in urban areas, this may avoid the observation bias that would occur with collecting data at the dispensing point. At modest-sized clinics in small town settings, it probably will not make any difference, as news that a poll is being taken will quickly make its way back into the clinic. Another disadvantage of the exit poll approach is that it may be difficult to get all of the required data from all patients. It may still be necessary to visit the dispensing point and review prescription slips.
- A potential problem with both of these approaches is that in health facilities with low utilization rates, it could take a considerable amount of time to accumulate 30 observations.

Each of the methods summarized above has been used successfully to collect indicator data on drug use. In almost all cases, some modification to the generic approach was required. In at least one case, it was necessary to employ both prospective and retrospective data collection in order to obtain complete data for all six drug use indicators. Retrospective data collection is quicker and easier if prescribing and dispensing records are accessible, and if the records are legible, reasonably complete and well organized. Otherwise, prospective data collection is required.

Third, select the drug retail outlet sample:

As with the health facilities, the sample size for drug retail outlets is 20 sites. The most commonly recognized drug retail outlets are pharmacies. However, there may be other types, such as over-the-counter (OTC) drug stores. It is important to obtain a clear idea of the different types of outlets operating, their relative proportions and geographic distributions, and regulations that affect what may be sold. The drug retail outlet sample should be selected to include proportional numbers of all major types. To do this, apply the principles described above for sampling different types of health facilities.

In selecting the drug retail outlet site sample, the simplest approach, from the logistical point of view, would be to choose the site that is geographically closest to each health facility visited. Two problems with this approach are that (a) those outlets situated closest to health facilities may not be representative of all outlets; and (b) in some settings where rural health facilities are located, there may be no pharmacies or other drug retail outlets. A better approach, from the point of view of representative sampling, is random selection within each of the four geographic areas in the sample design. The best way to accomplish this is to apply the systematic interval sampling method to site lists, as described above.

E. Defining Approaches for Collecting Survey Data

Completing the survey design, based on the three steps discussed above, determines where survey data will be collected. That is, it indicates exactly which health care facilities and drug retail outlets will be visited for purposes of data collection. It is still necessary to specify how the data will be collected. In order to do this effectively it is useful to proceed as follows:

- **First**, develop required survey instruments and forms, to use for collecting each type of data
- **Second**, visit a few health facilities and drug retail outlets to test the methods
- **Third**, revise the methods and forms based on the results of the tests

This is a matter wherein design and implementation issues overlap. This section covers the first of these steps, that is, suggesting generic approaches to collecting survey data that have been tested in a number of countries. It is up to the study investigators to take the information provided here and go on to complete the second and third steps. Those two steps will be addressed again in the following chapter.

In Health Facilities

The complete indicator study, as described in chapter 3, specifies that data for 17 indicators be collected in health facilities. The information provided on *data collection* in the indicator descriptions should provide sufficient explanation on how to collect the required data for most of the indicators; however, further clarification is needed for the drug use indicators. There are two basic options for collecting these data: either *retrospectively* through review of clinical records, or *prospectively* through observation. Details of the two approaches are given below.

- To measure the **practice of generic substitution**, proceed as follows:

  1. Select a brand name of an antibiotic product which is (a) commonly used in the local area for treatment of general bacterial infections, and (b) at the more expensive end of the range of products available. Examples of appropriate products are the brand name versions of co-trimoxazole, tetracycline or ampicillin. Very often, brands of these products that are produced or licensed by multinational manufacturers are more expensive than local brands or generically labelled equivalents.

  2. Develop a simple scenario, and train data collectors to follow it when visiting drug retail outlets:

     - The data collector will be carrying a prescription slip on which is written a prescription for a full course of treatment for the product selected.
     - The data collector is coached to respond, if asked, that the prescription is for an adult relative who has bronchitis.
     - The data collector presents the prescription, and asks what will be the cost of filling the prescription.
     - Upon hearing the response, the data collector asks the salesperson if he or she has a cheaper version of the same drug.
     - If the salesperson offers a cheaper product, the data collector buys it, and exits the store.
     - If the salesperson initially refuses to make a substitution, the data collector tries once to gently persuade him or her.
     - If the salesperson refuses a second time, the data collector makes no further argument, makes no purchase, and exits the store without comment.
     - Upon leaving the store, the data collector records the result of the encounter on the appropriate form, that is, either: (a) the drug seller declined to make a substitution, or (b) the name of the alternative drug purchased. If the drug seller stated that he/she could not offer a generic substitute because none was in stock, this should be recorded.

- To measure the **availability of antibiotic products without a prescription**, the steps are similar:

  1. Select an antibiotic commonly believed to be available through direct over-the-counter sales.

  2. Develop a distinct scenario for this indicator and train data collectors to use it.

     - The data collector will be carrying a piece of paper with the drug's name on it.
     - The data collector will tell the salesperson that one of his or her adult relatives is suffering from diarrhoea (other common conditions such as a bad cough may be used).
     - The data collector will then say that he or she has used the drug whose name appears on the piece of paper before, and ask to purchase four tablets.
     - If the salesperson agrees, the data collector buys the product and exits the store.
     - If the salesperson initially refuses, the data collector tries once to gently persuade him or her.
     - If the salesperson refuses a second time, the data collector leaves the store without complaint.
     - Upon leaving the store, the data collector records the results of the encounter on the appropriate form.

In Drug Retail Outlets

Chapter 3 notes that data for four indicators are collected in pharmacies or other drug retail outlets. These indicators include:

- Percentage of unregistered drugs on the market (A.3)
- Practice of generic substitution (A.7)
- Retail prices paid for indicator drugs (H.7)
- Availability of antibiotic products without a prescription (H.9)

Details on how to collect the data for each of these indicators are given below.

To assess the **registration status of drugs on the market**, work as follows: At each of the 20 drug retail outlets visited for the sample survey, select 10 products, and record the complete names and product specifications. This will produce a list of 200 products. When data are being collected by more than one data collector, avoid duplication by assigning to each data collector an exclusive range of letters of the alphabet. For example, if there are three data collectors (Joe, Mary and Bob), then Joe should select only products whose names start with the letters A-H; Mary selects products in the range I-Q; and Bob works with R-Z.

To collect the **prices paid for indicator drugs**, simply record the pharmacy sales prices of each of the indicator drugs on the appropriate form. If an item is not stocked, skip that drug and go on to the next one. Where a site stocks more than one brand of the same product, record the least expensive one.

Data collectors may use shelf checks to openly collect data for drug registration status and retail prices of indicator drugs. The matters of **practice of generic substitution** and **availability of antibiotics without a prescription**, however, must be handled by a different method. Although either of these practices may be common, in the case of generic substitution, it may not be legal; in the case of sale of antibiotics without prescription, it *is* illegal in most countries. Therefore, drug sellers may perceive risk in admitting to these practices. As a result, if asked directly, they are likely to deny or underreport these practices. Therefore, a *simulated purchase survey* is used, in which data collectors pose as ordinary customers and request product substitutions or attempt to purchase antibiotics without a prescription.

The first step is to recruit the data collectors for simulated purchases. They should be local people whose appearance and demeanor suggests that they are regularly employed, for example, as vehicle drivers or secretaries. As the sex of the data collector may affect results of the survey, make sure that all data collectors are of the same sex.

The data collectors will have two tasks to carry out at each drug retail outlet:

- Present a prescription for a brand name product and request that a cheaper product be substituted
- Attempt to purchase an antibiotic product without a prescription

At each site, these tasks should be carried out by different data collectors, and preferably on different days. If, for logistics reasons, these encounters cannot be arranged on different days, they should take place at least four hours apart. All data collectors should be trained to carry out both tasks.

Table 3: Indicators to Be Measured with Survey Methods and Data Collection Forms

Indicator	Forms
In Health Facilities	
A.7 Practice of generic substitution	Generic Substitution and Sale of Antibiotics Data Form
B.3 Percentage of MOH health facilities visited with the most current edition of an official manual based on the NDFL	Inventory Data Form
C.3 Percentage of patients who pay a charge for drugs they receive in MOH health facilities	Charge for Drugs Tally Form
E.1 Weighted average percentage of inventory variation for a set of indicator drugs in MOH storage and health facilities	Inventory Data Form
E.2 Average percentage of individual variation for a set of indicator drugs in MOH storage and health facilities	Inventory Data Form
E.3 Average percentage of stock records that corresponds with physical counts for a set of indicator drugs in MOH storage and health facilities	Inventory Data Form
E.4 Average percentage of a set of unexpired indicator drugs available in MOH storage and health facilities	Inventory Data Form
E.5 Average percentage of time out of stock for a set of indicator drugs in MOH storage and health facilities	Stockout Data Form
F.4 Average number of drugs prescribed per curative outpatient encounter in MOH health facilities	Drug Use Data Form
F.5 Percentage of drugs prescribed by generic name in MOH health facilities	Drug Use Data Form
F.6 Percentage of drugs prescribed from the NDFL in MOH health facilities	Drug Use Data Form
F.7 Percentage of outpatients prescribed injections at MOH health facilities	Drug Use Data Form
F.8 Percentage of outpatients prescribed antibiotics at MOH health facilities	Drug Use Data Form
F.9 Percentage of prescribed drugs presented for dispensing that are actually dispensed in MOH health facilities	Drug Use Data Form
In Drug Retail Outlets	
A.3 Percentage of unregistered drug products in a sample of private sector drug retail outlets	Drug Registration Data Form
A.7 Practice of generic substitution	Generic Substitution and Sale of Antibiotics Data Form
D.3 Percentage of average international price paid for last regular procurement of a set of indicator drugs	International Price Comparison Data Form
H.7 Average of median private sector drug retail prices as a percentage of MOH acquisition prices for a set of indicator drugs	Retail Price Comparison Data Form
H.9 Percentage of licensed drug retail outlets where an antibiotic was available without a prescription	Generic Substitution and Sale of Antibiotics Data Form

F. Developing Data Collection Forms and Structured Interview Questionnaires

Two types of formats are required for carrying out the assessment described in this manual. One is data collection forms, and the other is structured interview questionnaires.

Data for 18 indicators are collected through on-site survey methods, and require data collection forms. These include 14 to be measured in MOH health facilities and four to be measured in drug retail outlets. (There is one indicator which is measured in both groups of sites.) Eight forms are used for recording the data. Five are used in the health facilities and four are used in drug retail outlets.

The 17 indicators measured though on-site surveys and the corresponding forms are given in the Table 3 below. There are two sets of these sample forms given in Annex C. The first set contains forms that are filled in with illustrative data, and they are accompanied by brief instructions. The second set contains blank forms that may be photocopied and used in field tests. **It is essential to understand that all of these sample forms are drafts that must be tested and revised prior to launching survey activities in any specific country.**

As has been noted, data for many of the indicators, as well as background information, are collected through structured interviews. It is essential that all interview activities be carried out using *structured interview questionnaires*. These must be prepared separately in-country for each indicator assessment. Some field testing of these instruments may be required. Minimally, drafts should be reviewed by local counterparts and revised before use. An example of a structured interview questionnaire for indicator B.1 is given in Annex D.

G. Defining a Range of Dates for Retrospective Data

Before any data are collected, be sure to define the range of dates to be covered, and make sure that all data collectors understand which date range is to be used. If this step is omitted, data may not be useful for comparison of results from the various sites visited. Indicators for which specification of date ranges is particularly important include:

- All 18 of those for which data are collected through sample survey
- Those that involve budget, expenditure, and market values

Table 4: Provisional Work Plan

Task	Central Level	Regional and Health Facility Level
Design and Preparation One Week	• Gather vital statistics. • Prepare system overview. • Specify data collection date ranges. • Assist with training data collectors.	• Prepare indicator drug list. • Design sample survey. • Test data collection methods and forms. • Recruit and train data collectors.
Primary Data Collection One to Two Weeks	• Carry out central level data collection.	• Launch and supervise the sample survey. • Collect data to supplement work of data collectors.
Tabulation and Write Up One to Two Weeks	• Collate findings, write report with recommendations.	• Supervise data tabulation. • Analyze data, write report with recommendations.

B. Review of Data Collection Methods

The previous chapter described some approaches to data collection, in terms of their implications for study design, but it will be useful to review them. The methods to be employed are listed below.

- Structured interviews with key informants
- Reviews of reports and other descriptive documents
- Physical inventories and review of stock records in both storage and health facilities
- Review of clinical records in health facilities
- Observation of clinical encounters
- Shelf checks and price taking in drug retail outlets
- Simulated purchase surveys

V. IMPLEMENTATION OF AN INDICATORS STUDY

The previous chapter began with assurances that the pharmaceutical indicators study is a manageable activity, despite some apparent complexity. Getting valid results does, however, require good organization and management. This chapter discusses some of the practical matters to be resolved in implementing the study.

A. Work Plan

As noted in the preceding chapter, the basic organizational principles for implementing the indicators study are that: (a) it is composed of two separate data collection efforts; and (b) each of these efforts should be managed by one investigator. To recapitulate:

- One investigator should take charge of data collection at the *central* level, where the primary methods will be interview and document review; and

- The other investigator should take charge of data collection at *regional and health facility* levels, where a sample survey employing a range of data collection methods is required. A group of data collectors will be recruited to undertake actual data collection for the sample survey.

The work to accomplish falls into three phases:

- Preparatory activities

- Primary data collection

- Tabulation and write up

Table 4, below, provides a summary of the work to be carried out by each investigator. Experience suggests that three to six weeks are required to complete the basic indicators assessment. This assumes that local officials are cooperative, that is, that key informants, documents and records may be consulted without difficulty. It also assumes that sample sizes are on the order of five warehouses, 20 health facilities and 20 retail outlets, and that qualified data collectors are available.

There are two conditions that can greatly increase time requirements, and they occur frequently:

- Increasing the sample size beyond the standard design of five warehouses, 20 health facilities and 20 drug retail outlets

- Expanding the assessment beyond the standard set of 46 indicators, and conducting in-depth analyses of particular features of overall pharmaceutical management systems, such as procurement operations, or cost recovery programs

Assuming, however, that the objective is to carry out the basic assessment described in chapter 3, then experience suggests that three to six weeks are required for completing all work. Table 4, below, shows an illustrative four-week schedule in which *design and preparation* are allotted one week, *primary data collection* two weeks, and *write up* one week.

Finding data collectors for the simulated purchases poses less of a recruiting problem. No technical expertise is required to do this quick and simple work. It is, however, very important to train the data collectors through role playing, and to verify that they understand what to do by observing their performance in two or three encounters in drug retail outlets. This can be set up with the help of a sympathetic store owner whose store could be used as a training site.

Scheduling, Additional Staffing, Transport and Authorizations

Scheduling is a complicated issue which is affected by factors such as the average time required to collect data in each site, the number of data collectors available, distances between sites, and transport arrangements. It is best to begin by thinking in terms of averages, and then make refinements by considering the geographic implications of the site sample of the study. Experience with the indicator studies completed so far suggests that, on average, about one day of data collection time and one to two days of travel time are required for completing work at one health facility.

This suggests that five data collectors, each working in four sites, would require 10 work days each, or perhaps 11 to 12 calendar days for the whole group to travel out, complete work, and travel back. The time required for covering the drug retail outlets must also be considered. For this group of sites, however, work time is shorter, so the main variable is geographic distribution.

Thus far, discussions have covered the roles of the study investigators and the data collectors. Other types of *staffing* which may be required include one or more data collection managers, to supervise and coordinate groups of data collectors, persons to enter or process collected data, and drivers. It should be clear that the practical problems of managing a data collection schedule will be greatly simplified by employing these types of workers. Not employing them to save money will be false economy in most cases.

Concerning *transport*, it is certainly faster to chauffeur data collectors directly to sites, but buses or other public transport can also be used. In some cases, combination approaches will be useful, in which some data collectors working in closely grouped sites are ferried around by drivers, while others, who are going to remote sites, take the bus.

One important detail which can cause serious problems if overlooked is the matter of *letters of authorization*. Each data collector, supervisor, and investigator should be provided with letters from the appropriate authority (such as MOH) which introduce the bearer, request cooperation, and authorize data release. Letters from different authorities may be required for visits to health facilities and drug retail outlets. Whenever possible, central level officials should inform the health facility authorities by telephone communication or radio prior to the arrival of the data collectors.

D. Analyzing Data and Presenting Results

In order to avoid major confusion and a mad scramble at the end of an assessment it is advisable to collate and prepare data for analysis as it is collected. If a computerized system for collating survey results is used, data should be entered at night by team members (or by a local data entry person). Team members and counterparts should all play an active role in examining data and considering what type of additional analyses may be appropriate, in addition to those prescribed in the assessment workplan.

Structured interviews with key informants and *reviews of documents* are the methods through which data for most indicators are collected. This will usually take place using structured questionnaires. In carrying out this work, keep two points in mind:

- Informants should be selected for their capacity to provide current and reliable data. Take into consideration their official positions, and factors which may bias their views.
- To the extent possible, data collected through interviews should be validated through review of documents or records.

Previous discussions have noted that central level data collection centers on structured interviews and document review, and that peripheral level data collection is organized through sample surveys. Within this general framework, however, it should be noted that *physical inventory and review of records* is a data collection activity that take places at all levels.

C. *Logistical Arrangements*

Recruiting and Training Data Collectors

For the site visit component of the study, it is necessary to recruit and train two groups of data collectors. The number of data collectors recruited will depend on the size of the study sample. For a sample of 20 facilities, five well-trained data collectors in each group would be an appropriate number to carry out the work in a reasonable amount of time. The two groups would be designated as follows:

- one group to collect data in health facilities, and to obtain drug registration and price data in drug retail outlets
- another group to carry out the simulated purchases

For the first of these, the most effective data collectors will usually be doctors, pharmacists, nurses or paramedical personnel who have worked in health facilities. There is some risk in using students or other parties who have no practical experience in working with the record keeping systems which they will encounter. The risks are that the students will have difficulty identifying the required data, the work will be unduly slow and frustrating, and the result may be incomplete or even faked data sets. A related problem, which could produce similar results, lies in recruiting parties, particularly some doctors, who may consider themselves too senior to carry out the relatively tedious work required.

To minimize both risks, and promote productivity, a very useful strategy would be to pair health care providers and other workers with experience in storage facilities. This would provide a team that has practical experience with product names as well as both the stock and clinical record keeping systems.

No matter who is recruited, however, it is essential that they be trained, and that the training include actual practice in filling out all forms required for both health facility and drug retail outlet data collection. Table 5 (see page 121), illustrates a model training course which may be adapted to suit local circumstances.

Table 5: Illustrative Training Course for Data Collectors in Health Facilities and Drug Retail Outlets

Topic	Materials	Time
1. Overview of the indicator study - What the study is and why MOH is interested - Role of data collectors - Work to be carried out in both health facilities and drug retail outlets - Work schedule and compensation - Location of sites to be visited	Briefing package	1 hour
2. How the data are collected - Review types of data to be collected in both health facilities and drug retail outlets. - Group the forms into one set for each type of site; review them one by one and field by field.	Complete set of 8 forms	1-2 hours
3. Practice session for entering data - Begin with the five health facility forms. Use poster-sized examples to lead class through filling out each field. - Standardize data recording, e.g., abbreviations, decimal points, format for large numbers, format for numerals. - Repeat this exercise for the three drug retail outlet forms.	Complete set of eight forms	1-2 hours
4. How to draw a sample of patient encounters from health facility records	Sample register and patient encounter form	1 hour
5. Practice session in health facility - Visit and collect a complete set of data using all five forms. - Critique performances and trouble shoot problems.	Set of five health facility forms	1 day
6. Practice session in retail outlet - Visit and collect a complete set of data using all three forms. - Critique performances and trouble-shoot problems.	Set of three drug retail outlet forms	1/2 day
7. Final discussion - Review experiences of field test and address concerns and questions. - Discuss revisions in forms, if any have been made since the visits. - Assign data collectors to teams or groups, as required. - Finalize schedule and logistics arrangements.	Schedules; letters of introduction; sets of forms for each site; expense money	1/2 day

It is important to realize that no matter how well the assessment was designed and planned, the data obtained may not be totally reliable, for any number of reasons. Part of the job of the study team, when analyzing data, is to determine what biases, inaccuracies or inconsistencies may exist, and what precautions are necessary in interpreting the data. When developing presentations for policy makers, it is advisable to present a very clear executive summary and to the extent possible, present key findings, recommendations and projections of impact graphically as well as in text or table form.

Annex A: Sample Materials for an Overview of Pharmaceutical Management

DRUG REGISTRATION DATA FORM

DATE	14 September 1994
NAME OF OUTLET	Nova Farmacia
TYPE OF OUTLET	Pharmacy
LOCATION	Manabi
DATA COLLECTOR	Diego Guerra

BRAND NAME (DOSAGE FORM)	MANUFACTURER AND/OR SUPPLIER	GENERIC NAME (DOSAGE FORM & STRENGTH)	LICENSE NUMBER	REGISTERED?
Anasor tab	Alpha	Acetaminophen tab 500mg	DGSEF 2820-3	1
Actifed tab	Phasur	Pseudophedrine/Triprolidine tab	DGSEF 6641	1
Acimet tab	Alpha	Cimetidine tab 300mg	DGS 6439	1
Bactamox susp	Alpha	Amoxicillin susp 250mg	M - 009463	1
Betnovate crm	Inpharm	Betamethasone crm 0.1%	1865-3	1
Benzan lot	North			
Canestan vag crm	Phasur	Clotrimazole vag crm 1% 20gr	DGS 4272-2	1
Clyss-Go sol	Phasur	Dioctyl Sodium Sulfosuccinate sol	DGS 299-2	1
Chloromycetin cap	Inpharm	Chloramphenicol cap 300mg 50mg/15ml	N/A	

USE WITH INDICATOR: A.3

Key: 1=registered; 0=not registered

Drug Registration Data Form

This form is used for the indicator listed below.

A.3 Percentage of unregistered drug products in a sample of private sector drug retail outlets

Data Collection Summary:

The data for this indicator is collected in drug retail outlets and at the Drug Regulatory Authority. In a sample of 20 retail sites, data collectors collect, directly from the shelves, the brand names, generic names, manufacturer and/or supplier and license numbers of 200 products. In a sample of 20 sites, this would mean that data for 10 products are collected at each site. Next, for each product recorded, the study organizers check with the Drug Regulatory Authority to determine whether it is registered. Each data collector is given a different range of letters from which to select brand name products, in order to avoid duplication.

Instructions:

1. **Date:** Fill in the date on which the data are collected.

2. **Name of Outlet:** Fill in the name of the drug retail outlet in which data are being collected.

3. **Type of Outlet:** Fill in the type of drug retail outlet, for example, pharmacy or over-the-counter (OTC) drug store.

4. **Location:** Fill in the geographic location of the outlet, which will usually be the name of a region, district, city or town.

5. **Data Collector:** Fill in the name of the person collecting the data.

6. **Brand Name:** Fill in the brand name of the product, and include its dosage form. Select product based on brand name in the assigned alphabet range.

7. **Manufacturer and/or Supplier:** Fill in the name of the manufacturer and/or supplier of the product.

8. **Generic Name:** Fill in the generic name of the product, and include its dosage form and strength.

9. **License Number:** Fill in the license number, marketing authorization number or registration number, if any, for the product.

10. **Registered?:** Enter "1" (one) if the product is registered, or "0" (zero) if it is not registered.

Note: *All* blanks should be filled in on this data collection form. Enter "N/A" if data for a particular item is not available.

Annex C: Sample Data Collection Forms

LIST OF INDICATOR DRUGS, NEPAL

DESCRIPTION	STRENGTH	FORM
ASPIRIN	300 MG	TAB
ALUMINIUM HYDROXIDE	250 MG	TAB
AMOXICILLIN	250 MG	TAB/CAP
PENICILLIN G	1 MU	INJ
CHLORPHENAMINE	4 MG	TAB
DIAZEPAM	5 MG/2 ML	INJ
ERGOMETRINE	0.5 MG	INJ
FERROUS SALT	60 MG	TAB
HYDROCHLOROTHIAZIDE	50 MG	TAB
ISONIAZID	100 MG	TAB
MEBENDAZOLE	100 MG	TAB
ORS	SACHET	PDR
PARACETAMOL	500 MG	TAB
PARACETAMOL	125 24MG/ML	SYR
PROCAINE PENICILLIN	.3 MU	INJ
PROCAINE PENICILLIN	.4 MU	INJ
RIFAMPICIN	150 MG	TAB/CAP
STREPTOMYCIN	1 G	INJ
SULPHA/TRIMETHOPRIM	400/80 MG	TAB
TETRACYCLINE	250 MG	CAP
DOXYCYCLINE	100 MG	CAP
TETRACYCLINE EYE OINT.	1%	TUB
THIACETAZONE/ISONIAZID	150/300 MG	TAB
WATER FOR INJ	5 ML	INJ

LIST OF INDICATOR DRUGS, GHANA

DESCRIPTION	STRENGTH	FORM
ACETYLSALICYLIC ACID	325MG	TAB
AMODIAQUINE	200MG	TAB
AMOXYCILLIN	25MG/ML	SUS
AMOXYCILLIN	250mg	TAB
CHLORAMPHENICOL	250MG	TAB
CHLOROQUINE	150MG	TAB
CHLORPHENAMINE	4MG	TAB
CO-TRIMOXAZOLE	480MG	TAB
DEXTROSE IN WATER, I.V.	5%	VIAL
DIAZEPAM	5MG	TAB
FERROUS SULFATE	60MG IRON	TAB
FOLIC ACID + IRON	1MG/60MG	TAB
FRUSEMIDE	40MG	TAB
MEBENDAZOLE	100MG	TAB
METRONIDAZOLE	250MG	TAB
MULTIVITAMIN	BP	TAB
ORAL REHYDRATION SALT	BP	POW
PARACETAMOL	500MG	TAB
PENICILLIN PROCAINE	4MU	VIAL
PENICILLIN, BENZYL	5MU	VIAL
PIPERAZINE CITRATE	BP	ELIXIR
RESERPINE	0.25MG	TAB
TETANUS TOXOID VACCINE		LIQ

LIST OF INDICATOR DRUGS, ORGANIZATION OF EASTERN CARIBBEAN STATES

DESCRIPTION	STRENGTH	FORM
AMOXYCILLIN (100ML)	125MG/5ML	POW
AMOXYCILLIN	250MG	TAB
AMPICILLIN	500MG	POW
ANTACID (AL+MAG.OH) (360ML)		SUSP
BACITRACIN (15GM)		OINT
CAPTOPRIL	25MG	TAB
CEPHRADINE	500MG	TAB
CHLORPROPAMIDE	250MG	TAB
COUGH EXPECTORANT (2000ML)		SYRUP
DEXTROSE (1000ML)	5%	VIAL
DIAGNOSTIC URINE, GLUCOSE-PROTEIN (50)		STRIPS
DIGOXIN	0.25MG	TAB
ERYTHROMYCIN	250MG	TAB
IBUPROFEN	400MG	TAB
IMIDAZOLE		PESS
ISOPHANE INSULIN (10ml)	100U/ML	VIAL
METHYLDOPA	500MG	TAB
ORAL REHYDRATION SALT	BP	POW
PARACETAMOL	500MG	TAB
PARACETAMOL (150ML)	120MG/5ML	SUSP
PHENYTOIN	100MG	TAB
TIMOLOL MALEATE (5ML)	0.5%	DROPS
MEDROXY PROGESTERONE		LIQ
CONDOM		DISP
ORAL CONTRACEPTIVE LO-FEMENAL		PILL

LIST OF INDICATOR DRUGS, EL SALVADOR

DESCRIPTION	STRENGTH	FORM
FARMACOS		
CLOROQUINA	250 MG	TAB
CLOROQUINA	25 MG/5 ML	SUS
CLOROQUINA + PRIMAQUINA	150 MG + 15 MG	TAB
CLOROQUINA + PRIMAQUINA	75 MG + 7.5 MG	TAB
MEBENDAZOL	100 MG	TAB
METRONIDAZOL	500 MG	TAB
METRONIDAZOL	125 MG/5ML	JAR
CLORANFENICOL	250 MG	CAP
ERITROMICINA	250 MG/5ML	JAR
ERITROMICINA	500 MG	TAB
PENICILINA G BENZATINICA	2.400.000 IU	AMP
PENICILINA G PROCAINA	4.000.000 IU	AMP
TRIMETOPRIMA + SULFAMET0XAZOL	40 MG +200 MG/	JAR
TRIMETOPRIMA + SULFAMET0XAZOL	160 + 800 MG	TAB
AMOXICILINA	125 MG/5 ML	JAR
AMOXICILINA	500 MG	CAP
AMPICILINA	500 MG	CAP
L-ALFA METIL DOPA	500 MG	TAB
ACIDO FOLICO	TAB 5 MG	TAB
HIERRO (SULFATO)	125 MG/ML	GOT
HIERRO (SULFATO)	300 MG	TAB
IBUPROFENO	400 MG	TAB
ACETAMINOFENO	120 MG/5 ML	JAR
ACETAMINOFENO	500 MG	TAB
CLORFENIRAMINA	2 MG/5 ML	JAR
CLORFENIRAMINA	4 MG	TAB
ALUMINIO + MAGNESI0	200 MG/4 ML	JAR
FENITOINA SODICA	100 MG	CAP
MULTIVITAMINAS + MINERALES		JAR
MULTIVITAMINAS + MINERALES		GRA
SALES DE REHIDRATACION		SBR
BENZILO BENZOATO	20%	LOC
TOLNAFTATO		FRA
CLOTRIMAZOL	1%	TUB
INSUMOS DE PLANIFICACION FAMILIAR		
CONDONES	PRESERVATIVO DE LATEX	
ANOVULATORIO ORAL	CICLO DE TABLETAS	
INSUMOS MEDICOS		
JERINGA DESCARTABLE	3 ML	CON AGUJA 22 X 1"
JERINGA DESCARTABLE P/BCG Y		
TUBERCULINA	1 ML	CON AGUJA 25 X 5/8"
ALGODON HIDROFILO ABSORBENTE	LIBRA	
ESPARADRAPO	2" X 12" X 10	YDS BATON
VENDA DE GASA	4" X 10	YDS
BAJA LENGUAS DE MADERA	PIEZA	
PALILLOS APLICADORES	6" SIN ALGOD	
TERMOMETRO ORAL	PIEZA	
CLORURO DE BENZALCONIO	1%	SOLUCION
ALCOHOL DESNATURALIZADO		
AGUA OXIGENADA		
SUTURA 3.0 CON AGUJA	PIEZA	

LIST OF INDICATOR DRUGS, GUATEMALA

DESCRIPTION	STRENGTH	FORM
ACETAMINOFENO	120MG/5ML	JAR
ACETAMINOFENO	500MG	TAB
ACIDO ACETIL SALICILICO	500MG	TAB
FENOBARBITAL	100MG	TAB
METRONIDAZOL	250MG	TAB
AMPICILINA	500MG	TAB
AMPICILINA	125MG/5ML	SUSP
PENICILINA PROCAINA	4,000,000 IU	VIAL
TETRACLICLINA	500MG	TAB
CO-TRIMOXAZOL	80/400MG	TAB
MEBENDAZOL	100MG	TAB
CLOROQUINA FOSFATO	250MG	TAB
SULFATO FERROSO	300MG	TAB
SALES DE REHIDRATACION ORAL		SBR
TOXOIDE TETANICO		AMP
BENZOATO DE BENCILO	25%	LOC
CLORANFENICOL	1%	UNG OFT
VIOLETA GENCIANA	1%	SOL
ISONIAZIDA	100MG +450 MG	TAB
RIFAMPICINA	300MG	TAB

Annex B: Sample Lists of Indicator Drugs

LOCATIONS OF REGIONAL HEALTH OFFICES AND MEDICAL STORES, NEPAL

REGION	LOCATION OF REGIONAL HEALTH OFFICE	LOCATION OF REGIONAL MEDICAL STORE	HOURS OF TRAVEL TIME DRIVING FROM KATHMANDU
CENTRAL	KATHMANDU	HETAUDA	6.5
WESTERN	POKHARA	BUTWAL	5.0
MID WESTERN	SURKHET	NEPALGANJ	4.0
FAR WESTERN	SILGADHI	DHANGADHI	4.0
EASTERN	DHANKUTA	DHARAN	2.0

DISTRIBUTION OF HEALTH DELIVERY FACILITIES, NEPAL "

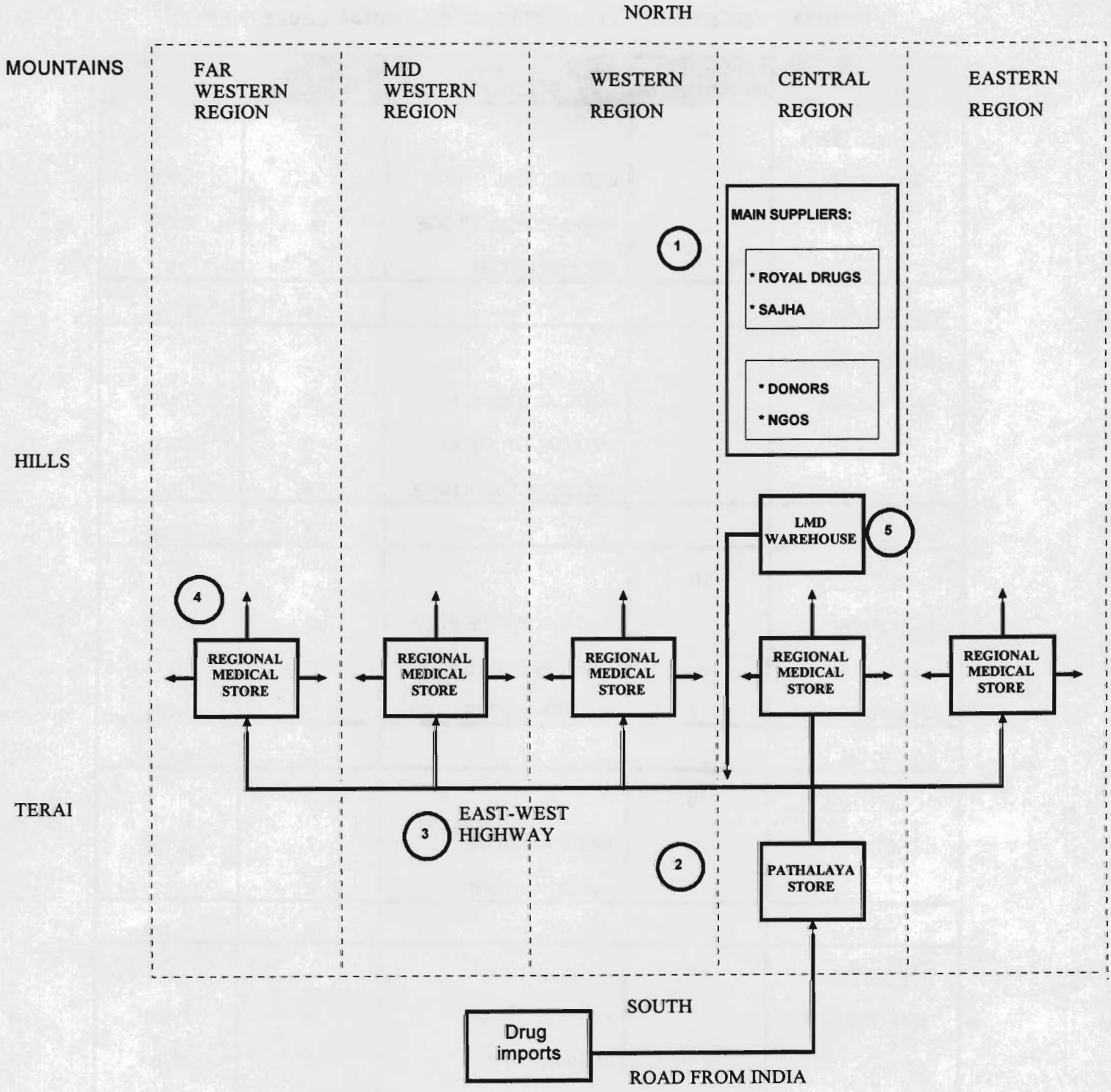
BY REGION

REGION	SUB HEALTH POST	STATIC HEALTH POST	I LAKA HEALTH POST	HEALTH CENTER	DISTRICT HOSPITAL	ZONAL HOSPITAL	REGIONAL HOSPITAL	CENTRAL HOSPITAL
Central		45	171	6	15	2	0	5
Western		4	144	2	15	1	1	0
Mid Western		16	135	5	9	1	0	0
Far Western		19	81	1	8	2	0	0
Eastern		27	144	4	14	3	1	0
TOTALS	+/-300	111	675	18	61	9	2	5

BY ECOLOGICAL BELT

REGION	SUB HEALTH POST	STATIC HEALTH POST	I LAKA HEALTH POST	HEALTH CENTER	DISTRICT HOSPITAL	ZONAL HOSPITAL	REGIONAL HOSPITAL	CENTRAL HOSPITAL
Mountain		12	144	8	12	0	0	0
Hill		84	351	9	34	0	1	5
Terai		45	180	1	15	9	1	0
TOTALS	+/-300	141	675	18	61	9	2	5

OVERVIEW OF PUBLIC SECTOR DRUG DISTRIBUTION SYSTEM BY LEVELS AND REGIONS, NEPAL



KEY:
1. Central Procurement Level
2. Transit warehouse for goods entering the country
3. East-west highway to distribute to 5 Regional Medical Stores
4. Regional Medical Stores in the 5 country regions
5. Logistics Management Division's central warehouse

SUMMARY OF STORAGE FACILITIES AT REGIONAL LEVEL, NEPAL [10]

REGION	NUMBER OF DISTRICTS	FACILITY	NUMBER OF ROOMS	SPACE IN SQUARE FEET
FAR WESTERN	9			
DHANGADI		OLD MEDICAL STORE	4	1,904
		NEW MEDICAL STORE	4	2,130
		MALARIA STORE	3	750
TOTAL			11	4,784
MID WESTERN	15			
NEPALGANJ		MEDICAL STORE #1	6	2,486
		MEDICAL STORE #2	2	1,000
		OLD OFFICE BUILDING	7	766
TOTAL			15	4,252
WESTERN	16			
BUTWAL		MEDICAL STORE #1	2	2,180
		MEDICAL STORE #2	2	1,100
BHAIRAHAWA		MALARIA STORE	9	1,024
TOTAL			13	4,304
CENTRAL	19			
HETAUDA		MEDICAL STORE	7	3,086
		MALARIA STORE	2	312
TOTAL			9	3,398
EASTERN	16			
BIRATNAGAR		MEDICAL STORE	6	2,486
		MALARIA STORE	3	578
		EPI STORE	4	440
DHARAN		MEDICAL STORE	27	5,935
TOTAL			40	9,439

Generic Substitution and Sale of Antibiotics Data Form

This form is used for the indicators listed below.

A.7 Practice of generic substitution

H.9 Percentage of licensed drug retail outlets where an antibiotic was available without a prescription

Data collection summary:

Data for both indicators are collected using simulated purchases. Details are provided in chapter 4, section E, "Defining Approaches for Collecting Survey Data." In this example, data collector Mary Smith, was assigned to visit eight drug retail outlets. At the first four of them she requested product substitutions, and at the second four of them, she attempted to purchase antibiotics without a prescription.

Instructions:

1. **Date:** Fill in the date on which data are collected. Use a separate form for each date.

2. **Data Collector:** Fill in the name of the person collecting the data, that is, the name of the data collector who carries out the simulated purchase.

3. **Simulated Purchase Product:** Record, first, the brand name of the product to be used in the simulated purchase encounters, followed by the generic name in parenthesis.

4. **Name of Outlet:** Data collectors will have lists of sites to visit. Fill in the names of the sites immediately after the simulated purchase encounter takes place.

5. **Made Substitution?:** Use the two columns below this heading for recording the results of encounters wherein data collectors request product substitution. Data entries should be made only after the encounter is completed and the data collector has left the store, and cannot be observed filling out the form.

   Yes/Product: If the sales person agrees to make the product substitution, record the name here of the product actually sold. Later, in order to compute this indicator, it will be necessary to consult an index of brand and generic names to determine if those products substituted for the original simulated purchase product are chemically equivalent. Enter "1" (one) in the blank if the product substitution is made, or "0" (zero) if it is not.

6. **Sold Antibiotic?:** Use the column below this heading for recording the results of encounters wherein data collectors attempt to purchase an antibiotic product without a prescription. Data entries should be made only after the encounter is completed and the data collector has left the store, and cannot be observed filling out the form.

   Yes: Enter "1" (one) in the column if the sales person sold the antibiotic, as requested, or "0" (zero) if the sales person declined to sell the antibiotic.

Note: *All* blanks should be filled in on this data collection form. Enter "N/A" if data for a particular item is not available.

GENERIC SUBSTITUTION AND SALE OF ANTIBIOTICS DATA FORM

DATE: 2 February 1993

DATA COLLECTOR: Mary Smith

SIMULATED PURCHASE PRODUCT: Septra (co- trimoxazole)

NAME OF OUTLET	MADE SUBSTITUTION? YES	MADE SUBSTITUTION? PRODUCT	SOLD ANTIBIOTIC? YES
Arrow Pharmacy	0		
Quality Drugs	1	Bactrim	
Pharmacy Center	1	Co-trimoxazole	
Hillcrest Pharmacy	0		
Value Drug Center			1
Seaview Pharmacy			0
Popular Pharmacy			1
Star Drugstore			1

USE WITH INDICATOR: A.7, H.9

Key: 1=yes; 0=no

Inventory Data Form

This form is used for indicators listed below.

B.3 Percentage of MOH health facilities visited with the most current edition of an official manual based on the NDFL

E.1 Weighted average percentage of inventory variation for a set of indicator drugs in MOH storage and health facilities

E.2 Average percentage of individual variation for a set of indicator drugs in MOH storage and health facilities

E.3 Average percentage of stock records that corresponds with physical counts for a set of indicator drugs in MOH storage and health facilities

E.4 Average percentage of a set of unexpired indicator drugs available in MOH storage and health facilities

Data collection summary:

For indicator B.3, which measures the availability of manuals based on the National Drug Formulary List, data collectors should ask staff to produce the document. Although this indicator is intended primarily for use in health facilities, it makes sense to take the measure in storage facilities too.

For indicators E.1-E.4, data are taken from any or all of computerized stock record keeping systems, manual stock ledgers or stock record cards and bin cards. Details are given in the indicator descriptions concerning how to collect the data from these types of records, as well as how to make required adjustments for recent receipts and issues, and take physical counts. The indicator descriptions also provide examples of how to use the data collected on this form to compute the indicators.

1. **Date:** Fill in the date on which data are collected. If at all possible, these data should be collected on the same day.

2. **Facility Name:** Fill in the name of the warehouse or health facility in which the data are being collected.

3. **Facility Type:** Fill in the type of facility in which the data are being collected, for example, warehouse, district hospital, health center or health post.

4. **Location:** Fill in the geographic location of the facility in which the data are being collected, usually the name of a region, district, city or town.

5. **Data Collector:** Fill in the name of the person collecting the data.

6. **Manual Available?:** Check "Yes" if staff are able to produce the most recent edition of a manual based on the National Drug Formulary List or National Essential Drug List. Check "No" if staff cannot produce this document. Record its year and title.

7. **Data Collected from:** Indicate if the data presented in the form are collected from a computerized system, manual ledger or stock record cards, or tally sheets or bin cards. In cases where more than one of these systems is being assessed, for example, the manual ledger and bin cards, it will be necessary to fill out this form separately for each system.

8. **Product:** In this column the list of 25 to 50 indicator drugs being used for the assessment should be pre-printed. For each indicator drug, the generic name, dosage form and strength should be included.

9. **Counting Unit:** In this column, indicate the smallest unit by which the product is counted.

10. **Record Count:** In this column write the number of units of each product shown to be present by the record system.

11. **Recent Receipts and Recent Issues:** It is often and understandably the case that posting of record keeping systems may lag behind recent receipts and issues of stock. For each of the indicator drugs, after the record count has been entered, ask staff to add up all receipts and all issues not yet reflected in the records. Enter the results of this exercise in these two columns.

12. **Adjusted Total:** This column is for recording the adjusted total of the record count, taking into account the recent receipts and issues. For each indicator drug, make the following calculation, and enter the result in this column:

    Adjusted = Record Count + Recent Receipts - Recent Issues

13. **Physical Count:** For each indicator drug take a physical count of the number of units actually present. Record the results in this column.

14. **How to calculate these indicators:** Indicators E.1-E.4 are all derived or calculated using the data entered into the six preceding columns. Instructions and examples on how to compute and present these indicators will be found in the individual indicator descriptions.

    Note: *All* blanks should be filled in on this data collection form. Enter "N/A" if data for a particular item is not available.

INVENTORY DATA FORM

DATE	February 5, 1993
FACILITY NAME	Central Medical Store
FACILITY TYPE	Warehouse
LOCATION	Freetown
DATA COLLECTOR	Bob Smith

Manual Available? [ ] Yes [X] No
Year:_____ Title:_____

Data Collected from:
[ ] Computer System
[X] Manual Ledger or Stock Record Cards
[ ] Tally Sheets or Bin Cards

PRODUCT	COUNTING UNIT	RECORD COUNT	RECENT RECEIPTS	RECENT ISSUES	ADJUSTED TOTAL	PHYSICAL COUNT
Acetylsalicylic acid tab 500mg	100 tab	140,000	50,000	70,000	120,000	119,000
Amoxycillin tab 250mg	100 tab	160,000	40,000	20,000	180,000	180,000
Erythromycin tab 250mg	100 tab	80,000	80,000	30,000	130,000	140,000
Co-trimoxazole tab 80/400mg	100 tab	124,000	0	40,000	84,000	80,000
Penicillin Procaine vial 800000MU	vial	0	0	0	0	0
Oral rehydration salts sachet	sachet	50,000	0	20,000	30,000	30,000
Aminophylline 100mg/ml ampoule (1ml)	ampoule	100,000	20,000	15,000	105,000	100,000
Mebendazole tab 100mg	100 tab	175,000	90,000	60,000	205,000	205,000
Chloroquine tab 150mg	100 tab	150,000	45,000	30,000	165,000	160,000
Ergometrine tab 0.2mg	100 tab	90,000	60,000	40,000	110,000	110,000
Glibenclamide tab 5mg	100 tab	0	0	0	0	0
Metronidazole tab 250mg	100 tab	120,000	55,000	70,000	105,000	105,000
Nystatin cream 100000 IU/g (15g)	tube	130,000	70,000	60,000	140,000	140,000
Paracetamol susp 100mg/ml	bottle	170,000	60,000	55,000	175,000	180,000
Rifampicin tab 300mg	100 tab	60,000	10,000	30,000	40,000	40,000
Isoniazid tab 100mg	100 tab	140,000	0	20,000	120,000	100,000
Salbutamol tab 2mg	100 tab	80,000	40,000	10,000	110,000	50,000
Vitamin A tab 200000 IU	100 tab	150,000	70,000	60,000	160,000	150,000
Multivitamin tab	100 tab	160,000	50,000	70,000	140,000	135,000
Ferrous Sulfate oral solution 40mg/ml 1000ml	bottle	100,000	60,000	80,000	80,000	80,000
Mefloquine tab 250mg	100 tab	125,000	0	50,000	75,000	75,000
Cimetidine tab 200mg	100 tab	0	0	0	0	0
Benzyl Benzoate lotion 25% (1000ml)	bottle	137,000	30,000	45,000	122,000	120,000
Diazepam tab 5mg	100 tab	110,000	40,000	60,000	90,000	90,000
Dextrose in Water 5%, I.V. (500ml)	bottle	0	0	0	0	0

USE WITH INDICATOR: B.3, E.1, E.2, E.3, E.4

Charge for Drugs Tally Form

This form is used for the indicator listed below.

C.3 Percentage of patients who pay a charge for drugs they receive in MOH health facilities

Data collection summary:

Data for this indicator are collected either retrospectively from records or prospectively through observation. At each facility in a sample of facilities record, for thirty consecutive patients receiving drugs, whether or not they pay a charge. Details on how charges for drugs are defined for purposes of this indicator will be found in the descriptions for indicators C.2 and C.3.

Instructions:

1. **Data Collector:** Fill in the name of the person collecting the data.

2. **Site and Date:** There is one column for each site at which data are collected. Results for five sites can be tallied on one sheet. In this space, record the name of the site and the date on which the data are collected.

3. **Numbered Rows:** For each site column, there are thirty numbered rows. Whether making the tally from records or through observation, enter "1" (one) for patients who pay a charge, or "0" (zero) for patients who pay no charge. By counting up the total of ones and dividing by the total number of patients in the sample for whom observations are recorded, the percentage of patients paying a charge can be calculated. Details and examples on how to compute and present this indicator will be found in the indicator description.

Note: *All* blanks should be filled in on this data collection form. Enter "N/A" if data for a particular item is not available.

CHARGE FOR DRUGS TALLY FORM

DATA COLLECTOR: Mary Smith

SITE AND DATE	SITE AND DATE	SITE AND DATE	SITE AND DATE	SITE AND DATE
National Children's Hospital 2/15/93	Metropolitan Health Center 2/15/93	Keta District Hospital 2/16/93	Tema Health Center 2/16/93	Puengasi Subcenter 2/17/93
1. 1	1. 1	1. 1	1. 0	1. 1
2. 1	2. 0	2. 0	2. 1	2. 1
3. 1	3. 0	3. 1	3. 0	3. 0
4. 0	4. 0	4. 1	4. 0	4. 1
5. 0	5. 1	5. 1	5. 1	5. 1
6. 1	6. 0	6. 0	6. 1	6. 0
7. 1	7. 0	7. 0	7. 1	7. 0
8. 0	8. 1	8. 0	8. 0	8. 1
9. 0	9. 0	9. 1	9. 0	9. 1
10. 0	10. 0	10. 0	10. 1	10. 0
11. 0	11. 0	11. 1	11. 0	11. 0
12. 1	12. 1	12. 0	12. 1	12. 0
13. 0	13. 1	13. 0	13. 0	13. 0
14. 0	14. 0	14. 1	14. 1	14. 1
15. 1	15. 1	15. 1	15. 1	15. 1
16. 1	16. 0	16. 0	16. 1	16. 0
17. 0	17. 0	17. 1	17. 0	17. 1
18. 0	18. 0	18. 0	18. 1	18. 1
19. 1	19. 1	19. 0	19. 0	19. 1
20. 1	20. 1	20. 1	20. 1	20. 0
21. 0	21. 1	21. 0	21. 1	21. 0
22. 1	22. 0	22. 1	22. 1	22. 1
23. 0	23. 1	23. 1	23. 0	23. 0
24. 1	24. 1	24. 0	24. 0	24. 0
25. 1	25. 0	25. 1	25. 0	25. 1
26. 0	26. 0	26. 1	26. 1	26. 1
27. 0	27. 0	27. 0	27. 1	27. 0
28. 1	28. 0	28. 1	28. 0	28. 1
29. 1	29. 0	29. 0	29. 1	29. 0
30. 0	30. 0	30. 0	30. 0	30. 0

USE WITH INDICATOR: C.3

Key: 1=charges collected, 0 = no charges

Stockout Data Form

This form is used for the indicator listed below.

E.5 Average percentage of time out of stock for a set of indicator drugs in MOH storage and health facilities

Data collection summary:

Data for this indicator are collected for each indicator drug from the central stock record keeping system in place in a given facility. This may be a computerized system or manual system based on ledgers or stock record cards.

Instructions:

1. **Date:** Fill in the date on which the data are collected.

2. **Facility Name:** Fill in the name of the warehouse or health facility where the data are collected.

3. **Facility Type:** Fill in the type of facility in which data are being collected, for example, warehouse, district hospital, health center or health post.

4. **Location:** Fill in the geographic location of the facility in which the data are collected, usually the name of a region, district, city or town,

5. **Data Collector:** Fill in the name of the person collecting the data.

6. **Product:** The list of 25 to 50 indicator drugs being used for the assessment should be pre-printed in this column. For each indicator drug, the generic name, dosage form and strength should be included.

7. **Numbered Columns:** To the right of the product names are twelve columns numbered in order from 1 to 12. They are for the twelve months preceding the one in which the data are being collected. For each product, record, for each of the twelve months, the number of days in which that product was out of stock.

8. **Total Days Out:** In this column, enter for each product, the total number of days, over the twelve month period, that the product was out of stock. In other words, for each product, add up the numbers in each of the twelve columns to the left and enter the total here.

9. **To calculate this indicator:** Instructions and examples on how to use the data collected on this form to compute and present the indicator will be found in the indicator description.

Note: *All* blanks should be filled in on this data collection form. Enter "N/A" if data for a particular item is not available.

STOCKOUT DATA FORM

DATE	5 February 1993
FACILITY NAME	Central Medical Store
FACILITY TYPE	Warehouse
LOCATION	Freetown
DATA COLLECTOR	Bob Smith

PRODUCT	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month12	TOTAL DAYS OUT
Acetylsalicylic acid tab 500mg	0	0	0	0	0	0	0	0	10	5	0	0	15
Amoxycillin tab 250mg	0	0	15	30	0	0	0	0	0	0	13	12	70
Erythromycin tab 250mg	0	0	0	0	10	10	0	0	0	0	0	0	20
Co-trimoxazole tab 80/400mg	31	15	0	0	0	0	0	0	0	31	30	31	138
Penicillin Procaine vial 800000MU	0	0	0	0	10	0	0	0	7	5	0	0	22
Oral rehydration salts sachet	0	0	31	30	31	15	0	0	0	0	0	0	107
Aminophylline 100mg/ml ampoule (1ml)	0	0	0	0	0	0	0	0	10	31	30	15	86
Mebendazole tab 100mg	0	0	0	0	0	0	0	0	0	0	0	0	0
Chloroquine tab 150mg	0	15	31	30	10	0	0	0	0	0	0	0	86
Ergometrine tab 0.2mg	0	0	0	0	0	0	0	0	0	0	0	0	0
Glibenclamide tab 5mg	31	28	0	0	0	0	0	15	15	0	0	0	89
Metronidazole tab 250mg	0	0	0	0	18	12	0	0	0	0	0	0	30
Nystatin cream 100000 IU/g (15g)	5	28	13	0	0	0	0	0	0	0	0	0	46
Paracetamol susp 100mg/ml	0	0	0	0	21	0	13	0	0	0	20	12	66
Rifampicin tab 300mg	0	0	0	0	0	0	0	0	0	0	0	0	0
Isoniazid tab 100mg	0	0	6	10	0	0	12	14	0	0	0	0	42
Salbutamol tab 2mg	0	0	0	9	17	0	0	0	0	0	0	0	26
Vitamin A tab 200000 IU	0	0	0	0	0	8	5	0	0	0	0	0	13
Multivitamin tab	0	0	0	0	0	0	0	0	15	20	30	30	95
Ferrous Sulfate oral solution 40mg/ml 1000ml	31	28	30	22	30	30	0	0	0	0	0	0	171
Mefloquine tab 250mg	0	12	0	0	0	16	15	0	0	0	0	0	43
Cimetidine tab 200mg	0	0	0	0	0	12	31	31	30	31	30	31	196
Benzyl Benzoate lotion 25% (1000ml)	0	0	0	0	0	0	0	0	6	0	18	30	54
Diazepam tab 5mg	0	8	11	0	0	0	15	10	0	0	0	0	44
Dextrose in Water 5%, I.V. (500ml)	0	0	0	0	0	0	0	0	0	0	0	0	0

USE WITH INDICATOR: E.5

Drug Use Data Form

This form is used for the indicators listed below.

F.4 Average number of drugs prescribed per curative outpatient encounter in MOH health facilities

F.5 Percentage of drugs prescribed by generic name in MOH health facilities

F.6 Percentage of drugs prescribed from the NDFL in MOH health facilities

F.7 Percentage of outpatients prescribed injections at MOH health facilities

F.8 Percentage of outpatients prescribed antibiotics at MOH health facilities

F.9 Percentage of prescribed drugs presented for dispensing that are actually dispensed in MOH health facilities

Data collection summary:

The data for all of these indicators are collected at the same time in one of two ways. The first, and preferred, method is to collect the data retrospectively from records including daily registers and individual patient files. The second method is to collet the data prospectively through observation at dispensing points. Details on both methods are provided in chapter 4, section E, "Defining Approaches for Collecting Survey Data."

Instructions:

1. **Date:** Fill in the date on which the data are collected.

2. **Facility Name:** Fill in the name of the warehouse or health facility where the data are collected.

3. **Facility Type:** Fill in the type of facility in which data are being collected, for example, warehouse, district hospital, health center or health post.

4. **Location:** Fill in the geographic location of the facility in which the data are collected, usually the name of a region, district, city or town,

5. **Data Collector:** Fill in the name of the person collecting the data.

6. **Patient Name:** In this column, fill in, for each outpatient curative encounter in the sample, the name of the patient. This information has no analytical value, but it is noted to facilitate entry of the other data collected for each encounter.

7. **Drugs Prescribed:** Fill in names of the drug or drugs prescribed for each encounter in the sample. In a case where a patient receives three drugs use three lines in this column. The name of the next patient would be entered on the fourth line. Fill in names exactly as they appear in records or on prescription slips, including the strength. If the prescriber prescribed a drug by its generic name, enter the generic name. If the prescriber used a brand name, enter the brand name.

8. **Dosage Form:** For each drug prescribed, fill in the presentation or dosage form in which the drug is prescribed. The most common examples are tablet, capsule, injection, lotion, cream, packet or suppository.

Note: Normally, the three columns discussed so far will be filled out at the time data are being collected. The remaining five columns, discussed below, will be filled out later. They all have to do with classifying the drugs that have been prescribed.

9. **Generic:** In this column, for each drug prescribed, enter "1" (one) if the item is prescribed by generic name, or "0" (zero) if the item is prescribed by brand name.

10. **NDFL/NEDL:** For each drug prescribed, enter "1" (one) if the item appears in the National Drug Formulary List or National Essential Drug List, or "0" (zero) if the item does not appear on one of these lists.

11. **Injectable:** For each drug prescribed, enter "1" (one) if the item is an injectable product, or "0" (zero) if the item is not an injectable product.

12. **Antibiotic:** For each drug prescribed, enter "1" (one) if the item is an antibiotic product, or "0" (zero) if the item is not an antibiotic product.

13. **Dispensed:** For each drug prescribed, enter "1" (zero) if the item was actually dispensed, or "0" (zero) if it was not dispensed.

Note: The final "Dispensed" column is for indicator F.9 "Percentage of prescribed drugs presented for dispensing that are actually dispensed in MOH health facilities." When data for the indicators of drug use are collected retrospectively from records, which is the preferred method, it may not be possible to determine which drugs were actually dispensed. In cases wherein it is not possible, a separate prospective sample of thirty encounters must be taken just for the dispensing indicator. In that case, data collectors will use a separate set of forms and fill in only the columns headed with "Name of Patient," "Drugs Prescribed" and "Dispensed."

In cases wherein all of the drug use indicator data is collected prospectively, this problem should not arise, and only one sample of encounters will be required.

Note: *All* blanks should be filled in on this data collection form. Enter "N/A" if data for a particular item is not available.

DRUG USE DATA FORM

DATE	10 February 1993
FACILITY NAME	Metropolitan Health Center
FACILITY TYPE	Health Center
LOCATION	Freetown
DATA COLLECTOR	Susan Brown

PATIENT NAME	DRUGS PRESCRIBED	DOSAGE FORM	GENERIC	NDFL/ NEDL	INJECT-ABLE	ANTI-BIOTIC	DIS-PENSED
Smith, H.	Paracetamol 100mg/ml	susp	1	1	0	0	1
	Vermax 100mg	tab	0	1	0	0	1
	ORS	pkt	1	1	0	0	0
Thompson, E.	Diazepam 5mg	tab	1	1	0	0	1
	B Complex	inj	1	1	1	0	1
Grant, G.	Amophylline 100mg/ml	inj	1	1	1	0	1
	Salbutamol 4mg	tab	1	1	0	0	1
	Paracetamol 500mg	tab	1	1	0	0	1
King, R.	Ibuprofen 100mg	tab	1	1	0	0	1
Witson, W.	Aralen 100mg	tab	0	1	0	0	0
	Penicillin 800000mu	inj	1	1	1	1	0
	Flagyl 500mg	tab	0	1	0	0	1
	Aspirin 500mg	tab	1	1	0	0	1
Paget, T.	Paracetamol 100mg/ml	susp.	1	1	0	0	1
	Amoxycillin 125mg/ml	syr	1	1	0	1	1
	Ferrous Sulfate 30mg/ml	susp	1	1	0	0	0
Loren, S.	Nystatin 100000 Iug 15gr	crm	1	1	0	0	1
	Tetracycline 500mg	cap	1	1	0	1	0
	Aspirin 500mg	tab	1	1	0	0	1
Coburn, B.	B Complex	inj	1	1	1	0	1
	Valium 5mg	tab	0	1	0	0	1
Tyler, T.	Erythromycin 250	tab	1	1	0	1	0
	Cimetidine 300mg	tab	1	1	0	0	0
Kosner, K.	Multivitamins	Syr	1	1	0	0	1
	Penicillin 800000 mu	inj	1	1	1	1	1
	Paracetamol 100mg/ml	susp	1	1	0	0	1
Gomez, C.	Cough Expectorant	syr	1	1	0	0	0
Mertens, M.	Tetanus toxoid	inj	1	1	1	0	1
	Motrin 100mg	tab	0	1	0	0	1
Hughe, H.	ORS	pkt	1	1	0	0	1

USE WITH INDICATOR: F.4, F.5, F.6, F.7, F.8, F.9

Key: 1=yes; 0=no

Retail Price Comparison Data Form

This form is used for the indicator listed below.

H.7 Average of median private sector drug retail prices as a percentage of MOH acquisition prices for a set of indicator drugs

Data collection summary:

The data for this indicator are collected in a sample of drug retail outlets and at the MOH office responsible for purchasing drugs. At each drug retail site, for the set of indicator drugs, the price of the least expensive product in stock (brand or generic name) is recorded. At the MOH, the CIF prices for the most recent regular are recorded.

Instructions:

1. **Date:** Fill in the date on which the data are collected.

2. **Outlet Name:** Fill in the name of the drug retail outlet in which data are being collected.

3. **Outlet Type:** Fill in the type of drug retail outlet, for example, pharmacy or OTC drug store.

4. **Location:** Fill in the geographic location of the outlet, which will usually be the name of a region, district, city or town.

5. **Data Collector:** Fill in the name of the person collecting the data.

6. **Currency Used:** Record the currency used to report the price data collected.

7. **Product:** In this column, the list of 25 to 50 indicator drugs being used for the assessment should be pre-printed. For each indicator drug, the generic name, dosage form and strength should be included.

8. **Name (Brand or Generic):** For each indicator drug, fill in the brand or generic name of the least expensive product that is sold at the site.

9. **Comp. Unit:** For each indicator drug, fill in the comparison unit being used (e.g., tab, ml).

10. **# Units Per Pack:** For each indicator drug, fill in the number of units per pack.

11. **Retail Pack Price:** For each indicator drug, fill in the retail pack price.

12. **Retail Unit Price:** For each product, fill in the retail unit price, calculated by dividing the retail pack price by the retail pack size. It is necessary to enter the price to four decimal places, because the units involved are so small.

13. **MOH Unit Price:** For each indicator drug, fill in the MOH CIF unit price for the most recent regular procurement.

Note: *All* blanks should be filled in on this data collection form. Enter "N/A" if data for a particular item is not available.

RETAIL PRICE COMPARISON DATA FORM

DATE	12 August 1994
OUTLET NAME	Cantonal Guamote
OUTLET TYPE	Hospital
LOCATION	Urbano-Rural
DATA COLLECTOR	Veronica Maldonado

currency used U.S. $

PRODUCT	NAME (BRAND OR GENERIC)	COMP. UNIT	# UNITS PER PACK	RETAIL PACK PRICE	RETAIL UNIT PRICE	MOH UNIT PRICE
Acetylsalicylic acid tab 500mg	Anaspirin	tab	100	1.1000	.0110	.0055
Amoxycillin tab 250mg	Cipamox	tab	20	2.4600	.1230	.0410
Erythromycin tab 250mg	Wemid	tab	50	5.8500	.1170	.0387
Co-trimoxazole tab 80/400mg	Batrisulf	tab	50	1.3400	.0268	.0134
Penicillin Procaine vial 800000MU	Retarpen	vial	50	32.8500	.6570	.2190
Oral rehydration salts sachet	ORS	sachet	50	12.6300	.2526	.0842
Aminophylline 100mg/ml ampoule (1ml)	Aminofilina	ml	10	2.8340	.2834	.1417
Mebendazole tab 100mg	Cofazole	tab	100	1.6000	.0160	.0080
Chloroquine tab 150mg	Aralen	tab	100	2.5200	.0252	.0084
Ergometrine tab 0.2mg	Ermetrine	tab	30	2.9880	.0996	.0332
Glibenclamide tab 5mg	Ciana	tab	30	.3600	.0120	.0060
Metronidazole tab 250mg	Flagul	tab	10	.2040	.0204	.0068
Nystatin cream 100000 IU/g (15g)	Candistatin	gm	1 tube	.1320	.1320	.0660
Paracetamol susp 100mg/ml	Dafalgan	ml	1 bottle	.0304	.0304	.0152
Rifampicin tab 300mg	Rifadin	tab	50	8.2800	.1656	.0828
Isoniazid tab 100mg	Isoniazid	tab	30	.1980	.0066	.0033
Salbutamol tab 2mg	Ventolin	tab	100	.8200	.0082	.0041
Vitamin A tab 200000 IU	A-Vitex	tab	100	7.5900	.0759	.0253
Multivitamin tab	Theragram	tab	50	1.425	.0285	.0095
Ferrous Sulfate oral solution 40mg/ml 1000ml	Feninsol	ml	1 bottle	.0456	.0456	.0228
Mefloquine tab 250mg	Lariam	tab	100	278.4600	2.7846	.9282
Cimetidine tab 200mg	Cimetase	tab	100	3.6400	.0364	.0182
Benzyl Benzoate lotion 25% (1000ml)	Ansar	ml	1 bottle	.0099	.0099	.0033
Diazepam tab 5mg	Ortopsique	tab	100	.7400	.0074	.0037
Dextrose in Water 5%, I.V. (500ml)	Dextrose	ml	Vial	.0042	.0042	.0021

USE WITH INDICATOR: H.7

International Price Comparison Data Form

This form is used for the indicator listed below.

D.3 Percentage of average international price paid for last regular procurement of a set of indicator drugs

Data collection summary:

The data for this indicator are collected at the MOH office responsible for purchasing drugs. For the set of indicator drugs, the CIF prices for the most recent regular procurement are recorded and compared to the international prices.

Instructions:

1. **Date:** Fill in the date on which the data are collected.

2. **Outlet Name:** Fill in the name of the drug retail outlet in which data are being collected.

3. **Outlet Type:** Fill in the type of drug retail outlet, for example, pharmacy or OTC drug store.

4. **Location:** Fill in the geographic location of the outlet, which will usually be the name of a region, district, city or town.

5. **Data Collector:** Fill in the name of the person collecting the data.

6. **Currency Used:** Record the currency used to report the price data collected.

7. **1 U.S. Dollar:** Record the equivalent of one U.S. dollar in the currency used to report the price data collected.

8. **Product:** In this column, the list of 25 to 50 indicator drugs being used for the assessment should be pre-printed. For each indicator drug, the generic name, dosage form and strength should be included.

9. **Name (Brand or Generic):** For each indicator drug, fill in the brand or generic name of the product purchased by the MOH.

10. **Comp. Unit:** For each indicator drug, fill in the comparison unit being used (e.g., tab, ml).

11. **# Units Per Pack:** For each indicator drug, fill in the number of comparison units per pack.

12. **MOH Pack Price:** For each indicator drug, fill in the MOH CIF pack price.

13. **MOH Unit Price:** For each product, fill in the MOH CIF unit price for the most recent regular procurement, calculated by dividing the MOH pack price by the number of units per pack. It is necessary to enter the price to four decimal places, because the units involved are so small.

14. **International Unit Price:** For each indicator drug, fill in the average international unit price for the most recent regular procurement, found in the MSH *International Drug Price Indicator Guide*.

Note: *All* blanks should be filled in on this data collection form. Enter "N/A" if data for a particular item is not available.

INTERNATIONAL PRICE COMPARISON DATA FORM

DATE	12 August 1994
OUTLET NAME	Cantonal Guamote
OUTLET TYPE	Hospital
LOCATION	Urbano - Rural
DATA COLLECTOR	Veronica Maldonado

currency used U.S. $

1 U.S. dollar = _____

PRODUCT	NAME (BRAND OR GENERIC)	COMP. UNIT	# UNITS PER PACK	MOH PACK PRICE	MOH UNIT PRICE	INT'L UNIT PRICE
Acetylsalicylic acid tab 500mg	Anaspirin	tab	100	.5500	.0055	.0090
Amoxycillin tab 250mg	Cipamox	tab	20	.8200	.0410	.3800
Erythromycin tab 250mg	Wemid	tab	50	1.9350	.0387	.0476
Co-trimoxazole tab 80/400mg	Batrisulf	tab	50	.6700	.0134	.0183
Penicillin Procaine vial 800000MU	Retarpen	vial	50	10.9500	.2190	.2280
Oral rehydration salts sachet	ORS	sachet	50	4.2100	.0842	.0964
Aminophylline 100mg/ml ampoule (1ml)	Aminofilina	ml	10	1.4170	.1417	.1412
Mebendazole tab 100mg	Cofazole	tab	100	.8000	.0080	.0076
Chloroquine tab 150mg	Aralen	tab	100	.8400	.0084	.0091
Ergometrine tab 0.2mg	Ermetrine	tab	30	.9960	.0332	.0612
Glibenclamide tab 5mg	Ciana	tab	30	.1800	.0060	.0049
Metronidazole tab 250mg	Flagul	tab	10	.0680	.0068	.0100
Nystatin cream 100000 IU/g (15g)	Candistatin	gm	1 tube	.0660	.0660	.0401
Paracetamol susp 100mg/ml	Dafalgan	ml	1 bottle	.0152	.0152	.0172
Rifampicin tab 300mg	Rifadin	tab	50	4.1400	.0828	.0927
Isoniazid tab 100mg	Isoniazid	tab	30	.0990	.0033	.0041
Salbutamol tab 2mg	Ventolin	tab	100	.400	.0041	.0040
Vitamin A tab 200000 IU	A-Vitex	tab	100	2.5300	.0253	.0229
Multivitamin tab	Theragram	tab	50	.4750	.0095	.0083
Ferrous Sulfate oral solution 40mg/ml 1000ml	Feninsol	ml	1 bottle	.0228	.0228	.0230
Mefloquine tab 250mg	Lariam	tab	100	92.8200	.9282	1.0252
Cimetidine tab 200mg	Cimetase	tab	100	1.8200	.0182	.0367
Benzyl Benzoate lotion 25% (1000ml)	Ansar	ml	1 bottle	.0033	.0033	.0028
Diazepam tab 5mg	Ortopsique	tab	100	.3700	.0037	.0028
Dextrose in Water 5%, I.V. (500ml)	Dextrose	ml	1 vial	.0021	.0021	.0017

USE WITH INDICATOR: D.3

Blank Sample Data Collection Forms

The following are blank data collection forms that may be used to make copies.

DRUG REGISTRATION DATA FORM

DATE	
NAME OF OUTLET	
TYPE OF OUTLET	
LOCATION	
DATA COLLECTOR	

BRAND NAME (DOSAGE FORM)	MANUFACTURER AND/OR SUPPLIER	GENERIC NAME (DOSAGE FORM & STRENGTH)	LICENSE NUMBER	REGISTERED?

USE WITH INDICATOR: A.3

Key: 1=registered; 0=not registered

GENERIC SUBSTITUTION AND SALE OF ANTIBIOTICS DATA FORM

ATE

ATA COLLECTOR

SIMULATED PURCHASE PRODUCT

NAME OF OUTLET	MADE SUBSTITUTION?		SOLD ANTIBIOTIC?
	YES	PRODUCT	YES

SE WITH INDICATOR: A.7, H.9

Key: 1=yes; 0=no

INVENTORY DATA FORM

DATE
FACILITY NAME
FACILITY TYPE
LOCATION
DATA COLLECTOR

Manual Available? [ ] Yes [ ]No
Year:_____ Title:_____

Data Collected from: [ ] Computer System
[ ] Manual Ledger or Stock Record Cards
[ ] Tally Sheets or Bin Cards

PRODUCT	COUNTING UNIT	RECORD COUNT	RECENT RECEIPTS	RECENT ISSUES	ADJUSTED TOTAL	PHYSICAL COUNT

USE WITH INDICATOR: B.3, E.1, E.2, E.3, E.4

CHARGE FOR DRUGS TALLY FORM

DATA COLLECTOR:

SITE AND DATE	SITE AND DATE	SITE AND DATE	SITE AND DATE	SITE AND DATE
1.	1.	1.	1.	1.
2.	2.	2.	2.	2.
3.	3.	3.	3.	3.
4.	4.	4.	4.	4.
5.	5.	5.	5.	5.
6.	6.	6.	6.	6.
7.	7.	7.	7.	7.
8.	8.	8.	8.	8.
9.	9.	9.	9.	9.
10.	10.	10.	10.	10.
11.	11.	11.	11.	11.
12.	12.	12.	12.	12.
13.	13.	13.	13.	13.
14.	14.	14.	14.	14.
15.	15.	15.	15.	15.
16.	16.	16.	16.	16.
17.	17.	17.	17.	17.
18.	18.	18.	18.	18.
19.	19.	19.	19.	19.
20.	20.	20.	20.	20.
21.	21.	21.	21.	21.
22.	22.	22.	22.	22.
23.	23.	23.	23.	23.
24.	24.	24.	24.	24.
25.	25.	25.	25.	25.
26.	26.	26.	26.	26.
27.	27.	27.	27.	27.
28.	28.	28.	28.	28.
29.	29.	29.	29.	29.
30.	30.	30.	30.	30.

USE WITH INDICATOR: C.3

Key: 1=charges collected, 0 = no charges

STOCKOUT DATA FORM

DATE	
FACILITY NAME	
FACILITY TYPE	
LOCATION	
DATA COLLECTOR	

PRODUCT	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month12	TOTAL DAYS OUT

USE WITH INDICATOR: E.5

DRUG USE DATA FORM

DATE	
FACILITY NAME	
FACILITY TYPE	
LOCATION	
DATA COLLECTOR	

PATIENT NAME	DRUGS PRESCRIBED	DOSAGE FORM	GENERIC	NDFL/ NEDL	INJECT-ABLE	ANTI-BIOTIC	DIS-PENSED

USE WITH INDICATOR: F.4, F.5, F.6, F.7, F.8, F.9

Key: 1=yes; 0=no

RETAIL PRICE COMPARISON DATA FORM

DATE	
OUTLET NAME	
OUTLET TYPE	
LOCATION	
DATA COLLECTOR	

currency used _____

PRODUCT	NAME (BRAND OR GENERIC)	COMP UNIT	# UNITS PER PACK	RETAIL PACK PRICE	RETAIL UNIT PRICE	MOH UNIT PRICE

USE WITH INDICATOR: H.7

INTERNATIONAL PRICE COMPARISON DATA FORM

DATE	
OUTLET NAME	
OUTLET TYPE	
LOCATION	
DATA COLLECTOR	

currency used _____

1 U.S. dollar = _____

PRODUCT	NAME (BRAND OR GENERIC)	COMP UNIT	# UNITS PER PACK	MOH PACK PRICE	MOH UNIT PRICE	INT'L UNIT PRICE

USE WITH INDICATOR: D.3

Annex D: Sample Structured Interview Questionnaire

CENTRAL SURVEY QUESTIONNAIRE

FORMULARY/ESSENTIAL DRUGS LIST AND DRUG INFORMATION

INDICATOR: ***B.1 Number of unique drug products on National Drug Formulary List***

Data Source: Director of Pharmaceutical and/or Medical Supplies Services (MOH), and Officer in charge/Director/Manager (Central Medical Stores)

1. Does the country have a National Drug Formulary List?

   A. NO
   B. YES: there are [_|_|_] items on the list.

IF YES, OBTAIN A COPY

IF THERE IS NO NATIONAL LIST, SKIP TO THE NEXT SECTION BELOW.

2. Who developed the list?

   A. Individual (Position) :_____
   B. Committee (Name) :_____

3. Who is responsible for updating the list?

   A. Individual (Position) :_____
   B. Committee (Name) :_____

4. If a committee develops and updates the list, provide committee membership:

Specialty	Position

5. In the past year, how often has the committee met?

   A. Once
   B. Twice
   C. Quarterly
   D. Monthly
   E. Ad hoc
   F. Other:_____

6. How often is the National Drug Formulary List updated?

   A. Once yearly
   B. Twice yearly
   C. Quarterly
   D. Monthly
   E. Ad hoc
   F. Other:_____

7. Does the National Drug Formulary List contain contraceptives: YES NO
   If yes, list those products:

8. Who is the person authorized to make requests for changes in the formulary?

9. What information is required to support requests?

   A. Drug consumption data
   B. Drug prescribing data
   C. References from the medical literature
   D. None
   E. Other

10. If references are required, who supplies them?

11. Describe the procedure for requesting and approving additions to the list:

12. How are drugs that are not on the National Drug Formulary List procured?

   A. Private sector
   B. Donations
   C. Transfer from other institutions
   D. Other:

Annex E: End Notes

End Notes

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