How to investigate drug use in health facilities

Selected drug use indicators

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HOW TO INVESTIGATE DRUG USE

IN HEALTH FACILITIES

Selected drug use indicators

Action Programme on Essential Drugs

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INTRODUCTION

Purpose of drug use indicators

In 1985 WHO convened a major conference in Nairobi on the Rational Use of Drugs[1]. Since that time efforts have increased to improve drug use practices[2,3]. An essential tool for such work is an objective method to measure drug use in health facilities that will describe drug use patterns and prescribing behaviour. However, the lack of agreement on such a method has been a recurrent problem.

The main purpose of this manual is to define a limited number of objective measures that can describe the drug use situation in a country, region or individual health facility. Such measures, or indicators, will allow health planners, managers and researchers to make basic comparisons between situations in different areas or at different times. Also, when an intervention is undertaken to improve aspects of drug use, the indicators can be used to measure impact. Indicators can also serve as simple supervisory tools to detect problems in performance by individual providers or health facilities.

The drug use indicators described in this manual are intended to measure specific aspects of the behaviour of health providers in health facilities in a reproducible manner, irrespective of *who* measures them or *when* the measures are taken. The techniques for using the indicators have been well tested, and can be implemented in a standard way by individuals without special training or access to many resources. The indicators can be quickly and efficiently used in many settings to assess potential problems in drug use, and to prioritize and focus subsequent efforts to correct these problems.

The process of diagnosis and pharmaceutical treatment is complex. Techniques do not yet exist for adequately assessing the quality of this process in a standardized, objective way. The indicators described in this manual do not measure all dimensions of the appropriateness of pharmaceutical care, nor even necessarily the most important ones. For many of the aspects of care addressed by the indicators it is unclear at this time what the "gold standard" for correct behaviour should be. The drug use indicators are best understood as *first-line measures*, intended to stimulate further questioning and to guide subsequent action.

For example, consider a situation where the average number of drugs per prescription was found to be 4.2, with 13% of patients receiving injections. Although objective norms may not exist for either indicator, the health managers carrying out the study may feel that in their local health environment the expected norm should be about 2 drugs per encounter,

with 20% of patients needing injections. In such a situation priority would be given to finding out why so many drugs were prescribed, and to reducing the total number if the reasons for such high use were inappropriate. Conversely, if they found an average of 1.8 drugs per encounter and 65% injectables, priority would be given to exploring the reasons for this apparent overuse of injections.

Other health programmes in developing countries have defined indicators and standard data collection methods with great success. For example, immunization coverage is used as one indicator of the success of immunization programmes, and in every country the same definitions and data collection methods are used. Within most health systems the provision of curative care is a far more substantial activity in terms of staff time, money spent on drugs and patient demand, and yet simple indicators of drug use do not widely exist.

This manual is a first attempt to fill this gap and to propose some standardization in the different methods that are increasingly being used in the field.

Objectives of a drug use study

Studies to measure drug use will vary from setting to setting. The nature and design of such studies will depend on many factors, which include: the specific information needs of health managers; the types of record-keeping systems available in health facilities; the types of providers whose behaviour is to be characterized; and the resources available to carry out the work. In general, however, drug use studies by means of indicators will fall into four broad categories:

- Describing current treatment practices: Such a cross-sectional survey is done by taking specific measures of treatment practices from carefully selected groups of facilities and patients.

- Comparing the performance of individual facilities or prescribers: Rather than being primarily concerned with summarizing the treatment practices of the group as a whole, such a study seeks to compare practices between individual facilities or prescribers, or between groups.

- Periodic monitoring and supervision of specific drug use behaviours: After the broad outlines of drug use behaviour are known, the indicators can be used to identify facilities or providers whose performance falls below a specific standard of quality, so that they can be targeted for intensive supervision.

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- <u>Assessing the impact of an intervention</u>: Specific indicators can be used to evaluate the effectiveness of an intervention designed to change prescribing practices, by providing the capability for reliably measuring practices both before and after the intervention, and in both an intervention and a control group.

The first step in designing a drug use study is to specify the objectives clearly. The size of the samples required, the design of the sampling process and the complexity of data analysis will vary greatly depending on the specific objectives. This manual will focus primarily on the design and implementation of a basic indicators study to describe treatment practices, and on how this basic design should be changed to allow for a comparison of regions or facilities. Ideas for using the indicators for supervision will also be presented briefly.

Background on the development of drug use indicators

Early studies in Yemen[4] and Uganda[5] have used some of the core indicators to quantify the impact of essential drugs programmes or of specific interventions within such programmes. Building on this early work INRUD network members undertook a systematic programme to develop, field test and refine drug use indicators. The methodology for collecting the necessary data was tested in Indonesia, Bangladesh and Nepal. In close collaboration with WHO the revised indicators were then used again in Sudan, Uganda, Malawi, Nigeria and Tanzania.

On the basis of these experiences the indicators were limited to those related to facility-specific data, eliminating those which had originally been included to describe the situation in the community or in the country as a whole. An explicit effort was also made to limit the number of indicators, with the intention of defining a core set that could be collected in any health system and would yield the maximum of information with the minimum of effort. Following a review of the revised indicators in 1991 and a second series of field tests in Nigeria and Tanzania in 1992, the present set of indicators was finalized.

Contents of the manual

This manual includes six sections that describe the selected indicators and detail the methods for their collection and analysis. These sections are:

1   <u>Overview</u> of the categories of indicators, and the basic features of a drug use study using selected indicators.

2   Definitions and methods of each of the core indicators, and details of their
       calculation with examples.

3   Description of some important issues in study design and sampling, and of
       procedures for drawing the required samples of health facilities and clinical
       encounters.

4   Issues related to study planning and field methods when carrying out the basic
       indicators study.

5   Suggestions for analysis and reporting of results, including a summary of
       experience in using the drug use indicators.

6   Suggestions for follow-up activities after a drug use study has been completed.

The methods used to collect data for the indicators strongly affect the validity of results.
For this reason the manual includes detailed descriptions of sampling and data collection
methods. In addition to the material in the main text, there are a series of annexes which
contain more detail on sampling methods, the use of indicators for monitoring, and
complementary indicators, as well as copies of all the necessary data collecting forms.
Review of these annexes is not necessary before undertaking and analyzing a drug use
study with indicators. The statistical background to the methodology of sampling and
sample size has been published in a separate document which is available from the WHO
Action Programme on Essential Drugs.

The indicators have been developed specifically so that all required data can be analyzed
manually. However, to assist those with access to a computer, the formulas given in
Chapter 5 can easily be used to design a simple spreadsheet. Moreover, two software
tools have been developed to facilitate data analysis and presentation. One programme
consists of a coordinated set of spreadsheets and macros intended for recording and
analyzing the indicators. The other programme is a data-base that can facilitate entry,
analysis and standard reporting of data from prescribing encounters, while preserving
detail about specific health problems and drugs[*].

Comments on the manual

The indicators and methods presented in this manual have been extensively reviewed and
field tested in many developing countries. However, some unanswered questions remain

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[*] More information on these programmes is available from INRUD, Management
Sciences for Health, 165 Allandale Road, Boston, MA 02130, USA

regarding the implementation of the methodologies in different health environments, and the long-term usefulness of some of the indicators and recommended approaches. It is planned that the indicators in this manual will be developed further as additional field experience with their use is accumulated. It is only when the indicators are actually used by different people in different countries that they can be refined and fully validated.

The WHO Action Programme on Essential Drugs invites any reports on experiences in using these indicators, and comments on practical problems in implementation and analysis. In addition, it would be most valuable to have descriptions of second-level questions addressed after an initial drug use study has been completed, and of actions implemented to improve observed drug use problems. These experiences will be collected by the Action Programme and included in any future revision of this manual. Please send comments and reports to the Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

CHAPTER 1

OVERVIEW

Types of indicators

These drug use indicators were developed to be used as measures of performance in three general areas related to the rational use of drugs in primary care:

- pharmaceutical prescribing practices by health providers;

- key elements of patient care, covering both clinical consultation and pharmaceutical dispensing;

- availability of facility-specific factors which support rational use, such as key essential drugs and minimum pharmaceutical information.

Only a small number of basic indicators are recommended, which are referred to as the *core indicators*. These are highly standardized, do not need national adaptation, and are recommended for inclusion in any drug use study using indicators. They do not measure all important aspects of drug utilization; this would require more intensive methodologies and more extensive and varied sources of data. Instead, the core drug use indicators provide a simple tool for quickly and reliably assessing a few critical aspects of pharmaceutical use in primary health care. Results with these indicators should point to particular drug use issues that need examination in more detail.

In addition to the core indicators, a set of *complementary indicators* have been defined. These indicators are no less important, but are often more difficult to measure and can not be collected reliably in some settings. In addition, the complementary indicators are less standardized, since many depend on local variables that have to be defined before the indicator can be used. The definitions of the complementary indicators, and the methods for collecting them, are described in Annex 5.

The drug use indicators would typically be measured within a defined geographic or administrative area, either to describe drug use at a given point in time or to monitor changes over time. All of the data needed to measure the core indicators are collected from medical records or direct observations at individual health facilities.

A brief list of the core drug use indicators is presented in Table 1. These indicators are the minimum set of measures to be calculated during a single drug use indicators survey.

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Table 1
Core drug use indicators

Prescribing indicators
1   Average number of drugs per encounter
2   Percentage of drugs prescribed by generic name
3   Percentage of encounters with an antibiotic prescribed
4   Percentage of encounters with an injection prescribed
5   Percentage of drugs prescribed from essential drugs list or formulary

Patient care indicators
6   Average consultation time
7   Average dispensing time
8   Percentage of drugs actually dispensed
9   Percentage of drugs adequately labelled
10   Patients' knowledge of correct dosage

Facility indicators
11   Availability of copy of essential drugs list or formulary
12   Availability of key drugs

Of course, there are many other useful measures of drug use performance. One reason these particular core indicators have been selected is that during field testing in a number of developing countries they have proved to be both feasible to measure and informative as first-level indicators.

Types of drug use studies with indicators

The indicators are facility-based measures, meant to describe practices in a representative sample of health facilities. Although there are many important factors which influence drug use at other administrative levels of the health system and in the community, these factors are not measured by the drug use indicators.

The drug use indicators can be collected at one time in a cross-sectional survey, or they can be measured at different points in time to assess change in performance. The number of health facilities at which data are collected will depend partly on the purposes of a particular study. For a basic cross-sectional survey, 20 health facilities will be selected to

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represent a larger group of facilities. The more facilities studied, the more representative the sample is likely to be. At other times, the indicators will be measured in every health unit within an administrative area, for example, as an activity during supervisory visits. The process of collecting and interpreting data for supervision is quite different from the sample survey approach. Issues related to sample sizes and study designs for the different types of indicator studies are discussed in Chapter 3.

One feature to note is that the prescribing indicators can be based on either *retrospective* or *prospective* data. Retrospective data describe drug use during patient visits that took place in the past, preferably over a one-year period to control for seasonal variations. These data are extracted from medical records kept at the health facilities. Prospective data, on the other hand, describe drug use during patient visits that take place on the day of the indicators survey. The strengths and weaknesses of retrospective versus prospective data and the methods for collecting them are also described in Chapter 3.

Steps in organizing and carrying out a drug use study with indicators

In order to produce results that are reliable and comparable across studies, the indicators should be measured in a standardized way. Many studies which have examined aspects of drug use have differed in their definitions of the measures used, the procedures for sampling health facilities and encounters, or the way results were reported. This manual describes standard methods for all aspects of a study with indicators in order to encourage consistency and reproducibility of results.

The following list describes the sequence of steps needed to carry out a basic cross-sectional drug use study using indicators. For each step, a reference is given to the sections of this manual where the activity is described in more detail.

- Specify study objectives (Introduction, Chapter 1)
- Develop methods for measuring indicators (Chapter 2)
- Select a sample of health facilities (Chapter 3, Annex 1)
- Decide on the type of prescribing data to sample (Chapter 3)
- Recruit and train data collectors (Chapter 4)
- Field test the methods (Chapter 4)
- Implement field work (Chapter 4, Annex 1)
- Code and record data for indicators (Chapter 4, Annex 2)
- Prepare summary tables and graphics (Chapter 5, Annex 3)
- Report to participating facilities and authorities (Chapter 5)
- Follow up (Chapter 6)

CHAPTER 2

CORE DRUG USE INDICATORS

This chapter describes the procedures for measuring
the three groups of core drug use indicators. For
each group, after a brief introduction, the intended
purpose, specific prerequisites and details for the
calculation of each indicator are outlined, and an
example is presented of how the indicator might be
used. This is followed by a description of the
general tasks required to measure the set of
indicators in each group.

Group 1: Prescribing indicators

The indicators of prescribing practices measure the performance of health care providers in
several key dimensions related to the appropriate use of drugs. The indicators are based
on the practices observed in a sample of clinical encounters taking place at outpatient
health facilities for the treatment of acute or chronic illness. These encounters can be
observed retrospectively, from data recorded in historical medical records, or they can be
observed prospectively, from a group of patients attending the clinic on the day the data
are collected. Details of how to draw a sample of health facilities and how to sample
clinical encounters are discussed in Chapter 3.

The core prescribing indicators do not require the collection of any information on signs
and symptoms. Because the samples of clinical encounters cover a broad spectrum of
health problems, the core prescribing indicators measure general prescribing tendencies
within a given setting, independent of specific diagnoses. Admittedly, many critical
questions in drug use have to do with whether health care providers follow appropriate

diagnostic procedures and whether they select products and dosage schedules to fit underlying health problems. However, determining the quality of diagnosis and evaluating the adequacy of drug choices is a complex undertaking in practice, and beyond the scope of the core indicators. After a first drug use study with selected indicators has been carried out to determine overall prescribing performance, it will usually be necessary to undertake more health problem-specific investigations and make an assessment of the quality of diagnosis and treatment.

The data to measure the prescribing indicators can be recorded on forms that are reproduced in Annex 2. The *detailed prescriber indicator form* requires recording the names and amounts prescribed for each drug, from which the values for each prescribing indicator can later be entered. The form also allows other information on patients, prescribers and health problems to be recorded. The advantages of the detailed form are that data can be collected by persons with less sophisticated knowledge about drugs, and also that later follow-up health problem-specific or drug-specific analyses can be carried out on the same data. The ordinary *prescriber indicator form* requires that each indicator be entered directly by data collectors in the field. This assumes that data collectors know enough about drugs to evaluate the indicators. Its main advantage is that it allows immediate summaries of the indicators to be produced and discussed with staff from the health facility; its disadvantage is that fewer possibilities exist to later validate the data. The detailed form can be used for secondary analysis of specific diagnoses or drugs.

1   Average number of drugs per encounter

Purpose	To measure the degree of polypharmacy.
Prerequisites	Combination drugs are counted as one. Guidelines are needed on how to count certain ambiguous prescribing practices (e.g. some standardized sequential therapies).
Calculation	Average, calculated by dividing the total number of different drug products prescribed, by the number of encounters surveyed. It is not relevant whether the patient actually received the drugs.
Example	In health centers in Indonesia patients are prescribed an average of 3.3 drugs per consultation.

2   Percentage of drugs prescribed by generic name

Purpose	To measure the tendency to prescribe by generic name.
Prerequisites	Investigators must be able to observe the actual names used in the prescription rather than only having access to the names of the

	products dispensed, since these may be different; a list must be available of specific product names to be counted as generic drugs.
Calculation	Percentage, calculated by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100.
Example	In health units in Nepal an average of 44% of drugs are prescribed by generic name.

3 Percentage of encounters with an antibiotic prescribed
4 Percentage of encounters with an injection prescribed

Purpose	To measure the overall level of use of two important, but commonly overused and costly forms of drug therapy.
Prerequisites	A list must be available of all the drug products which are to be counted as antibiotics; investigators must be instructed about which immunizations are not to be counted as injections.
Calculation	Percentages, calculated by dividing the number of patient encounters during which an antibiotic or an injection are prescribed, by the total number of encounters surveyed, multiplied by 100.
Example	In dispensaries in Nigeria 48% of all outpatient encounters were prescribed one or more antibiotics, while an injection was prescribed during 37% of all consultations.

5 Percentage of drugs prescribed from essential drugs list or formulary

Purpose	To measure the degree to which practices conform to a national drug policy, as indicated by prescribing from the national essential drugs list or formulary for the type of facility surveyed.
Prerequisites	Copies of a published national essential drugs list or local institutional formulary to which data on prescribed drugs can be compared; procedures are needed for determining whether or not brand name products are equivalent to ones appearing in generic form on the drug list or formulary.
Calculation	Percentage, calculated by dividing the number of products prescribed which are listed on the essential drugs list or local formulary (or which are equivalent to drugs on the list) by the total number of products prescribed, multiplied by 100.
Example	In dispensaries in Tanzania on average 88% of drugs prescribed appeared on the national essential drugs list.

Required tasks for measuring prescribing indicators

All prescribing indicators are based on behaviour observed in small samples of patient encounters which are collected retrospectively or prospectively from a group of health facilities. Therefore, the first two tasks for measuring any of the prescribing indicators are to select a group of health facilities and to define how the clinical encounters will be sampled at these facilities. Once the samples of facilities and encounters have been selected, specific types of data necessary to measure the indicators will be recorded for each encounter. In order to record these data in a consistent and reproducible way, certain other activities have to take place before the data collection can start. The sequence of activities for measuring the prescribing indicators in a standardized way is detailed below.

Define drugs to be regarded as antibiotics

Antimicrobial agents are not always classified in an identical way. Sometimes drugs such as antiprotozoals, antihelminthics or antituberculosis agents are placed in a separate category from other antibiotics, while other systems may classify all these products in a single category of anti-infectives or antimicrobials. The indicators of antibiotic use are quite sensitive to whether or not certain groups of drugs are included as antibiotics, especially in environments where problems such as parasitic infestation or tuberculosis are common. Another issue in the definition of antibiotics for drug use indicators is whether topical antibiotic preparations, such as skin creams and ophthalmic ointments, should be counted as antibiotics. In areas where trachoma, bacterial conjunctivitis or bacterial skin infections are common these products may be widely used. Table 2 provides a classification scheme for the common classes of anti-infective drugs derived from the WHO Model List of Essential Drugs[6]. The classes which are recommended to be counted as antibiotics are marked in this table. Variations from this scheme should be mentioned in the description of the methodology of an indicator study.

There are a number of common ambiguities addressed by this recommended list. Metronidazole, which could be considered as an antibiotic but is much more often used as an antiprotozoal, should in this context not be counted as an antibiotic. However, sulfa drugs are counted as antibiotics. Antibiotic eye ointments and skin creams, such as oxytetracycline or chloramphenicol, are counted as antibiotics under this system. Antidiarrhoeal preparations that contain an antibiotic, the two most common being streptomycin or neomycin, are counted as antibiotics as well. As these do not figure on the WHO Model List they are mentioned in a separate category in the table.

Define drugs to be classified as generic

To calculate the percentage of drugs prescribed by generic name, investigators need to have a list of drug names that are to be counted as generics. Without such a list it may be

Table 2
Antimicrobial classification for prescribing indicators

Count as antibiotic	Code in WHO Model List	Class
	6.1.3	Antifilarials
	6.1.4	Antischistosomals
yes	6.2.1	Penicillins
yes	6.2.2	Other antibacterials
	6.2.3	Antileprosy drugs
	6.2.4	Antituberculosis drugs
	6.3	Antifungal drugs
	6.4.1	Antiamoebic and antigiardiasis drugs
	6.4.2	Antileishmaniasis drugs
	6.4.3	Antimalarial drugs
	6.4.4	Antitrypanosomal drugs
yes	13.2	Anti-infective dermatological drugs
yes	21.1	Anti-infective ophthalmological agents
yes	*	Antidiarrhoeal drugs with streptomycin, neomycin, nifuroxazide or combinations

* Not on WHO Model List of Essential Drugs

difficult to reliably classify some product names as generic or brand name. Usually the national essential drug list or local formulary will be written using generic names rather than brand names, so this list can often be used as the basis. Alternatively, the WHO Model List of Essential Drugs can be used as a starting point.

An example of such a difficult choice is acetylsalicylic acid. It could make sense to classify some common brand names (e.g. aspirin) as generic if these are used interchangeably with other names. Other examples are the local names of common mixtures or combination products for which no generic name exists.

Group 2: Patient care indicators

In order to understand the way drugs are used it is important to consider what takes place at health facilities from both the provider's and the patient's perspectives. Patients enter facilities with a set of symptoms and complaints, and with expectations about the care they will receive; they typically leave with a package of drugs or with a prescription to obtain them in the private market. The patient care indicators address key aspects of what patients experience at health facilities, and how well they have been prepared to deal with the pharmaceuticals that have been prescribed and dispensed.

The time that prescribers and dispensers spend with each patient sets important limits on the potential quality of diagnosis and treatment. Patients for whom pharmaceuticals are prescribed should, at a minimum, receive well-labelled medications, and should understand how to take each drug.

Like the prescribing indicators, the patient care indicators do not capture many fundamental issues related to the quality of examination and treatment. A proper evaluation of quality of care should assess the content of interactions between patients and health workers. However, this is both practically and technically beyond the scope of a limited set of core indicators. As with the prescribing indicators, it may be necessary to examine the patient-provider interactions in more detail and to explore the beliefs and motivations regarding the use of drugs in more depth, after an initial survey has identified one or more specific problems.

All the data needed to measure the patient care indicators for each facility can be recorded and summarized on the *patient care form* included in Annex 2.

6   Average consultation time

Purpose	To measure the time that medical personnel spend with patients in the process of consultation and prescribing.
Prerequisites	Procedures for accurately recording the time spent during the consultation, that is, the time between entering and leaving the consultation room. Waiting time is not included.
Calculation	Average, calculated by dividing the total time for a series of consultations, by the number of consultations.
Example	In Malawi patients spend an average of 2.3 minutes with health workers in the consultation room.

7 Average dispensing time

Purpose	To measure the average time that personnel dispensing drugs spend with patients.
Prerequisites	Procedures for accurately recording the average time patients spent with pharmacists or drug dispensers, that is, the time between arriving at the dispensary counter and leaving. Waiting time is not included.
Calculation	Average, calculated by dividing the total time for dispensing drugs to a series of patients, by the number of encounters.
Example	In health centres in Tanzania patients spend an average of 78 seconds receiving their drugs.

8 Percentage of drugs actually dispensed

Purpose	To measure the degree to which health facilities are able to provide the drugs which were prescribed.
Prerequisites	Information on which drugs were prescribed, and whether these drugs were actually dispensed at the health facility.
Calculation	Percentage, calculated by dividing the number of drugs actually dispensed at the health facility by the total number of drugs prescribed, multiplied by 100.
Example	In health facilities in Nepal, 73% of prescribed drugs were actually dispensed at the health facility.

9 Percentage of drugs adequately labelled

Purpose	To measure the degree to which dispensers record essential information on the drug packages they dispense.
Prerequisites	Investigators must be able to examine the drug packages as they are actually dispensed at the health facility.
Calculation	Percentage, calculated by dividing the number of drug packages containing at least patient name, drug name and when the drug should be taken, by the total number of drug packages dispensed, multiplied by 100.
Example	In Region A only 10.2% of drugs dispensed were adequately labelled.

10 Patients' knowledge of correct dosage

Purpose	To measure the effectiviness of the information given to patients on

	the dosage schedule of the drugs they receive.
Prerequisites	Access to a written prescription or to a patient card against which patients' knowledge on the dosage schedule can be checked, or access to standards for how each common drug is supposed to be used; investigators must be trained to evaluate patient knowledge during the interview, or to record patient responses for later evaluation.
Calculation	Percentage, calculated by dividing the number of patients who can adequately report the dosage schedule for all drugs, by the total number of patients interviewed, multiplied by 100.
Example	In 23 health facilities in Bangladesh 63% of patients were able to repeat the correct dosage schedule of the drugs they had received.

Required tasks

In a simple drug use indicator study the adequacy of patient care is measured by observing a sample of patient encounters as they normally occur, and by interviewing patients as they leave the facilities. In addition to those described for the prescribing indicators, the following tasks are required to measure the patient care indicators.

Design a procedure for collecting prospective data

Because patient care encounters are always sampled prospectively it is necessary to arrange for patient observations and interviews. Since patient flow can be organized in many different ways attention should be given to the methods of data collection before the study begins. The methods should be reasonably consistent in all facilities and should not overly influence the routine process of patient care. Observing patient care in a few facilities before the start of the study is usually sufficient to design an efficient data collection process.

Procedures must be developed for measuring the consultation and dispensing time, and for intercepting and interviewing patients after they have received their medication. Because such interviews may disrupt the patient flow and even be a little threatening to health workers, interviews should ideally be held away from the main clinic area.

It is not necessary to measure consulting and dispensing time and do the interviews all with the same patients, and particularly if the investigating team is not structured to do this efficiently. However, measuring all the indicators for the same patients would give a better sense of the total service individual patients are receiving. It is recommended to start the observations in the middle of a clinic day. This helps to ensure that the results are not overly influenced by the rush to see patients at the beginning or end of a clinic session, or by freshness or fatigue of the health workers.

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Specify how consultation and dispensing times will be measured

It is necessary to develop a consistent method for observing the beginning and end of consultation and dispensing encounters. To reduce the variations in time that occur with different patients it is recommended that the patient care process be timed for at least 30 individual encounters. If there are fewer than 30 patient encounters per day in a particular facility all encounters should be included.

Based on an understanding of the patient flow at health facilities the procedures to record the times of clinical consultation and dispensing should be specified in advance. The basic procedure should be to record beginning and ending times for individual consultations. If patients are seen one by one in a consultation room, this would mean measuring the time between entering and leaving the room. In some settings multiple patients are seen by multiple providers in a single consultation room, and patients may even queue within the consultation room itself. In these situations it will be necessary to be in the room to observe the time when individual consultations actually begin and end.

A similar procedure should be used in the dispensing area where the beginning and ending times of patient interactions with dispensers should be recorded. Here, the encounter time refers to the period from when a patient approaches the dispensary window to receive his or her drugs to when the patient leaves the window. The waiting time before the patient hands the prescription in to be filled is *not* counted.

Identify the sources of data to compare prescribed and dispensed drugs

Not all prescribed drugs are actually dispensed at the health facility. This may happen because drugs which are usually available are out of stock, or when drugs are intentionally prescribed to be purchased in the private sector. Measuring the degree to which drugs must be obtained outside the health facility provides some indication about the reliability of drug supply, as well as how prescribing choices match the range of pharmaceuticals available in the system.

Information on drugs *prescribed* is usually either recorded on a prescription form or entered directly in the medical record, except when drugs are actually dispensed by the prescriber. The identity of drugs prescribed is the key measure of therapeutic choice. In many settings information about drugs *dispensed* is also available from pharmacy records or as additional notes on the prescription form. Drugs dispensed can also be determined by examining the products the patient has actually received.

If both types of information are available, investigators need instructions on how to score the comparison between prescribed and dispensed drugs. A confusing situation occurs when the drug dispensed is the one prescribed but in a quantity different from the prescription. The disparity may be due to low stocks or to an institutional policy limiting

the amount dispensed. In these situations the drug should be counted as if it had been dispensed as indicated, with a special note on the record form.

Define criteria for adequate patients' knowledge about medications

At some point during the examination or dispensing process, details about the medication prescribed should be explained to the patient. Ideally, this explication includes the reasons why the medication is being given, how each drug should be used, as well as information about precautions and possible side effects. Because most of these factors are difficult to measure patients should only be evaluated on their knowledge of when and in what quantity each drug should be taken. This should be evaluated for each medication actually dispensed to the patient. Failure to know either of these two points about any of the drugs dispensed should result in patient knowledge being scored as inadequate.

To reliably evaluate the correctness of patients' responses about when they are to take the drugs, clear guidelines should be developed about common dosage regimens. For example, is "three times per day" identical to "morning, noon, and night" or to "after every meal"? Is "six pills per day" the same as "two pills three times a day"? Guidelines for acceptable responses should be developed and taught during the training of data collectors.

Describe procedures for evaluating patients' knowledge

Patients' knowledge can be evaluated when the prescribed dosage has been recorded on the drug package, on a prescription form retained by the patient or on a patient-held medical record. If the necessary data (drug name, when to be taken and in what quantity) are available in written form, the knowledge of the patient can be evaluated against this record.

Even if data on drug dosage are not recorded it may still be possible to evaluate patients' knowledge. The method for doing so depends on the level of pharmaceutical knowledge of the investigators. If the data are collected by pharmacists or other health workers familiar with drug names and dosage, it is possible for them to evaluate the adequacy of patients' knowledge directly, and simply record each patient interviewed as having adequate knowledge or not. In this case consistency can be assured by a review of the proper dosage of major medications during the training of data collectors, who should also be provided with a summary list for use in the field. It might be useful to supply them with examples of the most common drugs supplied to health facilities, for easy recognition.

If data collectors are less experienced it may be more reliable to have them record the name of each drug and the patient's knowledge about it during the interview, and have these records evaluated by experienced coders. For each oral and topical drug prescribed

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to the patient the data collector should record drug name, strength, quantity dispensed and the patient's explanation of how and when the drug is to be taken.

Group 3: Health facility indicators

The ability to prescribe drugs rationally is influenced by many features of the working environment. Two particularly important components are an adequate supply of essential drugs and access to unbiased information about these drugs. Without these it is difficult for health personnel to function effectively.

The data for the health facility indicators can be recorded on the *facility summary form* included in Annex 2. The same form can be used to record information on the data collection process at each health facility, such as the names of the primary contact people at the facility, whether retrospective or prospective data were collected, how many cases were recorded for the prescribing and patient care indicators, and any problems that occurred during the visit.

11   Availability of copy of essential drugs list or formulary

Purpose	To indicate the extent to which copies of the national essential drugs list or local formulary are available at health facilities.
Prerequisites	A national essential drugs list or a local formulary must exist for that level of care; if not, the indicator would always be scored "no".
Calculation	Yes or no, per facility.
Example	In Country A only 28% of health facilities had a copy of the national list of essential drugs.

12   Availability of key drugs

Purpose	To measure the availability at health facilities of key drugs recommended for the treatment of some common health problems.
Prerequisites	A short list of 10-15 essential drugs must be compiled that should always be available (suggested list in Table 3).
Calculation	Percentage, calculated by dividing the number of specified products actually in stock by the total number of drugs on the checklist, multiplied by 100.
Example	In health centers in Nigeria, on average 62% of 14 key essential drugs were actually in stock.

Required Tasks

Determine whether a national essential drugs list or local formulary exists

One sign that the concept of essential drugs has been accepted is the development, dissemination and use of a national essential drugs list, a local essential drugs formulary, or equivalent reference material on essential drugs, such as drug information sheets. The availability of such drug information is one cornerstone for rational prescribing.

In order to be most effective, information must be widely disseminated to all health facilities to guide decisions about the purchase, distribution and therapeutic use of drugs. The investigators should determine whether a national essential drugs list, local formulary, or equivalent reference material exists, when this material underwent its most recent revision, and in what form it has been distributed to health facilities. To score this indicator in the field, data collectors should ask the prescribers in each facility to produce an up-to-date copy of the list or formulary.

Table 3
Model list of key drugs for testing drug availability

Diarrhoea	oral rehydration salts
	cotrimoxazole tablets
Acute respiratory tract infections	cotrimoxazole tablets
	procaine penicillin injection
	paediatric paracetamol tablets (*)
Malaria	chloroquine tablets
Anaemia	ferrous salt + folic acid tablets
Worm infestations	mebendazole tablets
Conjunctivitis	tetracycline eye ointment
Skin disinfection	iodine, gentian violet or local alternative
Fungal skin infection	benzoic acid + salicylic acid ointment (*)
Pain	acetylsalicylic acid or paracetamol tablets
Prophylactic drugs	retinol (vitamin A) (*)
	ferrous salt + folic acid tablets

* Included to measure the availability of a more complete range of essential drugs

Develop a short list of essential drugs to test availability

Prescribers can only treat patients in a rational way if essential drugs are available on a regular basis. One way of indicating the overall availability of essential drugs is to identify a short list of specific drugs (less than 15) that are essential to treat common health problems, and to examine their availability in the facility on the day of the survey.

A suggested list of drugs that might be used for this purpose is presented in Table 3. Investigators should modify this list, or develop a new list, to apply to a few important health problems in the local environment. Data collectors will then check the drugs on this list for availability in the facility. For the purposes of this indicator brand name and generic drugs are chemically equivalent, and the presence of any such chemically-equivalent form of the listed drug should therefore be counted. If there are questions about whether or not a particular drug qualifies, data collectors should be trained to record questions on the facility summary form so that a final decision can be made by the principal investigators. The quantity in stock should not be considered. Even if only one bottle or a few tablets are available, the drug should be recorded as being in stock.

CHAPTER 3

STUDY DESIGN AND SAMPLE SIZE

Surveys with drug use indicators may have different objectives:
to describe current treatment practices; to compare the
performance of individual facilities or prescribers; to monitor
or supervise specific drug use behaviours; or to assess the
impact of an intervention. This chapter discusses some
important study design and sampling issues.

The best design for a particular study depends not only on
statistical theory but also on the objective(s) of the study and
on the practical aspects of collecting the data. Guidelines for
the sample size for each of the different types of study are
therefore included and are based on extensive field testing.
They are summarized in Table 4. By following these
recommendations the results of the drug use studies will be
valid and comparable.

The methodological issues are discussed in full in a separate
document, in which theoretical and empirical support for the
recommendations made in this section are presented. If it is
essential that study results be highly accurate and reliable, for
example when the effects of an expensive intervention have to
be tested, it is recommended that a sampling expert be
consulted before the study is undertaken.

Select the type of facilities for the study

The first activity of an indicators study is to select the type of health facilities to be
studied, drawing randomly from a larger group of such facilities. The prescribing
indicators measure aspects of outpatient treatment. They are designed for use in health
centers, dispensaries or hospital outpatient departments, both public and private. In
general, a single drug use study would focus on one type of facility, so that the results
make sense. The prescribing indicators are less useful in inpatient settings, or in specialty
outpatient clinics in referral hospitals where the drug use patterns are more complex.

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Table 4

Basic parameters of different types of drug use studies

	Cross-sectional (basic)	Cross-sectional (comparative)	Supervision	Assess impact of intervention
Objective of the indicators study	To measure drug use indicators in a representative group of facilities	To compare between individual facilities or prescribers, or between groups	To identify whether a facility is above/below a set norm of practice	To assess the impact of an intervention in an intervention and a control group
# of facilities included	20	At least 10 in each group, 20 for more reliable comparisons; for individual comparisons, each facility is considered separately	Each facility sampled separately	At least 20 per group
# of prescribing encounters per facility	30	30 for comparing groups; 100 for individual facilities or prescribers	About 15 for identifying outliers with poor practices	At least 30, but depends on the need for precision
Type of prescribing data	Retrospective or prospective	Retrospective or prospective	Prospective preferred, but retrospective possible	Retrospective preferred, but depends on objectives and structure of intervention
Time frame of prescribing data	One year, if possible	One year, if possible	One day, or short period if retrospective	At least 4-6 months before and after the intervention
Type of patient care data	Prospective	Prospective	Prospective	Prospective (if necessary)

Define the types of prescribing encounters to be included

Sometimes there are different types of patient encounters taking place within the same health facility. In addition to general medical visits for acute or chronic illness, there can be separate clinics for well-child visits, pre-natal and post-natal visits, dental visits, specialist consultations, and so forth. There can also be separate clinics for adult and paediatric cases, and sometimes new patients are separated from re-attendances. Treatment practices for these different types of encounters can be quite different. A study which mixes different types of encounters in an unsystematic way will produce results that are difficult to interpret. Indicators studies should be restricted to a sample of general illness encounters, representing a mix of health problems and ages.

The types of encounters in the sample (e.g. general outpatients only) should be decided beforehand and described clearly to prevent arbitrary decisions by the investigators when they encounter unusual circumstances. This decision should reflect the purposes of the study, and it should also take into account the practical aspects of retrospective or prospective sampling. If samples of adult and paediatric cases are drawn from separate sources, half the sample should be taken from each age group, spread evenly over the chosen period.

Choose between retrospective and prospective data

Prescribing encounters can be sampled retrospectively, that is, by drawing random encounters from historical medical records, or they can be sampled prospectively, by collecting data from current patients as they present for treatment on the day of the study visit. Information on prescribing indicators can be collected by both methods. However, patient care and facility indicators always require the collection of prospective data.

One of the key questions in deciding between retrospective and prospective data for the prescribing indicators is whether adequate sources of retrospective data exist. Possible retrospective sources of data can include chronological clinic registers, treatment records kept by individual prescribers, copies of drug prescriptions that are retained at the dispensary, or patient records kept at the health facility.

Two essential elements that retrospective data sources must provide are: (1) a method of selecting a random sample of patient encounters that took place within a defined period of time; and (2) the specific names and routes of administration of all drugs prescribed. If these are not available, prospective data are needed to measure the prescribing indicators.

Records are typically kept as part of the normal morbidity or drug consumption recording systems, or else as part of a facility-based system of medical or pharmacy records.

Retrospective data are usually easier to collect than prospective data, and suffer fewer potential biases. It is often possible to define a retrospective study period of a year or longer and spread cases throughout this period, which minimizes bias due to seasonal variations or interruptions in the drug supply cycle.

The major weakness of retrospective data is that they are often incomplete. Individual or entire series of records can be missing, either because they were misplaced or because they were simply not recorded in the first place. In addition, the validity of retrospective data is often difficult to verify. Key data elements such as whether an injectable or oral form of a drug was ordered, or whether a drug was dispensed as prescribed, can be consistently missing or of uncertain accuracy.

Prospectively collected data are usually complete. However, since prospective data are generally collected over a very short period they may suffer from biases due to seasonality, peculiarities in staffing, inconsistencies in the supply cycle, or most importantly, due to the fact that providers are aware that their behaviour is being observed. Of course, in the absence of retrospective sources of data study planners have little choice but to collect data prospectively and try to guard against these possible sources of bias.

Pilot tests have shown that prospectively collected encounters can sometimes result in the prescribing indicators being biased in a "socially desirable" direction. Significant reductions have been observed in the percentage of encounters receiving injections. The differences between retrospective and prospective measures for other indicators (fewer drugs and antibiotics) have generally been very small.

If the medical record system can provide certain essential elements (a basis for sampling randomly within an identifiable period of time, name and route of delivery of all drugs prescribed), a retrospective sample has less chance of bias. If historical data sources are non-existent or incomplete, or if there is a need to collect other data not included in historical medical records, then a prospective sample can be used to measure the prescribing indicators. Prospective sampling is also more appropriate to measure short-term changes in performance following an intervention.

Sample size

Sampling units and units of analysis

Studies of drug use practices sometimes use an incorrect unit of analysis. The samples drawn in a study of prescribing practices in a group of health facilities can be thought of in a variety of different ways which include:

- areas or locations - a sample may include different regions or districts; or within a single region, it might include urban, peri-urban and rural areas;

- health facilities - a sample may be drawn from a number of health facilities of the same type, or from different types of facilities such as hospital outpatient departments, polyclinics and health centers;

- health providers - sometimes it will be possible to know the identity and background of the individual providers (doctors, nurses, paramedical workers, pharmacists) who treated patients in the sample, and to examine provider-specific differences in treatment patterns;

- prescribing encounters - encounters are collected from several health facilities in the sample, and studied as a whole.

Why are these distinctions important? One difficult aspect of designing a sample is deciding how many areas and health facilities to include, and how many encounters to collect for each prescriber at each facility. In many drug use studies the *primary sampling unit* is the health facility. This means that facilities are the first units randomly selected from a larger group. However, results can not then be reported with the prescribing encounter as the *unit of analysis*, with results as simple percentages or averages across all encounters sampled from the various facilities, as this would ignore the fact that sampling took place at two levels (health facility and patient encounter) and that real differences may exist at facility level. The methods of sampling and data analysis recommended in this manual attempt to deal with this problem.

For theoretical and practical reasons the health facility is the key unit for drug use studies. Many factors related to drug supply and utilization patterns vary at the facility level, that is, *between* facilities. For that reason it would be better to include as many different facilities as possible. However, this is generally more costly than it is to add additional encounters *within* facilities, because of extra transportation and lodging costs. Therefore, the primary goal in the design is to have a sample large enough to provide reliable answers to the major study questions, yet a sample which includes the smallest possible number of areas and facilities.

Guiding principles for sample size

On what grounds should decisions about the number of areas, facilities and encounters to include in the sample be based? The main guidelines that have been used as the basis for recommendations in this manual are listed below.

- Individual health providers tend to exhibit consistent practices over time, so that a sample drawn at one point in time will provide basically the same results as a

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sample that covers a longer period.

- Within facilities, differences between the type of prescriber (doctors, paramedical workers) are best ignored in both sampling and data analysis, unless a study or supervision of individual prescribers is an explicit objective.

- The goal of a drug use study should be to estimate percentage indicators that summarize values for the sample as a whole with a 95% confidence interval of plus or minus 7.5%.

- A study of individual facilities should measure facility-specific percentage indicators with a 95% confidence interval of plus or minus 10%.

- Above a certain number of encounters, adding additional encounters to a sample within a facility adds very little new information. However, increasing the number of facilities in the sample is a much better way to obtain more accurate and reliable estimates of overall prescribing practices.

- The study should be planned in such a way that data collection in one facility can be completed in a single day by a team of two investigators.

Recommendations on sample size

Surveys describing current treatment practices

There should be at least 600 encounters included in a cross-sectional survey, with a greater number if possible. If 20 health facilities are included, as recommended, this means about 30 encounters per facility. If fewer facilities are included, a larger number of cases should be selected in each, so that the minimum of 600 encounters is reached. Wherever possible, retrospective data collection over the past year should be used for prescribing indicators. Where records do not exist or key components are missing, use a prospective data collection, being aware of the possible problems of this method. Patient care and facility indicators are always collected prospectively.

Comparisons between individual facilities or prescribers

When it is important to compare individual facilities or prescribers, the size of samples drawn within each facility or per prescriber must be higher than 30 in order to get more reliable within-facility estimates of prescribing patterns. At least 100 cases per health facility or per prescriber would be recommended. If possible, retrospective data should be

used. If groups of facilities are to be compared, at least 10 facilities should be included in each group.

Periodic monitoring and supervision

Indicators for individual facilities or prescribers can be used for monitoring purposes, e.g. when they are measured regularly. However, indicator data can also be collected with the specific objective to identify those facilities or prescribers that are grossly different from a set standard with respect to one or more indicators. In that case the number of cases collected at any one time can be much lower, with the size of the sample defined by the degree of accuracy needed. The basic principles of this method of "Lot Quality Assurance Sampling" are discussed in Annex 4. Generally, prospective data would be used for such monitoring, but if of good quality, retrospective data could be used.

Studies to assess the impact of an intervention

Consecutive studies can be used to measure changes in practice that result from an intervention. However, they must be designed in such a way that the response to the intervention can be distinguished from changes that would have occurred anyway. One critical issue in designing such studies is to compare changes in the intervention group with change (or the lack of it) in an appropriate control group. Without such a comparison it is impossible to know whether or not it was the intervention that caused any observed change.

It is important to establish the data collection process for both the intervention and control groups in exactly the same way. If baseline data for the intervention group are collected prior to the intervention, baseline data for the control group should be collected then as well. Alternatively, if retrospective records in the intervention and control facilities are good, both pre- and post-intervention data might be collected in a single data collection exercise at the end of the follow-up period. In this way it might be possible to guard against the possibility that changes in the study groups result from changes in the data collection system, or from the knowledge that their practices were being observed.

Although it is not important that they be identical, the sizes of the intervention and control groups should be roughly similar, both in the number of facilities sampled and the number of encounters per facility. To provide reasonable accuracy when drawing conclusions from observed differences between the intervention and comparison groups, there should usually be at least 10 facilities in each group, with 20 for more reliable comparisons. The easiest way to collect prescribing data is by retrospective data collection after the intervention is completed and the possible effect has occurred. If prospective data collection is used, exactly the same procedures should be undertaken in the intervention and control groups to control for bias that might result from the observation process.

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CHAPTER 4

PLANNING AND FIELD METHODS

Drug use studies with indicators are intended to measure performance in pharmaceutical treatment and patient care practices. To ensure that these measures are reliable, procedures for sampling, data collection and analysis must be defined before field work starts. One key objective in planning should be to anticipate and minimize the errors that can affect the data because of unintended biases introduced by data collectors or inefficiencies in the organization of work.

This chapter reviews the organization of an indicator study, so that it can be carried out in a standardized way. It includes sections on personnel requirements, preparations for field work, including training of data collectors, data collection in the field and entering data for scoring the indicators.

Personnel requirements

There are three principal phases of activity during a drug indicators study: planning the study, collecting the data, and data processing. Personnel requirements for each phase are discussed separately.

Planning the study

Persons planning and carrying out a drug use indicator study need a basic knowledge of pharmaceuticals, some understanding of the principles of sample surveys and an appreciation of the logistical requirements for carrying out field studies. The indicators and methods recommended in this manual have been designed to minimize as far as possible the need for a high level of sophistication in these areas. Carrying out more in-

depth follow-up activities, or designing and mounting an intervention, will in many cases require a higher level of technical expertise.

Studies are most useful when they are designed to meet specific objectives. The results of an indicator study would be of most interest to managers and policy-makers responsible for administering a primary health care programme, or to health providers responsible for supervising the quality of medical care in public sector facilities. If the initiative for carrying out an indicators study does not originate with such people, they should be involved at an early stage in its design.

Collecting data

Data collectors should be familiar with pharmaceutical terms to be able to reliably extract information from records, and to record it accurately during observations. The most effective data collectors are persons with clinical experience such as physicians, nurses, pharmacists or paramedical staff. However, other MOH staff and temporary employees with some health-related experience hired specifically to collect and enter data can also be used.

It is possible to separate the process of collecting data from coding the specific indicators. Data collectors can be trained to record only the names of drugs and routes of delivery while in the field, and coders can later assign values to the indicators (for example, whether or not a drug is an antibiotic). In this case the *detailed prescribing indicators form* in Annex 2 could be used. In this way, personnel with less drug-related experience can be trained to collect data, while staff more familiar with pharmaceuticals can assign values to the indicators. This is one way to ensure that the rules for assigning codes and handling missing information will be applied uniformly. Alternatively, the indicators can be coded and recorded directly on the *prescribing indicators form* in Annex 2.

Data collection can be tedious work, and requires an aptitude for concentration and attention to detail. The best data collectors combine the discipline to collect data in a standardized way with the flexibility to adapt procedures to the requirements of unusual situations. People who have these traits, but lack technical knowledge, can be trained to perform effectively and will improve with experience; people without them will never perform effectively, regardless of their technical qualifications.

Data processing

There are two approaches to processing the data from an indicators study: manual tabulation and computerized analysis. The drug use indicators have been designed in such a way that it is possible to collect the data and calculate the indicators without the aid of a computer. However, if computers are available, the data can be a rich source of further

analyses on the use of drugs and costs of treatment. To facilitate the use of computers a special spreadsheet has been prepared to allow rapid entry and analysis of indicators data**. In addition, an X-Base compatible computer program is available to allow for the standardized data entry and analysis of the *detailed prescribing indicator form*. Although data in this format are more difficult to process, the possibilities exist for more complex, problem-specific secondary analyses.

If the indicators are coded in the field, the pharmaceutical knowledge of data collectors should be relatively high. Decisions about the coding of certain indicators, such as whether or not drugs are prescribed by generic name, are more efficiently made during data collection, but require reasonably thorough information about which names represent generic drugs. Support and supervision of the data collection process also need to be strengthened.

Many of the decisions on coding the prescribing indicators can be delayed until the data are returned to the study office. Under these circumstances an indicators study will need to have the services of one or more data coders familiar with pharmaceutical treatment and if data are to be computerized, data entry clerks to input the coded encounters.

Preparations for field work

Adequate planning and preparation for field work will increase the likelihood that data will be collected and recorded in a reliable way. Some of the necessary steps are reviewed below.

Create drug reference lists

The use of indicators 1-5 and 12 depends on the availability of lists of essential drugs, generic names, antibiotics and essential drugs that should always be in stock (see Chapter 2). These lists should all be prepared before the field work begins. As a study progresses, new drugs not on the initial lists will be found by data collectors. Efficient procedures are needed for updating and distributing new lists to all data collectors.

Select and train personnel, and conduct pilot tests

A key step in preparing for field work is to identify and train the persons to collect and code the data. A model training programme for data collectors is included in Table 5.

** Available free of charge from INRUD, Management Sciences for Health, 165 Allandale Road, Boston, MA 02130, USA

Table 5

Model training course for data collectors

TOPIC	AIDS	TIME
1. Overview of the project: • What an indicators study is and Ministry of Health's interest in indicators; • Role of the data collectors; • Work to be carried out; start and finish dates; • Days to work and compensation; • Number of sites to be visited by each data collector.	Study briefing package	60 minutes
2. How data are collected: • Show prescribing and patient care indicator forms; facility summary form; • Indicate fields for different types of data and point out that some require coded data.	Data collection forms	15 minutes
3. Coding prescribing encounters: • Data must be organized in a standard manner; • Form has space for both names and codes for patients, and codes for indicators; • The data collector's role is to locate in clinical records information on patient demographics and drugs prescribed, and enter it into the form.	Prescribing indicator form	15 minutes
4. Drug codes (if detailed prescribing indicator form is used): • Drug names can be similar, and there is need for precision; • All drugs must be recorded, whether dispensed or not.	Reference drug list	15 minutes
5. Practice session to enter data into the prescribing indicator forms: • 10 sample cases which are problem free, and illustrate how to transcribe data from the health facility records to the forms; • 10 additional sample cases illustrating various problems likely to be encountered, (illegible data, encounters for which no drug is prescribed, antibiotics not on drug list)	Prescribing indicator forms; sample data for entry	60 minutes
6. How to draw the retrospective sample of patient encounters (if needed): • Procedures for assembling the lists that comprise the sample frame, and listing cases; • Linking other necessary data on health problems and drugs for the encounters.	Listing/facility summary forms	60 minutes
7. Observing and interviewing patients: • How to sample patients for process of care and knowledge; • Getting accurate times on examination and dispensing; • Criteria for adequate knowledge.	Patient care forms	50 minutes
8. Collecting other indicators: • Criteria for essential drug lists and formulary; • Surveying health facility stores for drugs in stock.	Facility summary Forms	30 minutes
9. Field practice: • visit and collect complete set of data for 1-2 facilities; • complete facility summary table and report.	All forms	1 day
10. Final discussion: • review experiences of field test and address concerns and questions; • assign data collectors to working teams; • finalise data collection plan and organization of work (schedules, transport, communication).	Schedules	1/2 day

Based on previous experience, it is recommended to have at least two data collectors trained to work as a team, so that all data can be collected in a single day in each facility. To ensure consistency in results, all data collectors should be trained together, and then allowed to practise together at one or two pilot sites. This is an important step which will provide an opportunity to identify and solve unforeseen problems. It will also identify "natural leaders" who can assist the other data collectors in case of difficulty. Finally, training and pilot testing allows study planners to make realistic estimates of the time required for collecting data at each study site.

Select and prepare sample sites

Issues involved in the selection of an appropriate sample of facilities have been addressed in Chapter 3; sampling procedures are given in Annex 1. Once facilities have been selected and staff trained, the field work can begin. One key to the success of a study is adequate preparation of sample sites.

Political preparation includes adequate notification to relevant authorities of the purposes and methods of the study. This increases the likelihood that the results of the study will be accepted and utilized. If possible, it is also helpful to visit each sample site beforehand. These visits can be used to promote the active cooperation of clinical and pharmacy staff. The logistical preparation can also be done during such preparatory visits. Study planners can identify the required sources of data at each facility, prepare them for use by the data collectors, and note any special requirements in drawing the sample of encounters.

Plan the schedule of data collection visits

The number of days required to collect data can be estimated, based on the planned number of encounters for each facility. The number of sites that can be completed in a given period of time will depend on the number of data collectors, the sample sizes, the travelling time required between sites, and the level of activity at the facility. In general, it is possible for a two-person data collection team to survey one facility per day. Before data collection starts, a schedule of visits should be prepared with the dates of every site visit. Every facility should be told in advance when to expect data collectors' visits. When funds permit, it can be useful to "hire" one or more staff at each facility to assist the data collectors in finding records and deciphering handwriting.

Data collection in the field

The procedures to be followed on site should be communicated during the training sessions, tested during a pilot test at one or two facilities, and ideally provided in written form for reference in the field. The areas to be covered should include the following:

Selecting a sample of encounters

Data collectors will have been trained how to select cases for the sample. If the sample is to be drawn from historical records, the data collector will assemble the appropriate chronological records and select cases from them in a standardized way. If current encounters are to be sampled, data collectors must wait at the health facility until the necessary number of patients have been diagnosed, treated and interviewed. Details of how to select the sample of encounters within a health facility are given in Annex 1.

Filling in encounter forms

Data are collected on both prescribing encounters and episodes of patient care. Each type of encounter is recorded on a form that lists the data needed to calculate the various indicators. The data on prescribing encounters should preferably be coded and recorded directly on the *prescriber indicator form* (see Annex 2). If drugs are to be recorded by name the *detailed prescribing encounter form* should be used, for coding at a later stage. Written procedures should include instructions on how to handle any missing information in each of the possible fields on the form so that this will be done consistently in the field by different data collectors.

It is a good idea to provide enough space on each form for data collectors to be able to note questions or comments. An example of such an unusual situation might be when tablets have been crushed and mixed together to form a standard combination treatment for a particular illness. Data collectors should be trained to flag particular fields or entire cases in need of review for the attention of study managers.

Observing episodes of patient care

To collect data for the patient care indicators at least 30 encounters should be observed. Data can all be entered on a *patient care form*, and if logistics require, the observation and interview indicators can be recorded for different groups of patients. If data collectors are not sufficiently skilled to evaluate adequacy of patient drug knowledge, it is possible for them to list patient responses on a *patient drug knowledge form* (not included) for later assessment.

Completing a facility summary form

After all the prescribing and patient care encounters from a facility have been recorded, a *facility summary form* should be completed (see Annex 2) that provides the following descriptive and indicator-related information: name of facility and facility identifier; name(s) of persons who collected data and date(s) of the visit; names of the person in

charge and other individuals at the facility who assisted; whether retro- or prospective methods were used; numbers of encounters completed for both prescribing and patient care indicators; any changes in standard procedures, or other relevant information about the facility; presence of essential drugs list or formulary (indicator 11); and the availability of key drugs in stock (indicator 12).

Coding of the indicators

Coding in the field or at the study office

There are two basic strategies for coding the data for prescribing indicators. In one strategy, data collectors assign codes as they record individual cases. Alternatively, they may copy the drug names as they appear in clinic records, leaving the indicators uncoded for specially-trained persons to assign codes later. The choice between the two approaches depends on the level of training of the data collectors. People who are not very familiar with pharmaceuticals may be confused by drug names which look similar, and by different ways of referring to the same product. The possibility of assigning incorrect codes in such situations is greater than if better trained individuals assign all codes. A pilot test during the training process can provide an opportunity to evaluate whether data collectors are sufficiently knowledgeable to code the prescribing indicators reliably by themselves.

Recording drug names and diagnoses also allows for follow-up analyses after the basic indicator results are known. For example, cases of malaria can then be analyzed separately to look for problem-specific treatment patterns, or cases receiving injections can be analyzed for age of the patient and diagnosis. These follow-up analyses can be a starting point to focus attention on important areas for further exploration and intervention.

Review of completed forms

A procedure should be developed to verify each day that the data collected are complete and of good quality. The accuracy of the coding should be validated for a percentage of the forms completed by each data collector or coder. How to code any missing fields which have been highlighted by data collectors can be determined during review by the study managers.

Field supervision

Once data collection is underway, it is important that the coordinator meets regularly with the data collectors and goes out into the field regularly with them to ensure that the agreed procedures are being followed.

CHAPTER 5

ANALYSIS AND REPORTING

This chapter describes how to calculate, analyze and report study results. Such analysis and reporting can take place at the facility, or at a higher administrative level. The use of the different data collection and consolidation forms are described. All the calculations and analyses can easily be done manually, but a computerized spreadsheet can also be used to enter the data, consolidate the results and prepare reports.

Calculating results for each facility

The necessary data on prescribing indicators (1-5) are calculated and summarized on the *prescribing indicator form*, patient care indicators (6-10) on the *patient care form*, and facility indicators (11-12) on the *facility summary form*. Blank examples of all forms are reproduced in Annex 2, and annotated versions are given in the figures below.

Prescribing indicators

Data from one facility should be entered on the *prescribing indicator form*, even if the *detailed prescribing indicator form* was used initially. Details on the calculation of results, as described below, refer to the annotated version of the form presented in Figure 1. The calculations needed to summarize the indicators for each facility can be made directly on the form, or the data can be entered into the computer worksheet.

The date of treatment can be useful to verify that cases were distributed evenly throughout the review period. Age can be analyzed by counting the number of cases in each age group (under fives, and 5 years and above), which allows for a check that patients were collected from both groups.

Figure 1

PRESCRIBING INDICATOR FORM

Location: _____

Investigator:_____ Date: _1-4-1992_

Seq. #	Type (R/P)	Date of Rx	Age (yrs)	# Drugs	#Gen- erics	Antib. (0/1)*	Injec. (0/1)*	# on EDL	Diagnosis (Optional)
1	R	1-4-91	3	1	1	1	1	1	ARI
2		13-4	6m	2	2	0	0	2	Diarrhoea
3		25-4	15	1	1	1	0	1	Diarrhoea
4		7-5	4	0	0	0	0	0	Wound
5		19-5	8	3	2	1	0	2	ARI
6		31-5	2m	2	2	0	0	2	Diarrhoea
7		12-6	18	3	2	1	1	2	Scabies
8		24-6	17	2	2	1	1	2	Headache
9		7-7	2	1	1	0	0	1	Headache
10		19-7	20	4	2	1	0	2	Earpain
11		31-7	1½	2	2	0	0	2	Diarrhoea
12		12-8	8	1	1	1	0	1	Cough
13		24-8	5	3	3	0	0	2	malaria
14		8-9	12	1	1	0	0	1	Scabies
15		20-9	6m	2	2	1	0	2	Yellow urine
16		2-10	45	4	3	1	1	2	Hypertension
17		14-10	20	3	2	0	0	2	Hepatitis
18		26-10	3m	2	2	1	0	2	Cold
19		7-11	25	3	3	0	1	3	malaria
20		19-11	30	1	1	0	0	1	Weakness
21		1-12	10m	3	2	1	0	2	malaria
22		13-12	50	2	2	0	0	2	Headache
23		25-12	2½	2	2	0	0	2	ARI
24		7-1-92	16	3	3	1	1	3	Cough
25		19-1	3	2	2	0	0	2	malaria
26		31-1	7	3	3	1	1	3	Bronchitis
27		12-2	2	2	2	0	0	2	U.T.I.
28		24-2	1	2	2	0	0	2	malaria
29		8-3	2m	2	2	0	0	2	Cough
A 30		20-3	50	4	2	0	1	2	Vaginal Discharge
Total				66 B	57 D	13 F	8 H	55 J	
Average				2,2 C					
Percentage					86 % E of total drugs	43 % G of total cases	27 % I of total cases	83 % K of total drugs	

* 0=No 1=Yes

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1: Average number of drugs per encounter (C)

First count the number of encounters for which data were collected, even if no drugs were given (A). For a basic indicator survey this number will usually be 30. Then add up the total number of drugs prescribed during these encounters (B). Divide the total number of drugs by the number of encounters (A) and express the result with one decimal.

Formula: Average number of drugs $C = B/A$

2: Percentage of drugs prescribed by generic name (E)

Divide the total number of generic drugs prescribed (D) by the total number of drugs prescribed (B), and multiply by 100 to make a percentage (E).

Formula: % Prescribed as generic $E = (D/B) \times 100\%$

3: Percentage of encounters with an antibiotic prescribed (G)

Divide the total number of patients who received one or more antibiotics (F) by the total number of encounters (A) and multiply by 100 to make a percentage.

Formula: % Antibiotics $G = (F/A) \times 100\%$

4: Percentage of encounters with an injection prescribed (I)

Divide the total number of patients who received one or more injections (H) by the total number of encounters (A) and multiply by 100 to make a percentage.

Formula: % Injections $I = (H/A) \times 100\%$

5: Percentage of drugs prescribed from essential drugs list or formulary (K)

Divide the total number of EDL drugs prescribed (J) by the total number of drugs prescribed (B) and multiply by 100 to make a percentage (K).

Formula: % Drugs from essential drugs list $K = (J/B) \times 100\%$

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Figure 2

PATIENT CARE FORM

Location: _____

Investigator: _____ **Date:** 1-4-1992

Seq. #	Patient Identifier (if needed)	Consulting Time (mins)	Dispensing Time (secs)	# Drugs Pre-scribed	# Drugs Dis-pensed	# Ade-quately Labelled	Knows Dosage (0/1)*
1	DRD	5					
2	B	2					
3	RoL	2					
4	DoA	4					
5	AD	1					
6	GT	3					
7	VD	2					
8	BS	6					
9	AC	1					
10	KKK	2					
11	Bm	1					
12	Am	2					
13	FSA		75	2	2	2	1
14	PBY		90	3	2	1	1
15	HvH		15	2	2	2	1
16	Df		18	2	2	2	1
17	mA		25	4	2	2	0
18	GV		45	4	3	2	1
19	mHB		110	1	1	0	0
20	SH		45	2	2	2	1
21	JH		45	2	1	0	1
22	BXD		50	1	1	1	0
23	TS		60	2	2	2	0
24							
25							
26							
27							
28							
29							
30							
Count		12 N	11 Q				10 X
Total		31 O	578 R	25 B₁	20 T	16 V	7 Y
Average		2,6 P	53 S				
Percentage				80 % of pre-scribed	80 % of dis-pensed		70 % of cases asked

* 0=No 1=Yes

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Patient care indicators

Information on these indicators is collected and calculated on the *patient care form*. An annotated version of the form is given in Figure 2.

6: Average consultation time (P)

First count the number of cases observed (N), with a minimum of 10. Add all consulting times (O) and divide by the number of cases (N) to get the average consultation time (P). Express as time in minutes, with one decimal.

Formula: Average consultation time $P = O/N$ min

7: Average dispensing time (S)

First count the number of cases observed (Q). Add the dispensing times (R) and divide by the number of cases (Q); express time (S) in seconds.

Formula: Average dispensing time $S = R/Q$ sec

8: Percentage of drugs actually dispensed (U)

The total number (as B on the previous form) has to be calculated again because the group of patients is different. Add the drugs prescribed for this group (B1). Add up the number of drugs actually dispensed (T). Divide the total number of drugs dispensed (T) by the total number of drugs prescribed (B1) and multiply by 100 to make a percentage (U).

Formula: % Drugs actually dispensed $U = (T/B1) \times 100\%$

9: Percentage of drugs adequately labelled (W)

Add the number of drugs with adequate labels for each patient (V), divide by the total number of drugs dispensed (T) and multiply by 100 to make a percentage (W).

Formula: % Drugs adequately labelled $W = (V/T) \times 100\%$

10: Percentage knowledge of correct dosage (Z)

Divide the total number of patients who can correctly report the dosage for all their drugs (Y) by the number questioned (X) and multiply by 100 to make a percentage (Z).

Formula: % Knowledge of correct dosage $Z = (Y/X) \times 100\%$

Health facility indicators

The *facility summary form* contains information that requires very little calculation. The only calculation necessary is the percentage for the availability of key drugs.

11. Availability of copy of essential drugs list or formulary
This indicator reads either yes or no, for the facility as a whole. No calculation needed.

12. Availability of key drugs
Add the column for the number of key drugs in stock, divide by the total number of key drugs surveyed, and multiply by 100 to get a percentage. Express without decimals.

Formula: (no. drugs in stock / no. drugs surveyed) x 100

Displaying the results

Results need to be displayed for reporting at two levels: at the facility and at the higher administrative level. At the facility level it will usually only be possible to display the results in a simple table. However, at the district or regional level graphic displays should be used wherever possible.

Facility summary table

For displaying the results at the facility it may be useful to prepare a form which compares the results from the facility with those from a previous survey, with summary results for all facilities, or with national standards. The original form is reproduced in Annex 2. Fill in two copies of this form and leave one at the facility. The other form can be used to complete the consolidation form used to collect results for all facilities in the study.

Consolidation table for all facilities

After the data have been collected from each facility, enter the results each day onto a *consolidation form* (see Annex 2). Do this every day, in case a record or form for a facility gets lost. This way the missing information can be more easily traced closer to the time that it was lost. If available, an alternative is to enter the data directly into the computerized version of the form which is included with the computer spreadsheet. If the spreadsheet is used, minimum and maximum values and the standard errors for individual indicators can also be generated.

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Graphic displays of results

When the facility data have been entered into the consolidation table, it is easy to generate bar charts showing the number of facilities at different levels of each indicator and how the facilities vary. These charts are only indicative of how the different facilities compare, because the number of prescriptions studied in each facility (usually 30 in a basic survey) is too low to give a reliable picture of that individual facility. Yet these comparative data are useful for identifying facilities where follow-up activities could be undertaken. Note that it is also possible to highlight contrasts between different types of facilities in these figures, by using different shaded bars. Some examples are given in Annex 3.

Reporting results at the facility

When all data have been collected and the results calculated, a meeting should be held with staff of participating facilities to report the results. If the *prescribing indicator form* was used, results can be reported back to the health workers at the end of the day when data were collected.

Discuss the results in a non-judgmental way. Circulate the result sheet and ask participants to comment. Highlight any positive aspects of the assessment when comparing results with the national norms or previous performance. Ask participants for suggestions as to why there may be differences, or what makes their health facility different. If results are better than the national norms, ask for suggestions as to how the national situation could be improved. Where the results from the facility are worse, ask how the situation at the health facility could be improved. Make sure that all staff members participate in the discussion. Sometimes it is difficult to get junior staff to raise issues in front of superiors. In this case, go round the group asking for one suggestion from each group member. Record any suggestions or decisions on the back of the record sheet and leave the sheet in the facility. When a follow-up visit is made, the record sheet can be used as the basis for discussion.

CAUTIONARY NOTE: Remember that a sample of 30 prescriptions has a significant margin of error as an individual result. To obtain a more reliable result in one facility, a sample of 100 prescriptions should be examined. Examining additional encounters may be a good activity in which to involve facility staff, since self-assessment is a powerful long-term strategy to improve performance.

Reporting at the administrative level

A meeting of key managers and policy-makers in the administrative area where the survey was conducted should be held after all the data have been collected and analyzed. Summary tables and graphics should be prepared, and enough duplicates made to ensure that each participant has a copy. Invite all officials involved in drug use issues. For example, at the district level invite the district medical officer, district pharmacist, senior nurse, health service administrator, tutors of training schools, representatives from mission hospitals or other non-governmental organizations, and representative staff from the facilities surveyed.

Review with the group the purpose of the survey. Present the over-all summary results and compare these with other available results from previous studies in the country or with results from other countries reported in this manual (see Annex 3). Conduct a discussion on the overall pattern of results and reasons for any observed differences.

Circulate the graphics which demonstrate variation between facilities. Point out that the number of cases reviewed is limited, and that the differences may therefore not be as great as they appear. Ask participants to comment on why some facilities perform so differently, and discuss follow-up activities that could be conducted to explore these reasons. Point out that supervisory activities will have the greatest impact on those facilities with the greatest needs, identified by the indicators.

Discuss the possibility of carrying out simple indicator studies when routine supervision is undertaken. If there is interest in this concept, review briefly the procedures for using the indicators for monitoring and lot quality assurance sampling (Annex 4).

Record the issues reviewed during the discussion and whatever decisions are made. Discuss how the group could initiate a brainstorming session to identify what the next follow-up activities should be in light of this information.

Results of earlier drug use studies

Several drug use studies with these and other indicators have been performed in different countries. Some of the initial surveys only studied a small number of facilities with a limited number of indicators. The results of most of the earlier studies are summarized in Annex 3.

By examining these data it is possible to get an impression of the range of experiences in different countries. Excluding two countries with high figures, the average number of drugs ranges from 1.3 to 2.2. The Yemen study attempted to estimate the "correct" value

for that country on the basis of morbidity patterns and therapeutic guidelines. The figure for average number of drugs was 1.4. For antibiotics, apart from two values, all are between 29% and 43%. The Yemen study suggested a theoretical need of 22.7%.

What is striking about injectables is the considerable variation between countries from 0.2% to 48%. The indicator for percentage injections decreased in the Nigeria and Indonesia field tests when data were collected prospectively rather than retrospectively. This may indicate that health workers know that they should not give as many injections as they do. For Yemen the ideal figure was estimated to be 17.2%.

The figures for percentage of drugs prescribed by generic name are encouraging, in that they show that it is possible to reach high levels of generic prescribing. Levels as high as 82% or 94% offer hope to countries with lower levels. In most countries, consultation times range between 2.3 and 3.5 minutes, which is a short time to provide an adequate clinical interaction. Drug availability varies between countries, but in all studies, significant stock-outs existed.

Two studies have tried to quantify the effect of interventions. In Yemen three indicators were used for a comparison between a project area and a control area in which no activities had taken place. The number of drugs per encounter in the project area was 1.5 (compared to 2.4); the percentage of antibiotics 46% rather than 67%, and the number of injections 22% rather than 45%[4]. In Uganda the impact of training on drug use patterns was quantified. The study showed a decline in the use of injections (50.1% to 41.3%), an improvement in ORS use in diarrhoea (52.4% to 89.1%) and a reduction in antidiarrhoeal drug use (60.4% to 38.5%)[5].

By comparing indicator values with results from other countries and to previous local studies it is possible to measure the impact of an intervention, and better identify areas of concern on which further action should be concentrated.

CHAPTER 6

FOLLOW UP QUESTIONS

General directions

The core drug use indicators represent first-level measures of prescribing and patient care performance in health facilities. They can be measured rapidly by personnel with a minimum of specialized training in pharmaceuticals, and without reference to particular health problems. They are intended for use by district health staff or other personnel interested in improving the quality of care. The results of a drug use indicator study should trigger action to improve aspects of performance identified as major problems.

Because the core drug use indicators are general, and do not refer to particular health problems, they do not lead directly to particular focused interventions. For example, if it is found during an indicators survey that there is a high rate of injection use, it is not necessarily clear what is responsible for causing this, nor what the best strategy for reducing their use might be. Understanding the dynamics of behaviour and designing interventions that respond to underlying factors requires more depth of understanding than a basic indicators study is able to provide.

For this reason, measuring the core drug use indicators can be seen only as a first step in a process of investigation. It can serve to focus attention on one or two aspects of performance, narrowing down the area of subsequent inquiry.

What kinds of follow-up activities are appropriate after an indicators study? There are a few general directions that these activities are likely to take, and some specific questions that might be addressed for each of the individual indicators. Some possiblities are: evaluation of specific treatment practices; examination of factors causing the variations between facilities; and study of beliefs and motivations by means of qualitative techniques.

Evaluation of specific treatment practices

The measures of prescribing and patient care behaviour captured by the core drug use indicators represent averages across a range of health problems and patient types. Because of the sampling methods used, these aggregate measures represent reasonable summaries independent of actual disease patterns. However, without further investigation on individual health problems and how they are treated, it is difficult to know how to address identified problems.

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Follow-up studies that focus on particular health problems can take two general forms. If prescribing data have been collected on the *detailed prescribing indicator form*, and health problems have been recorded, it is possible to identify a subset of patients with particular diagnoses or reported symptoms and to conduct further investigations for this subgroup. This can be done by analyzing the basic indicators for patients with specific diseases (e.g. malaria, respiratory tract infections, diarrhoea). Although the sampling model will not allow strong statistical statements to be made about such subgroups, many of the conclusions about the treatment of particular health problems will be revealing and will point to areas for further work. For example, if 90% of patients with malaria receive an injection when this figure should be less than 10%, there is clearly a problem.

Alternatively, if data on health problems were not collected with the original sample, it is possible to return to health facilities to collect more data focused on cases with specific diagnoses. It might be possible to combine such return visits with interviews of health staff regarding particular practices and a feedback session on the overall survey.

Generally, the health problems studied at this second stage are those that have particular clinical or economic importance in the local area. For example, it may make sense in many countries to focus on malaria, acute respiratory infections or diarrhoea, since they are major sources of morbidity and mortality. Another approach might be to focus on particular sets of symptoms, to see how they are ultimately diagnosed and treated, including such complaints as fever, cough, or non-specific body pain.

Examination of factors causing variation between facilities

Another general area of inquiry is to examine the sources of variation in performance for one or more of the core indicators. Here the goal is to focus on identifiable factors which predict both appropriate and unsatisfactory performance. Rather than attending to sample-wide summaries, such a focus involves looking at the distribution of behaviour in the group of facilities studied. Do all facilities perform equally poorly or equally well? Are there clusters of facilities that stand out in either a positive or negative direction? If so, these facilities can be the focus of additional study. By understanding the reasons why some facilities are better or worse than average, suggestions for improvement may become apparent.

Bar charts similar to the ones given in Annex 3 can be used to identify facilities substantially different from the average. Initially, it may make sense to see if the subgroup of good or bad performers share certain characteristics. Factors such as staffing pattern (presence or absence of a physician), geographic location, socioeconomic levels of the surrounding communities, or features of medical administration, may stand out as important. If not, a series of interviews with key staff in these facilities, that focus on the particular behaviour in question, may begin to tease out some important factors that are shaping performance.

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Study of beliefs and motivations by means of qualitative techniques

Informal interviews represent only one of a range of qualitative methods that might be used to examine in more depth some of the beliefs and motivations which underlie drug use behavior. Other qualitative approaches would include structured but more open-ended observation of patient care encounters in specific facilities; open-ended, in-depth interviews with medical staff or patients focusing on particular topics; or a systematic series of focus groups with small numbers of health providers or patients on subjects where group interaction might be useful. Such qualitative techniques are described elsewhere.

Follow-up questions for specific indicators

Although the indicators as a whole provide a useful summary of pharmaceutical care in public facilities, each of the indicators separately addresses a specific aspect of behaviour. A level of performance on any of the indicators that would be considered unacceptable should provoke specific kinds of follow-up activities. Examples of some of these activities are described below. The questions listed could be used in individual or group interviews, or in focus group discussions. A series of structured observations of actual practices may also be very useful.

1. Average number of drugs per encounter

High number of drugs per encounter
Are there shortages of therapeutically correct drugs? Do prescribers lack therapeutic training or appropriate diagnostic equipment? How secure are prescribers in their ability to diagnose and treat the common illnesses? How strongly do prescribers feel that patient demand influences their practice, and do observations of clinical encounters support this? Are there financial incentives to encourage polypharmacy?

Low number of drugs per encounter
Are there absolute constraints in the drug supply system such that very few drugs tend to be available? Are there administrative regulations that limit the number of drugs that can be prescribed? Do prescribers have appropriate training in therapeutics? Is there significant drug "leakage" from the system?

Economic factors
Is there a drug revolving fund in place that increases pressure on prescribing? Do prescribers profit from the sale of dispensed drugs? What is the level of user fees, and are fees charged per visit or per drug?

Community characteristics

What is the age distribution of the patient population? Do differences in case mix explain some of the observed differences in prescribing, for example, a high proportion of older people with multiple diseases who need more drugs in some facilities?

2. Percentage of drugs prescribed by generic name

Supply factors

Are predominantly generic or branded forms of drugs available in health facilities? How closely have brand names of products been chosen to model their generic name? Are drugs supplied in bulk containers and labelled at the facility, and how are the names written on the labels? Are branded products being prescribed which are not available in health facilities?

Prescriber factors

Do prescribers know the correct generic names for most drugs? How often are prescribers visited by pharmaceutical representatives, and what kind of promotional material is left for them to use? Does the training of the prescribers affect their willingness to prescribe generically?

Health problem factors

Which classes of drugs seem to be particularly problematic? Are there certain common health problems for which a generic form of treatment is not supplied in the system?

3. Percentage of encounters with an antibiotic prescribed

Specifics of antibiotic prescribing

What types of antibiotics and which modes of delivery (injections, tablets, syrups) are most commonly prescribed? What is the relative use of narrow vs. broad spectrum antibiotics? What proportion of antibiotic prescribing is represented by dermatological products, by ophthalmologic products? How much do antibiotics cost, as a percentage of all prescribing or for particularly expensive forms of antibiotic?

Possible influences on antibiotic prescribing

What are the cultural beliefs in the community about antibiotics, and are patient expectations of receiving certain types of antibiotic very high? How strongly are particular antibiotics marketed? Are some antibiotics distributed in the system more than would be indicated by local morbidity patterns? How effective is the drug quality assurance system, and do prescribers have faith that the drugs they are prescribing contain the appropriate therapeutic amounts? Are laboratory facilities necessary for differential diagnosis available and used by prescribers?

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Impact of antibiotic use
What are the local resistance patterns to commonly-used antibiotics? How often are particular organisms treated with drugs to which they are likely to be resistant, for example, in specific sexually-transmitted diseases?

4. Percentage injections

Specifics of injection use
What are the specific health problems for which injections are given? Are injections given more often to adults or children treated for these conditions? What is the availability of syrups and mixtures as alternative modes of therapy for small children?

Possible influences on injection use
What are the beliefs and attitudes of patients and health providers about the relative efficacy of injections versus oral medications? Do prescribers report patient demand as an important factor in determining injection use, and do observations of clinical encounters support this? What is the availability of injections outside the public health facility, and is competition with the private injectionists for patient loyalty an important factor? Do patients bring their own needles or syringes? Is there a financial incentive for a health worker to give an injected rather than an oral form of medication?

Impact of overuse of injections
Are appropriate sterilizing units available in health facilities, and are they being used appropriately? What is the local prevalence of HIV and hepatitis-B infections, and is there evidence that lack of sterile technique is a possible source of these blood-borne infections? What are the cost implications of injection use, comparing oral and injected alternatives for the same health problem?

5. Percentage of drugs prescribed from essential drugs list or formulary

Specifics of prescribing
What are the most common drugs being prescribed that are not on the list or formulary? Which health problems are these drugs intended to treat? Are the drugs being prescribed from outside the list generic products or branded products? What is the value of non-EDL drugs compared to EDL drugs?

Supply factors
Is there an adequate supply of the drugs on the essential drugs list or formulary? Who makes decisions about which drugs are ordered for the health facility? Are the forms used for drug orders based on the essential drugs list or formulary, or are they developed from lists of previously-consumed drugs?

Characteristics of the list

How does the essential drugs list or formulary compare to other standard lists of this type, in terms of organization and number of products listed? Do prescribers know about the existence of the list, and which drugs are contained on the list? What efforts have been made to disseminate appropriate unbiased drug information linked to the list or formulary? What is the attitude of prescribers towards the essential drugs list or formulary and its role in the health system?

6. Average consultation time

Health facility aspects

What is the physical organization of the clinic, and is there appropriate allowance for privacy and confidentiality? What is the average workload of health staff, and does the volume of clinic visits allow time for appropriate interactions with patients? What is the volume of patient attendances at different times, during the course of the work day and by week? Could chronic disease patients be scheduled at times when the workload is less?

Prescriber factors

Do the training programmes for various categories of health workers include training in effective communication? Do health workers see communication as an important aspect of their work role? Are there important socioeconomic, ethnic, or status differences between health workers and their patients?

Characteristics of patient-provider interactions

What actually takes place during the clinical encounter between a patient and a health worker? What is the quality of this interaction in terms of effective communication about illness, explanation about illnesses and drugs, and nonverbal expressions of empathy? Are patients and health workers satisfied with what takes place during clinical encounters? Do their expectations about what should take place differ, for example, do patients expect to be more thoroughly examined than providers feel is necessary?

7. Average dispensing time

Health facility aspects

What is the layout of the dispensary, and does it allow for private pharmacist-patient interactions? What is the workload of dispensers, and do they have sufficient time to explain medications to patients? Are dispensing supplies available? What impact does drug supply have on the dispensing process, in terms of the availability of products, how efficiently they are stored, and whether appropriate hygienic techniques are followed? How is decision-making organized within the dispensary, in regard to product substitution, the number of days' supply dispensed, and so forth? What is the impact of patient fees for drugs on the type and quantity of drugs that are dispensed?

Dispenser's background
What is the average level of training of personnel working in the dispensary? Have they been appropriately trained in educating patients about drugs? What is the understanding of dispensary personnel about their responsibilities, and do they feel it includes patient education? Do dispensers ask patients to repeat how they will take the drugs?

Characteristics of patient-dispenser interactions
What is the quality of the interaction between dispensers and patients? Is there communication about the purpose for individual drugs, how they should be taken, and possible side effects? Are dispensers and patients satisfied with their interaction? What is the patient's understanding of the dispenser's role? Do patients expect to learn more from dispensers about drugs?

8. Percentage of drugs actually dispensed

Differences between prescribed and dispensed drugs
Are there certain types of drugs that are routinely prescribed, yet not dispensed? Is the problem more common for specific therapeutic classes or drugs to treat particular illnesses? Are drugs not being dispensed even when they are available in health facility stores? Are drugs which are not dispensed available in the local community? What are the reasons why pharmacists did not dispense the drugs as they were prescribed? Are there rules laid down for what they will dispense?

Patient attitudes
Do patients plan to purchase the drugs that were not dispensed at the health facility? If they do not plan to purchase them, is it because they cannot afford to pay for them, or because they do not think the drugs are important? If they plan to purchase only a proportion of the drugs prescribed, how do they prioritize? What do patients understand are the reasons for products not being given in the amounts they were prescribed, or are they even aware that this was the case?

9. Percentage of drugs adequately labelled

Specify inadequate labelling
What element of appropriate labelling is missing: the name of the patient, the correct generic name of the drug, or the drug strength? Is the information written legibly? Is information on how the drug is to be taken also written on the label, using terminology that patients are likely to understand? Is the information on dosage correct according to the standard for this drug?

Reasons for inadequate labelling
Are dispensers adequately trained in how drugs are to be packaged and labelled? Are

there adequate packaging materials available at health facilities? Do dispensers have time, given their typical workload, to package and label drugs appropriately? Are procedures adequately supervised by pharmacy and medical personnel?

10. Patients' knowledge of correct dosage

Patient-provider communciation

Is the physical layout of the clinic (examination and dispensing areas) conducive to communication about health problems and drugs? How do different health workers (physicians, nurses, pharmacy attendants) describe their role in communicating about drugs, and how often do they perform the functions they describe? What is the typical content of communication about pharmaceuticals: what drugs do, how they should be taken, possible side effects and precautions, relative importance of different products, and so forth? Is information about drugs offered voluntarily by health workers, or do they depend on patients to ask specific questions? Do patients ask questions?

Patient understanding and compliance

What do patients actually understand about the drugs they have received: what drugs do, how they should be taken, side effects, and so forth? How does patient understanding compare with the information communicated during clinical and dispensing encounters? What are the sources of misunderstanding about drugs: lack of correct information, cultural or language differences between patients and providers, lack of patient interest, or other factors? Do patients leaving health facilities intend to comply with recommendations about drugs? What are the reasons for expected or actual noncompliance with recommended drug therapies?

11. Availability of copy of essential drugs list or formulary

Characteristics of the list or formulary

Which products are included on the drugs list or formulary? How does the list compare with WHO recommendations? Does the same list apply to different levels of care, or are only subsets of drugs recommended at lower levels? Does the list or formulary contain descriptive information about drugs or therapeutic guidelines? What efforts have been made to disseminate the essential drugs list or formulary to individual prescribers? Is the formulary or EDL clean with unbroken binding, or dirty indicating that it has been used?

Prescriber attitudes

How do prescribers describe the purpose of the essential drugs list? Are they generally aware of which drugs are on the list? Do health personnel responsible for drug procurement at individual facilities consult the list when making purchase decisions? Do prescribers recommend similar types of therapy in both their public sector and private sector practices? Do prescribers think they could affect the next list?

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12. Availability of key drugs

Supply system
Are there particular classes of drugs or particular dose forms (for example, paediatric syrups) which are more likely to be out of stock? Does the incidence of the stock-outs tend to vary seasonally with the drug procurement cycle? Once products go out of stock, how long do they tend to remain out of stock? What is the system for informing prescribers about pharmacy stock-outs, and are there procedures for therapeutic substitution by pharmacists or dispensers?

Focus on key drugs
Are there particular health problems for which drugs tend to go out of stock on a regular basis, for example, malaria or tuberculosis? Are there therapeutic alternatives in stock for the drugs which are found to be out of stock? Do prescribers respond to the absence of a drug by continuing to prescribe it and expecting patients to purchase the product in the private sector, or by switching to a therapeutic alternative?

ANNEXES

ANNEX 1

SAMPLING PROCEDURES

To estimate the drug use indicators accurately, it is important to follow specific procedures for drawing samples of health facilities and patient encounters. These procedures will vary depending on the objectives of the study and the availability of data. The recommended process for sampling facilities and encounters in the basic drug use survey is described below.

Drawing a sample of health facilities

In order to draw conclusions about drug use practices in an area with many health facilities, it is necessary to select a representative sample of these facilities (usually 20). Drawing this sample in a haphazard way can bias the results. This section provides methods for drawing a systematic random sample of facilities in a way that will ensure maximum confidence in the estimates. The following steps should be followed.

Step 1: Identify the sample area and type of facilities for the study

First identify the geographic areas in which the survey is to be done. If there are to be study and control areas, develop and record clear criteria for including facilities in either group.

Choose the types of health facilities that are to be included in the study, for example, hospitals, health centers or dispensaries. Make a list of the names and locations of all these facilities; the sample will be taken from this list.

Step 2 (OPTIONAL): Organize the areas and facilities into groups

The health facilities to be included in the study can often be organized into groups. Sometimes the facilities are naturally grouped by geographic location, perhaps by district or by urban-rural location. Another natural grouping factor might be level of service, for example, multi-physician polyclinics versus dispensaries with only paramedical staff. One way of increasing the precision of indicator estimates is to ensure that these groups are appropriately represented when the sample is drawn, rather than running the risk that one group is over- or under-represented.

The easiest way to ensure an appropriate balance between these groups is to organize the list of facility names created in the previous step into groups before taking the sample. For example, put urban facilities at the top of the list, followed by the rural facilities. It is also possible to organize the list by more than one characteristic. For example, if three separate administrative districts are to be studied, group the facilities first by district. Within each district, list the urban facilities, then the rural ones. This grouping and pre-sorting will help to ensure that the sampling procedure will allocate an appropriate number of health facilities of each type.

Step 3: Select facilities by systematic random sampling

To draw a systematic sample, begin by numbering all facilities on the list. Then calculate a *sampling interval* by dividing the total number of facilities on the list by the number of facilities to be included in the sample (usually 20). For example, if there are 53 health centers in the study area and 20 are to be visited, the sampling interval is 2.65.

Now you have to choose a point on the sampling list from where to start your sampling. Choose the first facility in the sample as follows. Round the sampling interval up to the highest full number (in this case 3). Choose a random number between 1 and this number (in this case 1, 2 or 3). This can be done by using a table of random numbers, the latest figure of the number on a banknote, or simply by dice or paper lots. There are also electronic calculators that can select random numbers.

To identify the next facility to include in the sample, add the sampling interval to the previous result, and round up to find the facility number to include. In the example, if the first sample was facility 2 from the sampling list, the next three facilities selected would be number 5 (2 + 2.65 = 4.65, rounded up to 5), number 8 (4.65 + 2.65 = 7.30, rounded up to 8) and number 10 (7.30 + 2.65 = 9.95, rounded up to 10). Continue with this process until all facilities have been selected.

When the objective of the study is to compare indicators for two groups, the list should be divided and each subgroup should be treated as a separate list, with a separate equal-sized systematic sample drawn for each subgroup. Drawing an equal number of facilities in each subgroup ensures that the comparison of the subgroups will be as accurate as possible.

Step 4: Keep a record of the sampling frame

The list with the groupings from which the sample was selected is known as the *sampling frame*. This is the record of the sampling process, and can also be used to draw additional samples during future activities. If separate samples were drawn from this list to compare two groups, the sampling interval for each group should be recorded on the list.

Drawing a retrospective sample of patient encounters

The basic indicator study calls for a sample of 30 prescribing encounters per health facility, or 100 encounters if prescribing practices in individual facilities are to be compared. The following section describes how to draw these encounters from historical patient records.

Step 1: Confirm the availability and accessibility of medical records

Prescribing records can be organized in many different ways. Before actually implementing a retrospective sample it is necessary to become familiar with the organization of medical records in a few facilities, to ensure that it is possible to extract data from them in an efficient and reliable way. If the data systems in the intended sample of facilities are all similar, the accessibility of data needs to be tested at only a few sites. If there are substantial differences between facilities (based on size, urban-rural location, level of staffing, etc) the record systems and procedures should be tested in a few sites in each subgroup to be certain that the proposed sampling methods will work equally well in all types of facility.

Possible sources of retrospective prescribing encounter data include clinic registers, health worker treatment logbooks, patient- or family-files, or some type of pharmacy record (such as retained prescription forms). Particular questions to be answered at this preparatory stage are:

• What is the source of the chronological listing of patient encounters from which the sample will be drawn?

• What is the source of data on patients, providers, health problems, and drug treatments?

• How are the records stored, and are they available for the intended study period?

• If two or more record sources must be linked to collect information from one encounter (e.g. patient records and prescriptions kept in the pharmacy) what is the success rate of making this linkage?

If it is found during these preliminary tests that historical data sources are more incomplete than expected, or that the necessary medical record data are too difficult or time-consuming to extract, it may be preferable to switch to prospective sampling. However, if the record sources appear adequate, the process for sampling historical encounters, as described below, can be used.

Step 2: Locate encounters to be included in the sampling frame

Locate the chronological listings of all patient visits made during the selected study period, e.g. the twelve-month period prior to the survey date. These listings will constitute the sampling frame of prescribing encounters. If not all records for this period can be found, the list should cover as much of the study period as possible.

Potential biases to be avoided include: excluding or under-representing one or more providers in a facility because of missing records or misplaced log books; under- or over-representing some types of disease and treatments due to missing data from certain seasons during the study period; or excluding encounter records of a certain type, for example, prescriptions filled outside the health facility.

Put the available listings in a systematic order, by date if they are assembled that way, or perhaps by provider, if individual patient logs are kept. Record the dates for the study period covered by the available listings on the *facility summary form* for each facility.

Step 3: Select encounters at regular intervals over the study period

If the patient enounter listings are ordered by date, it is easy to spread the sample encounters evenly over the period represented. The total number of encounters to be sampled in each facility has already been determined by the purposes of the study (30 for a cross-sectional study, 100 to compare facilities). In a process similar to the one used for selecting facilities, dividing the number of days represented in the sample frame by the number of encounters to be selected gives a sampling interval.

For example, if there are 365 days (one year) in the chronological sample frame and 30 encounters to be drawn per facility, the sampling interval is 12.2 calendar days (about one encounter every 12 days). Start the sampling process at the first day represented in the chronological sample frame. Select an encounter from the listing for this day (procedure described below). Subsequent encounters should be selected by skipping the appropriate number of days indicated by the sampling interval. For example, when the sampling interval is 12.2 the second case is selected from the 14th day of the listing (1 + 12.2 = 13.2, rounded up to 14), the third from the 26th day (13.2 + 12.2 = 25.4, rounded up to 26), and so forth.

From each selected day a single encounter should be picked at random by multiplying the total number of encounters listed for the day by a random number between 0.0 and 1.0, and rounding upwards. If no source of random numbers is readily available, follow a procedure to spread the encounters selected over different times of the clinic day. For example, for the first selected day pick the encounter from the beginning of the patients listed for that day, for the second selected day from the middle, and so on.

An alternative method can be used when the total number of encounters over the study period is known or can easily be estimated. In that case the logbook can be used as a sampling list. Divide the total number of encounters in the study period by the desired size of the sample to obtain the sampling interval. For example, if about 5000 encounters were recorded in the study period and a sample of 100 is needed, the sampling interval would be 5000 / 100 = 50. This implies that every 50th encounter from the book would be selected.

These sampling procedures control for seasonal effects as well as for different times of the day. However, any reasonable alternative procedure for accomplishing the same distribution of cases is acceptable, provided it is clearly specified and followed in a similar way by all data collectors.

Step 4 (OPTIONAL): Select alternate encounters and link to other data

Sometimes not all the required data will be contained in the chronological listings from which a retrospective sample is drawn. Another type of record may need to be linked to identify the drugs prescribed for the encounter selected, e.g. medical records or pharmacy prescribing slips. This linkage can usually be made on the basis of patient name or identification number, and date. In such situations, where 100% successful linkage may not be possible, it is advisable to select an alternate encounter from the day in question to include in the sample when the primary encounter is not found. This alternate encounter should be specified, e.g. as the next case recorded in the treatment log.

It is usually more efficient to make a complete listing of the encounters to be included in the sample before trying to link to the second data source. When the actual prescribing information is recorded, an alternative encounter is only included in the sample if the primary encounter for that day cannot be found.

Prospective methods for sampling encounters

There are a number of situations where prospective sampling is needed to measure the drug use indicators. Historical drug prescribing data may not exist in health facilities, or the quality and accessibility of the data might be low. To learn about prescribing in such situations, it is preferable to record data for prospective cases as they present for treatment. The following section describes how to implement prospective sampling in an efficient and standardized way.

Step 1: Plan the logistics of obtaining the necessary information

In order to plan how data on prescribing encounters are to be collected, it is necessary to have a basic understanding of the daily procedures in the selected facility. The goal at this stage is to design the most practical prospective system for collecting encounter data. Particular questions that need to be answered are:

- What is the easiest way to identify patients who qualify for the study? Is it easiest to interview patients as they arrive? Is it less disruptive or more efficient to wait until they emerge from the treatment room, or even until they leave the health facility?

- What is the most efficient way to find out the type and quantity of drugs prescribed? Sometimes written information on drugs and quantities to be dispensed is carried by the patient from the treatment room to the dispensary. However, in some settings, prescribed drugs are dispensed in standard quantities by dispensary personnel; sometimes even the decision on which drugs to dispense for certain problems is made in advance, and dispensary attendants distribute a standard package of drugs for a given diagnosis. In such cases, data on which drugs and how much of each drug a patient will receive are not available until after the pharmacy visit has ended.

- If patient treatment cards or dispensed drugs are to be examined, where is the least disruptive location to intercept patients? Often the presence of outsiders collecting information in a clinic may not only interfere with patient flow, but can also make health workers very sensitive to their own behaviour. To reduce disruption, it helps to locate an area separate from the rest of the clinic activities in which to interview already treated patients.

- How long will it take to collect the desired number of cases? Are there certain facilities where data collection will need to be organized in a different way? Is the sample size feasible within existing financial and time constraints? If not, can sample size or study objectives be adjusted so that the study is feasible?

Step 2: Decide who will collect the data

There are two basic options for collecting prescribing data in a prospective study, which can be used alone or in combination. Specially trained data collectors may visit each site and remain there to record data on the planned number of patient encounters as they present for care. Alternatively, prescribers, dispensers or other staff already present at each site are trained to record the data on prescribing encounters and are provided with clear guidelines about which cases and how many cases are to be included in the sample.

The decision about the balance between these two methods of data collection involves a number of trade-offs. There is a cost involved in sending staff to each site to collect data, especially if the frequency of patient visits is low and the number of cases to be sampled is relatively high. If it will only take one or two days to collect all necessary data, or if transport and lodging costs are not excessive, using special data collectors is likely to result in more reliable data.

On the other hand, having facility staff collect the data offers the long-term prospect of actively involving them in quality improvement. Becoming more aware of their own prescribing practices can be one vehicle for improving drug use. However, having to collect and record prescribing data adds one more task to the duties of health staff, and it may be difficult to implement such a process in a reliable way.

There is potential bias in both methods. Staff may react to the presence of outsiders by altering their practices to conform more with a perceived norm. However, the danger of this bias may be even greater if staff at the facility collect data about their own behaviour.

If the goal is to establish a regular monitoring system, the best option may be to implement a system in which data are recorded and reported by facility staff with some mechanism for establishing their validity, perhaps through random site visits by supervisory staff.

For a study in which data need to be collected for a number of days, one possibility is for data collectors to record cases for one or two days, while training local staff in the use of *prescribing indicator forms*. Forms for the remaining cases can then be left at the facility for local staff to complete and return to the study office. Results for the cases collected by data collectors can then be compared with results from the forms completed after they left, to check for gross differences in key indicators that may be subject to reporting bias, e.g. the percent of patients receiving antibiotics or injections.

Step 3: Design the data collection process

Once a decision has been made about who will collect prescribing data, the process they will use to record the data needs to be clearly specified in order to ensure that data collected in different facilities are comparable. This data collection plan should be based on a pilot test of the logistics of collecting data at a number of sample facilities.

If trained data collectors are used, the procedures to be followed can be taught during pre-study training. The data collection plan should specify: where data collectors should position themselves in order to disrupt the process of clinical care and dispensing as little as possible; how to identify the drugs prescribed (pharmacy record, observation of actual drugs received, etc.); and what to do when the number of patients is less than required.

If local staff are to record encounters prospectively, or if a combination of special data collectors and local staff is to be used, the data collection plan should describe:
who should be responsible for recording the data; how they should determine whether or not a given patient is to be included in the sample, e.g. spreading cases over time; and the size of the sample.

Step 4: Select patient encounters

The selection of patient encounters is somewhat different for the groups of core indicators, and depends also on the lay out and procedures of the health facility. For example, the prescribing information (indicators 1-5) could be collected for 30 consecutive encounters if the data collector sits with the prescriber, or just outside the treatment room. In this case it seems advisable to take the 30 encounters somewhere in the middle of the clinic day. Information on consultation time (indicator 6) can then also be clocked. Preferably, patient encounters should be spread randomly over the day, but this may not always be practical. If more prescribers are working simultanously, a reasonable number of encouters should be taken from each.

Information on the other patient care indicators (7-10) is to be collected somewhere in or around the dispensing area or pharmacy. Dispensing time can easily be measured for a number of consecutive patients. The time needed to collect the information on the other three indicators will determine whether consecutive cases can be recorded or whether it will be necessary to skip patients who have passed through the system in the meantime.

Information on indicators 11 and 12 is facility specific and does not need prospective sampling.

ANNEX 2

DATA COLLECTION FORMS

Form 1: Prescribing indicator form

Form 2: Detailed indicators encounter form

Form 3: Patient care form

Form 4: Facility summary form

Form 5: Facility indicator reporting form

Form 6: Drug use indicators consolidation form

PRESCRIBING INDICATOR FORM

Location: _____

Investigator:_____ Date: _____

Seq. #	Type (R/P)	Date of Rx	Age (yrs)	# Drugs	#Gen-erics	Antib. (0/1)*	Injec. (0/1)*	# on EDL	Diagnosis (Optional)
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
22									
23									
24									
25									
26									
27									
28									
29									
30									
Total									
Average									
Percentage					% of total drugs	% of total cases	% of total cases	% of total drugs	

* 0=No 1=Yes

DETAILED INDICATORS ENCOUNTER FORM

Location: _____

Investigator: _____   Date: _____

ID#	Date	Name	Age	Sex	Prescriber

Health Problems	Health Problem Description		Code	
	1.			
	2.			
	3.			

Drugs	Name and Strength		Code	Quantity
	1.			
	2.			
	3.			
	4.			
	5.			
	6.			
	7.			
	8.			
	9.			
	10.			

ID#	Date	Name	Age	Sex	Prescriber

Health Problems	Health Problem Description		Code	
	1.			
	2.			
	3.			

Drugs	Name and Strength		Code	Quantity
	1.			
	2.			
	3.			
	4.			
	5.			
	6.			
	7.			
	8.			
	9.			
	10.			

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PATIENT CARE FORM

Location: _____

Investigator: _____ **Date:** _____

Seq. #	Patient Identifier (if needed)	Consulting Time (mins)	Dispensing Time (secs)	# Drugs Pre- scribed	# Drugs Dis- pensed	# Ade- quately Labelled	Knows Dosage (0/1)*
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							
Count							
Total							
Average							
Percentage					% of pre- scribed	% of dis- pensed	% of cases asked

* 0=No 1=Yes

FACILITY SUMMARY FORM

Location: _____

Investigator: _____ Date: _____

Contacts: _____

Problems or _____
Comments: _____
_____
_____
_____

Cases: Retrospective _____ covering dates _____ to _____
Prospective _____ covering dates _____ to _____
Patient Care _____ covering dates _____ to _____

Essential Drug List/Formulary available at facility? (0/1) _____

Key Drugs in Stock to Treat Important Conditions   In Stock (0/1)

_____   _____ % in stock
_____   _____ this facility
_____   _____
_____   _____ [_____ %]
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____
_____   _____

FACILITY INDICATOR REPORTING FORM

Location: _____

Investigator: _____   **Date:** _____

_____

		This Facility	National Standard
Number of Cases	Prescribing		
	Patient Care		
Average number of drugs prescribed			
Percentage of drugs prescribed by generic names		%	%
Percentage of encounters with an antibiotic prescribed		%	%
Percentage of encounters with an injection prescribed		%	%
Percentage of drugs prescribed on Essential Drug List		%	%
Average consultation time		mins	mins
Average dispensing time		secs	secs
Percentage of drugs actually dispensed		%	%
Percentage of drugs adequately labelled		%	%
Percent correct patient knowledge of dosage		%	%
Availability of Essential Drugs List or formulary		Yes / No	%
Percentage availability of key indicator drugs		%	%

COMMENTS:

SIGNATURES:

DRUG USE INDICATORS CONSOLIDATION FORM

Location: _____   Date: _____

Date	Facility	Avg. drugs prescribed	Percent generics	Percent antibiotics	Percent injections	Percent on EDL	Consult time	Dispense time	% Drugs Dispensed	% Adequate knowledge	% Drugs in stock	Impartial information
Mean												
Maximum												
Minimum												

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ANNEX 3

EXAMPLES OF EARLIER STUDIES

| Country	YEM	UGA	SUD	MAL	IND	BAN	ZIM	TAN	NIG	NEP	ECU
	(1)	(2)	(3)	(4)	(5)	(5)	(6)	(7)	(8)	(9)	(10)
Date	3/88	9/90	5/91	6/91	7/91	8/91	7/91	2/92	2/92	5/92	10/92
No. of facilities	19	42	37	72	20	20	56	20	20	20	19
Indicator											
No. of drugs per prescription	1.5	1.9	1.4	1.8	3.3	1.4	1.3	2.2	3.8	2.1	1.3
% Antibiotics	46%	56%	63%	34%	43%	31%	29%	39%	48%	43%	27%
% Injectables	25%	48%	36%	19%	17%	0.2%	11%	29%	37%	5%	17%
% Generics			63%		59%		94%	82%	58%	44%	37%
% EDL drugs								88%		86%	
Consultatation time (min)				2.3	3			3.0	6.3	3.5	
Dispensing time (sec)								77.8	12.5	86.1	
% Knowledge of dosage				27%	82%	63%		75%	81%	56%	
% Drugs dispensed									70%	83%	
% Drugs in stock				67%				72%	62%	90%	38%
% Impartial information										40%	

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(2) Christensen RF. A strategy for the improvement of prescribing and drug use in rural health facilities in Uganda. Uganda Essential Drugs Management Programme; 2 September - 11 October 1990.

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(9) Kafle KK and members of INRUD Nepal Core Group. INRUD drug use indicators in Nepal: practice patterns in health posts in four districts. INRUD News 1992; 3(1): 15.

(10) Sallet JP, Van Ommen AM. Ecuador: field test of the pharmaceutical management indicators matrix. Work carried out under the USAID/LAC Health and Sustainability Project. Draft report October 1992.

Examples of bar charts showing facilities by indicator value
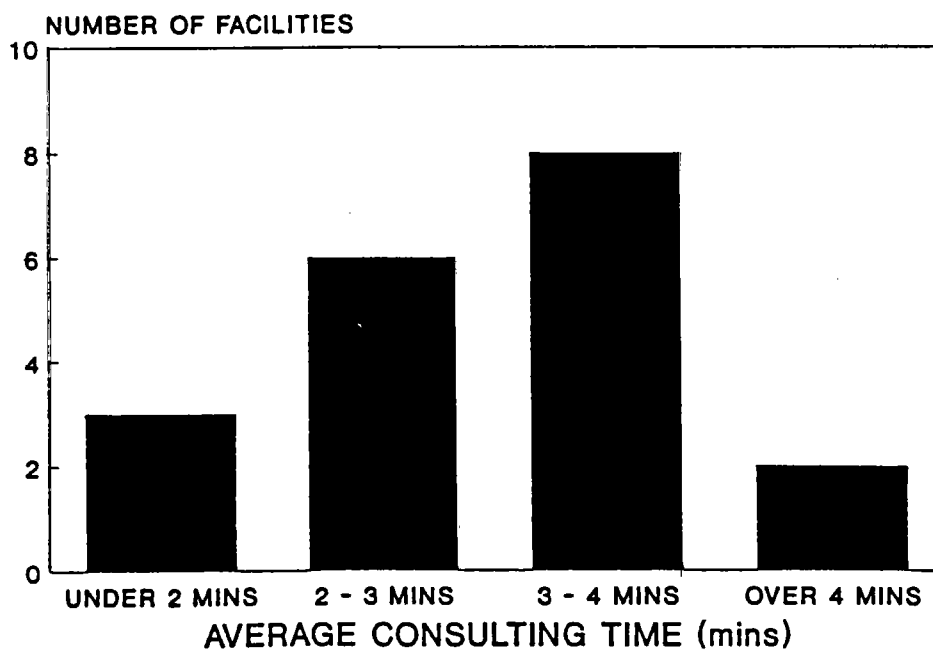
FACILITY-SPECIFIC PERCENT RECEIVING ANTIBIOTICS

PERCENTAGE OF PATIENTS

■ URBAN ▨ RURAL

FACILITY-SPECIFIC AVERAGE CONSULTATION TIME

AVERAGE TIME(mins)

■ URBAN ▨ RURAL

Tanzania Indicators Field Test 1992

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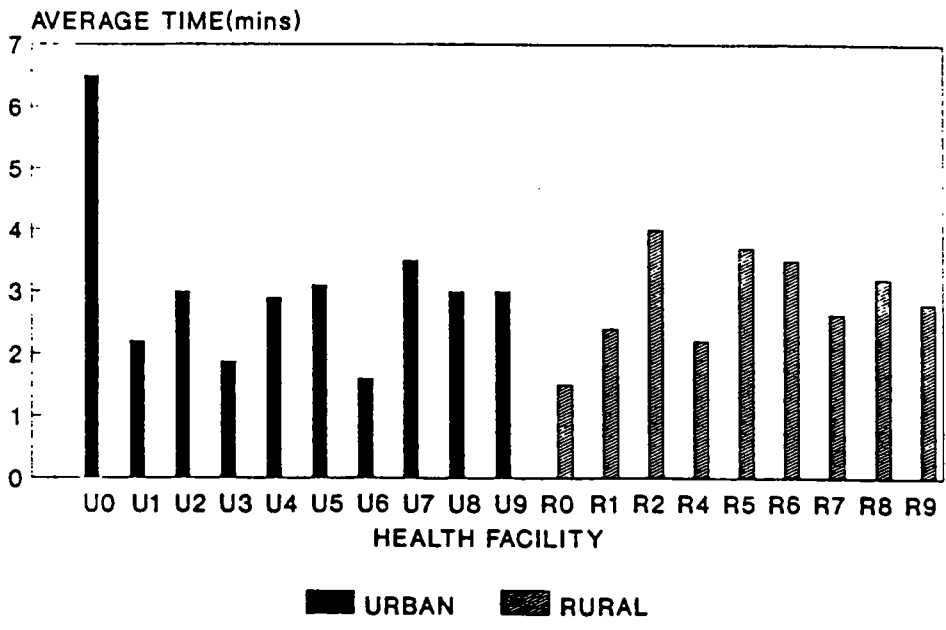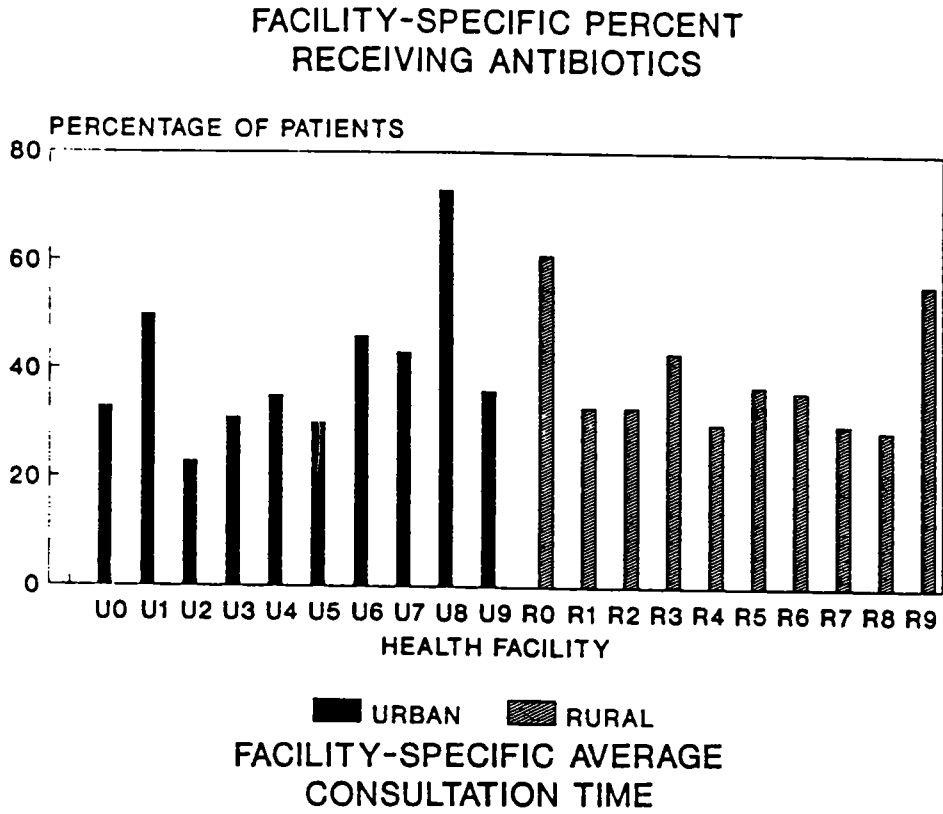
Examples of bar charts showing variability of facilities

SAMPLE-WIDE DISTRIBUTION OF
ANTIBIOTIC USE
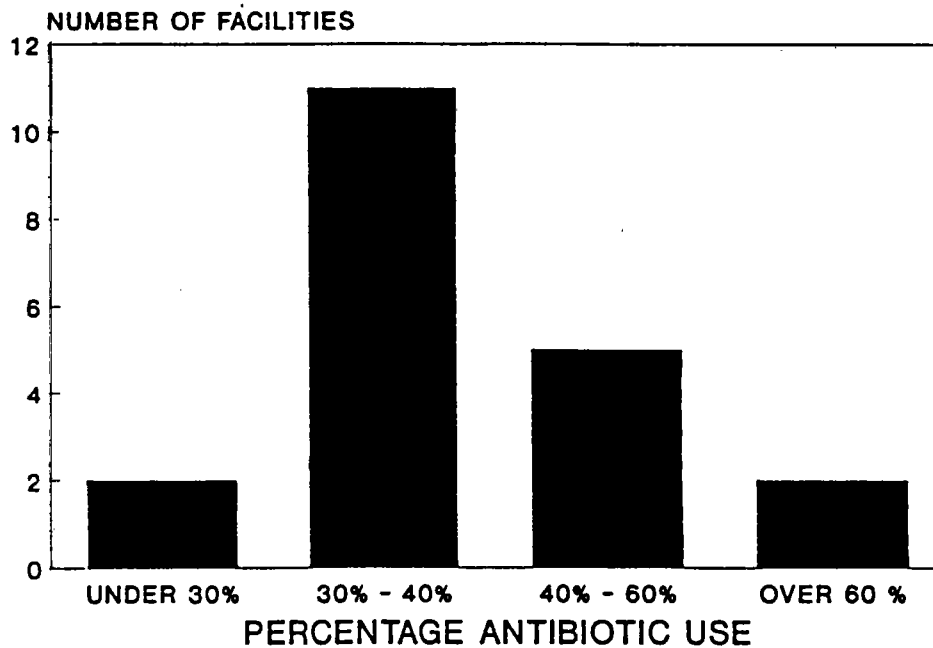
SAMPLE-WIDE DISTRIBUTION OF
CONSULTING TIMES

Tanzania Indicator Field Test 1992

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ANNEX 4

USING THE INDICATORS FOR MONITORING

Introduction

One possible reason for using the drug use indicators is to supervise the performance of a set of health facilities on an ongoing basis. The primary objective of such a monitoring process is not necessarily the estimation of the precise values of the indicators in each facility, but rather the identification of facilities which do not meet explicit standards of performance. As we have seen, examination of at least 100 encounters in a facility is necessary to obtain an estimate with a 95% confidence interval of plus or minus 10%. This number would be impractical to examine on a regular basis during routine supervisory visits.

To make the use of indicators for monitoring feasible, the procedures need to rely on sampling as small a number of encounters as possible, and there needs to be a rapid way of identifying those facilities which do not meet a specified norm. This annex describes such an approach using a technique called Lot Quality Assurance Sampling. Practical details of this approach will need further development as the indicators begin to be applied for monitoring and supervision. Those interested in a fuller treatment can refer to other recent publications on this topic[7,8,9,10].

Overview of lot quality assurance sampling (LQAS)

Lot quality assurance sampling (LQAS) is an efficient sampling method that can be used to identify geographical areas or health facilities which perform more poorly than a defined standard, as measured by a specific indicator. The method was developed in the manufacturing sector, to allow the selection of the smallest possible number of products from an assembly line for quality testing. It has recently begun to be applied more frequently in the evaluation of specific quality of care parameters in health programmes LQAS[11,12] is usually applied in situations where a binary measure of quality (adequate/inadequate) is being monitored, although it can also be used to monitor normally distributed parameters[13]; only the monitoring of binary indicators will be considered in this manual.

The primary advantage of LQAS is the fact that the method uses samples of minimum size to identify areas or facilities in need of special attention. Because of its efficiency, LQAS is suitable for monitoring the long-term performance of health facilities and

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evaluating the effects of supervision or intervention. The disadvantage of LQAS when used in its typical and most easily understood form is that there are no simple procedures for reliably estimating the actual value of the indicator being used as the standard of performance, or for calculating standard errors, as the sample sizes employed in each facility are too small. It also does not identify facilities with a particularly good performance.

The concepts underlying LQAS are similar to those underlying the evaluation of the presence or absence of a disease using a medical test. Most tests result in a certain proportion of erroneous classifications, that is, cases classified as diseased when they are actually healthy (false positives), or as healthy when actually diseased (false negatives). The ability of the test to correctly classify healthy patients is referred to as its sensitivity, while success at correctly classifying diseased patients is its specificity. LQAS can be thought of in the same way.

It is important to note that because decisions are all based on an arbitrarily chosen standard, the value of the standard will have major impact on the number of facilities flagged as deficient. Therefore, standards need to be set carefully in order for LQAS to be a meaningful and practical method. Choosing too stringent a standard will result in many "false positives"; however, too loose a standard results in poorly performing facilities being missed. It is reasonable for a given standard to set the allowable false negative rate relatively low at 5%, and the allowable false positive rate moderately high at 20%, minimizing the risk of missing a poor performer, while making it slightly more likely to misclassify an adequate performer as poor. These values will keep the required sample sizes at a reasonable level.

Procedures for using LQAS

There are a variety of different strategies for applying LQAS in a given setting. Some methods involve more complex procedures that allow examining a minimum number of encounters through a technique known as double sampling. This entails examining one small sample, and if the evaluation of performance is ambiguous, examining a supplementary sample to confirm. However, because the cost of examining health encounter records or observing patient care episodes is not inordinately high, a simpler procedure is described here that involves sample sizes that are practical in the context of a monitoring visit.

Step 1: Specify a standard for adequate performance

In the light of local circumstances, specify a standard for adequate performance on the indicator in question, that is, the level at which facilities are expected to be performing.

This level might be selected based on the results of a previous drug use study, or on an absolute standard of performance, if there is one available for this indicator.

Example: On the whole, not more than about 30% of patients should be treated with an injection.

NOTE Ofcourse there is some variation between facilities and prescribers. The aim of the monitoring exercise (and of LQAS) is to identify those facilities with a level of injections so high that they are beyond a reasonable "normal" variation.

Step 2: Specify a standard for inadequate performance

Specify a level of performance against which the facilities are to be rated, that will provisionally be considered inadequate for the indicator in question.

Example: Inadequate performance is arbitrarily defined as 60% or more of encounters in a facility receiving an injection.

NOTE The closer the levels of adequate and inadequate performance, the larger a sample of encounters is needed to identify the facilities that perform poorly. For practical reasons, it is recommended to begin a monitoring process with a goal of identifying only those facilities which perform most poorly, that is, 30% or more greater than (or less than) the specified standard of adequacy (in the example, the difference between 30% and 60%). Over time, as performance of all facilities becomes more similar due to supervision, it is possible to move the level of inadequate performance closer to the desired standard.

Step 3: Look up the necessary sample size

For the standards of adequate and inadequate performance chosen, look up the necessary sample size and critical number of "failures" in the table. This table is made on the basis of 5% false-negatives and 20% false-positives. Other percentages could be chosen, but then sample sizes will be different.

Example: For an inadequate performance level of 60% and adequate performance equal to 30%, 16 is the maximum number of prescriptions that need to be examined. If 6 or more of these encounters are found to have received an injection, performance at the health facility is considered inadequate.

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Table: Sample size and critical number of "failures" for LQAS

MAXIMUM NUMBER OF ENCOUNTERS TO EXAMINE								
Average Level of Adequate Performance	Level of Inadequate Performance							
	20%	30%	40%	50%	60%	70%	80%	90%
10%	83	26	13	8	5	3	2	1
20%		119	33	15	9	5	3	2
30%			143	37	16	9	5	3
40%				153	38	16	8	4
50%					151	35	13	6
60%						137	29	10
70%							109	20
80%								69

NUMBER OF "FAILURES" FOR INADEQUATE PERFORMANCE								
Average Level of Adequate Performance	Level of Inadequate Performance							
	20%	30%	40%	50%	60%	70%	80%	90%
10%	10	3	2	1	1	0	0	0
20%		27	8	4	2	1	1	0
30%			47	13	6	3	2	1
40%				66	17	8	4	2
50%					80	19	8	4
60%						87	19	7
70%							80	15
80%								57

Step 4: Draw and observe the samples

Draw and observe a random sample of encounters of the size required. Count each instance of "failure", that is, the behaviour that is to be considered inadequate. When the critical number that was identified from the table is reached within the sample of agreed size, the facility is considered to be performing inadequately.

> Example: In the above example, 16 encounters are to be studied. If 6 or more of these encounters receive an injection, total performance of the facility (with respect to this indicator) is classified as inadequate. In fact, as soon as 6 encounters with injections have been observed within the sample of 16, performance is classified as inadequate and the study can be stopped as it is of no use to continue; in bad performers this could already happen after 8 or 10 encounters have been studied.

> *NOTE* In this example not every instance of an injection, here classified as "failure", actually constitutes inadequate performance. Some patients will always require injections; in fact, according to the arbitrary standard, an average of 30% of patients will require them. However, the logic of the methodology asserts that the total number of patients receiving injections in a random sample of 16 encounters should not exceed 5 (with a certain margin of error) if the facility is averaging only 30% of patients injected.

ANNEX 5

COMPLEMENTARY DRUG USE INDICATORS

Introduction

The complementary drug use indicators represent measures of performance that can be used in addition to the core indicators, depending on local circumstances. These indicators are no less important than the core indicators, but the data to measure them may often be more difficult to obtain, or their interpretation may be highly sensitive to the local context. In addition to the complementary indicators described below, health managers may choose to collect other important items of information in a particular drug use survey. Beyond the core indicators, the methodology should represent a flexible tool to learn about drug use practices. If new indicators are to be added, careful definitions should be worked out in advance and the methods pre-tested for reliability and feasibility before being included in a full survey.

This annex provides definitions of some key complementary indicators, details of their collection and calculation, as well as descriptions of some of the constraints to using the indicators in a reliable way.

If the required data can be collected efficiently in a drug use survey with core indicators, the complementary indicators are suggested as additional measures of drug use. They are collected in the same basic steps as the core indicators, during reviews of historical records, observations of current patient encounters, or general observations at sample facilities.

13   Percentage of patients treated without drugs

Purpose	To measure the degree to which primary care prescribers treat patients seeking curative care with non-pharmaceutical therapies.
Prerequisites	Full data on drugs prescribed must be available, and not just data on drugs dispensed.
Calculation	Percentage, calculated by dividing the number of consultations in which no drug is prescribed by the number of consultations surveyed.
Example	In health centers in Region Y, no drug is prescribed during 2.2% of

curative visits.

Remarks The benefit of this indicator is that it measures the proportion of patients who are counselled or referred without being treated with drugs. As many as 35% of patients may not require drug treatment, so knowing the actual figure can be very revealing. However, failure to prescribe drugs can also indicate lack of availability in some settings, and this need for local interpretation requires that this be a complementary indicator.

14 Average drug cost per encounter

Purpose To measure the cost of drug treatment.

Prerequisites A method must be developed for assigning unit costs to each drug prescribed, or to the prescription as a whole; if actual costs to the health system are to be measured the portion reimbursed by the patient must be subtracted.

Calculation Divide the total cost of all drugs prescribed by the number of encounters surveyed.

Example A survey of health centers in Region X found that the average cost per treatment was $0.84.

Remarks See under (16).

15 Percentage of drug costs spent on antibiotics
16 Percentage of drug costs spent on injections

Purpose To measure the overall cost impact of two important, but commonly overused, forms of drug therapy.

Prerequisites Lists must be made of drugs to be counted as antibiotics and injections (already developed for core indicators 3-4); a method is required for assigning unit costs to each drug prescribed; if actual costs to the health system are to be measured, the portion reimbursed by the patients should be subtracted.

Calculation Percentages, calculated as the cost for all antibiotics or for all injections, divided by the total drug costs.

Example In a survey of dispensaries in Region Z, 37% of total drug costs were for antibiotics, while 58% of the costs were for injections.

Remarks Indicators 14-16 are difficult to measure. Unless unit treatment costs are routinely assigned, the *detailed prescribing indicator form* has to be used (see Annex 2), and the costs for injections, antibiotics and total drugs need to be calculated. There are a number of possible ways to assign drug costs:

- if drugs are sold on an actual cost basis, use the amount that each patient pays, either in total or for each drug;
- assign a unit cost based on the average unit price paid for each drug by a facility, either during the past year or at the time of last purchase, and multiply the unit cost by the number of units dispensed to obtain the costs for each drug;
- assign the same average unit cost to drugs from any facility based on values calculated from MOH order sheets, records of procurement prices, averages of true purchase costs at one or more facilities, or some other central or regional source, and again calculate drug cost through multiplication.

While laborious to collect and analyze, the information from these cost indicators can be useful when planning changes in drug supply, cost recovery systems, or fees.

17   Prescription in accordance with treatment guidelines

Purpose	To measure the quality of care for some important health conditions where clear standards of pharmaceutical treatment exist locally.
Prerequisites	A list must be made of the specific diagnostic categories or symptoms to be included, such as all acute respiratory illnesses; a list of products or therapeutic classes to be accepted as rational treatment for these conditions is also needed.
Calculation	Percentage, calculated by dividing the number of cases receiving the chosen treatment divided by the total number reviewed.
Example	In health centers in Country A, 47% of children with diarrhoea receive an antidiarrhoeal drug, while only 34% receive ORS.
Remarks	This indicator is potentially the most interesting measure of quality of care and has been field tested extensively. Problems exist in terms of defining health problems, in defining what is acceptable treatment, and in obtaining enough encounters with specific problems during the course of a drug use survey. However, the indicator is very useful where clear guidelines exist -- for example, all children with diarrhoea should receive ORS and no injections or antidiarrheal drugs, and only bloody diarrhoea should receive antibiotics. In collecting data to compare actual practice with such standards of practice, it is often discovered that prescribers know the correct treatment but use a different regime.

To make the evaluation of quality of prescribing manageable, it is recommended that attention be restricted to at most five important tracer health problems. Which health problems are selected will

depend on the features of the health system and the particular goals of an indicator study. It often makes sense to select the problems that present most frequently for care at health facilities, such as acute diarrhoea, acute respiratory infection, malaria or conjunctivitis, since these tend to occupy the most staff time, even if they do not consume the greatest share of pharmaceutical resources. In many environments there will be other problems that are of particular clinical or economic importance, even if they are not the most frequently treated, such as tuberculosis or gonorrhea.

One general approach for defining standards when carrying out an indicator study is to identify for each important health problem a set of drugs which are *acceptable* to use, depending on the severity of the problem, the accompanying symptomatology, or the clinical judgement of the health worker. Compliance with this list of acceptable drugs can then be used as a measure of performance. It is important to remember that acceptable drugs often include not only medications for treating the causative organism or syndrome, but also drugs that are acceptably prescribed for the relief of accompanying symptoms or to prevent complications.

Discussions with prescribers about the differences between what they are taught to do and what they actually do are often very interesting as illustrations of the limitations of training.

18 Percentage of patients satisfied with the care they received

Purpose	To measure the extent to which patients leave health facilities generally satisfied with the overall care they received.
Prerequisites	The question that patients are asked to score this indicator must be translated in a way that captures two key concepts: (1) being "generally satisfied" indicates that the visit generally met the patient's basic expectations and needs, rather than the absence of any complaint or criticism; (2) the phrasing for "overall care" should incorporate the entire service at the health facility, including diagnosis, treatment, interpersonal relations, and so forth.
Calculation	Percentage, calculated as the number of patients who report being generally satisfied divided by the total number of patients interviewed.
Example	In Country C, only 57.9% of patients leaving health facilities report that they were satisfied with the care they received.
Remarks	Patient satisfaction is a very important component of quality of care, but difficult to measure. The response often depends on how the

question is put. Different cultures express satisfaction in different ways. In addition, in some cultures, the expression of dissatisfaction is considered rude and unacceptable. So it is essential that a single method of asking is agreed upon and used, and that the method be pre-tested for cultural acceptability.

19   Percentage of health facilities with access to impartial drug information

Purpose

To determine whether accurate and unbiased information about drugs is locally available to prescribers.

Prerequisites

A list is needed of printed material to be considered a source of impartial information about drugs, e.g. non-commercial drug compendia, information bulletins, therapeutic and formulary guidelines.

Calculation

Percentage, calculated as the number of facilities where a listed source of impartial information is present, divided by the number of facilities surveyed.

Example

In Country A, 37% health centers had access to unbiased drug information.

Remark

The important point with this indicator is to define what is an impartial source of drug information. An industry-produced booklet such as MIMS would not be acceptable. However, publications such as *Diarrhoea Dialogue* or *ARI News* do contain drug information and are widely distributed. Books such as *Where There Is No Doctor* and MOH bulletins would obviously qualify. Data collectors should be provided with a list of acceptable materials and trained to score the indicator in strict compliance with this list.

Rather then scoring only "yes" or "no" per health facility, it could be considered to score the different key publications separately. For example, make separate scores for the national essential drugs list and the formulary for that level of care (indicator 11), national treatment guidelines, drug bulletin, WHO publications, wall-chart with treatment guidelines, basic textbooks, etc.

ANNEX 6

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