CHAPTER 28

Investigating medicine use

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SUMMARY

Medicine-use researchers, health care providers, policy makers, and managers collect data to describe patterns of medicine use, to address medicine-use problems, and to monitor medicine use over time. They use two basic methods: quantitative methods, to measure what is being done, and qualitative methods, to provide information on why it is being done. Both methods are used to better understand the causes of problems before intervening to correct them. The intervention design must include outcome indicators that are meaningful, reliable, and measurable. Appropriate study sites and a relevant comparison group must be randomly selected; outcomes need to be measured before and after the intervention in both groups. If an appropriate comparison group cannot be identified, study designs that measure change over time (interrupted time series) may be used. Medicine-use data can also help evaluate the effect of interventions.

Reliably measuring medicine use requires standardized indicators to provide consistency. In 1993, the World Health Organization (WHO) and the International Network for the Rational Use of Drugs (INRUD) produced a manual that defines core medicine-use indicators and provides a methodology for measuring these indicators for general outpatients in health care facilities. Similar indicators are needed to measure pharmaceutical use in hospital inpatients, in private pharmacies, and for pharmacy benefits for insurance schemes, as well as to measure adherence to antiretroviral therapy (ART).

Sources of data differ according to the intended use and setting. Common sources of quantitative data include pharmaceutical supply orders, stock cards, patient registers, medical and prescription records, medicine-use databases, and patient exit surveys. For qualitative studies, data routinely come from patient interviews, questionnaire surveys, patient observation, and focus group discussions. Each method has strengths and weaknesses and is appropriate for different circumstances.

Medicine-use investigations can occur in public health care facilities, in private-sector facilities, and in the community. Methods for investigating use in different settings may differ; for example, mystery shoppers or simulated patients who pose as customers with specific health problems are useful for studying practices in private-sector pharmacies, whereas public health facilities may rely on readily available, routinely collected data.

After a medicine-use study, meetings to discuss the results help health care providers, managers, and policy makers identify specific problems related to the medicine-use process and design appropriate interventions to address them. The effectiveness of different interventions depends on a number of factors, including the intervention itself, the setting, and the implementation process. Evaluating interventions is necessary to assess the overall impact of the program or to compare the relative effectiveness of different interventions.

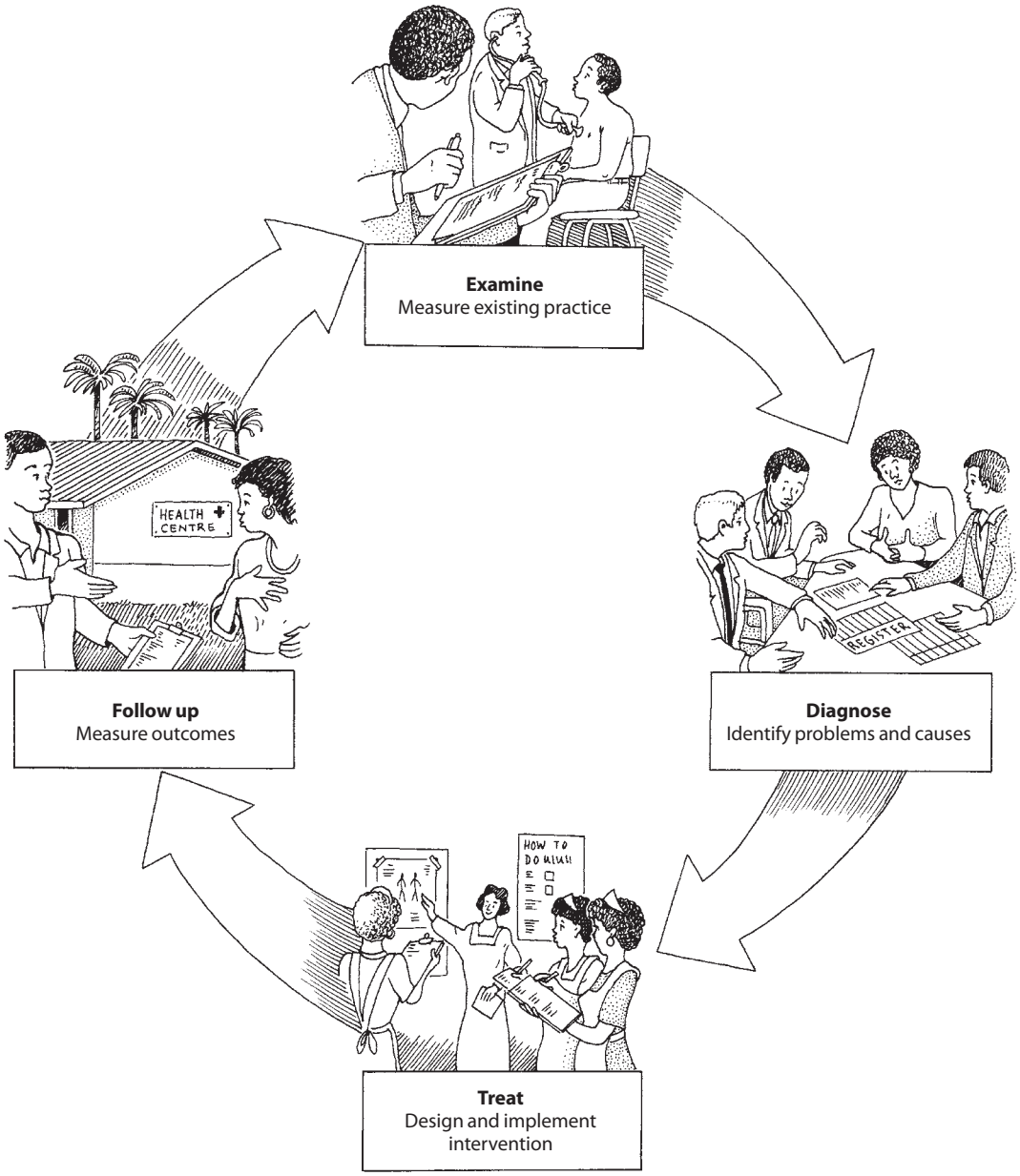
28.1 Reasons to investigate medicine use

Medicine-use researchers, managers, and policy makers collect data about medicine use for various reasons. These reasons can be grouped into three general categories—

1. To describe and compare current patterns of medicine use within a defined setting (for example, a health care facility or geographic area)—
   - Measuring consumption of particular medicines or therapeutic groups of medicines, such as acetylsalicylic acid versus paracetamol or acetaminophen
   - Comparing use by individual health facilities or prescribers
   - Deciding whether medicine use is clinically justified or cost-effective
   - Learning about the influence of prescribing on pharmaceutical costs
2. To identify and correct specific medicine-use problems—
   - Identifying the factors that cause specific problems related to medicine use
   - Designing interventions to address specific problems in prescribing, dispensing, or patient use
   - Measuring the effectiveness of behavior change interventions
3. To monitor medicine use over time—
   - Monitoring quality of care within a health facility or geographic area
   - Monitoring the efficiency and cost-effectiveness of prescribing
   - Monitoring the effect of drug regulatory interventions

A health manager who wishes to improve medicine use proceeds through a cycle of activities (Figure 28-1) that includes (a) assessing current patterns of medicine use,

Figure 28-1 Identifying and rectifying a medicine-use problem: An overview of the process



(b) identifying problems and their causes, (c) carrying out interventions to address specific problems, and (d) evaluating outcomes and monitoring subsequent practices. This process can be repeated to tackle increasingly complicated issues and to identify emerging problems.

The two main methods for gathering data on medicine use are quantitative and qualitative. Quantitative methods are better for answering the question *What is happening*? Qualitative methods are suited for answering the question *Why is it happening*?

Quantitative methods gather numerical data such as the number of antibiotics prescribed, the number of patients on antibiotics, or the cost of antibiotic therapy. Quantitative data can be used to create rates, averages, or other summary measures to describe the nature and extent of a medicine-use practice.

Qualitative methods, often in the form of observations, descriptions, opinions, or discussions, are frequently used to describe the beliefs and motivations that underlie particular practices. Without this information, it is difficult to determine why prescribers and patients act as they do and therefore how they can change their behavior. Qualitative studies can also be used to formulate appropriate questions for a quantitative survey.

28.2 Data sources and measurement issues

Health managers often need to describe the use of specific medicines or medicine classes or therapeutic categories; or compare use among different geographic areas, administrative units, or individual prescribers before or after certain interventions. Sources of data for such purposes differ, depending on the setting. A hospital administrator who wants to measure the use of expensive antibiotics requires different data from a program manager who needs to know how children in the community are treated for acute respiratory infection (ARI). Common sources of medicine-use data and their uses are outlined in Table 28-1.

Characteristics of medicine-use data

Medicine-use data differ in scope and level of aggregation. Researchers can look at previously collected data or records (retrospective) or collect specific data from one point in time forward.

Scope. Data may describe public-sector practices (in public facilities or administrative offices), private-sector practices (by private practitioners, pharmaceutical suppliers, or retail drug sellers), or community medicine use (practices in the community, independent of setting). Data on public-sector practices are the most readily available, because they flow out of routine record-keeping systems. Private-sector or community-based data are usually more expensive and time-consuming to collect.

Level of aggregation. Data on medicine use may be aggregated to measure consumption of specific medicines or medicine classes or therapeutic categories or may focus on patient-specific use. Data on patient-specific use are usually more informative, although aggregate consumption data may be sufficient to answer many cost-related questions.

Retrospective studies. These studies can be conducted using data from routine record keeping or past studies. Such existing data, although potentially incomplete, are less expensive to use. Retrospective studies can describe practices over a longer period of time.

Prospective studies. Prospective studies collect data, for example, from patient encounters. They provide information about the treatment setting, the diagnostic process, the communication between health providers and patients, or the time of consultation and dispensing.

Medicine-use encounters

A *medicine-use encounter* is the period of contact between a patient and a health care provider. Ideally, this encounter includes a number of components: history taking; the diagnostic process; selection of pharmacological and nonpharmacological treatment; prescription (and often dispensing) of treatment; and explanations about treatment, follow-up, or prevention. Medicine-use encounters that include one or more of these components occur in most settings with health care providers, who range from highly trained medical specialists to itinerant drug sellers.

Critical information on medicine-use encounters includes (a) the specific setting, provider, patient, and date of the encounter; (b) patient age and gender; (c) signs and symptoms (patient complaint) or diagnosis (by the health care provider); and (d) medicines prescribed or dispensed, including brand or generic name, strength, and route of administration (injection, oral, topical). Data on the total dose prescribed or dispensed (number of pills and duration of treatment), the instructions given, and the cost of the medicines dispensed are all valuable for specific purposes.

Studies in several settings have found that data collection forms need to allow for at least three diagnoses per encounter and at least ten medicines prescribed or dispensed. Data on total dose, duration of treatment, and medicine cost are often difficult to collect accurately and can add substantially to the cost of data collection. Unless specific reasons exist to collect this information, such as designing an intervention, medicine-specific data can be limited to brand or generic name, strength, and route of administration.

Measurement issues

Problems in identifying, classifying, and quantifying pharmaceuticals frequently occur when measuring medicine use. The same medicine is often available under different names and in many different dosages and forms. Identifying specific medicines and their ingredients, or grouping equivalent products, can be difficult and time-consuming. Similarly, grouping cases according to health problem can be difficult in environments where record systems are imprecise and diagnoses may be uncertain. Ways to overcome these common difficulties have been developed and are discussed below.

What is in a medicine? With hundreds or even thousands of products on the market, many medicine names are similar. When deciding which medicines to place in specific groups, the following steps may be taken—

- Use a list of generic medicines, such as the national essential medicines list or national formulary.
- If a system such as the Anatomical Therapeutic and Chemical (WHO Collaborating Centre 2009) or one of the other common systems is not used, develop a system of easy-to-recognize medicine codes based on medicine names and strengths (for example, "TET250T" for tetracycline 250 mg tablets). Coding systems are discussed in Chapters 16, 40, and 50.
- Use standard pharmaceutical references (MIMS, or the

Table 28-1 Sources of quantitative medicine-use data

Location of data	Sources of data (manual or computerized)	Potential uses of data
Public-sector administrative offices, medical stores	For retrospective studies: • Pharmaceutical supply orders • Stock cards • Shipping and delivery receipts	• Aggregate patterns of medicine use and expenditures • Comparative use of medicines within therapeutic classes • Comparative use by different facilities or areas
Health-facility clinical and medical record departments	For retrospective studies: • Patient registers • Health worker logs • Pharmacy receipts • Medical records For prospective studies: • Patient observations • Patient exit surveys • Inpatient surveys	• Aggregate patterns of medicine use and expenditures • Medicine use per case, overall, and by group (age, sex, health problem) • Provider-specific prescribing • Characteristics of patient-prescriber interactions
Health-facility pharmacies	For retrospective studies: • Pharmacy logs • Prescriptions retained in pharmacies For prospective studies: • Patient exit surveys • Patient observations	• Aggregate patterns of medicine use and expenditures • Dispensing practices • Characteristics of patient-dispenser interactions
Pharmacies and retail medicine outlets	For retrospective studies: • Prescriptions retained in pharmacies For prospective studies: • Customer exit surveys • Customer observations • Simulated patient visits	• Private-sector prescribing practices • Pharmaceutical sales without prescription • Self-medication practices • Characteristics of customer-salesperson interactions
Households	For retrospective studies: • Family medical records • Household surveys For prospective studies: • Household pharmaceutical audits • Family medical care logs	• Total community medicine use • Care-seeking behavior • Self-medication practices • Family medicine use patterns • Patient adherence to treatment

Monthly Index of Medical Specialities; *Martindale: The Extra Pharmacopoeia*; USP Drug Information; *British National Formulary*) to identify ingredients in brand-name medicines. Although expensive, the most useful single reference is probably *Martindale*. Free online references, such as http://www.drugs.com, are also available. Organize the medicines identified into therapeutic classes or categories, as relevant for analysis.

- Count combination products as single medicines (because of the difficulty in deciding which ingredients count as separate products).

Which medicines belong together? When attempting to place medicines in specific groups, beginning with an existing system of medicine categories, such as the WHO list of essential medicines or the more elaborate ATC, is useful. If necessary, the medicines can subsequently be reorganized into more useful local categories.

How many medicines are dispensed and how much do they cost? The following procedures can be helpful when encountering problems in estimating the amounts of medicines dispensed—

- Define the most common dispensing units (pills, milliliters, tubes, bottles) for every medicine, and be sure that enumerators record these units consistently when data from medication encounters are coded.
- Identify commonly used injections or liquids (for example, cough syrups) for which inconsistencies may occur in recording the correct basic unit (ampoule vs. mL, bottle vs. mL). Prepare a simple reference card for enumerators stating the correct units to be used for these medicines.
- For calculating medicine costs in public-sector studies, use a single, fixed set of unit costs (calculated per pill, per milligram, or per cubic centimeter; based on bulk purchase prices) for all health care facilities. This method ensures that any variations in cost are attributable to medicine selection and decisions about dosing.

How can cases be classified? When attempting to define reasons for treatment, it is important to develop explicit rules before data collection for classifying cases when only signs and symptoms are recorded and no diagnosis is made. In this way, health problems diagnosed as "malaria" can be distinguished from those recorded as "fever," or those diagnosed as "pneumonia" can be distinguished from "cough, fever, and difficulty in breathing." When possible, use the WHO *International Classification of Diseases, 10th Revision* (ICD-10) codes (WHO 2007). Separate categories can be developed for classifying frequently repeated clusters of problems (for example, ARI and otitis media, cough and fever).

How useful are standard treatment guidelines in measuring the quality of pharmaceutical use? One issue that frequently arises in medicine-use studies is how to apply information from standard treatment guidelines to measure the quality of prescribing. Because clinical guidelines are usually not developed as management tools, using them to measure quality of care introduces a number of practical problems. In the developing world, clinical guidelines frequently exist in the form of standard diagnosis and treatment protocols. These standard protocols are most commonly intended for use in primary health care facilities, although some countries have developed standards for secondary and tertiary care facilities as well.

Based on a given standard, some studies have tried to decide globally whether the use of medicines in a particular case is "correct" or "incorrect." In practice, this judgment is frequently difficult to make in a valid and reliable way. Local standard treatments may not be expressed in an explicit way that allows adherence to be accurately measured. Furthermore, standard guidelines are frequently difficult to apply for real patients with multiple health problems or problems that cannot be diagnosed accurately with available facilities.

A recommended approach for using standard treatments in medicine-use studies follows—

- Have local experts agree on explicit definitions of the standard diagnostic procedures and treatments for specific health problems.
- Define one or more explicit aspects of these standards as separate indicators rather than trying to measure global adherence. Example: Was oral rehydration solution (ORS), which should always be recommended to treat diarrhea with mild dehydration, given or not? Was an antidiarrheal, which should never be recommended to treat diarrhea with mild dehydration, given or not? Was the recommended dosage form of a pharmaceutical used—for example, oral ORS rather than injectable intravenous saline solution? Was the appropriate amount of the pharmaceutical used (daily dose times and duration of therapy)?
- Concentrate on measuring adherence to the most unambiguous aspects of the standard.

Unit of analysis. The *unit of analysis* is the basic entity being analyzed in the study. Depending on the focus of a medicine-use study, the patient, the prescriber, or the health facility can be the intended unit of analysis. For community-based surveys or studies of patient-level factors such as ability to pay for medicines, the patient may be the appropriate focus. The individual prescriber may be the best unit of analysis for studies of specific prescribing practices or influences on prescribing. In many health systems, the health facility is the appropriate study unit for examining medicine use in a geographic area or the reasons for differences in treatment practice. The geographic area may also be used as the unit of analysis for large-scale medicine-use studies.

Sample size. When measuring medicine use, the required sample size depends on which practices are being measured, how precise the measurements need to be, and the unit of analysis. A trade-off usually exists between the costs of collecting data and greater uncertainty. People carrying out scientific research usually need more precise data with larger samples than do managers or policy makers who measure medicine use to make decisions. Sample size must be planned accordingly.

Focusing on specific subgroups often improves the ability to make good decisions. When possible, the sample in a medicine-use study should be stratified to compare key groups. *Stratification* involves dividing a sample into homogeneous subsamples based on one or more characteristics of the population. For example, samples may be stratified by provider age or by area of practice; strata could be urban/rural, paramedic/physician, government/mission, or public sector/private sector. Where possible, the sample size should be greater in groups that are likely to have poor practices to learn more about the groups that are likely to be the focus of future interventions.

Ethical issues. Ethical issues must be considered in any study that measures individual behavior. Managers in a health system may have the right to examine performance, but these efforts are likely to be more favorably received if they involve representatives of the practitioners whose performance will be investigated—their supervisors, for example. Studies that deal with people directly should always include appropriate efforts to obtain informed consent from participants and to describe how the data will be used. Also, the protocols for all proposed medicine-use studies should be approved by institutional review boards or another competent health authority. In addition, efforts should be made to protect the privacy of all research participants, if applicable. Finally, emphasis should be placed on adequate and timely dissemination of findings for the benefit of those under study.

28.3 Measuring medicine use: quantitative methods

Medicine use encounters occur in many environments, including hospitals, health centers, private pharmacies or drug shops, and the home. Hospital medicine use is frequently studied by medicine-use review (described in Chapter 29). Although many different methods are used to investigate medicine use, this chapter emphasizes the methods published by WHO on investigating medicine use in health facilities (WHO/DAP 1993) and in the community (Hardon, Hodgkin, and Fresle 2004).

Studying medicine use in health care facilities using WHO indicators

Health managers and policy makers often need to know about the quality of medicine use in a group of health care facilities. To simplify and standardize the study of medicine use in these situations, WHO and INRUD produced the manual *How to Investigate Drug Use in Health Facilities* (WHO/DAP 1993; Hogerzeil et al. 1993). This manual describes in detail a set of reliable indicators to measure medicine use for general outpatients and a standard methodology to collect the data for these indicators. The major points of the manual are summarized here.

The WHO manual defines twelve core and seven complementary medicine-use indicators (see Box 28-1) that measure key aspects of pharmaceutical prescribing, patient care, and availability of pharmaceuticals and pharmaceutical information at outpatient facilities. The core indicators are highly standardized and do not require national adaptation.

Although not comprehensive, the core indicators provide a simple tool for quickly and reliably assessing a few critical aspects of medicine use. With these indicators, results should point to specific medicine-use problems that need to be examined in more detail. All the necessary data are collected from medical records or by direct observation at health care facilities.

The manual also defines a set of complementary indicators, which are less standardized and require defining variables specific to the country or location. One important complementary indicator measures adherence to treatment guidelines. This indicator requires clear, explicit criteria to be reliable and informative.

To measure medicine use, collect data from a sample of health care facilities. The number of health care facilities to include in the survey depends on the purpose of the survey. A regional or national medicine-use survey includes at least twenty facilities selected at random, with thirty medicine-use encounters sampled per facility, for a total of at least 600 encounters for the entire study. When the objective is to study medicine use by individual facilities or prescribers in a sample, at least 100 prescriptions should be obtained at each health facility or for each prescriber. When possible, the prescribing data are based on one year of retrospective encounters; prospective data can be collected if no

Box 28-1
WHO medicine-use indicators (outpatient facilities)

Core medicine-use indicators

Prescribing indicators

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

Patient care indicators

6. Average consultation time
7. Average dispensing time
8. Percentage of medicines actually dispensed
9. Percentage of medicines adequately labeled
10. Patients' knowledge of correct dosage

Health facility indicators

11. Availability of a copy of essential medicines list or formulary
12. Availability of key medicines

Complementary medicine-use indicators

1. Percentage of patients treated without medicines
2. Average pharmaceutical cost per encounter
3. Percentage of pharmaceutical costs spent on antibiotics
4. Percentage of pharmaceutical costs spent on injections
5. Prescription in accordance with treatment guidelines
6. Percentage of patients satisfied with the care they received
7. Percentage of health care facilities with access to impartial pharmaceutical information

Source: WHO/DAP 1993.

Table 28-2 Selected results of studies using WHO indicators

Country	Number of facilities	Number of medicines prescribed	Percentage antibiotics	Percentage injections	Percentage generics	Consulting time (minutes)	Percentage who know dosing	Percentage key medicines in stock
Africa								
Cameroon	20	3.0	51	41	58			
Ghana	20	4.3	47	56	59			
Malawi	72	1.8	34	19		2.3	27	67
Mozambique	26	2.2	43	18	99	3.7	82	87
Nigeria	20	3.8	48	37	58	6.3	81	62
Sudan	37	1.4	63	36	63			
Swaziland	20	3.0	54	38	63	6.1	87	92
Tanzania	20	2.2	39	29	82	3.0	75	72
Uganda	127	2.4	53	36	86	4.6	29	
Zimbabwe	56	1.3	29	11	94			
Asia								
Bangladesh	20	1.4	31	0			63	
Indonesia	20	3.3	43	17	59	3.0	82	
Nepal	20	2.1	43	5	44	3.5	56	90
Yemen	19	1.5	46	25				
Latin America and the Caribbean								
Eastern Caribbean	20	1.9	39	1	49			
Ecuador	19	1.3	27	17	37			38
El Salvador	20	2.2	32	7	72			
Guatemala	20	1.4	27	13	72			
Jamaica	20	2.4	30	4	40			

Source: Inrud Bibliography (http://www.inrud.org/Bibliographies/INRUD-Bibliography.cfm).

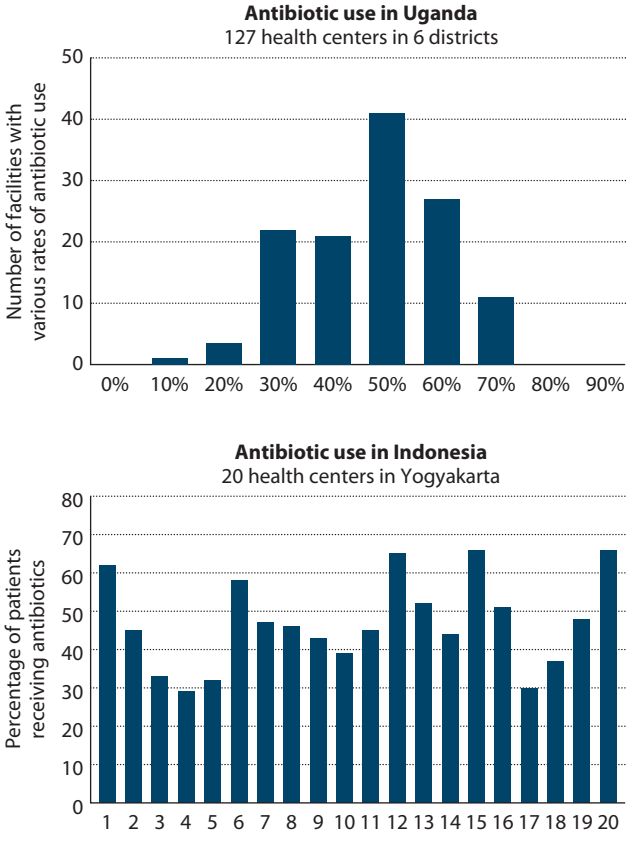
retrospective data are available. Data on patient care and facility indicators are always collected prospectively.

The principal use of an indicator survey is to obtain a snapshot of current medicine-use practices to contrast with surveys from other areas or with "optimal" values for the indicators. Data from an indicator study can be presented in a variety of ways. Table 28-2 presents selected results from twenty-one studies that used this basic methodology to study medicine use. Both similarities and differences in medicine-use patterns are apparent. At the time of these studies, Ghana and Nigeria showed a relatively high number of medicines per case (4.3 and 3.8, respectively); high injection use was evident in Uganda, Sudan, Nigeria, Swaziland, Cameroon, and Ghana (ranging from 36 to 56 percent); and Ecuador had low availability of essential medicines (38 percent). The rate of antibiotic use in primary care facilities was found to vary from 27 to 39 percent in Latin America and the Caribbean, from 31 to 46 percent in Asia, and from 29 to 63 percent in Africa. By focusing attention on specific areas of concern, the indicators can help identify priority areas for action.

Although a survey based on thirty encounters per facility mainly identifies overall patterns, performance in individual health care facilities can be contrasted. These facility-specific estimates can be unreliable because of low sample sizes, but interesting patterns often emerge (Figure 28-2). These estimates can show whether values of indicators are consistent or different across facilities and identify facilities that seem to have very low or very high values for specific indicators. By using qualitative methods, the reasons for these apparent differences can be explored in more depth before designing interventions. Box 28-2 describes a set of indicators used to measure facility-level treatment adherence for HIV/AIDS with the objective of identifying appropriate interventions and monitoring improvement.

Indicators can also be used to quantify the effects of an intervention. In 2004, researchers in Kenya evaluated the effect of two specific policy interventions on prescribing generic medicines, antibiotics, and injectables in a private hospital in Nairobi. Generics prescribing increased from 4 to 24 percent, the percentage of antibiotics prescribed decreased from 83 to 41 percent, and the proportion of

Figure 28-2 Comparison of facilities in indicator studies in Uganda and Indonesia



injectables fell from 17 to 7 percent following the intervention (Ojoo, Waning, and Maina 2004). In Ghana, a study assessing the effect of managerial and educational interventions for the treatment of lower respiratory tract infection showed the average number of medicines prescribed per patient as 3.8 in the intervention sites compared to 5.0 at control sites, indicating a marginal improvement (Ofei et al. 2004). In Uganda, a randomized, controlled, community-based trial was carried out in six districts, using the full set of WHO indicators as outcome measures (Kafuko, Zirabamuzaale, and Bagenda 1997). The study demonstrated that standard treatment guidelines plus prescriber in-service training resulted in significantly lower rates of overall medicine use, injection use, and antibiotic use compared to controls. Treatment guidelines alone did not result in any significant changes.

Medicine-use indicator studies have also been undertaken on inpatients (see Country Study 28-1). However, the interpretation of the results remains controversial, and consensus on a set of useful indicators is still needed. The WHO indicators were not designed for use with inpatients in hospitals or in specialty clinics, where medicine use patterns are more complex.

Finally, an indicator study can be a simple tool to motivate health personnel and policy makers. For example, before a nationwide prescriber training program in Malawi, each of twenty-four district medical officers surveyed three health care facilities in his or her own administrative area. This strategy was more effective for educating and motivating them than randomly surveying twenty facilities for the whole country for a baseline survey. While carrying out this survey, participants not only learned basic skills for measuring key aspects of quality of care but also became familiar with ideas about standards of practice and how their own areas conformed to these standards.

The WHO indicators can be used to study medicine use for specific problems, such as diarrhea, malaria, or ARI. Such research can be undertaken after an indicator study by selecting a limited number of common conditions for secondary analysis. This secondary analysis may highlight inappropriate treatment of common conditions (for example, antibiotics for the common cold or quinine injection for simple malaria).

WHO maintains a database of medicine-use surveys in developing and transitional countries to monitor the differences between different regions, provider types, public- and private-sector facilities, trends over time, and as a tool to identify effective interventions. The data have shown, for example, that over the sixteen years between 1990 and 2006, treatments for acute respiratory tract infection and malaria did not improve much; however, the use of generic and essential medicines in the public sector increased (WHO 2009).

Using aggregate data to measure medicine use

To understand how medicines are used to treat specific illnesses, researchers often have no alternative to collecting patient-specific data. However, these data may be expensive or difficult to obtain. Aggregate data on pharmaceutical consumption are often readily available from pharmaceutical procurement records, warehouse or pharmacy stock receipts, medicine-use databases (for example, IMS Health, or others), or even pharmaceutical importers' or manufacturers' records. Sometimes aggregate data can be used to answer specific questions about medicine use. Examples of questions about medicine use that might be answered using available aggregate data include—

What is the relative use of therapeutically substitutable products? For example, what is the relative use of paracetamol (acetaminophen) generic compared with branded products, or first-line recommended antimalarials compared with second- or third-line antimalarials?

What is the per capita use of specific medicines or medicine classes or therapeutic categories? For example, what is the per capita consumption of certain medicines that may

Box 28-2
Developing and implementing indicators to measure adherence to ART

Objectives of the INRUD Initiative on Adherence to Antiretrovirals include developing and validating a set of indicators that can be used to monitor adherence to ART and to investigate adherence rates and determinants for adherence for ART programs and individuals. During the initiative's first year, research teams in Ethiopia, Kenya, Rwanda, and Uganda tested the feasibility and reliability of a method to collect adherence data using routine pharmacy and clinic records. A validity study showed that the chosen adherence indicators correlated to increases in patients' CD4 counts and to weight gain. The five core indicators follow.

From pharmacy records for a sample of patients—

- Median percentage of days covered by ART dispensed over six months
- Percentage of patients with a thirty-day gap or more in medicines dispensed over six months
- Percentage of patients attending the clinic appointment set three months earlier on or before the scheduled appointment day
- Percentage of patients attending the clinic appointment set three months earlier within three days of the scheduled appointment day

From patient exit interviews—

- Percentage of patients who self-reported full adherence over the previous three days

On the basis of assessments using the indicators, national HIV/AIDS programs have helped clinics introduce interventions, such as appointment registers that assign blocks of time to patients and allow rapid identification of those who miss their appointments, protocols for calling or visiting patients who miss appointments, and the introduction of performance-based financing to compensate diligent staff.

Preliminary results show that these efforts have eased crowding and lessened waiting times at clinics. One clinic in Uganda reduced patients' average wait by more than an hour. These efforts have also enhanced teamwork among clinic staff, helped recruit new staff, and encouraged staff to start innovative programs for patients. One such program involved establishing groups of neighbors to share responsibility for picking up medicines so patients do not have to visit the clinics as often.

The indicators not only guide the development of appropriate interventions to address barriers to adherence, but also provide a useful way to measure facility performance both over time and in comparison with similar facilities.

Sources: Chalker et al. 2010; Ross-Degnan et al. 2010.

be widely overused, such as benzodiazepines or narcotic analgesics such as codeine?

What proportion of the pharmaceutical budget is spent on specific medicines or medicine classes or therapeutic categories? For example, how much is spent on ciprofloxacin or cephalosporins or on medicines to treat tuberculosis?

What proportion of specific medicines is being prescribed inappropriately? For example, what prescriptions contain contraindicated medicines or contraindicated medical conditions or lack of compliance with needed laboratory tests before or during therapy?

When aggregate data are used, similar products may not share a convenient unit of comparison. If the primary focus is cost, all pharmaceutical consumption data can be converted to monetary equivalents, using either actual or average purchase prices. However, if the focus is primarily clinical, this strategy will not work. Some researchers have established systems of therapeutic equivalence for particular medicine classes, such as antipsychotic agents.

One widespread system to deal with product equivalence is the system of defined daily doses (DDDs) (WHO Collaborating Centre 2009). A DDD is the "typical" dose of a medicine used to treat the most common medical problem for which the medicine is prescribed. The official DDD is usually the adult dose for the most common condition for which the medicine is used. Adjustments must be made to study pediatric medicine use. Converting aggregate quantities to DDDs indicates roughly how many potential treatment days of the pharmaceutical are procured or consumed. By using DDDs, pharmaceutical consumption in different settings or countries can be compared; for example, Table 28-3 compares patterns of use of narcotic analgesics in different countries, helping identify countries where potential overuse or underuse occurs. Because the comparison does not indicate which diseases medicines are being used to treat or in what dosages they are prescribed, these comparisons are inexact. Nonetheless, these analyses can be used to identify important medicine-use issues.

The use of appropriate denominators is important in interpreting analyses of aggregate data. Often the information sought is not how much of a medicine was used overall but how much was used per person, per visit, or

Table 28-3 Average medical consumption of narcotic medicines in Arab countries compared with three Western nations, 1996–2000 (DDDs/day/million inhabitants)

Country	Morphine	Fentanyl	Pethidine	Oxycodone	Codeine	Other	Average/ year	Cancer mortality/ million inhabitants
Syria	6	10	8		285	2,998 (Dextro)	3,307	61
Iran	19	8	4		1,051		1,082	481
United Arab Emirates	58	25	22		475		580	347
Lebanon	91	56	17		136		300	583
Bahrain	70	20	44		7		141	340
Egypt	12	3	5		46	46 (Dihydrocod)	112	205
Kuwait	38	18	37		12		105	227
Saudi Arabia	50	31	16	1	1	1 (Dextro)	100	411
Oman	39	12	19				70	316
Qatar	22	18	21			5 (Dihydrocod)	66	316
Jordan	27	14	25				66	389
Iraq	3	1	5				9	374
Yemen	1	0	1				2	402
United States	2,641	1,952	180	3,118	12	4,213 (Dextro)[a]	8,258	2,016
United Kingdom	1,860	930	53	21	13	9,347 (Dextro)[a]	2,901	2,612
Finland	736	895	13	525	137		2,307	19,63

Source: H. Enlund and L. Matowe, unpublished data.

Note: DDDs used in the calculations: morphine 30 mg, fentanyl 0.6 mg, pethidine 400 mg, oxycodone 30 mg, codeine 200 mg, dihydrocodeine 100 mg, dextropropoxyphene 250 mg.

[a] Consumption of exempt preparations (less than 135 mg/dosage unit).

per some other unit of analysis. The best denominator to use depends on the purpose of the analysis and the availability of data. Generally, the closer one can get to the population of concern, the better. For example, suppose the objective is to compare the use of ORS in one geographic area with its use in another area. One way would be to calculate packets of ORS used per child under five in each community. Another way would be to express use as ORS packets used per child visiting a health facility with a diagnosis of diarrhea; this method would control in part for possible differences in diarrhea incidence. For DDDs, the denominator is often per day per million inhabitants, as in Table 28-3.

Reviewing case records

Useful information can be obtained from case records at hospitals or health care facilities. The audit process can start with either a disease or a medicine. Criteria are usually defined for correct and incorrect treatment of a disease or correct and incorrect use of a medicine. Then case records of patients with the specified disease or who have received the medicine are identified and reviewed, and the treatment of the disease is recorded and classified as correct or incorrect. The cost of the treatment can also be determined. When records are selected by medicine, the use of the medicine can be classified as correct or incorrect. For example, if watery diarrhea is the diagnosis selected for study, ORS may be the correct treatment in most situations. Antidiarrheals, antibiotics, and injections would be incorrect. If a medicine such as procaine penicillin is the study medicine, its use would be correct for tonsillitis, skin infections, otitis media, and pneumonia, but incorrect for parasitic infections such as worms or malaria. Country Study 28-1 discusses the use of case records to investigate prescribing for hypertension in a Nigerian tertiary-care facility. Computerized case records make the data extraction process much easier.

When large numbers of records are surveyed, descriptive statistics can be generated, including the average number

Country Study 28-1
Using case records to investigate treatment for hypertension in Nigeria

Researchers reviewed 200 randomly selected case records of patients attending an antihypertensive clinic at University College Hospital in Ibadan, Nigeria. A pretested data collection form was used to collect information including the patient's age; gender; hypertension diagnosis; coexisting diseases; blood pressure reading at first clinic visit and at the time of study; and current antihypertensive drugs prescribed, including dose, frequency of dosing, antihypertensive medicine combination, documented level of patient's adherence, and documented adverse reactions. The results showed that diuretics were the most frequently prescribed class of medicines and that three-quarters of the patients were on combination therapies—but not on combinations that are recommended in standardized guidelines. Consequently, only 34 percent of patients had adequately controlled hypertension.

Because patients pay out of pocket for their medicines, the researchers hypothesized that cost considerations may have influenced prescribing patterns. In addition, the case records showed that over 17 percent of the combination prescriptions included potentially harmful pharmaceutical interactions; for example, the combination of lisinopril and amiloride or hydrochlorothiazide raises the risk of severe hyperkalemia, particularly without monitoring of serum potassium levels.

This case record study identified poor compliance with treatment guidelines and poor patient adherence as issues to address in an intervention to improve treatment practices for hypertension. Qualitative studies, such as interviews with prescribers and patients, may have been able to provide further detail on the reasons for these prescribing patterns.

Sources: Yusuff and Balogun 2005a, 2005b.

of medicines per contact, the average cost, and the percentage of patients receiving injections, antibiotics, or antidiarrheals. These indicators can be analyzed by specific diseases. A computer is required for studies in which a large number of records is surveyed and analyzed. Commercial software is available to analyze data on medicine use from large databases, but such programs are usually expensive. Spreadsheet software, such as Excel, is often used to generate such statistics. These descriptive statistics can form the basis for interventions focused on specific disease management or medicine use problems.

Investigating medicine use in the private sector

In many countries, pharmaceuticals are mostly prescribed and used in the private sector. Lack of access to data about private-sector medicine use prevents managers and policy makers from addressing problems in this area. The main method of collecting data on private-sector practices is through surveys conducted among private medical practitioners and retail medicine sales outlets. An example would be asking private doctors and other health care practitioners who prescribe medicines to provide information about their own practices. Private practitioners are often willing to share information about their behavior if they feel the reasons for collecting the data do not threaten them or their business. Private marketing companies in many countries have long collected these kinds of data from private doctors for use by pharmaceutical manufacturers and distributors; however, reported behavior is often rather different from actual behavior.

Surveys to investigate medicine use can also target retail outlets such as pharmacies, licensed drug shops, over-the-counter medicine sellers, and market vendors. Studies in many countries have found that persons selling medicines are often willing to explain what they know, to discuss their business, to have their interactions with customers observed, and even to keep records of the medicines they sell. To receive this kind of cooperation, persons collecting data must carefully explain the reasons for a study, show medicine sellers how they or their customers might benefit, and assure them of confidentiality. The *Community Drug Management for Childhood Illness: Assessment Manual* (Nachbar et al. 2003) includes techniques for assessing medicine use in retail outlets.

Many different methods can be used to collect quantitative data in retail pharmacy establishments. Some methods and the types of information they are best suited to collect include—

- Interviews with pharmacists or counter attendants to provide data about sales activity, knowledge and sources of information about medicines or clinical issues, and advising and sales practices
- Surveys of pharmaceuticals stocked or sold to measure product availability, retail cost, and sales volume
- Surveys of prescriptions received to describe the patterns of private-sector prescribing
- Observation of interactions with customers to examine customer demand, reasons for product selection, frequency of purchase without prescription, and communication about pharmaceuticals

- Exit interviews with customers to investigate knowledge about illness and medicines, care-seeking behavior, expectations, satisfaction with services, and reasons for product selection

Because reported practice is often much better than actual practice, a method for studying retail medicine use that deserves special attention is the simulated patient survey, or mystery shopper. This survey consists of visits to a sample of retail outlets by investigators posing as customers with specific types of health problems, for example, mothers of children with diarrhea (see Figure 28-3). These investigators are trained to seek advice about treatment and to respond in a standard way to questions asked by the counter attendant. They usually buy whatever medicines are recommended to complete the transaction. After leaving the shop, they record details of questions asked about signs and symptoms; advice given about medicines sold; and other advice given about case management, prevention, or referral.

Investigating medicine use in the community

Surveys of health care facilities, private practitioners, or drug retail outlets furnish information about medication decisions for cases seen by providers, but these studies do not tell much about medicine use from the community perspective. For example, studies of providers tell nothing about situations where people choose not to treat an illness or about failure to use medicines because of lack of knowledge, economic or geographic constraints, or other factors. Similarly, these studies tell little about the dynamics of care-seeking, the use of multiple health providers, or the total pharmaceutical consumption in a community. Also, one cannot learn how patients actually consume the medicines they receive.

To learn about community medicine use, techniques must be used that differ from those already discussed. In the past, medical anthropologists or sociologists have carried out community medicine-use studies by using extensive ethnographic or participant observation methods. The WHO publication *How to Investigate the Use of Medicines by Consumers* (Hardon, Hodgkin, and Fresle 2004) describes a methodology that combines household interviews, surveys of pharmaceutical distribution channels such as health centers or pharmacies, and qualitative investigations using focus groups or in-depth interviews.

The core of any quantitative study of community medicine use is the cross-sectional household survey. The survey should include a minimum of 100 to 400 households, depending on the desired precision of the results and available resources. The sample of households is drawn so that all important groups in the community are represented. Different types of information can be collected from the households, depending on the purposes and duration of the survey. These include—

- Knowledge about medicines and illness, including sources of community information about medicines
- Reported care-seeking and medicine-use behavior in general or during specific episodes of illness
- Illness diaries, in which respondents record all episodes of perceived illness, the actions taken to deal with these problems, any medicines received for the illness, and how they took these medicines

Figure 28-3 What is reported in interviews may be very different from what is done in practice

- Pharmaceutical inventories to identify the type and source of all medicines present in the household
- Health care and pharmaceutical expenditures
- Adherence, including purchase of prescribed medicines and actual patterns of pharmaceutical consumption

A useful guide to conducting medicine-use assessments in the community is available through Management Sciences for Health (Nachbar et al. 2003). An example of how the assessment was used in Senegal is also available (Briggs, Nachbar, and Aupont 2003). Chapters 31 and 33 also discuss the importance of understanding community attitudes about medicine use.

28.4 Investigating the reasons for medicine-use problems: qualitative methods

The many factors that contribute to the irrational use of medicines are discussed in detail in Chapter 27. The best way to find out how factors such as knowledge, economic incentives, or attitudes and beliefs affect medicine use and to identify the most important constraints to changing specific behaviors is to use qualitative methods. These methods have been developed to investigate the causes of behavior and are helpful in identifying constraints to changes in behavior and opportunities for correcting the problem.

Quantitative methods are used to describe medicine-use patterns or to pinpoint specific problems that need attention, but they are usually not good for understanding why these patterns or problems exist. Qualitative techniques are better suited to examine the feelings, beliefs, attitudes, or motivations that underlie an observed problem. For example, focus group discussions with patients attending rural health facilities in Nepal revealed that patients felt they needed more medicines than they were prescribed or dispensed but said that they would be willing to accept advice from prescribers advocating fewer medications (Holloway et al. 2002).

Qualitative methods are based on talking to people at length and in depth or observing their behavior. When used in a formal way, these methods often involve highly trained interviewers or observers directed by an experienced researcher. Increasingly, managers and policy makers are using qualitative methods to rapidly assess the causes of a problem. Managers themselves do not necessarily need to know how to carry out qualitative research, but they do need to know what these methods are and when they may be useful.

Five useful techniques for collecting qualitative data on medicine use are focus group discussions, in-depth interviews, structured observation, questionnaires, and simulated patient surveys. These methods are outlined briefly in Figure 28-4, and their strengths and weaknesses are compared in Table 28-4. *How to Use Applied Qualitative Methods to Design Drug Use Interventions* (MSH/INRUD 1996) is a useful manual that provides more detail on qualitative methods.

28.5 Defining problems and designing interventions with medicine-use data

The best understanding of the origins of problems can often be obtained by using quantitative and qualitative methods together.

Defining problems and selecting interventions

The first step in improving medicine use is to measure existing practices and identify specific problems (see Figure 28-1). This step is usually done quantitatively, by carrying out an indicator study, for example. After narrowing attention to specific problems, one must identify why they occur—the motivations and constraints—and then suggest possible actions to address the problems. The objectives of this process are to—

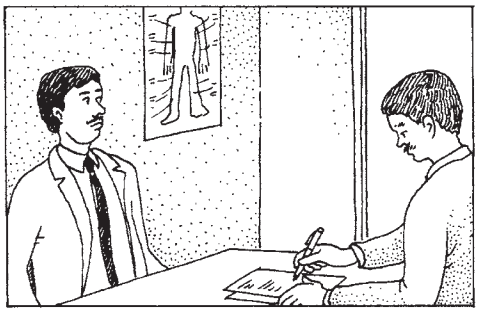
- Identify the problem and describe it in greater detail
- Choose an intervention to address the identified problem and evaluate its feasibility
- Target the proposed intervention to specific patients, providers, and behaviors
- Define intervention messages that can motivate changes in behavior
- Choose the most suitable format and activities to implement the intervention

Interventions implemented without gathering this information are more likely to fail. Explicit questions should be formulated to guide this process. The goal is to identify a practical strategy to change behavior. Only questions that can help in the design of an effective intervention should be asked. For example, imagine that a survey finds that 64 percent of patients treated in one district received injections, but that the percentage varies from 11 to 93 percent in the twenty facilities studied. Questions to be answered during the investigation process might include the following—

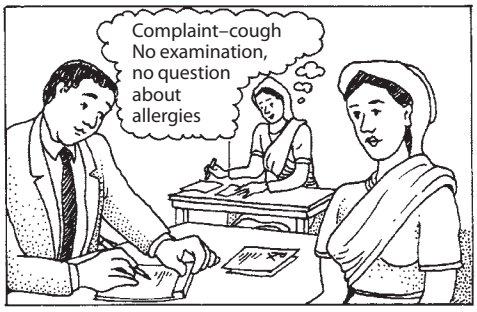
- Are injections given more frequently to adults or to children, and are they given more often for specific health problems? (greater detail)
- Do facilities with low and high injection use differ in number of staff, percentage of staff who are paramedics, patient volume, distance from the district center, or frequency of pharmaceutical stockouts? (greater detail, targeting)

Figure 28-4 Five useful qualitative methods

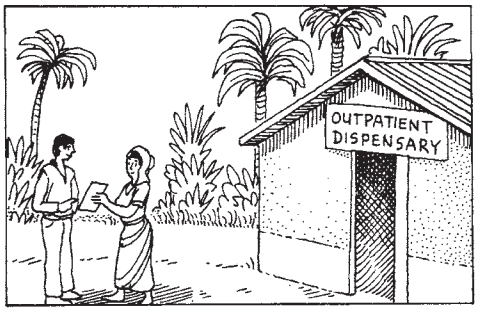
Focus group discussion
- 1.5- to 2-hour discussion
- guided by trained moderator
- group of 6 to 10 similar respondents (age, gender, social status)
- focus on defined list of topics
- informal setting
- reveals beliefs, opinions, motives



In-depth interview
- semistructured extended interview with respondent
- interviewer uses predefined open-ended questions
- usually covers 10 to 30 topics
- reveals attitudes, beliefs, knowledge



Structured observation
- systematic observation of verbal and nonverbal behavior
- usually patient-provider interactions
- trained observers use structured recording form
- assesses actual behavior



Questionnaire
- fixed set of standardized questions
- large sample of respondents
- respondents systematically selected to represent a larger population
- quantifies frequency of attitudes, beliefs, knowledge

Simulated patient survey
- someone (the "simulated patient") poses as a patient or a relative of a patient
- simulated patient seeks care for specific health problem
- questions, advice, actions of health care provider recorded after encounter
- assesses actual behavior in a standardized way

Table 28-4 Comparison of qualitative methods

Method	Key points	Strengths	Weaknesses
Focus group discussion	• Small; equal participation • Homogeneous; shared point of view • Informal; free interaction and open sharing of ideas • Recorded; analysis at later time possible	• Good at eliciting the beliefs and opinions of a group • Richness and depth • Easy and inexpensive to organize	• Need for skilled moderator • Beliefs and opinions expressed may not represent true feelings • Potential bias in analysis
In-depth interview	• Open-ended and in-depth questions • Targets key informants or opinion leaders • Five to ten interviews; enough to explore important issues • If target group is diverse, five to ten held with each subgroup	• Unexpected insights or new ideas • Creation of trust between interviewer and respondent • Less intrusive than questionnaire • Useful with nonliterate respondents	• Time-consuming compared to questionnaires • Data analysis can be difficult • Bias toward social acceptability • Need for well-trained interviewers
Structured observation	• Data can be coded indicators or scales, list of events or behaviors, or diaries • To count frequency of behaviors, at least thirty cases per group • To understand typical features, a few cases in five or six settings may be enough	• Best way to study provider-patient interactions, including patient demand, quality of communication, or interaction time • Opportunity to learn about provider behavior in its natural setting	• Threatening to those observed • Observers must spend enough time to "blend in" • Behavior may not be natural • Need for skilled, patient observers • Not useful for rare behaviors
Questionnaire	• Fixed or open-ended responses • Sample size depends on sampling method, desired accuracy, and available resources • At least fifty to seventy-five respondents from each subgroup	• Best method to study range of knowledge, beliefs, opinions, population characteristics • Familiar to managers and respondents • Required skills often locally available	• Attitudes difficult to quantify • Respondents may answer questions even if they do not apply • Results sensitive to specific questions and wording • Large surveys can be expensive
Simulated patient survey	• Details of the condition are standardized • Simulated patient purchases what is recommended • Each facility should be visited by at least five simulated patients • At least twenty facilities should be visited	• Useful to compare knowledge and practices • Identification of different practices for rich/poor, male/female, rural/urban	• Ethical issues • Need for simulators who can speak local language and are credible purchasers in the setting

- Do patients expect to receive injections, and do they tend to go to prescribers who give injections more frequently? (targeting, feasibility)
- Are health providers and patients aware that injections can transmit hepatitis and HIV/AIDS and that they can cause anaphylactic shock? (intervention messages)
- Are health providers and patients aware that injections may increase the overall cost of treatment? (intervention messages)
- How do prescribers react when they are shown data from the indicator study on their use of injections in relation to their peers? (intervention format and activities)

Asking focused questions keeps the process oriented toward intervention design. The optimal number of questions depends on how much is already known about the problem and the target group. Country Study 28-2 lists the questions that guided the diagnostic process in an educational intervention to improve diarrhea treatment by physicians in a city in southern Brazil.

After asking a set of specific questions, a manager or policy maker must choose quantitative and qualitative methods to answer them. As described earlier, each method has strengths and weaknesses. Often, the best approach is trying to answer the same question using different methods. For example, suppose one objective is to determine whether patients' demand for injections helps explain why they are given so frequently. One way to do this is to observe a sample of clinical encounters to see how many times patients indicate verbally or nonverbally that they prefer injections. Patients can also be interviewed to see if they are satisfied with their treatment or if they plan to go elsewhere to look for different treatment. Finally, in-depth interviews or focus group discussions with prescribers can explore their feelings about patient demand and their perceptions about whether it affects their practice.

Country Study 28-2
Improving diarrhea treatment in Pelotas, Brazil

A review of health center records in Pelotas, Brazil, found problems in treating diarrhea in children. Before launching an educational intervention for physicians to improve practices, the study team used patient exit interviews, in-depth interviews of physicians and patients, and observations of treatment episodes to answer questions in five areas.

Describing the problem in greater detail

- Are practices the same in facilities managed by the municipality, the university, and the state government?
- Is lack of correct knowledge about diarrhea or its treatment a common problem among physicians and patients?
- Does a lack of knowledge exist about the causes and correct diagnosis of diarrhea? About the need for ORS? About the dangers of specific antidiarrheals? About the efficacy of antibiotics or antiparasitics?
- How do physicians think other physicians manage diarrhea?

Deciding whether an intervention is feasible

- How much do patients' expectations influence physicians' treatment choices?
- How satisfied are patients with different kinds of treatment for diarrhea?
- How important is patients' satisfaction to physicians?
- Do physicians feel that patients are capable of learning about diarrhea and its treatments?
- Would physicians or other staff have time to counsel patients about diarrhea or other health problems?

Targeting the intervention

- How often do mothers ask directly for specific types of treatment?
- Do mothers influence physicians' decision making in nonverbal ways?
- How do physicians respond when asked for certain treatments?
- Do physicians feel a group identity with colleagues at the health center?
- To which respected peers do physicians turn with questions about treatment?
- How often do physicians approach colleagues with medical questions?

Defining specific intervention messages

- How important to physicians is the self-image of being a knowledgeable scientist or powerful healer?
- When physicians have changed their practices in the past, what has caused them to do so, and how do they feel about these changes?
- What do physicians think about prototype materials developed to promote correct diarrhea treatment practices?

Deciding on the format and style of the intervention

- How do physicians get information about new health problems or medicines?
- Do they ever attend continuing education sessions, and are these useful?
- Do they read any journals (which ones)?
- Do they learn about medicines from pharmaceutical package inserts, advertisements, or pharmaceutical company representatives, and is this information valued?
- How do physicians respond when presented with summaries of the practices of their health center in relation to similar facilities?
- How do physicians feel about different models for continuing education: group seminars, visits by medical experts, visits by pharmacists?

Designing interventions

Quantitative and qualitative methods address different or complementary questions whose answers can then be used to design interventions. Country Study 28-3 shows how the managers of the Control of Diarrheal Diseases Program in the Kenya Ministry of Health used qualitative methods to design an intervention—questionnaires, a simulated patient survey, and focus groups—that explored the nature of problems in diarrhea treatment in private retail pharmacies. The results of these methods helped inform the design of an intervention to train pharmacy attendants in appropriately treating diarrhea. Using the combined results of these methods, program managers targeted printed materials and training messages that proved effective in changing pharmaceutical sales and patient counseling behavior.

The intervention design process can begin with a synthesis meeting of everyone involved in the investigation process. If not everyone at the meeting is familiar with the studies, the first activity should be to present separate reports on each one. Each report should briefly cover the specific study questions addressed, the methods used, the

results, and the conclusions. Written summaries of findings and tables or graphs should be distributed. Discussion of specific findings can take place after all the reports have been presented. Sometimes findings from two methods are complementary, but other times the results contradict each other. If the findings suggest important issues for discussion, these issues should be listed as they are raised and covered later in the integrated discussion.

After systematically answering all the questions, the meeting participants should have a solid idea about an intervention that might be effective. The specific behaviors to focus on will be more apparent, as will the specific target groups of prescribers or patients that are most likely to benefit from the intervention.

The synthesis meeting should then focus on designing an intervention. The process of synthesizing data to draw conclusions about intervention design can be difficult. Before attempting this synthesis, the group should be familiar with what is known from experience with the different intervention models and their relative effectiveness (see Chapter 29). Familiarization with these interventions will help facilitate effective implementation of new interventions.

Country Study 28-3
Assessing product availability and service quality in retail drug outlets in Uganda

As part of a program to introduce accredited drug shops in Uganda's Kibaale district, the East African Drug Sellers Initiative assessed the availability of medicines and services in retail drug shops in Kibaale and a control district, Mpigi, in 2008. The assessors used a combination of interviews with customers exiting the shops, mystery shoppers who pretended to need treatment for a child with fever, shop visits to determine medicine availability and prices for a list of tracer medicines, and household surveys to determine community health-seeking practices.

Thirty tracer medicines were available in 50 percent of the outlets in Mpigi and in 46 percent of the drug shops in Kibaale. Availability of individual medicines varied widely in each district; some medicines, such as paracetamol, were available in more than 90 percent of the drug shops, whereas other medicines, such as artemether/lumefantrine, were available in less than 10 percent of the facilities. Chloroquine tablets and sulfadoxine/pyrimethamine (SP) tablets were the most widely available antimalarial medicines, despite the change in antimalarial treatment policy to artemether/lumefantrine.

Data collectors interviewed customers as they left the shops to determine how much information they were given about the medicines dispensed. The upper table shows that most drug sellers asked about symptoms, but few gave any information on what danger signs to look for or when to seek care from a health professional.

In the mystery shopper component of the assessment, each data collector pretended to be the parent of a six-year-old child with symptoms of simple malaria. The lower table indicates the variety of treatments sold to the mystery shoppers.

Dispensing practices	Kibaale n = 16 (%)	Mpigi n = 20 (%)
Did the drug seller ask about the symptoms?	9 (56)	15 (75)
Did the drug seller ask about any other medicines the child may have taken?	5 (31)	8 (40)
Did the drug seller give instructions on how to take the medicines?	12 (31)	14 (70)
Did the drug seller give information on how to look for danger signs?	2 (13)	2 (10)
Did the drug seller recommend referral to a doctor or clinic?	1 (6)	0
Did the drug seller recommend referral to a doctor or clinic if danger signs arose?	1 (6)	3 (15)
Did the drug seller recommend returning if symptoms did not get better?	3 (19)	2 (10)

Medicines dispensed for malaria	Kibaale n =16	Mpigi n = 20
Amodiaquine	1	1
Amodiaquine and SP	0	1
Chloroquine	0	9
Chloroquine and SP	6	1
Paracetamol	0	2
Quinine	6	3
Quinine and SP	1	1
Referral	1	0
SP	1	2

The assessment will be repeated after an intervention combining dispenser training, supportive supervision, and government accreditation to measure changes in medicine availability and dispensing quality.

Source: East African Drug Seller Initiative/Management Sciences for Health, unpublished data.

28.6 Evaluating interventions

Evaluation is the process of collecting and analyzing information about the effectiveness and impact of an intervention. A more technical definition describes evaluation as attributing value to an intervention by gathering reliable and valid information about it in a systematic way and by making comparisons so more informed decisions can be made or causal relationships or general principles can be understood. Every policy maker or program manager wants to have an effective intervention—appropriate evaluations are necessary to determine the effect of specific interventions.

Selecting appropriate measures

Interventions should be evaluated by looking for both intended and unintended changes in specific outcomes. For all the outcomes of interest, indicators that are meaningful, reliable, and measurable must be selected. When choosing the most useful outcomes to measure, consider the following—

- Select the key behaviors targeted by the intervention and the most likely substitute behaviors.
- Select outcomes that can be clearly and explicitly defined.
- Select outcomes that can be reliably measured, preferably using routinely collected data.
- Focus on important outcomes rather than measuring all possible changes.
- Measure more than one dimension of success, especially if some changes are secondary—for example, changes in prescribing that follow changes in knowledge about specific medicines.

Steps to take when evaluating interventions

Techniques for evaluating interventions are covered in detail in other books, but every evaluation should include the four basic steps described below.

Step 1. Select the correct study unit. Because the behavior of patients and prescribers is affected by other people, the most appropriate study unit is often the health facility. If individual prescribers are chosen as the study unit, for example, the effect of their colleagues on their prescribing behavior may make attributing any observed changes to an intervention difficult. For interventions that involve changes in administrative procedures, a region or district may be used as the unit of study.

Step 2. If possible, randomly assign study units to intervention and comparison groups. An appropriate comparison group is the most important feature of a sound evaluation (see Figure 28-5). Random assignment of study units to intervention or comparison groups is not always possible. If it is not, choose a comparison group that is as similar as possible. In situations in which everyone will receive a particular intervention, early recipients may be compared with those who have not yet received the intervention.

Step 3. Measure outcomes before and after the intervention in both the intervention and the comparison groups. With at least two measurement points, both equality at baseline and changes in practice can be examined. Data must be collected in the same way in the comparison and intervention groups, because the process of being observed often causes changes in behavior.

Step 4. Measure effects over time. Short-term effects often disappear unless they are reinforced. To know whether an intervention really works, look at short- (one month), medium- (six months), and long-term (one year or more) effects.

Often, an appropriate comparison group cannot be identified. For example, a nationwide mass media campaign to reduce prescribing of antibiotics for common colds cannot suitably be controlled. When a control group cannot be found, interrupted time series analysis can be used to compare patterns of medicine-use before and after the intervention (see Figure 28-6).

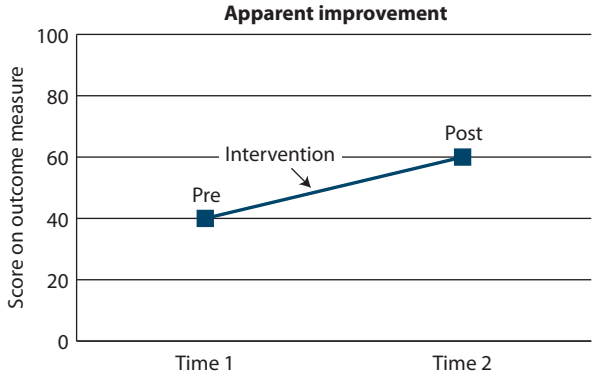
In time series analysis, each time point should represent an equal interval (for example, one week or one month). Ideally, at least three time points should precede the intervention and the same number of time points should follow the intervention to reliably determine underlying trends. Finally, investigators must examine any major changes that could have affected the outcome (for example, changes in personnel can affect prescribing patterns, making it difficult to attribute any effects to the intervention).

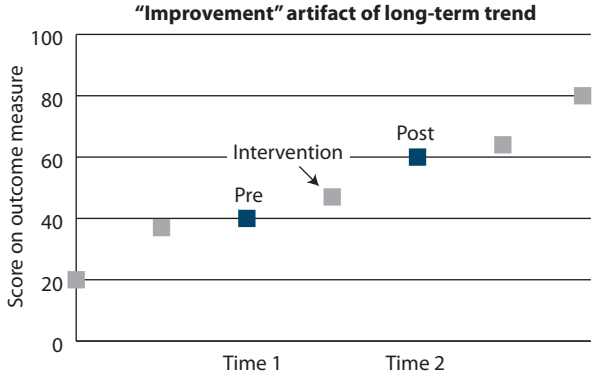
Relative effectiveness of different interventions

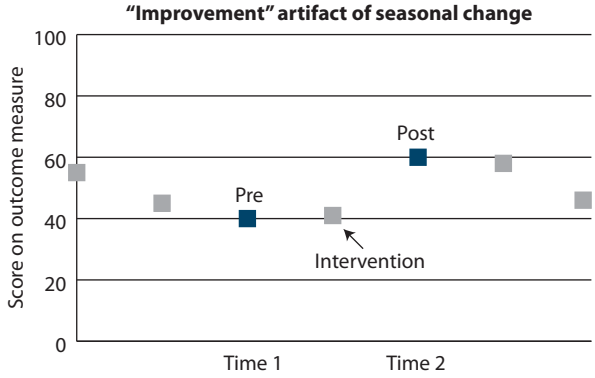
The effectiveness of different interventions depends on many factors, including the type of intervention, the setting, and the implementation process. Generally, interventions are most effective when they target specific problem behaviors. A training program discouraging polypharmacy as a general problem is less likely to have an effect than training that targets specific commonly overused medicines or specific health problems in which polypharmacy is common. Interventions can target several problems at once. For example, an intervention to improve pneumonia treatment might combine training for health care workers in how to use a standard ARI treatment protocol with community-based education about case recognition and care-seeking. Interventions can also have unintended outcomes, such as interventions addressing the overuse of injections that unintentionally cause a decrease in immunizations.

Figure 28-5 Importance of a comparison group

This figure shows an apparent improvement in outcome score from about 40 measured at Time 1 to more than 60 at Time 2. With information only from the group that received an intervention between these two times, it is tempting to conclude that the intervention caused the improvement in outcome scores.

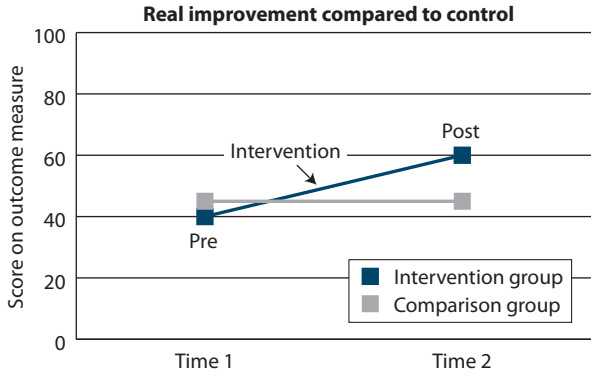






However, this conclusion can be misleading. The graph on the left shows that the intervention group has actually been experiencing a steady improvement in scores before, during, and after the intervention due to some external factor. On the right, the outcome seems to be seasonal, and it happened to be measured at a low point in the cycle at Time 1 and a high point at Time 2.

Only by using a comparison group can one guard against many possible incorrect conclusions about the effects of any intervention. Any reasons for change in outcomes outside of the intervention itself should affect both groups equally. Changes in the two groups can be compared to estimate the intervention's impacts.

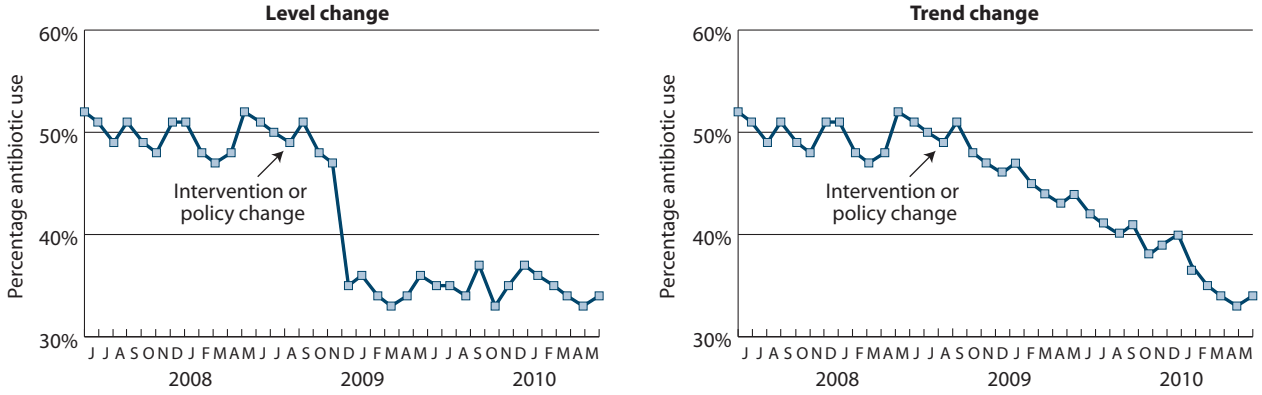


Research has shown that combining different types of interventions is more effective than using single interventions. However, multifaceted interventions tend to be more complex and may require more resources. Research has also shown that didactic lectures and passive distribution of educational material tend to have minimal effect, whereas supportive supervision and policy changes have been reported as generally effective. Chapters 27 and 29 describe examples of interventions to improve rational medicine use.

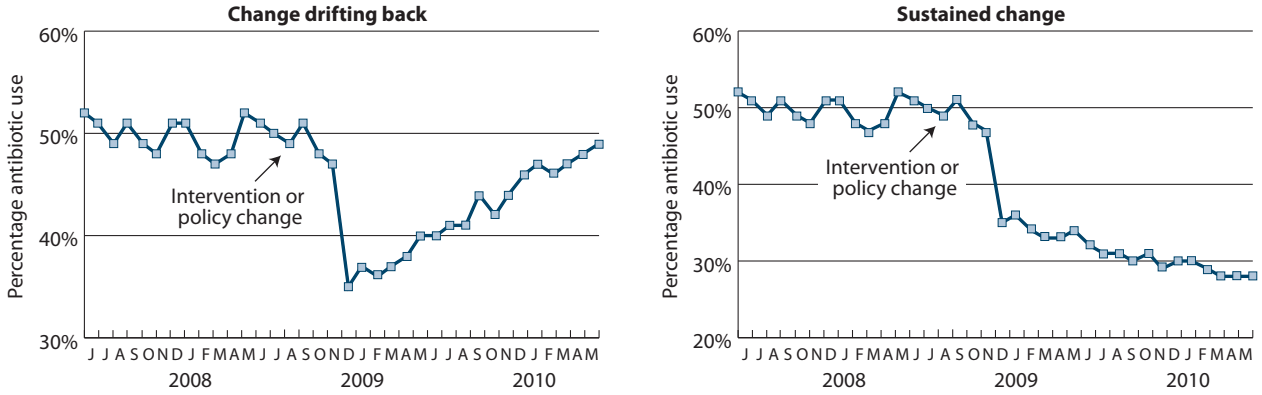
Researchers have used the techniques described in this chapter for many years. In a number of countries, managers of essential medicines programs have also used these methods to guide their decision making (see Country Study 28-4). The INRUD website has a searchable bibliography of more than 5,000 studies detailing the effect of various interventions to improve medicine use (http://www.inrud.org). Similarly, the website for the International Conferences on Improving Use of Medicines makes all conference presentations and abstracts accessible (http://www.icium.org). ■

Figure 28-6 Using interrupted time series

Time series are a powerful method for investigating medicine use. Data that are routinely collected in many health systems about the use of different types of medicines can easily be displayed as time series. It is also possible to look at patient-specific information on medicine treatment in sample medical records. In most cases, these series are made more stable by dividing by a meaningful denominator, such as rate per 100 attendances or proportion of total antibiotic expenditures.



The figure on the left shows a sudden reduction in the level of antibiotic use following an intervention. The figure on the right shows a reduction in the trend rather than a drop in the level.



Frequently there is a drift back to the previous baselines after an intervention, as shown in the figure on the left. In some cases, there may be a level change, which can be sustained or increased over time, as shown in the figure on the right. Time series techniques allow one to assess the individual and cumulative effects of interventions over time.

Country Study 28-4
Investigative surveys undertaken as part of national essential medicines program management

In Indonesia, multiple studies have been undertaken using aggregate consumption data, indicator studies, and intervention studies. These have been used to guide national programs and World Bank–supported regional activities.

In Kenya, an indicator study was undertaken in five regions as part of the overall planning management and evaluation of the essential medicines program.

In Malawi, a national medicine use indicator survey was undertaken in every district, covering seventy-two facilities, before national training on standard treatments.

In Nepal, simulated patient studies have been used to investigate practices of drug sellers to assist in designing training programs to improve their practices.

In Uganda, researchers studied the effect of training prior to redesign of training programs.

In Zambia, a study was performed in the capital in which different training methods were evaluated by detailed record review, using drug use review techniques.

In Zimbabwe, an indicator-based baseline survey was performed before the first national policy and planning workshop. This survey is repeated every two years, and it was expanded to include urban facilities and the private sector.

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ASSESSMENT GUIDE

When assessing a country's or program's capacity to investigate medicine use, two main issues should be considered—

- Results of previous studies
- Technical capacity to undertake medicine-use investigations

Previous studies

- Have any studies been performed on facility medicine use using the WHO/DAP manual *How to Investigate Drug Use in Health Facilities*? If yes, what were the results?
- Have any special studies been undertaken to investigate specific medicine-use problems (such as injection use)? If yes, what were the results?
- Have any routine surveys such as census or household surveys included questions on pharmaceutical expenditures or use?
- Are pharmaceutical consumption data easily available for the public or private sector?
- What are the prevalent attitudes that will have a positive or negative effect on the use of health services and medicines?

Technical capacity

- Are any experienced researchers involved in studying medicine use or health-seeking behaviors?
- Can local experts assist in quantitative or qualitative surveys?
- Is a unit within the ministry of health dedicated to health systems research?
- Do the medical or pharmacy training schools undertake field research or offer student training in the field?
- What types of records are available in the public and private sectors that would facilitate research on medicine use?