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CHAPTER 36

Pharmaceutical supply systems assessment

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SUMMARY

Pharmaceutical system assessments are useful to diagnose problems, plan major projects and interventions, monitor progress, and compare the performance of one system with that of another. Recent years have seen a growth in demand for such assessments because of the Global Fund to Fight AIDS, Tuberculosis and Malaria's policy to conduct procurement and supply management (PSM) assessments as a grant condition.

To produce useful results, all assessments should be structured. Two approaches may be useful—

- Comprehensive structured assessment, which generally involves a full-time, dedicated team using structured survey instruments to gather data through site visits, but may be done as a self-assessment exercise by managers
- Limited assessment, which uses interviews and document reviews

Four major categories of issues should be addressed in a comprehensive pharmaceutical sector assessment—

1. The functionality of the entire pharmaceutical system
2. The capacity of the private sector
3. “Political mapping” to understand the important actors and their attitudes and the feasibility of successfully implementing changes in the pharmaceutical system

4. Total operating costs of the existing pharmaceutical system and projected costs of potential alternative options

Special-purpose assessments, such as the Global Fund's PSM reviews, may be more limited in scope.

Specific information objectives should be set in advance, incorporating quantitative as well as qualitative data, performance indicators, and special-purpose analyses. The most important methods for collecting information are likely to be document review, key informant interviews, collection of data from existing records, and prospective observation.

Key issues in planning and managing the assessment are listed in this chapter, but readers should obtain one or more of the manuals mentioned throughout the chapter and in References and Further Readings for full details on organizing and conducting an assessment. When the data are in hand, they must be analyzed efficiently, and a user-friendly report should be produced, supplemented by presentations using graphic aids to help key decision makers absorb the findings. The assessment results must be used in developing new policies and procedures for the pharmaceutical system; otherwise, the process is a waste of resources.

36.1 Reasons for assessing pharmaceutical systems

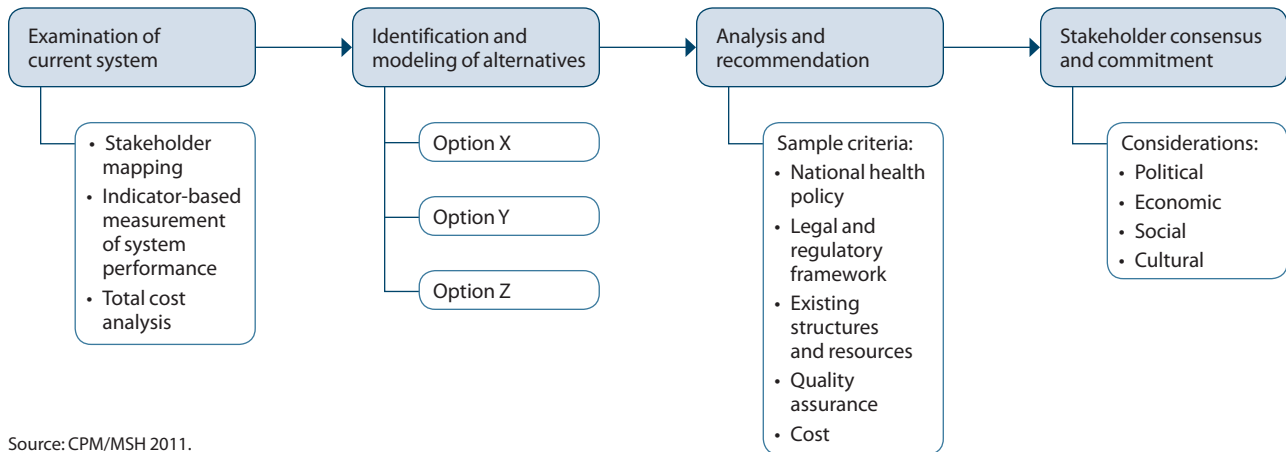
High-level commitment to pharmaceutical sector improvements can be stimulated by discontent among health staff and the public about medicine shortages, concern in the ministry of finance about rising pharmaceutical expenditures, or publicity about poor pharmaceutical quality. Too often, however, the pressure resulting from this commitment leads to hasty assessments and inadequately developed plans for change. Sustainable improvements in the pharmaceutical sector depend on high-level national commitment to improvement, technically sound plans based on an accurate situation assessment, and the technical and financial resources to implement proposed changes.

This chapter proposes comprehensive structured assessments for accurately diagnosing problems in the pharmaceutical supply system, identifying their root causes, prioritizing the problems, analyzing options to determine feasible interventions, developing short- and long-term action plans, and providing indicators for monitoring

progress. When a comprehensive structured assessment is carried out with full government commitment by an appropriate expert team (local or international), it enables the government to formulate a sound strategy for improving access, rational medicine use, and medicine quality. Figure 36-1 illustrates an options analysis framework.

A comprehensive assessment can be an invaluable input to the development of a national medicine policy (Chapter 4) or a strategic plan for pharmaceutical sector development (Chapter 38). It also provides government officials with a basis for coordinating donor involvement (see Chapter 14). Assessments may be required as a condition precedent for grants or other types of donor support, such as the PSM assessments that the Global Fund requires. The assessments discussed in this chapter do not take the place of an ongoing monitoring program (Chapter 48) or a management information system that tracks and reports on performance (Chapter 49). When good management information systems and monitoring programs are in place, the need for special-purpose assessment decreases, as does the effort and expense required to carry out an assessment when one is indicated.

Figure 36-1 Options analysis framework



Source: CPM/MSH 2011.

Proposals for pharmaceutical sector assessments sometimes meet with resistance. Decision makers may believe that action is needed instead of another study. Managers may think they already know the nature and causes of problems. Government officials responsible for donor coordination may be weary from the seemingly innumerable visits from representatives of donors and technical assistance organizations who ask the same questions but leave little behind. And some donors may prefer action to research.

In such situations, the general nature of the problems may be evident, but the true causes are often not so clearly known, and the full range of solutions that could produce sustainable improvements has not been considered. An assessment is needed—but an assessment of a different nature from those previously experienced.

Accurate systematic assessment is a prerequisite for planning changes in the pharmaceutical sector and, in particular, in the pharmaceutical supply system. Pharmaceutical sector assessments can serve any of four main purposes—

- Diagnosing emergent problems in the system and analyzing options
- Planning a project or formulating a pharmaceutical policy
- Monitoring change in the pharmaceutical system
- Comparing the performance of the supply system with that of other systems

Diagnosing emergent problems and analyzing options

Accurate diagnosis and action are urgently needed when major problems exist: medicines are out of stock in the rural health facilities, patients and politicians are complaining, and money is short. The assessment in such cases must be

done quickly, but it still needs to yield a thorough understanding of where the various subcomponents in the pharmaceutical system are functioning and where they are not, what factors are involved, and what sorts of interventions might be feasible and effective to address the problems. Country Study 36-1 shows how a rapid assessment approach was applied to help countries under pressure to scale up HIV/AIDS services analyze their pharmaceutical management situations and options.

Planning pharmaceutical management projects and formulating policies

Systematic assessments should be done before all major pharmaceutical management projects and certainly as part of the process of developing a national medicine policy (or making any significant legal or policy changes related to pharmaceuticals). In addition, the Global Fund requires grantees to develop PSM plans as a condition for funding. When a project is being planned, the preproject assessment should define precisely the problems to be addressed, the interventions and expected outcomes, and the resource requirements in terms of capital, equipment, infrastructure improvements, recurrent expenditures, and technical assistance.

Monitoring changes

After an intervention is undertaken or a policy put into place, it should be assessed periodically to measure progress toward achieving objectives and to determine whether strategy changes are warranted. At the end of the project, another assessment should look at process and outcome to determine the extent of change in the system, whether the reforms appear to be sustainable, and whether additional inputs are needed.

Country Study 36-1**Assessing pharmaceutical and commodity management for VCT, PMTCT, and ART programs: Ethiopia, Namibia, and Rwanda**

With the increased focus of governments and donors to effectively scale up HIV/AIDS-related programs at the national level, supply systems for voluntary counseling and testing (VCT), prevention of mother-to-child transmission (PMTCT) of HIV, and antiretroviral therapy (ART) programs must work effectively. Governments and donors need to identify specific intervention options that will promote better commodity management practices among the VCT, PMTCT, and ART programs they support.

The Rational Pharmaceutical Management (RPM) project of Management Sciences for Health developed a rapid assessment approach for pharmaceutical management systems that identifies areas of improvement and provides intervention options for government agencies and donors to guide the scale-up of HIV/AIDS programs. Two phases result in a set of findings and recommended options for strengthening pharmaceutical and commodity management of HIV/AIDS services.

Phase 1: Situational diagnosis

- A country team gathers background information and reviews country data, reports, and strategic program plans for VCT, PMTCT, and ART.
- In-country, the team identifies local stakeholders' contributions to the pharmaceutical sector and maps the flow of medicines and commodities specifically for HIV/AIDS services, from the international level to the user level.
- Interviews are conducted with a variety of stakeholders, including government policy makers, pharmaceutical experts, central procurement units, central medical stores, donors, national AIDS commissions, stakeholders in the laboratory sector, pharmaceutical manufacturers (if any), pharmaceutical regulatory and professional agencies, private-sector wholesalers or distributors, and staff at service delivery sites.

Phase 1 provides critical information on the national policy and legal framework for pharmaceuticals. The assessment team looks at the availability of standard national treatment guidelines related to HIV/AIDS, staffing policies, quality assurance, distribution systems, inventory management and control procedures, availability of essential products, national practices for rational medicine use, and monitoring and evaluation systems. This

phase culminates in the identification of key strengths and weaknesses of the overall pharmaceutical system, as well as potential areas for improvement related to HIV/AIDS services.

Phase 2: Options analysis

- Assessors use Phase 1 data to select study areas and indicators and to generate options analysis matrices.
- In collaboration with country counterparts and donors, the team chooses study sites.
- Data are collected in-country over a period of two to three weeks. Data collection addresses pharmaceutical management system weaknesses and improvement options related to staff capacity, infrastructure, product selection, procurement, distribution, medicine availability, storage conditions, inventory control and management practices, medicine use, and management information and reporting systems.
- After analysis and interpretation of findings, the team compiles a full report with all assessment findings and the feasibility of improvement options.
- Local stakeholders attend an options analysis workshop where results are presented, priorities are proposed, and options are selected. The options constitute the basis upon which RPM Plus prepares its developmental action plans for improving pharmaceutical management for VCT, PMTCT, and ART programs.

Ethiopia*Assessment findings*

Warehousing and distribution systems for PMTCT products at the central level were lacking. Pharmaceutical and laboratory structures at the facility level were limited in terms of space, storage, and handling capacity, thereby compromising product security and safety and patient confidentiality.

Assessment response

- Evaluated different options for the distribution of PMTCT supplies and started negotiations with PHARMID (a parastatal import and distribution company) to serve as a warehousing and distribution agent to PMTCT delivery sites.
- Conducted engineering and infrastructural assessments in more than ten target facilities and designed a renovation plan to ensure minimum operational

conditions. In five sites, renovations have been initiated to expand space, improve shelving, and ensure safety and security of PMTCT products.

- Developed standard operating procedures for the management of PMTCT supplies and providing training to pharmacy staff.

Namibia

Assessment findings

Inadequate capacity and information hampered procurement planning and quantification. Inventory control systems in the supply chain were weak.

Assessment response

- Developed and implemented systems to strengthen the procurement, storage, inventory control, and distribution functions of the central and regional medical stores
- Facilitated the quantification of rapid HIV test kits and antiretroviral drugs

- Developed standard operating procedures for pharmaceutical management for VCT, PMTCT, and ART programs in Namibia

Rwanda

Assessment findings

A lack of capacity existed to quantify and coordinate national needs for PMTCT and ART services.

Assessment response

- Facilitated links between the ministry of health, the central medical stores of Rwanda (CAMERWA), and VCT/PMTCT facilities
- Helped CAMERWA establish systems to collect data that will make quantification for procurement more accurate
- Developed standard operating procedures for VCT/PMTCT and ART sites to facilitate operation and scale-up

Source: MSH/RPM Plus 2004.

Comparing the performance of different systems

An assessment may be needed to compare the effectiveness of one pharmaceutical management system with that of others. For example, an assessment might address two vertical distribution systems (such as essential medicines and HIV/AIDS-related products in the ministry of health) to ascertain how well each is functioning and whether opportunities exist for integrating them. Or the goal might be to compare the strengths and weaknesses of the public and private pharmaceutical sectors to determine what potential exists for collaboration.

36.2 Structure of the assessment

Every pharmaceutical system assessment should have a formal structure; otherwise, any observations, conclusions, and recommendations are wholly subjective, and the opinion of one expert (or assessment team) may be radically different from that of another expert or team that has visited the same offices and talked to the same people. García-Núñez (1992, 49) stresses the need for structure in assessment and project evaluation: “A person who visits a project and conducts a casual assessment of project activities is not conducting an evaluation. He/she is merely making observations. Individual unsubstantiated assessments should not be used as tools for decision making. Evaluations have to be conducted according to specific guidelines and procedures. Without a recognized frame-

work from which to draw conclusions, evaluation results are not credible.”

Country Study 36-2 gives an example of an assessment using unstructured methods that failed to produce the necessary results; many others can be drawn from recent history around the world.

The primary questions to be answered when structuring a pharmaceutical system assessment are—

- What issues should be addressed in the assessment?
- What potential information sources exist?
- What information should be collected?
- What methods will be used to collect the information?
- What sort of team will do the assessment?
- What is the time frame and cost for the assessment?
- How will the study be managed?
- How will the results be presented for use by decision makers?

To fit the structure of the assessment to a specific purpose, many different combinations of answers might be appropriate. In some cases, the structure is defined and standardized by the funding agency. The rest of the chapter explores options that can be considered.

Prerequisites for assessment

Assessment approaches range from self-assessment by health system managers to assessment by a team of local

Country Study 36-2 Unstructured assessments

In one African country, several teams of international experts were given the responsibility of assessing the status of the public pharmaceutical supply system and quantifying resource needs for a World Bank loan. All the teams were experienced in the pharmaceutical management field, but none of the teams used a structured assessment approach—each team leader was free to develop his or her own methodology. The team responsible for identifying needs for equipment and infrastructure forgot to consider cold-chain equipment. Thus, the budget allocated for cold-chain equipment in the eventual project was a pure guess. The team assigned to evaluate treatment patterns and develop algorithms for morbidity-based quantification developed a treatment manual that was useless for quantification. Another team was assigned to look at the potential for private-sector collaboration in the public system; the team prepared a nice report on the issues that might be assessed but did not actually do the assessment. When decisions had to be made concerning what type of logistics system would be supported, no data were available on private-sector capacity. This gap was still in evidence five years later, when the country and the World Bank were again trying to figure out a way to salvage a viable pharmaceutical system.

experts to assessment by a full-time team of local and external experts doing extensive site visits. The approach should be tailored to the scope of the assessment and the quantity of data and quality of analysis needed for decision support. Four prerequisites for success exist with any of the approaches discussed in this section—

- Government commitment to the process
- A qualified assessment team
- A clear definition of objectives and procedures
- An unbiased approach

Government commitment. For a systematic assessment to be successful in public-sector programs, government commitment and active involvement are essential. If the study team is denied access to essential data or if key informants are never available, producing useful results will be difficult. Even if a report is produced, the likelihood of fruitful follow-up is greatly reduced without active senior-level commitment to using the assessment results for making policy decisions and instituting strategies for improvement.

Top management support must be translated into allocating both human and financial resources by making sure that operations staff members cooperate with the assessment and that health system staff assigned to the assessment actually participate fully in the process. Project budgets should include funding for scheduled assessments or for particular projects, at least a baseline and endline assessment.

Qualified assessment team. The team doing the assessment must be familiar with the intricacies of pharmaceutical systems in general and the local pharmaceutical sector in particular. The team also must be familiar with national administrative structures, the national health system, and local development experience. The team principals must be motivated and qualified to collect and analyze data and present the results in an organized fashion. The team should receive training to ensure the accuracy and validity of data collection and analysis. Outside experts are not always essential, but they can supplement local expertise by offering experience in comparable countries, a broader view, and an independent perspective.

Clearly defined objectives and procedures. Various assessment approaches and methods are discussed here; all have their place, but no matter which combination of methods is used, the goals, procedures, data to be collected, scope of the study, participants, and time frame should be clearly defined before the assessment begins. Once established, the structure should be followed within the bounds of normal constraints.

The assessment should be tailored to fit the purpose. The assessment may be broad in scope, to design a major essential medicines project, or it might have a limited focus, such as determining how many vehicles are needed for pharmaceutical distribution in a single region. Even in the latter example, the assessment should be structured broadly enough so that all potential options are identified (including contracts with the private sector).

The team should have a plan on how to analyze the data collected and how the assessment results will be presented to decision makers as well as disseminated to other stakeholders.

Unbiased approach. The assessment should be undertaken without preconceived notions as to what the findings will or should be. When a total lack of bias is not possible, all parties to the study should clearly understand what preconceptions exist.

A biased assessment may not identify the real causes of problems or consider all options for solution. For example, if an assessment is begun with the premise that all pharmaceutical services in the health system must be provided by government, it will probably overlook or downplay the potential for private-sector and nongovernmental organization (NGO) participation.

Assessment approaches

The two most common approaches to pharmaceutical system assessment are comprehensive structured assessment and limited assessment.

Comprehensive structured assessment. A comprehensive structured assessment gathers information from all levels of the pharmaceutical system. A specific team is responsible for making field visits to offices, warehouses, and health facilities and gathering multiple types of information through document review, interviews, data collection from records, and prospective observation. Preprinted survey instruments are used to collect data, which helps

ensure that a standard set of information is collected at each field site.

The survey instruments are structured questionnaires and data collection forms; they may be designed for a specific assessment or adapted from manuals (see for example, MSH/RPM 1995, WHO 2007). This type of assessment is often done as a rapid, intensive exercise by a full-time, dedicated team in cooperation with pharmaceutical system counterparts, but it can also be done as a self-assessment exercise by managers in the health system.

Limited assessment. Limited assessments rely primarily on interviews and document review, with limited field visits and little if any primary data collection from records or

Country Study 36-3 Developing and testing a procurement system assessment in India

In 2008, the Indian government recognized that agencies procuring health commodities for central and state health projects lacked consistent practice standards. To improve states' efficiency in procuring health commodities for public and World Bank projects, MSH's Center for Pharmaceutical Management (CPM) developed a tool incorporating international best-practice standards to serve as a basis for identifying strengths and weaknesses of procurement agencies or departments. CPM piloted the assessment tool at the Tamil Nadu Medical Services Corporation (TNMSC), which procures for both government- and World Bank-sponsored programs.

The specific assessment tool modules included the following—

- General requirements
 - Physical resources
 - Organization, structure, and functions
- Transparency
- Procurement cycle management
 - Bidding documents
 - Pre- and postqualification of suppliers
 - Advertisement and sale of bid document
 - Communication during the bidding process
 - Receipt of bids and bid opening
 - Bid evaluation
 - Contract award
 - Contract administration
- Support and control systems (audit)
- Record keeping
- Human resources and personnel
- General risk assessment
- Private-sector supplier assessment

The tool format included columns for standards, compliance rating (range of zero for noncompliant to three for fully compliant), assessor observations and comments, and instructions for the assessor.

Five important points were kept in mind when conducting the assessment—

1. The correct composition of the assessment team is critical.
2. Advance communication is necessary.
3. Assessment is an iterative process—not just the physical application of the tool.
4. Willingness of the agency to share the information and introduce improvement is a must.
5. The assessment tool must remain dynamic.

The TNMSC did not meet the minimum total combined score for each of the assessment modules that was required to immediately start national or international procurements. A thorough analysis revealed that the TNMSC had significant weaknesses pertaining to transparency, record keeping, information technology, and quality assurance, but at the same time, it exhibited many strengths, including the capability to follow World Bank guidelines for procuring nonpharmaceutical commodities. The assessment team debriefed TNMSC management and discussed the broader strengths and weaknesses. The TNMSC team stated its readiness to close gaps identified by the assessment and adhere to guidelines for World Bank procurements.

For more information on the assessment or to receive a copy of the tool, contact cpm@msh.org.

Source: Heltzer, Shrivastav, and Clark 2008.

prospective observation. The assessment may be done by a small dedicated team or by a working group from the pharmaceutical system. The assessment normally has a scope of work and should follow a predefined assessment plan; however, because the scope is constrained and time is not needed to prepare and validate survey instruments, a limited assessment can usually be completed more quickly and less expensively than a comprehensive structured assessment. Country Study 36-3 describes a limited assessment of the pharmaceutical procurement system in India.

In some cases, a limited assessment obtains a great deal of information; the constraint is that the information tends to be whatever is provided by the officials interviewed. When a structured survey instrument is not used, the quantity and type of data obtained may not be consistent from site to site, which may hamper efforts to compile a valid picture of the whole system. The self-assessment option requires less incremental funding, but the usefulness of the results will depend on the willingness of officials to document and report problems.

Time frame and assessment costs

The financial and human resources required for an assessment obviously depend primarily on the assessment approach. A locally managed self-assessment can be done in two or three months at low incremental cost, although a few thousand dollars (or the equivalent) would probably be needed to cover travel costs, meeting expenses, forms, and communication costs.

A typical limited assessment involves two to six person-weeks for site visits, plus another person-week or so to develop a report (Box 36-1 shows an example of an assessment timetable used in Rajasthan, India). Costs depend on how many experts are involved, but an average might be 25,000 U.S. dollars (USD) to USD 50,000 to cover all costs.

Time requirements and costs for a comprehensive structured assessment vary considerably, according to the number of levels in the pharmaceutical system and the size of the country. An experienced two-person team of experts might be able to manage a structured field-visit survey of public-sector pharmaceutical programs in a small country with three weeks on site, one week beforehand for preparation, and two to three weeks after for analysis and report writing. This schedule assumes that local officials and counterparts are active supporters and participants and that the health system has no more than three levels to be covered: central, provincial, and district. In the same country, one more experienced person plus a counterpart would be needed to cover the private sector in detail, and an additional person would be needed if the public-sector system had more levels.

Larger countries and more complex pharmaceutical systems require more effort for a thorough assessment; this effort can be managed by adding more team members or more field time for existing members, but in any case, costs will increase because of the logistics of sending data collectors to multiple districts across a large country. If the principal assessment team includes international experts, which costs more, the total cost of a comprehensive struc-

Box 36-1 Sample pharmaceutical assessment timetable

April 23 (Monday) a.m.	Assessment team arrives in Jaipur
April 23 p.m.	Meet with local NGO partner to discuss selection of districts and sample size
April 24	Adapt data collection forms and develop tracer drug list
April 25–27	Train field investigators and adapt questionnaires
April 26	Pilot instruments and make final adaptation of questionnaires
April 27	Photocopy and translate final data collection forms into Hindi
April 28 a.m.	Distribute forms and final instructions; review timetable for data collection in each district
April 28 p.m.	Field investigators leave for field
April 29–30	Data collection starts
May 1–4	Quality control teams leave for field
May 4–14	Use data collection forms at Jaipur SMS Hospital (state hospital and tertiary referral center)
May 14–15	Data collection complete
May 15–18	Input data and analyze

Source: CPM 2003e.

tured assessment of all sectors of a pharmaceutical system in a medium-sized country may still cost up to USD 250,000. Costs can be reduced by contracting with local companies for elements such as data entry, although a large-scale assessment is still going to be an expensive exercise. Nevertheless, a project or development loan to be based on the assessment might be worth tens of millions of dollars, making the expense worthwhile.

If only government budgetary resources are available, mounting a comprehensive structured assessment with external consultants may not be practical. However, multi-lateral or bilateral agencies may be prepared to support the assessment (and possibly provide experts). For example, the U.S. Agency for International Development (USAID) recognized the need for a comprehensive pharmaceutical assessment and options analysis in Uganda to frame its activities for a new system-strengthening project. Even if no donors are prepared to provide financial support or experts, advice and information may be available from international agencies such as the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF); however, people with expertise in the area need to be involved for the assessment to prove valuable.

36.3 Defining the scope of the assessment

The issues that should be addressed in an assessment depend on its purpose; the issues that can be realistically addressed depend on the availability of information, the capacities of the assessment team, and the time frame allowed to collect information (discussed in the previous section). Issues of importance to the pharmaceutical system fall into one of three general categories—

1. Functionality of the pharmaceutical system
2. Private-sector capacity, including faith-based and other NGOs
3. Political situation and attitudes of major players and interest groups in the pharmaceutical sector

Understanding and solving widespread problems in a pharmaceutical system require a broad assessment covering all three categories. If the assessment is looking at only one vertical program or one aspect of the system (for example, HIV/AIDS commodity management in mission hospitals, see Country Study 36-4), the scope will be narrower, but many of the issues discussed in this section still need to be considered, if on a smaller scale.

Functionality of the pharmaceutical system

A comprehensive pharmaceutical system assessment needs to look at several subcategories of functions. Historically,

assessments focused mainly on the public-sector system; however, an inclusive view of access to pharmaceuticals in a country should encompass a range of operations, such as manufacturing, wholesaling, retailing, and providing health care services in both the public and private sectors, and the relationship between the different sectors. The Strategies for Enhancing Access to Medicines (SEAM) Program conducted comprehensive pharmaceutical sector assessments in six countries that included the private sector (Country Study 36-5). The functions of a pharmaceutical system can be categorized in many ways; the following list is drawn mainly from the indicator manuals discussed in Section 36.4—

Policy, legislation, and regulation: Are policies, laws, and regulations consistent, comprehensive, and current? Are they enforced?

Budget and finance: What sources of funds are available? Are the funds adequate to purchase all necessary medicines and to manage the pharmaceutical system effectively? Are the funds that are available effectively managed?

Medicine selection: How are medicines selected for use in the system? Do consistent policies and procedures exist, or is the choice up to each purchaser and prescriber?

Pharmaceutical procurement: Does an effective procurement system exist that gets good prices and manages to purchase medicines in the quantities and time frame needed?

Pharmaceutical logistics and availability: Are medicines well managed at storage facilities and available at the points where they are needed? Are major losses caused by expiration or theft?

Geographic accessibility: Are the locations of pharmaceutical products and services close enough for the people who need them to get access?

Affordability: Can the health system afford to procure and distribute adequate supplies to provide access to target users? Are users able to pay for pharmaceutical products or services?

Medicine use: Do prescribers, dispensers, and patients use medicines rationally, or do major problems exist with irrational use?

Acceptability (or satisfaction): Do users find pharmaceutical products and services acceptable to them?

Product quality assurance: Are the products that are purchased and used in the supply system of good quality? Are quality assurance programs adequate to ensure good product quality?

System management: Are management procedures fully transparent with clear lines of accountability? (See Country Study 36-6.) Does each level of the system have adequate quantities of well-trained managers and operations-level staff? Are modern human resources

Country Study 36-4 Information targets for an assessment in Tanzania

The following list is an excerpt of information targets set for a structured field-visit assessment of five missionary hospitals in Tanzania in 2006; the goal of the assessment was to collect information on existing needs and gaps in HIV/AIDS commodity management to develop a plan of action for strengthening pharmaceutical management systems for HIV/AIDS commodities in the mission sector. The complete set of information targets (and the structured survey instruments used to collect the data) can be obtained from MSH's RPM Plus Program.

- *Policies and guidelines for HIV/AIDS services delivery:* availability and implementation of guidelines for prevention of mother-to-child transmission, voluntary counseling and testing, and clinical management of HIV and AIDS; health sector strategy for HIV/AIDS; national policy on HIV/AIDS
- *Capacity and training of human resources:* numbers of staff from different cadres dispensing anti-retrovirals (ARVs); number of staff trained in antiretroviral therapy commodity management; frequency of supportive supervision visits
- *Infrastructure supporting HIV/AIDS commodity management:* functionality of equipment (for example, refrigerator, dispensing trays, computers); availability of communications equipment (for example, telephone, fax machine, e-mail, Internet); number of burglar-proofed doors and windows; number of lockable cabinets; availability of cold room
- *Standard operating procedures (SOPs) that support HIV/AIDS commodity management:* availability and implementation of specific SOPs, such as requesting and ordering ARVs, medication use counseling for

ART, stock count discrepancy report for ARVs, disposal of ARVs

- *Supply procedures that support HIV/AIDS commodity management:* criteria used for medicine selection; pharmaceutical ordering process; data elements used to quantify needs; storage procedures for ARVs; procedures to manage medicine donations
- *Management information systems:* availability and use of records, such as ART Chart to Track the Expiry of ARV Drugs, Adverse Drug Reaction Form, Patient Log Book/Register; use of automated report systems (for example, computers, fax sheets, e-mail)
- *ART prescribing and dispensing practices:* number of reference books available in the pharmacy; adverse drug reaction monitoring and reporting system in place and functional for ARVs; mechanisms used to monitor ART adherence; adequate materials for labeling and packaging available
- *Monitoring and evaluation:* system in place for monitoring and evaluation at the pharmacy; list of indicators routinely tracked; percentage of ARVs whose physical count exactly match the records in the bin cards; current stock available and number of days that ARV medicines by type were out of stock during the last quarter
- *Commodity financing supporting HIV/AIDS services:* total budget of the hospital; percentage of budget spent on pharmaceuticals (current and previous three years); patient fees for any health service and how much

Source: Rutta, McCollum, and Mwakisu 2006.

management and training programs in place? Are salaries adequate to promote good performance?

Total operating costs: Do managers have information on the total costs associated with purchasing and inventory management needed to consider options for change in terms of their impact on total costs? (See Chapter 40.)

Monitoring and management information: Are effective monitoring programs in place at each level of the system? Does an effective management information system allow managers to track supplies and funds throughout the pharmaceutical system?

Assessment guides at the end of each chapter of this book contain suggestions about the information needed to answer these types of questions and, more important,

to understand why problems exist and what can be done about them.

When defining the scope of a particular assessment, one must determine what information will likely be available in that pharmaceutical system from government documents, records, and reports; from interviews with system managers and staff; and from officials in related government offices and ministries. If the assessment is to address the private sector in a meaningful way, a method is needed to obtain information about the current state of the private pharmaceutical sector—the current types and levels of service provided to clients in various parts of the country, the capacity for providing services to the public sector, the attitude toward public-private collaboration, and the constraints that would need to be resolved to establish a working

Country Study 36-5 Applying access indicators to the pharmaceutical sector in six countries

WHO and MSH organized a joint consultative meeting to identify an operational definition of access and propose testable indicators to measure it. Workshop participants developed a framework comprising seventeen key indicators to represent the four dimensions of access and the one cross-cutting characteristic. The SEAM Program used the framework to conduct an overall assessment of the pharmaceutical supply systems in six resource-limited countries: Brazil (State of Minas Gerais), Cambodia, El Salvador, Ghana, India (State of Rajasthan), and Tanzania. Local private, not-for-profit, and academic organizations collaborated in the adaptation of data collection instruments, sample selection, data collection, and analysis.

Select data came from public- and private-sector health care facilities—

- Public health facilities (clinics and hospital out-patient departments)
- Private not-for-profit clinics and hospitals (NGOs)
- Private for-profit facilities (hospitals and clinics)
- Private retail drug outlets (pharmacies, chemical sellers)

To gather data on these indicators, SEAM used prescription-dispensing records to measure the quality of medicine-dispensing activity from the previous year, interviewed patients as they exited facilities to gather information on their perceptions and experiences, and conducted an exercise where simulated patients went to private retail pharmacies and drug outlets to obtain information about the quality of the services provided. An example of the indicator results follows.

Sources: CPM 2003a, 2003b, 2003c, 2003d, 2003e, 2003f.

Prescribing indicators based on record review

Indicator	Ghana	Tanzania	Cambodia	El Salvador	Brazil	India ^a
Public facilities						
Average medicines per encounter	4.5	1.6	2.0	2.2	1.8	2.7
% by generic name	77	76	90	84	65	23
% on essential medicines list	70	NA	97	93	65	70
% antibiotics	56	41	56	33	18	45
% vitamins/tonics	NA	NA	37	31	0	9
Private, for-profit facilities						
Average medicines per encounter	4.7	1.8	3.8	2.2	1.8	3.2
% by generic name	63	66	42	57	26	11
% on essential medicines list	70	NA	58	70	49	63
% antibiotics	48	30	64	23	15	39
% vitamins/tonics	NA	NA	41	24	0	14
NGO facilities						
Average medicines per encounter	4.9	2.3	2.5	2.2	2.3	2.7
% by generic name	76	72	77	63	36	13
% on essential medicines list	66	NA	82	72	62	66
% antibiotics	52	20	51	28	25	40
% vitamins/tonics	NA	NA	30	31	2	12

NA = Data not available.

^a According to patient exit interviews.

Country Study 36-6**Pharmaceutical sector transparency assessments in four Asian countries**

WHO's Good Governance in Medicines initiative has created a tool for assessing the level of transparency in three functions of the public pharmaceutical sector—registration of pharmaceutical products, selection of essential medicines, and procurement. Assessors interview at least ten key informants for each function (at least thirty interviews for the country). The key informants, chosen using strict criteria, represent the public and private sectors, including civil society organizations.

When the interviews are complete, a rough quantification is used to characterize the level of transparency for each function—registration, selection and procurement—using a zero to ten scale. The interpretation represents the following degrees of vulnerability to corruption.

0.0–2.0	2.1–4.1	4.1–6.0	6.1–8.0	8.1–10.0
Extremely vulnerable	Very vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

WHO used this methodology to assess four Asian countries: the Lao People's Democratic Republic (Lao P.D.R.), Malaysia, the Philippines, and Thailand. The assessment

results showed that the four countries shared a number of strengths and weaknesses. For example, all four had information systems for the registration process of pharmaceutical products, an official national list of essential medicines, and SOPs for transparent procurement. A common weakness was the lack of a conflict of interest form or guidance for the members of committees responsible for registering pharmaceutical products or selecting essential medicines.

The following table lists the vulnerability scores calculated for the four assessment countries. WHO notes that the scoring indicates vulnerability to corruption based on procedures at the time of the survey and not that one country's system is more corrupt than another. The scoring system is meant to help countries monitor their progress in improving transparency and good governance practices. Assessment results will provide a starting point for countries to develop and implement a national strategy promoting good governance in regulation and procurement of medicines.

Source: WHO 2006.

Vulnerability scale scores in four-country assessment

Function	Lao P.D.R.	Malaysia	Philippines	Thailand
Registration	5.6 Moderate	6.8 Marginal	6.8 Marginal	7.0 Marginal
Selection	6.1 Marginal	5.7 Moderate	6.1 Marginal	8.0 Marginal
Procurement	6.9 Marginal	7.1 Marginal	8.5 Minimal	7.1 Marginal

relationship. Information access varies from country to country; access largely determines how detailed an assessment is feasible and sensible.

Private-sector capacity

Many countries are incorporating private-sector services into the public pharmaceutical system, particularly when problems in the public system seem intractable (Quick et al. 2005). Of course, private entities of all sorts—nongovernmental, faith based, for profit—operate in the pharmaceutical sector of any country, but the level of their intersection and relationship with the government vary. Any assessment that is done in the context of major problems in the public pharmaceutical system should investigate private-sector capacity and the potential for public-private collaboration

of the sort outlined in Chapter 8. Note that such assessments should encompass NGOs as well as the for-profit private sector.

The public sector may not have much reliable information on hand about the private sector, and establishing communication may be difficult if a history of mutual suspicion and hostility exists between the private and public sectors. For some countries, reports compiled by international companies that specialize in selling industry information can be obtained, but this information is expensive, not always detailed and current, and available for only a limited number of nonindustrialized countries. Most countries have associations that represent manufacturers, distributors, and pharmacies, but getting more than general information about the market and the member companies from these sources may be difficult.

Country Study 36-7

Data collection methodology for a pharmaceutical sector assessment in Tanzania

The Ministry of Health sponsored an assessment of the pharmaceutical sector in Tanzania to evaluate the situation in both public and private sectors and the viability of potential strategies for improving consumer access to essential medicines.

The pharmaceutical sector assessment, led by the Strategies to Enhance Access to Medicines (SEAM) Program, was based on two distinct sets of data collection efforts. First, a team of consultants worked with local counterparts to conduct key informant interviews, carry out site visits, and review documents (for example, policy documents, legislation and regulation relative to pharmaceuticals and public sector procurement, study reports, and financial reports).

Second, SEAM surveyed a sample of 104 facilities, including public, nongovernmental, and private hospitals; pharmacies; zonal medical stores; health centers; dispensaries; and *duka la dawa baridi*, or retail drugstores. The survey was conducted in six districts: Dodoma Urban, Njombe, Tanga Urban, Karagwe, Kilimanjaro Rural, and Masasi. Within each subsector, a representative sample included each relevant type of facility, focusing on outpatient care. Sampling issues for surveys were addressed and resolved in collaboration with local counterparts. Key issues considered included the existing information about the distribution of facilities and population, in particular the information's level of detail.

The following tasks were performed at each type of facility—

1. Public-sector facilities and private not-for-profit hospitals and clinics that also provide medicines to outpatients
 - Inspect and determine availability of a set of tracer essential medicines
 - Obtain prices charged for medicines (if relevant)
 - If possible, obtain prices paid by facility to its suppliers
 - Review inventory control record or bin card for tracer set of essential medicines

- Conduct interviews of relevant staff to fill in facility survey form
- Conduct patient or client exit interviews (minimum of ten patients)
- Review medical records or prescriber logs to collect prescribing data (thirty consultations)
- Obtain or purchase twenty units of a designated tracer essential medicine (for testing purposes)

2. Private for-profit hospitals and clinics

- Inspect or determine availability of a set of tracer essential medicines
- Obtain prices charged for medicines (if relevant)
- If possible, obtain prices paid by facility to its suppliers
- Review inventory control record or bin card for tracer set of essential medicines
- If possible, review medical records or prescriber logs to collect prescribing data (thirty consultations)
- Conduct interviews with relevant staff to fill in facility survey form
- Purchase twenty units of a designated tracer essential medicine (for testing purposes)

3. Private drug outlets (pharmacies and other types of drug outlets)

- Obtain a list of medicinal product names (brand or the manufacturer if generic) that are available for sale
- Determine availability of a set of tracer essential medicines
- Obtain prices for a set of tracer essential medicines; if possible, obtain prices paid by pharmacy or drug outlet to its suppliers
- Conduct questionnaire-based interview of drug outlet attendant
- Observe and record simulated patient or mystery client scenario
- Purchase twenty units of a designated tracer essential medicine (for testing purposes)

Source: CPM 2003f.

In most situations, the best option for assessing the private sector's capacity to play an increased role in the pharmaceutical system and contribute more to national medicine policy objectives is by conducting a special survey of the various components of the sector (including associations and their member companies). The SEAM

Program conducted detailed assessments of the private pharmaceutical sectors in six countries. Country Study 36-7 describes the methodology used in Tanzania; the other assessment reports describe the methodologies used in the other five countries (see <http://www.msh.org/seam>).

Political mapping

An assessment aimed at making significant changes in the pharmaceutical system needs to define the consequences of potential changes. The assessment should also determine which politically powerful individuals and groups are likely to support potential changes, which will be actively opposed to change, and which will be basically indifferent. This process, called political mapping, is also useful in evaluating the feasibility of successfully implementing options for change.

Defining the best sources of information to map interest groups, political feasibility, and attitudes is not always simple. In most countries, the assessment team will be able to assemble at least a rudimentary map of political issues; likely consequences of various options for change; supporters and opponents of change; and individuals, organizations, companies, and interest groups that are prominent in pharmaceutical management (public or private). Truly reliable political mapping requires the active cooperation of senior managers (or ex-managers) in the government who are knowledgeable about the various political issues and interest groups but who have no personal stake in the outcome of the assessment.

Political mapping is an essential component of pharmaceutical system assessment; for example, in most countries, the private pharmaceutical sector is hardly a monolith—often important differences in attitudes and interests exist between local and international manufacturers, manufacturers and distributors, chain and independent pharmacies, and so forth. As noted previously, NGOs are another part of the private sector that involves people with unique views, and the various NGOs active in the country are likely to have differences in interests and attitudes.

The mapping process, if done accurately, helps define the causes of problems in the pharmaceutical system, examine the likely consequences of various changes and interventions, and determine which options are feasible and sustainable. Brugha and Varvasovszky (2000) describe stakeholder analysis, and political mapping computer software called PolicyMaker is available to help organize and interpret information (<http://polimap.books.officelive.com>). Williams, Durrheim, and Shretta (2004) take a political mapping approach to decision making regarding malaria treatment policy.

36.4 Defining the information targets

When the issues to be addressed and the assessment approach and time frame have been determined, the next step is to define the specific set of qualitative and quantitative data targeted for collection. In many cases, these data are collected in the form of standard performance indicators and are later organized into tables that provide insight into the pharmaceutical system.

Quantitative and qualitative data

Quantitative data describe the what, where, and when of a situation—for example, the percentage of a list of essential medicines that is available in a sample of health facilities. Qualitative data provide insights into why and how the situation is as it is—for example, why key informants believe that essential medicines are not more widely available. Quantitative methods can be used to give precision to qualitative ideas. Therefore, qualitative research is often used initially to identify problems and define the scope of options and issues, whereas quantitative data can then define the magnitude of the problem and measure the changes over time. In-depth interviews, structured observation, and focus group discussions are qualitative methods that can be used to explore behavior, attitudes, practices, and causal factors. Some of the data collected by these methods may be quantified, but the analysis itself is a qualitative one.

Although a comprehensive assessment should include both qualitative and quantitative elements, collecting a valid sample of quantitative data from a widely varied sample can sometimes be more time consuming and involve more work than conducting a series of focused qualitative informant interviews (which are more informal than focus group discussions); therefore, many reports on country pharmaceutical systems contain very little quantitative data and many unsubstantiated observations from informants. When an assessment does not gather quantitative data for analysis and comparison, the magnitude of problems or how much a situation has changed over time is difficult to know. At the same time, qualitative information is essential to understanding quantitative data, the reasons that specific weaknesses and constraints exist, and what strategies might be effective in overcoming the problem.

As noted, a properly structured assessment gathers and interprets both quantitative and qualitative information; problems with imbalance usually result when an assessment has no formal structure. Chapter 28 discusses issues related to quantitative and qualitative data; for more information, see the starred entries in References and Further Readings.

Performance indicators

Performance indicators are standardized measurements that theoretically mean the same thing in every country; for that reason, they are widely used to compare the performance of different businesses, economies, and societies. A well-known set of indicators in international development is published annually by the World Bank in the *World Development Report*; the 1993 edition focused on health issues (World Bank 1993). In addition, the United Nations has drafted more than sixty indicators to measure progress toward the Millennium Development Goals, such as “the percentage of children under 5 years with fever being treated

Box 36-2**WHO pharmaceutical monitoring indicators for three levels of the pharmaceutical sector**

WHO has developed a core indicator package to monitor and evaluate country pharmaceutical situations. By repeating the assessment at regular intervals, WHO supports ministries of health in assessing the current pharmaceutical situation and giving them access to information that they can use to determine priority areas for intervention, track progress, plan programs, assess program effectiveness, coordinate donors and raise funds.

The core indicator package has three levels of assessment.

Level I: *The Questionnaire on Structures and Processes of Country Pharmaceutical Situation* measures structures and processes at the level of national governments, including policies, regulations, quality-control measures, essential medicines lists, supply systems, financing, access, production, rational use, and intellectual property rights legislation. WHO's plan is to distribute the questionnaire every four years to all member states. WHO uses this questionnaire to assess the global pharmaceutical situation, evaluate progress achieved toward goals set in the WHO Medicines Strategy, and make plans and set targets for WHO work for the next four years.

Level II: *The WHO Operational Package for Monitoring and Assessing Country Pharmaceutical Situations* is a practical and cost-efficient survey tool used by ministries of health to assess outcomes, including access, quality and safety, and rational use of essential medicines, at public health facilities and their pharmacies; central and district warehouses; or private, NGO, and mission pharmacies, as appropriate to country situation and households. The tool provides an evidence base for prioritizing health programs, developing and implementing plans, tracking progress, coordinating donors, and raising funds. More than forty member states have used this tool at least once to date.

Level III: A series of detailed survey packages to assess specific aspects of the pharmaceutical sector, such as medicine prices, the supply system, or traditional medicines. A country may implement a Level III survey to learn more about a specific area of the medicine sector after the results of the Level II survey have pointed to an area as needing more analysis.

Sources: WHO/TCM and DACP 2006; WHO 2007.

with antimalarial drugs" (see the indicator website at <http://unstats.un.org/unsd/mdg/Default.aspx>).

Performance indicators should be the foundation for ongoing monitoring in the pharmaceutical system (see Chapter 48) and should be a fundamental part of any pharmaceutical system assessment. Indicators to assess and monitor public pharmaceutical systems are a relatively recent development, and the optimal indicators to measure system performance have not been fully determined. WHO has developed pharmaceutical indicators to measure important aspects of a country's pharmaceutical situation at three different levels (see Box 36-2). Several other sets of performance indicators for pharmaceutical management systems have been developed; Box 36-3 discusses four of them and lists performance indicator resources and tools for specific public health programs.

Defining information targets for a specific assessment

Three principles guide the setting of information targets for a specific assessment—

- Get all the information needed for the purpose, within time limitations, but do not gather data that are un-

necessary (doing so wastes time and effort in two phases of the process—collection and analysis).

- Make sure that the data used in producing analyses and recommendations are as reliable as possible, and determine which data are likely to be reliable and which are not.
- Define information targets based on what is available, and do not try to collect information that is nonexistent or impossible to retrieve.

Country Study 36-4 shows some of the information targets for a pharmaceutical system assessment done in Tanzania in 2006.

36.5 Methods for collecting information

The basic methods of obtaining information in a pharmaceutical system assessment are—

- Document review
- Key informant interviews
- Collection of data from existing records
- Prospective studies

Box 36-3**Examples of indicators in pharmaceutical management**

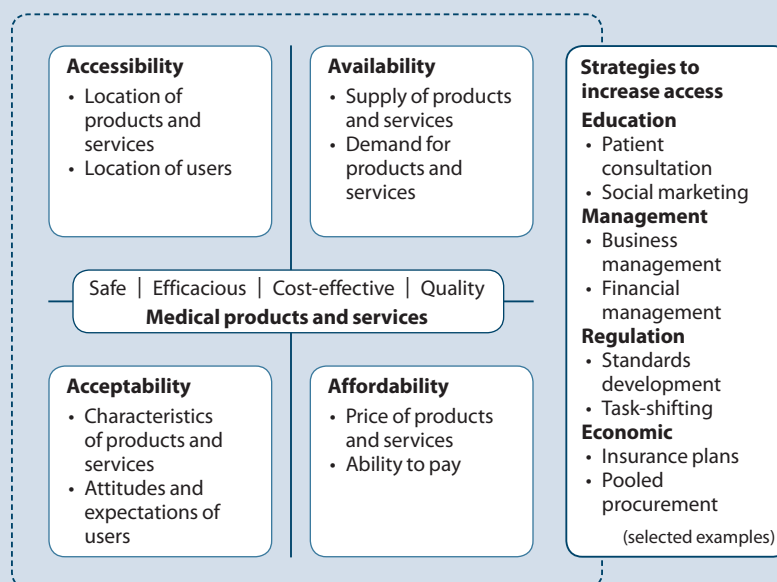
Working in collaboration with USAID, the International Network for the Rational Use of Drugs, the Harvard Drug Policy Research Group, and the Pan American Health Organization Essential Drugs Program, MSH's Drug Management Program developed and field-tested an initial list of thirty-three indicators plus methods for data collection in 1993. Under the auspices of the USAID-supported Rational Pharmaceutical Management project, this indicator set and manual were further tested and revised to include forty-six indicators for the rapid assessment of pharmaceutical systems. The manual that documents this rapid assessment method also provides practical guidelines for organizing and completing a structured field-visit assessment (MSH/RPM 1995).

In 1994, the WHO Action Programme on Essential Drugs published a manual that proposed a set of thirty-one background information indicators, fifty structural indicators, thirty-eight process indicators, and ten outcome indicators, primarily for countries to assess themselves on issues related to national medicine policy. The indicators were field-tested in twelve countries in 1995 and 1996. WHO published the second edition of the indicators in 1999 (Brudon, Rainhorn, and Reich 1999).

The Australian Department of Health and Ageing adapted the WHO indicator format to develop

pharmaceutical policy indicators focused on medicine use. The second edition of the indicator manual was published in 2004 (Quality Use of Medicines and Pharmacy Research Centre 2004). This set has sixty-seven process indicators, fifty-seven impact indicators, and six outcome indicators. The indicators are used to monitor the implementation and effect of Australia's National Strategy for Quality Use of Medicines.

WHO and MSH organized a joint consultative meeting to identify an operational definition of access and propose testable indicators to measure it. Four dimensions of access emerged as being of particular relevance to essential drugs, vaccines, and other health commodities—physical availability, affordability, geographic accessibility, and acceptability (or satisfaction). In addition, the quality of products and services was identified as a cross-cutting dimension. Workshop participants developed a set of seventeen key indicators to represent the four dimensions of access and the one cross-cutting characteristic (CPM 2003g). The SEAM Program used the resulting framework to conduct an overall assessment of the pharmaceutical supply systems in six resource-limited countries: Brazil (state of Minas Gerais), Cambodia, El Salvador, Ghana, India (state of Rajasthan), and Tanzania (<http://www.msh.org/seam>).

Increasing access framework

Source: CPM/MSH 2011.

Pharmaceutical system indicators and tools for specific public health programs

- *Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Programs* (http://www1.msh.org/projects/rpmplus/Documents/upload/Compendium_Indicators_ME_NTB_Programs.pdf)
- *Pharmaceutical Management for Tuberculosis Assessment Manual* (RPM Plus 2005)

- *Pharmaceutical Management for Malaria Manual* (RPM Plus 2004)
- *Drug Management for Childhood Illness Manual* (Keene et al. 2000)
- *Community Drug Management for Childhood Illness: Assessment Manual* (Nachbar et al. 2003)

Source: Rational Pharmaceutical Management Plus Program (<http://www.msh.org/rpmplus>).

This chapter summarizes these methods (see also Chapter 28; INRUD 1996, WHO 2007, MSH/RPM 1995).

Country Study 36-7 illustrates the methodology used to assess the public and private sectors of the pharmaceutical system in Tanzania.

Document review

Most countries have conducted studies of problems in the pharmaceutical sector and have made attempts to correct them. When donors have been involved in improving pharmaceutical services, many relevant reports are likely to exist. Government agencies can provide budget reports and, in many cases, files of technical reports by various agencies on the pharmaceutical sector. Contacting international agencies such as WHO, UNICEF, or the World Bank, bilateral donors, and technical assistance organizations to obtain copies of relevant documents is also useful.

A review of the literature should be one of the first steps in any assessment. Failure to include this important step inevitably results in a waste of time and money to regather data that are already available and reinvent analyses and recommendations that duplicate those already made. Worse, interventions that have been unsuccessful in the past may be tried again, with similar lack of success.

Key informant interviews

Interviews are one of the quickest ways to learn about urgent problems, if the assessment team is able to identify the people who are most knowledgeable about the situation and if these people are prepared to discuss the situation frankly. Interviews may be misleading, however, if the informants are not fully frank because of fear of retribution or if they have some vested interest in hiding or distorting information. Nevertheless, interviews are essential for insight into the political and administrative processes, which are major determinants of whether assessments will lead to real action.

Interviews may be conducted with or without structure. In the unstructured format, the interviewer relies on personal experience to ask relevant questions and to ensure that

important issues are not overlooked, which means the interviewer should be knowledgeable and well trained. In the structured approach, the interviewer uses a written survey form listing the important questions and the qualitative and quantitative information to be solicited.

Each format has advantages and disadvantages. The unstructured interview allows a free flow of conversation and may promote a more revealing interview, but it is subject to bias. Overlooking important issues is also easy when the interview is unstructured, and collating and analyzing responses from a series of such interviews are difficult, particularly if different interviewers are involved. The structured interview is usually more formal but is more likely to ensure that all important issues are addressed by each interviewer and that the responses are ordered in a manner that facilitates analysis. An interviewer using a structured format can combine both approaches by asking more probing questions to investigate an issue more thoroughly, but then return to the interview guide once the probing has finished.

Data collection from retrospective record review

A record review is a critical step in all structured assessments and should be done at each site where reasonably well-organized, complete, and current records exist. Where records are totally disorganized and badly out-of-date, the information gained may not be worth the effort, and other methods will be needed.

Relevant records include government publications on budgets and expenditures, drug regulatory inspection reports, patient medical records, pharmacy dispensing records, records of procurement and accounts payable to suppliers, warehouse ledgers, bin cards and computer records, and accounting and finance records. Private-sector records to review may include company financial reports, balance sheets, sales and stock data, and customs and import data.

Data collection by prospective field observation

When needed information cannot be obtained from a retrospective review of records, it may be possible to use

prospective observation to obtain the information. For example, one method of reviewing prescribing practices in a health facility is to examine clinical charts and dispensing records. If these records are not available, the team can observe patient encounters directly and record the prescribing in that manner (a patient exit survey).

Some types of data are best obtained by prospective methods. For example, to determine whether private pharmacies are selling prescription-only medicines without a prescription, the best method is a simulated purchase survey, where local data collectors visit a sample of pharmacies and actually attempt to purchase prescription medicines (see Boyce and Neale 2006b).

Other methods for collecting qualitative information

Other common methods for obtaining useful data include focus groups and household surveys, although both methods can be complex, technically demanding, and costly. These techniques, however, can be important tools in determining why attitudes and practices exist in one group or another (see Chapter 28), and sometimes they can be piggy-backed onto other household surveys or reports from previous efforts can be used, such as national demographic and health surveys (see <http://www.measuredhs.com>).

36.6 Planning and managing the assessment

The key issues in planning most assessments are—

- Defining the assessment approach
- Defining and locating financial resources
- Defining management and technical responsibilities
- Developing a draft workplan

After these issues are resolved, the assessment leader and the team develop a management plan. The plan must cover these issues—

- Making logistics arrangements
- Preparing a system overview
- Selecting sites to be visited
- Selecting indicator medicines
- Defining data collection methods
- Developing and refining data collection forms
- Selecting and training data collectors
- Revising the workplan to its final form

These issues are relevant to most comprehensive structured assessments, and they are covered in great detail in *Rapid Pharmaceutical Management Assessment* (MSH/RPM 1995) and the *WHO Operational Package for Assessing, Monitoring and Evaluating Country Pharmaceutical*

Situations (WHO 2007), which are available without charge. Any country or supply system that is planning a pharmaceutical assessment should get these manuals to aid in its planning and execution.

Given proper preparation, the actual data collection process may go relatively smoothly and produce reliable data for evaluation. However, one can safely assume that the assessment will not proceed entirely according to the workplan, no matter how well it was thought out. Minor frustrations will occur, such as unavailability of some key team members, weather-related delays for some site visits, and unexpected absence of key informants. These can be worked around, as long as the assessment team maintains its flexibility and sense of humor. Major problems such as widespread work stoppages can shut down the entire public health system and require postponement of the assessment, if it has not started, or interrupt the study until facilities reopen.

The following are vital issues to consider when analyzing situations and options—especially for fast-track assessments—

- Ability to quickly identify and mobilize the lead team of assessors, once a country need has been identified
- Continuity of the team throughout the different phases of the approach and their solid understanding of the methodology
- Experienced, knowledgeable assessors to facilitate interviews with national policy makers and officials, interpret policy data, and develop and analyze improvement options
- Full engagement of local stakeholders throughout the different implementation phases
- A logistics system to support scheduling, recruitment, and training of data collectors and then data entry and analysis

Data analysis

When a large amount of quantitative data is available on costs, purchases, medicine consumption, and use patterns, it must be organized to facilitate analysis. Chapter 40 is devoted to the issue of analyzing data to understand and control costs in the pharmaceutical supply system; most of the analytical techniques in that chapter can and should be incorporated into assessment information targets, if necessary data are available. Several other chapters offer suggestions for organizing data to facilitate analysis during an assessment (see Chapters 28, 48, and 49).

To avoid confusion and haste at the end of an assessment, one should collate and prepare assessment data for analysis as they are collected (see Chapter 48). If a computerized program such as Epi Info (see Chapter 50) or even an Excel spreadsheet is used for collating survey results, data should

ideally be entered at the end of each day by team members or a local data-entry person, or if teams are operating simultaneously in different parts of a country, then data should be collated at the end and entered into a system. Both team members and counterparts should play an active role in examining data that are recovered and considering what sorts of additional analyses may be appropriate beyond those prescribed in the assessment workplan.

Preparing the assessment report

Chapter 49 discusses how to interpret data from a pharmaceutical management information system. The issues are similar for interpreting results from assessments. No matter how well the assessment was designed, planned, and executed, the data obtained may not be totally reliable. Part of the job of the study team is to determine what sorts of biases, inaccuracies, or inconsistencies may exist and what precautions are necessary in interpreting the data. The report itself must be presented in a way that helps the decision makers who need to use the information; a clear outline and executive summary of not more than two pages, which includes a statement of the next steps, are important. The methodology and detailed results can be mentioned in the text and appended to keep the document concise for interested but nonspecialist readers.

Presentations and workshops

Many key decision makers may not have the time to read the whole report. Presentations and workshops are excellent ways to convey important results directly and may be useful before the final report is written, providing feedback for clarification. Charts and graphs are important visual aids to organize the presentation and ensure that key points are covered. Actual examples of graphic presentations of findings from a medicine use assessment are found in Chapter 28.

Using the assessment results

An assessment should be seen as only one of several steps involved in planning and implementing pharmaceutical system changes. The assessment may be part of the development process for a donor project proposal, a national pharmaceutical sector restructuring exercise, or a national five-year development plan.

If the assessment is leading to a donor project proposal, the assessment team should be aware of this goal from the outset. If possible, the prospective donor should contribute to the assessment design. As mentioned, some donors, such as the Global Fund, have standardized assessment protocols. To encourage a sense of involvement, the prospective donor might also be given an opportunity to participate at various

points in the assessment and report-writing process. The assessment team should be sure to collect all background information that may be needed. The content and format of the assessment should be compatible with what is needed for a project proposal. Depending on donor requirements, the assessment report may serve as a project proposal with little or no editing.

If the assessment is part of a national restructuring or planning exercise, key government officials must be involved from the beginning, as well as stakeholders from the private sector and the community. People are much more committed to implementing solutions that they have helped develop.

The whole assessment process will have been wasted if the report goes on a shelf and is not used to effect changes in policies and procedures. Follow-up may be tied to the development of national medicine policies, revisions in legislation and regulation, and consideration of public-private collaboration.

After the assessment is complete, a workshop to bring stakeholders together and work through the assessment results and related options will define next steps and stakeholder roles and responsibilities. The assessment results may suggest revised policies and procedures in pharmaceutical selection, procurement, distribution, and use. The assessment and subsequent stakeholder options workshop should guide the development of strategic plans for pharmaceutical systems (see Chapter 38) and monitoring programs, program planning, and management information systems. Country Study 36-8 looks at examples of how assessment results were used to address issues in pharmaceutical management for TB medicines in several countries. ■

References and further readings

★ = Key readings.

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Country Study 36-8

Using assessment results to improve TB pharmaceutical management in three countries

The RPM Plus Program's indicator-based *Pharmaceutical Management for Tuberculosis Assessment Manual* (PMTB) helps users, primarily national tuberculosis (TB) programs, conduct studies that—

- Provide data on TB pharmaceutical management practices
- Identify ways to improve the national TB pharmaceutical management system, thereby promoting an uninterrupted supply of quality TB medicines
- Build country-based research capacity

Findings from an assessment can provide the basis for policy dialogue, strategic planning, program monitoring, and intervention design.

The PMTB has been used in Armenia, Azerbaijan, Cambodia, China, Congo (Brazzaville), the Dominican Republic, Ethiopia, Georgia, Moldova, India (Uttar Pradesh), and Romania. Highlights from Ethiopia, China, and Cambodia follow.

Field-testing of the PMTB in Ethiopia and impact of findings on policy

In 2004, RPM Plus field-tested the PMTB tool in Ethiopia to evaluate TB medicine availability and use. Key assessment findings included the following—

- Inventory records were not regularly updated, resulting in discrepancies between stock records and actual stock.
- Standard treatment guidelines (STGs) differed slightly from recommendations of WHO: for example, STGs for Category I patients included injections instead of tablets.
- Health care providers gave incorrect medicines 10 percent of the time.
- Of intensive-phase patients, 76 percent were observed taking their medicines (a primary element of the DOTS strategy).
- Only 32 percent of patients had adequate knowledge about how to take their medicines.

Following the assessment, Ethiopia's TB and Leprosy Prevention and Control Program took specific measures to address some of these problems, such as—

- Recruiting a logistics officer to oversee the details of TB medicines and supplies management
- Incorporating information on logistics management into the newest national TB program manual
- Providing training to pharmacy staff on how to

manage TB medicines and commodities, and supporting supervision to reinforce their training

- Using new methods to record and report on the consumption of TB medicines and stock status
- Conducting pharmaceutical supply management assessments throughout the year to monitor progress and identify areas that still need improvement
- Revising STGs to align with WHO recommendations

Using PMTB findings to introduce new pharmaceutical management systems in China

After adapting the PMTB tool to the Chinese setting, RPM Plus used the tool in two provinces—Shandong and Henan. On the basis of the findings, Henan province was chosen to update its TB pharmaceutical management system. In 2006, three sets of SOP manuals were prepared for use at provincial, prefecture, and county levels, and training in procedures was completed for thirty personnel. The SOPs have been modified in line with feedback to make them more user-friendly in the Chinese context. With positive results in seven pilot facilities in Henan since July 2006, the plan is to expand the new system's implementation to the rest of the province and throughout China, reaching more than 3,500 TB facilities.

Using the PMTB to evaluate policy change in Cambodia

The Japan International Cooperation Agency used the PMTB methodology and questionnaires to conduct TB pharmaceutical management assessments in Cambodia during 2003–04 and 2005–06. The first assessment established a baseline and illustrated key problems in pharmaceutical management, such as medicine availability and rational medicine use. The second assessment measured any improvement in TB pharmaceutical management practices after switching the national TB program's policy from an eight-month to a six-month treatment regimen and evaluated whether any change occurred in TB medicine availability in the private sector.

A comparison of findings from the two surveys revealed improvement in a few areas and highlighted the need for further interventions emphasizing the following areas: periodic supervision, on-the-job training for drug storekeepers and TB service providers, further expanding community DOTS, strengthening public-private collaboration, and exploring the possibility of procurement and use of four fixed-dose combination TB medicines or patient kits.

Source: MSH/RPM Plus 2006.

ASSESSMENT GUIDE

- What are the reasons that the pharmaceutical system is being assessed?
- What issues should the assessment address?
- Have any assessments of the pharmaceutical system been conducted in the past?
- Who is sponsoring the assessment? Who is actually conducting the assessment?
- If the assessment covers the public sector, is the government committed and involved in the assessment process?
- What other stakeholders should be involved in the assessment?
- What information related to the pharmaceutical system will likely be available for review?
- Is the scope of the assessment comprehensive (covering the entire system—both public and private sectors)? Or is the scope more focused (for example, one sector or one vertical program)?
- What are the qualitative and quantitative information targets to be collected as part of the assessment? Are the information targets based on standard performance indicators?
- What methods will be used to collect the information?
- What is the time frame and cost for the assessment?
- What are the qualifications of the assessment team?
- Who will analyze the results?
- How will the results be presented for use by decision makers?

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