

THE MANAGER

MANAGEMENT STRATEGIES FOR IMPROVING HEALTH SERVICES

In This Issue

The Challenge of Controlling Tuberculosis in the 21st Century.....	2
Using the DOTS Strategy to Control TB	3
Managing TB Drugs Effectively.....	4
Understanding the TB Drug Management Cycle.....	4
The Drug Management Cycle.....	5
Establishing a Policy and Legal Framework for TB Drug Management.....	6
Selecting Essential Drugs.....	6
Ensuring Appropriate Drug Selection.....	7
Understanding DOTS-Plus and the Green Light Committee.....	8
Procuring Selected Drugs.....	9
How to . . . Practice Effective Pharmaceutical Procurement in Your Program	10
Quality Assurance of Fixed-Dose Combination Drugs.....	12
Distributing Procured Drugs.....	13
Using Distributed Drugs.....	14
Providing Effective Management Support.....	15
Working Solutions—Worldwide.....	16
Reviewers' Corner.....	17
Glossary.....	18
References.....	20
Checklist for Improving Drug Management to Control TB.....	22

Case Study

Springbok City's Hospitals Collaborate to Improve TB Drug Supplies

Improving Drug Management to Control Tuberculosis

Editors' Note

Tuberculosis (TB) is a highly contagious disease that people catch after inhaling a very small number of TB germs and becoming infected. One-third of the world's population is currently infected with the TB bacillus, and five to ten percent of these people will become sick or infectious at some time during their life. Nearly one third of people with HIV are also infected with TB. Because of the staggering spread of TB—over 8.4 million new cases a year—in 1993 the World Health Organization (WHO) declared this disease a global emergency. Since then, several global initiatives have been launched to control its spread and effectively treat TB patients.

Through one of these initiatives, the Global TB Drug Facility of the Stop TB Partnership purchases and provides TB drugs, free of charge, to countries in need. However, the number of countries it currently serves is limited, and numerous obstacles can hinder the flow of TB drugs in a country. Better drug management is needed to overcome the obstacles and increase the number of patients who are cured.

This issue of *The Manager* offers policymakers and managers of TB programs at all levels a practical, systematic approach to strengthening drug management so that TB drugs reach and are appropriately used by patients. It introduces the drug management cycle and describes how effective drug policies and laws can support this cycle. The issue also explains how specific improvements in drug selection, procurement, distribution, and use, as well as in management support, can help to maintain an adequate flow of TB drugs. ■

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The Challenge of Controlling Tuberculosis in the 21st Century

As the 21st century begins, tuberculosis (TB) remains the world's leading cause of death from a curable infectious disease. An estimated 2–3 million people die from TB each year. Although the final decade of the last century witnessed significant progress in combating the resurgence of this disease, in recent years advances made in some parts of the world have been offset by increases in the number of TB cases elsewhere. The worldwide costs directly linked to TB currently exceed US\$12 billion annually and continue to climb. These costs reflect over 8.4 million new TB cases every year and a death rate of 23 percent generally, and up to 50 percent in some countries with HIV. A disproportionate share of new cases and rising costs falls on developing countries struggling to provide adequate public health services and on individuals in poor populations who must pay for treatment.

The re-emergence of a global TB epidemic is especially disturbing because effective TB treatment using relatively inexpensive drugs has been available for more than 50 years. Success in controlling this disease clearly depends on more than a low price for first-line drugs (prescribed for initial therapy) that can cure TB. TB programs must ensure that patients receive drugs of high quality in the right dose at the right time. They must also support each patient's treatment for six months or longer to achieve a cure. This requires an unbroken cycle of effectively selecting, procuring, distributing, and using TB drugs.

Successful drug management supports this cycle to ensure that drugs reach and are properly used by the people who need them. TB control is a particularly useful example for understanding the role of drug management in providing effective health care and treating illness because TB treatment places complex, long-term demands on drug management. Countries that improve their drug management systems in order to cure TB are strengthening systems that will help them address the treatment of numerous other diseases.

The treatment of TB has been complicated by the emergence of drug-resistant TB resulting from incomplete treatment and the continuing spread of the HIV/AIDS epidemic. Almost 30 percent of people with HIV are also infected with TB, and TB is a leading cause of death among this population. Because of the connection between TB and HIV, it is critical for country programs to coordinate their approach to these two diseases. Regions suffering from high HIV infection rates, unreliable access to TB drugs, and the spread of drug-resistant TB could face an out-of-control TB epidemic.

The enormous threat posed by TB resurgence has triggered a global response. In March 2000, the Stop TB Partnership, managed by the World Health Organization (WHO), called for a global fund that would mobilize new resources for improved systems for procuring and distributing TB drugs. The Global TB Drug Facility (GDF) that the Stop TB Partnership subsequently established procures first-line TB drugs and provides them free of charge to countries in need. To receive these drugs, countries must meet specific requirements, including the use of effective treatment protocols. The most widely available and effective set of protocols for controlling TB is known as DOTS. More than 140 countries had adopted DOTS by 2000;

however, only 27 percent of infectious TB patients are currently treated through this strategy.

This issue of *The Manager* was written to support the goals of the Stop TB Partnership. It provides policymakers and managers of TB programs with a conceptual framework, the drug management cycle, that offers a practical, systematic approach to successful drug management. The issue describes the activities of the drug management cycle: drug selection, procurement, distribution, and use, along with the policy and legal framework and management support system that support the cycle. It explains how policymakers and TB program managers working at the local, regional, and national levels can help to ensure the consistent supply of high-quality TB drugs required to fully implement DOTS. A glossary of terms is provided at the end of the issue.

The issue was written by Thomas Moore, Senior Program Associate with Management Sciences for

Health's Center for Pharmaceutical Management (CPM), and Andrey Zagorskiy, Senior Program Associate, who coordinates the TB portfolio for MSH's Rational Pharmaceutical Management Plus Program (RPM Plus), funded by USAID. Mr. Moore is currently based at WHO headquarters, where he provides technical support to the Stop TB Partnership. Mr. Zagorskiy is based at CPM headquarters. Located in the Washington DC area, MSH's Center for Pharmaceutical Management provides technical assistance and training in pharmaceutical management worldwide to support the key role that pharmaceuticals play in the delivery of high-quality health care.

The authors and editors would also like to acknowledge the valuable contributions provided by Guido Bakker, Dr. Jim Kim, and their colleagues at Partners in Health; Dr. Souly Phanouvong of WHO/EDM; and Dr. Ian Smith of Stop TB in developing the content of this issue.

Using the DOTS Strategy to Control TB

FIVE ELEMENTS OF DOTS

DOTS is the global standard for TB treatment and the strategy recommended by WHO for controlling TB. The strategy's five elements are:

- **government commitment** to a national TB program;
- **case detection by sputum smear microscopy** (a laboratory test) among symptomatic patients who voluntarily report to health services (in contrast to detection through outreach, e.g., mass screening);
- **standardized treatment regimen** of six to eight months for at least all patients with positive sputum smears, with directly observed therapy for at least the initial two months;
- **a regular, uninterrupted supply** of all essential TB drugs;
- **a standardized recording and reporting system** that allows assessment of treatment results for each patient and of the TB control program's overall performance.

ADVANTAGES OF CONSISTENT USE

When used consistently, DOTS increases TB cure rates by 20 to 50 percent and decreases the proportion of patients who die by 10 to 30 percent. DOTS is also believed to prevent further emergence of drug-resistant strains of TB. The success of this strategy depends on direct observation during the first two months that the patient takes the drugs to ensure that the patient follows the regimen. Treatment can be observed by anyone who is willing, trained, responsible, acceptable to the patient, and accountable to the TB control services.

SHARING THE RESPONSIBILITY

The main advantage of DOTS is that the patient does not bear sole responsibility for adhering to treatment. Health care workers, public health officials, governments, and communities all share responsibility and provide a range of the support services necessary for patients to continue and finish treatment. With this in mind, effective TB control emphasizes integrating TB services into health services and giving each patient flexibility in where he or she receives treatment (for example, in the home or at the workplace).

Source: <http://www.who.int/gtb/publications/whatisdots>

Managing TB Drugs Effectively

Public health policymakers and managers at all levels who confront the spread and persistence of TB must work to improve the supply and use of TB drugs, while minimizing the costs of purchasing, distribution, and treatment. Using a planned approach, they can prevent TB drug shortages, avoid the most common problems in supply management, and reduce sickness and death.

Through effective drug management, TB program managers can:

- avoid crises through effective political, managerial, logistic, and financial planning;
- select TB drugs according to treatment protocols and correctly quantified needs;
- secure sufficient resources to procure TB drugs effectively and efficiently;
- ensure sufficient staff skills and protocols for distribution and inventory management;
- coordinate with health management systems set up to harmonize (coordinate) treatment;
- use available TB drugs appropriately.

Whether you are a policymaker, manager of a TB program, health care provider, drug wholesaler, pharmacist or pharmacy aide, doctor, nurse, or other care provider, the drug management cycle can help you understand the requirements for an uninterrupted drug supply and develop a systematic approach to improving the control and treatment of TB.

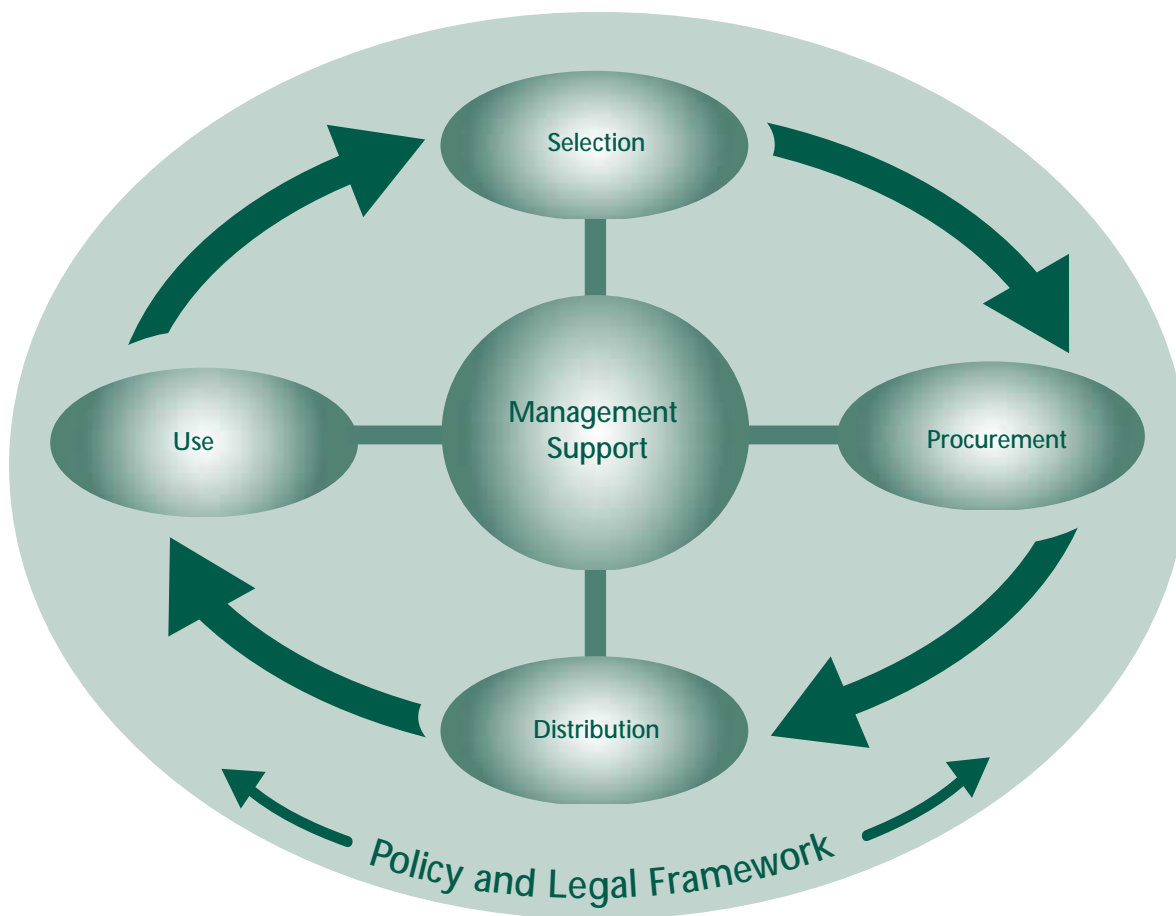
Understanding the TB Drug Management Cycle

The drug management cycle is a systematic approach that you can use to ensure that all drugs for a complete course of TB treatment are available and appropriately used according to an effective treatment strategy and timeline. The cycle was developed by Management Sciences for Health's Center for Pharmaceutical Management (CPM), in collaboration with the World Health Organization's Action Programme on Essential Drugs. It emphasizes connections among four drug management activities:

- selection of essential drugs
- procurement of selected drugs
- distribution of procured drugs
- use of distributed drugs

Each activity of the drug management cycle relies on the success of the previous activity and contributes to the effectiveness of the next activity. All activities require support from both a policy and legal framework and a management support system.

In addressing TB drug management, it is important to understand the role of each activity in the cycle, as well as the two supporting elements. This is essential since any flaw in the drug management cycle that interrupts the patients' appropriate use of TB drugs may lead to the failure of treatment and ultimately promote the spread of drug-resistant TB.



Activities of the Drug Management Cycle

Selection of essential drugs. The process of establishing and using a limited list of essential drugs. It involves reviewing prevalent health problems, identifying the best clinical treatments, choosing individual drugs, dosages, and dosage forms, and deciding which drugs will be available at each level of health care.

Procurement of selected drugs. The process of acquiring drugs through purchase, donation, or manufacture. Procurement includes quantifying drug requirements, selecting procurement methods, managing tenders, establishing contract terms, assuring drug quality, and ensuring adherence to contract terms.

Distribution of procured drugs. The process by which an organization receives, transports, and stores drugs. The distribution process includes clearing drugs through customs, transporting drugs from a central point to depots and health facilities where they are dispensed, controlling stocks, and managing stores.

Use of distributed drugs. The process of diagnosing, prescribing, labeling, repackaging, and dispensing drugs, and of securing patients' adherence to drug treatment. Achieving *rational drug use* requires effective interventions, such as active use of standard treatment guidelines, training linked to improved drug supply, and guided discussions among patients and providers.

Establishing a Policy and Legal Framework for TB Drug Management

The success of a country's TB control efforts depends on political commitment from the government and support for DOTS from health professionals. A framework of drug policies and laws upholds public commitment to essential drug supply and so supports the complete drug management cycle. Each country's policy and legal framework needs to define national goals for drug management. It is important for concerned health policymakers and program managers to participate in developing and advocating for pharmaceutical laws and regulations that promote:

A NATIONAL DRUG POLICY WITH A TB COMPONENT	Many countries have adopted the concept of a national drug policy (NDP) to achieve optimal availability and use of drugs for patients. An NDP should prioritize the supply of essential drugs for TB, include comprehensive strategies to achieve their appropriate use, and be supported by laws.
REGISTRATION OR LICENSING OF TB DRUGS	When a country requires drug registration, it establishes a regulatory agency with authority to examine each drug's quality, safety, and efficacy. Drug registration prior to procurement is one way to ensure that drugs meet international quality standards (such as those established by WHO).
AUTHORITY TO ASSURE QUALITY	Poor-quality drugs or drugs from unreliable manufacturers can jeopardize successful TB treatment. Drug quality assurance policies cover assessment of manufacture, importation, and distribution of drugs. They establish responsibility for monitoring drug quality, specify laboratories for drug testing, and establish formal systems for reporting product complaints.
PROCUREMENT AND DISTRIBUTION OF RELIABLE, HIGH-QUALITY TB DRUGS	Such policies generally define procurement method(s), drug quality standards, price limits (for example for distributors' markups over costs), local drug production requirements, and distribution and storage guidelines for drugs approved for procurement.
RATIONAL USE OF TB DRUGS	Drug policies and laws help to guarantee that drugs will be used rationally—appropriately, safely, and only when needed—if they specify major activities and responsibilities for promoting rational prescribing, dispensing, and patient drug use. Such policies restrict confusing drug promotion, require training for health providers, limit drug dispensing to trained persons, and encourage public education.
RESPONSES TO GLOBAL TB CONTROL INITIATIVES	Having well-defined policies can put a country in a better position to respond to global initiatives. For example, the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) recently issued its first call for funding proposals from countries hard hit by these epidemics and in need of essential drugs. A strong, supportive policy and legal framework, in addition to a well-conceived programmatic response built on the drug management cycle, will provide the GFATM and Global TB Drug Facility with evidence of a country's national commitment and need.

Selecting Essential Drugs

If you are a TB program manager, the first activity of the drug management cycle on which you should focus is selecting essential drugs and supplies for your TB program. Drug selection is perhaps the single most cost-effective action you can take to promote a regular supply of TB drugs.

If your program has sufficient resources, you should work with a drug therapeutics committee that includes a TB medical specialist, national TB program manager, epidemiologist, pharmacologist, pharmacist, nurse, and procurement specialist. If your program lacks resources, you can select drugs recommended by WHO.

To select drugs, you:

- review patterns of TB morbidity, drug resistance, and populations affected;
- identify standard treatments for your program's TB patients;
- develop a list of essential drugs and supplies to ensure these standard treatments.

In your list, specify each drug product—the drug's international nonproprietary name, strength, and dosage form (e.g., isoniazid 100 mg tablets). Also indicate at which level of health care the drugs will be available. In your selection, you need to:

- select first-line TB drugs with attention to quality;
- select second-line drugs for drug resistant TB, only if clinically necessary.

Selecting first-line drugs. Fortunately, the essential drugs best suited to treat TB are well known and widely available. WHO recommends selecting the five essential first-line drugs: isoniazid, rifampicin, etham-

butol, pyrazinamide, and streptomycin. All five drugs have been used in treatment for over half a century; have proven effective in treating TB; and are inexpensive, no longer under patent, and globally available from many manufacturers.

Also consider selecting fixed-dose combinations (FDCs) of the first-line drugs, since FDCs have proven effective over many years. FDCs contain two, three, or four essential drugs in one tablet, depending on the treatment regimens selected by national TB programs.

WHO recommends the use of FDCs because they simplify dose calculations for prescribers, provide the patient with fewer tablets to swallow at once, and reduce the risk of promoting drug-resistant TB by replacing single drug therapies. For example, therapy with rifampicin alone is known to contribute to drug-resistant TB.

While selecting first-line TB drugs has become relatively easy, you still need to address the need for data on drug safety, coordination and monitoring of treatment regimens, and control over prescribing practices.

Ensuring Appropriate Drug Selection

To ensure appropriate drug selection, you need to confirm registration of TB drugs, select only drugs that can be successfully used, and support controls on prescribing practices.

CONFIRM REGISTRATION OF TB DRUGS

Review registration documentation of foreign drugs registered in the country of manufacture, and use your own national drug regulatory authority's registration procedures, if these exist, as a step in confirming the safety and efficacy of the selected products. If any drug products you consider essential are not registered in your country (e.g., fixed-dose combinations), encourage their registration. By confirming registration and manufacturer reputation, you begin to gain assurance that the drugs you are considering for selection are appropriate.

CHOOSE DRUGS THAT CAN BE SUCCESSFULLY USED

Drug supply problems often begin when drug selection is not limited to widely accepted, proven treatment protocols, such as those established in DOTS, or when locally adopted treatment regimens are not followed. By using the selection process to screen out less effective and/or unnecessary products, you reduce inappropriate prescribing of these products. Even with appropriate selection of drugs, however, supply problems may increase if countries lack effective monitoring and control over drug prescribing.

SUPPORT POLICIES THAT CONTROL PRESCRIBING PRACTICES

In countries with ineffective national controls, providers often prescribe based on traditional practice, experience, aggressive drug promotion, or personal opinion. Policies that control prescribing decrease the demand for a wide variety of products (including dosage forms and drug combinations) that increase procurement costs, inventory costs, and inventory control resources. These policies also promote appropriate treatment, which can increase cures and reduce drug-resistant TB.

Selecting second-line drugs for multidrug-resistant TB. You will need to select second-line drugs (drugs prescribed after first-line drugs fail) *only* if your country has a *documented* outbreak of multidrug-resistant TB (MDR-TB) or life-threatening cases of MDR-TB. Recommend studies of drug resistance and implementation of DOTS-Plus before second-line TB drugs can be procured. Before you include second-line drugs in a list of essential TB drugs, it is important to understand that:

- **Clear recommendations and standards for treatment of MDR-TB with second-line drugs are only now being developed.** (See “Understanding DOTS-Plus and the Green Light Committee” below.) Where first-line treatment fails due to patient nonadherence to standard treatment guidelines, all existing resources should be used to complete first-line treatment.
- **Using second-line drugs may seriously increase resistance to a “last-resort” treatment.** If second-line drugs are not used properly or are not effective products, MDR-TB will spread further. Failure of second-line drugs to treat TB infection can also lead to death. Ministry of health and drug regulatory

authorities should restrict the use of second-line drugs and support application for DOTS-Plus only if data on TB drug resistance warrants it.

- **Drugs used to combat MDR-TB can be 100 to over 1000 times as expensive as first-line TB drugs.** The spread of MDR-TB can cause TB to become prohibitively expensive, and in some cases impossible to treat. You may be able to negotiate much lower prices for second-line drugs with suppliers at the government level or by procuring through the Green Light Committee of the Stop TB Partnership.
- **Qualified specialists should make decisions for selecting second-line drugs for their country, based on drug resistance patterns in that country.** The specialists should persuade the national drug authority to approve their decisions. To make these decisions, they need to perform a cost-benefit analysis that weighs the country’s medical needs and risks against its economic costs for second-line treatments.

The following box describes an international effort, headed by WHO, to address the needs for MDR-TB drugs within the DOTS-Plus strategy.

Understanding DOTS-Plus and the Green Light Committee

DOTS-Plus works as a supplement to the standard DOTS strategy. Its not required in all settings but is very important to prevent the further development and spread of MDR-TB in those areas with emerging epidemics of MDR-TB.

PRINCIPLES OF DOTS-PLUS

DOTS-Plus has two underlying principles:

- Appropriate implementation of DOTS should be the first step in fighting MDR-TB because it will help prevent the emergence of drug resistance.
- DOTS-Plus should be applied only in areas that already have effective DOTS-based TB control programs.

HOW DOTS-PLUS WORKS

A DOTS-Plus program usually begins with the establishment of a DOTS-Plus pilot project in order to access second-line drugs through the Green Light Committee. To qualify as a DOTS-Plus pilot project, a TB control program must meet WHO’s “Guidelines for Establishing DOTS-Plus Pilot Projects for the Management of Multidrug-Resistant Tuberculosis (MDR-TB).” Adherence to these guidelines promotes appropriate management of existing cases of MDR-TB and prevents the rapid development of resistance to second-line TB drugs. The guidelines provide DOTS-Plus pilot projects with sample protocols for standardized or individualized treatment regimens using second-line TB drugs.

PRICING OF SECOND-LINE TB DRUGS

The WHO Working Group on MDR-TB has identified high pricing of second-line TB drugs as a major obstacle to the implementation of DOTS-Plus pilot projects. As a result, the Working Group has made arrangements with both the proprietary and generic pharmaceutical industries to provide lower-priced second-line TB drugs to certified DOTS-Plus pilot projects. Its efforts have created a significant market for second-line drugs and lowered costs by increasing competition among generic suppliers.

THE GREEN LIGHT COMMITTEE

The Green Light Committee, a committee of the DOTS-Plus Working Group within the Stop TB Partnership, is located at WHO's world headquarters in Geneva, Switzerland. The committee reviews applications from potential DOTS-Plus pilot projects and determines whether they comply with guidelines for DOTS-Plus pilot projects.

If you are a program manager interested in applying for certification of your program as a DOTS-Plus pilot project, review the "Instructions for Applying to the Green Light Committee for Access to Second-line Anti-Tuberculosis Drugs," and contact WHO at:

CDS/Stop TB
World Health Organization
20, Avenue Appia, CH-1211 Geneva 27
SWITZERLAND

Tel. (41) 22 791 2708/3224
Fax (41) 22 791 4268
<http://www.who.int/gtb/policyrd/DOTSpplus.htm>

Source: <http://www.who.int/gtb/policyrd/PDF/DOTSGLC.pdf>

Procuring Selected Drugs

Once the national TB program or essential drugs program has selected standard drug treatments and TB drugs, both single and combined products, the program needs to procure the selected drugs—the next activity of the drug management cycle. Good drug procurement involves purchasing drugs in ways that contribute to their availability and quality, promote effective treatment, and preserve scarce resources by controlling costs. For these reasons, effective procurement is critical to the success of TB control programs.

If your country receives grants from the Global TB Drug Facility (GDF) or if you wish to procure through the GDF, you will need to harmonize (coordinate) your treatment regimens with the GDF product list. If you

are a country without GDF support and are responsible for procuring TB drugs and estimating drug requirements, it is important for you to:

- understand effective pharmaceutical procurement practices;
- identify the level of competition among suppliers;
- quantify drugs needed;
- choose the most appropriate procurement method;
- determine qualifications of suppliers;
- provide specifications for drugs and packaging;
- know the length of time that registration takes;
- assure drug quality;
- monitor suppliers' performance.

Practice Effective Pharmaceutical Procurement in Your Program

THE GOALS OF PHARMACEUTICAL PROCUREMENT

The goals of your program's procurement are to:

- procure the most cost-effective drugs in the right quantities;
- select reliable suppliers of high-quality products;
- ensure timely delivery;
- achieve the lowest possible cost for all drugs.

To reach these goals, it is important to follow these guidelines:

ESTABLISH A CLEAR AND EFFICIENT PROCUREMENT SYSTEM

- Divide procurement responsibilities among different offices, committees, and individuals with appropriate expertise and resources. These responsibilities include selecting drugs for purchase from the essential drugs list, determining quantities of drugs required, specifying desired product characteristics, prequalifying suppliers, and making final decisions on the outcome of tenders.
- Make procurement procedures transparent to potential suppliers, using formal written procedures throughout the process and explicit criteria to award contracts.
- Plan procurement thoroughly and monitor procurement performance regularly; include an annual external audit.

IDENTIFY DRUGS AND QUANTITIES USING CLINICALLY AGREED-ON DRUG REGIMENS

- Limit public-sector procurement to an essential drugs list.
- List drugs in procurement and tender documents by their international nonproprietary name (INN) or generic name.
- Order quantities based on a reliable estimate of actual need.

ENCOURAGE SOUND FINANCING AND COMPETITION FOR CONTRACTS

- Establish procedures to ensure timely, reliable financing for procured drugs. When funds are limited, set priorities for procurement.
- Procure the largest possible quantity to achieve economies of scale within centralized or decentralized health systems.
- Use competitive procurement except for very small or emergency orders.
- Purchase all contracted items from the supplier(s) who wins the contract so that suppliers will bid competitively.

ASSURE QUALITY OF SUPPLIERS AND DRUGS

- Prequalify prospective suppliers and monitor selected suppliers' product quality, service reliability, delivery time, and financial viability.
- Adopt quality assurance procedures that assure that drugs purchased meet international standards for high quality.

Adapted from "Operational Principles for Good Pharmaceutical Procurement" WHO/EDM/PAR/99.5

Identifying the level of competition among suppliers. You will need to determine the level of competition among potential drug suppliers. In most countries, first-line TB drugs are registered and readily available. Some countries manufacture these drugs locally. Countries may reduce competition by imposing high registration fees or other requirements to raise trade barriers and support domestic suppliers, often producing harmful double standards. For example, local manufacturers may not need to follow internationally accepted good manufacturing practices used by foreign manufacturers or to have their products pass tests for bioavailability (the availability of an active ingredient to the body once the drug is administered). Foreign competitors may find their registration applications rejected by countries for arbitrary reasons. For sound drug procurement, you should work toward having at least three, and preferably five, potential suppliers for each needed TB drug product.

Quantifying drugs needed. To estimate the number of drugs you will need, you estimate the number of expected cases of each category of TB patients to be treated in one year and multiply that number by the number of each drug or fixed-dose combination to be used for each TB treatment category. WHO recommends basing estimates on the TB morbidity in the country, as described in the *Tuberculosis Handbook*. Alternatively, countries with a functioning drug management information system can estimate needs based on past consumption of TB drugs.

Even with the best data, you may need to reduce quantities because of insufficient funds. All drugs must be available for a patient in both the intensive and continuous phases of treatment before treatment is started. To reduce quantities for a procurement cycle, adjust them on a per-patient basis.

When quantifying drugs, consider patient kits and blister-packed drugs. Each kit contains all the drugs needed for a patient's treatment and has a label with the patient's name to help ensure the patient does not run out of drugs. Each blister contains the drugs for a day or a week of treatment. Both types of packaging simplify prescribing, dispensing, and patient adherence to treatment.

Choosing the most appropriate procurement method. Once you know who the potential suppliers are, you can select the procurement method most appropriate for your program, based on market circumstances, volume of drugs needed, funding, and local

policies and regulations. The four procurement methods are:

- **open tender**, a request for bids that is open to all interested suppliers;
- **restricted tender**, a request for bids limited to known, reliable, prequalified suppliers;
- **competitive negotiation**, direct negotiation with a small number of selected sellers to achieve a specific price or service arrangement;
- **direct procurement**, purchase from a single supplier at its quoted price.

If your program purchases TB drugs through its own sources, your program should procure them through restricted tender to prequalified suppliers. These suppliers are qualified before participating in the tender. Your program should choose direct procurement only if it can obtain the TB drugs offered by the GDF.

Determining qualifications of suppliers. When you use a process that links restricted procurement with qualifying suppliers *before* procurement, you help to ensure a strong base of suppliers for your country. Prequalification establishes a list of acceptable suppliers and is considered a very important step in procuring drugs by both WHO and the World Bank. During prequalification, suppliers provide evidence that they can reliably supply the needed quantity of drugs and that the drugs supplied will meet specified quality standards.

Your prequalification process should be transparent and open equally to domestic and international companies. Until you develop documents that specify your program's or country's prequalification requirements, you can use documents developed by the World Bank. In the future, United Nations agency procedures for prequalification will be available. To prequalify a supplier, you should:

- review drug certificates provided by the manufacturer and regulatory authority of the manufacturing country. "The Certificate of a Pharmaceutical Product Moving in International Commerce," which follows WHO's guidelines, tells you whether the manufacturer has been inspected and has conducted appropriate tests on its drugs;

- require suppliers to provide references from other buyers, information on contracts with other programs or countries, information on quality control procedures and capacity, data on drug recalls, and a list of licenses from the manufacturer to sell its products;
- complete a full, independent audit of the factory's manufacturing practices, or obtain the results of an audit completed by a strong drug regulatory authority, or reputable organization or inspector;
- require data, both before and after qualification, showing ongoing monitoring of the finished product's quality through batch certification (testing each batch of a product after it is produced);
- request and test for quality several samples from the manufacturer that are representative of the manufacturing process to be used;
- require the supplier's financial reports, a letter from tax authorities, and bank references to establish the supplier's financial viability.

Providing specifications for drugs and packaging.

You should list your specifications for drugs and packaging in your tender documents as conditions for accepting suppliers' bids for TB drugs. Your specifications should indicate the desired characteristics of drugs, including standard requirements from a pharmacopeia for a product's quality and quality-testing procedures, and the drug's shelf life. A drug's shelf life should be at least 75 percent of the label's expiration date.

Knowing the length of time registration takes. Find out whether your country has a rapid registration for TB drugs, in case the suppliers who win your procure-

ment have not registered their drugs in your country. If you ignore the time needed for drug registration, TB shipments can be delayed, jeopardizing the availability of drugs in health facilities.

Assuring TB drug quality after qualification. Quality assurance is extremely important for successfully combating TB. The manufacturing audit and review of documents support quality assurance during prequalification. After procuring and receiving the drugs, you can help ensure the quality of drug products purchased by:

- assuring that quality specifications are included in the drug supply contracts;
- having each drug inspected for appearance of the product and its packaging;
- having laboratory tests conducted to test the quality of the drug's active ingredients;
- verifying that the drug manufacturing process follows good manufacturing practices;
- verifying the reliability of the suppliers;
- monitoring handling and storage conditions of the drug.

While you may not be able to implement all of the above quality assurance safeguards, you should *always* establish a quality surveillance system that will monitor adherence to suppliers' qualification criteria, drug specifications, details in contracts, and suppliers' performance. If you need to procure fixed-dose combination drugs, your methods of quality assurance must be effective and reliable.

Quality Assurance of Fixed-Dose Combination Drugs

UNDERTAKE SPECIAL MONITORING OF FDC DRUGS

Fixed-dose combination (FDC) drugs, especially combinations containing rifampicin, require special monitoring to assure quality, including laboratory testing and verifying bioavailability in humans. In countries that lack clearly defined, functional quality assurance programs or skilled specialists, managers may need to compare data from tests of FDC products with data from tests of single-ingredient drug products using accepted international pharmacopeial standards and good manufacturing practices.

VERIFY COMPLIANCE WITH TREATMENT STANDARDS

Some suppliers have inaccurately promoted their products as FDCs containing WHO-approved combinations of drugs and strengths. Some have even attached WHO treatment guidelines to drug shipments, falsely attempting to validate their products. When selecting FDCs, managers always need to verify that these drugs comply with approved treatment standards.

Monitoring suppliers' performance. You need a formal system for monitoring suppliers' performance needs. Many supply programs rely on informal impressions from procurement personnel when selecting suppliers; however, procurement personnel may be unaware of problems that users have had with the TB drugs of specific suppliers.

Your system for monitoring suppliers should be based on simple indicators that take into account all activities of the drug management cycle. The indicators should monitor:

- lead time (the waiting period from the time an order is prepared until it arrives in the country) to ensure compliance with quoted delivery times;
- product quality, based on a review of the packaging, labeling, and expiration date, as well as results from a quality analysis;
- customer service, including each supplier's response to inquiries, provision of documents, and provision of additional services.

Distributing Procured Drugs

Once your TB program, the national essential drugs program, or the Global TB Drug Facility (GDF) has selected and procured high-quality drugs, and they have arrived in the receiving warehouse, the next step is to deliver the drugs from the receiving warehouse to distribution warehouses, hospitals, and health centers. The distribution activity of the drug management cycle must ensure that TB drugs are available in the quantities needed for all patients during all treatment phases. The distribution phase of the cycle includes clearing drugs through customs, transporting them, making timely deliveries, keeping records, maintaining adequate stock levels, and following appropriate storage procedures in all facilities. If you are from a country that receives GDF assistance, you, and not the GDF, are responsible for the distribution phase once TB drugs are delivered to your country.

Unlike most drugs, first-line TB drugs do not have effective substitutes if stock runs out. Good distribution ensures that all first-line TB drugs are available in the quantities needed, at all points of administration to patients, at all times.

During the first two months of intensive treatment under DOTS treatment guidelines, your distribution system must ensure that each patient receives all five essential TB drugs, whether in their separate or combined forms. During the continuation phase, your system must deliver the two to four drugs each patient needs for an additional four to six months. It must deliver these drugs wherever patients are being treated. Some countries treat TB patients only in hospitals, others rely on outpatient clinics, and some use both. To maintain an effective distribution system, you must:

- implement a plan to distribute drugs to warehouses and storerooms;
- train stock managers.

Implementing a distribution plan. As program manager, you must assure immediate clearance of drugs and appropriate storage while awaiting clearance. Once drugs reach the receiving warehouse, you can implement a distribution plan. Your distribution plan should be based on available transportation and levels of stocks in subsequent storage facilities.

Training stock managers. After drugs reach warehouses and health facility storerooms, stock managers must monitor both expiration dates and inventory levels and maintain proper storage conditions, such as light, temperature, and sanitation, at all times. As a program manager, you should build training for these skills into your program. During training and monitoring, you should verify the capacity of stock managers to accurately control, record, and report the drug quantities distributed and dispensed. Reporting accurate distribution data to the procurement agency or national TB program helps the agency or program estimate drug needs and be successful in their next procurement.

In countries where the public sector lacks reliable systems for distribution, governments and/or international donors sometimes establish separate (or parallel) distribution networks for different health programs. These may function well as long as donors' support lasts but become difficult to sustain once this support ends. Many international donors and nongovernmental organizations (NGOs) offer assistance in developing local capacity to appropriately manage and distribute drugs in a timely way.

Using Distributed Drugs

Once distribution and stock managers have distributed high-quality drugs to health facilities on time, managers of prescribers and dispensers must ensure that they are used appropriately, safely, and according to protocol. The “use” activity of the drug management cycle includes appropriate diagnosing, prescribing, and dispensing drugs by health providers, and their consumption by patients.

Effective TB drug management achieves rational drug use when patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

The most common failure in TB treatment involves patients’ and providers’ poor adherence to the lengthy, complicated treatment regimens. Some treatment failures can lead to the development of MDR-TB or to death. Whether you are a TB program manager or manager of prescribers and dispensers of TB treatment, you need to promote the fact that TB can be successfully treated with first-line TB drugs *only if* these drugs are taken appropriately and consistently for the full course of treatment. DOTS helps to support patients in continuing treatment even after they feel better. To reduce problems with adherence to treatment, you need to:

- train providers;
- set up a system for direct observation of drug administration;
- monitor prescribing practices;
- establish relations with private providers;
- provide unit dose packages;
- educate patients and communities;
- develop incentives for both providers and patients.

Train prescribers. You should develop initial and continuing training programs on appropriate prescribing for physicians, nursing staff, and dispensers. Training must involve reviewing prescription writing and documentation in medical records in the health facility. If coupled with monitoring and feedback, training can help reduce variations in prescribing in countries that have few or no treatment standards and also encourage appropriate treatment to patients, based on their differ-

ent treatment categories. Finally, training can help providers both support patients who cope with drug reactions and withstand the pressures of using heavily promoted, but inappropriate, drugs.

Set up a system for direct observation of patients who are taking drugs. You need to develop a system where the provider or other authorized observer can directly observe and document that patients are taking the drugs in the health facility during initial treatment. In the continuation treatment phase, this person needs to verify patients’ timely visits to the health facility for additional drugs.

Monitor prescribing practices. It is essential to continuously monitor prescribing by health care providers to ensure they are following DOTS standards. You can use DOTS forms, available from WHO, for monitoring adherence. Careful monitoring of medical records will help determine if each provider understands the treatment regimen and if each patient is adhering to the prescribed treatment. Also be alert for signs of MDR-TB, which a patient’s past treatment and response to current treatment may indicate. To be most effective, monitoring and training programs must work together.

Establish relations with private providers. If private providers in your country treat many TB patients, you need to gain the support of medical, pharmacy, and nursing associations for the government’s protocols for TB treatment. Organize presentations at association meetings and distribute government materials on selected drugs and protocols for first-line treatment. This may lead to arrangements where private providers diagnose patients and send them to government facilities for free drugs, or where the government reimburses private providers for TB treatment. Good relations between the public and private sector will promote effective treatment for all TB populations within the health system.

Provide unit dose packages. Blister packs containing daily doses of individual drugs are easy for providers to prescribe and patients to use. They should have easy-to-understand instructions, but will still require direct observation.

Educate patients and communities. Patient education should be required for all TB programs. Like providers, patients must understand their role in treating TB and limiting its transmission to other people. Your strategies for public health and drug education should provide individuals and communities with the informa-

tion, skills, and confidence necessary to both use TB drugs appropriately, safely, and effectively and decrease TB's spread. The Stop TB Partnership provides educational materials and ideas.

Develop incentives and enablers for both providers and patients. Find out effective ways to influence patients' and providers' behavior in your country. Incentives motivate people to act in certain ways; for example, food baskets can encourage patients to complete their treatment. Incentives that can motivate providers and other observers include food for those who properly supervise patients and monetary bonuses for private providers who refer persons suspected of having TB to testing centers. Enablers facilitate the participation of people in disease control. Examples include vouchers that cover patients' transportation expenses to the clinic or that facilitate providers' community outreach.

Remember that poor patients may need financial and nutritional support to continue treatment.

Providing Effective Management Support

Even if all four drug management activities are in place, they cannot be carried out well without management support. The management support component at the center of the drug management cycle represents a variety of different management support systems that are required during all activities of the cycle and at all organizational levels, from the national program level down to where drugs are prescribed and dispensed to patients.

If you are the overall manager of TB drug activities in your country, then the organizational framework you establish is critical to each activity of the cycle. To accomplish the goals of your TB program, you must frequently fulfill three roles. As a leader, you provide direction for the TB program, motivate staff, maintain connections with other organizations, and lead organizational changes in response to external changes. As a communicator, you maintain networks of formal and informal contacts, disseminate information, and speak for the program. You are also a decision-maker who decides how to allocate resources, solve problems, negotiate agreements, and improve the TB program.

You must understand changing internal and external forces, sources of resistance, and change management. For example, when you decide to promote the use of fixed-dose combination drugs (FDCs) to improve prescribers' and patients' adherence to treatment protocols, your response will involve improvements in TB drug selection, procurement, distribution, and use. Using conversion from single drugs to FDCs as an example, the rest of this section will illustrate how you support changes in drug management through:

- planning for improvements
- implementing plans
- monitoring and evaluating changes
- thinking about the whole drug management cycle.

Planning for improvements in drug management.

To plan for an improvement such as the conversion to FDCs, you need to plan and allocate resources for updates of procedural manuals and for training stock managers and prescribers on new procedures. You must also decide whether to introduce the conversion as a pilot project in a few facilities or in all facilities at once, and how staff will phase in the FDCs and phase out single drugs.

Implementing plans. Good planning does not necessarily result in effective implementation of the FDC changeover. You must involve managers of drug procurement, distribution, storerooms, prescribers, and dispensers in implementing the plan. You must effectively manage finances and budgets; institute useful, accurate information systems; and motivate capable staff to champion the change.

Monitoring and evaluating changes. Once you have communicated with staff about plans and targets for the phase-in of FDCs, you need to evaluate their progress and take corrective action or request additional information, if appropriate. For example, you need to make sure enough FDCs and single drugs are available when needed. To do this, you must check that the program's needs for these drugs are accurately quantified, procurement and distribution are timely, and capacity for stock management is strong. Monitor the program's performance by using proven indicators to track routinely reported data, such as the numbers of days FDCs were out of stock in warehouses or health clinics during a given period.

Through evaluations, you can periodically assess your progress toward achieving goals for FDCs. Your goals need to be based on standards of performance and local factors such as time frames for interventions, available resources, national policies, and the level of decentralization.

Thinking about the whole cycle. When you improve the performance of TB drug selection, procure-

ment, distribution, and use, you help to ensure an adequate supply of FDCs or other TB drugs. You should continually use the drug management cycle as a framework to decide on necessary improvements by identifying patterns in information reported about drug supply and underlying causes. Without effective drug management, TB drugs will not reach those who need them and millions more people will die of a treatable disease.

Working Solutions—Worldwide

The following working solutions address improvements in drug procurement in Kazakhstan and in appropriate drug use in Bangladesh and Peru.

Kazakhstan: Improving the Quality of TB Drug Supplies

In Kazakhstan, rapidly rising rates of TB and MDR-TB over the last decade have led to the highest TB-related mortality rates in the Commonwealth of Independent States. The Kazakhstan Ministry of Health (MOH), with assistance from MSH's Rational Pharmaceutical Management (RPM) Project, improved its standard bidding documents for its second national TB drug tender. It inserted explicit instructions to suppliers and clear drug specifications in its documents.

As a result, drug suppliers were more explicit in their bids, and in 1999 the MOH was able to purchase all its TB drugs from reputable manufacturers at lower prices and higher quality. In one year, the proportion of drug products complying with DOTS that were purchased through the national tender increased from 26 percent to 83 percent. The Ministry of Home Affairs also improved standard bidding documents for supplies of TB drugs needed by prisons.

Bangladesh & Peru: Supporting TB Drug Use through Incentives and Enablers

In Bangladesh, the national Bangladesh Rural Advancement Committee (BRAC) introduced an innovative scheme to increase treatment completion rates. To encourage patient adherence to treatment and to motivate community-based treatment observers, BRAC asks TB patients to post a deposit and sign a written agreement when they begin treatment. The agreement specifies that they must complete treatment in the presence of an observer, such as a village or family member. If the patient completes treatment, the patient receives part of the deposit back, and the observer keeps the other part. If a patient drops out, the full deposit is retained by BRAC. BRAC attributes their high cure rate of 89 percent to this incentive scheme.

In Peru, a comprehensive program to provide incentives and enablers to both patients with MDR-TB and treatment observers has shown considerable success. If patients show up regularly to take their medicines, they receive free food, subsidized transportation, loans for small businesses, work referrals, and comprehensive health care for their families. Treatment observers also receive monthly food baskets and subsidized transportation. This comprehensive approach to providing incentives and enablers has helped reach a cure rate of over 80 percent for MDR-TB patients.

On the importance of building strong national drug regulatory authorities...

One reviewer emphasized, "We appreciate that WHO supports the development of strong drug regulatory authorities. While the objective of registration of drugs at a national regulatory authority is to assure the quality of drugs available on the market, many national regulatory authorities do not adequately assure drug quality.

For example, in one country, the Ciprofloxacin widely used in TB control was all produced and registered by one manufacturer. Although the national regulatory authority had approved its product, the Green Light Committee determined that the manufacturer did not, at that time, comply sufficiently with WHO's guidelines for manufacturing practices. We could have severely jeopardized the health of our patients had we administered this specific drug."

On including important steps in quality assurance...

One reviewer stressed, "A review of documents is only one of three core steps in a reliable quality assurance system. Since it is rather easy to compile excellent documents on bad products, a good quality assurance system should also include factory audits of manufacturing practices and continuous testing of batch samples. In many countries where TB is endemic, regulatory authorities rarely include the last two steps."

On false representation...

A reviewer reported, "False documentation can be very common. Our national regulatory authority's criminal unit has uncovered interesting examples. Generic drug fraud scandals shook our regulatory authority awake."

Another reviewer warned, "It is common practice among manufacturers to send samples of much higher quality for testing. Many companies have different production plants and different sources of raw materials, which makes it harder to predict drug quality. Testing of these samples is therefore likely to provide the program with false assurances."

bioavailability	The availability of a drug in the body over time from the moment it enters the blood stream until it is metabolized or excreted. Measuring this availability helps to determine whether drugs with the same active ingredients, but manufactured by different companies, behave the same way inside the body.
competitive negotiation	A method of procurement in which the buyer approaches a limited number of suppliers selected by the buyer and bargains with them to achieve specific price or service arrangements.
direct procurement	The simplest, but often most expensive, method of procurement in which the buyer purchases an item from a single supplier at its quoted price.
dosage form	The physical form in which a drug is produced or prepared for administration to a patient (e.g., as a tablet, capsule, intramuscular injection, subcutaneous injection, or ointment).
DOTS	The official name for the WHO-recommended strategy for TB control and formerly an acronym for directly observed treatment, short course. DOTS includes five elements: government commitment to sustained TB control activities; case detection by sputum smear microscopy among symptomatic patients self-reporting to health services; a standardized treatment regimen of six to eight months for at least all cases with positive sputum smears, with directly observed therapy (DOT) for at least the initial two months; a regular, uninterrupted supply of all essential TB drugs; and a standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program performance overall.
DOTS-Plus	A management initiative by the Stop TB Partnership for the control of multidrug-resistant TB (MDR-TB), built on the five elements of the DOTS strategy. If a TB control program already uses DOTS, it can subscribe to this initiative and obtain lower prices for second-line TB drugs needed for treating MDR-TB.
drug product	The combination of an active ingredient (drug) in a specific amount (strength) and physical form (dosage form) (e.g., isoniazid 100 mg tablets).
enabler	An item or action that helps a patient receive treatment, such as provision of transportation, bus fare, or funds for outreach, in contrast to an <i>incentive</i> or small reward, such as food.
essential drugs	Drugs that satisfy the basic health care needs of the majority of a population (e.g., a country or community). Essential drugs are selected by considering the drugs needed to treat the common diseases affecting that population and standard treatment guidelines. Essential drugs should be available at all times in adequate amounts, in the appropriate dosage forms, and at a price that individuals and communities can afford.
first-line drugs	Drugs prescribed for initial therapy of the patient. If first-line drugs fail to successfully treat the infection, providers prescribe <i>second-line drugs</i> .
Global TB Drug Facility (GDF)	A procurement service managed by the Stop TB Partnership. GDF's negotiated and contracted prices are often lower than those obtained by other procurement services.

harmonize	The process of reaching agreement on a common approach to treating a disease (or using or making drugs available) in order to decrease the number of different approaches used in a system, and so increase efficiency and reduce cost.
multidrug-resistant tuberculosis (MDR-TB)	Tuberculosis that is resistant to at least isoniazid and rifampicin, two of the most powerful first-line TB drugs. MDR-TB is typically caused by inconsistent, partial, or incorrect treatment of TB that was otherwise treatable by first-line drugs.
national drug policy (NDP)	A document containing a government's goals for the pharmaceutical sector and the main strategies for reaching these goals. It provides a framework for coordinating activities of the public and private pharmaceutical sectors, NGOs, donors, and other interested groups. It serves as a valuable guide for improving access to drugs, use of drugs, and quality of drugs.
prequalification	A process in drug procurement by which a buyer determines whether a supplier meets specific criteria before advertising tenders. The buyer later invites only suppliers who meet the prequalification criteria to bid on the drug tenders. Prequalification is one form of selecting suppliers. (See selection of suppliers .)
rational drug use	Programs achieve rational drug use when patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.
selection of suppliers	A process in drug procurement by which buyers identify the suppliers from whom they can reliably order drugs of good quality at reasonable prices. Selection of suppliers can occur as prequalification, before tenders are advertised, or as postqualification, after tenders are advertised and bids are received. To select suppliers, buyers should require certificates from manufacturers and regulatory agencies indicating that the manufacturers are licensed and inspected by local authorities, gather information on suppliers' reliability and product quality, inspect samples of products, and, if necessary, conduct laboratory tests of drugs that may be unstable or have problems with bioavailability.
standard treatment guidelines (STGs)	Recommended treatment practices for a diagnosed illness. DOTS recommends different treatment regimens depending on a TB patient's situation. For example, the DOTS STGs specify different drug combinations and duration of therapy for patients who have recently developed active infectious TB and those who are being retreated due to previous treatment failure or relapse.
tender	The procedure in which a buyer formally invites bids from suppliers for a particular contract. The contract defines the buyer's specific terms and conditions. In an <i>open tender</i> , a buyer formally invites bids from any local or international manufacturer for the supply of drugs under their nonproprietary names. In a <i>restricted tender</i> , a buyer limits bidding to suppliers who meet certain prequalification requirements.
transparent	A feature of a process meaning that the process is so clear and open that outside parties can understand all actions and decisions.

The TB data in this issue was drawn from the World Health Organization; the Stop TB Partnership's Web site; R. Colebunders and M. L. Lambert, "Management of Co-Infection with HIV and TB" (*British Medical Journal* vol. 324 [April 6, 2002]: 802–3); and C. Dye et al., "Global Burden of Tuberculosis: Estimated Incidence, Prevalence, and Mortality by Country" (*Journal of the American Medical Association* vol. 282 [August 18, 1999]: 677–86). For more information about drug management, please refer to the following sources.

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- requirements for quantifying drugs and supplies
- procurement strategies and supplier selection
- managing the tender process
- principles of contracting
- quality assurance
- monitoring and evaluating supplier performance

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Checklist for Improving Drug Management to Control TB

- Advocate for policies and laws that promote availability and appropriate use of TB drugs.
- Use DOTS guidelines to select all five of the essential first-line TB drugs, and consider fixed-dose combinations of these drugs. Do not select second-line TB drugs unless your country's program has qualified as a DOTS-Plus pilot project.
- Follow effective pharmaceutical procurement practices, quantify drug needs, use appropriate procurement methods to foster competition, determine qualifications of suppliers, provide suppliers with specifications for drugs and packaging, assure drug quality, and monitor suppliers' performance.
- Assure effective distribution systems to ensure that TB drugs are available at all times in the quantities needed at all service delivery points where drugs are administered to patients.
- Support DOTS standard treatment guidelines and develop a system for direct observation of patient adherence. Monitor prescribing practices; establish relations with private providers; develop educational programs for providers, patients, and communities about appropriate use of TB drugs; and develop incentives for patients and providers.
- Include TB control in strategic, annual, and short-term work planning. Implement plans to improve TB drug management. Monitor and evaluate TB drug management.
- Use the framework of the drug management cycle to think through the impact of potential decisions on TB drug selection, procurement, distribution, and use.

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