

## **6. Drug Management**

### **Introduction**

One of the five components of the DOTS scheme is an uninterrupted supply of quality-assured drugs. The NTP must ensure that patients have their medicines when they need them to prevent transmission of the disease. Therefore, NTP managers must be involved at all levels of the medicines supply system, including selection, procurement, distribution, use, and quality assurance.

### **Selection**

There are no indicators included in this manual for the selection component of drug management. Even so, the NTP must be a member of the essential medicines committee that updates and approves the standard TB treatment regimens. The committee must select appropriate drugs on the basis of incidence of the disease as well as drug strengths, use of fixed dose combination products, dosage forms, and type of packaging.

### **Procurement**

The NTP should be a major player in estimating final drug quantities needed for the national program, regardless of whether calculations are done centrally or peripherally. In addition, the NTP should communicate to the procurement department other product-related issues, such as providing feedback on problems encountered in treatment centers with the quality of a particular supplier's products and confirming that the procurement department received product quality specifications with the tender documents. A key indicator in this manual concerns the existence of buffer stock (Indicator 6.3). Once buffer stocks are received, they can be shared with district stores as explained within the indicator. When buffer or reserve stocks are procured in addition to the estimated quantities needed, the national program will have sufficient stocks to respond to unplanned occurrences (e.g., an unexpected increase in TB cases).

### **Distribution**

To participate in the supply of quality-assured drugs, the NTP should know that deliveries throughout the national program are made in a timely manner and that good stock management practices are followed within storage facilities. Several indicators in this section allow the NTP to monitor those aspects of drug management. For example, Indicators 6.4 through 6.6 will show whether annual quantity estimates are appropriate and whether the medicines supply system is capable of managing inventories, placing orders, and making deliveries in a timely manner.

### **Use**

The use component of drug management requires that the NTP monitor prescriptions to ensure that medicines are ordered according to the standard treatment guidelines of the country and that directly observed treatment is being used in administering medicines to patients, especially during the initial phase. Indicators for the use component are included in Section 5, Case Management and Treatment.

### **Quality assurance**

Quality assurance applies to all of the drug management components. To ensure that quality products are being used, the NTP must be involved at all levels of the medicines supply system. If there is a requirement that anti-TB drugs used by MOH must first be registered by the drug registration authority, the NTP could be the catalyst to ensure that this is arranged and thus avoid later delays when shipments arrive in-country. In a comprehensive QA system, anti-TB medicine samples of incoming products and of products already in storage and treatment facilities should be pulled and tested. To stay abreast of product quality problems, the NTP should receive reports from the quality control laboratory when anti-TB medicines are found to have problems. The two key indicators included in this section are Indicators 6.1 and 6.2, which measure the existence of a drug quality assurance system and the proportion of anti-TB drugs that meet international minimum quality standards, respectively. A complementary indicator (Indicator 6.8) is also included, which measures the percentage of anti-TB drug samples that fail quality control tests.

It is recognized that NTP managers usually do not have full responsibility for procuring and distributing anti-TB medicines. However, the indicators in this section will allow NTP managers to monitor weaknesses in the procurement and supply of anti-TB medicines as they occur and work with other departments to take appropriate actions, such as training staff, obtaining technical assistance from TB partners, and instituting double checks to validate critical activities. Using these indicators, NTP managers can contribute to an uninterrupted supply of quality-assured drugs for patients in their health systems.

### **Indicators**

- Existence of a quality assurance system for drug management
- Anti-TB drugs meeting international minimum quality standards
- Existence of buffer stock at central, regional, or district-level facility
- Accuracy of stock records for anti-TB drugs
- Time anti-TB drugs are out of stock—storage facilities
- Time anti-TB drugs are out of stock—treatment facilities

- Basic management units where anti-TB drugs are available
- Anti-TB drug samples that fail quality control tests

### **Resources**

Brudon P, Rainhorn JD, Reich M. *Indicators for monitoring national drug policies*. Geneva, World Health Organization, 1999 (WHO/EDM/PAR/1999.33).

*Operational guide for national tuberculosis programs on the introduction and use of fixed-dose combination drugs*. Geneva, World Health Organization, 2002 (WHO/CDS/TB/2002.308).

Quick J et al. *Managing drug supply*. Boston, MA, Management Sciences for Health, 1997.

Rational Pharmaceutical Management Plus Program. *Drug management for tuberculosis manual (DMTB)*. Arlington, VA, Management Sciences for Health, 2003.

Trebucq A, Rambert C. *A guide for the procurement of anti-tuberculosis drugs*. Paris, International Union Against Tuberculosis and Lung Disease, 2001.

**Indicator 6.1**

**EXISTENCE OF A QUALITY ASSURANCE SYSTEM FOR DRUG MANAGEMENT**

**Definition**

Existence of a quality assurance system for drug management that monitors the safety of drugs for use by inhabitants of the country. This is a yes/no indicator.

**What It Measures**

This indicator measures whether a comprehensive QA system exists and includes agencies or committees for registering drugs, selecting quality products and suppliers, conducting product certification, developing contract specifications, and performing physical inspections and laboratory analyses when drugs are received, as well as feedback procedures for reporting drug problems. The availability of high-quality drugs is critical to the successful management of TB in countries with multiple sources for anti-TB drugs (e.g., imported from several different countries and/or produced locally).

**How to Measure It**

The indicator is measured by reviewing MOH documents describing the QA system, because these documents are rarely available from the NTP. The QA system can consist of one agency or many, but it must conduct all of the activities mentioned above. A health system could use the subindicators to identify specific weaknesses in the quality system. The overall indicator should be scored as a “yes” only if all of the following components are present:

- Existence of drug legislation and regulation
- Existence of registration service
- Availability of inspection service
- Availability of laboratory testing service.

**Data Sources**

- MOH documents
- National Pharmaceutical Committee documents

**Frequency & Function**

This indicator should be reported annually for national use.

### **Strengths & Limitations**

This indicator is not limited to TB, rather the existence of QA standards is critical for all medications and for the health system in general. In many countries, a drug QA system is already in place. This indicator is an additional check on the quality of anti-TB drugs manufactured locally and/or procured internationally by the health system. The indicator may not be appropriate for external monitoring, especially on a regular basis. Some MOH documents may describe a complete QA system, but in reality, it is only partially functional. This indicator measures the presence of the system, but it does not assess its function.

**Indicator 6.2**

**ANTI-TB DRUGS MEETING INTERNATIONAL MINIMUM QUALITY STANDARDS**

**Definition**

Percentage of anti-TB drugs that meet the batch certificate component of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

$$\frac{\text{Number of batches of anti-TB drugs procured locally and internationally where a batch certificate was received and showed acceptable results during a specified time period}}{\text{Total number of batches of anti-TB drugs procured during the same time period}} \times 100$$

**What It Measures**

Availability of high-quality drugs is critical to the successful management of TB, particularly to avoid the emergence of drug-resistant strains. This indicator measures whether a minimum standard has been met in the procurement of anti-TB drugs both from local and international suppliers. It can also be used for other drugs procured by a health system. The QA model “Scheme on the Quality of Pharmaceutical Products Moving in International Commerce” requires that health systems obtain three certificates when procuring drugs: 1) product certificate, a description of the product and its specifications; 2) statement of licensing of a pharmaceutical product, a business license to produce the product; and 3) batch certificate of a pharmaceutical product, the results of quality analysis and inspection for each batch of product manufactured.

To meet the minimum standard, this indicator requires that the batch certificate is requested and received and that the data are acceptable. The batch certificate is chosen as the minimum because all manufacturers that follow good manufacturing practices (GMP) should produce this report and thus be able to supply it to the procuring agency. Also, the batch certificate can be easily examined by an evaluator to calculate this indicator. (Appendix E contains a model batch certificate.) Information on bioavailability of rifampicin in fixed dose combination products is a key component of QA; even though this information is not included on a batch certificate by the manufacturer, the NTP should communicate with the drug registration authority (DRA) to ensure that the rifampicin bioavailability data have been received and are acceptable.

### **How to Measure It**

The indicator is measured by reviewing drug records from the procurement agent of the NTP and the DRA, if one exists. The numerator is the number of TB drug batches received by the program during the specified time period. Batch certificates should be requested from the procurement agent or the DRA for each batch received. The number of batches with a batch certificate showing acceptable results is recorded as the denominator.

### **Data Sources**

- Procurement agency records
- DRA records

### **Frequency & Function**

This indicator should be reported annually for national use

### **Strengths & Limitations**

The WHO QA scheme was designed for internationally purchased drugs, but WHO and its partners want to promote quality drugs manufactured by local companies as well. The minimum acceptable standard would be to receive a batch certificate indicating the acceptability of each batch of a drug received since all manufacturers who follow GMP standards should produce this document as a matter of course. This indicator allows quick identification of potential serious QA problems within the health system (i.e., if the NTP is unable to produce the required supporting documentation).

**Indicator 6.3**

**EXISTENCE OF BUFFER STOCK AT CENTRAL, REGIONAL, OR DISTRICT-LEVEL FACILITY**

**Definition**

The existence of a buffer stock of anti-TB drugs to ensure regular supplies at TB treatment centers. The standard recommendation is to have a 6-month buffer stock at central storage areas and a 3-month buffer stock at regional or district levels. This is a yes/no indicator.

**What It Measures**

This indicator measures whether the NTP has the resources and organizational capacity to avoid drug stockouts by keeping additional quantities of drugs on hand. Buffer stock is an essential element of the drug supply system for avoiding stockouts at treatment centers. It is difficult for NTPs to determine exact quantities of anti-TB drugs needed from one procurement period to another because of inaccuracy in the reporting system, insufficient financial resources, and supplier delays.

**How to Measure It**

This indicator is determined after a review of quantification records of the NTP or essential drugs program. From the records, data collectors will observe whether a buffer stock has been calculated, ordered, and received at the central and district levels. For example, if the NTP procures once annually, then in addition to the quantity needed for the 12 months, an additional 6-month buffer stock should be procured at the same time. At the district level, the quantity needed for the next 3 months is ordered from the central warehouse plus an additional buffer stock equal to 3 months' treatment. An inadequate buffer stock of any individual anti-TB drugs would result in a "no" score for this indicator regardless of whether or not all other drugs had adequate buffer stock.

**Data Sources**

- TB drug quantification records
- Procurement records

**Frequency & Function**

This indicator should be reported annually for national warehouses and biannually for regional and district warehouses.

**Strengths & Limitations**

This indicator does not measure whether problems exist further down the supply line, whereby stockouts could still occur at the treatment center level. However, this indicator will measure whether the NTP has the ability and resources to avoid stockouts at storage levels to regularly supply anti-TB medications.

**Indicator 6.4**

**ACCURACY OF STOCK RECORDS FOR ANTI-TB DRUGS**

**Definition**

Percentage of stock records that correspond with physical counts for a set of anti-TB tracer drugs in drug storage facilities.

$$\frac{\text{Number of stock records that correspond with physical counts}}{\text{Total number of stock records examined}} \times 100$$

**What It Measures**

Managing drug storage facilities appropriately is important for providing a constant supply of anti-TB drugs to treatment centers. One important activity is the accurate accounting of drugs that are received and distributed by the storage facility. When physical counts of drugs are different from those on stock records, under- or overordering is likely to result.

**How to Measure It**

The quantity of each anti-TB drug in stock must be counted in the warehouses and storage areas of health centers. This quantity is compared with the quantity of each drug documented on the individual stock cards. If this quantity is more than or less than the physical quantity counted, this drug is recorded as not corresponding with stock records. The number of stock records corresponding with physical counts should be summed and then divided by the total number of stock records examined. This number is multiplied by 100 for obtaining the percentage of stock records that are accurate in the storage facility.

**Data Sources**

- Storage facility stock cards for individual drugs
- Physical observations at the facility

**Frequency & Function**

This indicator should be reported biannually for national, regional, and district stores

### **Strengths & Limitations**

This indicator allows managers to monitor the work of stock managers and identify weaknesses in maintaining a constant supply of anti-TB drugs. The frequency of reporting this indicator may be changed to annually once compliance by stock managers has been stabilized.

**Indicator 6.5**

**TIME ANTI-TB DRUGS ARE OUT OF STOCK—STORAGE FACILITIES**

**Definition**

Average percentage of time that first-line anti-TB drugs are not available in storage facilities.

$$\frac{\text{Total number of stockout days for all first-line drugs stocked}}{(365 \times \text{number of anti-TB drugs})} \times 100$$

**What It Measures**

This indicator measures a key DOTS component, uninterrupted drug supply. This is based on the principle that all core anti-TB drugs used in the program must be available when the patient needs them for appropriate treatment and for preventing development of MDR-TB. This indicator should be used in conjunction with Indicator 6.7 for understanding the actual availability of anti-TB drugs and underlying management practices.

**How to Measure It**

Data should be collected from as many storage facilities at the central and district levels as possible. This indicator is calculated by recording the number of days that any drug was out of stock in the past year (or the past 12 months) as recorded on the stock cards and by summing the total number of days out of stock. The number of days is then divided by 365 times the total number of drugs normally stocked, and this fraction is multiplied by 100.

**Data Sources**

- Storage facility stock cards of individual drugs

**Frequency & Function**

This indicator should be reported quarterly for national, regional, and district stores.

### **Strengths & Limitations**

Measurement of this indicator should be a routine activity for internal monitoring. When used during an external monitoring review, an in-depth analysis may not be possible since data are collected only from those sites visited by the evaluation team. Recall bias on the part of providers may result in an inaccurate numerator, and it may be necessary to extrapolate from the most recent quarter to assess stockouts in the previous year. Some health systems do not consistently record movements of stock into and out of the treatment areas.

**Indicator 6.6**

**TIME ANTI-TB DRUGS ARE OUT OF STOCK—TREATMENT FACILITIES**

**Definition**

Average percentage of time that first-line anti-TB drugs are not available in treatment facilities.

$$\frac{\text{Total number of stockout days for all first-line drugs stocked}}{365 \times \text{number of anti-TB drugs in treatment facilities}} \times 100$$

**What It Measures**

The availability of medication is critical to the successful management of TB, and an uninterrupted supply of drugs at treatment centers is crucial to cure patients and to avoid the emergence of drug-resistant strains of TB. This indicator measures a key DOTS strategy component, uninterrupted drug supply. This is based on the principle that all core anti-TB drugs must be available when the patient needs them for appropriate treatment and for preventing development of MDR-TB. This indicator should be used in conjunction with Indicator 6.7 for understanding the actual availability of anti-TB drugs and underlying management practices.

**How to Measure It**

Data should be collected from as many treatment facilities at central, regional, and district levels as possible. This indicator is calculated by recording the number of days that each drug was out of stock in the past year (or the past 12 months) as recorded on the stock cards and by summing the total number of days out of stock for any drugs. The number of days is then divided by 365 times the total number of drugs normally stocked, and this fraction is multiplied by 100.

**Data Sources**

- Facility stock cards of individual drugs

**Frequency & Function**

This indicator should be reported quarterly for regional, district, and community health centers.

**Strengths & Limitations**

This indicator should be a routine activity for internal monitoring. However, when used during an external monitoring review, an in-depth analysis may not be possible since data are collected only from those sites visited by the evaluation team.

**Indicator 6.7**

**BASIC MANAGEMENT UNITS WHERE ANTI-TB DRUGS ARE AVAILABLE**

**Definition**

Proportion of basic management units where anti-TB drugs are present on the day of the survey.

$$\frac{\text{Number of basic management units visited where anti-TB drugs are present}}{\text{Total number of basic management units visited}} \times 100$$

**What It Measures**

The availability of medication is critical to the successful management of TB. This indicator measures the performance of the country's procurement and inventory management system to provide drugs at treatment units when patients need them. This indicator should be used in conjunction with Indicators 6.5 and 6.6 for understanding the actual availability of anti-TB drugs and underlying management practices.

**How to Measure It**

Data should be collected from as many TB BMUs as possible. This indicator is calculated by recording which anti-TB drugs are available on the shelves and in storage areas on the day of the visit for each management unit. This is compared with a list of drugs that should be available. Expired drugs should not be included as being available since they cannot be used to treat patients. The units that have any missing anti-TB drugs should be documented. The number of BMUs where all anti-TB drugs are available on the day of the survey is summed. This number is then divided by the total number of BMUs visited.

**Data Sources**

- Drugs stocked in TB BMUs and stock records

**Frequency & Function**

This indicator should be reported quarterly for national use.

**Strengths & Limitations**

This indicator could be a routine activity for internal monitoring. However, when used during an external monitoring review, an in-depth analysis may not be possible since data are collected only from those sites visited by the evaluation team.

**Indicator 6.8**

**ANTI-TB DRUG SAMPLES THAT FAIL QUALITY CONTROL TESTS**

**Definition**

Percentage of anti-TB drug samples that failed quality tests in the country's quality control analysis laboratory.

$$\frac{\text{Number of anti-TB drug samples that failed quality control testing}}{\text{Total number of anti-TB drug samples tested in the country's quality control analysis laboratory}} \times 100$$

**What It Measures**

Anti-TB drugs must be purchased from reputable sources and certified by the authority in the recipient country to be safe, efficacious, and of good quality. The drug supply system must take care to store drugs appropriately. This indicator measures the proportion of anti-TB drugs tested that did not meet the standard quality criteria set by the recipient country. Ideally, no samples should fail quality testing, but this is usually not the case. Failed samples indicate poor manufacturing and delivery practices on the part of the supplier and poor distribution practices on the part of the recipient country.

**How to Measure It**

The total number of anti-TB drug samples that failed quality control testing is recorded and divided by the total number of anti-TB drug samples actually tested. This number is multiplied by 100 for obtaining the percentage of drugs that failed quality control tests.

**Data Sources**

- Quality control laboratory register
- MOH reports

**Frequency & Function**

This indicator should be reported annually for national use.

**Strengths & Limitations**

This indicator will not be useful in the few countries that do not have a local product quality testing laboratory. Such countries usually rely on the product manufacturer's quality testing (Indicator 6.2).