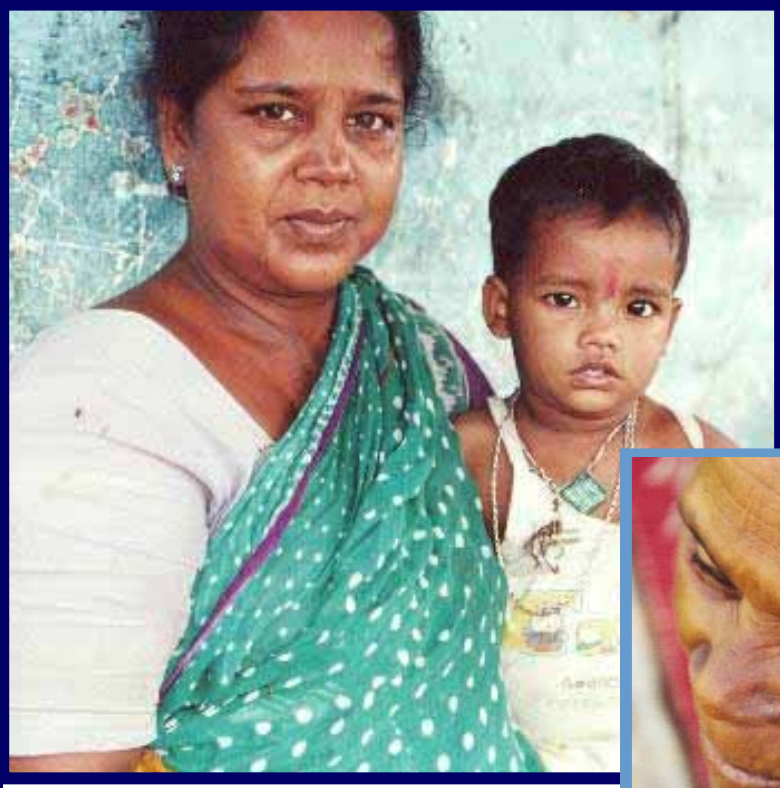

Pharmaceutical Management for Tuberculosis

Assessment Manual

MSH
MANAGEMENT SCIENCES for HEALTH
RPM Plus | Rational Pharmaceutical Management Plus

USAID
FROM THE AMERICAN PEOPLE

PMTB

PHARMACEUTICAL MANAGEMENT FOR TUBERCULOSIS

ASSESSMENT MANUAL

Revised Edition 2005

MSH
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FROM THE AMERICAN PEOPLE

This manual was made possible through support provided by the U. S. Agency for International Development, under the terms of Cooperative Agreement Number HRN-A-00-00-00016-00. The opinions expressed herein are those of the authors and do not necessarily reflect the views of the U.S. Agency for International Development.

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen pharmaceutical and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation in improving the availability of health commodities—medicines, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning, as well as in promoting the appropriate use of health commodities in the public and private sectors.

Acknowledgments

Cover photo, left (IN464_1): © 2001 MSH. Photographer: Moumina Dorgabekova. *A mother and her young child in Calcutta, India.*

Cover photo, right (ZA433_1): © 2002 MSH. Photographer: Carmen Urdaneta. *A closeup view of an elderly woman in the Kwazulu Natal Province in South Africa.*

Recommended Citation

Rational Pharmaceutical Management (RPM) Plus Program. 2005. *Pharmaceutical Management for Tuberculosis Assessment Manual*. Edited by A. Zagorskiy, C. Owunna, and T. Moore. Submitted to the U.S. Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health.

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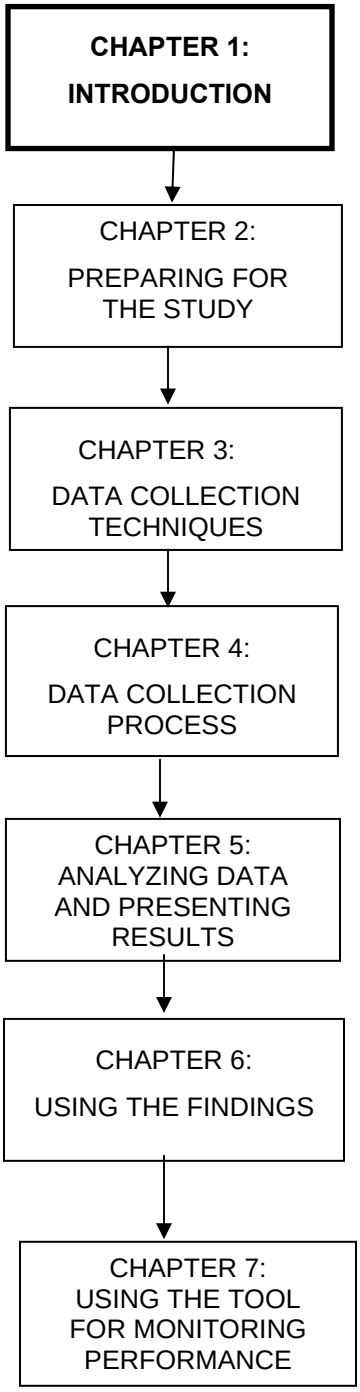
CONTENTS

ACRONYMS

AFB	acid fast bacilli
AIDS	acquired immunodeficiency syndrome
BCG	bacillus Calmette-Guérin
BASICS	Basic Support for Institutionalizing Child Survival [project]
CDC	U.S. Centers for Disease Control and Prevention
CIF	cost, insurance, and freight
CMS	central medical store
DOTS	internationally recommended strategy for tuberculosis control
EML	essential medicines list
FDC	fixed-dose combination [medicine]
FOB	free on board
GDF	Global TB Drug Facility
GFATM	Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
HIV	human immunodeficiency virus
IDA	International Dispensary Association
INN	international nonproprietary name
MOH	Ministry of Health
MDR	multidrug resistant
MSH	Management Sciences for Health
NGO	nongovernmental organization
NTP	national tuberculosis program
PHC	primary health care
PMTB	Pharmaceutical Management for Tuberculosis
PTB	pulmonary tuberculosis
RMS	regional medical store
RPM Plus	Rational Pharmaceutical Management Plus [Program]
STGs	standard treatment guidelines
TB	tuberculosis
UNION	International Union Against Tuberculosis and Lung Disease
USAID	U.S. Agency for International Development
VEN	vital, essential, nonessential
WHO	World Health Organization

PHARMACEUTICAL MANAGEMENT FOR TUBERCULOSIS ASSESSMENT MANUAL



Chapter 1.

INTRODUCTION

Tuberculosis Situation and Control

Tuberculosis (TB) is an infection that spreads like the common cold and accounts for more than two million deaths each year. Although an inexpensive curative treatment is available that is effective in up to 95 percent of cases, more than 8 million people still develop active TB each year.[1] The disease is on the rise in many developing and transitional countries, arising from a combination of economic decline, the collapse of health systems, inadequate application of TB control measures, the spread of HIV/AIDS, and the emergence of multidrug-resistant TB (MDR TB).

The World Health Organization (WHO) recommends DOTS as a cost-effective treatment strategy for detection and cure of TB. DOTS consists of five main elements: sustained political commitment; access to quality-assured sputum microscopy; standardized short-course chemotherapy for all cases of TB under proper case management conditions, including direct observation of treatment; uninterrupted supply of quality-assured drugs; and a recording and reporting system to enable outcome assessment of all patients and assessment of overall program performance.[2]

[1] World Health Organization. 2004. "Tuberculosis." Fact Sheet No. 104. <http://www.who.int/mediacentre/factsheets/who104/en/> (accessed Dec. 2004).
[2] World Health Organization (WHO). 2003. *Treatment of Tuberculosis: Guidelines for National Programmes.* 3rd ed. WHO/CDS/TB/2003.313. Geneva: WHO.

Global initiatives such as the Stop TB Partnership, the Global TB Drug Facility (GDF), the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and the Green Light Committee (GLC), as well as WHO working groups (DOTS expansion, DOTS Plus, TB/HIV, TB laboratory), were established in response to the escalating prevalence of the disease. However, while it was proved that tuberculosis could be successfully treated with modern medicines and treatment regimens, many countries fail to reach the WHO global targets of cure rates of at least 85 percent and 70 percent detection of patients with sputum smear-positive pulmonary TB. This situation is largely due to lack of political commitment and funding, failure to manage cases adequately, and inconsistent supply of TB medicines to patients. TB intervention strategies should be continuously monitored to identify gaps in national TB control programs exhibiting low cure rates.

In 2000, the Rational Pharmaceutical Management Plus (RPM Plus) Program, supported by the U.S. Agency for International Development (USAID), prepared the *Drug Management for Tuberculosis (DMTB) Assessment Manual* to assist TB program managers, governments, and partners in evaluating pharmaceutical system capacity to provide a constant supply of TB medicines. This update, renamed the *Pharmaceutical Management for Tuberculosis (PMTB) Assessment Manual*, was completed in 2004.

The Role of WHO in National Tuberculosis Program Surveys

In 1998, WHO published its *Guidelines for Conducting a Review of a National Tuberculosis Programme*.[3] The *Guidelines* summarized 10 years of experience by WHO and national governments in conducting national tuberculosis program (NTP) reviews and provided tools that could be used to evaluate the success of an NTP. The tools consist of data collection forms and questionnaires that cover all aspects of diagnosing and treating tuberculosis. The tools allow reviewers to produce a comprehensive report on the TB situation in a country, including epidemiology, demographics, reporting, treatment methods, and outcomes.

The PMTB tool was designed so that it can be integrated into the WHO review of the NTP process in host countries or be used to conduct stand-alone studies. In 2000, Management Sciences for Health (MSH) participated in a survey by WHO, USAID, and the U.S. Centers for Disease Control and Prevention (CDC) of the NTP in Ukraine, where some of the indicators discussed in the *PMTB Assessment Manual* were successfully utilized. This latest revision of the manual is based on experiences and feedback received from field-tests conducted in the Republic of the Congo (Brazzaville), India (Uttar Pradesh), and Ethiopia. The revision is also harmonized with other RPM Plus manuals for assessing pharmaceutical system capacity in childhood illness and malaria supply systems.

Another publication helpful for TB program managers and other stakeholders is WHO's August 2004 *Compendium of Indicators for Monitoring and Evaluating National Tuberculosis*

[3] World Health Organization (WHO). 1998. *Guidelines for Conducting a Review of a National Tuberculosis Programme*. WHO/TB/98.240. Geneva: WHO.

Programs.[4] The compendium includes inputs from various partners, and MSH's RPM Plus Program contributed to the development of the pharmaceutical management section.

It is important to mention that the challenge of ensuring an efficient and cost-effective pharmaceutical supply system is constantly evolving. Changes in country policies, budgets, and economic priorities can have an impact on TB pharmaceutical systems. The GDF and GLC initiatives were established by the global Stop TB Partnership to assist countries that are implementing DOTS to increase their access to high-quality TB medicines and promote expansion of DOTS. The GDF focuses on first-line TB medicines, while the GLC focuses on second-line medicines for MDR TB. USAID, WHO, and others interested in pharmaceutical supply systems will continue to work toward updating and improving the tools and strategies presented in this manual.

Objectives of the *PMTB Assessment Manual*

The purpose of the *PMTB Assessment Manual* is to assist the user in assessing those aspects of the pharmaceutical management systems that are critical to ensuring the availability and proper use of essential TB medicines. This manual is not intended for users who need or wish to conduct a complete assessment of the entire pharmaceutical system. Such an assessment is beyond the scope of this manual. The Rational Pharmaceutical Management Project (the precursor to RPM Plus) developed the *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach* manual[5] to serve as a guide for conducting a comprehensive assessment. The *PMTB Manual*, while based on the rapid assessment model, is tailored to the needs of an NTP and partners (GDF, GFATM, GLC, WHO, and others) and complements the more comprehensive manual.

The main objective of this manual is to provide an approach for conducting studies that will:

- Provide data on TB pharmaceutical management practices
- Identify ways to monitor and improve the NTP pharmaceutical management system, thereby promoting an uninterrupted supply of quality TB medicines
- Create country-based operations research capacity by transferring this self-assessment technology

[4] World Health Organization (WHO). 2004. *Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Programs.* WHO/HTM/TB/2004.344. Geneva: WHO.
[5] Rational Pharmaceutical Management Project, University Research Corp., and Pan American Health Organization. 1995. *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach.* Arlington, VA: Management Sciences for Health.

Cornerstones of Pharmaceutical Management

Selection, Procurement, Distribution, and Use

A TB pharmaceutical management system involves four basic functions: *selection*, *procurement*, *distribution*, and *use*. *Selection* involves choosing high-quality TB medicines, appropriate dosage forms (e.g., fixed-dose combination [FDC] medicines), and appropriate packaging such as patient kits. *Procurement* requires quantifying TB medicine needs, selecting appropriate procurement methods, managing tenders, establishing contract terms, ensuring adherence to those terms, and assuring pharmaceutical quality. *Distribution* includes clearing commodities through customs, performing inventory control and stores management, and delivering pharmaceuticals to medicine depots and TB facilities. *Use* includes diagnosing, prescribing, dispensing, administration, and proper consumption by the patient. Each function builds on the next, forming the pharmaceutical management cycle (Figure 1).

At the center of the pharmaceutical management cycle is a core of management support systems: overall organization, financing and sustainability, information management, overall quality assurance, and human resources management. These management support systems hold the pharmaceutical management cycle together. Finally, the entire cycle rests on a policy and legal framework that establishes and supports the public commitment to TB medicine supply. Figure 1 shows a graphic display of the pharmaceutical management cycle.

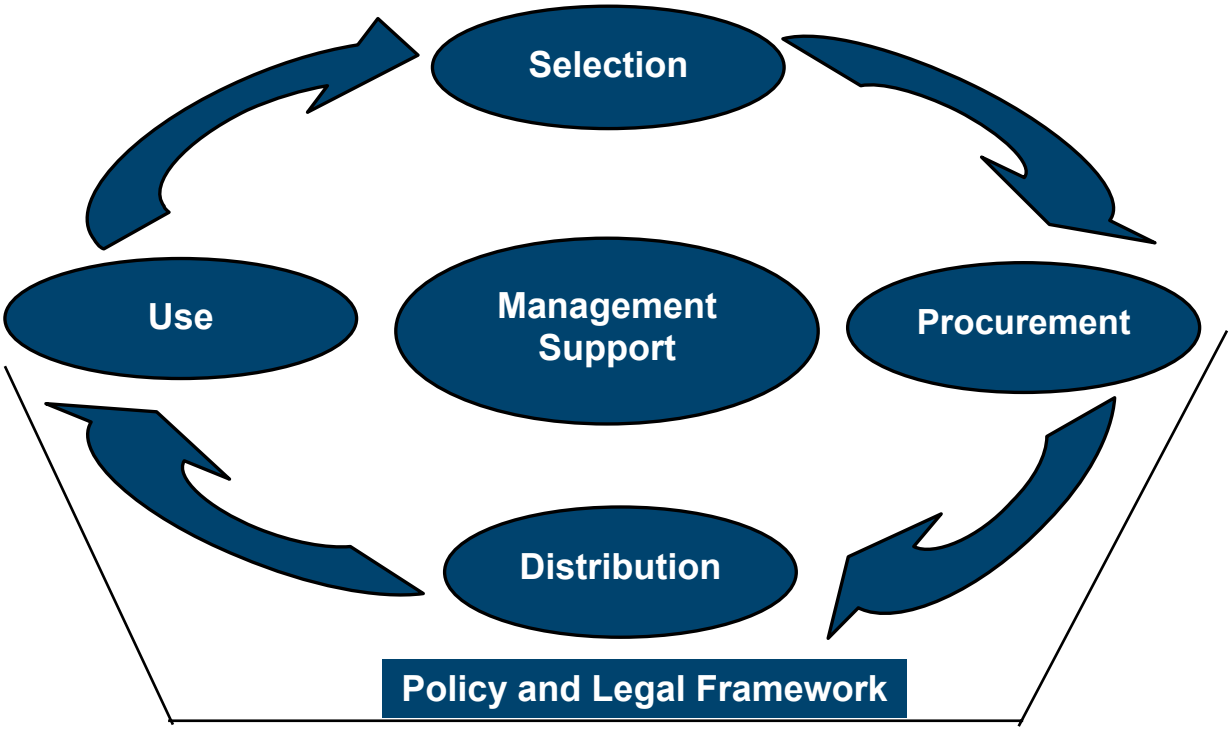


Figure 1. The pharmaceutical management cycle

As described in Chapter 2, this manual will be used to review and discuss the different areas of the pharmaceutical management cycle (selection, procurement, distribution, use, management support, and policy and legal framework).

Pharmaceutical Management in Support of National Tuberculosis Programs

One barrier to effective TB case management in the health system is that the needed medicines are often not available or accessible. The NTP requires that health workers and patients have access to specific medicines and supplies. If these commodities are not accessible, the NTP will not function.

The actual management and use of pharmaceuticals is influenced by a wide range of factors, including medicine availability, provider experience, economic influences, cultural factors, community belief systems, and the complex interactions among these factors.

Medicines have special importance for the following reasons:

- Medicines save lives and improve health.
- Medicines promote trust and participation in health services.
- Medicines are costly.
- Significant improvements in the supply and use of medicines are often feasible.
- The treatment of TB is long term and requires many months in a full course of treatment; therefore, any interruption in medicine supply can easily nullify treatment and lead to drug resistance.

Poor pharmaceutical management can result in losses that exceed more than 70 percent of initial acquisition costs of medicines, and such medicine shortages contribute to the spread the TB epidemic. Poor pharmaceutical management practices can result in inappropriate selection of TB medicines (not selecting in accordance with WHO DOTS recommendations or national treatment guidelines), incorrect quantification, high acquisition prices, poor medicine quality, theft, improper storage, expiration of medicines, irrational prescribing, and incorrect medicine use by patients. Improving the supply and management of TB medicines needed by an NTP is possible. Effective management saves money, improves treatment outcomes, and reduces the chance that drug-resistant TB bacteria (*Mycobacterium tuberculosis*) will develop.

Purpose of the Assessment and Target Audience

Purpose of the Assessment

A national tuberculosis program should ensure that the medicines recommended in the national treatment guidelines of DOTS coverage areas are available to patients. This process requires a systematic assessment. The *PMTB Assessment Manual* presents an indicator-based approach for assessing pharmaceutical management systems (in the public and private sectors) and activities specifically tailored to the needs of an NTP and its partners. This manual has a number of potential applications, including the following:

- Evaluating the status of the TB pharmaceutical system, revealing its strengths and weaknesses
- Designing and planning interventions
- Providing information for budget or resource planning
- Monitoring changes in procedures and measuring the impact of interventions
- Comparing the performance of different systems, programs, or countries

Completion of the assessment should result in the identification of problems, the determination of which problems might be solved in the short or long term, and the analysis of which types of interventions are practical in terms of cost-effectiveness and feasibility.

Target Audience

This manual is intended for use by health professionals with an interest in pharmaceutical management systems who work at the central or district level. The users of this manual may include the following:

- The Stop TB Partnership (led by WHO)
- International partners and organizations involved in tuberculosis programs (such as GDF, GFATM, GLC, and USAID bilaterals)
- Managers of national tuberculosis programs, Ministry of Health (MOH) decision makers, health planners, health economists, and donor representatives
- System managers at the national, regional, or local levels wishing to measure the performance of the NTP pharmaceutical management and supply system
- Social scientists and health project or facility managers who are interested in NTP operational research and management tools

How to Use the PMTB Tool

The *PMTB Assessment Manual* is designed to take users step by step through the NTP pharmaceutical management process, beginning with introducing the concept of indicator-based assessments, then describing studies that identify specific strengths and weaknesses of the pharmaceutical supply system for the NTP, and ending with recommendations for ongoing performance monitoring and possible strategies for improvement.

The studies use specific indicators to measure the performance of a particular aspect of the NTP pharmaceutical supply system. Objective indicators and specific program targets provide concrete measures against which actual performance can be compared. The four general criteria for useful indicators are:

- *Importance:* Each indicator must reflect an important dimension of performance.
- *Measurability:* Indicators must be measurable within the constraints of time, variable quality, and availability of data.
- *Reliability:* Each indicator must be reliable over time and with different observers.
- *Validity:* Each indicator must allow a clear and consistent interpretation and have a similar meaning across different environments.

The indicators used in the study are listed as follows and meet these basic criteria.

List of PMTB Indicators

Following is the list of 13 PMTB indicators that are used to assess a TB pharmaceutical management system. The list includes five key indicators and eight complementary indicators. Key indicators should be measured by the NTP to ensure a regular supply of cost-effective, high-quality TB medicines and determine if they are being used correctly according to the program's standard treatment guidelines (STGs). Complementary indicators can be used by the NTP to broaden its monitoring of the TB pharmaceutical management activities. Detailed descriptions of the PMTB indicators are included in Annex 2.

Key Indicators

K-1. Average percentage of time out of stock for a set of TB tracer commodities in TB facilities

K-2. Average percentage of a set of TB commodities available in TB facilities and medical stores

K-3. Percentage of new smear-positive patients with pulmonary TB who were prescribed correct medicines in conformity with the standard treatment guidelines used in the country

K-4. Percentage of TB medicines received in the past three shipments that were accompanied with a batch certificate

K-5. Percentage of median international price paid for a set of TB commodities that was part of the last regular procurement

Complementary Indicators

C-1. Percentage of NTP medicine products included on the national essential medicines list (EML)

C-2. Percentage of NTP medicine products included on the WHO tuberculosis essential medicines list

C-3. Percentage of TB medicine samples that failed quality-control testing out of the total number of TB medicine samples tested during the past year

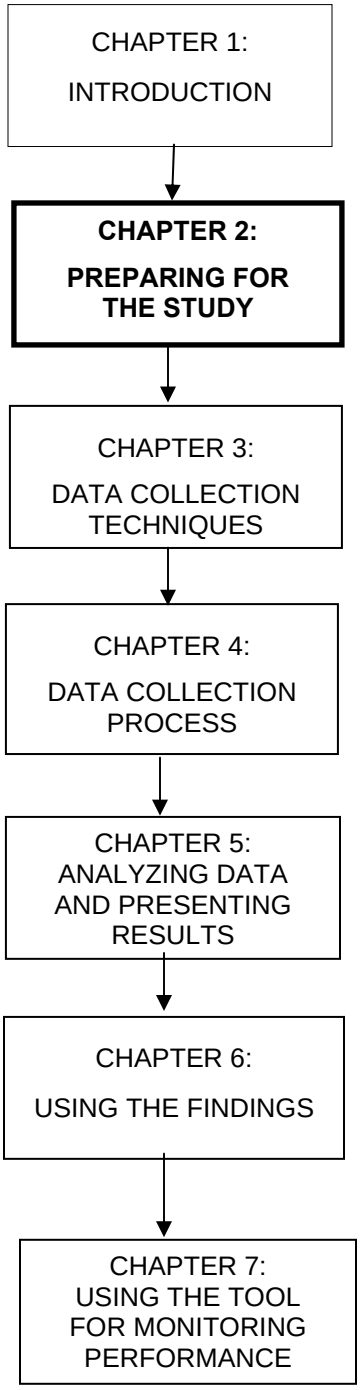
C-4. Percentage of TB facilities visited where the most recent official manual of treatment guidelines for TB was present

C-5. Percentage of TB outpatients who could correctly describe how the prescribed medication should be used

C-6. Percentage of TB patients who reported regular observation by a health care worker during medicine intake

C-7. Average percentage of stock records that correspond with physical counts for a set of TB tracer commodities in TB storage facilities

C-8. Number of days that a person has to work at minimum wage to pay for a complete TB treatment course, taking into account the price of medicines in the public or private market


CHAPTER 1:
INTRODUCTION
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ANALYZING DATA AND PRESENTING RESULTS
CHAPTER 6:
USING THE FINDINGS
CHAPTER 7:
USING THE TOOL FOR MONITORING PERFORMANCE

Chapter 2.

PREPARING FOR THE STUDY

Introduction

This manual is intended as a tool to assess the pharmaceutical management system in support of an NTP. The PMTB tool is an indicator-based study. The general approach to a systematic assessment requires answers to the following questions:

1. What national policies and procedures support national TB control activities?
2. Are the medicines and supplies required to treat TB patients available in public and private TB facilities?
3. What are the determinants of product availability in the public sector and what can be done to bring about improvement?
4. What systems are in place to ensure acceptable quality assurance of TB medicines?
5. What are current prescribing practices for tuberculosis?
6. Are the current TB prescribing practices clinically appropriate?
7. Are medicines that are required to treat tuberculosis affordable in the public and private sectors?
8. Are TB patients well informed about the disease and importance of adherence to treatment regimens?

As part of the preparation to conduct the study, two tasks must be completed: gathering background information and preparing an overview of the TB pharmaceutical management operations. Both will be useful in training data collectors and in putting the findings in the proper context.

In most countries, tuberculosis control is the responsibility of the public sector, on which this manual is mainly focused; however, in some countries, the private sector plays a significant role in TB treatment. Key and complementary indicators can be adapted to suit specific country situations with the consideration of certain factors, such as the types and format of patient records and accessibility of patient records for data collection within the public and private sectors.

Gathering Background Information

As mentioned earlier, certain figures, rates, and statistics on tuberculosis are important to the study of TB pharmaceutical management. Investigators should collect and document the data shown in Table 1 before commencement of data collection for the study.

Table 1. Background Information to Collect Before Study

National and regional population figures
Rates of population increase
Dates covered by the government fiscal year
Exchange rates of local currency for U.S. dollars for the data collection periods
Inflation rates for the previous five years
Average income by population groups and minimum wage
Medicine financing strategy in the country
Epidemiological data on tuberculosis in the country (and surveyed region)
Epidemiology data on TB patients with HIV/AIDS in the country (and surveyed region)
Policies for tuberculosis control
Policies for referral of TB patients to HIV/AIDS services and vice versa
Structure of government TB services
Structure of private TB coverage programs
National (regional) official STGs for tuberculosis
TB diagnostic methods
Percentage of children covered by bacillus Calmette-Guérin (BCG)
List of all antiretrovirals, TB medicines, and supplies registered in the country (including FDCs) and registration policy
Policies and regulations pertaining to medicine quality (tendering, contracting, postmarketing surveillance)
Description of existing TB reporting mechanisms
Description of the NTP monitoring system
All available data on drug-resistant tuberculosis
Information on private sector involvement in TB treatment

Preparing an Overview of MOH Pharmaceutical Management Operations

To efficiently carry out the study, analyze data, interpret results, and make recommendations for supply system improvement, it is essential to have a good understanding of current pharmaceutical management operations. At a minimum, this knowledge should include qualitative descriptions of major problems that affect the movement of medicines through the procurement and distribution system, as well as all the information listed in Table 2.

Table 2. MOH Pharmaceutical Management Operations

Numbers and distribution of TB facilities, storerooms, and warehouses
Numbers and distribution of TB drug outlets and pharmacies
Numbers and distribution of TB pharmaceutical wholesalers, distributors, and manufacturers
Diagram showing system of TB medicine procurement and distribution, which should also include the offices responsible for managing procurement of TB medicines (by both purchase and donation), location of storage facilities, and TB facilities
List of sources of TB medicines flowing through the supply system and estimated values for each source, including budgets, and contributions of donors and nongovernmental organizations (NGOs)
Summary of transport arrangements linking storage and TB facilities. This summary should be as specific as possible, indicating numbers and types of vehicles available by geographic zone. If transport is through contract arrangements with parastatal or commercial agencies, describe those arrangements and indicate the budgets.
Lists of all TB medicines by international nonproprietary name* (INN) and brand name in the country
Copy of the national medicine formulary/EML or total number of TB medicines plus total number of all medicines on the formulary/EML
Description of a system(s) for recovering the cost of TB medicines dispensed in MOH TB facilities

*The international nonproprietary name, also called the generic name, is the pharmaceutical's official name irrespective of who manufactures or markets the product. This name is recommended by WHO as a universal term for a given pharmaceutical.

In most countries, investigators will gather all of these items through interviews and document review. The best approach is to prepare a plan for collecting this information (see Table 3). The information should be distributed to the data collectors at the start of the training.

Table 3. Plan for Collecting Information to Provide an Overview of Pharmaceutical Management Operations

Information Required	Whom to Ask/Interview	What Document to Review or Data to Collect
Organigram	Central Health Administration, Pharmaceutical Section	Organizational structure of health system, including job titles and names of staff
TB medicine sources	Central Warehouse Administration	Invoices of medicine orders and receipts
Central/district budgets	Central and District Health Administrative Offices	Budgets for past two years plus current year
Warehouse distribution	Central/Regional Warehouse Administration	Distribution plan (list of pharmacies and health centers that indicates the flow of medicines)
Transport arrangements	Central/Regional Warehouse Administration	Transportation schedule for all pharmacies and health centers, indicating how medicines are delivered
Major procurement problems	Central/Regional Warehouse and Pharmaceutical Section of Central Health Administration	Reports of past tenders, medicine orders, and receipts; interviews with Section Director and Warehouse Director
Major distribution problems	Central/Regional Warehouse and Pharmaceutical Section of Central Health Administration	Reports of distribution problems; interviews with Section Director and Warehouse Director

Planning the Study

The PMTB study collects data from four different settings: central level, regional level, TB facilities, and TB drug outlets (which include public, private, and NGO/Mission-type drug outlets). Each part addresses some aspect of the questions listed at the beginning of this chapter and when viewed together provide the status of the NTP pharmaceutical system.

Selection of Personnel to Conduct the Assessment

RPM Plus's experience in conducting a countrywide assessment of a pharmaceutical management system suggests that the most practical way to carry out this type of study is for two or more experienced investigators to work together over a period of approximately four weeks. An ideal combination would include the following:

- A *pharmaceutical management specialist* to take charge of study coordination and data collection for logistics at the *central and regional* levels. For this task, familiarity with pharmaceutical policy, logistics management, procurement, and budget issues would be most useful.

- A *health care provider* such as a physician, pharmacist, or nurse to take charge of the surveys to be carried out at the *TB facility and retail outlet* levels. For this, familiarity with TB pharmaceutical commodities and work routines in TB facilities would be an asset.

- A team of trained data collectors to supplement the work of the investigators by visiting medical stores, TB facilities, and TB drug outlets.

However, in some countries, personnel with the above-mentioned expertise might not be available. In this case, schoolteachers, university graduates, and MOH workers may be used. Rigorous training is essential before the data collection process begins.

Selection of Target Sites

National TB programs vary greatly in their organization, goals, and availability of financial and human resources. This manual provides basic indicators and methodology that should be tailored to a specific NTP before the survey is done. This tailoring may require changes in data collection approaches and in selection of data collection sites.

No uniformity exists in where TB patients are treated, even among countries that adopted DOTS as their official strategy. In some countries, new smear-positive TB patients[6] are diagnosed and receive intensive treatment as inpatients in TB hospitals, and then they continue treatment as outpatients, getting their medication at the same facility. In other countries, patients are diagnosed and receive their first prescriptions in one place—for example, at a central TB center—and then are treated as outpatients at primary health care units close to their homes. TB medicines may be free to patients at TB facilities, or patients may be referred to private pharmacies and have to pay out-of-pocket the full or partial price of TB medications.

It is thus important prior to planning data collection to identify all sites and levels of care where TB patients are diagnosed and treated and where medicines are stored and dispensed. Table 4 provides a list of possible venues for data collection, with the check marks (√) indicating potential sites for obtaining the indicator data and the dashes (—) denoting those sites that would not be appropriate for that indicator.

[6] A new smear-positive pulmonary TB patient is defined by WHO as one who has never had treatment for TB or who has taken TB medicines for less than one month.

Table 4. Data Collection Sites for Each Part of the Assessment

Facility	Key Indicators					Complementary Indicators							
	1	2	3	4	5	1	2	3	4	5	6	7	8
MOH	—	—	—	√	√	√	√	√	√	—	—	—	—
MOH pharmaceutical storage	√	√	—	√	—	—	—	—	—	—	—	√	—
Regional pharmaceutical storage	√	√	—	—	√	—	—	—	—	—	—	√	—
Treatment center (initial prescription)	√	√	—	—	√	—	—	—	√	√	√	√	—
TB center (intensive phase)	√	√	√	—	√	—	—	—	√	√	√	√	—
TB center (continuation phase)	√	√	√	—	√	—	—	—	√	√	√	√	—
Drug outlet that dispenses TB medicines	√	√	—	—	√	—	—	—	—	—	—	—	√
Private pharmacy	√	√	—	—	√		—	—	—	—	—	—	√

After completing the two preparatory steps previously discussed, the next activity is to plan the study and to develop a preliminary budget. This manual will provide guidance for planning and carrying out the study. The study plan consists of three steps:

1. Appoint investigators and assign responsibilities
2. Plan data collection
3. Develop the sample design

Step 1: Appoint Investigators and Assign Responsibilities

The investigators will spend about one week planning the study, one to two weeks in data collection, and one week analyzing data and writing the report. The basic organizational strategy is to approach the assessment as two separate data collection efforts:

- Collection of data at central and regional levels
- Sample survey of TB facilities and TB drug outlets

As described earlier in the section on Selection of Personnel to Conduct the Assessment, each of the two investigators should be in charge of one of the data collection efforts. Specifically, the pharmaceutical management specialist should be in charge of organizing the collection of central and regional data, and the health care provider should be in charge of the surveys of TB centers and TB drug outlets. A team of data collectors will likely handle actual data collection. Each of

the investigators should be responsible for carrying out the preparatory steps for their respective data collection areas, as described earlier in this chapter.

Another important planning assignment is the preparation of a budget for the assessment. The budget preparation should be a collaborative effort and, at a minimum, involve both investigators. The budget should include a detailed list of the costs to be incurred, which could include the following:

- Salaries of investigators and data collectors
- Preparation and photocopying of data collection forms
- Communications with district and local authorities
- Training of data collectors
- Travel and per diem for the investigators
- Travel and per diem for data collectors
- Data entry costs
- Miscellaneous costs during the study

Step 2: Plan Data Collection

All of the data required at the central level should be available in the capital city, and most of it should be obtainable through structured interviews and document review. Most of the vital statistics and background information in Tables 1 and 2 will be collected at the central level. Data collection at the levels of the TB centers and TB drug outlets will require a visit to each TB center and drug outlet included in the sample.

Two types of data collection instruments are required for carrying out the study described in this manual. They are (1) the central and regional level data collection checklists and questionnaires and (2) the data collection forms for TB centers and TB drug outlets. Sample data collection forms are listed in Table 5 and are included in Annex 3.

Table 5. Data Collection Instruments Required for the Study

Key Indicators
A-0: General Data Collection Preparation Checklist
A-1: Stock-Out Data Form
A-2: Inventory Data Form
A-3: Medical Records Review Form
A-4: International Price Comparison Form
A-7: Minimum Quality Standards Form
Complementary Indicators
A-2: Inventory Data Form
A-5: Exit Poll Interview Form
A-6: Private/Public Sector Price Comparison Form

Step 3: Develop the Sample Design

Developing the sample design is discussed in detail in this chapter under the section titled Selecting Data Collection Sites.

Adapting the Tool

To adapt and test the data collection instruments, follow these procedures:

- **First,** one of the investigators should review the sample data collection instruments and identify any terms, references, or questions that are not applicable to the country-specific setting. For example, some countries may use the terms *central*, *regional*, *district*, and *community* to describe the levels of MOH facilities, while others may use the terms *national*, *provincial*, and *peripheral* for MOH levels. The suggested changes should then be reviewed by the other investigator (or other study team members) and a consensus reached on the needed changes.

REMEMBER: Include the PMTB tracer commodities on the forms where required during field-testing. See Preparing the List of PMTB Tracer Commodities on the following page.

- **Second,** visit a few TB centers and test the data collection instruments and the methods for collecting the data as described in this chapter.

- **Third,** revise the data collection instruments and, if necessary, the data collection methodology based on the findings from the visit to the TB center. Once they are familiar with the entire data collection process, the study organizers can train all data collectors.

REMEMBER: It is essential to understand that all examples in this tool are sample forms, and although they have been used in a number of countries, they still must be tested and adapted prior to launching data collection activities in a specific pharmaceutical system.

Preparing the List of PMTB Tracer Commodities

Some of the indicators are measured on the basis of a predetermined list of medicines. This list, which is called a tracer commodity list, may also include TB supplies such as syringes, needles, and water for injection. There is no "universal" tracer product list. The PMTB tracer product list will be used at the central, regional, TB facility, and retail levels to collect data for determining inventory management practices and acquisition prices. First- and second-line TB medicines that are on the WHO EML and are recommended for DOTS and DOTS Plus treatments are listed in Annex 5. Because a host country may not be using DOTS as its standard treatment guidelines, or because not all WHO EML TB medicines are registered in all countries, the sample PMTB tracer commodity list should be adapted to the country-specific setting.

It is strongly recommended that NTPs implement DOTS Plus, which manages the second-line medicines, but only if DOTS has already been implemented. The success of TB treatment in countries may depend on more than just the availability of first- and second-line therapies. Sometimes, other patient- and medicine-related variables, such as degree of adverse reaction to the medicine, must be considered.

Preparing a TB tracer commodity list is a two-step process:

1. Use the methods recommended by WHO's *Treatment of Tuberculosis: Guidelines for National Programmes* to adapt the list in Annex 5 to the specific country setting. Annex 1 of this manual provides the WHO-recommended treatment regimens.

2. Gather a group of local TB and pharmaceutical experts to review the list created in the step above and prepare a list of commonly used commodities that should be available in the warehouses and TB centers.

Table 6 contains a sample list of TB medicines and supplies that can be used as a tracer commodity list. The list is meant only as an example. For some of the medicines listed in this sample, more than one strength and/or formulation of the product is presented. For example, isoniazid is listed as tablet 100 mg *or* tablet 300 mg. When adapting the PMTB tracer commodity list and when preparing the data collection forms, only one unique formulation (the one most readily available) should be selected. If more than one strength and/or dosage form of a medicine is included on the tracer list, it should be listed as a separate medicine on the data collection form to ensure accuracy of the data.

Table 6. Sample List of PMTB Medicines and Supplies

International Nonproprietary Name (INN)	Symbol	Strength	Dosage Form	Comment
Ethambutol	E	400 mg	Tablet	
Ethambutol/isoniazid	EH	400/150 mg	Tablet	
Isoniazid	H	100 mg	Tablet	
Isoniazid	H	300 mg	Tablet	
Pyrazinamide	Z	400 mg	Tablet	
Rifampicin/isoniazid	RH	150/75 mg	Tablet	
Rifampicin/isoniazid	RH	150/150 mg	Tablet	For intermittent therapy
Rifampicin/isoniazid/pyrazinamide	RHZ	150/75/400 mg	Tablet	
Rifampicin/isoniazid/pyrazinamide/ethambutol	RHZE	150/75/400/275 mg	Tablet	
Streptomycin	S	1 g	Vial	For category II
Syringe/needle	SYN	5 mL	—	For streptomycin
Water for injection	W	5 mL	Vial	For streptomycin

REMEMBER: This sample TB tracer commodity list must be adapted and finalized—taking into consideration local commodities used, dosage forms, and strengths—before using it in the studies.

Notice that the sample data collection forms list only one formulation (strength and dosage form) of a particular medicine per line for more concrete reporting. Once the tracer list adaptation process is complete, the data collection forms should be revised to reflect the country-specific PMTB list of medicines and supplies.

Selecting Data Collection Sites

Sampling

The goal of the sampling process is to collect enough data, in terms of the actual number of patient encounters and variety and number of sites, for the results to be considered representative of the country. This aspect of the planning process is very important and deserves careful consideration by organizers of the assessment. Failure to ensure that the data set collected is a large enough and varied enough sample to be considered representative could seriously limit the utility of the data analysis and conclusions, since the findings would not be representative of the country's TB pharmaceutical management situation. The following section addresses the four areas of sampling that are critical to the NTP pharmaceutical management assessment process.

To understand the approach for the study design proposed in this manual, it is important to review the purpose and intent of the NTP pharmaceutical management assessment. To summarize:

- The purpose of the assessment is to identify high-priority problem areas that might hinder the implementation of NTP activities and to point to appropriate follow-up activities.
- The study design is a cross-sectional descriptive summary to establish the baseline for monitoring of future interventions.
- The study design is not intended to compare regions, districts, or facilities but rather to describe a reasonably representative TB pharmaceutical management profile for the sample as a whole.
- The study design is intended to facilitate the logistics of the data collection effort within a reasonably short time (one day per TB facility) and with limited financial resources.

The next step in the design process is the selection of patient encounters and the selection of TB facilities and TB drug outlets.

REMEMBER: This survey design task is divided into four steps:

1. Selection for central and regional sites sample
2. Selection for the TB facility sample
3. Selection for patient encounter sample
4. Selection for the TB drug outlet sample

Step 1: Selection for Central and Regional Sites Sample

The exercise of constructing the overview of MOH pharmaceutical management operations often reveals that important variations exist within a procurement and distribution system, and that those differences may affect the supply of NTP medicines and supplies. Some features of the system vary from region to region, from facility to facility, and from prescriber to prescriber. These local variations include such items as climate, financing, sources of pharmaceutical supply, ease of access to facilities, condition of inventory records, or patterns of prescribing practices.

It is important to include facilities representing all significant variants of the overall system in the sample. One way to do this is to choose four geographic areas (that is, districts or regions) in which to work, based on an informed division of the country into groupings determined by such variables as geography, socioeconomic factors, population density, or key features of the health care system. Below are some criteria for selecting four areas in a country:

- The capital city and the main population center (if different) should always be included as one or two of the study areas.
- If the country is relatively homogeneous geographically and epidemiologically, simply choose the capital city and three other regions or districts at random.
- If you expect varying conditions in different areas of the country to influence the way pharmaceuticals are managed, first organize all regions or districts into groups based on these characteristics; then select the capital city and three study areas at random from these groups.

The following three examples show how geographic considerations may be used to develop a sample that is representative of the country:

Example 1: (1) Capital city, (2) highland agricultural district, (3) lowland agricultural district, and (4) arid district

Example 2: (1 and 2) Capital city and one other densely settled urban area, and (3 and 4) two rural agricultural districts

Example 3: (1) Capital city, (2 and 3) two rural districts with reasonably good transportation links, and (4) one relatively inaccessible rural district

Step 2: Selection for TB Centers Sample

The sample size will depend on the structure of TB services and number of TB facilities in the host country. The sample size used in this manual is 20 TB centers, five from each of the four selected geographic regions of the country. The rationale for selecting a sample size of 20 TB facilities is based on experience and the study design factors and assumptions previously discussed.

In some countries, TB patients are diagnosed and receive initial prescriptions at the central or regional level, but are actually treated at the facility closest to their homes. This system means that it may be fairly easy to collect prescription data for 30 patients at each of 20 central/regional level facilities where a record-keeping system is in place. The situation may be more complicated, however; for example, patients may be diagnosed in one place (central diagnostic center), have prescriptions written for them elsewhere (e.g., at regional TB facilities), and then obtain the actual medicines at a small primary health center or from a nurse or community worker close to their homes.

It is impossible to predict what the situation will be like in any particular region. It is thus necessary to involve a host country's TB specialists early in the planning stage of the assessment to discuss the structure of TB services in the country and ways of collecting data at all levels of the system.

To make the actual site selections, follow these procedures:

- First, select the main district TB hospital, which should always be one of the facilities selected in each study district. Select randomly if there is more than one district hospital in the district.

- Then randomly choose four other TB facilities from the list of health centers in the selected district. For systems organized with only one basic tier of outpatient facilities below the district TB hospital (for example, rural health centers), select the other four as follows:

    - If geographic distances and transportation logistics are such that all facilities can be visited and all data can be collected in one day, select four of these second-level units at random, from all of those in the district.

    - If transportation is more difficult, select two facilities at random, and then choose two other facilities that are geographically close to them so that the paired facilities may be visited in one trip.

- For systems with two tiers below the district hospital level (for example, polyclinics staffed by physicians and lower-level health posts staffed by paramedics), select the other four facilities as follows:

    - Choose two second-level TB facilities at random.

    - For each of those two second-level TB facilities, choose one site from the group of third-level facilities that are geographically close. The result is paired sets of second- and third-tier facilities.

- For systems that are organized in a different way, distribute the five facilities to be studied in each district among the possible types of TB facilities, according to such factors as their geographic location or patient load.

Step 3: Selection of Patient Encounter Sample

For new smear-positive pulmonary TB cases (as defined by WHO or according to local criteria), a minimum of 600 patient encounter records must be reviewed (examples of patient encounter records include TB unit registers, medical records, or prescription slips). This number is achieved by randomly selecting 30 medical records in each of the 20 TB facilities. As mentioned earlier, in some health systems where TB patients are treated at small primary health care units close to their homes, it will be necessary to visit more than 20 facilities to acquire data on 600 patients. Local health professionals may help to develop a viable data collection plan.

> **REMEMBER:** An important principle to remember at each phase of this process is *random selection of health facilities and patient records.*

The simplest approach to random selection is to apply the interval method to health facilities. Make sure that the facility lists are complete and organized alphabetically, and then select every n^{th} facility, where n is determined by dividing the total number of available health facilities where TB patients are treated by the desired sample size. For example, if there are 40 health facilities available and 4 are needed for the study, the calculation would be $40 \div 4 = 10$. In this case $n = 10$, so every 10th facility ($n = 10$) on the list would be selected.

Step 4: Selection of TB Drug Outlet Sample

The sample size for TB drug outlets is 20: five from each of the chosen four geographic regions of a country. The most commonly recognized TB drug outlets are pharmacies at TB facilities and pharmacy outlets to which prescribers refer their patients for medicines. It is important to obtain a clear idea of the different types of outlets in operation, their relative proportions and geographic distributions, and regulations that affect sales of TB medicines. The TB drug outlet sample should be selected to include proportional numbers of all major types of outlets. To do this, apply the principles described above for sampling different types of TB facilities.

In selecting the TB drug outlet sample, the simplest approach from the logistical point of view would be to choose the site that is geographically closest to each randomly selected TB facility visited. Two problems with this approach are that (1) those outlets situated closest to TB facilities may not be representative of all outlets; and (2) in some settings where rural TB facilities are located, there may be no pharmacies or other TB drug outlets. A better approach, from the point of view of representative sampling, is random selection within each of the four geographic areas in the sample design. The best way to accomplish this goal is to apply the systematic interval sampling method to health center lists, as described in this chapter under Step 2: Selection for TB Center Sample.

Arranging Logistics

Scheduling

Scheduling is a complicated issue that is affected by factors such as the average time required to collect data at each site, the number of data collectors available, distance between sites, and

transportation arrangements. It is best to begin by thinking in terms of averages and then make refinements by considering the geographic implications of the site sample of the study. Experience with the indicator studies completed so far suggests that, on average, about one day of data collection time and one to two days of travel time are required to complete work at one TB facility.

This experience suggests that 12 data collectors, working in teams of three members at the four geographic sites, would require 10 workdays each, or 11 to 12 calendar days for the whole group to travel out, complete work, and travel back. The time required to cover the TB drug outlets must also be considered. For this group of sites, however, work time is much shorter, so the main variable is geographic distribution.

Staffing

Thus far, discussion has covered the roles of the study investigators and the data collectors. Other types of staff that may be required include one or more data collection managers to supervise and coordinate groups of data collectors, persons to enter or process the collected data, and vehicle drivers. It should be clear that the practical problems of managing a data collection schedule would be greatly simplified by employing these types of workers. Not employing them to save money will be a false economy in most cases.

Transport

It is certainly faster to chauffeur data collectors directly to sites, but buses or other public transport can also be used. In some cases, combination approaches will be useful. For example, some data collectors working in closely grouped sites could be ferried around by drivers while those going to remote sites take the bus, or vice versa.

Letters of Authorization

One important detail that can cause serious problems if overlooked is providing letters of authorization. Each data collector, team manager, and investigator should be provided with letters from the appropriate authority (such as the MOH) that introduce the bearer, request cooperation, and authorize release of data. Letters from different authorities may be required for visits to TB facilities and TB drug outlets. Whenever possible, central level officials should inform the TB facility authorities by telephone or radio prior to the arrival of the data collectors.

Training Data Collectors

Recruiting and Training Data Collectors

The most effective data collectors will usually be doctors, pharmacists, nurses, or paramedical personnel who have worked in TB facilities. There is some risk in using students or other parties who have no practical experience in working with the record-keeping systems that they will encounter. The risks are that the students will have difficulty identifying the required data, and the work will be unduly slow and frustrating; these factors could negatively affect the quality of

the data. A related problem that could produce similar results lies in level of education; some doctors may consider themselves too senior to carry out the relatively tedious work required.

To minimize those risks and promote productivity, a useful strategy would be to pair health care providers with workers who have experience in storage facilities. Perhaps a doctor could be a manager of a data collection team who monitors that data are correct before collectors leave the heath facilities. This system would provide a team that has practical experience with product names and with both stock and clinical record-keeping.

No matter who is recruited, however, it is essential that they are trained and that the training includes actual practice in filling out all forms required for both TB facility and TB drug outlet data collection. Annex 6 provides an outline of a model training course that may be adapted to suit local circumstances.

Training Tips

To make sure that data are collected as intended, it is necessary to provide data collectors with adequate training and practice before they begin work. This preparation helps build the necessary skills and confidence for the upcoming activities. In addition, using the data collection forms during training serves several purposes:

- Identifies and corrects questions that are inappropriate or unclear for the health setting
- Familiarizes data collectors with the questionnaires
- Provides a medium for learning and practicing data collection techniques

The amount of training will vary depending on the caliber of personnel employed and the study methodology. For example, in-depth interviews require more elaborate training, but structured questionnaires use focused questions and therefore require less training.

To ensure that the training activity is carried out properly, the trainers should do the following in advance:

- Identify data collection team managers and data collectors; assign tasks
- Identify a training venue with a space that allows the entire group to gather for lecture-style presentations but also the flexibility to break up into small groups
- Make necessary travel arrangements for data collectors to get to the training venue, if necessary
- Identify at least one TB facility and one TB drug outlet where data collectors can practice data collection during training sessions
- Make sufficient copies of all data collection forms and create individualized packets (described below)

- Prepare practice data for use in practical exercises and role playing
- Schedule training dates to allow sufficient time for all aspects of training

The data collector's packet should include the following (contents may vary depending on the country-specific situation):

- The PMTB *Data Collection Forms and Instructions* (provided separately; also see Annex 3). Note that a separate data collection form is needed for each facility visited and for each patient interviewed in most cases.
- Letter of introduction from a recognized authority to introduce the data collectors to staff at the TB facilities
- Contact information of the team manager (name, mobile telephone number)
- Data collection schedule
- Notebook for taking field notes, two pens, paper clips for securing forms

Data Collection Team Managers

Depending on the context (size of region, number of data collectors, etc.), it may be useful to build a team of managers. The team managers should meet at least one day in advance of the training in order to do the following:

- Receive briefings on all aspects of the study (background, objectives, methods, etc.)
- Review the roles and responsibilities of the supervisors (these should be put into writing)
- Review assignments of sample sites and data collectors
- Review the training program

At a minimum, a team of at least two data collectors with one person serving as team manager is needed.

Training Techniques

To assist in the training process, the following general points about training have been adapted from the *Handbook for Drug Supply Management at the First-Level Health Facility* developed by Basic Support for Institutionalizing Child Survival (BASICS) and WHO in 1998.[7]

Help Data Collectors to Use the Forms Correctly

The data collector may need only a small bit of information to use a particular form correctly. However, if the data collector is not familiar with certain terms or items on the forms, clarify them. There is a good chance that if one data collector is not familiar with the terms or items, others are having the same problem.

[7] World Health Organization (WHO)/Division of Child Health and Development and Basic Support for Institutionalizing Child Survival (BASICS). 1998. *Handbook for Drug Supply Management at the First-Level Health Facility*. Geneva: WHO.

Check the Data Collector's Understanding

A data collector may not understand a procedure and may need individualized help. The data collector may be inexperienced, tired, or less educated than the other data collectors. Be patient and:

- Ask the data collector why he or she is having a problem. Listen carefully. Help the data collector to think through the problem and propose his or her own solutions.

- Encourage the data collector to ask specific questions about how to perform a particular data collection technique.

- Show the data collector where to find the material in the PMTB *Data Collection Forms and Instructions*. Explain that step-by-step instructions on how to collect data are provided with the *Data Collection Forms and Instructions* and in Annex 3 of this manual.

Giving Feedback

The data collectors will be involved in active learning throughout the workshop. Give them feedback as they review the forms and practice the different data collection techniques. Always give constructive feedback. The feedback should occur while or after the participant does the activity, such as completing a question-and-answer exercise, using a checklist, or acting in a role play. It should include showing the participants how to do the activity correctly and giving the participants practice in doing the activity themselves.

Steps for Leading a Simulation or Role Play

Several of the data collection techniques will require data collectors to observe and interview health care workers and TB patients. Role play can be a useful training tool to help data collectors become familiar with such data collection situations. The steps for conducting the simulation or role play follow:

1. Introduce the activity and state its purpose. Give data collectors as much instruction and background information as necessary. Tell them to refer to Annex 3 (sample Data Collection Forms and Instructions). If necessary, demonstrate how to perform the activity.

2. Assign individual roles and responsibilities. Hand out any necessary supplies or job aids.

3. Give data collectors enough time to prepare. You can estimate the time if you have practiced the activity yourself before the training workshop. Remind data collectors to work together to develop simulations and role plays.

4. Arrange the room so that the presenting group is separated from the others. Make sure everyone is able to see the simulation or role play.

5. After groups are prepared, introduce the role play.

- In a simulation, describe the order in which the groups will present their work.
- In a role play, introduce the players and their parts. Remind those data collectors involved in a role play to speak loudly so that everyone can hear.

6. Begin the activity. Ask the groups to present the simulation or role play.

7. Instruct data collectors observing the activity to take notes during the activity for later discussion. Interrupt only if participants are not able to complete the activity.

8. When the activity is finished, thank the group. Ask participants to comment on aspects of the activity that were successful. Then ask about and discuss those parts of the activity that could be improved. Be supportive.

9. Lead a discussion among the data collectors. Conclude the activity by asking data collectors what they have learned.

Following are brief "how to" instructions for data collectors. Review these instructions with the data collectors. The simulation and/or role play exercises can be used to test how well data collectors perform different data collection techniques.

To collect data using the **interview** technique, do the following:

- Review the basic TB treatment requirements with data collectors (in countries where DOTS is officially adopted, review principles of DOTS treatment).
- Review the treatment information that should be provided to a patient by a physician.
- Review the form A-5: Exit Poll Interview Form before the interview begins.
- Wait for patients to leave the health center before you interview them one by one.
- Explain the purpose of your interview (conducting a health care survey).
- Fill in the information at the top of the form indicating the facility, patient, and data collector.
- Ask what was the reason for the consultation (the health problem).
- Ask, "How long have you been taking your medicines?"
- Ask, "Does anybody on the medical staff or a caregiver look at you while you take your medicine?"
- Ask, "How many different kinds of medicines are you taking?"
- Ask, "How many days in a week or in a month do you come to take or collect your medicines?"

- Ask, "When you started taking your TB treatment, how long did your doctor/caregiver tell you that you have to take your medicine before you complete treatment?"
- Ask, "Did your doctor/caregiver tell you to return to the clinic or health center if any sign of adverse effects such as fever, ringing in the ears, or blurred vision, or vomiting occur?"
- Ask, "What will happen if you do not take your medicines as prescribed?"
- Do not leave any spaces blank or unanswered questions on the forms unless the TB patient does not know any of the information.
- Give the completed data forms to the team manager for quality checking before leaving the facility.

To collect data using the **record review** technique, do the following:

- Review the forms A-1, A-2, A-3, and A-10 before starting data collection.
- Based on sample size and time frame of the study, select the MOH records to be studied.
- Record the facility, data collector, and record system information at the top of the forms.
- For each commodity on the list, record all requested information.
- Do not leave any spaces blank unless the information is not documented in the records you are reviewing or not available for use in the study.
- Give the completed data forms to the team manager for quality checking before leaving the facility.

To collect data using the **simulated price inquiry** technique, do the following:

- Review form A-6 before beginning data collection.
- Review the Scenarios for Simulated Price inquiry for tuberculosis in *Data Collection Forms and Instructions* before beginning data collection.
- Based on the sampling plan established for the study, go to the TB drug outlet.
- Enter the drug outlet as any normal client would.
- Present your prescription (see sample form 6b) to the pharmacist or dispenser and request the lowest price for each medicine (same strength and dosage form) on the prescription.
- Review the prices to clarify if it is a unit price or container price.
- Express thanks to the attendant and leave the drug outlet. For each medicine, record the cost of treatment obtained on form A-6.

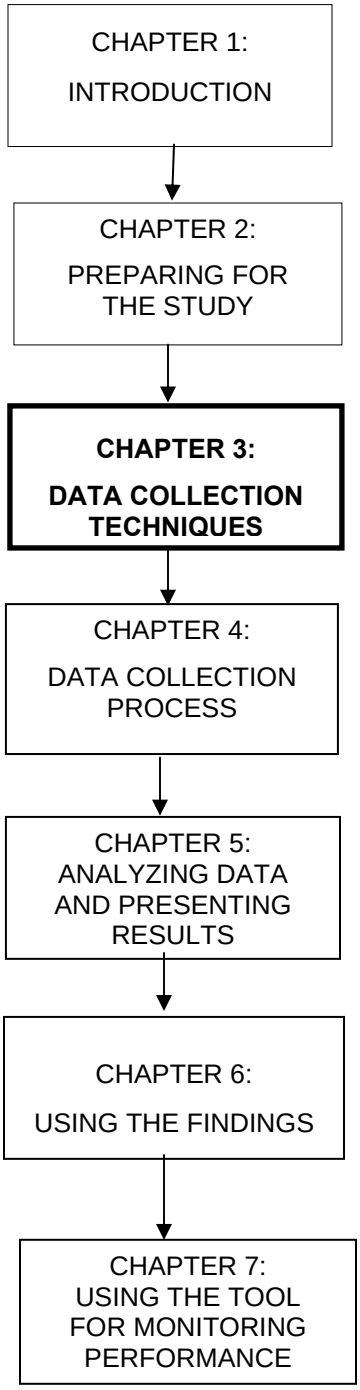
- Answer all questions on the forms and do not leave any spaces blank.
- Give the completed data forms to the team manager for quality checking before leaving the location.

Data Collection in TB Facilities—Practice Session

A half-day may be dedicated to practicing data collection in a local TB facility. Data collectors should be split into small groups and assigned the task of completing some of the forms. They should be required to debrief the other data collectors afterwards on the experience. Once back in the training venue, the groups should present their "findings," elaborating on how easy or difficult it was to find required data and do data entry, the time required to complete the task, and other observations. After all groups have completed their presentations, groups should exchange their completed data collection forms. Groups will review the forms and critique them for completeness, legibility, and other relevant observations.

Training Schedule

Annex 6 is an outlined schedule of training activities to use in training data collectors for the study of health centers and drug outlets.


CHAPTER 1:
INTRODUCTION
CHAPTER 2:
PREPARING FOR THE STUDY
CHAPTER 3:
DATA COLLECTION TECHNIQUES
CHAPTER 4:
DATA COLLECTION PROCESS
CHAPTER 5:
ANALYZING DATA AND PRESENTING RESULTS
CHAPTER 6:
USING THE FINDINGS
CHAPTER 7:
USING THE TOOL FOR MONITORING PERFORMANCE

Chapter 3.

DATA COLLECTION TECHNIQUES

Data for calculating the 13 indicators are collected using six different data collection techniques at the central, regional, TB facility, and TB drug outlet levels. The six techniques are structured interviews, document reviews, physical inventory checks, record reviews, simulated price inquiries, and exit poll interviews. Some of the techniques will be used at more than one level. Annex 3 provides data collection forms and checklists as well as a detailed description for each technique.

Structured Interviews

Structured interviews of key informants are person-to-person discussions used to gather information and documentation. The most important aspect of the interview is asking the questions in a structured or standardized way. Using an interview guide will help the data collector/interviewer organize his or her thoughts. The guide can also serve as a checklist to ensure that all the topics for which the data collector needs information are covered. To carry out this work, it is important to keep two points in mind:

1. Informants should be selected for their knowledge about the issues and their ability to provide current and reliable data. The selection of informants should also take into consideration their official position and factors that may bias their views.

2. To the extent possible, data collected through interviews should be verified through review of background documents or records.

Document Reviews

Chapter 2 outlines several planning activities to do as you prepare to conduct the study. Reviewing documents to collect country-specific vital statistics, background information, and data on MOH pharmaceutical operations is an important part of the planning. Tables 1, 2, and 3 provide guidance on what information to collect. It is important to remember that information gathered during one-on-one interviews should be confirmed or supported through documentation. Also, always make sure to note the date and have an understanding of the context (e.g., regional versus national, public versus private) for the data or documents collected.

Physical Inventory Checks

The physical inventory and review of records take place in MOH storage and health centers as well as in TB drug outlets. The physical inventory and review of stock records serve as a "point-in-time" check that is carried out by examining the stock record of each TB tracer commodity in stock. A physical count of stock on hand will be necessary to check that the stock balance records are correct. A physical inventory count in MOH facilities will provide an additional level of evaluation that may reveal defects in the warehousing system and identify surplus, expired, depleted, and obsolete stock.

Patient Medical Record Reviews

Patient medical records serve as the primary source of retrospective data on the prescribing practices used to treat tuberculosis. The retrospective method is less time-consuming, less expensive, and can describe practices over a longer period of time. This method requires that adequate sources of data exist; however, the information available is often incomplete.

Whether retrospective data are incomplete or not, the prospective data collection method can also be used. But obtaining prospective data through observational methods for morbidity-specific analysis is expensive and time-consuming because it is necessary to remain at one site until a sufficient number of cases for the target health problem have been observed. On the other hand, prospective methodologies can provide useful information about the diagnostic process and on the communication between health providers and patients.

For the purpose of this study, only the retrospective data collection method is described. Chapter 2 (Preparing for the Study) describes how the records will be selected, and Annex 3 (sample Data Collection Forms and Instructions) describes how information will be collected.

Simulated Price Inquiry

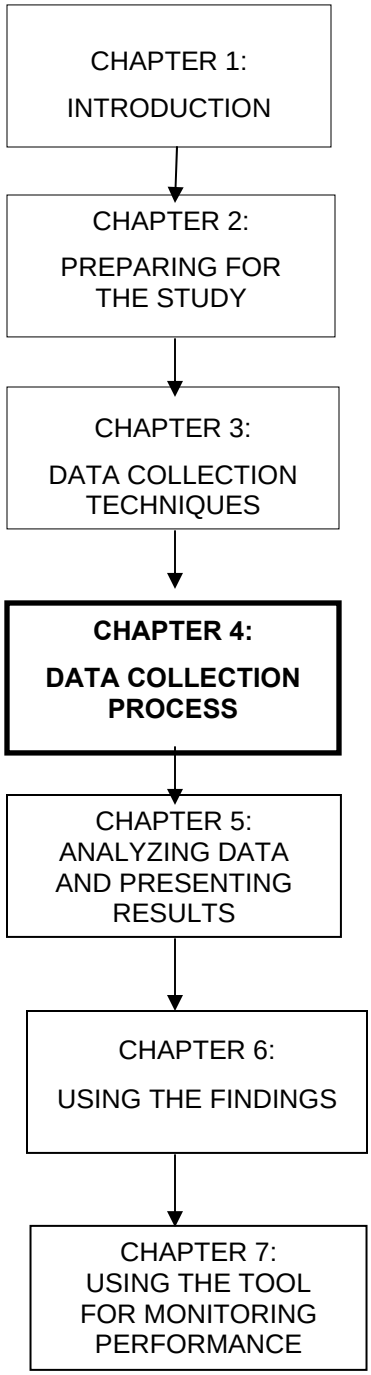
The simulated price inquiry technique serves as a primary source of prospective data. Using this method, the data collectors pose as ordinary customers to obtain the prices of TB medicines. For the study, data collectors are asked to present a TB medicine prescription to the dispenser at the drug outlet. The dispenser fills out the medicine prices on the prescription, and the data collector

reviews it to ensure accuracy of prices (unit price versus container price). This method minimizes errors that might be made by either the dispenser or the data collector.

Exit Poll Interviews

New smear-positive TB patients are the target audience for the exit poll interviews. The purpose of the exit poll interviews is to determine how well patients understood the instructions given to them by health workers or medicine dispensers about the medicine prescribed, and whether the patients are directly observed by a caregiver during treatment. This technique is explained in more detail in Annex 3 (sample Data Collection Forms and Instructions).

PHARMACEUTICAL MANAGEMENT FOR TUBERCULOSIS ASSESSMENT MANUAL



Chapter 4.

DATA COLLECTION PROCESS

Planning Prior to Data Collection

By conducting an accurate and systematic assessment of the pharmaceutical supply system for TB medicines used in an NTP, the investigator will identify specific strengths and weaknesses of the system and, in the process, gather information that will be useful in planning corrective interventions for weaknesses identified in the system.

Before data collection begins, it is critical to the success of the study that investigators and other study team members complete the planning steps outlined in Chapter 2. To summarize, investigators should have planned a schedule for collecting the following information:

- Vital statistics and background information such as exchange rates, national and regional population figures, incidence of tuberculosis, and so forth
- Overview of MOH pharmaceutical management operations such as schematics of flow of pharmaceuticals; transport; delivery schedules; numbers and locations of MOH TB facilities and TB pharmaceutical wholesalers, distributors, and manufacturers; budgets at central and regional levels; and pharmaceutical cost-recovery systems
- How the management of TB fits into the rest of the health sector service delivery

Once this information has been collected, it should be distributed to the investigators prior to the start of data collection.

An important point to understand and remember while conducting the study is that the NTP may not be a distinct program in and of itself. The TB medicines may be supplied through the vertically managed National Essential Medicines Program and thus have a separate logistics system of pharmaceutical product supply. At the same time, there may be TB programs managed by international donors, private voluntary organizations, NGOs, or religious organizations. Therefore, it is important to collect all the information that is needed to provide a picture of the logistics system for all TB medicines that is as complete as possible.

The data collection sites for the PMTB indicators include MOH central offices, central medical stores (CMSs), regional medical stores (RMSs), TB treatment centers, and TB medicine dispensaries/retail outlets. Among these sites, the six different data collection techniques will be used to gather information for calculating the PMTB indicators. These techniques include document reviews, structured interviews, patient medical record reviews, physical inventory counts, exit poll interviews, and simulated price inquiries.

Selecting the Study Time Period

Several of the indicators are based on a retrospective review of stock records. For the TB pharmaceutical management assessment, investigators should select a study time period to cover the previous consecutive 12 months or an equivalent period of time. It is important for all data collectors to use the same time period to ensure that the data received from all sites are comparable. Therefore, the time period should be decided prior to the start of the data collection process, and every data collector should know the agreed-upon time period.

Preparing to Conduct Survey

As part of the planning process, a workplan should be completed that includes all the specific sites, facilities, departments, and personnel to be visited; a timetable of when the visits will occur; the assignment of teams to specific locations or areas; and the transport and accommodation arrangements. In preparation for conducting the survey of MOH offices, facilities, and drug outlets, it is important to review the workplan with the whole study team. Maintaining a high level of open communication among study team members and making sure that all team members know their respective responsibilities will help to minimize problems during the data collection process.

Before sending data collectors into the field, study investigators should make sure that each person has enough copies of and is familiar with all the data collection instruments they will need for the site(s) for which that person is responsible. Explicit, written instructions for using the data collection instruments should be given to each data collector. Samples of written instructions are included with the respective samples of data collection instruments in Annex 3.

Supplies such as pens, notebooks, bags for carrying forms, and so on should also be given to each data collector. Study investigators should also make sure that all the site visits have been approved and scheduled by the MOH. Data collectors should be given copies of letters of introduction that confirm their identity and authorization to survey that site. Study investigators should develop a system for collecting, grouping, and storing completed data collection forms.

Troubleshooting

As mentioned earlier, the key to successful data collection is good planning. However, no matter how thorough the planning, problems can always arise. Such unexpected problems can be minimized if good, open communication among study team members is maintained and all participants remain flexible and willing to adapt to new situations. Table 7 presents a few typical problems, along with suggested solutions, that can happen while conducting the study. However, remember these examples are only illustrative. Every country is different and can present the investigator with different, country-specific problems.

Table 7. Illustrative Examples of Potential Problems and Possible Solutions

Potential Problems	Possible Solutions
Key informants do not keep scheduled appointments.	Reconfirm meeting times, clinic hours, and drug outlet hours. Create backup options and, if possible, try to schedule meetings in the same geographic area on the same day.
Data collectors do not show up for training and work.	Recruit a few extra data collectors to anticipate any transportation or personal emergencies among data collectors. Also, pairing data collectors into teams will ensure having a backup option.
PMTB tracer commodities are not available in the country.	As mentioned in Chapter 2, the study team should adapt the sample list of TB tracer commodities (Table 6) to the country setting.
The dosage form of the medicine is different than indicated on the sample data collection form.	The sample data collection forms should also be adapted and tested as outlined in Chapter 2. This step should catch any inconsistencies before the data collection begins. Write down the medicine dosage form as seen in records.
Health facility and drug outlet managers are skeptical or resistant to permitting someone to go through confidential patient records.	Sometimes having an "official government letter of authorization" may not be enough to gain cooperation of managers. Try to gain support for the study from health professional groups such as associations for doctors or pharmacists. Also talk to the managers about the study and the ultimate benefit to the country.
A sample facility is closed or not functioning for some reason.	Have a defined "substitute" list of facilities in anticipation of any closings. Data collectors should not be left to make the decision on their own about selecting sites.
Fewer than 30 medical records exist for the case definition studied.	Collect as many records as available and build in a process of either asking the team leader for advice or going to a predetermined backup facility for additional records.
There are not enough drug outlets close to the sampled health facility in rural areas.	Use proportional sampling, whereby a larger portion of the drug outlets sampled are concentrated in urban areas.
Medicines prescribed are recorded by brand names that are unfamiliar to the data collectors.	All information should be recorded on the data collection forms exactly as written in the patient encounter record, even if unfamiliar to the data collector. Data collectors should be instructed to avoid making any interpretation.
Medicines prescribed are identified, but numbers of units are not.	All of the data needed for a particular patient encounter may not be in the same source of records. Start with the patient register, then move to the medical records. If data are still missing on the medicines prescribed, check to see if the facility has pharmacy or dispensing records. If all else fails, present a specific case and ask facility staff how many units of each medicine they would normally provide for that TB patient. **Then record this information, but with a circle drawn around it.** The circle indicates that the information was missing and has been filled in provisionally, based on an interview.
Data collectors are not completing the data forms correctly, and some forms are not legible.	Make sure that the data collectors use pen, not pencil, to fill out the data collection forms. Conduct spot-checks of the forms to catch any problems early in the process, and make payment contingent upon receiving acceptable forms.

Recording Data

It is important to instruct data collectors to write legibly with a pen (not pencil) and to use marks or phrases that indicate a complete thought or response when filling out the data collection instruments. Depending on the data collection instrument, this marking may mean using a check mark, writing *Yes* or *No*, *Y* or *N*, circling a response, or writing a phrase or sentence to explain a particular finding. This instruction is important because the person completing the form may not be the same person who will enter the data or tabulate the results.

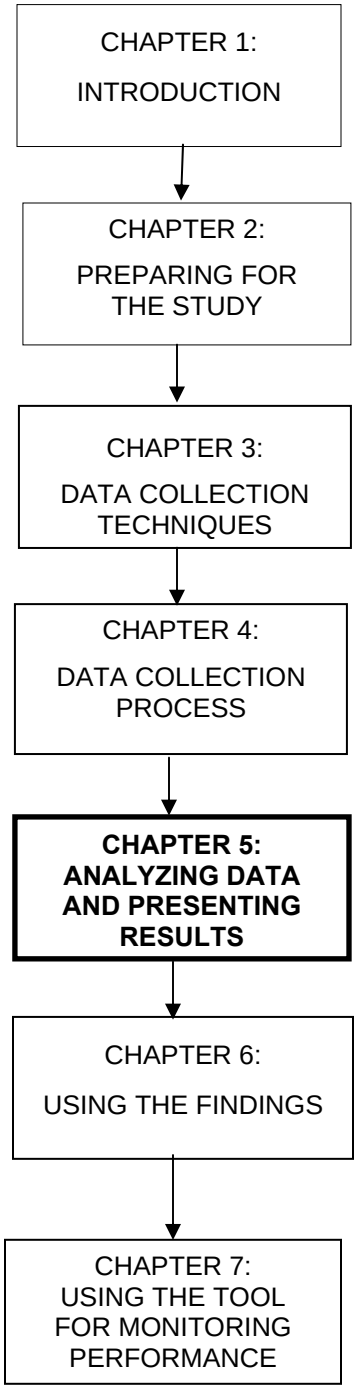
Someone on the study team, usually the data collection team manager, should be designated to review each data collection instrument when it is completed and to check the data for completeness and correctness. This process is useful because it will allow identification of any problems early in the data collection phase, and corrective interventions can be implemented to prevent future mistakes.

To avoid confusion, it is advisable to collate and prepare data for analysis as it is collected. The most efficient approach for data entry is to hire experienced data entry clerks. While this represents an additional expense, it is more cost-effective over time. The data entry clerks should be instructed to put their initials on each data collection form in a designated spot to indicate that the data entry is completed for that form.

Completing the Data Collection Instruments

At the end of each site visit, every data collection questionnaire, checklist, or form completed during the visit should be examined for incomplete data. The responsible data collector should make every attempt to collect all the data before leaving the site.

Before beginning the process of calculating specific indicators, a complete recheck and editing is necessary to clean the data. If data for a particular item on the data collection form are missing or incomplete, that item (not the entire data collection form) should be eliminated. The number of eliminated items should be counted and discussed in the final report.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Chapter 5.

ANALYZING DATA AND PRESENTING RESULTS

Now that the data have been collected, the next step is the analysis. Analysis should proceed in a systematic fashion by (1) calculating the indicators and summarizing the information; (2) interpreting the results; (3) disseminating preliminary findings; and (4) preparing a written report.

Calculating the Indicators and Summarizing the Information

Once the data have been collected, the results for each specific indicator can be calculated manually from the appropriate data collection instrument. Annex 2 (PMTB Indicators) of this manual provides specific instructions on how to calculate each indicator, with illustrative examples. Alternatively, the following computerized methods could be used for collating the survey results and calculating the indicators:

1. Spreadsheet (e.g., Excel)
2. Database (e.g., Access)
3. EPI Info software

The instructions and examples in Annex 2 provide the information needed to design the structure of the computer tool chosen.

Some thought should be given to how the data should be grouped or summarized. It is important to distill the large volume of data down to a few key findings that capture the study results. Summarize the data by indicator, noting subgroupings that may be useful in the analysis, such as geographic region, type of health facility, and/or target audience. Once the data are summarized and presented in a table as shown in Annex 4, they will be easier to review and analyze.

An Excel spreadsheet for data entry has been developed by Management Sciences for Health's Rational Pharmaceutical Management Plus (RPM Plus) Program. This spreadsheet does not accompany this manual and can be requested by e-mailing RPM Plus at rpmplus@msh.org.

Interpreting the Results

At the end of the fieldwork and prior to the implementation of a particular intervention, it is important to spend time as a team interpreting the findings. No matter how well the assessment was designed and planned, the data obtained may not be totally reliable, for any number of reasons. Part of the job of the study team when analyzing data is to determine what biases, inaccuracies, or inconsistencies may exist and what precautions are necessary in interpreting the results.

Researchers and study team members should all play an active role in examining data and considering what type of additional analyses may be appropriate. One strategy is to hold a synthesis meeting of everyone involved in the investigation. If not everyone at the meeting is familiar with all aspects of the data collection, the first activity should be to present the draft reports for the study. The draft reports should be brief and cover the specific study questions addressed, methods used, results, and conclusions. Written summaries of findings, along with tables and graphs, should be distributed. Through the analysis, specific pharmaceutical management system problems will become more apparent, as will the group of prescribers or patients most likely to gain the most from an intervention. Using this understanding of the problems to be addressed, the synthesis group should then direct its attention to designing an intervention.

Table 8 presents the PMTB indicators, their interpretation, and the potential actions that can be taken as next steps. It is important to understand that none of the PMTB indicators should be viewed in isolation or taken at face value. It is the complete set of indicators that helps to give a meaningful picture of the TB pharmaceutical management situation. The results become even more indicative when they can be compared to a baseline over time.

Table 8. Interpretation of Indicators for PMTB Study

Indicator Name	Desired Change Over Time	Interpretation	Potential Actions
K-1. Average percentage of time out of stock for a set of TB tracer commodities in TB facilities	Decrease	The target for this indicator should be 0%, or no stock-outs. The result of the data collection will help determine if availability is constant over time.	For stock-outs, investigate where the breakdown occurs in the system. Check for seasonal variations, changes in stock levels that correlate with procurement activities, etc.
K-2. Average percentage of a set of TB commodities available in TB facilities and medical stores	Increase	Theoretically, all, or 100%, of these commodities should be available, all of the time. However, this indicator provides only a snapshot of the availability of tracer commodities for the NTP at the time of the study.	To determine why availability is low requires further analysis. For example, problems could be in the area of budgeting, theft, wastage, quantification, and/or inventory management. Once the specific causes have been identified, potential interventions can be developed.
K-3. Percentage of new smear-positive patients with pulmonary TB who were prescribed correct medicines in conformity with the standard treatment guidelines used in the country	Increase	This indicator measures adherence to standard treatment guidelines and measures a positive behavior that should be reinforced or encouraged. Low percentages identify the need for improvement.	For low percentages, investigate to determine why the prescribing behavior exists. For example, one factor contributing to the behavior could be incomplete training of prescribers. Then design appropriate interventions to correct the behavior.
K-4. Percentage of TB medicines received in the past three shipments that were accompanied with a batch certificate	Increase	This indicator should target 100%. A batch certificate should be requested as a mandatory component of the tender document for every batch of TB medicines purchased both from local and international suppliers to attest to the quality of the medicine batch. The batch certificate does not guarantee the quality of the pharmaceutical commodities; however, batch samples can be tested for quality confirmation.	For low percentages, investigate to determine why batch certificates are not being received. For example, the survey country may not be aware of the importance of requesting this certificate during pharmaceutical procurement. Provide appropriate recommendations as needed.

Indicator Name	Desired Change Over Time	Interpretation	Potential Actions
K-5. Percentage of median international price paid for a set of TB commodities that was part of the last regular procurement	Decrease	The result for each tracer commodity should be reviewed. The higher the percentage, the greater the potential cost savings for the MOH. The goal should be for the MOH to achieve a 1:1 ratio or better when the MOH procurement price is compared to the international price.	Examine all factors that contribute to the MOH procurement price before deciding on possible interventions. Possible areas to review include the terms of tender, amounts ordered and potential economies of scale, and supplier prices for each commodity. For health facilities in decentralized settings, compare prices through local private sector procurement versus prices through regional or national warehouses. If revolving drug funds are used, compare the sales price at MOH health facilities to the sales price at drug outlets.
C-1. Percentage of NTP medicine products included on the national essential medicines list	Increase	Target for this indicator is 100%, especially if the health system in the country is centralized and the selection of medicine products for procurement is strictly dependent on the national EML.	Advise and emphasize the importance for the NTP and the EML selection committee to collaborate their efforts to ensure that all NTP TB medicines used for treatment in the country are included on the national EML during the next revision of the EML.
C-2. Percentage of NTP medicine products included on the WHO tuberculosis essential medicines list	Increase	A high percentage denotes that the selection of TB medicines used in the country follows WHO's recommended guidelines for TB medicines with proven evidence of efficacy for TB treatment. (The WHO EML is updated to reflect new therapeutic options and changing therapeutic needs; to meet changing resistance patterns; and to increase the use of cost-effective medicines.[8])	Advise NTPs to select TB medicines using the WHO TB EML and/or treatment guidelines as a reference to optimize treatment outcomes and ensure cost-effective therapy.

[8] World Health Organization/Essential Drugs and Medicines Policy. 2005. "Guidelines for Drug donations: What are essential medicines?" <http://www.who.int/medicines/default.shtml> (accessed Jan. 2005).

Indicator Name	Desired Change Over Time	Interpretation	Potential Actions
C-3. Percentage of TB medicine samples that failed quality-control testing out of the total number of TB medicine samples tested during the past year	Decrease	A low percentage (zero) is desired for this indicator. A high percentage might mean that prequalification of supplier or quality assessment of pharmaceutical commodities was not properly evaluated before procurement and shipment, or that the supplier intentionally supplied low-quality commodities under the belief that there will be no further testing carried out after shipment. Other factors might also be responsible for high percentages of TB medicines failing quality-control testing.	Investigate to determine the reason for the high percentages. Take into consideration at what stage quality-control testing was conducted by the health system, as well as other contributing factors like transportation, climate, and storage that can affect medicine quality. Ask supplier for quality-control results of the same batch. Make appropriate recommendations according to findings.
C-4. Percentage of TB facilities visited where the most recent official manual of treatment guidelines for TB was present	Increase	Theoretically, all, or 100%, of facilities should have a copy of the most recent official manual of treatment guidelines for TB. Although the presence of guidelines does not mean that staff use them and does not ensure rational prescribing, treatment guidelines do provide a reference source that supports more appropriate prescribing.	Identify resources to provide at least one copy of the most recent treatment guidelines per facility. Distribution of the guidelines should be accompanied by training on how to use the guidelines.
C-5. Percentage of TB outpatients who could correctly describe how the prescribed medication should be used	Increase	Low percentages indicate that health workers are not providing enough information to patients about their medication, which may lead to nonadherence and treatment failure.	Identify the need for training or specific communication problems. Investigate the usefulness of alternative communication strategies such as the use of local idioms, pictograms, or demonstrations.
C-6. Percentage of TB patients who reported regular observation by a health care worker during medicine intake	Increase	Low percentages indicate that treatment is not observed. Directly observed treatment of TB patients by caregivers at least during the intensive phase of treatment, especially when rifampicin therapy is used, has been identified as an essential component of the WHO DOTS strategy to ensure treatment compliance by patients and prevent the emergence of drug-resistant strains of TB.	Identify underlying causes and make appropriate recommendations based on findings emphasizing the need to strengthen directly observed treatment practices to improve outcomes. Findings could point to the need for more or better training of health workers, to find alternative sources of funding, or to hire additional human resources.

Indicator Name	Desired Change Over Time	Interpretation	Potential Actions
C-7. Average percentage of stock records that correspond with physical counts for a set of TB tracer commodities in TB storage facilities	Increase	This measures the quality of the stock record-keeping system. Caution: Some facilities update records periodically rather than on an ongoing basis. Study investigators should consider this when reviewing the accuracy of the record-keeping system and make every attempt to determine if the data are available in a different location.	A low percentage may suggest a need to review the record-keeping system. Training may be needed in math skills, stock record-keeping, and/or inventory procedures.
C-8. Number of days that a person has to work at minimum wage to pay for a complete TB treatment course, taking into account the price of medicines in the public or private market	Decrease	The fewer the number of days, the more cost-effective the treatment will be and the lower the out-of-pocket payment by patients at private/public drug outlets. TB infection is prevalent among poor populations. TB medicines should be affordable to promote compliance to treatment.	Investigate and determine what factors drive prices up. Some factors to consider include combination versus single medicines, procurement sources, tender prices obtained, distribution costs, product availability from suppliers, and percentage markup on medicines. Make appropriate recommendations based on findings.

Disseminating Preliminary Findings

Until this point in the study, only the few people involved in the data collection process have been aware of the study findings. The next step is to give TB facility managers, MOH representatives, and others an opportunity to be informed. A formal presentation should be given that encourages in-depth discussions about the meaning of the results, specific pharmaceutical management concerns, and potential interventions.

Those deciding how to present the findings should take into consideration both the intended audience and what specific results the audience should understand by looking at the findings. When presenting the findings, give equal attention to both strengths and weaknesses. The goal of the presentation is to determine a course of action for building on the strengths and increasing capacity in the weaker pharmaceutical management areas.

When developing presentations for policy makers, it is advisable to include a very clear executive summary, and to the extent possible, present key findings, recommendations, and projections of impact. Usually, this type of presentation is best achieved using a mix of graphic, text, and table formats. Visual presentations of data in the form of tables, graphs, pie charts, and so forth work best, supported by the written report to explain details. Annex 4 includes a sample table for presenting the indicator data.

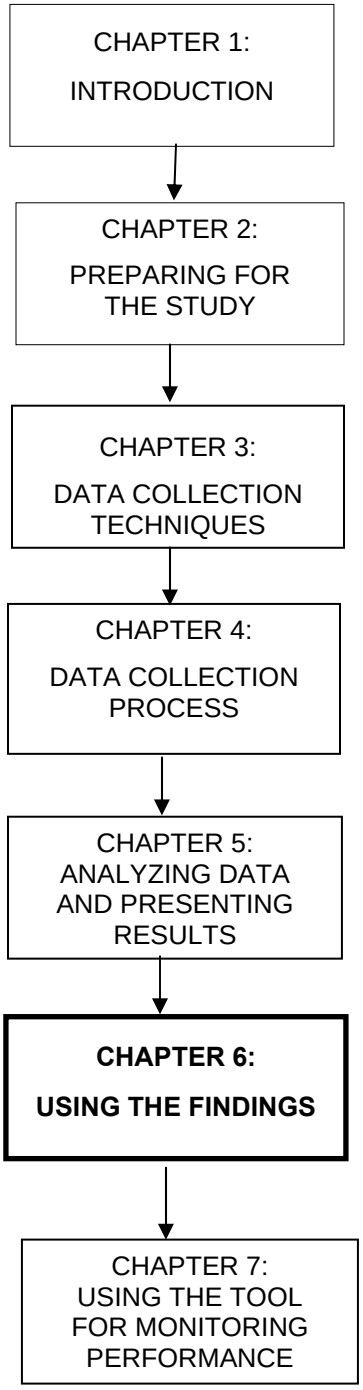
The presentation should provide an overview of the goals and objectives of the TB pharmaceutical system study, the process undertaken, and the major indicators measured. This will help people understand how the conclusions were reached. Emphasize how current pharmaceutical systems management practices affect the ability of the NTP strategy to achieve treatment outcome goals and to improve staff performance and the quality of services. The session can lead to increased support for improvement in prioritized areas by reinforcing the audience's understanding of the need for and interest in improving pharmaceutical systems management for the NTP.

Preparing a Written Report

A written report should be prepared to document the data collection experience and the findings. At a minimum, the report should include indicator tables, a list of the medicines most often prescribed, observations made during data review, survey background, and the different methodologies used to collect the data. In general, the report should include the following sections:

Executive Summary	Present key findings, recommendations, and projections of impact
Introduction	Summarize the study objectives, the scope of the study, and the outline of the way the report is presented
Methods	Summarize the indicator-based approach, the data collection techniques, instruments, sites, sampling design process, personnel, fieldwork organization and supervision, and mode of data analysis
Findings	Present the indicator calculations. Tabulate and describe the study results, including the strengths and weaknesses identified in the TB pharmaceutical management system. Also, discuss any assumptions, biases, inaccuracies, or inconsistencies that may exist, and what precautions are necessary when interpreting the data
Discussion	Address the problems encountered in conducting the study and possible underlying reasons and explanations for the main findings
Conclusion	Present inferences, recommendations for corrective actions, and likely follow-up interventions

A copy of the written report should be presented to the MOH NTP health system manager. The report, along with the recommendations for follow-up interventions, will provide the necessary documentation that can help to clarify the need for system improvements.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Chapter 6.

USING THE FINDINGS

Responding to the PMTB indicator results and other assessment findings requires a well-thought-out approach for selecting and implementing the most appropriate interventions to address NTP pharmaceutical systems management problems. The underlying reasons for the problems then need to be investigated. Intervening before understanding the reasons for a medicines shortage or a problem with prescribing practices can lead to unintended and negative consequences.

Developing an Interventional Strategy

Developing an intervention strategy involves six major steps. These are:

1. Identify the problem and recognize the need for action
2. Identify underlying causes and motivating factors
3. List possible interventions
4. Assess resources available for action
5. Choose an intervention to test
6. Monitor the impact and restructure the intervention as necessary

The PMTB indicators have been developed to measure key aspects of the pharmaceutical management system in the public sector and to an extent in the private sector, and they should be viewed as the first step of an investigation. A PMTB study should reveal specific problems that

may be addressed, but it may not provide enough information on the underlying causes and motivating factors that contribute to the problems. Therefore, each problem identified should be examined individually to ensure an in-depth understanding of the cause. Probing for a more in-depth understanding of a particular problem may require supplementing the findings with additional structured interviews or small focus groups. The information from the follow-up studies can be used to design interventions.

Some problems may be due to policies or procedures of the national or regional pharmaceutical management system and not specifically related to the NTP. Data developed through the assessment will be significant in documenting the negative effects of such policies or procedures on the management of tuberculosis. While it is possible that one intervention could solve more than one problem, in order to monitor for specific improvements, as discussed later, it is important to have a clear perspective on what the intervention is intended to do, problem by problem.

Following is a brief listing of some of the more common problems encountered in TB pharmaceutical systems management. Each problem statement is followed by a summary of key points that should be considered when developing an appropriate response. This list is not exhaustive and is only meant to be illustrative. Many problems may be unique to a specific country or region and thus require a unique solution. Selecting and implementing interventions requires time, teamwork, and commitment. The time spent in the planning and coordination phase will help ensure a successful outcome.

Common Problems Encountered in Pharmaceutical Systems Management

Procurement

An effective procurement process ensures the availability of the right medicines in the right quantities, at reasonable prices, and at recognized standards of quality. Effective procurement is a collaborative process between the procurement office and technical and policy officials.

Problem: Too many medicines are on the procurement list.

Key Points: Virtually no health program can afford to purchase all pharmaceuticals on the market. A limited medicines list or formulary, defining which medicines for the NTP to purchase, is one of the most effective ways to control procurement costs. It simplifies other supply management activities and reduces inventory-holding costs as well.

Possible Response: The first step is to order all medicines for the NTP by international nonproprietary name (INN), and the second step is to avoid generic duplication by only ordering one brand of each generic product. Other options for reducing the procurement list are limiting the number of dosage forms of each product or switching to WHO-recommended fixed-dose combination medicines.

The health system needs to be prepared for resistance from some doctors, who may prefer a certain brand or combination of TB medicines, and from pharmaceutical suppliers, whose products may be removed from the procurement list. Resistance can often be overcome by documenting (through the use of indicators) the cost savings possible with the restricted procurement list and by pointing out the benefits of year-round access to the limited list rather than sporadic access to a larger list of medicines.

Problem: There is too much stock of some medicines and not enough of others.

Key Points: Accurate estimates of medicine requirements are needed to avoid stock-outs of some commodities and overstock of others. One way to quantify medicine needs is to start with accurate past consumption data from all units being supplied. Unfortunately, in many countries, consumption data are incomplete or do not reflect real need because the supply pipeline has never been full.

Another method to estimate medicine requirements is to base the estimate on morbidity data. The morbidity method estimates the need for specific medicines based on the expected number and types of TB cases and on STGs for tuberculosis. This method requires data on the service population, accurate morbidity data, and use of the NTP standard treatment guidelines for the target case definitions.

The issue of multiple medicine sources complicates good management even more. For example, in many countries, some medicines are procured centrally by the MOH, others are donated by international organizations, and still others are procured from the regional or district level independent of the central MOH.

Possible Response: Expert technical assistance in how to quantify medicine needs for the NTP may be useful in the initial phases of the procurement program, with local officials participating to gain an understanding of the methodology. Also, arranging meetings with the major donor organizations to discuss donor coordination for pharmaceutical procurement can improve the management of commodity supply.

Problem: Financing mechanisms cause problems with the procurement cycle.

Key Points: Inventory management improves when medicines can be ordered when needed rather than at an arbitrary point in the government fiscal year. When suppliers know that orders will be placed promptly after tendering and that payment will be made upon delivery, prices will be much more competitive.

Possible Response: Decoupling the medicine procurement cycle from the government budget cycle has substantial management advantages. Strategies such as decentralized financial management are increasingly being employed to separate pharmaceutical procurement from the annual MOH budget cycle. This separation often requires some form of cost recovery, such as revolving drug funds.

Alternative systems for supplying medicines to public health programs include the CMS, autonomous supply agency, direct delivery, prime vendor, and private pharmacy systems.

Whichever system is used, checks and balances must be put in place for all major procurements and involve the procurement officer, health practitioners, and other user representatives.

Distribution

Problem: The pharmaceutical distribution system is unreliable.

Key Points: Pharmaceutical distribution systems in some developing countries are constantly challenged by problems such as not enough money for fuel, bad roads, union strikes, and so on. A well-run distribution system should maintain a constant supply of medicines, keep medicines in good condition, minimize losses caused by spoilage and expiry, minimize shortages, use available transport as effectively as possible, reduce theft and fraud, and provide information for forecasting medicine needs.

Possible Response: There should be a program of performance monitoring to ensure that the distribution system works as intended. Senior managers should regularly monitor the cost and performance of the distribution system as important indicators of the health system's operations. In some countries, private or parastatal distribution companies can provide cost-effective alternatives for the storage and distribution of medicines, especially at the national and regional levels. Major alterations in the system should be introduced only after careful evaluation and planning, taking into account available human, financial, and material resources.

Inventory Management

Problem: Stock records are poor.

Key Points: Accurate and current stock records are essential to good inventory management. Stock records are a key source of information used to calculate needs, and inaccurate records will produce inaccurate needs estimations as well as problems with stock-outs, leaks, and expiry.

Possible Response: Each inventory system should monitor performance with indicators and produce regular reports on inventory and order status, operating costs, and consumption patterns. As part of the plan to improve inventory management, it may be necessary to provide staff training, such as the WHO/BASICS Drug Supply Management Training Workshop for First-Level Facilities or the International Dispensary Association (IDA)/MSH Managing Pharmaceutical Supply for Primary Health Care Course for middle to higher level facilities.

Problem: Inadequate quantities of medicines are in storage.

Key Points: The primary reason for holding stock in a medicines supply system is to ensure availability of essential items at all times. This supply is particularly important for TB programs. Ideally, there should always be a buffer stock of TB medicines equal to the number and nomenclature of medicines required for a full treatment course multiplied by the projected number of patients. One solution to prevent stock-outs is to have enough stock at the national level for six months and at regional levels for three months.

Possible Response: The selection of NTP items to stock should be based on their value to the treatment of tuberculosis and on the regularity and volume of consumption. VEN (vital,

essential, non-essential) and ABC analyses are useful tools for defining which NTP commodities on the essential medicines or formulary list must be held in stock. Most of the medicines for the NTP (all first-line TB medicines) should be promoted as vital (V) and, therefore, should always be available. Whichever formulas are used, it is necessary to adjust purchase quantities to take into account factors such as seasonal demand, disease pattern, expected changes in utilization or prices, currency fluctuations, and availability of storage space. One possible source of information on how to use ABC and VEN analysis is the MSH book *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals.*[9]

Medicine Use

Problem: First-line TB medicines are overused or underused, or regimens fail to produce the desired therapeutic effect.

Key Points: Numerous cases have been documented in which as many as all five first-line TB medicines are prescribed simultaneously for a full of six months' duration to treat common cases of pulmonary TB. Such overprescribing can significantly increase the cost of medicine therapy and can result in adverse effects that may be difficult to treat. At the same time, in many countries patients are prescribed single medicines or FDC medicines of unproven efficacy and quality. One consequence of misuse of TB medicines is the development of resistance. Resistance to common TB medicines has increased, making them ineffective in certain populations.

Possible Response: Training is a common intervention to implement in response to inappropriate prescribing practices. Training can be conducted in different ways with a broad range of objectives. In general, training interventions targeting health providers are most successful when the training does the following:

- Is problem-oriented and focuses on a single health problem or practice at a time
- Incorporates multiple training approaches (e.g., lectures, group problem-solving, role playing, opportunity to practice skills)
- Provides training at the work site
- Uses opinion leaders or district level staff as trainers
- Involves practical skills orientation
- Provides multiple sessions over time

Training interventions can be made more effective through ongoing supervision, the use of incentives and messages intensified through concurrent community and health worker education, and good pharmaceutical supply management.

[9] Management Sciences for Health and World Health Organization. 1997. *Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals.* 2nd ed. West Hartford, CT: Kumarian Press.

Problem: Medicine treatment costs are high.

Key Points: One of the basic tenets for promoting the DOTS strategy is that if standardized treatment guidelines are followed, providers will give appropriate care that is likely to be more cost-effective than if guidelines are not followed. Factors contributing to the high cost of medicine treatment include the unnecessary prescribing of multiple medicines, overprescribing of injections, and prescribing of brand-name products rather than generics. Also, because many consumers hold the belief that public health facilities have limited stocks of medicines, some consumers bypass the health facility and go directly to private sector sellers for medicines, risking inconsistent prescribing but choosing the likelihood of greater availability in spite of probable higher costs.

Possible Response: As mentioned earlier, developing a limited TB medicines list, or formulary, is one of the most effective ways to control medicine costs. Promoting the use of generic medicines over brand-name products, using FDCs, and monitoring prescribing practices for the unnecessary use of medicines (overprescribing) can also help to gain control over medicine costs.

Procurement of first-line TB medicines through the GDF is another effective way of bringing down medicine costs. The GDF, through the direct procurement service provided to DOTS-implementing countries, purchases quality first-line TB medicines from reliable procurement agents at low prices on behalf of the countries. The GLC also provides the same services for second-line TB medicines used in treatment of MDR-TB.

Problem: Standard treatment guidelines are not followed.

Key Points: The treatment of TB is the cornerstone of any NTP. While some countries are using DOTS, others have developed their own STGs. These policies should be taken into account when the study is designed. Deviations and noncompliance with standards, or ineffective standards, inevitably lead to treatment failure, development of resistant strains, and spread of the epidemic.

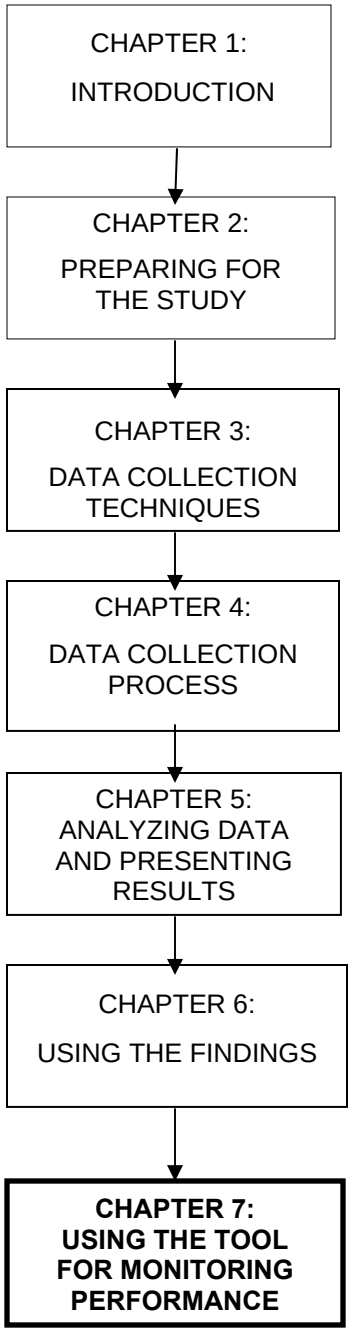
The modern strategy of TB treatment is based on standardized short-course chemotherapy regimens applied under proper case-management conditions. The WHO-recommended TB control strategy is known as DOTS and provides the TB patient with all the necessary elements for cure. For the purpose of the *PMTB Manual*, the WHO treatment algorithms serve as the standards by which prescribing behaviors are assessed. Each country should adapt the WHO DOTS guidelines to its local context and support their dissemination and implementation.

Possible Response: First, make sure that each facility has an official copy of the national or WHO DOTS standard treatment guidelines. Group commitment to treatment standards by the staff at a health facility or establishing a peer monitoring system may motivate and sustain change. Routine supervision and monitoring using indicators or simple protocols, as well as monthly audit and feedback of performance indicators, can be effective for improving specific practices.

The reasons for clinically inappropriate medicine use practices may be quite complex and multifactorial, including perceived patient demand, cultural misconceptions about medicines,

prescribers' limited clinical experience, and the promotion practices of pharmaceutical representatives. Such practices can also contribute to higher costs.

Whatever the prescriber behavior may be, interventions should generally be targeted to improving a few specific aspects of medicine use. Program managers should involve researchers in the design and implementation of national programs to strengthen and better evaluate the programs' impact on prescriber behavior.


CHAPTER 1:
INTRODUCTION
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Chapter 7.

USING THE TOOL FOR MONITORING PERFORMANCE

After the PMTB assessment has been completed and the data analyzed, the findings can represent a source of quantifiable baseline measures. Having baseline measures is critical to monitoring the impact, negative or positive, of any intervention.

Monitoring and Supervision

It is important to monitor medicine availability and use as a way to evaluate the efficacy of an intervention. To determine if adequate progress is being achieved, it is necessary to know what is expected. A well-designed monitoring and evaluation system can usually provide information on what happened or what did not happen when an intervention was implemented. The PMTB tool can be used for three types of monitoring activities: progress monitoring, program monitoring, and performance monitoring.

Progress monitoring is the periodic oversight of implementation, which seeks to establish the extent to which targets for input deliveries, work schedules, and preparation of expected deliverables are being reached so that timely action can be taken to correct any deviation from plan.

Program monitoring is the routine collection of data for a defined set of indicators and the observation of changes over time and across populations. The selection of indicators for monitoring is based on prior evidence that these indicators are sensitive and specific to program activities, assuming that effects observed are caused by these interventions. In general terms, monitoring includes the tracking of inputs, processes, outputs, and outcomes.

Performance monitoring is the repeated measurement (baseline and follow-up) and comparison with expected results, which are formulated as performance targets and indicator benchmarks.

The PMTB indicators can also be used as a supervisory tool. In selecting indicators for monitoring, it is important to consider how the data will be collected. Data for some indicators may be routinely available from standard recording and reporting systems (such as percentage of TB medicines available), whereas data for other indicators may require a special survey (such as percentage of stock records that correspond with physical counts). Thus, the sources and the costs of collecting and processing these data must be carefully considered in selecting indicators to monitor.

Monitoring and evaluation should ideally be considered at the outset of the intervention so that procedures may be put in place to collect any additional information that may be needed. A few potential problems can develop when using indicators for monitoring. Such problems include failure to take action based on findings, overambitiousness (using too many indicators), failure to focus on key questions, selecting indicators that are too complex, lack of integration with work planning, failure to build on existing information, and lack of objectivity.

Collecting data on a few specific indicators on a semiannual or annual basis should be a key management strategy to measure progress toward improvements in TB medicines availability and use.

Evaluation

Evaluation is the observation of changes in selected indicators over time and across populations, plus a comprehensive assessment of program outcomes and impacts using qualitative and quantitative instruments. A program evaluation attempts to establish a causal relationship between effects and program interventions by describing what works and what does not work and why. It is an objective and systematic process for assessing the extent to which goals have been achieved, looking at relevance, effectiveness, efficiency, and impact of activities. Results are usually compared to baseline or midterm measurements. Evaluation is a learning and action-oriented management tool as well as an organizational process for improving both current activities and future planning, programming, and decision making.

After an intervention has been identified, performance targets should be established. A performance target is a desirable and, in principle, attainable standard of practice. The PMTB indicators can be used to measure the extent to which the targets and objectives of an intervention are being attained. For example, the indicator may be the percentage of five PMTB medicines in stock, and the performance target may be 100 percent availability at each treatment level for this list of medicines. Locally appropriate performance targets should be set for each indicator.

When choosing the most useful outcomes to measure, consider the following:

- Select outcomes that can be clearly and explicitly defined.
- Select outcomes that can be reliably measured by the indicator, preferably using routinely collected data.
- Prioritize monitoring to focus on a few important outcomes rather than measuring all possible changes.
- Measure more than one dimension of success, especially if some changes are secondary—for example, changes in prescribing that follow changes in knowledge about specific TB medicines.

After the outcomes to measure are chosen, proceed by doing the following:

- Identify the key behaviors targeted by the intervention and the most likely substitute behaviors.
- Decide how often to monitor and evaluate.
- Budget for human and financial resources needed for monitoring.
- Disseminate the results.

There are no universal targets of "acceptable" performance. Each country is unique, and setting performance targets will depend on many factors, such as the time frame of the intervention, the human and economic resources available, national policies, and the level of decentralization. Most important, however, is that targets should be established based on previously agreed-upon standards of performance and according to the local situation. By comparing indicator values among districts and among health facilities, it should be possible to measure the impact of an intervention over time and better identify areas of concern that warrant further action.

After the selected pharmaceutical targets have been met, the NTP may want to change the monitoring indicators with the aim of improving another weak pharmaceutical management area. Following is a list of suggested PMTB indicators that could serve as a means to begin performance monitoring, particularly at the health facility level. The performance target (included only for illustrative purposes) is noted in parentheses following the indicator. See Table 8: Interpretation of Indicators for PMTB Study (Chapter 5) for ideal performance targets.

K-1. Average percentage of time out of stock for a set of TB tracer commodities in TB facilities *(1%)*

K-2. Average percentage of a set of TB commodities available in TB facilities and medical stores *(98%)*

C-5. Percentage of TB outpatients who could correctly describe how the prescribed medication should be used *(95%)*

C-7. Average percentage of stock records that correspond with physical counts for a set of TB tracer commodities in TB storage facilities *(99%)*

A well-designed monitoring system can usually provide information on what happened or what did not happen. Managers should always check to see whether the performance information has been used, how it has been used, and what action has been taken.

No monitoring system is complete without feedback. Giving feedback to individual units or staff members tells them how well the reporting has been done and how useful the information is. Feedback also demonstrates the value and importance of reports. As such, it represents one of the most powerful tools for motivating staff.

ANNEX 1. DOTS GUIDELINES

Note: Information presented in this annex is taken in its entirety from: World Health Organization (WHO). 2003. *Treatment of Tuberculosis: Guidelines for National Programmes*. 3rd ed. WHO/CDS/TB/2003.313. Geneva: WHO, pp. 25 and 33.

Case Definitions

New case: A patient who has never had treatment for TB or who has taken tuberculosis medicines for less than one month

Relapse: A patient previously treated for TB who had been declared cured or treatment completed, and is diagnosed with bacteriological positive (smear or culture) tuberculosis

Treatment after failure: A patient who is started on a re-treatment regimen after having failed previous treatment

Treatment after default: A patient who returns to treatment, positive bacteriological, following interruption of treatment for two months or more

Transfer in: A patient who has been transferred from another TB register to continue treatment

Other: All cases that do not fit the above definitions. This group includes chronic cases and patients who are sputum-positive at the end of a re-treatment regimen.

Note: Smear-negative pulmonary cases and extrapulmonary cases may also be treatment failures, relapses, returns after default, or chronic cases. This should, however, be a rare event, supported by pathological or bacteriological evidence (culture).

The Essential TB Medicines

There are three main properties of TB medicines: bactericidal ability, sterilizing ability, and the ability to prevent resistance. The TB medicines possess these properties to different extents. Isoniazid and rifampicin are the most powerful bactericidal medicines, active against all populations of TB bacilli. Pyrazinamide and streptomycin are also bactericidal against certain populations of TB bacilli. Pyrazinamide is active in an acid environment against TB bacilli inside macrophages. Streptomycin is active against rapidly multiplying extracellular TB bacilli. Ethambutol is a bacteriostatic or sterilizing drug that is used in association with more powerful bactericidal drugs to prevent the emergence of resistant bacilli.

Recommended Treatment Regimens for Different Treatment Categories

There are several different possible regimens. The regimens recommended in each country's NTP depend on that country's budget, health coverage by primary health care (PHC) services,

and qualifications of health staff at the peripheral level. For each patient, the regimen that is recommended depends on the patient treatment category. The following table shows possible alternative regimens for each treatment category that can be used under various circumstances and in certain subpopulations. Follow the official regimens listed in the NTP manual of your country.

Table A-1. Possible Alternative Treatment Regimens for Each Treatment Category

TB Treatment Category	TB Patients	Alternative TB Treatment Regimens	
		Initial Phase (Daily or 3 Times per Week)	Continuation Phase (Daily or 3 Times per Week)
I	New smear-positive patients New smear-negative patients with PTB with extensive parenchymal involvement Patients with severe concomitant HIV disease or severe forms of extrapulmonary TB	2 HRZE	4 HR or 6 HE daily
II	Previously treated sputum smear-positive PTB patients, including: - Relapse - Treatment failure - Treatment after interruption	2 HRZES/ 1 HRZE	5 HRE
III	New smear-negative PTB patients (other than those in Category 1) Patients with less severe forms of extrapulmonary TB	2 HRZE	4 HR or 6 HE daily
IV	Chronic and MDR-TB patients (who are still sputum-positive after supervised re-treatment)	Refer to WHO TB guidelines for use of second-line medicines in specialized centers	

Note: PTB = pulmonary tuberculosis, H = isoniazid, R = rifampicin, Z = pyrazinamide, E = ethambutol, S = streptomycin.

ANNEX 2. PMTB INDICATORS

Indicators Description Format

This section presents detailed descriptions for each PMTB indicator. Each description follows exactly the same format, which is summarized below.

Indicator data can be collected at four different levels of the health care system. Each indicator in the descriptions that follow is coded according to the level at which it is measured, with the code appearing in parentheses after the indicator title. The health system level codes used are:

C Central level: under direct supervision of the central government

R Regional or district level: acts as the intermediary; provides supplies to the health facilities and not directly to patients

F Health facility level: provides direct care to the patient population

D Drug outlet level: usually serves as the patient's primary private sector source for medicines

Indicator Name

The name of the indicator, along with the different system levels that may be examined (for example, **C/R/F** signals that the indicator may be applied at the central, regional, and health facility levels).

Rationale

The reason that the indicator is important.

Definition

The meaning of the indicator and the terms used to describe the indicator.

Data Collection

The most likely sources of information are summarized in a table indicating *where* the data are to be collected, *whom* to ask for assistance, and *what* documents and records to review.

Brief discussions of methods and issues related to data collection.

Citations of the data collection forms to be used, if any.

Computation and Example

Computations, if any are needed, are accompanied by an example using illustrative data.

Presentation

Brief example of how results may be presented.

Notes

Suggestions for additional information or discussion required to put the indicator in proper context, or to provide more detail.

Definitions

Key Indicators

Key indicators should be measured by the NTP to ensure regular supply of cost-effective, quality TB medicines that are used correctly according to the program's standard treatment norms.

Complementary Indicators

Complementary indicators can be used by the NTP to broaden the monitoring of TB pharmaceutical product management activities.

Key Indicators

K-1. Average percentage of time out of stock for a set of TB tracer commodities in TB facilities (C/R/F)

Rationale

The percentage of time out of stock for a set of TB tracer commodities and supplies provides a measure of the capacity of the procurement and distribution system to maintain a constant supply of commodities. Successful implementation of the TB control strategy is dependent on medicine availability.

Definition

Time out of stock, or stock-out time, is defined as the number of days that a product was not present in a warehouse or health center over a recent 12-month period (usually the 12 months preceding the month during which the assessment takes place). To be considered a stock-out, there must have been none of an unexpired medicine in stock. If even small quantities of an unexpired medicine were present, the medicine should be counted as in stock. Percentage of time out of stock is defined as the percentage of days during a 12-month period that a commodity has been out of stock (based on inventory records).

Data Collection

Data Collection Sites	Whom to Ask	What to Get
Central medical store	Inventory Officer/Storekeeper	Inventory records of commodities that are normally stocked for the tracer list, number of days these normally stocked commodities were out of stock during the 12 months prior to assessment or during previous year
Regional medical store	Manager	
20 MOH TB health facilities	Dispenser/Pharmacist/Storekeeper	
NGO/Mission clinics and hospitals		

This indicator is based on the list of TB medicines used to treat tuberculosis developed by study organizers. In order to determine stock-out duration, a reasonably accurate inventory recording system (computer, ledger, bin cards, etc.) must be in place. The TB tracer commodity list can be used for the calculations. To determine average stock-out duration, identify which of the normally stocked commodities were out of stock during the past year, and then determine how many days the product was out of stock during that time. Ideally, this indicator should be determined for the 12 months prior to the month in which the assessment visit occurs. The critical issue is that the same 12-month period and same tracer commodities should be used for all health facilities and warehouses visited.

See form A-1: Stock-Out Data Form in Annex 3.

Computation and Example

Enter the historical stock data into a table, recording the names of the TB commodities and the number of days of stock-out in the previous 12 months. To compute this indicator, carry out the following steps:

First, record the number of days out of stock in the past 12 months for each TB commodity in the table. Then add the total numbers of days out of stock over the past 12 months for all medicines.

Second, to record this indicator, compute the *average percentage of time that all TB medicines were out of stock* within the 12-month period by adding the stock-out days for all medicines and then dividing this sum by 365 days, multiplied by the total number of medicines normally stocked, and finally multiplying by 100.

$$\text{Average \% of time that TB commodities were out of stock} = \frac{\text{Total number of stock-out days for all TB tracer commodities}}{365 \times \text{total number of TB commodities normally stocked}} \times 100$$

Present this data in tables, and report averages for each type of facility visited (CMS, RMS, and peripheral TB health facilities).

For purposes of illustrating the computation, assume a TB commodity list of four products:

Product	Total Days Out of Stock
Ethambutol 400 mg	36
Rifampicin 150 mg + isoniazid 75 mg	64
Pyrazinamide 400 mg	123
Ethambutol 400 mg + isoniazid 150 mg	70

Assume that in a CMS, all three of these medicines are normally stocked.

$$\text{Average \% of time that TB commodities were out of stock} = \frac{36 + 64 + 123 + 70}{365 \times 4} \times 100 = 20\%$$

Presentation

In country X, over a 12-month period, the TB commodities were out of stock an average of 20 percent of the time at the CMSs. In the RMSs, the tracer commodities were out of stock an average of 30 percent of the time. In the sample of health clinics, the TB commodities were out of stock an average of 40 percent of the time.

K-2. Average percentage of a set of tracer TB commodities available in TB facilities and medical stores (C/R/F)

Rationale

Successful implementation of the TB treatment strategy is dependent on commodity availability. This indicator will provide insight into the efficiency of the country's inventory management and procurement system. Components of an efficient pharmaceutical supply system include selection, quantification, procurement, distribution, and inventory control.

Definition

A commodity is defined as available if even one unit of *unexpired* commodity is in stock. Because expired commodities are inappropriate for use in all situations, they cannot be counted as stock available for use.

Data Collection

<table>
<tr><th>Data Collection Sites</th><th>Whom to Ask</th><th>What to Get</th></tr>
<tr><td>Central medical store</td><td>Inventory Officer/Storekeeper</td><td rowspan="5">Inventory records and stock count for TB commodities</td></tr>
<tr><td>Regional medical store</td><td>Manager/Storekeeper</td></tr>
<tr><td>20 MOH TB facilities</td><td rowspan="2">Dispenser/Pharmacist/Storekeeper</td></tr>
<tr><td>NGO/Mission clinics and hospitals</td></tr>
</table>

This indicator is based on the list of TB medicines used to treat tuberculosis developed by study organizers. First, in consultation with staff at the national TB program, CMSs, RMSs, local health and NGO/Mission facilities, determine at which level these commodities are normally stocked. The figure for commodities *normally stocked* becomes the denominator in calculations. Then, determine whether each of the normally stocked commodities is available on the day of the assessment visit. If any of the available TB commodities are unexpired, record that item as "present," even if it is likely to be out of stock very soon. If all stock for a product on the list is expired, record 0. Do not worry about stock levels for this indicator.

See form A-2: Inventory Data Form in Annex 3.

Computation and Example

This indicator is recorded as a percentage, calculated by dividing the number of unexpired TB commodities found in stock by the total number of commodities normally stocked, and multiplying by 100.

$$\text{\% of TB racer commodities available} = \frac{\text{Number of unexpired TB commodities in stock}}{\text{Total number of commodities normally stocked}} \times 100$$

Present the data in separate tables for each type of facility (CMS, RMS, and peripheral health facilities) visited. For the sample of health facilities, the indicator is calculated as the average of the facility-specific averages:

$$\text{Average \% of TB tracer commodity available} = \frac{\text{Sum of \% for each facility}}{\text{Total number of facilities in sample}}$$

To calculate the average percentage of TB tracer commodities available for the sample of health facilities, carry out the following steps:

For one health center with three unexpired TB medicines in stock, from a list of five tracer commodities normally stocked, the calculation is:

$$\text{\% of TB tracer commodity available} = \frac{3 \times 100}{5} = 60\%$$

For a sample of 20 health facilities, for which the sum of percentages of tracer commodities in stock is 960%, the average percentage of tracer commodities in stock is calculated as:

$$\text{Average \% of TB tracer commodity available} = \frac{960\%}{20} = 48\%$$

Presentation

In a survey of 20 health facilities, where five TB tracer commodities were confirmed to be normally stocked, an average of 48 percent of the listed commodities was found in stock. The range among facilities was 25 percent to 85 percent, with the lower end of the range being associated with more peripheral health facilities. The facility-specific averages are listed below:

- Regional medical stores: 85 percent
- District hospitals: 64 percent
- Health centers and posts: 48 percent

K-3. Percentage of new smear-positive patients with pulmonary TB who were prescribed correct medicines in conformity with the standard treatment guidelines used in the country (F)

Rationale

This indicator attempts to measure the degree of adherence to the TB national treatment guidelines. Failure of health care providers to adhere to the recommended TB standard treatment guidelines can result in the development of drug-resistant TB strains that are more difficult to manage. For the purpose of this study, only new cases of smear-positive pulmonary tuberculosis are considered.

The indicator consists of two separate percentages, one to identify compliance of correct medicine prescriptions with country TB norms or STGs for the intensive phase of treatment and another for the continuation phase of treatment. Adhering to norms or STGs is especially important if TB treatment is administered at different facilities for the intensive and continuation phases of treatment.

This indicator will identify only whether the correct medicines were prescribed at the beginning of each phase of treatment. The indicator is not designed to trace adherence to correct medicines during the whole course of treatment. Such research is done by other means, such as drug utilization review (DUR) programs.[10]

Definition

WHO defines a sputum smear-positive pulmonary TB case as having had two or more initial sputum smear examinations using the acid fast bacilli (AFB) staining method that were positive for TB-causing microorganism; one sputum smear examination that was positive for AFB plus radiographic abnormalities consistent with active pulmonary TB as determined by a clinician; or one sputum smear that was positive for AFB plus a sputum culture positive for *M. tuberculosis*. Pulmonary TB refers to disease involving the lungs. A new case is a patient who has never before had treatment for TB or who has taken TB medicines for less than four weeks.

The surveyed country may have developed its own STGs for TB, or it may be using internationally accepted standards, such as those developed by WHO (DOTS), the International Union Against Tuberculosis and Lung Disease (UNION), the American Thoracic Society, or others. For the purpose of this indicator, local official standard treatment norms should be used as a reference to collect data and calculate indicators. If no local norms exist, then WHO guidelines should be used.

[10] Moore, T., A. Bykov, T. Savelli, and A. Zagorski. 1997. *Guidelines for Implementing Drug Utilization Review Programs in Hospitals.* Arlington, VA: Rational Pharmaceutical Management Project/Management Sciences for Health.

Data Collection

Data Collection Sites*	Whom to Ask	What to Get
20 MOH TB health facilities and/or NGO/Mission clinics and hospitals where initial prescribing for **intensive** phase of treatment is done	Medical Records Officer/ Health Facility Manager/ Pharmacist	Identify a sample of 15 recent new cases of smear-positive pulmonary tuberculosis per TB facility and determine the prescribed medicines for the **intensive phase** of treatment. Identify encounters by consulting daily registers, patient records, or prescription slips or through observation.
20 MOH TB health facilities and/or NGO/Mission clinics and hospitals where initial prescribing for **continuation** phase of treatment is done	Medical Records Officer/ Health Facility Manager/ Nurse/Pharmacist	Identify a sample of 15 recent new cases of smear-positive PTB per TB facility and determine the prescribed medicines for the **continuation** phase of treatment. Identify encounters by consulting daily registers, patient records, or prescription slips or through observation.

* It may not be possible to find records for 30 new smear-positive cases at one facility. It will then be necessary to visit more than 20 facilities to collect data for a sample of 600 cases for both treatment phases. If intensive and continuation phases of treatment take place in the same facility, the data are collected separately for 15 intensive and 15 continuation phase patients.

Before the study, organizers should identify TB treatment standards officially used in the survey country, including medicine name and strength, and identify where the treatment takes place. (In most countries treatment takes place in outpatient clinics, but in some countries, intensive phase treatment is done in hospitals and continuation phase treatment is done in the outpatient setting.)

Data for the indicator can be collected retrospectively or concurrently, depending on the accuracy and availability of patient records. In settings where patient records have no data missing, the retrospective method may be the most efficient option. However, the concurrent method may be preferable when the survey is focusing on currently treated patients.

Review clinic/hospital records for the past 12 months. For each patient record, write down the medicines prescribed.

See forms A-3a: Medical Records Review Form (Intensive Phase of Treatment) and A-3b: Medical Records Review Form (Continuation Phase of Treatment) in Annex 3.

Computation and Example

Both figures (for intensive and continuation phases) are recorded as percentages, computed by dividing the number of new smear-positive TB cases prescribed correct medicines in accordance with accepted national STGs by the total number of new smear-positive patient encounters surveyed, and multiplying by 100. The overall indicators are the averages of these facility-specific percentages. Along with this average, provide range figures.

If for 20 health facilities surveyed, data obtained from a sample of 300 patient encounters showed that a total of 153 patient encounters in the **intensive** phase were prescribed correct medicines in accordance with the national STGs, then the average for all facilities would be:

$$\text{\% of TB patients in intensive phase prescribed correct medicines in all TB facilities} = \frac{153 \times 100}{300} = 51\%$$

For the 20 health facilities that are responsible for the **continuation** phase, data for a sample of 300 patient encounters showed that a total of 129 patient encounters were prescribed correct medicines in accordance with the national STGs, so the average for all facilities would be:

$$\text{\% of TB patients in continuation phase prescribed correct medicines in all TB facilities} = \frac{129 \times 100}{300} = 43\%$$

Presentation

In a survey of 20 health facilities in country X, 51 percent of all patients in the intensive phase were prescribed correct medicines, with a range of 8 percent to 73 percent among facilities. For the same 20 facilities, 43 percent of patients in the continuation phase were prescribed appropriate medicines, with a range of 5 percent to 71 percent among facilities.

K-4. Percentage of TB medicines received in the past three shipments that were accompanied with a batch certificate (C)

Rationale

This indicator is a quality measure that will be used to ascertain whether the survey country requests batch certificates along with individual orders of TB medicines and to determine if the supplier actually provides individual batch certificates with each shipment.

Definition

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce[11] requires that health systems obtain three certificates when procuring medicines, namely a Certificate of a Pharmaceutical Product, a Statement of Licensing Status of a Pharmaceutical Product, and a Batch Certificate of a Pharmaceutical Product.

The batch certificate attests to the quality and expiry date of a specific batch or consignment of a product that has already been licensed in the importing country. Confirmation of medicine quality can only be done by conducting in-country quality-control tests on individual batches upon receipt of shipment.

For countries that request the batch certificate in their tender documents, this certificate is intended to accompany every batch of TB medicine upon receipt of shipment. It should include the specifications of the final product at the time of batch release and the results of a full analysis undertaken on the batch in question by the supplier.

This indicator can be measured in all countries, first to determine if a batch certificate is a mandatory component in tender documents, and second to obtain a percentage of TB medicines accompanied with individual batch certificates for countries that include this requirement as a mandatory component in tender documents.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
CMSs/ MOH Procurement Office/ NTP	Officer in charge of pharmaceutical procurement/ drug regulatory authority	Find out if a batch certificate is a mandatory component in tender documents. Request to see individual batch certificates for TB medicines received during the past three shipments.

[11] World Health Organization/Essential Drugs and Medicines Policy. 2004. "WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce."
<http://www.who.int/medicines/organization/qsm/activities/drugregul/certification/certifscheme.shtml> (accessed Dec. 2004).

Annex 7 presents a model batch certificate for pharmaceutical products. The batch certificate information could be obtained from the national regulatory authority, CMSs, and/or the MOH Pharmaceutical Procurement Unit if the system is centralized. For decentralized systems, collect information from any office responsible for TB medicine procurement—for example, the NTP or district procurement offices.

Using key informant interviews, determine if a batch certificate is a mandatory component of the tender documents by asking the questions below:

- Do you always request a batch certificate from TB medicine suppliers?
- Is the batch certificate requirement included as a mandatory component in TB medicine tender documents?

If the answer to either question is *Yes,* request to see a tender document and obtain a copy if possible.

Data collectors should then request to see batch certificates for individual batches of TB medicines for the past three shipments. Review and determine the total number of individual batch certificates received during the past three shipments for each TB medicine. Record findings in the form provided.

See form A-7: Minimum Quality Standards Form in Annex 3.

Computation and Example

The indicator is expressed as a percentage. It is computed as the total number of batches of TB medicines received in the past three shipments accompanied with batch certificates divided by the total number of batches of TB medicines received during the past three shipments.

$$\text{\% of TB medicines accompanied with batch certificates in the past three shipments} = \frac{\text{Number of batches of TB medicines with batch certificates from the past three shipments}}{\text{Total number of batches of TB medicines in the past three shipments}} \times 100$$

For illustrative purposes, let us assume that country X ordered 5,000 bottles containing 1,000 tablets of ethambutol 400 mg from supplier Y. Supplier Y ships 15 different batches of the order to country X. Upon receipt of the shipments, country X received only 6 accompanying batch certificates for the 15 batches. The percentage can be computed thus:

$$\text{\% of TB medicines accompanied with batch certificates in the past three shipments} = \frac{6 \times 100}{15} = 40\%$$

Carry out the same computation for the other TB medicines received during the same shipment period.

Presentation

In country X, the results obtained demonstrated that out of 15 batches of ethambutol 400 mg tablets that were received during the past three shipments, 40 percent (6) were found to have accompanying batch certificates.

K-5. Percentage of median international price paid for a set of TB commodities that was part of the last regular procurement (C/R/F)

Rationale

This indicator will help determine the potential savings that could be achieved if procurement practices are improved, consequently supporting changes in the pharmaceutical supply system. Percentage of median international price for a set of TB medicines is a measure of the effectiveness of procurement in the country.

Definition

Median international price is the median free on board (FOB) price from a set of international suppliers, adjusted to reflect estimated cost, insurance, and freight (CIF) prices. One source of price information is MSH's *International Drug Price Indicator Guide* (available at http://erc.msh.org). The GDF price catalogue can also be used for comparison purposes. The GDF prices are not median prices (see http://www.globaldrugfacility.org).

Data Collection

Data Collection Sites	Whom to Ask	What to Get
MOH Procurement Unit	Officer in charge of pharmaceutical purchases	List of most recent prices paid for a set of PMTB tracer commodities Tender documents Supplier invoices
Central medical store	Manager or Reception Officer	
Regional government administration or medical store	Manager	
MOH health facilities	Pharmacist or Procurement Officer	

Note: This information can be collected at the central level. However, if the system is decentralized and TB commodities are procured at different levels, collect data at all levels in the public health sector where TB commodities are procured.

This indicator is based on the list of TB tracer commodities developed by study organizers. Information on CIF prices paid by the MOH for the tracer commodities should apply to the last regular procurement. Any more recent ad hoc or emergency procurement that may have taken place should be compared separately to international prices. The median international unit prices for the tracer commodities may be obtained from the *International Drug Price Indicator Guide*. Do *not* use the average cost listed in this *Guide*. Instead, use the median price for each tracer

commodity.[12] When medicine name and strength is the same, comparison can also be made to GDF prices.

The *median* (or middle-most) price should be used instead of the *mean* (or average) retail price to avoid bias caused by outlying high or low prices for a given commodity.[12]

Note: The median price is already available in the *International Drug Price Indicator Guide*. However, if you were using prices from another source, you can calculate the median price as illustrated below.

To determine the median price for each product, arrange the average prices obtained from each site where TB commodities are procured in ascending order. If the list contains an even number of items, pick the middle two numbers (in the second example, third and fourth numbers). Add these two numbers and divide by two to obtain the median. If the list contains an odd number of items, simply select the middle-most number as the median. See the following examples.

Ex. 2, 3, 4, 5, 6 Median is **4**
Ex. 2, 3, 4, 5, 6, 7 Median: 4 + 5 = 9; 9 ÷ 2 = **4.5**

The prices in the *International Drug Price Indicator Guide* are FOB and should be adjusted upward by 10–15 percent to reflect average shipping and insurance costs. Significant fluctuations in exchange rate should be taken into consideration when adjusting for the FOB prices. Specify the source of international prices and the year. If all purchases are not made by one central agency, compile information separately by type of institution, and compute the percentage of international price for each type of purchasing institution (e.g., RMSs, hospitals, health centers). Note the date of the most recent regular TB commodity procurement. When making calculations, it may be necessary to convert prices paid in local currencies into U.S. dollars. It is important to use the exchange rates in effect at the time the purchases were made and to use the edition of the *International Drug Price Indicator Guide* that corresponds with the year in which purchases were made.

See form A-4: International Price Comparison Form in Annex 3.

Computation and Example

The indicator should be presented as the percentages of median international prices for the set of TB tracer commodities. If data are collected from different levels of the system, a separate average should be calculated for each level. The computation involves the following steps:

First, the percentages are calculated for each of the PMTB tracer commodities by dividing the purchase cost of the *comparison unit* (e.g., tablet, milliliter) at the last regular procurement by the median international price of that unit and multiplying the result by 100.

$$\text{\% of Median international price} = \frac{\text{Comparison unit price}}{\text{Median international unit price}} \times 100$$

[12] Management Sciences for Health (MSH), in collaboration with the World Health Organization. 2003. *International Drug Price Indicator Guide* (updated annually). Boston, MA: Management Sciences for Health.

For purposes of illustration, assume a tracer list of three products:

Product	Comparison Unit Price (USD)	Adjusted Median International Unit Price (USD)*
Isoniazid 300 mg tablets	0.0143/tablet	0.0082/tablet
Streptomycin 1 g vial	0.1558/vial	0.1060/vial
Rifampicin 150 mg/isoniazid 75 mg tablets (combination)**	0.0191/tablet	0.0136/tablet

* The figures in this column have been adjusted to reflect estimated CIF prices. Prices were obtained from MSH's *International Drug Price Indicator Guide* (2003).

** The unit price for rifampicin 150 mg/isoniazid 75 mg tablet was used for the adjusted median international unit price.

Then, calculate the percentage for each product.

For isoniazid, the first product on the list, the calculation is done as follows:

$$\text{\% of Median international price} = \frac{0.0143 \times 100}{0.0082} = 174\%$$

Using the data in the table, the percentages for streptomycin and rifampicin 150 mg/isoniazid 75 mg combination are calculated as 147 percent and 140 percent, respectively.

According to similar calculations, the percentages for hospitals were 149 percent, 123 percent, and 319 percent for the three products, respectively.

Presentation

In country X, comparisons of medicine purchase prices with median international prices were made at both the CMS and at a sample of one national and three regional hospitals. In 2003, the CMS paid 174, 147, and 140 percent of the median international price for the different medicines, while the hospitals paid 149, 123, and 319 percent for the set of TB tracer commodities.

Complementary Indicators

C-1. Percentage of NTP medicine products included on the national essential medicines list (C)

Rationale

This indicator will ascertain the percentage of NTP commodities that are included on the national EML. The national EML plays a major role in some countries; this list is utilized for medicine procurement in the public sector and is also used as a reference for medicine reimbursement by health insurance programs.

Definition

This indicator determines the percentage of TB commodities utilized for treatment by the NTP that are included on the national EML. A national EML is a selection of a limited range of medicines for treatment of major or common diseases intended to provide high quality of care and cost-effective use of health resources. The country's NTP commodities may include first- and second-line TB medicines. Only the first-line NTP medicines should be used for this indicator.

Note: This indicator should not be used if a national EML does not exist in the survey country.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
MOH or NTP office	Officer in charge or Director of Pharmaceutical and/or Medical Supplies Services	Copy of the national EML and a list of the NTP commodities utilized in the country*

*See also PMTB sample tracer commodity list in Table 6 (Chapter 2).

Find out if a national EML exists in the country. If one exists, obtain a copy and evaluate the number of TB commodities on the list. Also determine for what level of health care the EML was developed. For example, some countries develop EMLs for primary health care levels, hospital levels, and specialist levels. If that is the case, compute and obtain separate percentages for each of the levels. The TB tracer commodity list may be used if it contains a list of first-line medicines used to treat TB by the country's NTP.

It is necessary to specify criteria for counting products containing the same active ingredient(s). Products that are counted as the same item include:

- Fixed-dose combination medicines, no matter how many chemicals they contain, are counted as one product. For example, a combination product containing rifampicin and isoniazid will be counted as one medicine.

- Brand-name products that are chemically equivalent to generic products of the same strength and dose on the list are counted as one product. For example, Rifadin® 150 mg capsule and rifampicin 150 mg capsule are counted as the same product.

Products that are counted as different items include:

- Different strengths of the same chemical entity. For example, isoniazid 50 mg and isoniazid 100 mg are counted as two medicines.

- Dosage forms for different routes of administration. For example, tablets, capsules, oral liquids, and injectables (IM, IV, or SC) are all counted as different medicines.

- Different dosage forms for the same route of administration, such as isoniazid 50 mg tablet and isoniazid 50 mg/mL oral liquid, are counted as two different medicines.

Computation and Example

This indicator is computed as the total number of TB medicines included on the national EML divided by the total number of NTP medicines. The quotient obtained is multiplied by 100 to obtain the percentage. Record the year of the most recently published edition of the national EML.

$$\text{\% of NTP medicines on national EML} = \frac{\text{Total number of medicines on the national EML}}{\text{Total number of NTP medicines}} \times 100$$

$$\text{\% of NTP medicines on national EML} = \frac{5 \times 100}{10} = 50\%$$

Presentation

Country X has an essential medicines list for use in PHC facilities. Of the TB commodities used by the country's NTP, 50 percent is included on the national EML for treatment of TB infection. The list was last revised in 2001.

C-2. Percentage of NTP medicine products included on the WHO tuberculosis essential medicines list (C)

Rationale

This indicator will determine if the NTP's TB medicines were selected in accordance with the WHO-recommended medicines for treatment of TB infection presented in the WHO Essential Medicines List.

Definition

This indicator will be used to obtain the percentage of a country's NTP medicines that are included on the WHO EML for TB medicines. The WHO EML for TB includes first- and second-line medicines for treatment of all categories of TB infection. The second-line medicines are used in cases of multidrug-resistant TB. If use of second-line medicines or multidrug resistance is not addressed in the survey country's STGs, be sure to compare just the first-line medicines used in the country to the first-line medicines stated on the WHO EML.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
NTP	Officer in charge or Director of Pharmaceutical and/or Medical Supplies Services	List of NTP medicines

Obtain a list of TB medicines used in the NTP. The most recent WHO EML for TB treatment could be collected before the study commences from any WHO office or the WHO Web site. It is necessary to specify criteria for counting products containing the same active ingredient(s).

Products that are counted as the same item include:

- Fixed-dose combination medicines, no matter how many chemical entities they contain, are counted as one product. For example, a combination product containing rifampicin and isoniazid will be counted as one medicine.

- Brand-name products that are chemically equivalent to generic products of the same strength and dose on the list. For example, Rifadin® 150 mg capsule and rifampicin 150 mg capsule are counted as the same product.

Products that are counted as different items include:

- Different strengths of the same chemical entity. For example, isoniazid 50 mg and isoniazid 100 mg are counted as two medicines.

- Dosage forms for different routes of administration. For example, tablets, capsules, oral liquids, and injectables (IM, IV, or SC) are all counted as different medicines.

- Different dosage forms for the same route of administration, such as isoniazid 50 mg tablet and isoniazid 50 mg/mL oral liquid, are counted as two different medicines.

Computation and Example

This indicator is computed as the total number of TB medicines included on the WHO EML for TB treatment divided by the total number of the NTP medicines. The quotient obtained is multiplied by 100 to get the percentage. Record the year of the most recently published edition of the WHO EML used.

$$\text{\% of NTP medicines included on WHO EML} = \frac{\text{Total number of NTP medicines on WHO EML}}{\text{Total number of the NTP medicines}} \times 100$$

$$\text{\% of NTP medicines included on WHO EML} = \frac{6 \times 100}{15} = 40\%$$

Presentation

In country X, 40 percent of NTP medicines used in the country are included on the WHO tuberculosis EML. This comparison was made using the year 2002 WHO EML for TB medicines.

C-3. Percentage of TB medicine samples that failed quality-control testing out of the total number of TB medicine samples tested during the past year (C)

Rationale

This indicator is a quality measure that will be used to determine the effectiveness of the health system to procure and distribute quality, safe, and efficacious medicines. Medicine quality is a fundamental concern in TB treatment. Poor-quality or substandard medicines can cause treatment failures with resultant unfavorable treatment outcomes.

Definition

This indicator will determine the percentage of TB medicines tested that did not meet the standard quality criteria required in the survey country. TB medicines must be purchased from reputable sources and certified by the authority in the country to be safe, efficacious, and of good quality; at a minimum, medicines should conform to WHO standards for quality. Locally manufactured TB medicines should also undergo quality-control testing.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
MOH	Officer in charge of quality-control and product testing laboratory services	Number of TB medicine samples/batches subject to laboratory testing in the previous 12 months Number of TB medicine samples/batches that were actually tested Number of samples/batches of TB medicines that failed quality-control tests
Drug regulatory authority or quality-control testing laboratories	Health Officer/Manager in charge of product quality testing and laboratory services	

Note: This indicator should be used only for countries that conduct in-country quality-control tests for TB medicines.

Use interviews with key informants to determine and record the following:

- Whether or not the MOH has an active pharmaceutical product testing program
- Names and affiliations of the laboratories that actually perform the tests
- Types of tests conducted and types of equipment used
- Occasions on which testing is carried out (e.g., for registration purposes only, through random inspection at receipt of purchased medicines, or other)

- Total number of samples/batches of TB medicines collected or submitted for testing within the past 12 months

- Total number of samples/batches of TB medicines actually tested within the past 12 months

- Total number of TB medicine samples/batches that failed quality-control testing within the past 12 months (e.g., from June 2003 to June 2004)

- Information about the pharmaceutical testing laboratories concerning staff level and capacity, equipment, record systems, access to reagents, reference standards, technical information, types of tests performed, and types of equipment used

Computation and Example

This indicator is calculated by dividing the number of TB medicine samples that failed quality-control testing by the total number of TB medicine samples actually tested. The quotient obtained is multiplied by 100 to calculated a percentage. For example, a total of 20 samples/batches of TB medicine products were collected for testing from June 2003 to June 2004 by the drug regulatory authority, and 18 of the medicine products were actually tested. If eight of the medicine samples/batches failed quality-control tests, the percentage will be computed thus:

$$\text{\% of TB medicines that failed quality control test} = \frac{\text{Total number of TB medicine samples that failed}}{\text{Total number of TB medicine samples actually tested}} \times 100$$

$$\text{\% of TB medicines that failed quality control test} = \frac{8 \times 100}{18} = 44.4\%$$

Presentation

Twenty TB medicine samples/batches collected by the drug regulatory authority within a period of 12 months (June 2003 to June 2004) in country X were presented for testing in 2004. At the time of the survey, only 18 of the medicine products had been tested. Results obtained showed that 44.4 percent or 8 out of 18 of the medicines tested were substandard. Interviews with the Director of the regional pharmaceutical testing laboratory revealed some degree of inefficiency in the performance of the quality management system, which was attributed to low staff levels and capacities, outdated equipment, inadequate supply of reagents and chemical supplies for testing, poor record-keeping system, outdated reference standards, and little or no technical information for improved performance.

C-4. Percentage of TB facilities visited where the most recent official manual of treatment guidelines for TB was present (C/F)

Rationale

This indicator is used to measure the level of access to recent information on effective TB control and management by determining whether standard treatment guidelines are present.

Definition

This indicator measures the presence of the most current edition of official treatment guidelines. To qualify as official treatment guidelines for the purposes of this indicator, a document must be intended as a clinical reference for health care providers who see and treat TB patients. It must present information on the treatment regimens for TB cases, including diagnosis and medicines.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
MOH	Director of Health Services	Most recent copy of treatment guidelines
20 MOH TB health facilities and/or 20 NGO/Mission clinics and hospitals	Health Officer/Director/ Manager Facility Manager	

Such treatment guidelines must officially exist for this indicator to be meaningful. If so, obtain the most recent copy of the guidelines that has been prepared to provide information about how to diagnose and treat tuberculosis. Evaluate whether the information in the treatment guidelines meet all the following criteria, specified in the definition above:

- The information is intended as a clinical reference for health care providers.
- Information is presented on the diagnosis and treatment regimens of tuberculosis patients by diagnostic categories.

Data for this indicator are collected by surveying a sample of 20 health facilities. At each site, the staff is asked to produce information that meets the above criteria.

See forms A-3a and A-3b: Medical Records Review Form in Annex 3.

Computation and Example

The indicator is expressed as a percentage. It is computed as the number of facilities at which official treatment guidelines are found divided by the total number of facilities surveyed, and multiplied by 100.

$$\text{\% of Facilities with official treatment guidelines} = \frac{\text{Number of facilities with official treatment guidelines}}{\text{Number of facilities surveyed}} \times 100$$

$$\text{\% of Facilities with official treatment guidelines} = \frac{12 \times 100}{20} = 60\%$$

Presentation

In country X, a national manual exists: it was adapted in 2003 from WHO's *Treatment of Tuberculosis: Guidelines for National Programmes*. The manual is intended for use by physicians, nurses, and laboratory and other health care personnel who treat tuberculosis. It contains information on diagnosis, care (including medicines), and follow-up services for TB patients. An indicator study carried out in country X revealed that in 60 percent of health facilities, or 12 health facilities out of a sample of 20 surveyed, staff could produce a copy of the 2003 edition of the manual.

C-5. Percentage of TB outpatients who could correctly describe how the prescribed medication should be used (F)

Rationale

It is absolutely crucial in TB treatment that patients comply with the prescribed treatment course. If the patient understands the disease and treatment, not only will a positive outcome be more likely, but also this information will be passed on to the community and, as a result, other individuals with tuberculosis will be encouraged to seek diagnosis and treatment. That is why international manuals on TB treatment place special emphasis on patient education.[13]

The indicator may be of special importance in countries where TB treatment is not directly observed by a health care worker, as the treatment outcomes depend on whether patients follow the schedule for the whole duration of treatment.

The indicator is useful to measure the potential for nonadherence and possible treatment failure caused by the lack of knowledge of patients on how to take medications correctly and the possible consequences of failed treatment.

Definition

Ideally, every patient should be fully aware of the nature of TB, length and phases of the treatment course, number of medicines to be taken, necessity and timing of returning for treatment over the requisite amount of time (number of months) on the requisite days (which days per week), possible side effects, what to do if a dose is missed, and consequences of noncompliance with the treatment regimen.

For this indicator, to correctly describe how to use the medications, a patient should know all of the following:

- What medicines to take (name, color, or other marker of a pharmaceutical product)
- How many tablets of each to take
- How many times a day/week to take them
- Total length of treatment
- Potential signs of adverse reactions, such as unusual skin rash, and what to do about them
- Consequences of not taking the prescribed medicines (missing doses)

Note: This indicator should be used for the initial and continuation phases of treatment.

[13] See, for example, World Health Organization. 1998. *Tuberculosis Handbook.* WHO/TB/98.253. Geneva: WHO; or International Union Against Tuberculosis and Lung Disease (UNION). 1996. *Management of Tuberculosis: A Guide for Low Income Countries.* Paris: UNION.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
20 MOH TB facilities	Director of health facility for permission to conduct exit poll interviews with outpatients	Answers to interview questions by a convenience sample (i.e., patients in the clinic during the day of data collection) of 10 new smear-positive patients; use same sample as for C-6

At each of the 20 MOH TB health facilities, conduct the exit poll interviews as described in Annex 3. Record the information provided by the patient, using prompting questions if necessary.

See form A-5: Exit Poll Interview Form in Annex 3.

Patients must correctly answer all of the following questions:

- How long have you been taking your medicines?
- Does anybody on the medical staff or a caregiver[14] look at you when you take your medicine?
- How many different kinds of medicines are you taking?
- How many tablets of each medicine are you taking?
- How many days in a week or in a month do you come to take or collect your medicines?
- When you started your TB treatment, how long did the doctor/caregiver tell you that you have to take your medicine before you complete treatment?
- Did your doctor/caregiver tell you to return to the clinic or health center if any sign of side effects such as fever, ringing in the ears, blurred vision, or vomiting occur?
- What will happen if you do not take your medicines as prescribed?

Computation and Example

For each MOH facility in the sample, indicators are recorded as percentages, computed by dividing the number of patients who could correctly describe how to take the prescribed medications by the total number of interviewed patients and multiplying by 100. The overall indicator is an average of TB facility-specific percentages. Along with this average, provide the range figures.

[14] A caregiver is defined as a medical doctor, physician assistant, nurse, nurse attendant/assistant, pharmacist, staff in TB facility or health care center, community health worker, or family member providing directly observed treatment.

$$\text{\% of TB patients who correctly describe how to use the medications} = \frac{\text{Number of TB patients who correctly describe how to use medications}}{\text{Number of TB patients interviewed}} \times 100$$

The result for one TB facility is calculated as follows:

$$\text{\% of TB patients who correctly describe how to use the medications} = \frac{6 \times 100}{10} = 60\%$$

For 20 MOH health facilities, data for a sample of 200 (about 10 patients per facility) exit poll interviews showed that 143 TB patients described correctly how to take the medications; the average for all TB facilities are calculated as follows:

$$\text{Average \% of TB patients who correctly described how to use the medications} = \frac{143 \times 100}{200} = 72\%$$

Presentation

In country X, for a sample of 20 MOH health facilities, an average of 72 percent of TB patients correctly described how to use their medication, with a range from 37 percent to 90 percent among health facilities.

C-6. Percentage of TB patients who reported regular observation by a health care worker during medicine intake (F)

Rationale

This indicator will help determine if directly observed treatment is practiced at TB care facilities in the survey country. Directly observed treatment for TB patients by a caregiver when taking TB medicines promotes compliance with treatment by patients and can prevent development of multidrug-resistant TB strains.

Definition

This indicator will estimate the percentage of TB patients who are regularly observed by a caregiver during administration of TB medicines. For the purpose of this study, a caregiver is defined as a medical doctor, physician assistant, nurse, nurse attendant/assistant, pharmacist, staff in TB facility or health care center, community health worker, or family member providing directly observed treatment.

The DOTS approach has been identified by WHO as an effective TB control method, and its strategy recommends direct observation during the initial and continuation phases of TB treatment, especially when rifampicin is included in the treatment regimen.

If TB patients are not observed during any treatment phase in the country, indicator C-6 should not be used.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
20 MOH TB facilities and/or NGO/Mission clinics and hospitals where initial phase treatment occurs	Director of health facility for permission to conduct exit poll interviews with outpatients	Answers to interview questions by a convenience sample (i.e., patients in the clinic during the day of data collection) of 10 new smear-positive patients; use same sample as for both C-5 and C-6
20 MOH TB facilities and/or NGO/Mission clinics and hospitals where continuation phase treatment occurs		

At each of the 20 MOH TB health facilities and/or NGO/Mission clinics and hospitals, conduct exit poll interviews. Record the information provided by the patients, using prompting questions if necessary. A total of 200 samples should be collected, with approximately 10 samples from 20 different TB health care facilities.

See form A-5: Exit Poll Interview Form in Annex 3.

The following questions will be asked of the patients. Ensure that all questions are answered correctly. Record the information collected.

- How long have you been taking your medicines?
- Does anybody on the medical staff or a caregiver look at you when you take your medicine?

Computation and Example

This indicator is expressed as a percentage. Compute the percentage by dividing the number of patients who reported regular observation of TB medication by the total number of interviewed patients and multiplying by 100. The overall percentage of patients observed is an average of all TB facility-specific percentages. Along with this average, provide the range figures.

$$\text{\% of TB patients who reported being observed while taking TB medicines} = \frac{\text{Number of TB patients who reported being observed}}{\text{Number of TB patients interviewed}} \times 100$$

Assume the result for one TB facility is calculated as illustrated below, where 10 TB patients were interviewed and only 6 were observed:

$$\text{\% of TB patients who reported being observed while taking TB medicines} = \frac{6 \times 100}{10} = 60\%$$

For 20 MOH health facilities, data for a sample of 200 (about 10 patients per facility) exit poll interviews showed that a total of 126 TB patients reported being observed while using TB medicines. To calculate the average percentage for all TB facilities, divide the total number of TB patients who reported being observed by the total number of TB patients interviewed and multiple by 100.

$$\text{Average \% of TB Patients who reported being observed while using TB medications} \quad \frac{126}{200} \times 100 = 63\ \%$$

Presentation

In country X, for a sample of 20 MOH health facilities treating TB infection, an average of 63 percent of TB patients reported being observed by a caregiver while taking their TB medication, with a range from 23 percent to 80 percent in the health facilities providing TB treatment. Fewer than 30 percent of the TB patients interviewed reported that they were counseled by their caregiver about possible adverse reactions or effects that might occur during therapy.

Suggestion: When analyzing data in this indicator, the study investigator may want to calculate separate percentages for patients in the intensive phase (less than 2 months or 60 days) of treatment and those in the continuation phase (more than 2 months or 60 days).

C-7. Average percentage of stock records that correspond with physical counts for a set of TB tracer commodities in TB storage facilities (C/R/F)

Rationale

The average percentage of stock records that correspond with physical counts is a measure of the quality of the stock record-keeping system in the survey country. This indicator will identify problems that contribute to financial losses, such as incorrect inventory/poor record-keeping, waste, or pilferage.

Definition

This is the average percentage of in-stock TB tracer commodity inventory records that correspond exactly with the physical stock count for a set of TB tracer commodities. Stock records are official inventory forms and registers used to document medicine receipts, issues, balances, and other related information.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
Central medical store	Inventory Officer/Storekeeper	Most accurate records of current stock levels for each TB tracer commodity, issues and receipts not entered, method of recording stocks, physical count of unexpired stock levels
Regional medical store	Manager	
20 MOH health facilities	Dispenser/Pharmacist/ Storekeeper	

This indicator is based on the TB tracer commodity list for treating new smear-positive pulmonary TB patients, developed by study organizers.

Visit the CMS, at least one RMS if such stores exist in this system, and a sample of 20 TB health facilities. At each site, carry out the following procedure:

- Ask staff to produce the most accurate records of current stock level for each of the TB tracer commodities. Ask them to produce their records for any recent issues or receipts that have not been entered in their stock level records.

- Take note of the means used to produce these estimates (computerized system, manual ledgers, bin cards). If bin cards exist, and if they were not used to produce the best estimates, obtain a second set of data based on bin cards.

- Finally, carry out a physical count of the unexpired stock levels for these medicines, and record the number of units for each TB tracer commodity in stock. The expired units should not be counted because they are not available for distribution. Tracer commodities that are not normally stocked by the facility should be excluded.

See form A-2: Inventory Data Form in Annex 3.

Computation and Example

For the set of tracer commodities, calculate the percentage of records checked that correspond exactly with the physical counts according to the tally and the ledger. To do this, divide the number of records for which no discrepancy was found by the total number of records checked, and multiply this result by 100.

$$\text{\% of Stock records corresponding with physical counts} = \frac{\text{Number of stock records with no discrepancies}}{\text{Total number of records examined}} \times 100$$

Present the data in separate tables for each type of facility in the sample (CMS, RMS, or peripheral health facility). For the sample of health facilities, the indicator is calculated as the average of the facility-specific averages:

$$\text{Average \% of stock records corresponding with physical counts} = \frac{\text{Sum of average percentage for each facility}}{\text{Total number of facilities in sample}}$$

For purposes of illustrating this computation, assume a TB tracer commodity list of three products:

Product	Record	Count
Isoniazid 100 mg tablet	10,000	10,000
Rifampicin 150 mg/isoniazid 75 mg tablet (combination)	1,000	990
Streptomycin 1 g vial	88	87

To calculate the percentage of stock records that correspond exactly with physical counts, carry out the following steps:

For one health center, using the TB tracer commodity list above—

Number of records examined = 3

Number of records with no discrepancy = 1

$$\text{\% of Stock records corresponding with physical stock counts} = \frac{1 \times 100}{3} = 33\%$$

For illustration, for the 20 health facilities, the sum of percentages of stock records that correspond exactly with physical counts is 600 percent. The average percentage of TB tracer commodities that correspond exactly with physical counts is calculated as:

$$\text{Average \% of stock records corresponding with physical counts} = \frac{600\%}{20} = 30\%$$

Presentation

After adjusting for issue quantities not yet entered in the records at the CMS in country X, the percentage of records for six TB tracer commodities that corresponded exactly with physical counts was 33 percent. The average percentage of health center records that corresponded exactly with physical counts was 30 percent, with the range among facilities from 10 percent to 60 percent.

C-8. Number of days that a person has to work at minimum wage to pay for a complete TB treatment course, taking into account the price of medicines in the public or private market (D)

Rationale

This indicator gives an approximate estimate of the population's ability to pay for a full treatment course of TB. In some countries, the MOH does not provide free TB medicines to patients, and there may also be a prevailing private sector market for TB medicines influenced by factors such as inaccessibility to public sector TB care facilities, frequent stock-outs of TB medicines in the public facilities, and others.

Definition

This indicator will determine the number of days a person earning minimum wage or the lowest-paid government worker will have to work to pay out-of-pocket for a complete treatment course of TB (usually six months for new smear-positive patients). If the country does not have a minimum wage established, the lowest salary paid to a government employee will be used.

Circumstances in the health care system under study will determine whether the indicator needs to be measured in the public sector as well as in the private sector. For example, if a country's public health system demands that a patient pay for the medicines, totally or partially, the analysis will be performed accordingly to estimate the price of full treatment. In the case of the private nonprofit and private for-profit sectors, the prices that the public has to pay for purchasing the medicines will be used to estimate the cost of the full treatment.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
MOH or official newspaper MOH or NTP	Human resources or policy official Officer in charge	Minimum wage or salary of lowest-paid government worker in the country A copy of STGs for TB
10 retail drug outlets for category I (profit or nonprofit sector or health facility if public sector prices will be used) 10 retail drug outlets for category II (profit or nonprofit sector or health facility if public sector prices will be used)	Pharmacist or dispenser	Price to the public of TB medicine for complete treatment *(not price at which medicines were procured)*

Minimum wage information can be obtained from the officer in charge at the MOH or from national newspapers documenting this information. Use key informants to answer and record the following questions:

- What is the minimum wage in the country? If this information is not available, what is the salary of the lowest-paid government worker?
- What year was the minimum wage last revised? Or what year was the salary of the lowest-paid government worker revised?
- How often is the minimum wage revised?

Ensure and verify that the wage figure provided is documented by asking to see the written document. Get a copy if possible. The information obtained might not be representative for all the sectors. The lowest-paid salary in the private sector might be smaller than the lowest-paid salary in the public sector. Salary variations may also exist in rural and urban areas. Some countries have a different minimum wage bracket for the rural workers as well. Use whichever is applicable to the survey country.

The full treatment course for TB should be obtained from the country's treatment norms or STGs for category I and II TB patients (for both initial and continuation phases). Determine how many tablets or units of each medicine are needed to complete a treatment course for each TB medicine. The STGs for TB provided for the middle weight-band category I and II could be used to obtain the estimate.

Note: Do not use this indicator if the TB program does not have its own set of norms or STGs.

Visit 10 drug outlets for each category and present a prescription containing the medicines required for category I and II treatment. Obtain the prices to the public of all TB medicines on the prescription.

See forms A-6a: Private/Public Sector Price Comparison Form and A-6b: Sample Prescription Form in Annex 3.

Computation and Example

To obtain the daily wage, the monthly minimum wage or the monthly salary of the lowest-paid government worker should be divided by the total number of days that an individual works in a month. For example, if the minimum wage is $40.00 per month and the individual has to work a total of 20 days in a month, the wage per day can be computed thus:

$$\text{Daily wage} = \frac{\text{Monthly wage}}{\text{Total number of work days per month}}$$

$$\text{Daily wage} = \frac{\$40.00}{20 \text{ days}} = \$2.00 \text{ per day}$$

The cost of a complete TB treatment course can be estimated by multiplying the total number of tablets used for the complete duration of treatment by the unit price of the tablets.

The example below illustrates the price comparison for a full treatment course of a category I TB patient. The initial phase medication for the first two months includes rifampicin/isoniazid (combination), ethambutol, and pyrazinamide, while the continuation phase for the next four months includes rifampicin/isoniazid. The unit price of each medication is multiplied by the total number of tablets required to complete the full six-month course to obtain the cost of each medicine. Add the cost of each individual medicine to obtain the total cost of full TB treatment.

For illustration purposes, compute the number of days of work under minimum wage using the treatment regimen and cost listed below for a middle weight-band category I TB patient.

TB Medicines	Initial Phase Treatment (2 months, 56 doses)	Continuation Phase Treatment (4 months, 112 doses)	Total Units Required (A)	Unit Cost in U.S. Dollars (B)	Total Cost in U.S. Dollars (A × B)
Rifampicin 150 mg/ isoniazid 75 mg	3 tablets (3 × 56)	3 tablets (3 × 112)	504 tablets	0.019	9.60
Ethambutol 400 mg	2 tablets (2 × 56)		112 tablets	0.021	2.35
Pyrazinamide 400 mg	3 tablets (3 × 56)		168 tablets	0.015	2.50
TOTAL					$14.45

From the illustration above, the total cost of full treatment for TB (that is, the cost of complete doses of TB medicines used for both the intensive and continuation phases) is $14.45. The number of days a person has to work at minimum wage to pay for a full treatment course is computed as follows:

$$\text{Number of days of work at minimum wage for a full TB treatment} = \frac{\text{Cost of full TB treatment course}}{\text{Minimum wage per day}}$$

Cost of full TB treatment course = $14.45 (calculated above)

Minimum wage per day = $2.00 (calculated above)

$$\text{Number of days of work at minimum wage for a full TB treatment} = \frac{\$14.45}{\$2.00}$$

= 7.2, or almost 8 days of work at minimum wage to pay for a full TB treatment

To compute the average number of days of work at minimum wage for full TB treatment, sum all the total costs found at the 10 drug outlets visited for category I TB infection, and divide by 10. Do the same for the 10 drug outlets visited for category II infection. Divide the average cost obtained by the minimum wage for category I and II, respectively, to obtain the number of work days for each category.

Presentation

In country X, the minimum wage or the lowest-paid salary of a government worker is $40.00 per month. Results show that a category I TB patient will have to work a total of approximately 8 days a month at the minimum wage to pay for a full TB treatment course when medication is obtained from the public sector.

ANNEX 3. DATA COLLECTION FORMS AND INSTRUCTIONS

Data Entry and Analysis

The following information provides instructions for data collectors on how to go about collecting required data to complete the data collection forms. Although not included in the document, MSH's Rational Pharmaceutical Management Plus Program has developed a data analysis spreadsheet for compilation and categorization of collected data. This spreadsheet can be requested by e-mailing rpmplus@msh.org.

General Instructions for Filling Out Data Forms

The following header information should be filled in on each form as applicable:

Facility Name: Write the name of the health center or warehouse in which the data are being collected.

Data Collector Code: Write your identification code. Codes will be assigned during data collector training.

Facility Type: Write the type of facility in which you collect the data, for example, warehouse, district hospital, health center, or health post.

Location: Write the name of the geographic location of the facility, usually the name of a region, province, district, city, or town.

Date: Write the date on which the data are collected. At each facility, the data should be collected in one day, if possible.

Currency Used: Write in the currency used for the price data for TB tracer commodities.

One U.S. Dollar: Write in the exchange rate for a U.S. dollar for the currency used. This information must be obtained from a reputable source (such as local newspaper or ministry of finance) and filled in here before the commencement of data collection.

A-0: General Data Collection Preparation Checklist

Each data collector or data collection team will need all of the following items before starting the actual collection of data. The study coordinator or team manager will likely provide these items. Check each item as you receive it.

Item	Collected? (√ = Yes)
1. List of data collection teams and the sites to be visited	
2. Workplan and timeline by data collection teams	
3. Samples of information source documents (e.g., clinic record or medical chart, stock cards, bin cards)	
4. List of medical terms and symptoms used locally for diagnosing pulmonary TB	
5. List of equivalent medicine names (brand and INN)	
6. Sample of a batch certificate	
7. Contact information for data collectors	
8. Copies of letters of authorization or introduction	
9. Set of data collection forms	
10. Pens and other supplies	
11. Per diem for local expenses	

A-1: Stock-Out Data Form

This form is used for the indicator listed below:

K-1. Average percentage of time out of stock for a set of TB tracer commodities in TB facilities (C/R/F)

Collect data for this indicator on each commodity (medicines and supplies). Use data from each facility's stock record-keeping system, whether computerized or manual. Systems based on ledgers or stock record cards, for example, are manual systems.

Data Summary

Data Collection Sites	Whom to Ask	What to Get
Central medical store	Inventory Officer/Storekeeper	Inventory records of commodities that are normally stocked for tracer list
Regional medical store	Manager	
20 MOH TB health facilities	Dispenser/Pharmacist/ Storekeeper	Number of days these normally stocked commodities were out of stock during the 12 months prior to assessment or during previous year
NGO/Mission clinics and hospitals		

Note: In situations where a commodity is physically on the shelves—that is, has been counted but not recorded in the inventory card—the commodity may be considered as in-stock. Verify this information from the invoice receipt showing when the medicine was received.

Instructions for Filling Out Form A-1

The name of each column on the form is in **bold** below.

Commodity: The study's list of TB commodities should be preprinted in Column 1. Each product should include the INN, dosage form, and strength.

Normal Stock: This column should be marked with a *Y* (for yes) if the commodity is normally stocked at the facility visited or with an *N* (for no) if the commodity is not usually stocked at the facility visited.

Columns for the Months (and Reference Year): Preprinted abbreviations of the months, the number of days in each month, and a space for the last two digits of the year are at the top of each column. The number of days are to facilitate counting how many days in the month the product was out of stock. The months should be adjusted to coincide with the 12 months in which the data are being collected. Fill in the years accordingly.

- For each tracer commodity and each of the 12 months, count the number of days that the product was out of stock and write it in.

- Exclude the first day but include the last day out of stock so as not to double count.
- If the commodity was out of stock for a period longer than one month, count all the days out of stock for the first month, write that number in the space provided, and continue with days out of stock for the second month.
- If a commodity was not out of stock for a particular month, write zero (0). If data or stock records are not available for any particular month, write a dash (—) indicating that the data were not available.

Total Days Out of Stock

In this column, for each product add up the total number of days in the 12-month period that each product was out of stock. In other words, in each row, add up the numbers in the 12 columns and enter the total in the far right column.

Note: All unshaded blanks should be filled in on this data form. Enter *N/A* if data for a particular item are not available.

Instructions for Team Manager's Sections

The team manager for each data collection team will complete the shaded portions of form A-1 as follows:

Row 1: Sum the numbers in the *Total Days Out of Stock* column and place the total to the far right of Row 1.

Row 2: Count the total number of commodities checked *"Y"* in the *Normal Stock* column. Record this number to the far right of Row 2.

Row 3: Calculate the *Average percentage of time out of stock for a set of TB tracer commodities* according to the following formula and record to the far right of Row 3:

$$\text{Average \% time out of stock} = \frac{\text{Number in Row 1} \times 100}{365 \times \text{number in Row 2}}$$

Use form A-1 to collect information on stock availability in public health centers and hospitals, NGO/Mission clinics and hospitals, and medical stores.

Sample A-1: Stock-Out Data Form

Facility Name:	**Data Collector Code:**	
Facility Type:	**Location:**	**Date:**

For each product, write the number of days out of stock for each month.

Commodity	Normal Stock?	Jan 31 *03*	Feb 28 *03*	Mar 31 *03*	Apr 30 *03*	May 31 *03*	Jun 30 *03*	Jul 31 *03*	Aug 31 *03*	Sep 30 *03*	Oct 31 *03*	Nov 30 *03*	Dec 31 *03*	Total Days Out of Stock
1. Rifampicin 150 mg/isoniazid 75 mg tablet (RH)	Y	0	0	1	0	0	5	0	3	2	0	0	0	11
2. Rifampicin 150 mg/isoniazid 75 mg/ pyrazinamide 400 mg/ ethambutol 275 mg tablet (RHZE)	N	0	0	0	0	0	0	0	0	0	0	0	0	0
3. Ethambutol 400 mg tablet (E)	Y	—	—	—	5	0	0	3	5	10	0	0	0	23
4. Streptomycin 1 g vial (S)	N													
5. Water for injection	Y													
6. Syringe/needle	Y													
Row 1: Sum total days out of stock for all stocked commodities														
Row 2: Count total number of products checked "Y" in the Normal Stock column														
Row 3: Average percentage time out of stock = (Number in Row 1 × 100) ÷ (365 × number in Row 2)														

Use Form A-1 with indicator K-1. Data collectors should not fill in the shaded rows.

A-2: Inventory Data Form

This form is used for the indicators listed below:

K-2. Average percentage of a set of tracer TB commodities available in TB facilities and medical stores

C-7. Average percentage of stock records that correspond with physical counts for a set of TB tracer commodities in TB storage facilities

For indicators K-2 and C-7, data are collected during a physical inspection of the TB commodities (medicines and supplies). Other data are collected from any or all of the computerized stock record-keeping systems, manual stock ledgers, or stock record cards and bin cards.

Data Summary

Data Collection Sites	Whom to Ask	What to Get
Central medical store	Inventory Officer/Storekeeper	Inventory records and stock count of TB commodities
Regional medical store	Manager/Storekeeper	
20 MOH TB facilities	Dispenser/Pharmacist/Storekeeper	
NGO/Mission clinics and hospitals		

Instructions for Filling Out Form A-2

Existing inventory control systems: Check all the inventory control systems that exist in each facility that you survey.

Data collected from: For each facility, check the types of inventory control system that you used to collect the data.

The name of each column on the form is in **bold** below.

1. **Commodity:** The study's list of TB commodities should be preprinted in Column 1. For each product, include the INN and strength.

2. **Counting Unit:** In Column 2, indicate the smallest unit by which the product is counted, for example, tablets or milliliters (mL).

3. **Normal Stock:** This column should be checked with a *Y* (for yes) if the product is normally stocked at the facility visited or with an *N* (for no) if product is not usually stocked at the facility visited.

4. **Record Count:** In Column 4, write the record system's count of the units in stock. Example, if the record system used at the facility is the stock card records, record the total count from the stock cards at time of visit. If inventory data are not available, write a dash (—).

5. **Unrecorded Receipts:** Recording of recent receipts is not always up to date. After the record count of each product has been entered, ask the staff to add up the unrecorded receipts. Enter the results in Column 5. If inventory data are not available or a record is not used, write a dash (—).

6. **Unrecorded Issues:** It is often the case that recent issues of stock have not been recorded. For each commodity, add unrecorded issues of stock after the record-keeping tally has been entered. Enter the results in Column 6. If inventory data are not available or a record is not used, write a dash (—).

7. **Adjusted Total:** Column 7 equals the system's record count plus recent receipts minus recent issues of stock. For each product, make the following calculation, and enter the results in Column 7:

   Adjusted Total = Record Count + Unrecorded Receipts – Unrecorded Issues

   (Column 7) = (Column 4) + (Column 5) – (Column 6)

8. **Physical Count:** For each product, take a physical count of the number of units actually present in the facility. Write the results in Column 8.

9. **Expired Stock:** Check the expiration date of each product in stock that has an expiration date. In Column 9, write the number of units that have expired as of the day of the data collection. Write 0 in this column if there are no expired commodities. Write *N/A* (not available) if the product does not have an expiration date.

Note: All unshaded blanks should be filled in on this data form. Enter *N/A* if data for a particular item are not available.

Instructions for Team Manager's Sections

The team manager for each data collection team will complete the shaded portions of form A-2 as follows:

Column 10: For each medicine, calculate the *Percentage Expired* by dividing the amount of *Expired Stock* recorded in Column 9 by the *Physical Count* quantity recorded in Column 8 and multiplying the result by 100.

Example on form: $\frac{15}{755} \times 100 = 1.98\%$

Row 1: Examine the numbers recorded in Columns 7 and 8. Count the number of commodities for which the number in Column 7 exactly equals the number in Column 8. Write the total number to the far right of Row 1.

Row 2: Examine the numbers recorded in Column 8 and 9. Count the number of commodities for which the number in Column 8 is greater than the number in Column 9. Write the total to the far right of Row 2.

Row 3: Count the total number of commodities checked *"Y"* in the *Normal Stock* column. Record this number to the far right of Row 3.

Row 4: Calculate the *Percentage of Records Corresponding with Physical Counts* by taking the number recorded in Row 1, multiplying it by 100, and dividing the result by the number in Row 3. Record the percentage to the far right of Row 4.

Row 5: To calculate the percentage of TB tracer commodities available, divide the number in Row 2 by the number in Row 3. Multiple the result by 100 to convert it to a percentage. Record the final percentage obtained to the far right in Row 5.

Row 6: To get an average of the percentage of expired commodities for the facility, sum the numbers in Column 10 and divide the result by the number in Row 3. Record the average percentage calculated in the far right of Row 6.

Sample A-2: Inventory Data Form

Facility Name:	**Data Collector Code:**	
Facility Type:	**Location:**	**Date:**

Existing inventory control systems: Computer system
Manual ledger

Data collected from: Computer system
Manual ledger
Stock record cards
Tally sheets

Commodity	Counting Unit	Normal Stock?	Record Count	Unrecorded Receipts	Unrecorded Issues	Adjusted Total	Physical Count	Expired Stock	Percentage Expired
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**	**Col. 6**	**Col. 7**	**Col. 8**	**Col. 9**	**Col. 10**
1. Rifampicin 150 mg/isoniazid 75 mg tablet (RH)	Tablets	Y	*783*	*100*	*34*	*849*	*755*	*15*	*1.98*
2. Rifampicin 150 mg/isoniazid 75 mg/ pyrazinamide 400 mg/ ethambutol 275 mg tablet (RHZE)	Tablets	N	0	0	0	0	0	0	0
3. Ethambutol 400 mg tablet (E)	Tablets	Y							
4. Streptomycin 1 g vial (S)	Vial	N							
5. Water for injection	Vial	Y							
6. Syringe/needle	Syringe/ needle	Y							
Row 1: Total number of commodities for which Col. 7 equals Col. 8									
Row 2: Total number of commodities for which Col. 8 is greater than Col. 9									
Row 3: Total number of commodities checked "Y" in the Normal Stock column									
Row 4: Percentage of records corresponding with physical counts (Number in Row 1 × 100 ÷ number in Row 3)									
Row 5: Percentage of TB commodities available (Number in Row 2 × 100 ÷ number in Row 3)									
Row 6: Average percentage of expired commodities (Sum of Col. 10 ÷ number in Row 3)									

Use Form A-2 with indicators K-2 and C-7. Data collectors should not fill in shaded rows or columns.

A-3a and A-3b: Medical Records Review Form

This form is used for the indicators listed below:

K-3. Percentage of new smear-positive patients with pulmonary TB who were prescribed correct medicines in conformity with the standard treatment guidelines used in the country

C-4. Percentage of TB facilities visited where the most recent official manual of treatment guidelines for TB was present

Indicator K-3 is presented by **two** separate percentages, one to identify compliance with correct medicine prescribing according to the STGs for the **intensive phase** of treatment, and the other for the **continuation phase** of treatment. It may require collecting data at different settings, depending on where each phase of treatment takes place (for example, intensive phase at a central TB hospital and continuation phase at local PHC unit).

Data Summary

Data Collection Sites	Whom to Ask	What to Get
20 MOH TB health facilities and/or NGO/Mission clinics and hospitals where initial prescribing for **intensive phase** of treatment is done	Medical Records Officer/ Health Facility Manager/ Pharmacist	Identify a sample of 15 new cases of smear-positive pulmonary tuberculosis per TB facility and determine the number of correct medicines prescribed for **intensive phase** of treatment. Identify encounters by consulting daily registers, patient records, prescription slips, or through observation.
20 MOH TB health facilities and/or NGO/Mission clinics and hospitals where initial prescribing for **continuation phase** of treatment is done	Medical Records Officer/ Health Facility Manager/ Nurse Pharmacist	Identify a sample of 15 new cases of smear-positive pulmonary tuberculosis per TB facility and determine the number of correct medicines prescribed for **continuation phase** of treatment. Identify encounters by consulting daily registers, patient records, prescription slips, or through observation.

Instructions for Filling Out Form A-3a

Data collected from: Check the appropriate box to designate whether the data were collected from medical records or a patient registry.

Is an official manual of treatment guidelines available? Check the appropriate box to designate whether an official treatment manual is available. If a manual is available, request to see it and record the year it was written.

INN (international nonproprietary name) abbreviation: TB medicines may be prescribed and found in patient records by brand names. The task of the data collector is to identify INN (generic) equivalents for those medicines. For this form, the INN name for isoniazid is abbreviated as "H."

The name of each column on the form is in **bold** below.

1. **Patient Number:** Write the patient's identification number. If no identification exists, simply number the encounter (patient) records studied as 1, 2, 3, and so on.

2. **Date:** Write the date that the prescriber saw the patient using only the month and year, with the month first. For example, all the following dates would be written as 10/02: 28-10-02, 02-10-28, 28/10/02, 28 Oct 02.

3. **R:** This is the abbreviation for rifampicin. Write the medicine strength in milligrams (mg) under Column 3 (representing rifampicin). If the medication used is a fixed-dose combination, write a plus (+) sign in front of the second, third, or fourth combination medicine, as the case may be, to indicate that it is an FDC medicine. See examples in the sample form.

   If the medicine name and strength are not written in the medical record, the patient's medical record should not be included in the data sample. Replace with another patient's record that has all the required information. When one or more of the medicines listed in the columns are not prescribed for the patient, use a dash (—) to represent that the medicine is not prescribed, as shown in the sample form.

4. **H:** Abbreviation for isoniazid tablet. See instructions for Column 3.
5. **E:** Abbreviation for ethambutol. See instructions for Column 3.
6. **Z:** Abbreviation for pyrazinamide. See instructions for Column 3.
7. **S:** Abbreviation for streptomycin. See instructions for Column 3.
8. **Other drugs used:** Leave blank.

Note: All unshaded blanks should be filled in on this data form.

Instructions for Team Manager's Sections

The team manager for each data collection team will complete the shaded portions of forms A-3a and A-3b as follows:

Correct Drug? Yes/No: Data manager should compare the medicine name and medicine strength on the form with those stated in the country's standard treatment regimen for the level of care facility where data are obtained.

Correct Drug (A): Compare the medicine name obtained from the patient's medical records to the country's standard treatment norms to determine if the medicine name prescribed corresponds to that recommended in the country's treatment norms for the specified level of care facility. Write *Yes* if correct and *No* if incorrect.

Correct Strength (B): If the medicine (A) is correct, then compare the patient's prescribed dosage strength with that recommended in the country's standard treatment norms. Write a *Yes* if correct and *No* if incorrect.

Summary: Count as a *Yes* if columns (A) and (B) are both correct and *No* if either one or both is a *No*. Write one (1) when both columns are *Yes* and zero (0) when one or both columns is a *No*.

Row 1: Total number of correct prescriptions: Sum the numbers from the *Summary* column and write the total in the space provided at the far right of the row.

Row 2: Total number of patient records reviewed: Count the total number of patient records reviewed from Column 1 (patient number). Remember not to include any prescriptions that were not used because they did not meet study criteria.

Note: Complete form A-3b using the same instructions as for form A-3a.

Sample A-3a: Medical Records Review Form (Intensive Phase of Treatment)

Facility Name:	**Data Collector Code:**	
Facility Type:	**Location:**	**Date:**

Data collected from: ☐ Medical records ☐ Patient registry

Is an official manual of treatment guidelines available? Yes___ No___

If yes, from what year?

Patient Number	**Date**	**R**	**H**	**E**	**Z**	**S**	**Other Drugs Used**	**Correct Drug? Yes/No**		
								Col. 9		
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**	**Col. 6**	**Col. 7**	**Col. 8 (Leave Blank)**	**Correct Drug (A)**	**Correct Strength (B)**	**Summary**
1	5/03	150 mg	+ 75 mg	400 mg	400 mg	—	—			
2	5/03	150 mg	+ 75 mg	+ 275 mg	+ 400 mg	—	—			
3	6/03	150 mg tablet	+ 150 mg	—	+ 500 mg	—	—			
Row 1: Total number of correct prescriptions										
Row 2: Total number of patient records reviewed										

Use Form A-3a with indicators K-3 and C-4. Data collectors should not fill in shaded columns.

Sample A-3b: Medical Records Review Form (Continuation Phase of Treatment)

Facility Name:	**Data Collector Code:**	
Facility Type:	**Location:**	**Date:**

Data collected from: ☐ Medical records ☐ Patient registry

Is an official manual of treatment guidelines available? Yes___ No___

If yes, from what year?

Patient Number	**Date**	**R**	**H**	**E**	**Z**	**S**	**Other Drugs Used**	**Correct Drug? Yes/No**		
								Col. 9		
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**	**Col. 6**	**Col. 7**	**Col. 8 (Leave Blank)**	**Correct Drug (A)**	**Correct Strength (B)**	**Summary**
1	5/03	150 mg	+ 75 mg	—	—	—	—			
2	5/03	—	150 mg	+ 400 mg	—	—	—			
3	6/03	150 mg tablet	+ 150 mg	—	—	—	—			
Row 1: Total number of correct prescriptions										
Row 2: Total number of patient records reviewed										

Use Form 3-b with indicators K-3 and C-4. Data collectors should not fill in shaded columns.

A-4: International Price Comparison Form

This form is used for the indicator listed below:

K-5. Percentage of median international price paid for a set of TB commodities that was part of the last regular procurement

Note: For those countries that have a decentralized system of pharmaceutical procurement, this form can be adapted to collect price data at the MOH health facility level. During the data collector training, the instructor will provide specific instructions for the use of this form at the health facility level.

Data for indicator K-5 are collected at the MOH office that is responsible for purchasing medicines. The last regular procurement price should include the cost, insurance, and freight. For the set of TB medicines, the CIF prices for the most recent regular procurement are written in and compared with international prices.

Data Summary

Data Collection Sites	Whom to Ask	What to Get
MOH Procurement Unit	Officer in charge of pharmaceutical purchases	List of most recent prices paid for a set of TB tracer commodities Tender documents, supplier invoices
Central medical store	Manager/Reception Officer	
Regional government administration or medical store	Manager	
MOH health facilities	Pharmacist/Procurement Officer	

Instructions for Filling Out Form A-4

Year of Last Regular Procurement: Write the year of the survey country's last regular procurement of the TB tracer commodities for which you are obtaining prices.

District Level: Circle if information is obtained from the district or regional medical store.

Central Level: Circle if information is obtained from the central medical store.

Facility Level: Circle if information is obtained from the health facility medical store.

The name of each column in the form is in **bold** below.

1. **Commodity:** The study's list of TB commodities should be preprinted in Column 1. For each TB medicine, include the INN, dosage form, and strength.

2. **Other Names (Brand or INN):** For each TB medicine, write the brand name or INN of the medicine purchased by the MOH medical store, warehouse, or health facility.

3. **Comparison Unit:** For each TB commodity, write the comparison unit being used (e.g., tablet, milliliter, vial).

4. **Number of Units per Pack:** For each TB commodity, write the number of comparison units per pack (e.g., 1,000 tablets per pack or 5 vials per pack).

5. **MOH Comparison Pack Price:** For each TB commodity, write the MOH CIF pack price.

Instructions for Team Manager's Sections

6. **MOH Comparison Unit Price:** For each commodity, write the MOH CIF unit price for the most recent regular procurement, which is calculated by dividing the MOH pack price by the number of units per pack. The unit price is the price, for example, per tablet, milliliter, or ampule. You must enter the price to four decimal places because the units involved are so small.

Note: All unshaded blanks should be filled in on this data form. Enter *N/A* if data for a particular item are not available.

Sample A-4: International Price Comparison Form

Facility Name:	Data Collector Code:	Facility Type:	Year of Last Regular Procurement:
Location:	Date:	Currency Used:	One U.S. Dollar =

District Level **Central Level** **Facility Level**

Commodity	Other Names (Brand or INN)	Comparison Unit	Number of Units per Pack	MOH Comparison Pack Price	MOH Comparison Unit Price
Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6
1. Rifampicin 150 mg/isoniazid 75 mg (RH) tablet		Tablet			
2. Rifampicin 300 mg/ isoniazid 150 mg (RH) tablet		Tablet			
3. Rifampicin 150 mg/isoniazid 75 mg/ pyrazinamide 400 mg/ ethambutol 275 mg (RHZE) tablet		Tablet			
4. Ethambutol 400 mg (E) tablet		Vial			
5. Streptomycin 1 g (S) injection		Vial			
6. Water for injection		Syringe/needle			
7. Syringe/needle		Tablet			

Use Form A-4 with indicator K-5. Data collectors should not fill in the shaded columns.

A-5: Exit Poll Interview Form

This form is used for the indicators listed below:

C-5. Percentage of TB outpatients who could correctly describe how the prescribed medication should be used

C-6. Percentage of TB patients who reported regular observation by a health care worker during medicine intake

Data Summary

Data Collection Sites	Whom to Ask	What to Get
20 MOH health facilities	Health facility supervisor for permission to conduct exit poll interviews with outpatients	Identify a convenience sample (i.e., patients in the clinic during the day of data collection) of 10 smear-positive patients. Use same sample as for both C-5.

General Instructions for Filling Out Data Form A-5

Interview Number: To keep track of the TB patients interviewed, use a number for each exit poll interview. DO NOT USE THE NAME OF THE PERSON BEING INTERVIEWED. Write the number of the interview (e.g., 1, 2, 3) per survey site. In each health center, start the numbering at 1.

Instructions for Filling Out Form A-5

After the TB patient visits the TB facility with a pharmacy or dispensing unit, ask the TB patient the following questions. If the clinic does not have a pharmacy or dispensing unit, approach the TB patient immediately before or after the TB patient leaves the clinic (depending on the layout of the clinic). Use a new copy of form A-5 for each interview.

Ask the patient the following eight questions. Write *Yes* if patient knows the answers:

1. How long have you been taking your medicines?

2. Does anybody on the medical staff or a caregiver look at you when you take your medicine?

3. How many different kinds of medicines are you taking? (Indicate name, color, or other marker of a medicine.)

4. How many tablets of each medicine are you taking?

5. How many days in a week or in a month do you come to take or collect your medicines?

6. When you started your TB treatment, how long did the doctor/caregiver tell you that you have to take your medicine before you complete treatment?

7. Did your doctor/caregiver tell you to return to the clinic or health center if any sign of side effects such as fever, ringing in the ears, blurred vision, or vomiting occur?

8. What will happen if you do not take your medicines as prescribed?

Fill out the table with the answers the patient provides. The patient must know answers to each of the eight questions for the data collector to write *Yes* in the indicator box.

Fill in the rows in form A-5 as described below:

1. **How long have you been taking your medicines?** The patient should know how long he or she has been taking medicines for TB treatment. This is used to determine if the patient is in the intensive or continuation phase of treatment. Write how long the patient has been taking his or her medicines in the space provided. If the patient does not know, mark *No.*

2. **Does anybody on the medical staff or a caregiver look at you when you take your medicine?** The patient should know if he or she is observed when taking TB medicines. If the patient does not know, mark *No;* otherwise, mark *Yes*.

3. **How many different kinds of medicines are you taking? (Indicate name, color, or other marker of a medicine.)** Write the name of each prescribed medicine as mentioned by the TB patient—for example, rifampicin (INN) or Rofact (commercial/brand name)—or use any other marker provided by the patient (e.g., "two white tablets, and one red"). The data collector should *not* read the prescription; however, the TB patient may read the prescription to provide this information. Write the patient's answer in the column called *Medicines.* If the TB patient knows all of the medicines he or she is taking, mark *Yes;* otherwise, mark *No*.

Note: For question 3, the patient may not know the exact medicine names, but there should be at least one marker by which a patient knows how to distinguish the medicines. Any such marker may be acceptable if it serves the purpose. The marker to be used should be decided upon by the survey team before any patient interviews take place.

4. **How many tablets of each medicine are you taking?** This refers to the dose of the medicine. Write the TB patient's version of the quantity or unit amount of each medicine mentioned in question 3 in the space provided in Row 4. Write exactly what is stated by the TB patient (e.g., one tablet, two capsules, one vial). If the TB patient does not know the dose of all of the medicines he or she is taking, mark *No*.

5. **How many days in a week or in a month do you come to take or collect your medicines?** For each medicine mentioned by the patient in question 3, write exactly what the patient recalls about how often he or she comes to the health center to take or collect his or her medicine. The frequency can be expressed as once a day, three times a week, and so on. If the TB patient does not know for all medicines, mark *No*.

6. **When you started your TB treatment, how long did the doctor/caregiver tell you that you have to take your medicine before you complete treatment?** For each medicine mentioned by the TB patient in question 3, write what the patient recalls as the number of days, weeks, or months that his or her doctor/caregiver said that the medicine should be taken before treatment can be completed. The duration could be expressed in days or in months. If the TB patient does not know for all medicines, mark *No*.

7. **Did your doctor/caregiver tell you to return to the clinic or health center if any sign of side effects such as fever, ringing in the ears, blurred vision, or vomiting occur?** The doctor/caregiver should counsel the patient on adverse reactions or side effects that might occur while taking TB medications. This should be part of patient education. If the patient has no knowledge of this, mark *No*.

8. **What will happen if you do not take your medicines as prescribed?** The patient should understand that if medicines are taken as prescribed, the treatment is likely to succeed. If medicines are not taken as prescribed, the treatment will fail. This information is provided to the patients during TB patient education in some countries. If the patient mentions words or phrases like d*eath, get sicker, increased cost, resistance,* and so on, mark *Yes;* otherwise, mark *No*.

Instructions for Team Manager's Sections

Instructions for Data Analysis

For indicator C-6, use questions 1 and 2 to analyze the data, which will depend on the country's TB treatment regimen. For example, perhaps the intensive phase is observed by a caregiver for the duration of two months and the continuation phase is not observed. If for question 1 (How long have you been taking your medicines?) the patient has been taking his or her medicine for less than 2 months or 8 weeks, then question 2 (Does anyone on the medical staff or a caregiver look at you while you take your medicine?) must be answered *Yes* before the patient can be counted because the patient must be in the intensive phase. Obtain the total number of counted patients (that is, those who have been receiving TB treatment for less than 8 weeks and are always observed by a caregiver while taking their medicine). Divide it by the total number of patients who have received treatment for less than 8 weeks and multiply the result by 100 to obtain a percentage.

For indicator C-5, use indicators 1, 3, 4, 5, and 6 for analysis. Team managers should know the local names and colors of all TB medicines used in the country. They should also be familiar with the treatment regimen and how often patients come to health facilities to collect medicines.

For question 3 (How many different kinds of medicines are you taking?), cross-check the tablet name or color with the length of treatment (question 1). If the medicines correspond to the treatment phase, count as *Yes*.

For question 4 (How many tablets of each medicine are you taking?), if the patient provided any information, count as *Yes*.

For question 5 (How many days in a week or month do you come to take or collect your medicines?), cross-check the patient's response with question 1 (length of treatment or treatment phase) and the country's NTP policy on how patients should receive their medicine. If the information corresponds, count as *Yes*.

For question 6 (When you started your TB treatment, how long did the doctor/caregiver tell you that you have to take your medicine before you complete treatment?), if the information provided by the patient corresponds with the NTP guidelines for treatment, count as *Yes*.

On each data form, identify all forms that have *Yes* responses for questions 3, 4, 5, and 6 and count each form as one *Yes*. If even one of these questions is a *No,* count the sum of these questions as *No*. Sum all the *Yes* responses and divide by the total number of patients or forms examined, that is, all *Yes* and *No* responses. Multiply the result by 100 to obtain a percentage for indicator C-5.

You may also want to determine the percentage of patients that have *some knowledge* about how prescribed medicines should be used. In this case, if a patient responded *Yes* to any of questions 3, 4, 5 and 6, count the form as *Yes*. If all questions are *No,* count the form as *No*. Sum all *Yes* responses and divide by the total number of patients interviewed (*Yes* and *No* responses). Multiply by 100 to obtain a percentage.

Questions 7 and 8 can be analyzed and reported separately to determine the status of patient education.

Data analysis for indicator C-5 can be stratified and reported separately for the intensive and continuation phases of treatment.

Sample A-5: Exit Poll Interview Form

Facility Name:		**Data Collector Code:**	
Facility Type:	**Location:**	**Interview Number:**	**Date:**

#	Ask the Patient the Following Questions		YES	NO
1	How long have you been taking your medicines?			
2	Does anybody on the medical staff or a caregiver look at you when you take your medicine?			
3	How many different kinds of medicines are you taking? (Indicate name, color, or other marker of a pharmaceutical product.)	Medicines	YES	NO
4	How many tablets of each medicine are you taking?			
5	How many days in a week or in a month do you come to take or collect your medicines?	___ Daily ___ Once a month ___ Other (specify)		
6	When you started your TB treatment, how long did the doctor/caregiver tell you that you have to take your medicine before you complete treatment?			
7	Did your doctor/caregiver tell you to return to the clinic or health center if any sign of side effects such as fever, ringing in the ears, blurred vision, or vomiting occur?			
8	What will happen if you do not take your medicines as prescribed?			

Use form A-5 with indicators C-5 and C-6.

A-6: Private/Public Sector Price Comparison Form

This form is used for the indicator listed below:

C-8. Number of days that a person has to work at minimum wage to pay for a complete TB treatment course, taking into account the price of medicines in the public or private market

Data for indicator C-8 are collected at drug outlets or pharmacies in the private or public sector. Remember, data for this indicator are only collected in the public sector if TB medicines are not free to patients.

Data Summary

Data Collection Sites	Whom to Ask	What to Get
10 drug outlets for category I	Pharmacist or dispenser	Obtain the out-of-pocket price paid by the patient to the drug outlet for a complete treatment course of 6–8 months using a list of medicines from the country's STGs for TB.
10 drug outlets for category II		

For this study, category I and category II TB treatment categories are considered for indicator C-8 because category I and II are the most common TB categories present in most countries.

Data are collected using a price inquiry technique. As the data collector, you should enter a drug outlet and present the prescription to the dispenser or pharmacist, telling him or her that you were sent (e.g., by your boss or a relative) to obtain the cheapest prices for the exact commodities (medicines and supplies) listed on the prescription for the stated duration (e.g., one week). Inform him or her that the individual that sent you to inquire about the prices will come and purchase the items later. Review the prescription before leaving the pharmacy and ask questions if required to determine the accuracy of information given (e.g., ask for the price of each medicine per tablet; ask if this is the best price). Express thanks to the dispenser and leave the store. Follow the instructions below to fill out the data form.

Instructions for Filling Out Form A-6

Facility Number: To keep track of the drug outlets visited, assign a number to each one. In this column, write the number you have assigned for each site from which prices for TB treatment were collected.

Private: Circle if information is obtained from a private retail drug outlet.

Public: Circle if information is obtained from a public drug outlet.

The name of each column in the form is in **bold** below.

1. **Commodities:** The list of TB commodities from the country's STGs used for treatment of category I and II TB infections should be preprinted in Column 1. For each TB medicine, include the INN, strength, and dosage form.

2. **Total Units Required:** For each TB commodity, write the total number of units of each medicine required for complete TB treatment from the country's STGs in Column 2.

   If your computation is based on a daily regimen, multiply the quantities of tablets or injections for initial phase of treatment by 56 doses (that is, 28 doses per month) and the quantities for the continuation phase by 112 doses for category I patients. For category II patients, multiple by 84 doses (three months) for initial phase and 140 doses (five months) for continuation phase. Add these totals to obtain the total units required for each medicine.

   However, if computation is based on a regimen of three times per week, multiply the quantity of tablets and/or injections for the initial phase of treatment by 24 doses (that is, 12 doses per month) and the quantity of tablets for the continuation phase of treatment by 48 doses for category I patients. Multiple by 36 and 60 doses, respectively, for initial and continuation phases for category II patients. Add the results to obtain the total units required for complete TB treatment. This information should be preprinted on the form before data collection.

3. **Unit Price:** Visit a drug outlet and present a prescription adapted to the country situation to the pharmacist or shop attendant to obtain the prices of medicines listed on the prescription for complete treatment (see sample form A-6b; or you may want to write the same information on a blank piece of paper). Allow the pharmacist/shop attendant to fill out the prices for the listed quantities on the prescription. Calculate the unit price and write it in the space provided on form A-6.

Instructions for Team Manager's Sections

4. **Cost of Treatment in Local Currency:** Multiply the total units required in Column 2 by the unit price in Column 3.

5. **Cost of Treatment in Dollars:** For each product, convert the local cost to U.S. dollars by dividing the cost of treatment in local currency (Column 4) by the present exchange rate. Record the number to four decimal places.

Row 1. Total cost of treatment in dollars: For each TB medicine, add the numbers in Column 5 to obtain the total cost of treatment in dollars. Write the number obtained in the space provided to four decimal places.

Note: All unshaded blanks should be filled in on this data form. Enter *N/A* if data for a particular item are not available.

Sample A-6a: Private/Public Sector Price Comparison Form

Facility Number:	**Data Collector Code:**	**Facility Type:**	
Location:	**Date:**	**Currency Used:**	**One U.S. Dollar =**

Private **Public**

Commodities	Total Units Required (A)	Unit Price	Cost of Treatment in Local Currency	Cost of Treatment in U.S. Dollars (B)
Col. 1	**Col. 2**	**Col. 3**	**Col. 4**	**Col. 5**
Category I				
1. Rifampicin 150 mg (R)/isoniazid 75 mg (H) tablets	504			
2. Ethambutol 400 mg (E) tablets	112			
3. Pyrazinamide 400 mg (Z) tablets	168			
Row 1: Total cost of treatment in dollars				
Category II				
1. Rifampicin 150 mg/isoniazid 75 mg/pyrazinamide 400 mg/ethambutol 275 mg (RHZE) tablets	252			
2. Streptomycin 1 g (S) vials	56			
3. Water for injection vials	56			
4. Rifampicin 150 mg (R)/isoniazid 75 mg (H) tablets	420			
5. Ethambutol 400 mg (E) tablets	280			
Row 1: Total cost of treatment in dollars				

Use Form A-6 with indicator C-8.

Sample A-6b: Prescription Form

REGAN HOSPITAL
Private Bag x8, Wynberg,
Plumstead 7800, Pretoria
Tel: 0028 21 976

PRESCRIPTION

Patient's name: _____(Print name)

Date: _____

Prescription:

Rifampicin (R) 150 mg/isoniazid (H) 75 mg tabs. Three tablets daily by mouth for one week.
Qty. 21 _____

Ethambutol (E) 400 mg tabs. Two tablets daily by mouth for one week.
Qty. 14 _____

Pyrazinamide (Z) 400 mg tabs. Three tablets daily for one week.
Qty. 21 _____

Streptomycin (S) 1 g injection. One vial of injection daily for one week.
Qty. 7 _____

Water for injection. One with each vial of streptomycin daily for one week.
Qty. 7 _____

Doctor's name: _____

Doctor's signature: _____

Use form A-6b with indicator C-8.

A-7: Minimum Quality Standards Form

This form is used for the indicator listed below:

K-4. Percentage of TB medicines received in the past three shipments that were accompanied with a batch certificate (C)

Data for indicator K-4 can be collected by reviewing medicine records from the central medical stores, the MOH Procurement Office, and procurement agents of the NTP or other appropriate departments of the health system.

Data Collection

Data Collection Sites	Whom to Ask	What to Get
Central medical stores/ MOH Procurement Office/ drug regulatory authority/NTP	Officer in charge of pharmaceutical procurement	Find out if batch certificate is a mandatory component in tender documents. Request to see individual batch certificates for TB medicines received during the past three shipments.

Instructions for Filling Out Form A-7

The name of each column in the form is in **bold** below.

Col. 1 **Medicine Name and Strength:** Write the generic medicine name (INN) and medicine strength of all TB medicines received during the past three shipments in Column 1.

Col. 2 **Normal Stock:** This column should be marked with a *Y* (for yes) if the product is normally stocked at the facility visited or *N* (for no) if the product is not usually stocked at the facility visited.

Col. 3 **Number of batches from the past three shipments:** For each TB medicine, write the number of batches from the first, second, and third shipments in the space provided. If a medicine was not received during this period, write zero (0).

Col. 4 **Number of batches accompanied with individual batch certificates:** For each TB medicine, determine how many batches were accompanied with individual batch certificates. Write the number obtained for each medicine in the space provided for the first, second, and third shipments.

Instructions for Team Manager's Sections

Total (A) & Total (B): For each medicine, add the numbers in the first, second, and third shipments and write the totals in the *Total (A)* or *Total (B)* columns.

Col. 5. **Percentage:** For each medicine, divide the number in Column 4, *Total (B)*, by the number in Column 3, *Total (A)*, and multiply the result by 100 to obtain the percentage of batches that were accompanied with batch certificates. Record percentages in the spaces provided.

Row 1: Count the total number of medicines marked *"Y"* in the *Normal Stock* column. Record this number to the far right of Row 1.

Row 2: **Total Percentage:** Add the percentages in Column 5 and record the total in the space provided.

Row 3: **Average percentage of medicines with individual batch certificates:** Divide the number in Row 2 by the number Row 1. Record the result in the space provided.

Sample A-7: Minimum Quality Standards Form

Facility Name:	**Data Collector Code:**	
Facility Type:	**Location:**	**Date:**

Medicine Name and Strength	**Normal Stock?**	**Number of Batches from the Past Three Shipments**				**Number of Batches Accompanied with Individual Batch Certificates**				**Percentage**
		Col. 3				**Col. 4**				
Col. 1	**Col. 2**	**First Shipment**	**Second Shipment**	**Third Shipment**	**Total (A)**	**First Shipment**	**Second Shipment**	**Third Shipment**	**Total (B)**	**Col. 5**
1. Isoniazid 100 mg										
2. Isoniazid 300 mg										
3. Ethambutol 400 mg										
4. Pyrazinamide 400 mg										
5. Rifampicin 150 mg / isoniazid 75 mg										
6. Rifampicin 150 mg / isoniazid 150 mg										
7. Ethambutol 400 mg/ isoniazid 150 mg										
8. Rifampicin 150 mg/ isoniazid 75 mg/ pyrazinamide 400 mg										
9. Rifampicin 150 mg/ isoniazid 75 mg/ pyrazinamide 400 mg/ ethambutol 275 mg										
10. Streptomycin 1 g										
11. Water for injection 5 mL										
12. Other										
Row 1: Total number of commodities marked "Y" in the Normal Stock column										
Row 2: Sum of percentages in Col. 5										
Row 3: Average percentage of products with individual batch certificates (Row 2 ÷ Row 1)										

Use Form A-7 with indicator K-4. Data collectors should not fill in the shaded areas.

ANNEX 4. SAMPLE FORMAT FOR PRESENTING PMTB INDICATOR DATA

Key Indicators

Indicator Name	Computation	Rationale	Results (example only)
K-1. Average percentage of time out of stock for a set of TB tracer commodities in TB facilities	(a) Each medicine: Record the number of days out of stock for past 12 months (b) All commodities: Sum total numbers of days out of stock for past 12 months (c) $\frac{\text{Total number of stock-out days for all TB commodities}}{365 \times \text{Total number of TB commodities normally stocked}} \times 100$ All commodities presented for each level: MOH storage, district TB facilities, peripheral TB facilities, and retail outlets	The successful implementation of the TB strategy is dependent on the medicines being available.	20.0%
K-2. Average percentage of a set of tracer TB commodities available in TB facilities and medical stores	(a) Each facility: $\frac{\text{Number of unexpired TB tracer commodities in stock}}{\text{Total number of commodities normally stocked}} \times 100$ (b) All facilities: $\frac{\text{Sum of \% for each facility}}{\text{Total number of facilities in sample}}$	The successful implementation of the TB strategy is dependent on the continuous availability of unexpired medicines and supplies at all levels of care.	48.0%
K-3. Percentage of new smear-positive patients with pulmonary TB who were prescribed correct medicines in conformity with the standard treatment guidelines used in the country	$\frac{\text{Total number of TB patients prescribed appropriate TB medicines}}{\text{Total number of TB patients}} \times 100$	To identify whether practitioners are complying with treatment guidelines	MOH: 38.0% (n = 413)

Indicator Name	Computation	Rationale	Results (example only)
K-4 Percentage of TB medicines received in the past three shipments that were accompanied with a batch certificate	(a) Individual medicine: # of Batches of TB medicines with batch certificates from the past three shipments × 100 Total number of batches of TB medicines in the past three shipments (b) All medicines: Total sum of percentages with batch certificates Total number of tracer commodities employed	To determine if this minimum quality requirement (batch certificate) is requested by countries from TB pharmaceutical suppliers	40.0%
K-5. Percentage of median international price paid for a set of TB commodities that was part of the last regular procurement	(a) Individual medicine: Comparison unit price × 100 Median international unit price	To determine potential savings to the MOH that could be achieved with improved procurement practices	174.0%

Complementary Indicators

Indicator Name	Computation	Rationale	Results (example only)
C-1. Percentage of NTP medicine products included on the national essential medicines list	Total number of medicines on the national EML × 100 Total number of NTP TB medicines	The national EML is utilized in some countries for pharmaceutical procurement or as a reference for medicine reimbursement by health insurance programs.	50.0%
C-2. Percentage of NTP medicine products included on the WHO tuberculosis essential medicines list	Total number of NTP medicines included on the WHO EML × 100 Total # of NTP TB medicines	To determine the NTP selection practice for TB medicines in comparison with that recommended by WHO	50.0%
C-3. Percentage of TB medicine samples that failed quality-control testing out of the total number of TB medicine samples tested during the past year	Total number of medicine samples that failed × 100 Total number of TB medicine samples actually tested	To determine the effectiveness of the health system to procure and distribute quality, safe, and efficacious medicines	44.4%
C-4. Percentage of TB facilities visited where the most recent official manual of treatment guidelines for TB was present	Number of facilities with manual × 100 Number of facilities in sample	To measure the level of access to information to promote effective care and management of TB patients based on national or international guidelines	60.0%
C-5. Percentage of TB outpatients who could correctly describe how the prescribed medication should be used	Total number of TB patients who correctly describe how to take medication × 100 Total number of TB patients interviewed	TB patients who do not know how to take the medicine properly may not comply with the treatment regimen, and develop and spread resistant TB strains	MOH: 79.6%

Indicator Name	Computation	Rationale	Results (example only)
C-6. Percentage of TB patients who reported regular observation by a health care worker during medicine intake	Number of TB patients who reported being observed / Number of TB patients interviewed	To determine the extent to which directly observed treatment is practiced	63.3%
C-7. Average percentage of stock records that correspond with physical counts for a set of TB tracer commodities in TB storage facilities	(a) Each facility: Number of stock records with no discrepancies × 100 / Total number of records examined (b) All facilities: Sum of average % for each facility / Total number of facilities in sample	To gain control over inventory and identify problems such as theft, spoilage, poor record-keeping, and so on	30.0%
C-8. Number of days that a person has to work at minimum wage to pay for a complete TB treatment course, taking into account the price of medicines in the public or private market	Cost of full treatment course / Minimum wage per day	To determine how affordable TB medicines are for patients in countries that do not provide free TB medicines	7.8 days

ANNEX 5. WHO TB MEDICINES

Table A-5. List of WHO TB Medicines[15]

No.	Product (Generic Name [INN])	Strength	Dosage Form
First-Line Medicines (Single-Dose Medicines)			
1.	Isoniazid	100 mg	Tablet
2.	Isoniazid	300 mg	Tablet
3.	Rifampicin	150 mg	Tablet or capsule
4.	Rifampicin	300 mg	Tablet or capsule
5.	Pyrazinamide	400 mg	Tablet
6.	Ethambutol	100 mg	Tablet
7.	Ethambutol	400 mg	Tablet
8.	Streptomycin	1,000 mg	Powder injection, vial
First-Line Medicines (Fixed-Dose Combinations)			
9.	Isoniazid + ethambutol	150 + 400 mg	Tablet
10.	Rifampicin + isoniazid	150 + 75 mg	Tablet
11.	Rifampicin + isoniazid	300 + 150 mg	Tablet
12.	Rifampicin + isoniazid	150 + 150 mg	Tablet
13.	Rifampicin + isoniazid	60 + 30 mg	Tablet
14.	Rifampicin + isoniazid	60 + 60 mg	Tablet
15.	Rifampicin + isoniazid + pyrazinamide	150 + 75 + 400 mg	Tablet
16.	Rifampicin + isoniazid + pyrazinamide	150 + 150 + 500 mg	Tablet
17.	Rifampicin + isoniazid + pyrazinamide	60 + 30 + 150 mg	Tablet
18.	Rifampicin + isoniazid + pyrazinamide + ethambutol	150 + 75 + 400 + 275 mg	Tablet

[15] World Health Organization (WHO). 2003. "Essential Medicines: WHO Model List." <http://www.who.int/medicines/organization/par/edl/eml.shtml> (accessed Dec. 2004).

No.	Product (Generic Name [INN])	Strength	Dosage Form
Second-Line Medicines (for MDR TB)			
19.	Capreomycin	1,000 mg	Powder injection, vial
20.	Cycloserine	250 mg	Capsule, tablet
21.	Para-aminosalicylic acid (PAS)	500 mg	Tablet
22.	Para-aminosalicylic acid (PAS)	4 g	Granules (in sachet)
23.	Ethionamide	125 mg	Tablet
24.	Ethionamide	250 mg	Tablet
25.	Amikacin	1,000 mg	Powder injection, vial
26.	Kanamycin	1,000 mg	Powder injection, vial
27.	Ciprofloxacin	250 mg	Tablet
28.	Ciprofloxacin	500 mg	Tablet
29.	Ofloxacin	200 mg	Tablet
30.	Ofloxacin	400 mg	Tablet
31.	Levofloxacin	250 mg	Tablet
32	Levofloxacin	500 mg	Tablet

ANNEX 6. DATA COLLECTION TRAINING GUIDE

Following is a sample agenda of an illustrative four-day training course for data collectors in health facilities and drug outlets. The course agenda may be adjusted depending on experience of data collectors.

Day	Training Activities	Time
1	1. Opening—Introduction of the data collectors 2. General presentation: • Purpose of the survey: to document the strengths and weaknesses of TB pharmaceutical supply system for the NTP • Training objectives: to familiarize data collectors with survey questionnaires and data collection techniques • Introduction of the Data Collection Forms and Instructions • Where to collect data: TB facilities and TB drug outlets • Data collection techniques to use: direct observations, interviews, record reviews, simulated price inquiries • Discuss data collectors' expectations or concerns 3. Work schedule and compensation 4. Location of sites to be surveyed	1 to 2 hours
	5. Review survey form A-0: General Data Collection Preparation Checklist 6. With the remaining survey forms grouped according to where data are to be collected, review the forms one by one as follows: <u>Central Medical Stores/Regional Medical Stores</u> • A-1: Stock-Out Data Form • A-2: Inventory Data Form • A-4: International Price Comparison Form • A-7: Minimum Quality Standard Form <u>MOH Health Facilities</u> • A-1: Stock-Out Data Form • A-2: Inventory Data Form • A-3a: Medical Records Review Form (Intensive Phase of Treatment) • A-3b: Medical Records Review Form (Continuation Phase of Treatment) • A-4: International Price Comparison Form • A-5: Exit Poll Interview Form • A-7: Minimum Quality Standard Form <u>TB Drug Outlets</u> • A-6: Private/Public Sector Price Comparison Form	2 to 3 hours

Day	Training Activities	Time
	7. Central medical stores/regional medical stores visits: • Practice filling out survey forms A-1, A-2, A-4, and A-7 • Practice role play for forms A-1, A-2, A-4, and A-7 in small groups 8. MOH health facility visits: • Practice filling out survey forms A-1, A-2, A-3a, A-3b, A-4, A-5, and A-7 • Practice role play for forms A-1, A-2, A-3a, A-3b, A-4, A-5, and A-7 in small groups 9. TB drug outlets: • Practice filling out survey form A-6 10. Discuss policy of patient confidentiality	2 to 3 hours
2	1. Practice how to draw a sample of patient encounters from health facility records	1 hour
	2. Visit predetermined health center and collect a complete set of data using these survey forms: A-1, A-2, A-3a, A-3b, A-4, A-5, and A-7	5 to 6 hours
3	1. Debrief on health facility practice visits: critique performances and troubleshoot problems 2. Discuss revisions of forms if any are necessary as a result of the practice visits 3. Role play in small groups—check reliability (quality) of data collector knowledge, skills, and abilities for filling in the data collection forms	3 to 4 hours
	4. Visit predetermined drug outlet and collect a complete set of data using form A-6 (prices)	2 to 3 hours
4	1. Debrief on drug outlet practice visits: critique performance and troubleshoot problems 2. Discuss revision of forms if any are necessary as a result of the practice visits 3. Role play in small groups—check reliability (quality) of data collector knowledge, skills, and abilities for filling out the data collection forms	1 to 2 hours
	4. Assign data collectors to teams and appoint a team manager for each team 5. Discuss purpose of regular team meetings during data collection: to discuss successes, problems, and how to overcome data collection problems 6. Give a general review and open question-and-answer session	3 to 4 hours
	7. Review supervisory role with all team managers • Direct team managers in periodic observation of data collectors • Direct team managers to ensure completeness of data collection forms before leaving the facility • Instruct on how to fill in shaded areas of data collection forms and establish standardized coding for identifying individual data collectors, patient records, encounters, and so on • Instruct on how to select an alternate health center when one becomes inaccessible to data collectors • Instruct on cleaning up data forms before data analysis	1 to 2 hours

ANNEX 7. MODEL BATCH CERTIFICATE OF A PHARMACEUTICAL PRODUCT[16]

Manufacturer's/Official[1] Batch Certificate of a Pharmaceutical Product

This certificate conforms to the format recommended by WHO (general instructions and explanatory notes follow).

1. No. of Certificate:

2. Importing (requesting) authority:

3. Name of product:
   3.1. Dosage form:
   3.2. Active ingredient(s)[2] and amount(s) per unit dose:
   3.2.1. Is the composition of the product identical to that registered in the country of export? yes/no/not applicable[3] *(key in as appropriate)*
   If no: please attach formula (including excipients) of both products.

4. Product license holder[4] (name and address):
   4.1 Product license number:[4]
   4.2 Date of issue:[4]
   4.3 Product license issued by:[4]
   4.4 Product certificate number:[4,5]

   5.1 Batch number:
   5.2 Date of manufacture:
   5.3 Shelf life (years):
   5.4 Contents of container:
   5.5 Nature of primary container:
   5.6 Nature of secondary container/wrapping:
   5.7 Specific storage conditions:
   5.8 Temperature range:

6. Remarks:[6]

7. Quality analysis:
   7.1 What specifications apply to this dosage form? Either specify the pharmacopoeia or append company specifications.[7]
      7.1.1 In the case of a product registered in the exporting country, have these company specifications[7] been accepted by the competent authority? yes/no *(key in as appropriate)*
   7.2 Does the batch comply with all parts of the above specifications? yes/no *(key in as appropriate)*
   7.3 Append certificate of analysis[8]

[16] World Health Organization (WHO). 1998. Annex 2: Guidelines for Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (Appendix 3). In *Marketing Authorization of Pharmaceutical Productus with Special Reference to Multisource (Generic) Products: A Manual for Drug Regulatory Authorities*. Geneva: WHO. <http://www.who.int/medicines/library/qsm/manual-on-marketing/multisource-annex2.html#Model>.

It is hereby certified that the above declarations are correct and that the results of the analyses and assays on which they are based will be provided on request to the competent authorities in both the importing and exporting countries.

Name and address of authorized person:

Telephone number:
Fax number:
Signature of authorized person:
Stamp and date:

General Instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme.

These forms are suitable for generation by computer. They should always be submitted as hard copy, with responses typed rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory Notes

Certification of individual batches of a pharmaceutical product is only undertaken by the competent authority of the exporting country. Even then, it is rarely applied other than to vaccines, sera, and biologicals. For other products, the responsibility for any requirement to provide batch certificates rests with the product license holder in the exporting country. The responsibility to forward certificates to the competent authority in the importing country is assigned to the importing agent.

Any inquiries or complaints regarding a batch certificate should always be addressed to the competent authority in the exporting country. A copy should be sent to the product license holder.

[1] Strike out whatever does not apply.
[2] Whenever possible, use international nonproprietary names (INNs) or national nonproprietary names.
[3] "Not applicable" means that the product is not registered in the country of export.
[4] All items under 4 refer to the product license or the Certificate of a Pharmaceutical Product issued in the exporting country.
[5] This refers to the Certificate of a Pharmaceutical Product as recommended by the World Health Organization.
[6] Indicate any special storage conditions recommended for the product as supplied.
[7] For each of the parameters to be measured, specifications give the values that have been accepted for batch release at the time of product registration.
[8] Identify and explain any discrepancies from specifications. Government batch release certificates issued by certain governmental authorities for specific biological products provide additional confirmation that a given batch has been released, without necessarily giving the results of testing. The latter are contained in the manufacturer's certificate of analysis.

ADDITIONAL READING

Brudon-Jakobowicz, P., J.-D. Rainhorn, and M. R. Reich. 1999. *Indicators for Monitoring National Drug Policies: A Practical Manual.* 2nd ed. WHO/EDM/PAR/99.3. Geneva: World Health Organization.

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International Union Against Tuberculosis and Lung Disease (UNION). 1999. *Epidemiologic Basis of Tuberculosis Control*. 1st ed. Paris: UNION.

Management Sciences for Health. 2001. Improving Drug Management to Control Tuberculosis. *The Manager* 10(4)1–22.

Ross-Degnan, D., R. O. Laing, B. Santoso, et al. 1997. *Improving Pharmaceutical Use in Primary Care in Developing Countries: A Critical Review of Experience and Lack of Experience.* Paper presented at the International Conference on Improving Use of Medicines, April 1–4, 1997, Chiang Mai, Thailand.

U.S. Pharmacopeia (USP). 2003. Dispensing Information. In *Drug Information for the Health Care Professional, Volume I*. 23rd ed. Greenwood Village, CO: Thomson Micromedex.

World Health Organization (WHO). 2002. *Operational Guide for National Tuberculosis Control Programmes on Introduction and Use of Fixed-Dose Combination Drugs*. WHO/CDS/TB/2002.308, WHO/EDM/PAR/2002.6. Geneva: World Health Organization.

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