

Pharmaceutical Management for Tuberculosis Manual

Management Sciences for Health/Rational Pharmaceutical Management Plus (RPM Plus)

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Background

Tuberculosis (TB) remains a major killer of adults worldwide, surpassed only by HIV/AIDS. In 2002, TB caused two million deaths, and the toll is rapidly worsening in some regions, especially in sub-Saharan Africa, where the TB and HIV/AIDS epidemics are closely linked. TB has the greatest impact on the poor, but all income groups are at risk. Global initiatives such as the Global Drug Facility (GDF), the Stop TB Partnership, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and the Green Light Committee (GLC) have been established to combat TB.

Among the top challenges faced by TB programs are lack of access to effective, high-quality medicines, irrational treatment decisions and behaviors, and the counterproductive financial priorities of some national health systems. TB patients can be treated using medicines that are off-patent and readily available on the international market; however, access to vital TB medicines can be undermined by weak pharmaceutical systems with poorly trained managers and ineffective pharmaceutical management practices. DOTS is a proven, cost-effective strategy to detect and cure TB that was developed by the World Health Organization (WHO) and the International Union Against Tuberculosis and Lung Disease (IUATLD). More than 125 countries have now adopted this approach, but only about one-third of the estimated infectious TB patients worldwide receive DOTS-based care.

In 2000, RPM Plus, supported by the U.S. Agency for International Development (USAID), developed an evaluation tool that would assist TB program managers, governments, and partners in evaluating country pharmaceutical system capacity to provide an uninterrupted supply of TB medicines. The evaluation tool also provides decision makers with information required for development of interventions. This tool was field-tested in India (Uttar Pradesh) and the Republic of the Congo (Brazzaville) in 2002. Based on subsequent use a revised version of the tool was published in 2004 and field tested in Ethiopia. In addition to the countries mentioned above to date the tool has been used for TB pharmaceutical sector evaluations in China, Moldova, Romania, Dominican Republic, Armenia, Georgia and Azerbaijan.

PMTB Assessment Manual

The Pharmaceutical Management for Tuberculosis [PMTB] Assessment Manual presents an indicator-based approach for evaluating pharmaceutical management systems as well as activities specifically tailored to the needs of a national TB program (NTP) and its partners (e.g. GDF, GFATM, GLC, WHO). The assessment approach and corresponding indicators included in the manual were designed for conducting stand-alone studies or for integration into on-going program reviews by the NTP in a host country.

The PMTB indicators encompass the four basic functions of TB pharmaceutical management: selection, procurement, distribution, and use. Selection involves choosing high-quality TB medicines in appropriate dosage forms, strengths and special packaging such as patient kits. Procurement includes quantifying TB medicine needs, selecting an appropriate procurement method, managing tenders, establishing contract terms, assuring medicine quality, and monitoring compliance to contract terms. Distribution includes meeting customs requirements, stock control, stores management, and delivery to pharmaceutical storerooms and TB treatment centers in a timely manner. Use involves diagnosing, prescribing, and administration by the provider and proper adherence to treatment by the patient. The functions build on each other, forming a pharmaceutical management cycle. At the center of the cycle is the core management support system, which includes organization, financing, information flow, training, human resource management and product quality assurance. Finally, the entire cycle rests on a policy and legal framework that establishes and supports the public commitment to fighting TB by ensuring the support needed for an uninterrupted supply of medicines.

The main objectives of the Pharmaceutical Management for Tuberculosis Manual include—

- Providing data on TB pharmaceutical management practices
- Identifying ways to improve the NTP pharmaceutical management system
- Monitoring to ensure an uninterrupted supply of quality TB medicines
- Creating country-based operations research capacity by transferring this self-assessment technology

Potential applications of the manual include—

- Quantifying the status of the pharmaceutical system revealing strengths and weaknesses, for NTP managers and partners
- Designing and planning interventions
- Contributing to budget and resource requirements
- Monitoring changes in systems and measuring the impact of interventions
- Comparing the performance of different systems, programs, and countries

The PMTB tool addresses methodology issues, such as sample design, survey logistics, and training for data collectors, and includes an annex containing model data collection forms. The manual is intended for use by health professionals with a background in pharmaceutical management who work in central- or district-level TB health facilities.

Completion of an evaluation should result in the identification and prioritization of problems and the identification of potential and cost-effective interventions.

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PMTB Indicators

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 medicines products included on the national essential medicines list
- 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 medicines 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 drugs 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