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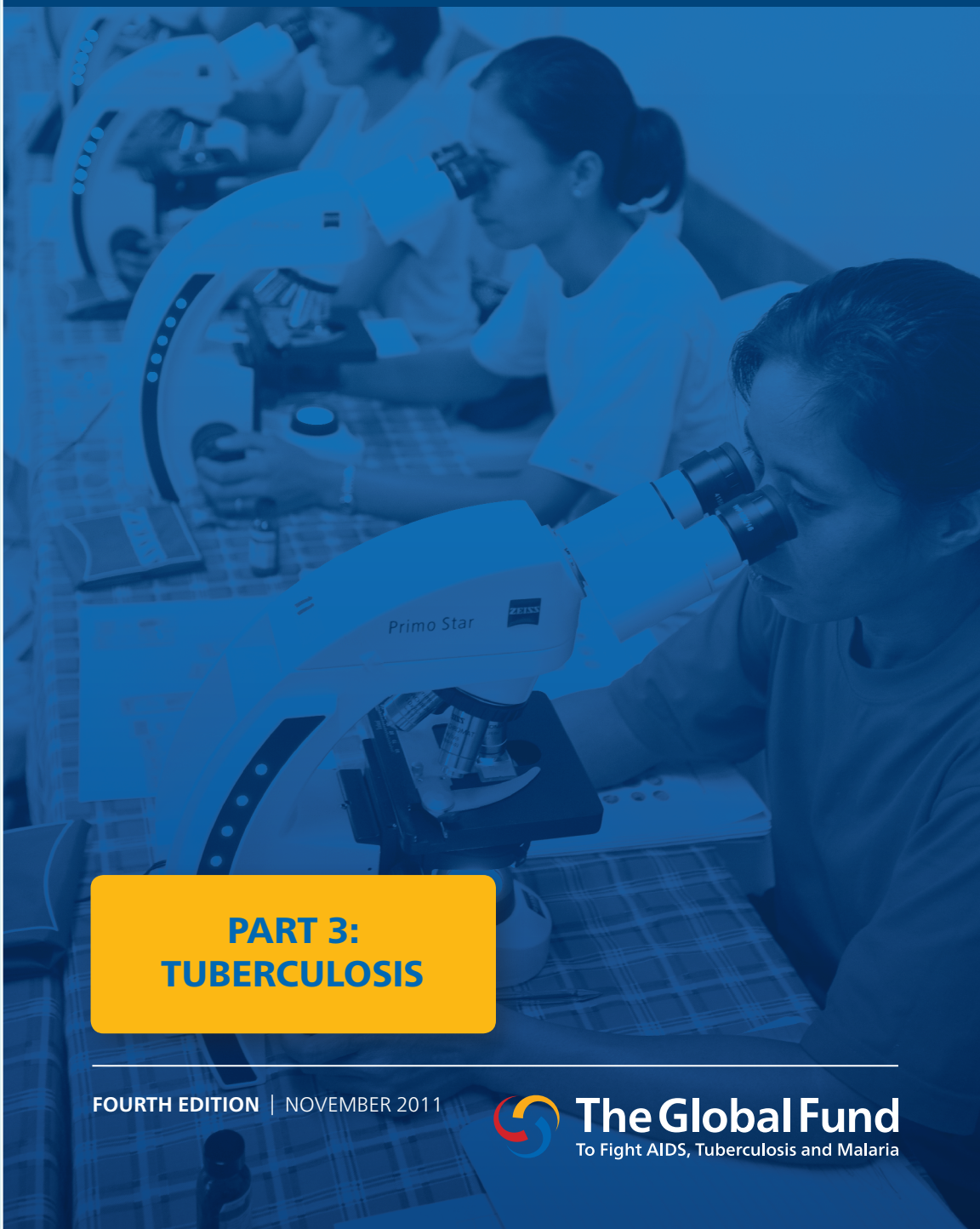
MONITORING AND EVALUATION TOOLKIT

HIV, Tuberculosis, Malaria and Health and Community Systems Strengthening



PART 3: TUBERCULOSIS

FOURTH EDITION | NOVEMBER 2011

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Copy-edited by Mary Mederios Kent, graphic design and layout by Creative Lynx.

The Monitoring and Evaluation Toolkit is available electronically at: http://www.theglobalfund.org/en/me/documents/toolkit/

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Monitoring and Evaluation Toolkit - 4th Edition English Hard Copy.

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Contents

Acronyms

ACSM	Advocacy communication and social mobilization
AFB	Acid-fast bacilli
ART	Antiretroviral therapy
BMU	Basic management unit
CPT	Co-trimoxazole preventive therapy
DOTS	Directly Observed Treatment, Short-course
GDF	Global Drug Facility
GLC	Green Light Committee
GLI	Global Laboratory Initiative
IPT	Isoniazid preventive therapy
LED	Light-emitting diodes
MDR-TB	Multidrug-resistant TB
PAL	Practical Approach to Lung Health
PMTCT	Prevention of mother-to-child transmission
SDA	Service delivery area
WHO	World Health Organization

Acknowledgements

This Monitoring and Evaluation Toolkit is the outcome of an extensive, collaborative process involving M&E experts of international organizations, bilateral agencies, government agencies, nongovernmental and private organizations and major partners, in particular: the Global Fund, the United States Centers for Disease Control and Prevention, the Health Metrics Network, the Roll Back Malaria Partnership, the Stop TB Partnership, UNAIDS, UNICEF, the Global Alliance for Vaccines and Immunization, WHO (including the Global Malaria Program, the HIV/AIDS Department, the Stop TB Department, and the Department of Making Pregnancy Safer), the World Bank, the United States President's Emergency Plan for AIDS Relief (Office of the United States Global AIDS Coordinator), the United States Agency for International Development, the President's Malaria Initiative and MEASURE Evaluation. Input from several work streams addressing global health and M&E issues helped to shape relevant sections of the toolkit. The collaborative and consultative process ensured that the recommendations made in this toolkit are in accordance with those used across most organizations, promoting a common understanding of M&E within and among the three diseases and health systems strengthening as well as the use of a common set of indicators. Our sincere appreciation goes out to all those who contributed to this truly collaborative effort.

Tuberculosis

1. Introduction

The increasing scale and complexity of HIV, tuberculosis (TB) and malaria programs in recent years have intensified the need for data to inform decision-making and to demonstrate progress toward international goals and targets, such as the Millennium Development Goals. To meet these needs, countries must have strong monitoring and evaluation (M&E) systems to report accurate, timely and comparable data that can be used to strengthen programs. This section discusses the M&E of TB programs, including overall goals and strategies in TB control, crosscutting considerations, indicators and data sources, and additional resources.

Countries have made significant progress in expanding and implementing high-quality DOTS programs — the underlying strategy for the global TB control efforts. Recent years have also seen a major scale-up of other components of World Health Organization's new Stop TB Strategy, especially collaborative TB/HIV activities, multidrug-resistant TB services, engaging all care providers through innovative public-private mix interventions, and contributing to community and health systems strengthening. The Global Plan to Stop TB was updated (for the 2011-2015 period)[1] to take into account actual progress since 2006. The new plan reflects changes in policies and costs related to antiretroviral therapy for HIV (ART) and multidrug-resistant TB (MDR-TB), increased emphasis on strengthening laboratories — including the roll-out of newer diagnostic tools — and the need to address the full spectrum of research, from fundamental to operational research. The plan includes updated estimates of the epidemiological burden and trends. The targets for 2005[2] were to detect at least 70 percent of the new cases of smear-positive TB arising each year, and to successfully treat at least 85 percent of detected cases. Since 2005, there has been a shift to measuring progress against impact targets, that is, targets for reducing the burden of disease (measured in terms of incidence, prevalence and mortality).

The Global Fund, a major supporter of the TB control programs, has also seen changes in its architecture, moving from a grant-based, project approach to a broad-based programmatic approach.[3] This is achieved by promoting Single Streams of Funding per Principal Recipient per disease or health systems strengthening area, alignment of all principal recipients contributing to the specific portfolio and alignment with in-country cycles. Under this system the Global Fund will maintain one funding agreement for each Principal Recipient per component (by consolidating existing grants under a Principal Recipient to create a Single Stream of Funding), which will then be amended each time additional funding in the same component is approved and at the time of Periodic Review. Where there are several Principle Recipients implementing activities under a disease/HSS program, each will have a Single Stream of Funding agreement with the Global Fund, and their implementation periods will be aligned to ensure a holistic program based approach. The new architecture favors an improved performance-based funding approach and an assessment of progress towards proposal goals in which impact and outcome assessment at the national programmatic level becomes an integral part of Global Fund's grant-renewal decision matrix.

The fourth edition of the Toolkit takes into consideration all the recent changes and includes updated sets of indicators that reflect evolving strategies and recommendations. It elaborates on the Global Fund processes and requirements and the enhanced emphasis on data quality, quality of services, and program reviews and evaluations.

2. Goals and Strategies of TB Programs

The main objective of national TB control programs is universal access to high-quality diagnosis and patient-centered treatment, reducing the human suffering and socioeconomic burden associated with TB. This aim can be achieved by implementing the World Health Organization (WHO) Stop TB Strategy (Box 1 on page 162).[4] The Stop TB Strategy builds on and incorporates the DOTS strategy to address the challenges to successful TB control more comprehensively.

The Stop TB Strategy addresses gender issues through its patient-centered approach to TB management, identifying people's needs regardless of their gender. The other elements of the Stop TB Strategy also endeavor to ensure that men and women have equal and sufficient access to high-quality services. For more details on addressing gender and equity in M&E systems, see Part 1 of this toolkit.

1 World Health Organization (WHO) Stop TB Partnership. The Global Plan to Stop TB 2011-2015: Transforming the fight. Towards elimination of TB. Geneva: WHO; 2011. Available from: http://www.stoptb.org/assets/documents/global/plan/TB_GlobalPlanToStopTB2011-2015.pdf

2 The targets were originally set for 2000, and later reset to 2005.

3 The Global Fund to Fight AIDS, TB and Malaria. Our Activities: Grant Architecture [Internet]. Available from http://www.theglobalfund.org/en/activities/grantarchitecture/

4 WHO Stop TB Partnership. The Stop TB Strategy [website] building on and enhancing DOTS to meet the TB-related Millennium Development Goals. Geneva: WHO; 2006. WHO/HTM/TB/2006.368. Available from: http://www.stoptb.org/assets/documents/resources/publications/plan_strategy/The_Stop_TB_Strategy_Final.pdf

BOX 1.
Components of the WHO Stop TB Strategy

1. Pursue high-quality DOTS expansion and enhancement

- *secure political commitment, with adequate and sustained financing;*
- *ensure early case detection and diagnosis through quality-assured bacteriology;*
- *provide standardized treatment with supervision and patient support;*
- *ensure effective drug supply and management;*
- *monitor and evaluate performance and impact.*

2. Address TB/HIV, multidrug-resistant TB, and the needs of poor and vulnerable populations

- *scale up collaborative TB/HIV activities;*
- *scale up prevention and management of multidrug-resistant TB;*
- *address the needs of TB contacts and of poor and vulnerable populations.*

3. Contribute to health system strengthening based on primary health care

- *help improve health policies, human resource development, financing, supplies, service delivery and information;*
- *strengthen infection control in health services, households and other congregate settings;*
- *upgrade laboratory networks and implement the Practical Approach to Lung Health;*
- *adapt successful approaches from other fields and sectors and foster action on the social determinants of health.*

4. Engage all care providers

- *involve all public, voluntary, corporate and private providers through Public-Private Mix (PPM) approaches;*
- *promote use of the International Standards for Tuberculosis Care.*

5. Empower people with TB and communities through partnerships

- *pursue advocacy, communication and social mobilization;*
- *foster community participation in TB care, prevention and health promotion;*
- *promote use of the Patients' Charter for Tuberculosis Care.*

6. Enable and promote research

- *conduct program-based operational research;*
- *advocate for and participate in research to develop new diagnostics, drugs and vaccines.*

Boxes 2 and 3 include the globally recommended targets for an optimal national TB control program. These global targets should be adopted to national context based on the current achievement and planned TB control efforts over the next few years.

BOX 2.
Millennium Development Goals and Targets[5]

Millennium Development Goal 6: Combat HIV/AIDS, malaria and other diseases

Target 6.C: Halt and begin to reverse the incidence of malaria and other major diseases

6.9 Incidence, prevalence and death rates associated with tuberculosis

6.10 Proportion of tuberculosis cases detected and cured under directly observed treatment short course

3. TB-specific Considerations

This section highlights some of latest developments in the field of TB, components requiring further emphasis or those pertaining to specific Global Fund requirements. Other resources related to the various components of the Stop TB Strategy are listed under section 7.3.

3.1 New diagnostics

Conventional light microscopy of Ziehl-Neelsen-stained smears prepared directly from sputum specimens is the most widely available test for diagnosis of TB in resource-limited settings. Ziehl-Neelsen microscopy is highly specific, but its sensitivity is variable (20 percent to 80 percent)[6] and is significantly reduced in patients with extrapulmonary TB and in HIV-infected TB patients. There have been several new tools developed to diagnose TB in recent years. Some of the recent policy recommendations from WHO or newer diagnostics are described in this section.

5 United Nations Development Programme. Millennium Development Goals [Internet]. Available at http://www.undp.org/mdg/goal6.shtml

6 World Health Organization. Policy statement: Fluorescent light-emitting diode (LED) microscopy for diagnosis of tuberculosis [Internet]. Available from: http://whqlibdoc.who.int/publications/2011/9789241501613_eng.pdf

BOX 3.
Stop TB Partnership Targets

- *By 2015: reduce prevalence and deaths due to TB by 50 percent relative to 1990;*
- *By 2050: eliminate TB as a public health problem (<1 case per 1 million population)*

The Global Plan to Stop TB (2011-2015): Indicators and Targets

By 2015, all countries should be reporting treatment outcomes for all cases (not just those with smear-positive pulmonary TB, which was the original emphasis in recording and reporting when the DOTS strategy was launched in the mid-1990s).

By 2015, systematic assessments of the quality and coverage of notification and vital registration data should be undertaken on a regular basis, using the framework and associated tools developed by the WHO Global Task Force on TB Impact Measurement.[7]

Some of the other important Global Plan indicators (see Section 4 for indicator definitions and details) and targets for 2015 are summarized below.

GLOBAL PLAN COMPONENT AND INDICATORS[8]	BASELINE (2009)	TARGET (2015)
Treatment success rate among sputum smear-positive cases	86%	90%
Number of countries with ≥1 laboratory with sputum smear microscopy services per 100,000 population	≥ 75	149
Number of countries among 22 high-burden countries and 27 high MDR-TB burden countries with ≥1 culture laboratory per 5 million population	18-21	36
Percentage of confirmed cases of MDR-TB enrolled on treatment according to international guidelines	36%	100%
Treatment success rate among confirmed cases of MDR-TB	60%	≥75%
Percentage of TB patients tested for HIV	26%	100%
Percentage of HIV-positive TB patients treated with ART	37%	100%
Percentage of people living with HIV attending HIV care services who were screened for TB at their last visit	~25%	100%
Percentage of national reference laboratories implementing a quality management system according to international standards	<5%	≥ 50%

Xpert MTB/RIF

The Xpert MTB/RIF system is a recently developed TB-specific application designed for the GeneXpert platform. It detects Mycobacterium tuberculosis as well as rifampicin resistance-conferring mutations directly from sputum, and provides results within two hours. It is considered an important breakthrough in the fight against TB, providing, for the first time, a molecular test simple and robust enough to be introduced outside conventional laboratory settings. The development of the Xpert MTB/RIF assay for the GeneXpert platform was completed in 2009 and endorsed by WHO in December 2010.[9]

The WHO evidence synthesis process[10] confirmed a solid evidence base to support widespread use of Xpert MTB/RIF to detect TB and rifampicin resistance. It resulted in the following main recommendations:

- *Xpert MTB/RIF should be used as the initial diagnostic test in individuals suspected of having multidrug-resistant TB or HIV-associated TB;*

7 For further details, see the Task Force website at http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/en/index.html

8 WHO Stop TB Partnership. The Global Plan to Stop TB 2011-2015. Transforming the fight towards elimination of TB. Available from http://www.stoptb.org/assets/documents/global/plan/TB_GlobalPlanToStopTB2011-2015.pdf

9 WHO. Policy statement: Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF system. Geneva: WHO; 2011. Report No.: WHO/HTM/TB/2011.4 Available from: http://whqlibdoc.who.int/publications/2011/9789241501545_eng.pdf

10 WHO. Rapid Implementation of the Xpert MTB/RIF diagnostic test: technical and operational "How-to;" practical considerations. Geneva: WHO; 2011. Report No.: WHO/HTM/TB/2011.2 Available from: http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf

- *Xpert MTB/RIF may be considered as a follow-on test to microscopy in settings where multidrug-resistant TB or HIV is of lesser concern, especially in further testing of smear-negative specimens. (This recommendation is conditional. WHO acknowledges major resource implications for its use in some settings).*

Xpert MTB/RIF technology does not, however, eliminate the need for conventional microscopy culture and drug susceptibility testing, which are required to monitor treatment progress and to detect resistance to drugs other than rifampicin. In settings or patient groups where rifampicin resistance is rare, Xpert MTB/RIF results indicating rifampicin resistance should be confirmed by conventional drug susceptibility testing, including line probe assay.

All TB cases that are diagnosed with Xpert MTB/RIF and are rifampicin susceptible, irrespective of smear results, should be registered as Xpert MTB/RIF-positive TB cases. Registration of diagnosed TB cases using conventional TB diagnostics remains unchanged if results of Xpert MTB/RIF are not available. All TB cases diagnosed with Xpert MTB/RIF and are rifampicin resistant should be registered as Xpert MTB/RIF-positive with rifampicin resistance. If isoniazid resistance is confirmed by conventional or molecular techniques, the case should be registered as MDR-TB. Registration of diagnosed MDR-TB cases using conventional diagnostics remains unchanged if results of Xpert MTB/RIF are not available. The WHO Rapid Implementation guidance document provides guidelines for recording and reporting TB cases and their treatment outcomes in settings implementing Xpert MTB/RIF.[10]

Given the significant number of TB diagnostics in the pipeline, it is conceivable that additional stand-alone diagnostics may become available. As a consequence of these developments, the definitions of cases and treatment outcomes for TB and drug-resistant TB need to be updated. A consultative/iterative process was initiated in May 2011 by the WHO Stop TB Department that ensures participation of all stakeholders, and especially national TB programs. The process pilots revised recording and reporting forms in sites rolling out Xpert MTB/RIF. Based on WHO recommendations, paper-based systems of recording and reporting forms will be updated and countries will receive support for implementing the necessary changes to their recording and reporting systems.

LED Microscopy

"Light-emitting diodes" (LED) have been developed to offer the benefits of fluorescence microscopy without the associated costs. In 2009, the evidence for the efficacy of LED microscopy was assessed by WHO, on the basis of standards appropriate for evaluating both the accuracy and the effect of new TB diagnostics on patients and public health. The results showed that the accuracy of LED microscopy was equivalent to that of international reference standards. It was more sensitive than conventional Ziehl-Neelsen microscopy and it had qualitative, operational and cost advantages over both conventional fluorescence and Ziehl-Neelsen microscopy. WHO recommends that conventional fluorescence microscopy be replaced by LED microscopy, and that LED microscopy be phased in as an alternative for conventional Ziehl-Neelsen light microscopy. WHO also noted that the switch to LED microscopy should be carefully phased in at country level, with LED technology that meets WHO specifications. Countries using LED microscopy should train laboratory staff, validate the technique, introduce appropriate quality assurance and monitor the effect on TB case detection rates and treatment outcomes.[11]

Commercial Serodiagnostic tests

While WHO is supporting some new diagnostics and systems, it recently issued a policy statement advising against the use of commercial serodiagnostic tests for diagnosis of active tuberculosis. WHO noted that, *"Commercial serological tests provide inconsistent and imprecise findings resulting in highly variable values for sensitivity and specificity. There is no evidence that existing commercial serological assays improve patient-important outcomes, and high proportions of false-positive and false-negative results adversely impact patient safety. Overall data quality was graded as very low and it is strongly recommended that these tests not be used for the diagnosis of pulmonary and extra-pulmonary TB."*[12]

3.2 Monitoring TB/HIV Collaborative Activities

In the last two decades, the number of new TB cases has tripled in high HIV-prevalence countries. TB is now the leading cause of death among people living with HIV in Africa and a major cause of death elsewhere. TB accounts for almost 1.68 million deaths per year globally, including 0.38 million deaths among TB patients who were HIV-positive.[13] It is also the leading presenting illness among people living with HIV who are seeking medical care. The Global Fund recognizes that many HIV and TB control activities are implemented with little interaction between the two programs. As a result, significant issues related to TB/HIV co-infection are not given sufficient attention.

At its November 2008 meeting, the Global Fund Board acknowledged the slow progress in implementing core TB-HIV collaborative services as a risk to achieving successful outcomes under current and future Global Fund tuberculosis and HIV grants. Given the large gap in tuberculosis screening in HIV settings and HIV

11 World Health Organization. Policy statement: Fluorescent light-emitting diode (LED) microscopy for diagnosis of tuberculosis. Available from http://whqlibdoc.who.int/publications/2011/9789241501613_eng.pdf

12 World Health Organization. Commercial serodiagnostic tests for diagnosis of tuberculosis. 2011: Policy statement. Geneva: WHO; 2011. WHO/HTM/TB/2011.5 Available from http://whqlibdoc.who.int/publications/2011/9789241502054_eng.pdf

13 The Global Fund to Fight AIDS, Tuberculosis and Malaria. Collaborative TB/HIV activities. Information note. Available from: http://www.theglobalfund.org/en/application/infonotes/

screening among TB cases, the Board emphasized that all grant applicants should include and implement significant, robust tuberculosis interventions in their HIV/AIDS proposals and HIV/AIDS interventions in their tuberculosis proposals (Decision Point GF/B18/DP12).[14]

M&E of collaborative TB/HIV activities is challenging because of the need to share information among programs. HIV programs need to monitor interventions to reduce the burden of TB (e.g. TB screening among people living with HIV), while TB programs need to monitor interventions to reduce the burden of HIV (for example, the proportion of people living with TB/HIV co infection who receive antiretroviral therapy). TB and HIV programs need to work together to collect, analyze and report data related to TB/HIV activities. Most indicators are captured routinely in either TB or HIV care and treatment registers at the facility or district level and reported quarterly. However, the experience over the past two or three years indicates that annual statistics on core indicators, for example, the annual numbers of TB patients on antiretroviral therapy, tend to show widely different values depending on whether the data were collected by HIV or TB programs. Inconsistent reporting between HIV and TB programs continues to affect several countries with a high burden of TB/HIV. Greater attention is needed at all levels to ensure consistency and quality of reporting of essential TB/HIV indicators.

WHO has issued guidance on the recording and reporting forms that are necessary to monitor and evaluate HIV care, including antiretroviral therapy. These forms include the data necessary to report the recommended indicators for TB/HIV.[15]

3.3 Community TB Care

Community participation in TB care implies establishing a working partnership between the health sector and the community – the local population, especially the poor, and TB patients who are currently on treatment and those who are cured. In this context, "community" refers to trained community volunteers or community members supporting patients and supported by the ministry of health or other ministries and/or nongovernmental organizations. This operational definition excludes formal and informal providers such as doctors, traditional healers and salaried community health workers.

Community-based TB activities[16] represent a range of activities contributing to TB case notification, treatment adherence and improved outcomes. They also include activities for health promotion, including generating demand for TB prevention, diagnosis and treatment services. Ensuring that patients and communities alike are informed about TB, enhancing general awareness about the disease and sharing responsibility for TB care can lead to patient empowerment and community participation. This empowerment and participation can increase the demand for health services and bring care closer to the community.

It is essential to scale up these activities and to carefully measure their impact and effectiveness. The indicators suggested for inclusion in the Performance Framework can measure the contribution of these activities to key TB outcomes (case notification and treatment outcomes) and will enable the national TB program, the implementers (if not the national TB program) and the Global Fund to regularly assess the effectiveness of community-based TB approaches.

In addition, operational research is imperative to regularly assess the effectiveness of community-based approaches and the effective collection and reporting of the indicators. For example, key TB outcomes (case notifications and treatment outcomes) may be compared among target populations where community-based activities are implemented and control populations without such activities. Likewise, TB outcomes may be analyzed for the same target population before and after the adoption of such community-based approaches. Such research and assessment should be conducted jointly by national TB programs (or their equivalents) and any other program implementers to inform strategic planning of further activities. The Global Fund will also increasingly demand documentation of such assessments in proposals for further funding.

3.4 Advocacy, Communication and Social Mobilization

Advocacy, communication and social mobilization (ACSM) include a set of crosscutting activities that are relevant to all aspects of the Stop TB Strategy. ACSM can support specific objectives for interventions for TB, TB/HIV co-infection, multidrug-resistant TB, childhood TB, public-private mix (PPM) programs or other program components to address the political, social, cultural, financial and psychological barriers to successful implementation.

ACSM has sometimes been misunderstood as being an independent Service Delivery Area (SDA) rather than a crosscutting component. It is often noted that ACSM proposals lack appropriate indicators to measure the outcomes. ACSM activities are often generic without clear links to actual TB control challenges on the ground. Advocacy and communication activities should be integrated into every other SDA to reinforce the idea

14 The Global Fund to Fight AIDS, Tuberculosis and Malaria. Board Decisions. 18th Board meeting. New Delhi India. Available from http://www.theglobalfund.org/en/board/decisions/

15 World Health Organization. Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006 [Internet]. Available from: http://www.who.int/tb/dots/r_and_r_forms/en

16 The Global Fund. Community-based activities for improved TB prevention, diagnosis, treatment and care [Internet]. Available from: http://www.stoptb.org/assets/documents/global/tbfriends/R11_communities.pdf

that advocacy and communication are not an end in themselves, but should be used as tools to achieve a specific purpose in a specific SDA.[17]

Advocacy and communication are tools used to reach targets that are supported by a number of interwoven interventions. Accordingly, the focus should be on measuring the end-result of what those activities were meant to support, such as additional cases detected or additional cases cured. Some activities have clear objectives — such as advocacy for resource mobilization (the outcome to measure would be the level of funding before and after the advocacy intervention). However, other activities are much harder and more expensive to measure — such as the impact of mass media campaigns or distribution of information, education and communication (IEC) materials.

In the future, proposals should strengthen their justification for specific advocacy and communication activities. Ideally all interventions should be based on quantitative and/or qualitative research to determine which advocacy and/or communication interventions are the most appropriate and likely to be effective within the target population or geographic area. Proposals should always include a budget line for formative research and/or situation analysis, if it has not already been completed and a mid- or end-term assessment to measure the outcomes, effectiveness and relevance of planned advocacy and communication interventions.

3.5 Equity

The main thrust of the TB control strategy is to ensure access to high-quality diagnosis and treatment of TB for the entire population, including the most vulnerable groups.[18] The main barriers to reaching vulnerable groups with effective curative interventions have been categorized as access barriers, barriers to successful treatment and financial barriers for the TB patient. To overcome these barriers, TB programs continue to target such population groups through innovative program planning, public-private partnerships and community involvement.

Successful scale-up of DOTS programs through integration of TB diagnosis and treatment services into the general primary health care services has helped improve geographical access substantially in several countries. To reduce financial barriers, national TB programs offer free TB diagnosis and anti-TB drugs. In addition, long before DOTS, there was a shift from

TABLE 1.
Illustrative example of strategic implementation and monitoring of ACSM initiatives

National TB control objective	Challenge	Barriers (possible contributing factors)	Needed changes	Potential advocacy or communications interventions to address barriers and support changes	Expected results
Increase case notification rate	Case notification rate is low and it is estimated that nearly 45 percent of incident TB cases are not being notified	High level of stigma related to TB and HIV prevents people from seeking services	Reduce stigma around TB and HIV and behavior change among TB suspects to allow for greater access to services	Survey of specific issues related to stigma and implementation of a communications strategy to address those issues	Ten percent increase in number of suspected cases of TB reporting to health care services for evaluation
Improve and maintain treatment success rate to ≥ 85 percent	High default rates High proportion of deaths among notified cases	DOTS inconvenient Delay in seeking care or diagnosis Patient or community poorly informed	Make DOTS accessible, e.g. by mobilizing community care providers Inform patient/ community and providers about - TB signs/symptoms for early diagnosis - need for ensuring treatment adherence	Identify issues related to causes of delay in diagnosis and or default Identify possible interventions to suit local context and needs Implement targeted communication or social mobilization interventions	Default rates reduced from 12% to <3% Time lag between onset of symptoms and diagnosis reduced from 12 weeks to 3 weeks Decline in deaths among notified TB cases from 8% to <5% Cost effectiveness / cost-benefit analysis of interventions

17 The Global Fund. Global Fund Information Note: Advocacy and communication. Available from http://www.stoptb.org/assets/documents/global/tbfriends/Information%20note%20Advocacy%20and%20Communication.pdf

18 The Global Fund. Global Fund Information Note: Tuberculosis and human rights [Internet] 2011. Available from: http://www.stoptb.org/assets/documents/global/tbfriends/R11_TB-HumanRights_InfoNote_en.pdf

hospital-based to ambulatory care to reduce the financial impact of lengthy hospitalizations. Nevertheless, several studies show that people with TB still experience high expenditures related to seeking TB care. Research has shown that most of this cost occurred even before treatment started, and costs were much higher for patients with the lowest socioeconomic status. Financial costs can be monitored by tracking out-of-pocket spending as a percentage of total health spending. This indicator is closely linked to the incidence of financial catastrophe and impoverishment due to out-of-pocket spending. There is little financial catastrophe or impoverishment when out-of-pocket health payments are less than 15 percent to 20 percent of total health spending, but the percentage is still above this level in many countries.[19]

As part of its new grant structure, the Global Fund aims to consolidate past efforts to ensure equity and incorporate equity assessments more systematically into its performance-based funding model.[20] The key issues that need to be considered include: (1) inequities in access, coverage and outcomes, (2) weaknesses in current programming and implementation and (3) structural barriers. Countries are expected to review and develop strategies to address inequities within proposals and during grant implementation. It is equally important to monitor the potential effect on equity of inputs, outputs and outcomes of planned interventions. Countries are expected to analyze and report disaggregated information on some of the common output/outcome indicators in identified population groups. At the time of grant renewals or Periodic Reviews, for example, case notifications and treatment outcomes can be reported separately by sex, age, urban-rural residence, or for other vulnerable target populations, such as migrants, slum dwellers or prisoners. Health information systems should collect such disaggregated information using the recommended recording and reporting tools.

3.6 Quality of Services

The Stop TB Strategy emphasizes "pursuing high-quality DOTS expansion and enhancement" with an emphasis on quality-assured diagnosis and standardized treatment with supervision and patient support. The Global Fund emphasizes the need to build capacity in establishing and using routine systems as an integral part of disease or health systems strengthening program implementation to ensure service quality. The term quality of services, has been defined as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."

Quality of services will be assessed by the Global Fund at three different stages, at proposal stage, during grant negotiation and during grant implementation (see Part 1 of the M&E toolkit for details). For the purpose of routine monitoring, a minimum set of indicators have been identified that reflect the quality of TB services and programs (see Table 4 on page 174). In addition, a Rapid Service Quality assessment (RSQA) tool has been developed for routine assessment of quality of services during grant implementation. The assessment focuses on the availability of evidence-based policies and guidelines at the national level and on the compliance with those at facility level. The assessment reviews the application of national guidelines at the facility level for diagnosis and treatment, and looks at certain elements of program management, for example, a patient-centered approach or pharmaceutical and health product management.

3.7 Strengthening maternal, newborn and child health (MNCH) through TB programs[21]

The Global Fund recommends integrated approaches to achieve Millennium Development Goals (MDGs) 4 (reducing child mortality), 5 (improving maternal health) and 6 (combating HIV, malaria and other diseases).

In 2008, around 38 percent of incident TB cases occurred in women, who bear a relatively higher burden of TB in high HIV-prevalence countries. Nine million TB cases occur globally every year; an estimated 1 million are in children under age 15. Children and mothers are particularly vulnerable because of TB-associated poverty, making it critical to address their needs. The integration of child mortality reduction approaches and childhood TB control could play a pivotal role in achieving the MDGs.[22]

Several priority TB interventions have been identified that contribute to improvements in maternal, neonatal and child health.[23] These include:

- Improving maternal and newborn health:
  - *integrating TB screening and diagnosis into prevention of mother-to-child transmission (of HIV) and antenatal care services and related maternal and child health services in high-HIV prevalence settings and subsequent treatment where required;*
  - *isoniazid preventive therapy (IPT);*
  - *promote routine HIV counseling, testing and access to HIV prevention and care among those suspected of having TB in high-HIV prevalence settings.*

19 World Health Organization. The world health report: Health systems financing. Geneva: WHO; 2010.

20 The Global Fund. Periodic reviews and commitments policy (Annex 2a Version 2 to GF/B20/4 "Report of the policy and strategy committee"). Available from: http://www.theglobalfund.org/en/board/meetings/twentieth/

21 The Global Fund MNCH Practical Guidance Tool. Strengthening support for maternal, newborn and child health within Global Fund proposals. Geneva: The Global Fund; 2011. Available from: www.theglobalfund.org/documents/rounds/11/R11_MNCH_Guidance_en

22 The Global Fund. Global Fund information note: Addressing and preventing childhood TB. Available from: http://www.stoptb.org/assets/documents/global/tbfriends/ADDRESSING%20AND%20PREVENTING%20CHILDHOOD%20TB.pdf

23 The Global Fund. Strengthening maternal, newborn and child health interventions. Information note. Available from: http://www.theglobalfund.org/en/application/infonotes/

- Improving child health:
  - *TB prevention including additional resources for vaccination programs;*
  - *TB screening, diagnosis, treatment and care;*
  - *ensuring procurement of quality-assured child-friendly formulations of medications for treatment and prevention of TB;*
  - *contact investigation of infectious TB cases (identify children with TB disease and children eligible for preventive therapy).*

There is an urgent need to recognize that prevention, diagnosis and treatment of TB in children are important for public health as well as for ensuring the individual right of the child to health. Children suffer severe TB-related illness that contributes significantly to the overall burden of TB and to overall child mortality. The risk of progression from infection to disease is increased among children, particularly those who are under age 5, HIV-infected and malnourished. Diagnosis and confirmation of TB among children are challenging and contribute to delays in starting treatment. Young children are also at greater risk of developing severe and disseminated TB, such as miliary TB and TB meningitis.

BOX 4.
Indicators for monitoring MNCH activities in TB programs

- *Number of children in two age groups (0 to 4 and 5 to15) who are routinely reported in NTP data.*
- *Numbers of children who are contacts of cases of sputum smear-positive disease that are screened.*
- *Numbers of children who are contacts of cases of sputum smear-positive disease that receive TB treatment or isoniazid preventive therapy.*
- *Numbers of babies born to mothers with TB in pregnancy who receive TB treatment or isoniazid preventive therapy.*

There are many opportunities for integration and linkages for maternal, neonatal and child health interventions in TB and TB/HIV service settings and vice versa. Entry points for interventions include primary and secondary care; health facility and community settings, such as sexual and reproductive health services; antenatal clinics; child health, well-baby and immunization clinics; post-partum care; family planning services; and outreach services for prevention, care and support. Timeliness, location and accessibility of interventions for TB and TB/HIV along the continuum of maternal, neonatal and child health need to be coordinated and integrated to maximize uptake and delivery of needed services in a comprehensive and user-friendly manner.

As part of the programmatic needs assessment, equity assessments, and development of key intervention strategies, countries are encouraged to identify opportunities to maximize synergies between TB programs and maternal, neonatal and child health programs. Disaggregation of routine HIV and TB indicators, collected and reported through routine TB information systems (e.g. routine screening, counseling and testing, prevention of mother-to-child transmission of HIV, isoniazid preventive therapy, TB case notification or TB treatment outcomes) among pregnant women and children is encouraged for proposals focusing on MNCH.

3.8 Strengthening TB surveillance systems

There is growing attention by countries and development partners to strengthening M&E systems and enhancing data quality to support program implementation and assess health outcomes. Ensuring the quality of data enhances program implementation at the country level and improves the efficient allocation of resources. It also increases the Global Fund's confidence in the data it uses for performance-based funding decisions, for external reporting and resource mobilization. The WHO Global Task Force on TB Impact Measurement and the Global Fund have a shared interest and commitment to assess and strengthen the quality and coverage of surveillance data and to measure the impact of TB control efforts within countries.

Over the years, M&E system strengthening activities have often been limited to field supervisions and program monitoring through regular review meetings at the facility or basic management unit level, or at the district, regional and national level. While these activities are critical, there is also a need to focus on strengthening recording and reporting systems and on routine assessments of data quality. Recent years have seen increasing use of electronic recording and reporting systems and the regular use of routine internal and external data validation exercises. National and subnational capacity to analyze data from TB surveillance is often not sufficient to optimize policy decisions and to assess the outcome and impact of control programs. The analysis of datasets from TB prevalence surveys or generated through vital registration records, requires skills and expertise often not available within national TB programs. Building such capacity is essential to improving the performance of TB surveillance.

The Global Fund encourages using the routine TB recording and reporting system in countries receiving grants. If, however, these systems do not collect data for the newly implemented components of the strategy (such as public–private mix, TB/HIV or MDR-TB), the system must be revised to align with the latest WHO recommendations on TB recording and reporting,[24]

24 World Health Organization. Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva: World Health Organization; 2008 [cited 2008 Sept 15]. Available from: http://www.who.int/tb/dots/r_and_r_forms/en

including recording MDR-TB.[25,26] The aims of TB recording and reporting are:

- *to ensure high-quality patient care, a continuum of care, information-sharing with patients and transfer of information between health facilities;*
- *to aid staff in providing adequate services to individual patients;*
- *to allow managers at different levels in the national TB control program to monitor program performance in a standardized and internationally comparable way;*
- *to provide the basis for programmatic and policy development.*

TB surveillance data and systems should meet certain, ideally redefined, standards to provide data of sufficient quality and coverage so that:

- *TB incidence can be estimated directly from TB notifications*
- *TB mortality can be estimated directly from vital registration records*

Reliable information on TB burden and trends can then reliably be used for:

- *informing policymakers, guiding policy decisions and tracking the progress of preventive and control efforts;*
- *developing and seeking funding for targeted interventions and planning and evaluating programs.*

3.8.1 Essential features

National TB surveillance should cover all geographical areas and all public and private providers of TB diagnostic and care services. Policy decisions on TB control and resource allocation should be based on the surveillance system output. Data on TB mortality should ideally be captured through nationwide vital registration systems by coding underlying causes of deaths according to the tenth revision of the International Classification of Diseases. Sample vital registration systems are an acceptable interim solution where surveillance coverage is incomplete. In general, TB surveillance systems should include the characteristics shown in Table 2.

TABLE 2.
Essential features and benchmarks of a national TB surveillance system

Feature	Method of evaluation	Benchmark	Corrective actions
Surveillance budget	Financial statement	> 5% of TB control budget	Incremental budget
Person in charge of the TB surveillance system	National Health Sector Report or National Program Report	Epidemiologist (at least a master's degree in epidemiology)	Recruit or shift TB surveillance responsibilities to an epidemiologist from another department
M&E team in middle- and low-income countries with populations > 10 million	National Program Report	– Data manager – Statisticians (at least master's degree level)	Recruit, provide continuing education
Data management processes • *recording* • *reporting* • *case definitions* • *database operations* • *data dictionary* • *resolving discrepancies* • *contingency and recovery plan* • *confidentiality procedures*	Audit	Standard operating procedures available at all user levels	Develop and disseminate standard operating procedures
Data quality documentation	Audit	Reports disseminated to all users	Provide means for implementing routine checks, developing and disseminating reports on data quality
Surveillance system output documentation	Audit	National TB Report disseminated to users on an annual basis	Provide means for report writing and dissemination
Use of data quality reports and surveillance outputs	Audit of sample of reporting units	>80% of users actually access these types of results (or, alternatively, >80% attend a periodic update convened by the national TB program	Provide means for implementing capacity-building activities

25 World Health Organization. Guidelines for the programmatic management of drug-resistant tuberculosis, Emergency update 2008. Geneva: World Health Organization; 2008. Report No. WHO/HTM/TB/2008.402.

26 World Health Organization. Multidrug-resistant tuberculosis (MDR-TB) indicators. A minimum set of indicators for the programmatic management of MDR-TB in national tuberculosis control programmes. Geneva: World Health Organization; 2011. Report No. WHO/HTM/TB/2010.11 Available from: whqlibdoc.who.int/hq/2010/WHO_HTM_TB_2010.11_eng.pdf

3.8.2 Framework for assessment of surveillance data

WHO recommends a conceptual framework for the systematic assessment of TB surveillance data made up of three major interrelated components (Figure 1):

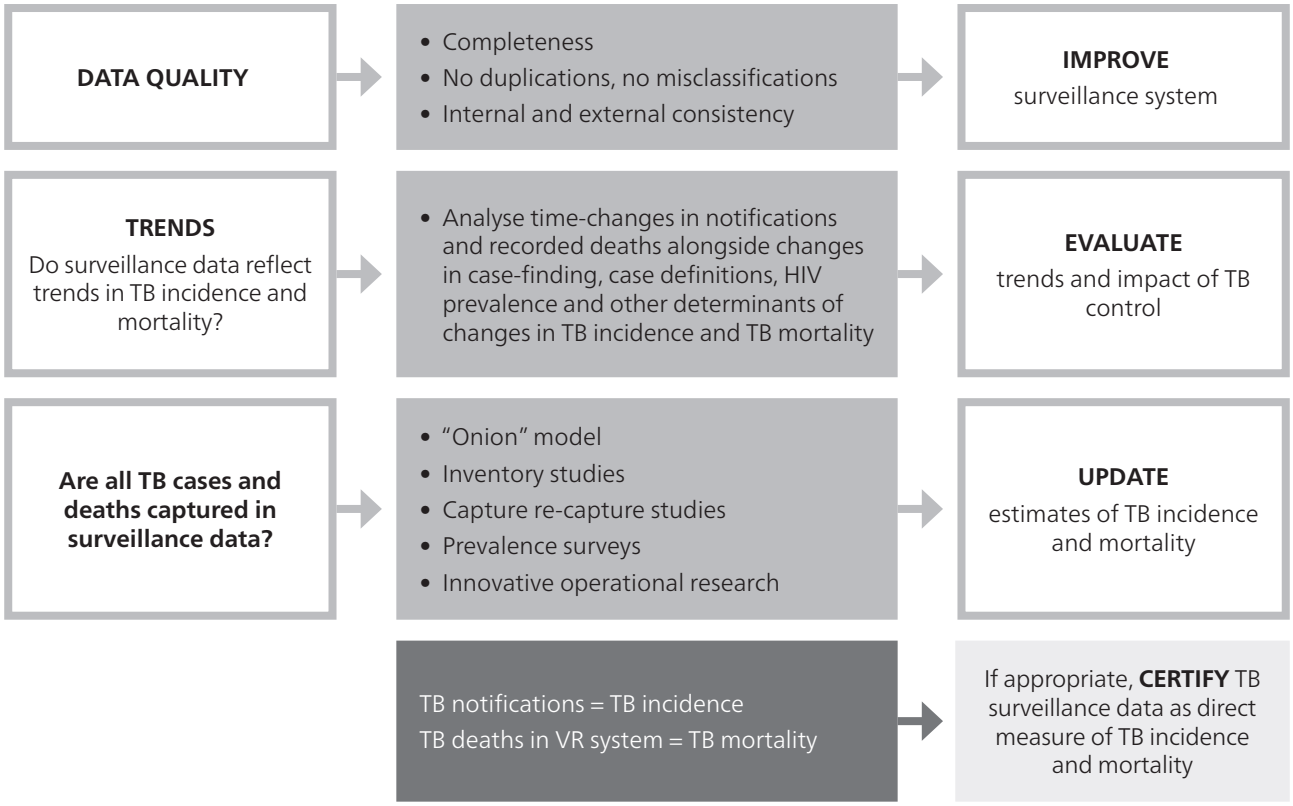
- *assessment of the quality and completeness of notification data for TB cases (in the TB routine notification system) and deaths (in the vital registration system);*
- *assessment of the extent to which notification and vital registration data reflect trends in TB incidence and mortality;*
- *assessment of the number of incident TB cases and deaths that are "missing" from surveillance data ("undetected" cases and deaths).*

To be effective, the framework must help countries identify weaknesses and strengthen their national TB surveillance systems. Completeness, consistency and accuracy of surveillance data should be adequately assessed and documented (Table 3).

Quality of data: The quality of reported data is dependent on the underlying data management and reporting systems and regular supervision. Stronger systems accompanied by effective supervision should produce better quality data. For high-quality data to be produced by and flow through a data management system, key functional components need to be in place at all levels of the system: (1) community level; (2) peripheral health centers and district health centers – also known, in TB program terms, as basic management units (BMUs); (3) the intermediate level(s) where the data are aggregated (e.g. provinces or regions) and (4) the M&E unit at the highest level to which data are reported. Electronic recording and reporting systems can be used to manage and integrate TB data collection, aggregation, validation and reporting.

The Global Fund and partners have developed a number of data quality tools.[28] These include the Routing Data Quality Assessment (RDQA) tool that implementers can use for their own internal data quality assurance. A TB-specific RDQA tool is also available for reference.[29] Implementers can use this tool (or adapt it to local contexts) to strengthen the internal data quality assurance mechanism. The On-Site Data Verification tool is used by the Local Fund Agent (LFA) to conduct on yearly basis data verification for each grant (or per Principal Recipient per disease). The Data Quality Audit (DQA) tool is used by independent institutions contracted by the Global Fund to conduct an in-depth data audit on selected grants.

FIGURE 1.
A framework for the assessment of TB surveillance data[27]



27 World Health Organization. Tuberculosis: WHO global task force on TB impact measurement [Internet]. Available from: http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/resources_documents/en/index.html

28 The Global Fund. Monitoring and evaluation: Data quality tools and mechanisms [Internet]. Available from http://www.theglobalfund.org/en/me/documents/dataquality/

29 World Health Organization/Stop TB Department. Manual on use of Routine Data Quality Audit (RDQA) tool for TB monitoring. 2010 March. Available from: http://www.who.int/tb/dots/planningframeworks/RDQA_Tool_guideline_final.pdf

TABLE 3.
Benchmarks for quality and completeness of national TB surveillance systems

Test	Method	Benchmark	Corrective action
All cases reported from NTP providers	Audit	>95%	Increment supervision and feed backing
Under-reporting from all providers	Inventory study, record linkage - case-based	<10% of detected cases are not reported	Engage all providers through PPM Capture-TB studies to be done in settings where the share of non-NTP providers expected to be substantial Periodicity to be determined
Low proportion of undiagnosed cases	Capture- recapture, where applicable; universal health insurance (or equivalent); low under-5 mortality rate; or TB drug distribution centralized and linked to TB notification	<10% <5% out of pocket expenditures for health <10/1000 < 1% first line TB drugs distributed to cases not accounted for in the TB surveillance system	Dependent on health system strengthening activities and overall performance of health systems, availability of health insurance or related schemes to ensure that primary care and investigations leading to TB diagnosis are affordable to all populations
Vital registration (VR): coverage	Routine	>80% of census population covered	NTP to routinely use VR data and provide feedback
Vital registration (VR): high proportion of deaths with a cause of death coded	Routine	<20% of deaths without a code for cause of death low proportion of garbage codes* - <20 percent of coded deaths	NTP to routinely use VR data and provide feedback

*Garbage codes are ill-defined underlying cause of death based either on symptoms, signs or ill-defined conditions that are not in the standard ICD classification list. For TB the standard codes included in ICD-10 are A15-A19, equivalent to ICD-9: 010–018.

Completeness of data: Inventory studies,[30,31,32] should be conducted to assess the level of TB under-reporting, that is, the proportion of detected but routinely not reported TB cases out of all detected TB cases. An inventory study may be based on a representative sample of geographical areas, involving all private and public providers of health services within the sampled areas, over a specified study period (three months, for example), during which all detected TB cases are recorded by type of provider (for example, the national TB program, private providers, general hospitals or laboratories). Inventory studies are particularly important in countries with a sizable private sector that is not formally linked to national programs through a public-private partnership.

Under certain circumstances, in particular when at least three types of providers are distinguished, capture-recapture modeling may be used to assess the number of undetected cases and calculate estimated ratios of notified-to-incident cases and detected-to-incident cases.

A high level of underreporting highlights the need for establishment of public-private and public-public mix initiatives.

3.9 Measuring Impact

WHO has developed a guidance publication on measuring TB incidence, prevalence and mortality.[33] This publication reiterates the importance of strengthening the routine recording and reporting systems and surveillance of all cases and deaths in all countries to improve estimates of the TB burden and trends (see Section 4.2). Where surveillance systems are not reliable, other measures are recommended. Summarized on page 172 are some of the key methods recommended in the WHO publication.

30 VAN Hest NA, Story A, Grant AD, Antoine D, Crofts JP, Watson JM. Record-linkage and capture-recapture analysis to estimate the incidence and completeness of reporting of tuberculosis in England 1999-2002. Epidemiol Infect. 2008 Dec; 136(12):1606-16. Epub 2008 Mar 17.

31 Van Hest NA, Smit F, Baars HW, De Vries G, De Haas PE, Westenend PJ, Nagelkerke NJ, Richardus JH. Completeness of notification of tuberculosis in The Netherlands: how reliable is record-linkage and capture-recapture analysis? Epidemiol Infect. 2007 Aug; 135(6):1021-9. Epub 2006 Dec 7.

32 Bassili A, Grant AD, El-Mohgazy E, Galal A, Glaziou P, Seita A, Abubakar I, Bierrenbach AL, Crofts JP, van Hest NA. Estimating tuberculosis case detection rate in resource-limited countries: a capture-recapture study in Egypt. Int J Tuberc Lung Dis. 2010 Jun;14(6):727-32.

33 WHO. TB impact measurement: Policy and recommendations for how to assess the epidemiological burden of TB and the impact of TB control (Available at http://whqlibdoc.who.int/publications/2009/9789241598828_eng.pdf)

3.9.1 Prevalence

The prevalence of TB is the number of cases of TB in a population at a given point in time (expressed as number of cases per 100,000 population). The prevalence of TB determines the risk of TB infection in a community, that is, how much transmission is occurring. The prevalence of TB is approximately the incidence of TB multiplied by the average duration of disease. Improved case-finding and treatment both shorten the duration of disease, so prevalence responds more rapidly than incidence to changes in TB control. Periodic assessment of the prevalence of TB disease can therefore be more useful for measuring the short-term impact of TB control (for example, within five to ten years) than efforts to measure changes in TB incidence. Changes in TB prevalence over time are best measured by implementing at least two surveys at sufficient intervals.

There are two methods for estimating the TB prevalence. Direct measurement uses a cross-sectional population-based survey. TB prevalence surveys typically require sample sizes of 50,000 to 100,000 people in high TB-burden countries, and implementation is expensive and logistically challenging. Indirect estimation of TB prevalence is derived from estimated TB incidence multiplied by the average duration of disease. However, neither incidence nor disease duration is typically measured directly and indirect estimates of prevalence have a high level of uncertainty.

Indirect estimates of TB prevalence (estimates not obtained from a population-based survey) should not be used for targeting or program evaluation purposes. Only direct measurements from population-based surveys are suitable for program monitoring and evaluation purposes.

The WHO Task Force on TB Impact Measurement has identified 21 focus countries where surveys of TB prevalence are strongly recommended. TB prevalence surveys should also be considered as an option in other countries with a high burden of TB, if there are serious doubts about the performance of the country's TB surveillance. In addition to providing a direct measure of the burden of TB disease, TB prevalence survey results inform national TB programs about the relative size of undetected TB and about health-seeking patterns leading to delays in the diagnosis of TB. The Global Fund is the major financer of TB prevalence surveys in more than ten African countries and six Asian countries, with a cumulative investment of more than US$ 25 million.

A TB prevalence study should be carefully designed with experts' consultations. If a study or survey is planned, it is advisable to refer to the general guidance found in the WHO policy and recommendations for measuring progress in global TB control.[34] It is also advisable to discuss this process with a WHO office or other technical partners in TB control. It is important to ensure sufficient funding and time to conduct these special studies. A typical survey is designed to detect 70 to 100 smear-positive cases, using X-ray as a screening tool. Culture examinations are also essential for confirmation of diagnosis. A TB prevalence survey is not usually recommended in countries with estimated TB prevalence of less than 100 per 100,000 population because it requires a large sample size, high cost and lengthy timeframe. The WHO publication, *TB Prevalence Surveys: a handbook,* contains further details on the costs and methodology of these surveys.

3.9.2 Incidence

The incidence of TB is the number of new cases of TB (including recurrent episodes of disease in patients who had previously been declared cured of a prior episode of TB) that occur each year. Incidence (cases arising in a given time period) gives an indication of the burden of TB in a population, and of the size of the task faced by a national TB control program. Incidence can change as the result of changes in transmission (the rate at which people become infected with Mycobacterium tuberculosis), or changes in the rate at which people infected with Mycobacterium tuberculosis develop TB disease (for example, as a result of changes in nutritional status or of HIV infection). Because TB can develop in people who became infected many years previously, the effect of TB control on incidence is less rapid than the effect on prevalence or mortality.

There are three practical methods of measuring or estimating TB incidence in a given year:

- *direct measurement from TB notification data when TB surveillance meet high standards of coverage and quality (see Section 4.2);*
- *estimation by assessing the completeness of TB notification data through inventory studies using record-linkage and capture-recapture modeling;*
- *estimation from expert opinion using the "onion model" framework.*[35]

Other methods for measuring incidence are impractical and resource-intensive (for example, nationwide cohort studies of TB incidence) or they rely on difficult-to-validate assumptions and poorly performing tests (for example nationwide tuberculin surveys in children). Indirect estimates of incidence derived from measurements of prevalence or mortality have wide confidence intervals and are not used by WHO because of the absence of reliable measurements of average disease duration or TB case fatality rates at the country level.

Estimates of incidence should always provide documentation of their range of uncertainty (confidence intervals). In countries where the performance of TB surveillance systems do not allow the use notifications as a proxy for incidence, incidence estimates should not be used for national program planning and targeting

34 World Health Organization. Tuberculosis prevalence surveys: A handbook. WHO; 2011. Available from: http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/resources_documents/en/index.html

35 World Health Organization. Global taskforce on TB impact measurement. Available from: http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/resources_documents/en/index.html.

purposes. Instead, series of case notification rates should be carefully analyzed; and short-term forecasts may be used for planning and budgeting. WHO recommends that all countries strengthen their surveillance systems until TB notifications are a direct measure (or close proxy) of TB incidence. WHO also recommends that countries periodically assess TB incidence (its absolute values and trends) using a standard framework and tool for analyzing and documenting the reliability and coverage of TB notification data.

3.9.3 Mortality

TB mortality is the number of deaths from TB that occur in a given year (expressed as deaths per 100,000 population per year). There are three ways to measure TB mortality:

- *routine measurement using vital registration data if death registration data collected in vital registration systems are coded according to the International Statistical Classification of Diseases (ICD-10) and the data are of proven completeness and accuracy*
- *direct measurement using verbal autopsy studies, in which caregivers or family members of people who have died are asked a structured set of questions with the aim of determining the cause of death, with validation of causes of deaths using medical records;*
- *indirect measurement using estimates of case-fatality rates and TB incidence, in which TB mortality is estimated from the TB incidence multiplied by the estimated case-fatality rate.*

WHO recommends measuring TB deaths using a national vital registration system in which the causes of death are coded using the ICD-10. WHO also recommends that, where vital registration systems are weak or not yet developed, sample vital registration be used as an interim source for the reliable measurement of deaths, including deaths from TB.

In countries where direct measurements of TB mortality through a nationwide vital registration system or a sample vital registration system are not available, indirect estimates of mortality derived from estimates of incidence and case fatality are not suitable for program planning and monitoring, due to their high uncertainty.

4. Monitoring Tuberculosis Programs

This section of the toolkit presents selected (1) programmatic output and (2) outcome and impact indicators for monitoring the implementation of the Stop TB Strategy. In addition, this section includes indicators for the strengthening of health systems and community systems along with indicators that measure equity and quality of services. Summary tables (Tables 4, 5 and 6) provide an overview of selected indicators, supported by detailed descriptions (Section 8). These indicators have been developed in collaboration with the WHO Stop TB Department and the Stop TB Partnership. They have been developed for the specific purpose of minimizing information demands on countries. The process of developing indicators was guided by the following principles:

- *building on existing nationally and globally agreed indicators and linking these indicators to the objectives to be achieved;*
- *harmonizing with other international frameworks, such as the framework of the Millennium Development Goals and the Stop TB Partnership;*
- *limiting the number of indicators to be collected to avoid overburdening M&E systems and to stay focused on issues that directly affect decision-making;*
- *selecting indicators that are collected regularly through routine recording and reporting systems, a health information system, health facility surveys or surveys of knowledge, attitudes and practices, ensuring that these indicators have clear data sources and methods of analysis;*
- *conciliating the M&E needs of the country and donors;*
- *covering all the components of the WHO Stop TB Strategy.*

The indicator descriptions provide information on:

- *rationale for use;*
- *definition, including numerator and denominator;*
- *measurement – details on instruments and process, comprising:*
  - *measurement tools: routine recording and reporting system, statistics on health services, health facility surveys, qualitative methods, and population-based surveys;*
  - *recommended periodicity of data collection;*
- *resources, including the source documents.*

The programmatic output, outcome and impact tables presented for TB do not aim to provide a comprehensive overview of all indicators. Rather, they aim to provide users with a set of the most common indicators used for specific activity areas. For a complete listing of existing indicators, see the guidelines and resources listed in Section 7.3, including the Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Programs.[36]

4.1 Monitoring output indicators

Table 4 on page 174 provides a list of key programmatic indicators that are grouped under the respective components of the Stop TB Strategy. Most of these indicators measure the quality of performance at the service delivery level. Each indicator is described in detail in Section 8. This table also provides guidance on measuring indicators such as data sources and the level and frequency of data collection. This is not an exhaustive list, and readers are encouraged to consult the listed references (such as the Compendium of Indicators for Monitoring and Evaluating National Tuberculosis Programs) and relevant literature for further information.

36 World Health Organization. Compendium of indicators for monitoring and evaluating national tuberculosis programmes. Geneva: World Health Organization; 2004. Available from: http://www.who.int/tb/publications/2004/en/index.html

TABLE 4.
Selected programmatic output indicators for TB

	Service delivery area (SDA)	Indicators	Additional Information	Data source	Frequency of reporting	Equity/ MNCH	Quality of Services	Core Programmatic (Top 10) Indicator
Objective 1: Expand and enhance high-quality DOTS	High-quality DOTS	**Notification rate of all forms of TB cases** TB cases (all forms) notified to the national health authorities during a specified period (number)	All forms of TB includes new smear-positive, new smear-negative, extra-pulmonary and relapse cases[a] For countries using culture for TB diagnosis, the number of bacteriologically confirmed cases may be reported as an additional indicator. For countries using Xpert MTB/RIF for TB diagnosis, the number of cases confirmed by Xpert MTB/RIF may be reported as an additional indicator. Notification rates are known to vary by age, sex, urban/rural residence or other risk category. Where applicable (in proposal objectives, equity assessment etc.), based on routine reporting; or in a sample of randomly selected districts or sites, report disaggregated information on cases notified by the identified risk group at Periodic Review.	TB register Quarterly report on TB case registration in district or basic management unit	Quarterly and annually	X		X
		Notification rate of new smear-positive TB cases[b] New smear-positive TB cases notified to the national health authority during a specified period (number)	For countries using culture for TB diagnosis, the number of bacteriologically confirmed cases may be reported as an additional indicator. For countries using Xpert MTB/RIF for TB diagnosis, the number of cases confirmed by Xpert MTB/RIF may be reported as an additional indicator. Notification rates are known to vary by age, sex, urban/rural residence or other risk category. Where applicable (in proposal objectives, equity assessment etc.), based on routine reporting; or in a sample of randomly selected districts or sites, report disaggregated information on cases notified by the identified risk group at Periodic Review.	TB Register Quarterly report on TB case registration in district or basic management unit	Quarterly and annually	X		X
		Treatment success rate,[c] new smear-positive TB cases New smear-positive TB cases successfully treated (cured plus completed treatment) among the new smear-positive TB cases registered during a specified period (number and percentage)	Treatment outcomes may vary by age, sex or other risk category due to differential access to care, or compliance to treatment, or other underlying risk factors. Where applicable (in proposal objectives, equity assessment, etc.), based on routine reporting; or in a sample of randomly selected districts or sites, report disaggregated treatment outcomes by risk category for new smear-positive TB cases at Periodic Review. Where applicable, report separately for new smear-positive TB cases provided with treatment in prisons, or by a specific type of health care provider or by the community and by HIV status.	Quarterly report on TB treatment outcome in district or basic management unit	TB Register Quarterly and annually	X	X	X

a In countries with a sizeable number of retreatment cases being notified (failures, treatment after default, and others), these cases may be reported separately in addition to all forms (new and relapse) of TB cases; case notification rate (per 100,000 population) is an outcome indicator and should be included in the performance framework in addition to the number of cases notified during each reporting period (quarterly/six monthly).

b While there is emphasis on monitoring case notification of all forms of TB, new smear-positive TB cases will continue to be monitored; and will be used for purposes of monitoring treatment outcomes among notified new smear-positive cases.

c Treatment success rate is an outcome indicator to be reported quarterly and annually. Although several Service Delivery Areas support this indicator, for routine reporting purposes this indicator and case notifications are included under Service Delivery Area: High-Quality DOTS. Countries are encouraged to monitor treatment outcomes for all notified cases (new, relapse and retreatment) and where available may report on treatment outcomes for all forms of TB, and for retreatment cases separately; countries may consider including specific adverse outcomes (ex. default, failures) for which specific programmatic activities are directed.

TABLE 4.
Selected programmatic output indicators for TB

	Service delivery area (SDA)	Indicators	Additional Information	Data source	Frequency of reporting	Equity/ MNCH	Quality of Services	Core Programmatic (Top 10) Indicator
Objective 1: Expand and enhance high-quality DOTS	Improving diagnosis	**Quality assurance for smear microscopy** Laboratories showing adequate performance in external quality assurance for smear microscopy among the total number of laboratories that undertake smear microscopy during the reporting period (number and percentage)		External quality assurance report	Annually		X	
		Quality assurance for culture examination Laboratories showing that the proportion of culture positive results in AFB-positive TB patients not yet initiated on treatment, is >90% among the laboratories that undertake culture examination during the reporting period (number and percentage)		External quality assurance report	Annually		X	
		Quality assurance for drug sensitivity testing Laboratories showing at least 95% proficiency for isoniazid and rifampicin drug susceptibility testing among the total number of laboratories that undertake drug susceptibility testing during the reporting period (number and percentage)		External quality assurance report	Annually		X	
	Procurement and supply management (first-line and second-line anti-TB drugs)	**Stock-outs of first-line anti-TB drugs** Reporting units (districts or basic management units) reporting no stock-out of first-line anti-TB drugs on the last day of the quarter (number and percentage)		Quarterly report on drug orders or remaining stock on the last day of the quarter in district or basic management unit	Quarterly			
		Stock-outs of second-line anti-TB drugs Reporting units (districts or basic management units) reporting no stock-out of second-line anti-TB drugs on the last day of the quarter (number and percentage)		Quarterly report on drug orders or remaining stock on the last day of the quarter in district or basic management unit	Quarterly			
	Monitoring and evaluation	**Timeliness of routine reporting** Reporting units submitting timely reports according to national guidelines (number and percentage)	This indicator measures the timeliness (according to the national TB program guidelines) of submitting the case-finding and treatment outcome reports. The indicator may be analyzed at national, provincial or district level.	Quarterly report on TB case registration / TB treatment outcome in districts or basic management units	Quarterly and annually			

TABLE 4.
Selected programmatic output indicators for TB

	Service delivery area (SDA)	Indicators	Additional Information	Data source	Frequency of reporting	Equity/ MNCH	Quality of Services	Core Programmatic (Top 10) Indicator
Objective 2: Address TB/HIV, MDR-TB and other challenges	**TB/HIV**[d]	**Proportion of TB patients with known HIV status** TB patients registered during the reporting period who had an HIV test result recorded in the TB register among the total number of TB patients registered during the reporting period (number and percentage)		TB register Quarterly report on TB case registration in districts or basic management units	Quarterly		X	
		Proportion of HIV-positive TB patients who receive co-trimoxazole preventive therapy (CPT) HIV-positive TB patients, registered over the reporting period, starting or continuing CPT treatment during their TB treatment among all HIV-positive TB patients registered during the reporting period (number and percentage)		TB register Quarterly report on TB treatment outcome and TB/HIV activities in districts or basic management units	Quarterly			
		Proportion of HIV-positive registered TB patients given antiretroviral therapy during TB treatment HIV-positive TB patients who are started on or continue previously initiated antiretroviral therapy, during TB treatment, among all HIV-positive TB patients registered during the reporting period (number and percentage)	This is a subset of the total number of people receiving antiretroviral drugs.	TB register Quarterly report on TB treatment outcome and TB/HIV activities in districts or basic management units	Quarterly		X	X
	Multidrug-resistant TB (MDR-TB)	**TB cases with result for drug susceptibility testing** TB cases with results for diagnostic drug susceptibility testing for MDR-TB among those eligible for drug susceptibility testing according to national policy during the specified period of assessment (number and percentage)	This indicator may be disaggregated by results among eligible new and retreatment TB cases	MDR-TB register Aggregated reports of (1) notifications of new and retreated TB cases targeted, and (2) cases with drug susceptibility testing results for both isoniazid and rifampicin	Six monthly and annually		X	
		Confirmed MDR-TB cases enrolled on treatment Laboratory-confirmed MDR-TB cases enrolled on second-line anti-TB treatment during the specified period of assessment (number)	For countries using Xpert MTB/RIF, the number of rifampicin resistant cases detected by Xpert MTB/RIF alone enrolled on treatment may be reported as an additional indicator. For countries with sizeable proportion of XDR-TB, the number of confirmed XDR-TB cases registered and started on a prescribed XDR-TB treatment regimen during the reporting period may be reported as an additional indicator.	MDR-TB register	Six monthly and annually			X

d See the HIV/TB indicators in the HIV section for HIV/TB indicators collected by the HIV program.

TABLE 4.
Selected programmatic output indicators for TB

	Service delivery area (SDA)	Indicators	Additional Information	Data source	Frequency of reporting	Equity/ MNCH	Quality of Services	Core Programmatic (Top 10) Indicator
Objective 2: Address TB/HIV, MDR-TB and other challenges	**Multidrug-resistant TB** (MDR-TB)	**Delay in start of MDR-TB treatment** Delay between the date of MDR confirmation (DST result showing resistance to both isoniazid and rifampicin in the MDR-treatment register) and the date when the patient started a prescribed second-line drug regimen as per MDR-treatment register (average number of days)		MDR-TB register	Six monthly and annually			
		Interim results: culture conversion at six months MDR-TB cases initiated on a second-line anti-TB treatment who have a negative culture at the end of six months of treatment during the specified period of assessment (number and percentage)		MDR-TB register	Six monthly and annually			
		Treatment success rate, laboratory confirmed MDR-TB Laboratory-confirmed MDR-TB cases successfully treated (cured plus completed treatment) among those enrolled in second-line anti-TB treatment during the year of assessment (number and percentage)		MDR-TB register	Annually		X	X
	High-risk groups (contacts, prisoners, migrants, refugees and displaced populations, ethnic minorities, slum dwellers and people exposed to TB in other congregate settings etc.)	**Screening of high-risk groups** Identified high-risk groups screened for TB (for example: migrants, refugees, ethnic minorities, prisoners, contacts of TB cases etc.) (number)		Register of TB contacts	Quarterly / six monthly and annually	X		
		Notification of all forms of TB in prisons TB cases (all forms) notified in prisons to the national health authorities during a specified period (number)	Where applicable (proposal objectives, equity assessment etc.), report separately the treatment outcomes among new smear-positive TB cases in prisons.	TB register in prisons Quarterly report on TB treatment outcomes and TB/HIV activities in prisons	Annually	X		
	Infection control	**Infection control in health facilities** Health care facilities that have infection control practices in place that include airborne infection control for TB control among the total number of facilities (number and percentage)	At a minimum, these should include health-care facilities where services are provided for TB and for people living with HIV.	Data for the numerator of this indicator should be obtained from yearly survey or routine reporting. Data for the denominator are reported routinely by all countries Facility Risk assessment or Evaluation Report	Annually			
		Ratio of TB notification rate (all forms) in health care staff (all staff) over the TB notification rate in general population, adjusted for age and sex.		Data for the numerator of this indicator should be obtained from yearly survey or routine reporting. Data for the denominator are reported routinely by all countries	Annually			

TABLE 4.
Selected programmatic output indicators for TB

	Service delivery area (SDA)	Indicators	Additional Information	Data source	Frequency of reporting	Equity/ MNCH	Quality of Services	Core Programmatic (Top 10) Indicator
Objective 3: Contribute to health system strengthening	**Practical Approach to Lung Health (PAL)**	Health facilities implementing Practical Approach to Lung Health (PAL) among the total number of health facilities (number and percentage)		National TB program database	Annually			
Objective 4: Engage all care providers	**All care providers (public–private mix (PPM) and International Standards for Tuberculosis Care)**	Private and public health providers (different types[e]) collaborating with the national TB program (number and percentage)		Annual report on program management in districts or BMUs or other sources	Annually			
		TB cases (all forms) contributed through referral and / or diagnosis by private sector (all types of private and nongovernmental health facilities) among all TB cases notified in the PPM implementation areas (number and percentage)		TB Laboratory register TB register	Quarterly and annually			
		TB cases (all forms) contributed by public sector institutions not covered by the national TB program (country specific, e.g. general hospitals, social security, health insurance, educational institutions, railways, etc.) among all TB cases notified in the PPM implementation areas (number and percentage)		Annual report on program management in districts or basic management units TB register or other sources such as institutional reports	Quarterly and annually			
		New smear-positive TB cases successfully treated (cured plus completed treatment) among the new smear-positive TB cases managed or treated according to national policies by the collaborating public and/or private health facilities/providers (number and percentage)	This may be disaggregated by specific type of provider or institutional setting, based on the type of intervention, or programmatic need	Annual report on program management in districts or basic management units TB register or other sources such as institutional reports	Quarterly and annually			

e Suggested categories and codes for all care providers may include:
- government and other public sector health facilities not directly under the scope of the national TB program, such as public hospitals, medical colleges, military etc. (G); and
- private health facilities, including hospitals and clinics run by nongovernmental and faith-based organizations and formal and informal private providers (P).

TABLE 4.
Selected programmatic output indicators for TB

	Service delivery area (SDA)	Indicators	Additional Information	Data source	Frequency of reporting	Equity/ MNCH	Quality of Services	Core Programmatic (Top 10) Indicator
Objective 5: Empower people with TB, and communities through partnerships	**Advocacy, communication and social mobilization**	No Indicator proposed. See section 3.4 for guidance on monitoring and evaluating ACSM interventions						
	Community TB care	TB cases (all forms) referred by the community[f] among the TB cases (all forms) notified in the BMU(s) covered by the grant (number and percentage)		Annual report on program management in districts or basic management units TB laboratory register and TB Register	Quarterly and annually			
		TB cases (all forms) provided treatment observation (DOT) (according to national policies) by the community[f] among the TB cases (all forms) notified in the BMU(s) covered by the grant (number and percentage)		Annual report on program management in districts or basic management units TB treatment card and TB register	Quarterly and annually			
		New smear-positive TB cases successfully treated (cured plus completed treatment)[c] among the new smear-positive TB cases provided treatment observation (DOT) (according to national policies) by the communityf in the BMU(s) covered by the grant (number and percentage)		TB treatment card TB register Quarterly report on TB case registration in districts or basic management units	Quarterly and annually			
Objective 6: Enable and promote research	**Operations Research**	No Indicator proposed. See section 6.3 for guidance on Operations Research interventions						

f Community in the context of community TB care refers to trained community volunteers or community members supporting patients and supported by the ministry of health, other ministries or nongovernmental organizations. This operational definition excludes formal and informal private providers such as doctors, traditional healers and salaried community health workers.

4.2 Monitoring outcome and impact indicators

Monitoring TB programs over the lifetime of the Global Fund grant requires tracking outputs, outcomes and ultimately impact. For TB, "impact" refers to changes in TB incidence, prevalence and mortality for which targets have been set within and by the framework of the Millennium Development Goals and the Stop TB Partnership.

Impact may, however, not be demonstrated by routinely collected data alone and typically not within a time frame of four to five years. If the activities are ambitious and broad in geographical scope, assessing the impact of TB control efforts may be appropriate. In this regard, special studies or surveys (such as in-depth analysis of routine surveillance data), population-based prevalence of disease surveys, population-based mortality surveys to measure impact or to establish a baseline for measuring impact play an important role. Tuberculin surveys are not recommended for the assessment of TB incidence. Tables 5 and 6 show selected indicators for monitoring the impact and outcome of the implementation of this strategy in reducing TB morbidity and mortality. The recommended impact indicators should be included when the data could be collected through direct measures such as surveys or vital registration systems. In the absence of direct measures, impact in all Global Fund TB grants will be assessed using trends in case notifications.

5. Data Sources

Data sources used for TB control include patient treatment cards, medical records (in countries using electronic case-based information systems), laboratory records and vital registration records (death certificates). In addition, other country-specific sources may be used to compile essential budget and other information that are used to monitor national indicators. Also, survey-specific records constitute source documents for TB surveillance.

In countries with paper-based information systems, selected items included in source documents are transcribed onto TB registers and then into quarterly and annual reporting forms. Sample WHO-recommended

TABLE 5.
Selected impact indicators for TB

	Indicator	Millennium Development Goals & Target	Measurement
Impact indicators*	**TB prevalence rate*** Number of bacteriologically confirmed TB cases per 100,000 population at a given point in time	Halving the prevalence by 2015 relative to 1990	Measured by a population-based disease prevalence survey,[37] where applicable. If conducting a disease prevalence survey is not applicable for a country, TB prevalence can be measured indirectly from TB incidence. This indicator will be used for making performance-based funding decisions only in countries where it is measured through population-based surveys. The trend in TB prevalence can be assessed for countries that have conducted at least two national surveys of the prevalence of TB disease.
	TB mortality rate* Number of deaths due to TB (all forms) per year per 100,000 population according to the ICD10 definition	Halving TB mortality by 2015 relative to 1990	This indicator will be used for countries with a high-quality vital registration system or interim systems such as sample vital registration or population-based mortality survey (such as a verbal autopsy study)
	TB incidence rate* Number of TB cases (all forms) occurring per year per 100,000 population	Halt the increase in TB incidence by 2015 and begin to reverse	The notification rate can be a close proxy of TB incidence where the coverage and quality of the routine surveillance system is high. The trend in TB incidence can be measured by assessing trends in case notifications if case-finding efforts and/or recording and reporting practices have not changed significantly.

* For the purpose of impact-outcome assessment at the time of Periodic Reviews to inform Global Funds grant renewal decisions. Trends in TB prevalence (in countries that have conducted at least two national surveys of the prevalence of TB) or trends in TB mortality (based on data from national vital registration (VR) or sample VR systems whenever possible) will be used when they are directly measured. In all other countries, an in-depth assessment of impact will be based on assessment of trends in the case notification rate, all forms (new and relapse cases) using the WHO framework for assessment of surveillance systems. Trends in case notifications will need to be analyzed alongside other data, such as efforts in case-finding and trends in the prevalence of risk factors associated with TB. Such an assessment needs to be undertaken by countries in collaboration with WHO and other partners, linked to the timing of program reviews and decisions regarding continuation of funding.

37 World Health Organization. Tuberculosis prevalence surveys: A handbook. Geneva: World Health Organization; 2011. Report No. WHO/HTM/TB/2010.17 Available from: http://whqlibdoc.who.int/publications/2011/9789241548168_eng.pdf

TABLE 6.
Selected outcome indicators for TB

	Indicator	Global Plan to Stop TB Targets	Measurement
Outcome indicators	**Notification rate of all forms of TB cases** TB cases (all forms) registered during a specified period and notified to the national health authorities (number per year per 100,000 population)	Targets should be set in the context of changes in the epidemiology of TB and HIV, and the efforts of the program to improve coverage of the TB program through, for example, involvement of private sector and other care providers	Measured by routine recording and reporting system (quarterly report on TB case registration in Basic Management Units).
	Notification rate of new smear-positive TB cases New smear-positive TB cases notified to the national health authorities during a specified period (number per year per 100,000 population)	Targets should be set in the context of changes in epidemiology of TB and HIV, and the efforts of the program to improve coverage of the TB program through, for example, the involvement of private sector and other care providers	Measured by routine recording and reporting system (quarterly report on TB case registration in Basic Management Units).
	Treatment success rate, new smear-positive TB New smear-positive TB cases successfully treated (cured plus completed treatment) among the new smear-positive TB cases notified to the national health authorities during a specified period (number and percentage)	At least 85% successfully treated	Measured by routine recording and reporting system (quarterly report on TB treatment outcomes and TB/HIV activities)
	Treatment success rate, laboratory-confirmed MDR-TB Laboratory-confirmed MDR-TB cases successfully treated (cured plus completed treatment) among those enrolled in second-line anti-TB treatment during the year of assessment (number and percentage)	≥75% of laboratory confirmed MDR-TB cases successfully treated	Measured by routine recording and reporting system

registers and forms are available on the web (http://www.who.int/tb/dots/r_and_r_forms/en/index.html). Core TB indicators can be captured and monitored using WHO-recommended reporting forms.

6. Program Reviews, Evaluation and Operations Research

This section outlines the guidance on national program reviews or joint external monitoring missions, the need for planning evaluations to evaluate specific program interventions and the scope of operations research for strengthening TB programs.

6.1 Program reviews

One of the goals of the Global Fund's new grant architecture is to place greater emphasis on outcome and impact evaluations. Countries are encouraged to plan for a program evaluation or program review assessing outcomes and impact of the program as a part of their proposal. It is recommended that the Country Coordinating Mechanisms (CCMs) submit to the Global Fund Secretariat a program review and/ or evaluation report analyzing outcomes and impact. The analysis of outcome and impact should ideally be a part of an existing country-led review process (national program reviews, joint health sector reviews, external program evaluations etc.) and should be used to inform the Global Fund Periodic Review[38] / Phase 2 decisions[39]. Reviews should occur within a year prior to the date of the submission of the CCM Request.

At the time of Periodic Reviews, countries will also be assessed on data quality, quality of services and equity. The Global Fund, through the Local Fund Agent, routinely undertakes assessment of data quality through on-site data verification. A Rapid Quality of Services Assessment (RSQA) will be rolled out, which will assess the quality of service delivery in health facilities. Countries are also asked to report disaggregated data for notification and treatment outcomes by identified risk categories. The identification of risk categories and the progress among identified risk groups should be based on equity assessments. Countries should also plan for such assessments as part of program M&E and national reviews. For more information on these requirements, see Part 1 of the toolkit.

38 See OPN on periodic reviews in the Operational Policy Manual, available at: http://www.theglobalfund.org/WorkArea/DownloadAsset.aspx?id=7125

39 See Guidance Note to The Global Fund. Value for money checklist for Round 10 grant negotiations. Available at: http://intranet.theglobalfund.org/Operational-Policy/Documents1/VFM%20Guidance%20Note%20and%20Checklist_%20Final.doc

Several countries already have been undertaking Joint Monitoring and Evaluation Missions to assess the performance of a TB program/project and to ascertain whether activities are carried out according to guidelines and plans. The reports of these joint monitoring missions could provide additional input to the Global Fund Periodic Review process.

BOX 5.
Joint Program Monitoring and Evaluation

WHO has developed an M&E guide for national TB programs[40], which describes the process of monitoring, and provides guidance to program staff, external consultants and civil society organizations (including nongovernmental, community-based, patient-based, and faith-based organizations) on how to conduct a mission to assess performance. The guide provides a common platform that responds to both project and program performance assessments required by national TB programs and other funding partners. A project-monitoring mission is restricted to activities specified in the project design, geographical area or a specific technical area.

Joint M&E missions should cover as many aspects of a country's TB control program as possible, including all implementing partners, and provide a description of the country's situation. However, there is a practical limit to the number of program areas than can be covered and sites that can be monitored given time constraints and the size of the mission team.

An in-depth analysis of the epidemiological situation of TB in the country[41] is an essential step that needs to be undertaken prior to the monitoring mission. An epidemiological report should be prepared by a national team and sent in advance to the mission coordinators. The external monitoring coordinator should prepare clear terms of reference for the epidemiological report, which will usually include a review of past trends in TB epidemiology and predictions for the future.

6.2 Evaluations

In addition to program reviews, countries should adequately plan for and strategically use evaluations to improve their TB response. Evaluations provide the opportunity to systematically and objectively assess the relevance, performance, quality and impact of ongoing and completed programs.

Ideally, evaluations are planned at the beginning of the programs and can be undertaken at any stage of program implementation (formative or process evaluations, or outcome/impact evaluations). The design of program evaluations should coincide with the development of a national TB strategic plan. As part of the development of a national M&E plan, the design of an integrated and comprehensive program evaluation plan should be consultative, participatory and inclusive, to ensure relevance and methodological and scientific soundness. In addition to the overall program evaluations to assess progress towards program goals and objectives, specific interventions could be evaluated for their feasibility, efficiency, effectiveness, impact, relevance and sustainability. The interventions that cannot be routinely monitored through a set of programmatic indicators (due to limitations of routine TB information systems) such as PAL, PPM DOTS, community TB care, ACSM, operational research investments etc., should be evaluated periodically as part of the overall evaluation of TB programs.

6.3 Operations Research

TB programs require knowledge and evidence of the effectiveness of interventions to optimize policies, improve coverage, enhance service quality and increase operational efficiency. The demand for evidence has led to a more proactive approach to promoting operational/implementation research to benefit TB control efforts. Designing and conducting locally relevant operational research also helps identify problems, determine and field-test workable solutions and plan for scale-up. For this purpose, sustainable partnerships and networks should be established between program managers and researchers. To facilitate and encourage programmatic research, national programs should prioritize and develop an operations research agenda relevant to the country context. WHO has recently developed a guidance document on operations research priorities for TB control.[42]

As a general guidance, operations research should be low cost and require limited staff time. It should not divert excessive resources from service delivery and disease reduction activities. Such studies should be of relatively short duration, so that the results are available rapidly and necessary program changes could be initiated quickly. The studies should be based on simple standard protocols, repeated in different environments. They should give priority to testing solutions to identified problems and developing new implementation methods to improve programs.

40 World Health Organization (WHO). Operational Guide for Conducting a Joint Monitoring and Evaluation of a National Tuberculosis Programme. Geneva, WHO, 2011 (WHO/HTM/TB/2011.13).

41 World Health Organization. TB epidemiology and surveillance virtual workshop – status analysis and trend analysis. Available from: http://apps.who.int/tb/surveillanceworkshop/trend_analysis/exploration_of_notification_data.htm

42 World Health Organization. Priorities in operational research to improve tuberculosis care and control. Geneva: World Health Organization. Available from: http://www.who.int/tb/features_archive/operational_research_priorities/en/index.html

BOX 6.
Illustrative List of Operations Research Priorities[43,44]
(Reproduced from *Priorities in Operational Research to Improve Tuberculosis Care and Control*)

- **Improving access, screening and diagnosis of TB**
  - *How to improve access to TB diagnosis?*
  - *How to improve screening of patients and high-risk groups?*
  - *How to use the introduction of new tools to improve service delivery practices?*
  - *How to improve active TB case-finding?*
  - *How to build accessible, effective and efficient diagnostic services with new diagnostic tools?*
- **Developing sustainable collaboration with all care-providers for TB care and control:**
  - *How to improve and scale up existing approaches to engaging all care-providers?*
  - *How to measure the contribution of different provider groups to TB care and control?*
  - *How to encourage involvement of as yet unengaged providers?*
  - *How to encourage involvement of the nonpublic sector in MDR-TB management and TB/HIV collaborative activities?*
  - *How to develop and assess responses to the changing involvement of diverse providers in TB care and control?*
  - *How to encourage introduction of regulatory approaches to collaborating care-providers?*
- **Prevention of TB in people living with HIV (PLHIV) and joint treatment of TB and HIV:**
  - *What are the barriers to TB diagnosis, and how to overcome these barriers?*
  - *What are the barriers to initiation of isoniazid preventive therapy?*
  - *What are the barriers to optimal combined TB/HIV diagnosis and treatment, and what are the optimal models for joint TB and HIV care activities?*
- **Treatment of drug-susceptible (DS) and M/XDRTB: optimal access, delivery and community participation:**
  - *What are the reporting gaps and deficiencies in first-line management of TB cases?*
  - *How to address these deficiencies and improve management of drug-sensitive TB?*
  - *What are the drivers of drug-resistant TB at the individual and programmatic levels?*
  - *What are the potential strategies for integration/scale-up of drug-resistant TB management within TB control programs?*
  - *How to reinforce PPM collaboration for treatment of DS- and DR-TB?*
  - *How to improve decentralized and fully integrated access to TB and antiretroviral treatment?*
- **Capacity-building for operational research:**
  - *What are the existing models of operational health research capacity?*
  - *What is the impact of existing training models in terms of products, outputs and outcomes?*
  - *How to ensure sustainable operational research capacity at the national level?*

7. Resources

This section provides a brief overview of the technical resources and support available to grant implementers and national TB programs. It also provides an updated list of TB guidelines and other reference documents.

7.1 General resources

The WHO Stop TB Department regularly produces updates on the assessment of the TB epidemic and progress made in TB control at global, regional and country level. They also contribute to strengthening TB measurement frameworks and tools, and strengthen national capacity in monitoring and evaluating TB control programs.

The following Stop TB Partnership Working Groups on implementation provide a focus for coordinated action and support monitoring and evaluation of country-level activities related to:

- *DOTS expansion, including subgroups, public-private mix and childhood TB;*
- *TB/HIV;*
- *multidrug-resistant TB;*
- *advocacy, communication and social mobilization (ACSM);*
- *the Global Working Group on Indicators – a partnership between WHO, the World Bank, the United States Centers for Disease Control and Prevention, the International Union against Tuberculosis and Lung Disease, the KNCV Tuberculosis Foundation, the United States Agency for International Development and MEASURE Evaluation.*

43 Priorities in Operational Research to Improve Tuberculosis Care and Control. Geneva: WHO; 2011. Available from: http://www.stoptb.org/assets/documents/resources/publications/technical/StopTB%20Guide.pdf

44 World Health Organization. A research agenda for childhood tuberculosis. Available from: http://whqlibdoc.who.int/hq/2007/WHO_HTM_TB_2007.381_eng.pdf

7.2 Technical support: TBTEAM

TBTEAM, the TB Technical Assistance Mechanism of the Stop TB Partnership, coordinates technical assistance from Stop TB technical partners to countries for Global Fund grant proposal preparation, implementation of grants and ongoing grant monitoring.

TBTEAM optimizes the functioning of the network of Stop TB partners, including national TB programs, local and international nongovernmental organizations, funding partners and WHO at the country, regional and global levels. It links with the Green Light Committee Initiative, the Global Laboratory Initiative, the Global Drug Facility, the Tuberculosis Control Assistance Program (TBCAP) and all working groups of the Stop TB Partnership. It provides a platform for coordination, encourages collaboration, promotes available expertise and facilitates planning for technical assistance according to needs. TBTEAM aims to promote local ownership of planning for and access to technical assistance based on sound technical discussion by national interagency coordinating committees or other TB coordination mechanisms.

The TBTEAM tools launched in September 2007 were developed to facilitate access to high-quality technical assistance; to encourage planning at national, regional and global levels, but most importantly at national level. The tools help to improve the efficiency of technical assistance by ensuring that needs are met while minimizing redundant technical assistance, and they promote capacity-building at all levels through technical assistance planning and training of consultants according to international standards.

The team facilitates access to and coordination of technical assistance through Stop TB missions and events (including open requests for assistance), Stop TB experts, and Stop TB partner mapping. These tools can be viewed at http://www.stoptb.org/countries/tbteam/gdocs.asp. Countries may apply for technical assistance through the standard WHO channels by submitting requests to country offices or other TBTEAMs at the country, regional and global levels. For help in identifying the relevant TBTEAM focal point or other information, the global TBTEAM Secretariat can be contacted at: tbteam@who.int.

BOX 7.
Global TB Initiatives

- *The Green Light Committee (GLC) Initiative:[45] The GLC Initiative was launched by the Stop TB Partnership in 2000 to support countries in their fight to halt MDR-TB. The initiative is comprised of the GLC Committee, the WHO/GLC Secretariat, the Global Drug Facility (GDF), and partners who provide financial and technical assistance. (http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/)*
- *Global Drug Facility (GDF): Established in 2001 as an initiative to increase access to high quality TB drugs for DOTS implementation: a TB control strategy. The global drug facility provides a unique package of services, including technical assistance in TB drug management and monitoring of TB drug use, as well as procurement of high-quality TB drugs (first-line and second-line), diagnostics and consumables at low cost. (http://www.stoptb.org/gdf/)*
- *Global Laboratory Initiative (GLI): Established in 2008, GLI works closely with national TB programs, nongovernmental organizations, technical and financial agencies, scientific and academic institutions, and WHO offices at country and regional levels in strengthening TB laboratory services. Initiative activities include: global policy guidance on appropriate laboratory technology and best practices; effective technology transfer and coordination of technical assistance; laboratory advocacy and resource mobilization; laboratory capacity development; interface with other laboratory networks to ensure appropriate integration; standardized laboratory quality assurance; and effective knowledge sharing. (http://www.who.int/tb/laboratory/gli/en/index.html)*

7.3 Guidelines and essential references

Stop TB Strategy and Global Plan

- The Stop TB Strategy: Building on and enhancing DOTS to meet the TB-related Millennium Development Goals. Geneva, World Health Organization and Stop TB Partnership, 2006. (http://www.stoptb.org/assets/documents/resources/publications/plan_strategy/The_Stop_TB_Strategy_Final.pdf)
- The Global Plan to Stop TB 2011-2015. Transforming the fight. Towards elimination of TB. Geneva: World Health Organization and Stop TB Partnership, 2011. (http://www.stoptb.org/assets/documents/global/plan/TB_GlobalPlanToStopTB2011-2015.pdf)
- Implementing the Stop TB Strategy: a handbook for national tuberculosis control programs. Geneva: World Health Organization; 2008. (http://www.who.int/tb/publications/2008/who_htm_tb_2008_401_eng.pdf).

45 The Global Fund to Fight AIDS, TB and Malaria. Scaling-up effective management of drug-resistant tuberculosis. Information note. Available from: http://www.theglobalfund.org/en/application/infonotes/

- Stop TB Planning Matrix and Frameworks Tool. Geneva: World Health Organization; 2011 (http://www.who.int/tb/dots/planningframeworks/en/index.html).
- Planning the development of human resources for health for implementation of the Stop TB Strategy - A handbook. Geneva: World Health Organization; 2009. (http://whqlibdoc.who.int/publications/2009/9789241597715_eng.pdf)
- Stop TB Policy Paper: Contributing to health system strengthening. Guiding principles for national tuberculosis programs. Geneva: World Health Organization; 2008. (http://whqlibdoc.who.int/publications/2008/9789241597173_eng.pdf)

Tuberculosis

- Treatment of tuberculosis: guidelines - 4th edition. Geneva: World Health Organization; 2010. (http://whqlibdoc.who.int/publications/2010/9789241547833_eng.pdf)
- Rapid advice: treatment of tuberculosis in children. Geneva: World Health Organization; 2010. (http://whqlibdoc.who.int/publications/2010/9789241500449_eng.pdf)
- Management of Tuberculosis Training for Health Facility Staff - 2nd edition. Geneva: World Health Organization; 2009. (http://www.who.int/tb/publications/2010/who_htm_tb_2009_423/en/index.html)
- An expanded DOTS framework for effective tuberculosis control. Geneva: World Health Organization; 2002 (http://www.who.int/gtb/publications/dots/pdf/TB.2002.297.pdftb/dots/framework/en/index.html).
- Good practice in legislation and regulations for TB control: an indicator of political will. Geneva: World Health Organization; 2001 (http://whqlibdoc.who.int/hq/2001/WHO_CDS_TB_2001.290.pdf).

Laboratory Diagnosis

- Laboratory services in tuberculosis control. (http://www.who.int/tb/publications/who_tb_98_258/en/index.html)
- Briefing note: TB diagnostics and laboratory and laboratory strengthening. (http://www.stoptb.org/wg/gli/assets/documents/BRIEFING%20NOTE%20LABS%20for%20GC.pdf)
- A Roadmap for Ensuring Quality Tuberculosis Diagnostics Services within National Laboratory Strategic Plans, 2010. (http://www.who.int/tb/laboratory/tool_set/en/index.html)
- Laboratory tool set. (http://www.who.int/tb/laboratory/tool_set/en/index.html)
- Acid-Fast Direct Smear Microscopy Training Package (http://wwwn.cdc.gov/dls/ila/acidfasttraining/)
- External Quality Assessment for AFB Smear Microscopy (http://wwwn.cdc.gov/dls/ila/documents/eqa_afb.pdf)
- Rapid implementation of the Xpert MTB/RIF diagnostic test. Technical and operational 'How-to'. Practical considerations, 2011. (http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf)
- Prerequisites to country implementation of Xpert MTB/RIF and key action points at country level: Checklist, 2011. (http://whqlibdoc.who.int/hq/2011/WHO_HTM_TB_2011.12_eng.pdf)
- Policy Framework for Implementing New Tuberculosis Diagnostics (http://www.who.int/tb/laboratory/whopolicyframework_rev_june2011.pdf)
- Policy statement: Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF system, 2011. (http://whqlibdoc.who.int/publications/2011/9789241501545_eng.pdf)
- Policy statement: Same-day diagnosis of tuberculosis by microscopy (http://whqlibdoc.who.int/publications/2011/9789241501606_eng.pdf)
- Policy statement: Fluorescent light-emitting diode (LED) microscopy for diagnosis of tuberculosis (http://whqlibdoc.who.int/publications/2011/9789241501613_eng.pdf)
- Policy statement: Molecular line probe assays for rapid screening of patients at risk of multidrug-resistant tuberculosis 2008. (http://www.who.int/tb/features_archive/policy_statement.pdf)
- Policy Statement: Commercial Serodiagnostic Tests for Diagnosis of Tuberculosis, 2011. (http://whqlibdoc.who.int/publications/2011/9789241502054_eng.pdf)

Drug-Resistant TB

- Guidelines for the programmatic management of drug-resistant tuberculosis 2011 update. Geneva: World Health Organization;2011 (http://whqlibdoc.who.int/publications/2011/9789241501583_eng.pdf)
- Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva: World Health Organization; 2008 (http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf).
- Multidrug-resistant tuberculosis (MDR-TB) indicators: A minimum set of indicators for the programmatic management of MDR-TB national tuberculosis control programs. Geneva: World Health Organization;2011 (http://whqlibdoc.who.int/hq/2010/WHO_HTM_TB_2010.11_eng.pdf)
- Towards universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis by 2015 WHO progress report 2011. Geneva: World Health Organization; 2011. (http://whqlibdoc.who.int/publications/2011/9789241501330_eng.pdf)
- Guidelines for surveillance of drug resistance in tuberculosis. Fourth Edition. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241598675_eng.pdf)

TB/HIV

- Antiretroviral therapy for HIV infection in adults and adolescents. Recommendations for a public health approach. 2010 revision. World Health Organization 2010. (http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf)

- Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings. Geneva: World Health Organization; 2011. (http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf)
- Priority research questions for TB/HIV in HIV-prevalent and resource-limited settings. Geneva: World Health Organization; 2010. (http://whqlibdoc.who.int/publications/2010/9789241500302_eng.pdf)
- WHO policy on collaborative TB/HIV activities: Guidelines for national programmes and other stakeholders: http://whqlibdoc.who.int/publications/2012/9789241503006_eng.pdf
- Patient monitoring guidelines for HIV care and antiretroviral therapy (ART). Geneva: World Health Organization; 2006. Available at: http://www.who.int/hiv/pub/imai/PatientGuide/en/index.html.
- A guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2009. Available at: http://whqlibdoc.who.int/publications/2009/9789241598194_eng.pdf.

Others: Public Private Mix (PPM); Advocacy Communication & Social Mobilization (ACSM): Infection Control; Practical Approach to Lung Health (PAL); etc.

- Engaging all health care providers in TB control: guidance on implementing public–private mix approaches. Geneva: World Health Organization; 2006 (http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.360_eng.pdf).
- Public–private mix for DOTS: practical tools to help implementation. Geneva: World Health Organization; 2003 (http://www.who.int/tb/publications/2003/en/index.html).
- Public–private mix for TB care and control: a tool for national situation assessment. Geneva: World Health Organization; 2007 (http://www.who.int/tb/publications/2007/en/index.html).
- Public-PrivateMixforTBcareandcontrol:atoolkit.Geneva: World Health Organization; 2010. (http://whqlibdoc.who.int/publications/2010/9789241500487_eng.pdf)
- Guidelines for control of Tuberculosis in prisons. (http://www.tbcta.org//Uploaded_files/Zelf/GuidelineTBPrisons1252321251.pdf)
- Advocacy, communication and social mobilization (ACSM) for tuberculosis control. A handbook for country programs. Geneva: World Health Organization; 2007. (http://whqlibdoc.who.int/publications/2007/9789241596183_eng.pdf)
- Advocacy, communication and social mobilization for TB control: A Guide to Developing Knowledge, Attitude and Practice Surveys. Geneva: World Health Organization; 2008. (http://whqlibdoc.who.int/publications/2008/9789241596176_eng.pdf)
- Advocacy, communication and social mobilization: collection of country-level good practices. (http://www.stoptb.org/assets/documents/resources/publications/acsm/ACSM_final_24%20Nov.pdf)
- TB/MDR TB Advocacy Toolkit: (http://www.advocacypartnership.org/userfiles/files/AP_fulldocument_web.pdf)
- Partnership Centre for Resource Mobilization. (http://www.stoptb.org/getinvolved/resmob/)
- Working with the media: how to make your messages on tuberculosis count: (http://www.stoptb.org/assets/documents/resources/publications/acsm/Working%20with%20the%20Media%20Final%20Web.pdf)
- WHO policy on TB infection control in health-care facilities, congregate settings and households. Geneva: World Health Organization; 2009. (http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf)
- guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2009. Available at: http://whqlibdoc.who.int/publications/2009/9789241598194_eng.pdf.
- WHO policy on TB infection control in health-care facilities, congregate settings and households. Geneva, World Health Organization, 2009. (http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf)
- Implementing the WHO Policy on TB Infection Control in Health-CareFacilities,CongregateSettingsandHouseholds (http://www.stoptb.org/wg/tb_hiv/assets/documents/TBICImplementationFramework1288971813.pdf)
- TB IC Advocacy Strategy Final April 2010. (http://www.stoptb.org/wg/tb_hiv/assets/documents/TB%20IC%20Advocacy%20Strategy%20Final%20April%202010.pdf)
- Practical approach to lung health Manual on initiating PAL implementation. Geneva: World Health Organization; 2008. (http://whqlibdoc.who.int/hq/2008/WHO_HTM_TB_2008.410_eng.pdf)
- Somma D et al. Gender in tuberculosis research. Geneva: World Health Organization; 2005 (http://www.who.int/gender/documents/TBlast2.pdf).
- Gender and tuberculosis. Geneva: World Health Organization; 2002 (http://www.who.int/gender/other_health/en/genderTB.pdf).

Monitoring & Evaluation and Operations Research

- Compendium of indicators for monitoring and evaluating national tuberculosis programs. Geneva: World Health Organization; 2004 (http://www.who.int/tb/publications/2004/en/index.html).
- Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva: World Health Organization; 2006 (http://www.who.int/tb/dots/r_and_r_forms/en).

- A guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241598194_eng.pdf)
- Manual on use of routine data quality assessment (RDQA) tool for TB monitoring. Geneva: World Health Organization; 2011. (http://whqlibdoc.who.int/publications/2011/9789241501248_eng.pdf)
- TB impact measurement: policy and recommendations for how to assess the epidemiological burden of TB and the impact of TB control (WHO/HTM/TB/2009.416). Geneva: World Health Organization; 2009. (http://whqlibdoc.who.int/publications/2009/9789241598828_eng.pdf)
- Tuberculosis prevalence surveys: a handbook (The lime book). Geneva: World Health Organization; 2011. (http://whqlibdoc.who.int/publications/2011/9789241548168_eng.pdf)
- Dye C, Bassili A, Bierrenbach AL, Broekmans JF, Chadha VK, Glaziou P, et al. Measuring tuberculosis burden, trends, and the impact of control programs. Lancet Infect Dis 2008;8:233-43. doi:10.1016/S1473-3099(07)70291-8 PMID:18201929
- Korenromp EL, Bierrenbach AL, Williams BG, Dye C. The measurement and estimation of tuberculosis mortality. Int J Tuberc Lung Dis 2009;13:283-303. PMID:19275787
- Global tuberculosis control: surveillance, planning, financing – WHO report 2008. Geneva: World Health Organization; 2008 (http://www.who.int/tb/publications/global_report/en/index.html).
- Global tuberculosis control 2010 (WHO/HTM/TB/2010). Geneva: World Health Organization; 2010.
- Multidrug and extensively drug-resistant TB (M/XDR-TB): 2010 global report on surveillance and response. Geneva: World Health Organization; 2010. (http://whqlibdoc.who.int/publications/2010/9789241599191_eng.pdf)
- The use of indicators for communicable disease control at district level. Geneva: World Health Organization; 2001 (http://whqlibdoc.who.int/hq/2001/WHO_CDS_TB_2001.289.pdf).
- Priorities in Operational Research to Improve Tuberculosis Care and Control. Geneva: WHO. 2011. (http://www.stoptb.org/assets/documents/resources/publications/technical/StopTB%20Guide.pdf)

8. Description of TB indicators

TB outcome indicator
High-quality DOTS

Notification rate of all forms of TB cases: **TB cases (all forms) notified to the national health authorities during a specified period (per 100,000 population)**

Rationale

The indicator provides information on the burden of disease, number of cases to be treated and resources required. Information on the true incidence or prevalence of TB disease is unlikely to be available. However, the notification rate can be a close proxy of TB incidence where the coverage and quality of the routine surveillance system is high. Trends over time in case notification usually indicate changes in program coverage and capacity to detect TB cases. At high levels of case detection, the indicator reflects changes in the prevalence of TB in the community. For example, an upward trend in case notification rates can reflect an improvement in program performance or, in some cases, the impact of the HIV/AIDS epidemic.

Case notification represents only a subset of the true number of cases arising in a country because of incomplete coverage by health services, inaccurate diagnosis, or deficient recording and reporting. Notifications reported by ministries of health often do not include cases managed by the private sector; this emphasizes the need to improve efforts to gather data from the private sector. Although in most countries, case notifications underrepresent the true burden of disease, they often represent the most useful data for estimating incidence.

The number of total TB cases is influenced by the capacity to diagnose extra-pulmonary and smear-negative pulmonary cases (availability of culture and other diagnostic methods), by clinician skill in interpreting chest X-ray abnormalities, by the capacity and criteria to diagnose TB in children, and by the coverage of reporting of TB in children. When possible, this indicator should also be analyzed by age and gender.

Definition of the indicator

Numerator: Number of TB cases (all forms) registered and reported [in a specified area] to the national health authority in the past year (x 100,000)

Denominator: Total population in the specified area

All forms of TB includes new smear-positive, new smear-negative, extra-pulmonary, and relapse cases.

The numerator is also reported as an output indicator.

Measurement

This indicator is measured annually at the national, regional or district level.

The numerator is the number of all forms of TB cases reported to the national TB control program (reports ultimately come from TB registers in each operational unit). The denominator is the total population in the country/region/district/BMU that is reporting.

Platform: quarterly reports on TB case registration, TB register. This indicator is collected as part of routine quarterly reporting.

Frequency: quarterly and annually

Disaggregation: For countries using culture for TB diagnosis, the number of bacteriologically confirmed cases may be reported as an additional indicator. For countries using Xpert MTB/RIF for TB diagnosis, the number of cases confirmed by Xpert MTB/RIF may be reported as an additional indicator.

In countries with sizeable number of retreatment cases being notified (failures, treatment after default and others), these may be reported separately in addition to all forms (new and relapse) of TB cases.

Notification rates are known to vary by age, sex, urban/rural residence or other risk category. Where applicable (in proposal objectives, equity assessment etc.), based on routine reporting or in a sample of randomly selected districts or sites, report disaggregated information on cases notified by the identified risk group at Periodic Review.

Target setting: The target setting should be based on an assessment of the TB surveillance systems, reviewing the completeness of data, identifying where cases are being missed, and estimating the likely yield of case-finding efforts (e.g. intensified case-finding for TB/HIV, PPM, ACSM, and Community mobilization). At the national level, the trends in case notification should be in line with trends over the last four to five years, and should take into account case finding efforts, and documented evidence of changes in disease epidemiology. Stagnant or declining case notifications in absence of documented evidence should not be equated to decline in TB incidence.

Resources

Compendium of indicators for monitoring and evaluating national tuberculosis programs. Geneva, World Health Organization, 2004 (http://www.who.int/tb/publications/2004/en/index.html).

Global tuberculosis control: epidemiology, strategy, financing – WHO report 2009 Update. Geneva, World Health Organization, 2009. http://www.who.int/tb/publications/global_report/2009/update/en/index.html.

Rapid implementation of the Xpert MTB/RIF diagnostic test. Technical and operational 'How-to.' Practical considerations, 2011. (http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf)

TB outcome indicator

High-quality DOTS

Notification rate of new smear-positive TB cases: **New smear-positive TB cases notified to the national health authorities during a specified period (per 100,000 population)**

Rationale

The indicator is a direct measure of program capacity to identify infectious cases. In line with the WHO recommendations, less emphasis is now being placed on the case detection rate. However, there is an increasing emphasis on achieving universal access to health care, which implies detecting and treating well in excess of 70 percent of cases. Effort should be to increase the percentage of TB cases that are diagnosed and treated according to international guidelines. In many countries, one of the best ways to do this is for national TB programs to establish collaboration with the full range of health-care providers through various PPM and community initiatives. NTPs should start recording the data on the source of referral and the place of treatment of TB cases on a routine basis to quantify the increase in case detection through PPM and community involvement.

Trends over time in case notification usually indicate changes in program coverage and the capacity to detect TB cases. At high levels of case detection, the indicator reflects changes in the incidence of TB in the community. Trends in notification rates inform program planning and M&E, and should be used to guide these activities. For example, an upward trend in case notification rates can reflect an improvement in program performance or, in some cases, the impact of the HIV/AIDS epidemic. When possible, this indicator should also be analyzed by age and sex.

The number of new pulmonary smear-positive TB cases provides a better comparison and trends over time between countries and areas than the number of total cases, because it uses a single, objective method (sputum microscopy). However, case notifications represent only a subset of the true number of cases arising in a country because of incomplete coverage by health services or deficient recording and reporting. Although, in most countries, case notifications underrepresent the true burden of disease, they often represent the most useful data for estimating incidence.

Definition of the indicator

Numerator: Number of new smear-positive pulmonary TB cases [in a specified area] registered and reported to the national health authority in the past year (x 100,000)

Denominator: Total population in the specified area

The numerator is also reported as an output indicator.

Measurement

This indicator is measured annually at the national, regional or district level.

The numerator is the number of new smear-positive TB cases reported to the national TB control program (reports ultimately come from TB registers in each operational unit). The denominator is the total population in the country/region/district/BMU that is reporting.

Platform: quarterly reports on TB case registration, TB register. This indicator is collected as part of routine quarterly reporting

Frequency: annually

Disaggregation: For countries using culture for TB diagnosis, the number of bacteriologically confirmed cases may be reported as an additional indicator. For countries using Xpert MTB/RIF for TB diagnosis, the number of cases confirmed by Xpert MTB/RIF may be reported as an additional indicator.

Notification rates are known to vary by age, sex, urban/rural residence or other risk category, Where applicable (proposal objectives, equity assessment etc.), based on routine reporting or in a sample of randomly selected districts or sites, report disaggregated information on cases notified by identified risk group at Periodic Review.

Resources

Compendium of indicators for monitoring and evaluating national tuberculosis programs. Geneva, World Health Organization, 2004 (http://www.who.int/tb/publications/2004/en/index.html).

Global tuberculosis control: epidemiology, strategy, financing – WHO report 2009 Update. Geneva, World Health Organization, 2009. http://www.who.int/tb/publications/global_report/2009/update/en/index.html.

Rapid implementation of the Xpert MTB/RIF diagnostic test. Technical and operational 'How-to'. Practical considerations, 2011. (http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf)

TB outcome indicator

High-quality DOTS

Treatment success rate of new smear-positive TB cases: **New smear-positive TB cases successfully treated (cured plus treatment completed) among the new smear-positive TB cases notified to the national health authorities during a specified period (number and percentage)**

Rationale

Evaluation of successful treatment outcomes of new smear-positive pulmonary TB cases is used to determine the quality and effectiveness of DOTS implementation at all levels. A treatment success rate of 90 percent is the global target.

Definition of the indicator

Numerator: Number of new smear-positive pulmonary TB cases in a specified period who subsequently were successfully treated (sum of WHO outcome categories "cured" plus "treatment completed")

Denominator: Total number of new smear-positive pulmonary TB cases registered for treatment in the same period

This indicator is also reported as an output indicator to facilitate performance-based funding at each Progress Update and Disbursement Request (PU/DR).

Measurement

Each smear-positive TB case is assigned a treatment outcome, which is recorded in the TB register. Outcomes for all new smear-positive TB cases are reported by registration period (usually a quarter or year) after initial registration.

Platform: TB register; quarterly reports on TB treatment outcomes and TB/HIV activities in districts or BMUs

Frequency: quarterly and annually

Disaggregation: Treatment outcomes may vary by age, sex or other risk category due to differential access to care, or compliance to treatment, or other underlying risk factors. Where applicable (proposal objectives, equity assessment), based on either routine reporting; or in a sample of randomly selected districts or sites, report disaggregated treatment outcomes by sex or risk category for new smear-positive TB cases at least at Periodic Review/ Phase 2.

Where applicable (proposal objectives, equity assessment), report separately for new smear-positive TB cases provided with treatment in prisons, or by a specific type of health care provider or the community and by HIV status.

Resource

Compendium of indicators for monitoring and evaluating national tuberculosis programs. Geneva, World Health Organization, 2004 (http://www.who.int/tb/publications/2004/en/index.html).

TB indicator
Improving diagnosis

Quality assurance for smear microscopy: **Laboratories showing adequate performance in external quality assurance for smear microscopy among the total number of laboratories that undertake smear microscopy during the reporting period (number and percentage).**

Quality assurance for culture examination: **Laboratories showing that the proportion of culture positive results in AFB-positive TB patients (not yet initiated on treatment), is >90% among the laboratories that undertake culture examination during the reporting period (number and percentage)**

Quality assurance for drug susceptibility testing: **Laboratories showing at least 95 percent proficiency for isoniazid and rifampicin drug susceptibility testing among the total number of laboratories that undertake drug susceptibility testing during the reporting period (number and percentage).**

Rationale

This indicator is divided into three parts that measure separately the presence and performance of external quality assurance for smear microscopy, culture and drug susceptibility testing. An external quality assurance system is defined as a system to continually improve the reliability, efficiency and use of TB laboratory services. National TB programs should have a quality assurance system that covers all TB laboratories in the country.

Definition of the indicator

Numerator: Number of laboratories showing adequate performance (specify: (a) smear microscopy, (b) culture or (c) drug susceptibility testing)

Denominator: Total number of laboratories undertaking (a) smear microscopy (b) culture, and (c) drug susceptibility testing during a specified period for smear microscopy, culture or drug susceptibility testing (as relevant)

Measurement

External quality assurance for smear microscopy is performed by rechecking slides. No error of any type is considered a target for optimal performance. Any major error (high false-positive or high false-negative) may indicate unacceptable performance.

External quality assurance for culture is monitored by :

- *contribution of culture to diagnosis over microscopy (smear-negative culture-positive/number of specimens processed for culture): at least 20 percent;*
- *culture tube contamination rate: <5 percent on solid media and <10 percent on liquid media; and*
- *smear-positive culture-negative rate, not > 2-3 percent*

  (All rates calculated for adults with pulmonary TB investigated for diagnosis)

External quality assurance for drug susceptibility testing is performed using stain panel testing, minimum agreement higher than 95 percent for isoniazid and rifampicin.

Platform: laboratory register; DST register, culture records, patient laboratory request form; quality assurance results forms

Frequency: quarterly and annually for microscopy and culture, annually for drug susceptibility testing

Resources

A Roadmap for Ensuring Quality Tuberculosis Diagnostics Services within National Laboratory Strategic Plans, 2010. (http://www.who.int/tb/laboratory/tool_set/en/index.html)

Laboratory tool set. (http://www.who.int/tb/laboratory/tool_set/en/index.html)

TB indicator

Procurement and supply management

Stock-outs of first-line anti-TB drugs: **Reporting units (districts or basic management units) reporting no stock-out of first-line anti-TB drugs on the last day of the quarter (number and percentage)**

Stock-outs of second-line anti-TB drugs: **Reporting units (districts or basic management units) reporting no stock-out of second line anti-TB drugs on the last day of the quarter (number and percentage)**

Rationale

This indicator is a simple, easily collected measure from the quarterly TB drug order on availability of stock on the last day of previous quarter at the district or basic management unit (BMU) level (column F of the quarterly drug order). It does not measure the availability of TB drugs at the peripheral health center or at patient level but only at the district or BMU level. District and BMU data are aggregated at the upper level and nationwide. For second-line drugs, these are again measured for districts or basic management units that stock second line drugs.

Definition of the indicator

Numerator: Number of reporting units (districts or BMUs) reporting no stock-out of any of the (1) first-line anti-TB drugs or (2) second-line anti-TB drugs used in the national TB program during a defined period:

- ***Recommended first-line anti-TB drugs following national guidelines:***
  - *rifampicin*
  - *isoniazid*
  - *pyrazinamide*
  - *ethambutol*
  - *streptomycin*
- ***Recommended second-line anti-TB drugs following national guidelines***
  - *second-line injectable drug (kanamycin/ amikacin/ capreomycin)*
  - *second-line fluoroquinolones (levofloxacin/ moxifloxacin/ gatifloxacin/ ofloxacin)*
  - *second-line oral bacteriostatic drug (ethionamide/ prothionamide/ cycloserine/ terizidone/ p-aminosalicylic acid)*

Denominator: Total number of reporting units (districts or BMUs)

Measurement

Ideally, a national TB program records the remaining drug stock every quarter or year.

Platform: national TB program records; quarterly drug order at the district or BMU level

Frequency: quarterly and annually

Resource

Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006 (http://www.who.int/tb/dots/r_and_r_forms/en).

TB indicator
Monitoring and evaluation

Timeliness of routine reporting: **Reporting units at all levels of data flow submitting timely reports according to national guidelines (number and percentage)**

Rationale

This indicator measures the timeliness (as required by the national TB program) and completeness (submitting both case-finding and treatment outcome reports) of TB report submission. Ideally, all required case-finding and treatment outcome reports should be complete and submitted on time. Each national TB program should determine the acceptable level of completeness required for each report in the designated time frame. If the total number of reports submitted falls below this threshold, this indicates a need to consider an appropriate course of action to increase to an acceptable level the number of complete reports submitted. The indicator may be disaggregated by completeness or timeliness based on identified gap in M&E systems. The indicator may be analyzed at national, provincial or district level.

Definition of the indicator

Numerator: Number of reporting units at all levels of data flow that submitted timely case-finding and treatment outcome reports to the national TB program in the previous quarter

Denominator: Total number of reporting units at all levels of data flow required to submit case-finding and treatment outcome reports to the national TB program each quarter

Measurement

The numerator is the number of units that submitted case-finding and treatment outcome reports to the national TB program in the previous quarter. A unit is included in the numerator only if it submitted both reports to the national TB program. The denominator is the total number of units required to submit case-finding and treatment outcome reports to the national TB program in the previous quarter. This indicator is measured at the central level in a country on a quarterly basis. In addition, the indicator should be separated into different levels of reporting (district to region and region to national TB program) and measured for the most recent reporting period for monitoring purposes.

Platform: national TB program statistics and reports

Frequency: quarterly and annually

Resource

Compendium of indicators for monitoring and evaluating national tuberculosis programs. Geneva, World Health Organization, 2004 (http://www.who.int/tb/publications/2004/en/index.html).

TB indicator
TB/HIV

Proportion of TB patients with known HIV status: **TB patients registered during the reporting period who had an HIV test result recorded in the TB register among the total number of TB patients registered during the reporting period (number and percentage)**

Rationale

This indicator measures the HIV status among TB patients. TB is the leading cause of morbidity and mortality among people living with HIV in many countries. In addition, TB patients have high rates of HIV co-infection in settings with high HIV prevalence. In these settings, ensuring that TB patients receive HIV testing and counselling services should be a high priority. Knowledge of HIV status enables HIV-positive TB patients to access the most appropriate HIV prevention, treatment, care and support services. Trends over time will demonstrate progress towards national and international targets.

Definition of the indicator

Numerator: Number of TB patients registered during the reporting period who had an HIV test result recorded in the TB register

Denominator: Total number of TB patients registered during the reporting period

Measurement

The numerator should include all TB patients who were previously known to be HIV-positive (documented evidence of enrollment in HIV care) or their negative HIV result from previous testing was acceptable to the clinician (such as performed in the past three to six months in a reliable laboratory).

Ideally, all TB patients with unknown HIV status should be offered an HIV test, preferably within the context of the TB service provider, allowing the HIV test to be recorded in the patient record and the TB register. Patient confidentiality must be maintained. Where HIV counseling and testing is carried out in a different part of the same facility or even at a distant site, a referral system needs to be established so that the TB program records when a TB patient is referred for an HIV test and receives the result. TB patients should preferably be tested at the start of TB treatment so that they can benefit from appropriate care throughout TB treatment. However, a recording and reporting system should be able to capture these late tests; otherwise the total number of TB patients knowing their HIV status will be underreported. This indicator measures the combined services' ability to ensure that TB patients know their HIV status under program conditions. If a high proportion of TB patients know their status, then this provides a sufficiently robust estimate of the true HIV prevalence among TB patients for surveillance purposes. It also forms the basis for more in-depth prevention efforts (such as condoms and partner testing) and access to care and treatment.

Platform: both the numerator and denominator are obtained from facility TB registers and quarterly case-finding reports. In addition, countries may wish to record this as part of quarterly TB treatment outcome analysis to include the data of those who are tested for HIV later during TB treatment.

Frequency: data are recorded continuously and reported and analyzed quarterly at the time TB case-finding is reported. Additional reporting at the end of TB treatment enables HIV testing to take place and the results to be recorded at any time during TB treatment.

Resources

A guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241598194_eng.pdf)

WHO policy on collaborative TB/HIV activities: Guidelines for national programmes and other stakeholders: http://whqlibdoc.who.int/publications/2012/9789241503006_eng.pdf

Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006 (http://www.who.int/tb/dots/r_and_r_forms/en).

TB indicator
TB/HIV

Proportion of HIV-positive TB patients who receive CPT: **HIV-positive TB patients, registered over the reporting period, starting or continuing CPT treatment during their TB treatment among all HIV-positive TB patients registered during the reporting period (number and percentage)**

Rationale
The commitment and capacity of programs to provide co-trimoxazole preventive therapy to HIV-positive TB patients need to be monitored. It is important for programs to know the proportion of HIV-positive TB patients who receive this potentially life-saving therapy.

Definition of the indicator
Numerator: Number of HIV-positive TB patients registered over the reporting period, starting or continuing CPT treatment during their TB treatment

Denominator: Total number of HIV-positive TB patients registered during the reporting period

Measurement
All HIV-positive TB patients should be given co-trimoxazole preventive therapy during their TB treatment and lifelong thereafter unless local guidelines include discontinuation criteria or co-trimoxazole preventive therapy is otherwise contraindicated. TB patients may have been identified as HIV-positive and started co-trimoxazole preventive therapy before being diagnosed with TB; they should continue co-trimoxazole preventive therapy throughout TB treatment and be included in the denominator. To gain maximum benefit, TB patients should begin co-trimoxazole preventive therapy as soon as possible after HIV infection is diagnosed, as mortality is highest early in the course of TB treatment. However, TB patients may not have access to HIV testing immediately after diagnosis of TB or may not wish to be tested until later in their TB treatment. Including all HIV-positive TB patients who start co-trimoxazole preventive therapy during TB treatment requires assessing and reporting this at the end of TB treatment. This can be achieved by using a TB register for recording HIV status and co-trimoxazole preventive therapy. These data can then be reported along with the quarterly cohort outcome data. If HIV care or other services provide co-trimoxazole preventive therapy and not the TB program, a mechanism should be established to ensure that the information about commencing co-trimoxazole preventive therapy is passed on to, and recorded by, the national TB program again in a modified TB register.

Platform: both the numerator and denominator are obtained from TB registers and quarterly reports on TB treatment outcomes and TB/HIV activities in the district.

Frequency: the data for this indicator should be collected continuously and reported and analyzed quarterly at the end of TB treatment along with the outcome of TB treatment. In addition, countries may wish to report the provision of co-trimoxazole preventive therapy as part of quarterly case-finding reports, as co-trimoxazole preventive therapy should be started at the beginning of TB treatment.

Resources
Provisional WHO/UNAIDS secretariat recommendations on the use of co-trimoxazole prophylaxis in adults and children living with HIV/AIDS in Africa. Geneva, UNAIDS and WHO (http://www.unaids.org/publications/IRC-pub04/recommendation_en.pdf).

A guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241598194_eng.pdf)

WHO policy on collaborative TB/HIV activities: Guidelines for national programmes and other stakeholders: http://whqlibdoc.who.int/publications/2012/9789241503006_eng.pdf

Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006 (http://www.who.int/tb/dots/r_and_r_forms/en).

TB indicator
TB/HIV

Proportion of HIV-positive registered TB patients given antiretroviral therapy during TB treatment: **HIV-positive TB patients who are started on or continue previously initiated antiretroviral therapy during or at the end of TB treatment, among all HIV positive TB patients registered during the reporting period (number and percentage)**

Rationale

This indicator measures the commitment and capacity of TB services to ensure that HIV-positive TB patients are able to access antiretroviral therapy. Antiretroviral therapy significantly improves the quality of life, reduces morbidity and enhances the survival of people with advanced HIV infection or AIDS. HIV-positive TB patients are one of the largest groups already in contact with the health service who are likely to benefit from antiretroviral therapy. Efforts should be made to identify and treat those who are eligible. ART has been reported to reduce TB rates by up to 90 percent at the individual level, and by approximately 60 percent at the population level, and to reduce TB recurrence rates by 50 percent. The current guidelines for management of TB/HIV coinfection recommends starting ART in all HIV-infected individuals with active TB, irrespective of the CD4 cell count. ART should be provided as soon as possible to HIV positive TB patients and no later than eight weeks after TB treatment begins. It should be given as a matter of emergency within the first two weeks of TB treatment among HIV-positive TB patients with profound immune-suppression (i.e.CD4 count < 50 cells/mm^3).

Definition of the indicator

Numerator: Number of HIV-positive TB patients registered over the reporting period, who receive antiretroviral therapy (are started on or continue previously initiated antiretroviral therapy)

Denominator: Total number of HIV-positive TB patients registered during the reporting period

Measurement

The TB register can capture data for this indicator. The data should be reported at the completion of TB treatment to include all TB patients starting antiretroviral therapy at any time over the course of their TB treatment. In settings where TB patients are referred to HIV or other care services to be assessed and start antiretroviral therapy, a system must be established to ensure that the TB program is informed of the outcome of the referral (whether TB patients start antiretroviral therapy). This information should be recorded in a modified TB register or TB/HIV register. Not only is this important for program management, it is also important for individual patient care. TB staff members need to know whether a TB patient starts antiretroviral therapy so that they can manage drug reactions and interactions appropriately. The data collection methods should be able to capture antiretroviral therapy treatment starting at any time during TB treatment.

Platform: TB register with data periodically crosschecked against any co-terminal antiretroviral therapy registers.

Frequency: the data for this indicator should be collected continuously and reported and analyzed quarterly at the end of TB treatment along with the outcome of TB treatment. In addition, countries may wish to report the provision of antiretroviral therapy as part of quarterly case-finding reports, as it is now recommended that antiretroviral therapy should be initiated as soon as possible, within 8 weeks after the beginning of TB treatment.

Resources

A guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241598194_eng.pdf)

Antiretroviral therapy for HIV infection in adults and adolescents. Recommendations for a public health approach. 2010 revision. World Health Organization 2010. (http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf)

WHO policy on collaborative TB/HIV activities: Guidelines for national programmes and other stakeholders: http://whqlibdoc.who.int/publications/2012/9789241503006_eng.pdf

Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2008 (http://www.who.int/tb/dots/r_and_r_forms/en).

TB indicator
MDR-TB

TB cases with result for drug susceptibility testing: **TB cases with results for diagnostic drug susceptibility testing for MDR-TB among those eligible for drug susceptibility testing according to national policy during the specified period of assessment (number and percentage)**

Rationale

Drug susceptibility tests (DST) for rifampicin and isoniazid are indicated in patients suspected to harbor drug-resistant TB strains. This indicator measures the availability of and access to diagnostic drug susceptibility testing for at least isoniazid and rifampicin. Limited resources usually mean that DST is reserved for patients considered at increased risk of drug resistance. Groups to be targeted for DST vary by national policy but usually include patients who have been previously treated but failed a first or a subsequent course of TB medication, contacts of confirmed MDR-TB patients, and - in some settings - patients with HIV-associated TB.

Drug susceptibility testing coverage in groups targeted for drug susceptibility testing could be assessed by comparing the number of patients receiving diagnostic drug susceptibility testing with the total number of patients in the target groups. For example, a program may aim at having everyone who starts retreatment undergo drug susceptibility testing and, by comparing the names of the patients who started retreatment with the names in the laboratory register for culture and drug susceptibility testing, determine the coverage of drug susceptibility testing in this group.

Definition of the indicator

Numerator: Number of TB cases (new and retreatment) who received diagnostic drug susceptibility testing for at least isoniazid and rifampicin during the period of assessment

Denominator: Total number of people eligible for drug susceptibility testing according to national policy during the same period

Measurement

Platform: recording and reporting system for drug-resistant TB

Data source: All data can be extracted from the basic TB register, TB treatment card and the laboratory register for culture and DST. Aggregated reports of (1) notifications of new and retreated TB cases targeted, and (2) number of these cases with DST results for at least isoniazid and rifampicin/

Frequency: six monthly and annually. The indicator is measured three months after the end of the six-month period.

Disaggregation: This indicator may be reported disaggregated by results among eligible new and retreatment TB cases.

Resources:

Guidelines for the programmatic management of drug-resistant tuberculosis 2011 update. Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/publications/2011/9789241501583_eng.pdf)

Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, World Health Organization, 2008 (http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf).

Multidrug-resistant tuberculosis (MDR-TB) indicators: A minimum set of indicators for the programmatic management of MDR-TB national tuberculosis control programs. Geneva, World Health Organization,2011 (http://whqlibdoc.who.int/hq/2010/WHO_HTM_TB_2010.11_eng.pdf)

TB indicator
MDR-TB

Confirmed MDR-TB cases enrolled on treatment: **Laboratory confirmed MDR-TB cases enrolled on second-line anti-TB treatment during the specified period of assessment (number)**

Rationale

This indicator measures the capacity of programs to enroll MDR-TB cases on appropriate treatment. The program manager is responsible for ensuring that all cases in whom MDR-TB is detected are placed on appropriate treatment in the shortest time possible. Early detection of resistance is intended to ensure a correct drug regimen from the start and lower risks of further amplification of drug resistance.

A comparison of the number of enrolled MDR-TB cases to those detected gives an indication of access to care. It is a crude indicator given that patients started on treatment during a given six-month period may have been detected prior to the period of assessment.

Definition of the indicator

Numerator: Number of laboratory-confirmed MDR-TB cases registered and started on a prescribed second-line anti-TB treatment regimen during the specified period of assessment

Measurement

Platform: recording and reporting system for drug-resistant TB

Data source: aggregated reports of MDR cases enrolled on MDR-TB treatment regimens

Frequency: six monthly and annually. Indicators are measured in the month following the end of the six-month period.

Disaggregation: Four minimum indicators have been identified to assess the pattern of enrolment of TB cases on second-line drug treatment, including that among children and females. An additional stratification for HIV-positive MDR-TB cases assesses the proportion of them on antiretroviral treatment (ART). Confirmed XDR-TB cases should be put on adequate medication.

Resources

Guidelines for the programmatic management of drug-resistant tuberculosis 2011 update. Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/publications/2011/9789241501583_eng.pdf)

Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, World Health Organization, 2008 (http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf).

Multidrug-resistant tuberculosis (MDR-TB) indicators: A minimum set of indicators for the programmatic management of MDR-TB national tuberculosis control programs. Geneva, World Health Organization,2011 (http://whqlibdoc.who.int/hq/2010/WHO_HTM_TB_2010.11_eng.pdf)

TB indicator
MDR-TB

Delay in start of MDR-TB treatment: **Delay between the date of MDR confirmation (DST result showing resistance to both isoniazid and rifampicin in the MDR-treatment register) and the date when the patient started a prescribed second-line drug regimen as per MDRtreatment register (average number of days)**

Rationale

Detection of resistance is expected to be followed by the start of an appropriate treatment regimen to increase chances of survival and lower the risk of acquisition of additional resistance ("amplification") in the patient, as well as avoid transmission of drug-resistant strains to others. This indicator measures the effectiveness of the program in placing MDR-TB patients on adequate treatment quickly and whether intervals change over time.

The calculation is done on all confirmed MDR-TB cases recorded on the MDR-treatment register during the six-month period of assessment. The indicator is expressed as the arithmetic mean number of days with the minimum and maximum ranges for all episodes included in the calculation. If treatment was started before the confirmatory DST was reported then the delay is marked as zero days. The number of episodes included in the calculation should be indicated.

Measurement

Platform: recording and reporting system for drug-resistant TB

Data source: aggregated reports of culture status at six months from start of treatment ("interim results")

Frequency: six monthly and annually. Indicators are measured in the month following the end of the six-month period.

Disaggregation: For countries using Xpert MTB/RIF, the number of rifampicin resistant cases detected by Xpert MTB/RIF alone enrolled on treatment may be reported as an additional indicator. For countries with sizeable proportion of XDR-TB, the number of confirmed XDR-TB cases registered and started on a prescribed XDR-TB treatment regimen during the reporting period may be reported as an additional indicator.

Resources

Guidelines for the programmatic management of drug-resistant tuberculosis 2011 update. Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/publications/2011/9789241501583_eng.pdf)

Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, World Health Organization, 2008 (http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf).

Multidrug-resistant tuberculosis (MDR-TB) indicators: A minimum set of indicators for the programmatic management of MDR-TB national tuberculosis control programs. Geneva, World Health Organization,2011 (http://whqlibdoc.who.int/hq/2010/WHO_HTM_TB_2010.11_eng.pdf)

TB indicator
MDR-TB

Interim results – culture conversion at six months: **Number and percentage of MDR-TB cases initiated on a second-line anti-TB treatment regimen who have a negative culture at the end of six months of treatment during the specified period of assessment (number and percentage).**

Rationale
This indicator provides an early, interim measure of performance of the treatment program for MDR-TB cases regardless of the length of the intensive phase. Once a program "matures," the final outcomes become more useful to monitor and this indicator may be phased out of the performance framework. This indicator is usually measured nine months after the closing day of the respective patient cohort. This gives sufficient time for culture results at month six to be issued and retrieved.

Definition of the indicator
Numerator: Number of MDR-TB cases initiated on a second-line anti-TB treatment regimen during a specified period of time, who have a negative culture at the end of 6 months of treatment

Denominator: Number of MDR-TB cases initiated on second-line anti-TB treatment regimen during a specified period of time.

Measurement
Platform: recording and reporting system for drug-resistant TB

Data source: Aggregated reports of culture status at six months from start of treatment ("interim results")

Frequency: six monthly and annually

Resources
Guidelines for the programmatic management of drug-resistant tuberculosis 2011 update. Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/publications/2011/9789241501583_eng.pdf)

Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, World Health Organization, 2008 (http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf).

Multidrug-resistant tuberculosis (MDR-TB) indicators: A minimum set of indicators for the programmatic management of MDR-TB national tuberculosis control programs. Geneva, World Health Organization,2011 (http://whqlibdoc.who.int/hq/2010/WHO_HTM_TB_2010.11_eng.pdf)

TB outcome indicator

MDR-TB

Treatment success rate, cases with laboratory confirmed MDR-TB: **Laboratory-confirmed MDR-TB cases successfully treated (cured plus completed treatment) among those enrolled on second-line anti-TB treatment during the year of assessment (number and percentage)**

Rationale

This indicator measures the effectiveness of treating MDR-TB patients. The period of assessment is 12 calendar months and referred to as an annual cohort. The indicator is measured 24 months after the end of the year of assessment. This gives sufficient time for most patients to complete their treatment and for the final culture results to be issued and retrieved. All data can be extracted from the MDR-TB treatment register.

Definition of the indicator

Numerator: Number of laboratory-confirmed MDR-TB cases enrolled on second-line anti-TB treatment during the year of assessment who are successfully treated (cured plus completed treatment)

Denominator: Total number of laboratory-confirmed MDR-TB cases enrolled on second-line anti-TB treatment during the year of assessment

Measurement

Platform: recording and reporting system for drug-resistant TB

Data source: aggregated reports of final cohort treatment outcomes. All data can be extracted from the MDR-TB treatment register. All patients starting treatment during this period are included in the calculation.

Frequency: annually

Resources

Guidelines for the programmatic management of drug-resistant tuberculosis 2011 update. Geneva, World Health Organization, 2011 (http://whqlibdoc.who.int/publications/2011/9789241501583_eng.pdf)

Guidelines for the programmatic management of drug-resistant tuberculosis. Geneva, World Health Organization, 2008 (http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf).

Multidrug-resistant tuberculosis (MDR-TB) indicators: A minimum set of indicators for the programmatic management of MDR-TB national tuberculosis control programs. Geneva, World Health Organization,2011 (http://whqlibdoc.who.int/hq/2010/WHO_HTM_TB_2010.11_eng.pdf)

TB indicator
High-Risk Groups

Screening of high-risk groups: **Identified high-risk groups screened for TB (example – migrants, refugees, ethnic minorities, prisoners, contacts of smear-positive TB patients etc.). (number)**

Rationale

TB is generally identified among patients who spontaneously seek care for symptoms or signs suggesting TB (for example, productive cough for two weeks or more). TB is also detected by screening high-risk groups, such as people who have been in close contact with patients with infectious TB, or communities with high TB incidence.

The individual contacts of patients with infectious TB should be investigated routinely as an important component of TB control activities. Data from countries have shown that the prevalence of TB is very high among such contacts, especially household members (up to 5 percent). Under TB control program conditions, the index TB case and the contact should be clearly identified.

Definition of the indicator

Numerator: Number of people from the identified high-risk groups screened for TB

Measurement

Platform: TB suspect or TB contact registers

Data source: aggregated programmatic reports

Frequency: six monthly and annually

Resources

Review and policy recommendations for the investigation of contacts of people with infectious tuberculosis in high-incidence settings. Geneva, World Health Organization, in preparation.

Guidelines for control of Tuberculosis in prisons. (http://www.tbcta.org//Uploaded_files/Zelf/GuidelineTBPrisons1252321251.pdf)

Claessens NJM et al. High frequency of tuberculosis in households of index TB patients. International Journal of Tuberculosis and Lung Disease, 2002, 6:266–269.

Eckhoff CT. Evaluation of a clinical index among adult contacts of children with tuberculosis in rural Haiti. International Journal of Tuberculosis and Lung Disease, 2000, 4:1143–1148.

Etkind SC, Veen J. The role of contact tracing in low and high prevalence countries. In: Raviglione MC, ed. Tuberculosis: a comprehensive international approach. New York, Informa Healthcare USA, 2006;555–582.

Reichler MR et al. Tuberculosis contact investigations. International Journal of Tuberculosis and Lung Disease, 2003, 7:S325–S327.

Rieder H. Contacts of tuberculosis patients in high-incidence countries. International Journal of Tuberculosis and Lung Disease, 2003, 7:S333–S336.

TB indicator
High Risk Groups

Notification of all forms of TB in prisons: **TB cases (all forms) notified in prisons to the national health authorities during a specified period (number)**

Rationale

This indicator measures the program's ability to detect and identify TB patients among prisoners. The numerator of this indicator could be used for routine reporting (quarterly or six-monthly).

In addition to monitoring number of cases notified, it is also important for countries to evaluate the notification rates in prisons compared with those in the general population to define programmatic needs and gaps. The notification rate in prisons can be computed by dividing the number of cases notified to the total number of prisoners during the reporting period. If the mean duration of imprisonment does not exceed one quarter, the denominator should be the number of prisoners during the period multiplied by the average duration of imprisonment (expressed in years) during the year. Thus, the denominator expresses an average person-time of exposure. If a country has a case notification rate among prisoners higher than that in general population, it may reflect higher TB transmission in prison settings and the need for regular screening activities among prisoners. It may also be due to a backlog of cases, over-reporting or over-diagnosis. If a country has low case notification rate among prisoners (lower than that in the general population), it may reflect incomplete reporting, limited coverage or use of facilities that provide DOTS or insufficient referral of TB suspects for diagnosis. Low case detection may indicate that supplemental approaches to detecting new cases among prisoners may be required.

Where applicable, the program should also routinely monitor treatment outcomes among prisons (including adverse outcomes), screening for TB/HIV co-infection and provision of care according to national guidelines.

Definition of the indicator

Numerator: Number of TB cases (all forms) registered in prisons and reported to the national health authority in the past year

All forms of TB includes new smear-positive, new smear-negative, extra-pulmonary, and relapse cases

Measurement

Platform: TB suspect or TB contact registers

Data source: aggregated programmatic reports

Frequency: six monthly and annually

Resources

GuidelinesforcontrolofTuberculosisinprisons.(http://www.tbcta.org//Uploaded_files/Zelf/GuidelineTBPrisons1252321251.pdf)

Review and policy recommendations for the investigation of contacts of people with infectious tuberculosis in high-incidence settings. Geneva, World Health Organization, in preparation.

TB indicator
Infection Control

Infection control in health facilities: **Health care facilities that have infection control practices in place that include airborne infection control for TB control among the total number of health facilities (number and percentage)**

Rationale

All health care facilities, both public and private, and all other settings where TB patients or persons suspected of having TB congregate, should implement TB Infection Control (TB-IC) measures. The measures selected will depend on the infection control (IC) risk assessment, which in turn is based upon the local epidemiological, climatic and socioeconomic conditions, as well as the burden of TB, HIV and drug-resistant TB.

To ensure that facility-level policy exists to minimize the risk of transmission of TB in health care settings, such as primary health care clinics and hospitals. Counties are encouraged to undertake periodic facility assessments at each facility (annually from each facility at the time of supervisory visits and/or external review of TB/HIV activities or TB and HIV program reviews), particularly prioritizing large hospitals, MDR-TB facilities and facilities which care for HIV patients, and that TB-IC problems and infrastructure issues are addressed and promptly remedied.

Set of measures for TB infection control has been grouped into: (1) facility level managerial activities; (2) administrative controls, (3) environmental controls and (4) personal protective equipment. An illustrative list of questions for facility review is listed below.

- ***Managerial activities:***
  - *Is there a written infection control plan?*
  - *Is there a person responsible for implementing TB infection control?*
- ***Administrative controls:***
  - *Are TB suspects identified on arrival at the facility and separated from other patients?*
  - *Are TB cases among health care workers routinely monitored and reported?*
- ***Environmental controls:***
  - *Is the waiting area well ventilated (e.g. windows and doors open)?*
- ***Personal protective equipment***
  - *Do health staff / patients use particulate respirators*

This indicator goes a step beyond measuring the simple existence of an infection control policy. However, the existence of a policy does not mean that it is effectively implemented. Further inquiry will be needed to establish whether the infection control policy is implemented and adhered to. Countries should define standards, as per local context, that must be met in order for there to be an acceptable practice that addresses the issue of control of TB infection in health-care and congregate settings according to international guidelines – thus eliminating some, though not all, subjective judgment.

Definition of the indicator

Numerator: Number of health facilities that have infection control practices in place in a defined area (such as country, region, state or province)

Denominator: Total number of health facilities in the same area

Measurement

Data for the numerator of this indicator should be obtained from yearly facility surveys or routine reporting. Data for the denominator are reported routinely by all countries.

Platform: information system on implementation of TB infection control measures

Data source: aggregated programmatic reports and or Facility Assessments Reports

Frequency: annually

Resources

WHO policy on TB infection control in health-care facilities, congregate settings and households. Geneva, World Health Organization, 2009. (http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf)

Implementing the WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households (http://www.stoptb.org/wg/tb_hiv/assets/documents/TBICImplementationFramework1288971813.pdf)

TB IC Advocacy Strategy Final April 2010. (http://www.stoptb.org/wg/tb_hiv/assets/documents/TB%20IC%20Advocacy%20Strategy%20Final%20April%202010.pdf)

TB indicator
Infection Control

Ratio of TB notification rate (all forms) in health care staff (all staff) over the TB notification rate in general population, adjusted for age and sex.

Rationale

The Risk Ratio of developing active TB among health care workers compared with the risk in the general population ranges from 1.9 to 5.7, depending on country setting and on the existence of IC measures in health care facilities. Administrative and environmental measures, as well as the use of personal protective equipment by health care workers (as recommended in infection control policy guidelines) should progressively reduce the occurrence of TB infection and the development of active TB among health care workers. When greater than one, the ratio of TB notification rates in health care workers to the TB notification rate in the general population reflects the excess risk of TB in health care workers due to exposure in health care settings. Effective infection control measures can bring the notification rate ratio below.

Definition of the indicator

Numerator: Number of TB cases (all form) among health care workers (all types) during the assessment year divided by the total number of Health Care Workers at the end of the year.

Denominator: Number of TB cases (all form) among general population during the assessment year divided by the population size at the end of the year.

Measurement

This indicator is a ratio (and has no unit) and reported annually. Data for the numerator of this indicator should be obtained from annual surveys or routine reporting. Data for the denominator are reported routinely by all countries.

The indicator should be adjusted for differences in age and sex distributions between health care workers and the general population.

Platform: annual report

Data source: aggregated programmatic reports and or Facility Assessments Reports

Frequency: annually

Data for the numerator of this indicator should be obtained from yearly facility survey or routine reporting. Data for the denominator are reported routinely by all countries.

Platform: Information system on implementation of TB infection control measures

Resources

Global tuberculosis control: epidemiology, strategy, financing – WHO report 2009 Update. Geneva, World Health Organization, 2009. (http://www.who.int/tb/publications/global_report/2009/update/en/index.html.)

WHO policy on TB infection control in health-care facilities, congregate settings and households. Geneva, World Health Organization, 2009. (http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf)

Implementing the WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households (http://www.stoptb.org/wg/tb_hiv/assets/documents/TBICImplementationFramework1288971813.pdf)

TB IC Advocacy Strategy Final April 2010. (http://www.stoptb.org/wg/tb_hiv/assets/documents/TB%20IC%20Advocacy%20Strategy%20Final%20April%202010.pdf)

TB indicator

Practical Approach to Lung health (PAL)

Health care facilities implementing PAL among the total number of health facilities (number and percentage)

Rationale

Up to one-third of the patients who attend primary health care facilities for any reason seek care for respiratory symptoms. The Practical Approach to Lung health (PAL) strategy is a patient-centered integrated approach to diagnosis and treatment of common respiratory illnesses in primary health care. PAL promotes a symptom-based and integrated management of respiratory conditions and seeks to standardize service delivery by developing and implementing clinical guidelines, improve the efficiency of health care delivery services for respiratory illnesses within primary health care, and to improve the quality of care for everyone who seeks care for respiratory symptoms, including TB care, especially the quality of TB diagnosis. PAL is a minimum package of care provisions that should be offered to any respiratory patient in primary health care setting.

PAL is likely to improve the identification and management of TB with respect to other respiratory illnesses and the identification and management of non-TB respiratory conditions with respect to TB. Over time in health facilities with PAL services, the proportion of respiratory outpatients is expected to increase and the proportion of respiratory cases among inpatients to decrease. Moreover, the demand of care for acute respiratory episodes, such as asthma attacks, is expected to decrease in the emergency rooms of first-referral-level facilities.

Definition of the indicator

Numerator: Number of health facilities providing PAL services in a defined area (such as country, region, state or province)

Denominator: Total number of health facilities in the same defined area

Measurement

Platform: information system on PAL implementation and expansion

Data source: aggregated programmatic reports and or PAL Implementation reports

Frequency: annually

Resources

Practical approach to lung health Manual on initiating PAL implementation. Geneva, World Health Organization, 2008. (http://whqlibdoc.who.int/hq/2008/WHO_HTM_TB_2008.410_eng.pdf)

Ottmani S-E et al., eds. Respiratory care in primary care services – a survey in 9 countries. Geneva, World Health Organization, 2004 (http://www.who.int/tb/publications/2004/en/index.html).

Ottmani S-E et al., eds. Practical Approach to Lung health (PAL): a primary health care strategy for integrated management of respiratory conditions in people five years of age and over. Geneva, World Health Organization, 2005 (http://www.who.int/tb/publications/2005/en/index.html).

Murray JF, Pio A, Ottmani S. PAL: a new and practical approach to lung health. International Journal of Tuberculosis and Lung Disease, 2006, 10:1188–1191.

Bheekie A et al. The Practical Approach to Lung Health in South Africa (PALSA) intervention: respiratory guideline implementation for nurse trainers. International Nursing Review, 2006, 53:261–268.

Fairall LR et al. Effect of educational outreach to nurses on tuberculosis case detection and primary care of respiratory illness: pragmatic cluster randomized controlled trial. British Medical Journal, 2005, 331:750–754.

English RG et al. Diagnostic accuracy of an integrated respiratory guideline in identifying patients with respiratory symptoms requiring screening for pulmonary tuberculosis: a cross-sectional study. BMC Pulmonary Medicine, 2006, 6:1–9 (http://www.biomedcentral.com/1471-2466/6/22).

Camacho M et al. Results of PAL feasibility test in primary care facilities in four regions of Bolivia. International Journal of Tuberculosis and Lung Disease, 2007, 11:1246–1252.

Me'emary F et al. Results of the feasibility test of the Practical Approach to Lung Health in Syria. Eastern Mediterranean Health Journal (in press).

TB indicator
All care providers

Private and public health providers (different types[a]) collaborating with the national TB program (number and percentage)

Rationale
This indicator measures the extent to which relevant public and private health care providers have been formally involved in national TB program efforts. Depending on capacity, different provider types may take up different roles, such as referring of TB suspects, diagnosing TB or providing treatment support. The suggested indicator below does not distinguish between the type of activities in which the respective providers are involved, but that may be further disaggregated according to the need for precision.

Definition of the indicator
Numerator: Number of facilities belonging to a specified health care provider category[a] that is formally involved in implementing the national TB program in the country

Denominator: Total number of facilities belonging to that specified health provider category in the country

[a] Suggested categories and codes may include:

- *government or other public sector health facilities not directly under the scope of the national TB program such as public hospitals, medical colleges, military, prison health service etc. (G); and*
- *private health facilities, including hospitals and clinics run by nongovernmental organizations, faith-based organizations and formal and informal private providers (P).*

These categories may be further disaggregated.

Measurement
Platform: inventory (mapping and line-listing) of relevant health care providers; yearly report on program management in district or BMU or other sources

Data source: Aggregated programmatic reports

Frequency: annually

Resources
Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006 (http://www.who.int/tb/dots/r_and_r_forms/en).

WHO 2006. Engaging all health care providers in TB control: guidance on implementing public–private mix approaches. Geneva, World Health Organization, 2006 (http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.360_eng.pdf).

WHO 2003. Public–private mix for DOTS: practical tools to help implementation. Geneva, World Health Organization, 2003 (http://www.who.int/tb/publications/2003/en/index.html).

WHO. Public–private mix for TB care and control: a tool for national situation assessment. Geneva, World Health Organization, 2007 (http://www.who.int/tb/publications/2007/en/index.html).

WHO 2010. Public-Private Mix for TB Care and Control: A Tool-kit. 2010. http://whqlibdoc.who.int/publications/2010/9789241500487_eng.pdf

TB indicator
All care providers

TB cases (all forms) contributed through referral and / or diagnosis by private sector (all types of private and nongovernmental

Rationale
This indicator measures the contribution of different types of private and public health care providers to detecting new smear-positive cases of TB.

Definition of the indicator
Numerator: Number of TB cases (all forms) referred and or diagnosed by a specific type of health care provider[a]

Denominator: Total number of TB cases (all forms) notified to the national health authority in the PPM implementation areas

[a] Suggested categories and codes may include:

- *government or public sector health facilities not directly under the scope of the national TB program such as public hospitals, medical colleges, military, prisons etc. (G); and*
- *private health facilities including hospitals and clinics run by nongovernmental organizations, faith-based organizations and formal and informal private providers (P).*

These categories may be further disaggregated.

Measurement
The numerator and denominator both should correspond with the target areas (national or targeted PPM implementation areas, as applicable). If the PPM implementation areas do not match with NTP reporting units, this indicator may be reported as numbers only.

Platform: standard laboratory registers (column indicating referring unit); TB treatment register; referral and feedback forms

Data source: Aggregated programmatic reports

Frequency: quarterly and annually

Resources
Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006 (http://www.who.int/tb/dots/r_and_r_forms/en).

Engaging all health care providers in TB control: guidance on implementing public–private mix approaches. Geneva, World Health Organization, 2006 (http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.360_eng.pdf).

Public–private mix for DOTS: practical tools to help implementation. Geneva, World Health Organization, 2003 (http://www.who.int/tb/publications/2003/en/index.html).

Stop TB Partnership. Public–private mix for TB care and control: a tool for national situation assessment. Geneva, World Health Organization, 2007 (http://www.who.int/tb/publications/2007/en/index.html).

TB indicator
All care providers

TB cases (all forms) contributed by public sector institutions not covered by the national TB program (country specific - e.g. general hospitals, social security, health insurance, educational institutions, railways etc.) among all TB cases notified in the PPM implementation areas (number and percentage)

Rationale
This indicator measures the contribution of different types of private and public health care providers to the case management of all types of TB cases.

Definition of the indicator
Numerator: Number of TB cases (all forms) managed or supervised by a specific type of health care provider[a]

Denominator: Total number of TB cases (all forms) notified to the national health authority in the PPM implementation areas

[a] Suggested categories and codes may include:

- *government or public sector health facilities not directly under the scope of the national TB program such as public hospitals, medical colleges, military, prisons etc. (G); and*
- *private health facilities including hospitals and clinics run by nongovernmental organizations, faith-based organizations and formal and informal private providers (P).*

These categories may be further disaggregated.

Measurement
The numerator and denominator both should correspond with the target areas (national or targeted PPM implementation areas, as applicable). If the PPM DOTS implementation areas do not match with NTP reporting units, this indicator should be reported as numbers only.

Platform: standard laboratory registers (column indicating referring unit); referral and feedback forms; treatment cards maintained by health providers

Data source: Aggregated programmatic reports

Frequency: quarterly and annually

Resources
Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006 (http://www.who.int/tb/dots/r_and_r_forms/en).

Engaging all health care providers in TB control: guidance on implementing public–private mix approaches. Geneva, World Health Organization, 2006 (http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.360_eng.pdf).

Public–private mix for DOTS: practical tools to help implementation. Geneva, World Health Organization, 2003 (http://www.who.int/tb/publications/2003/en/index.html).

Stop TB Partnership. Public–private mix for TB care and control: a tool for national situation assessment. Geneva, World Health Organization, 2007 (http://www.who.int/tb/publications/2007/en/index.html).

TB indicator
All care providers

New smear-positive TB cases successfully treated (cured plus completed treatment) among the new smear-positive TB cases managed or treated according to national policies by the collaborating public and/or private health facilities/ providers (number and percentage)

Rationale
This indicator measures the contribution of different types of private and public health care providers to TB treatment outcomes.

Definition of the indicator
Numerator: Number of new smear-positive pulmonary TB cases in a specified period successfully treated (sum of WHO outcome categories "cured" plus "treatment completed") among the new smear-positive TB cases managed or treated by a specific type of health care provider[a]

Denominator: Total number of new smear-positive TB cases managed or treated by a specific type of health care provider[a] in the same period

This indicator may be disaggregated by specific type of provider or institutional setting, based on the type of intervention, or programmatic need

[a] Suggested categories and codes may include:

- *government or public sector health facilities not directly under the scope of the national TB program such as public hospitals, medical colleges, military, prisons etc. (G); and*
- *private health facilities including hospitals and clinics run by nongovernmental organizations, faith-based organizations and formal and informal private providers (P).*

These categories may be further disaggregated.

Measurement
Each sputum smear-positive TB case is assigned a treatment outcome, which is recorded in the TB register. The outcomes for all TB cases are reported by registration period (usually a quarter or year) after initial registration.

Platform: TB register; quarterly report on TB treatment outcome and TB/HIV activities in district or BMU; disaggregated cohort analysis based on treatment cards maintained by health providers and TB treatment register

Data source: Aggregated programmatic reports

Frequency: quarterly and annually

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TB indicator
Community TB Care

TB cases (all forms) referred by the community[a] among all TB cases notified in the BMU(s) covered by the grant (number and percentage)

Rationale

The indicator is intended to measure the extent of community involvement in TB-related issues. It is applicable to any type of provider in an area where community involvement is implemented, as long as the provider is formally collaborating with the government. Examples of community providers are: nongovernmental organizations, faith-based organizations and community-based organizations. Efficient community involvement translates into early detection of cases, one of the main and most effective strategies for reducing the transmission of TB.

Definition of the indicator

Numerator: Number of TB cases (all forms) referred by the community to a health facility for diagnosis in the BMU(s) covered by the grant during a specified period

Denominator: Total number of TB cases (all forms) notified in the BMU(s) covered by the grant in the same period

[a] Community in the context of community TB care refers to trained community volunteers, or, community members supporting patients and supported by ministry of Health or other ministries, and or nongovernmental organization. This operational definition excludes formal and informal providers such as doctors, traditional healers, salaried community health workers etc.

Measurement

Platform: TB laboratory register; quarterly report on TB case registration in the districts or BMUs; yearly report on program management in districts or BMUs

Data source: Aggregated programmatic reports

Frequency: quarterly and annually

The current version of the recording and reporting forms is under revision and will provide tools to monitor community contribution to case detection. For guidance on how to revise the current forms available in your setting before the new set of forms become published and available, please contact tuberculosis@who.int or TBTEAM@who.int.

Resources

Community Systems Strengthening Framework, Geneva, Global Fund to fight AIDS, TB & Malaria, 2011. Available from: www.theglobalfund.org/documents/civil_society/CivilSociety_CommunitySystemsStrengthening_Framework_en

Community involvement in tuberculosis care and prevention: towards partnerships for health. Guiding principles and recommendations based on a WHO review. Geneva, World Health Organization, 2008 (http://www.who.int/tb/people_and_communities/involvement/about/en/index.html).

Expert Group on TB Recording and Reporting Forms and Registers. Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006 (http://www.who.int/tb/dots/r_and_r_forms/en).

TB indicator
Community TB Care

TB cases (all forms) provided treatment observation (DOT) (according to national policies) by the community[a] among all TB cases notified in the BMU(s) covered by the grant (number and percentage)

Rationale

Evidence has shown that community-based treatment results in treatment success rates comparable to or higher than those of hospital- or facility-based treatment. In settings with high-quality implementation, the vast majority of patients choose community-based treatment. The indicator therefore is intended to measure the scope and quality of implementation of community involvement as well as the acceptability of the initiative to patients with TB.

Definition of the indicator

Numerator: Number of TB cases (all forms) given DOT by the community in the BMU(s) covered by the grant during a specified period

Denominator: Total number of TB cases (all forms) notified in the BMU(s) covered by the grant in the same period

[a] Community in the context of community TB care refers to trained community volunteers, or, community members supporting patients and supported by ministry of Health or other ministries, and or nongovernmental organization. This operational definition excludes formal and informal providers such as doctors, traditional healers, salaried community health workers etc.

Measurement

This indicator can be calculated quarterly and annually. Ideally, a national TB control program will have information related to the administrative areas that implement community-based interventions, in accordance with national guidelines; and will have available (from the health ministry) the approximate number of TB patients in these areas at any given time.

Platform: treatment card; TB register; quarterly report on TB case registration in districts and BMUs

Data source: aggregated programmatic reports

Frequency: quarterly and annually

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TB indicator
Community TB Care

New smear-positive TB cases successfully treated (cured plus completed treatment) among the new smear-positive TB cases provided treatment observation (DOT) (according to national policies) by the community[a] (number and percentage)

Rationale

Evidence has shown that community-based treatment results in treatment success rates comparable to or higher than those of hospital- or facility-based treatment. In settings with high-quality implementation, the vast majority of TB patients community-based treatment. The indicator is therefore intended to measure the scope and quality of implementation of community involvement as well as the acceptability of the initiative to TB patients.

Definition of the indicator

Numerator: Number of new smear-positive TB cases successfully treated (sum of the WHO outcome categories "cured" plus "treatment completed") in the BMU(s) covered by the grant during a specified period

Denominator: Total number of new smear-positive TB cases given DOT by the community during the same period

[a] Community in the context of community TB care refers to trained community volunteers, or, community members supporting patients and supported by ministry of Health or other ministries, and or nongovernmental organization. This operational definition excludes formal and informal providers such as doctors, traditional healers, salaried community health workers etc.

Measurement

Each sputum smear-positive TB patient is assigned a treatment outcome, which is recorded in the TB register. The outcomes for all TB patients are reported by registration period (usually a quarter or year) after initial registration. Ideally, a national TB control program will have information related to the administrative areas that implement community-based interventions, in accordance with national guidelines and will have available (from the health ministry) the approximate number of TB patients in these areas at any given time.

Platform: treatment card; TB register; quarterly report on TB case registration in districts or BMUs

Data source: Aggregated programmatic reports

Frequency: quarterly and annually

The current version of the recording and reporting forms is under revision and will provide tools to monitor community contribution to treatment support. For guidance on how to revise the current forms available in your setting before the new set of forms become published and available, please contact tuberculosis@who.int or TBTEAM@who.int.

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ISBN number: 978-92-9224-283-1
Monitoring and Evaluation Toolkit - Fourth Edition English Hard Copy