

## 1. Indicators for Global Reporting

### Introduction

The indicators described in this section are based on data reported by NTPs. Data are used to monitor progress in DOTS expansion and achievement at national and global levels of the WHO targets for TB control: treatment success of at least 85% and case detection rate of at least 70%. National data reported to WHO allow comparisons between countries, monitoring trends in TB case reporting and age/sex distribution of pulmonary smear-positive cases, and comparisons of the results of DOTS with other strategies in routine conditions. WHO requests results on these indicators as a means to encourage their adoption and use at the national level, as well as to enable global TB surveillance and intercountry comparisons. These indicators are, however, first and foremost critical to monitoring, evaluation, and problem-solving at national and local levels.

Data reported to WHO are complemented by reports of joint reviews of national TB programs, involving national and external experts, following the guidelines produced by WHO and the UNION. The information and conclusions, together with epidemiological estimates, are published annually in a WHO report on global tuberculosis control.

Indicators 1.1 to 1.3 are reported to WHO every year by national TB programs (or relevant public health authorities) and are included in the annual WHO report on global TB control. These indicators measure NTP progress towards international targets for case detection, treatment success, and DOTS coverage.

Indicators 1.4 and 1.5 provide important information on whether countries are aware of the prevalence of MDR-TB and HIV among TB cases. WHO has recently published criteria to provide guidance to NTPs on the type of collaborative activities that should be pursued with the national AIDS program, and these programs vary from country to country. However, it is important to monitor whether or not NTPs are performing surveillance to estimate the prevalence of HIV among TB cases, and vice versa, because they need these data in order to make decisions with regard to collaborative programs. Additionally, although not every country will pursue activities to address drug-resistant TB, every country should be tracking the prevalence of MDR-TB among pulmonary TB cases so that action can be taken if necessary. This has important implications for advocacy activities, planning resources, and the design and implementation of appropriate TB control activities.

### Indicators

- TB case detection rate
- Treatment success rate
- DOTS coverage
- Surveillance of multidrug-resistant TB
- HIV seroprevalence among TB patients

### Resources

- A guide to monitoring and evaluation for collaborative TB/HIV activities*. Field test version. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.342, WHO/HIV/2004.09).
- Corbett EL et al. The growing burden of tuberculosis: global trends and interactions with the HIV epidemic. *Archives of Internal Medicine*, 2003, 163:1009–1021.
- Dye C et al. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *Journal of the American Medical Association*, 1999, 282:677–686.
- Enarson D et al. *Management of tuberculosis: a guide for low income countries*. Paris, International Union Against Tuberculosis and Lung Disease, 2000.
- Global tuberculosis control: surveillance, planning, financing*. WHO report 2003. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.316).
- Global tuberculosis control: surveillance, planning, financing*. WHO report 2004. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.331).
- Treatment of tuberculosis: guidelines for national programs*. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.313).

Indicator 1.1

**TB CASE DETECTION RATE**

**Definition**

The percentage of TB cases detected (diagnosed and reported to the national health authority) among the total number of TB cases estimated to occur countrywide each year. This indicator can be analyzed in three ways: in terms of all forms of TB (i.e., pulmonary and extrapulmonary), in terms of smear-positive TB cases only, and in terms of smear-positive TB cases detected under DOTS. The corresponding definitions follow:

1. Case detection rate: all forms

$$\frac{\text{Number of new TB cases detected}}{\text{Estimated number of new TB cases countrywide}} \times 100$$

2. Case detection rate: new smear-positive cases

$$\frac{\text{Number of new smear-positive TB cases detected}}{\text{Estimated number of new smear-positive TB cases countrywide}} \times 100$$

3. Case detection rate: new smear-positive cases reported under DOTS

$$\frac{\text{Number of new smear-positive TB cases detected under DOTS}}{\text{Estimated number of new smear-positive TB cases countrywide}} \times 100$$

**What It Measures**

This indicator measures an NTP's ability to diagnose and collect data on TB cases. A high case detection rate will mean that transmission by undiagnosed infectious TB patients is curtailed, leading to the impact of less TB disease and less TB mortality in the population. A high case detection outcome relies, in turn, on a number of processes, for example, identification of TB suspects by clinicians, laboratory services that are adequate (in terms of equipment, staffing, geographical distribution, and quality control), and completeness of reporting.

There is an emphasis on smear-positive cases (definitions 2 and 3 above) because these are the "bacteriologically confirmed" cases that even the most basic TB control programs should be able to identify and because they represent infectious cases of TB that are of the highest priority in terms of TB control. There is an emphasis on detection

under DOTS (definition 3) because detection in the context of an internationally recommended TB control strategy is important. Where DOTS is implemented widely, detection under DOTS will approach detection countrywide. Reasons for low TB case detection countrywide include limited access or utilization of health facilities, insufficient clinical suspicion and referral of TB suspects for diagnosis, incomplete disease reporting within a given information system, and lack of coordination among parallel disease reporting systems (e.g., dispensary system versus that of hospitals or private practitioners, or prisons or other institutions). Incomplete and/or uncoordinated reporting often accounts for a large gap in detection.

Reasons for low TB case detection under DOTS specifically include all of the above plus incomplete implementation of DOTS. In some situations where all of the above issues have been addressed, at least in the public sector, low case detection may prompt supplemental case-finding activities, for example, bringing private and nongovernmental organization (NGO) providers into the DOTS program.

Reasons for low smear-positive TB case detection may include all of the above, plus inadequate use or functioning of smear microscopy services. For example, a sufficient number of sputum samples may not be obtained, a smear examination may not be requested on sputum samples submitted for culture, laboratories may not be equipped with all reagents to perform the smear, or laboratory staff may not be sufficiently trained to identify a positive smear.

On the other hand, the smear-positive case detection rate may be high if reporting requirements stipulate that only pulmonary cases need to be reported or if reporting forms sent to the national level do not distinguish new smear-positive cases from other cases (neither of these scenarios is advised). The smear-positive case detection rate may be high if there is some secondary motive or “gain” involved (e.g., bounties paid to clinicians for smear-positive cases only, or free treatment allocated to smear-positive cases only). Smear-positive case detection may also be high if laboratory staff are not adequately trained in the staining and reading of slides.

The TB case detection rate (whether all forms or smear-positive cases) may exceed 100% during the first few years of rapid DOTS implementation/expansion because of diagnoses among a backlog of prevalent new cases (never diagnosed previously) and perhaps also a backlog of “relapse” cases (previous episode of TB presumably cured but suboptimally treated outside the DOTS program). In a more “steady-state” scenario, the TB case detection rate may exceed 100% because of overdiagnosis of TB (a large proportion of extrapulmonary cases is sometimes a clue in this regard). It is also possible for the TB case detection to exceed 100% if TB incidence has been

underestimated by WHO. (Dye and others provide an explanation of how WHO estimates are made.<sup>1</sup>)

### **How to Measure It**

The numerator is available from the TB register or quarterly case detection reports. “All forms” refers to all sites—pulmonary and extrapulmonary. By convention, the numerator includes relapses as well as new cases, on the grounds that “relapse” cases may represent exogenous reinfections and can therefore be counted as new “events” in surveillance (erring on the side of inclusiveness). In contrast to new and relapse cases, the various other cases registered (all being “retreatment” case types) do not represent new disease episodes or events; they represent ongoing events that—in theory—were already “reported” in the surveillance system as new cases.

The numerator for detection under DOTS depends on whether a basic management unit is implementing the DOTS strategy. Cases are attributed to DOTS if they are reported from a BMU implementing DOTS. A BMU is a unit where a TB register is kept and where quarterly reports are made. It is internationally recommended to have one BMU per 50,000 to 150,000 people, up to 300,000 for large cities. Implementation of DOTS means that all components of the internationally recommended approach to TB control are in place:

- Political commitment
- Uninterrupted drug supply
- Use of smear microscopy in diagnosing TB cases
- Standardized short-course treatment regimens
- Direct observation of treatment
- Monitoring of treatment outcomes for 100% of patients with TB.

The NTP should have a record of the year and quarter when each BMU officially began implementation of the DOTS strategy, as per national guidelines. It should also have available (from the appropriate Ministry) the populations living in these BMUs.

The denominator is a WHO estimation of new cases—pulmonary and extrapulmonary—based on a mathematical model that takes into account all available data, including case notifications, an estimate of the completeness of notifications, the trend in notifications, TB mortality in the population, studies on TB disease prevalence and risk of infection, HIV prevalence, duration of TB illness, likelihood of receiving TB treatment in different sectors, and case fatality given different treatment scenarios. In

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<sup>1</sup> Dye C et al. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *Journal of the American Medical Association*, 1999, 282:677–686.

essence, the starting point for the model depends on the information available for any given country, and the remaining elements in the model are either imputed from regional averages or generated as outputs of the model. These estimations are reported every year by WHO in the annual report on global TB control.

### **Data Sources**

- Quarterly reports on TB case registration
- TB register
- WHO estimates of incidence for each country

### **Frequency & Function**

This indicator should be calculated annually. Seasonal fluctuations in TB incidence and care-seeking behavior may affect the numerator if it is based on a period of data collection that is less than 12 months. This indicator should be calculated at the national level only because the WHO estimated incidence for each country applies only to the country as a whole.

### **Strengths & Limitations**

As noted above, the case detection numerator may be affected by a number of factors; these are potential problems that are “indicated” by the analysis, rather than limitations of the indicator itself (e.g., underreporting of cases to the NTP). Limitations of the indicator are that it can only be used at the national level and that it can only be used on an “annualized” basis. In addition, there are certain limitations inherent in the calculation of DOTS coverage and in WHO’s estimate of incidence.

The limitation of use only at the national level (countrywide analysis) is related to the accuracy and appropriateness of the denominator, WHO’s estimated incidence for the country as a whole. There may be real differences in TB epidemiology in urban/rural areas and/or at subnational levels, which mean that the national estimate should not be used at subnational levels. In essence, the subnational unit calculating detection rate on the basis of the national estimate may be simply dividing a real number (registered cases) by a meaningless constant. Inasmuch as the meaningless constant is stable, following the trend of this quotient is not harmful (although it would be preferable to divide by the population instead). The real danger is that these subnational units might be congratulated for having met the target (or, worse, admonished for not having met the target), leading to laxity or despondency (respectively), when in fact the truth is simply not known. In short, subnational units are obliged to focus not on absolute levels but rather on trends—of whatever they choose to monitor (absolute number of cases, cases divided by the population, or cases divided by a potentially meaningless constant).

Indicator 1.2

**TREATMENT SUCCESS RATE**

**Definition**

The percentage of a cohort of TB cases registered in a specified period that successfully completed treatment, whether with bacteriologic evidence of success (“cured”) or without (“treatment completed”). The cohort of new smear-positive cases successfully treated is calculated using the following numerator and denominator:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that were cured plus the number that completed treatment}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

The same definition is used to calculate success among other cohorts (or case types) (e.g., new smear-negative cases, relapse cases, treatment-after-failure cases, treatment-after-default cases).

**What It Measures**

This indicator measures a program’s capacity to retain patients through a complete course of chemotherapy with a favorable clinical result. It is an outcome indicator (in the logical framework sense), and it is noteworthy because it is the only outcome indicator that can (and should) be used at all levels (e.g., from operational level to international level). There is a direct and immediate link between this outcome of treatment success and the impact of reduced TB mortality. This outcome is, in turn, influenced by a variety of factors (e.g., uninterrupted drug supply, supportive environment for the patient), which are assessed via certain process indicators described in this compendium.

For new smear-positive cases, there is a target of 85% treatment success, based on the assumption of what can be reasonably achieved assuming the baseline proportion of unfavorable outcomes (death and failure and default) to be about 15%. The 85% level formally became a global target via the World Health Assembly resolution of 1991 (originally 85% cure, later 85% success). It is arguable that populations with high HIV prevalence or with a preponderance of older adults may have difficulty reaching the 85% target because of higher percentages of death outcomes.

For pulmonary smear-positive cases, the cure rate is more trustworthy—or more valuable—than the success rate because patients who completed treatment but who do not have bacteriological confirmation of cure could conceivably still have smear-positive TB disease. The large majority of successfully treated cases should have bacteriological confirmation of cure.

Success among retreatment case types is normally lower than that for new patients—more so for treatment-after-failure (because previous failure may have been due to drug resistance) and treatment-after-default cases (because cases that defaulted previously are likely to have poor compliance and/or drug resistance) than for relapse cases. There is no international target for success in retreatment cohorts, but it is recommended that success be monitored in each of these cohorts.

This indicator relies on accuracy and effort in the determination of treatment outcomes at the facility level. In a program where there is no mechanism for treatment facilities to communicate with each other, for instance, the success rate may be low because of a preponderance of unknown outcomes related to transferring patients.

### **How to Measure It**

At the end of the treatment course, one of six treatment outcomes is recorded for each sputum smear-positive TB case: cured, treatment completed, died, failed, defaulted, or transferred out, which is recorded in the TB register. The numerator for this indicator is treatment success, which is the sum of cases registered in a specified period (e.g., quarter or year) and recorded with the treatment outcome, either “cure” or “treatment completed.” The denominator is the number of cases. Because of the applicability of this indicator to the lowest level, measurement has always been based on 100% of TB cases.

### **Data Sources**

- Quarterly reports on treatment outcomes
- TB register
- TB treatment card

### **Frequency & Function**

This indicator should be calculated on a quarterly and annual basis.

### **Strengths & Limitations**

As noted, the strength of this indicator is the fact that it can be used at all levels. All information needed to calculate the indicator is available at the local level; there is no need to refer to an estimate. At higher levels, this indicator is affected by completeness of reporting; that is, if reporting on cases registered is more complete than reporting (1

year later) on treatment outcomes, then the outcomes of some cases in the denominator will be unaccounted for.

Another important limitation is that success (and other treatment outcomes monitored routinely in TB programs) is an outcome of treatment regimens, not patient results. Although it might be useful to analyze a cohort of TB patients in terms of survival or TB-free status at a given point in time (e.g., 12 months, 24 months), the routine TB monitoring system was not designed to facilitate such an analysis. In the routine TB monitoring system, an outcome is an irrevocable event (or status assignment) that signals an end of the current treatment regimen. An end is declared because the regimen was completed (cured, completed), because the regimen is no longer applicable (failure, default), or because no information could be obtained (death, transfer out, and not evaluated). Obviously, some cases with recorded outcomes of failure or default may go on to be cured (after reregistration for retreatment regimens), and some cured cases may go on to relapse. Some default cases are never seen again and may therefore have died or spontaneously healed or found treatment elsewhere. The only status assignment serving both types of analysis (routine monitoring versus survival analysis) is death. Where there is interest in monitoring outcomes of patients (as distinct from outcomes of regimens), more sophisticated relational linkages must be introduced into the record-keeping system.

**Indicator 1.3**

**DOTS COVERAGE**

**Definition**

Percentage of the population living in the area of basic management units implementing the DOTS strategy

$$\frac{\text{Population living in the area of basic management units implementing the DOTS strategy}}{\text{Total population}} \times 100$$

**What It Measures**

This indicator measures the extent of a country's population "covered" by DOTS. The goal is to cover 100% of the population.

**How to Measure It**

A basic management unit is a unit where a TB register is kept and where quarterly reports are made. It is internationally recommended to have one BMU per 50,000 to 150,000 people, up to 300,000 for large cities. Implementation of DOTS means that all components of the internationally recommended approach to TB control are in place:

- Political commitment
- Uninterrupted drug supply
- Use of smear microscopy in diagnosing TB cases
- Standardized short-course treatment regimens
- Direct observation of treatment
- Monitoring of treatment outcomes for 100% of patients with TB.

Obviously, the implementation of these components is a serious undertaking, involving training of staff in the use of new definitions and reporting forms and an approach to diagnosing and treating and supporting the patient. It may also involve considerable planning and collaboration of various members of the community (which, in itself, demonstrates commitment), and it may involve considerable renovation and equipping of laboratories and treatment facilities.

The NTP should have a record of the year and quarter when each BMU officially began implementation of the DOTS strategy, as per national guidelines. It should also have available (from the appropriate Ministry) the populations living in these BMUs.

### **Data Sources**

- NTP records
- Census statistics

### **Frequency & Function**

This indicator should be measured annually.

### **Strengths & Limitations**

It must be emphasized that DOTS population “coverage” does not measure “access” to care. DOTS coverage is a simple indicator that is particularly useful in the early stages of DOTS implementation. But it is also somewhat simplistic, as it only measures the presence or absence of DOTS services within a given administrative area; it does not provide information on geographic distance or financial or other barriers to care. Also, “DOTS” implementation in a given unit does not depend on having reached a certain level of performance; it is expected that the performance of DOTS units will improve during the early stages of being called a “DOTS” unit. Overall, it is fairly assumed that BMUs implementing DOTS have a higher level of performance and TB patients are getting a better standard of care.

All countries may not always follow the same process in designating BMUs performing DOTS. For instance, a unit that services 2 million people with only three diagnostic facilities and only one part-time coordinator/supervisor who has no travel budget clearly should not be considered to perform DOTS, no matter how much training has been done. “BMU DOTS” designation may wrongly imply that TB control in the community at large is well coordinated (e.g., between dispensaries and hospitals and specialty clinics and private practitioners).

**Indicator 1.4**

**SURVEILLANCE OF MULTIDRUG-RESISTANT TB**

**Definition**

The national TB control program assesses the prevalence of multidrug-resistant TB at least once within a 5-year period. This is a yes/no indicator.

**What It Measures**

This indicator measures the availability of information on drug susceptibility in new and previously treated TB patients, mainly with regards to multidrug resistance (i.e., resistance to at least isoniazid and rifampicin), on the basis of national or subnational representative surveys. This information is useful for monitoring the quality of the program because MDR-TB prevalence rates indicate the potential effectiveness of the treatment regimens, the expected load of MDR-TB patients for program decisions on treatment implementation of chronic and MDR-TB patients, and the need of resources.

**How to Measure It**

A “yes” response to this indicator should be based on the availability of data from a national or subnational representative survey following protocols and quality assurance mechanisms of the WHO/International Union Against Tuberculosis and Lung Disease Global Project on Anti-Tuberculosis Drug Resistance Surveillance.<sup>1</sup>

**Data Sources**

- NTP data and reports

**Frequency & Function**

If this indicator is “no,” then this indicator should be measured every year until MDR-TB surveillance has taken place within the country. If the indicator is “yes,” then this indicator should be measured every 2 to 5 years to monitor whether MDR-TB surveillance is taking place within the recommend timeframe.

**Strengths & Limitations**

The information is useful for planning and monitoring. However, as many yes/no indicators, this indicator measures only whether the surveillance takes place, not the quality of the data collected or the strength of the methodology used to collect the data.

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<sup>1</sup> WHO/IUATLD Global Project on Anti-Tuberculosis Drug Resistance Surveillance. *Anti-tuberculosis drug resistance in the world. Report 2. Prevalence and trends.* Geneva, Communicable Diseases, World Health Organization, 2000 (WHO/CDS/TB/2000.278).

A major limitation of this indicator is the narrow range within which to act on its results. The available medications that can be effectively used for standard case management at the community level are severely limited, resulting in a very limited possible policy response where significant problems with MDR-TB are detected.

**Indicator 1.5**

**HIV SEROPREVALENCE AMONG TB PATIENTS**

**Definition**

Number of all newly registered TB patients who are HIV positive, expressed as a percentage of all registered TB patients.

1. All cases:

$$\frac{\text{Total number of newly registered TB patients (registered over a given period of time) who are HIV positive}}{\text{Total number of newly registered TB patients (registered over the same given time period) who were tested for HIV and included in the surveillance system}} \times 100$$

2. Smear-positive cases:

$$\frac{\text{Total number of newly registered smear-positive TB patients (registered over a given period of time) who are HIV positive}}{\text{Total number of newly registered smear-positive TB patients (registered over the same given time period) who were tested for HIV and included in the surveillance system}} \times 100$$

**What It Measures**

Surveillance of HIV prevalence among TB patients will give information about the epidemics of both TB and HIV. In particular, it gives an indication of the degree of overlap in the epidemics in any given setting, and when compared with the HIV prevalence in the general population, it will give an indication of the contribution that HIV is making to the TB epidemic in any given setting. Estimating the prevalence of HIV among TB patients is an important step in planning TB control activities, planning and targeting integrated TB and HIV activities, and monitoring the effectiveness of these activities over time.

**How to Measure It**

Ideally, all newly registered patients with TB, in accordance with the standard international case definition, should be considered for HIV surveillance. However, it is important to focus on new smear-positive TB patients because of the specificity of the diagnosis of this group. Countries with scarce resources and where the HIV epidemic

state is either low or concentrated may also choose to only include patients between the ages of 15 and 59 years. There are three main methods for surveillance of HIV among TB patients: data from routine testing of TB patients for HIV, sentinel methods, and special surveys. Selecting the appropriate strategy for HIV surveillance among TB patients will depend on the existing surveillance system, the underlying HIV epidemic state of a country, the status of implementation of antiretroviral therapy, and the overall TB situation.

### **Data Sources**

- Routine data from HIV counseling and testing of TB patients collected continuously in a modified TB register or a separate TB/HIV register
- Sentinel surveillance
- Special surveys

### **Frequency & Function**

In the absence of a national recording and reporting system where data are continuously collected and reported quarterly, data should be collected every 2 to 3 years. In countries that have a low HIV prevalence level in TB patients (less than 5%) and that have a stable and low HIV epidemic state and TB burden in the general population, periodic surveys may be repeated at 5-year intervals. In resource-poor countries, where the HIV and TB burden in the general population may be concentrated or generalized, but where the institution of more systematic methods of surveillance is not possible, tailored periodic surveys should be undertaken at least every 3 to 5 years.

### **Strengths & Limitations**

Measuring HIV seroprevalence among TB patients can inform the targeting of resources and the planning of activities for people with HIV and TB and for monitoring the effectiveness of these activities over time. It can raise both political and professional awareness of HIV-related TB and the need for a collaborative approach to addressing the problem. It is also helpful to corroborate surveillance data on HIV prevalence in the general population obtained from other sources. In states with a low HIV epidemic, it will provide an early indication of changes in the HIV epidemic, alerting policy-makers of the need for joint strategies. In concentrated or generalized HIV epidemics, it will help in assessing the impact of HIV on TB and will monitor the effectiveness of joint strategies to reduce the burden of HIV and TB. The use of unlinked anonymous surveys to derive such information is increasingly criticized because of the advantages of knowing one's status and the ethics of carrying out HIV testing in patients not offered voluntary counseling and testing (VCT).