

2. Indicators for Program Outcomes

Introduction

The indicators in this section are routinely calculated by TB control programs at district, regional, and national levels, and they are based on data from the TB register and quarterly reports on TB case registration, smear conversion, and treatment outcomes. (Appendix B contains examples of these forms.) They are used to monitor progress towards achievement of the national targets for case detection and treatment outcomes and to monitor program quality and effectiveness.

This section includes treatment outcome indicators (Indicators 2.9 through 2.15) that are calculated with cohort analysis. A cohort analysis is a review of patient outcomes using a set cohort, that is, a cohort (or group of individuals) that started treatment during the same time period (usually during the same quarter). The outcomes of each patient in the cohort are reviewed after a sufficient amount of time for all of them to have completed therapy (allowing for interruptions and restarts). This is typically somewhere between 12 to 15 months after the last date a patient could have started therapy. Each patient should have had a treatment outcome recorded by that time in the TB register. Cohort analysis is the key management tool for evaluating the effectiveness of the TB control program. It allows the identification of problems so that the program can institute appropriate action to overcome them and improve program performance. Cohort analyses are conducted on a regular basis as part of routine reporting.

Indicators

- Case notification rate
- Case notification rate—new smear-positive pulmonary TB cases
- New pulmonary TB cases with no smear result
- New adult smear-positive cases
- Retreatment TB cases
- New extrapulmonary TB cases
- New TB cases with no smear conversion result
- Sputum conversion rate at the end of the initial phase of treatment
- Cure rate
- Treatment completion rate
- Death rate
- Treatment failure rate
- Default rate
- Transfer-out rate
- Retreatment failure rate (chronic TB rate)

Resources

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 2004. Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.331).

Pio A, Chaulet P. *Tuberculosis handbook*. Geneva, World Health Organization, 1998 (WHO/TB/98.253).

Treatment of tuberculosis: guidelines for national programs. Geneva, World Health Organization, 2003 (WHO/CDS/TB/2003.313).

Indicator 2.1

CASE NOTIFICATION RATE

Definition

The number of TB cases reported to the NTP per year per 100,000 population.

1. Case notification rate: new cases

$$\frac{\text{Number of new TB cases reported in the past year}}{\text{Total population in the specified area}} \times 100,000$$

2. Case notification rate: new and relapse cases

$$\frac{\text{Number of new and relapse TB cases reported in the past year}}{\text{Total population in the specified area}} \times 100,000$$

3. Case notification rate: all cases

$$\frac{\text{Number of all TB cases reported in the past year}}{\text{Total population in the specified area}} \times 100,000$$

What It Measures

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 number of cases reported can be compared with incidence estimates to detect deficiencies in case detection and registration. 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. The case notification rate provides data for program planning and M&E purposes, and it 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 gender.

How to Measure It

The numerator is the number of newly notified TB patients per year, which can be obtained from reports at the national level for the previous year. The denominator, the total number of population in a specific area, can be obtained from census data.

Data Sources

- Quarterly reports on TB case registration
- Census statistics

Frequency & Function

This indicator should be calculated on an annual basis.

Strengths & Limitations

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 MOH 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 extrapulmonary 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.

Indicator 2.2

CASE NOTIFICATION RATE—NEW SMEAR-POSITIVE PULMONARY TB CASES

Definition

The number of new smear-positive pulmonary TB cases reported to the NTP per year per 100,000 population.

$$\frac{\text{Number of new smear-positive pulmonary TB cases reported}}{\text{Total population in the specified area}} \times 100,000$$

What It Measures

The numerator provides information on the number of infectious TB cases detected. Because effective treatment of infectious TB patients reduces TB transmission, early detection is one of the main strategies of TB control, and the indicator measures the program's capacity to identify those sources. Information on true incidence or prevalence of TB disease is unlikely to be available. However, the number of cases reported can be compared with incidence estimates to detect deficiencies in case detection and registration. 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. Additionally, it provides data for program planning and M&E purposes, and it should be used as a measure 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 gender.

How to Measure It

The numerator is the total number of notified smear-positive TB patients per year, which can be obtained from reports at the national level for the previous year. The denominator can be obtained from census data.

Data Sources

- Quarterly reports on TB case registration
- Census statistics

Frequency & Function

This indicator should be calculated on an annual basis.

Strengths & Limitations

The indicator is a direct measure of program capacity to identify infectious cases. The number of new pulmonary smear-positive TB cases provides a better comparison and trends over time between countries and areas, as compared with the number of total cases, because it uses a single, objective method (sputum microscopy). However, case notification represents 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.

Indicator 2.3

NEW PULMONARY TB CASES WITH NO SMEAR RESULT

Definition

The percentage of new pulmonary cases registered that do not have results of sputum smear examinations on diagnosis.

$$\frac{\text{Number of new pulmonary cases registered during a specified time period that do not have results of sputum smear examinations on diagnosis}}{\text{Total number of new pulmonary TB cases registered during the same period}} \times 100$$

What It Measures

This is an indicator of program quality and diagnostic procedures. It reflects medical diagnostic practices (use of radiological diagnosis without use of sputum microscopy). The ideal is to have no adult patients with pulmonary TB diagnosed without sputum smear examination, and the smear results of all patients recorded in the register. Exceptions include young children or HIV-positive patients who are generally unable to produce sputa and very ill individuals for whom sputa could not be collected on diagnosis and initiation of treatment was very urgent. A proportion of patients without smear results (particularly in adults) requires further study to determine the reason why there are no results. If this is the common medical practice, information and training of medical practitioners should be provided. If the reason is poor transfer or recording of data from the laboratory register to the TB register, staff should be retrained and monitoring should be strengthened. This indicator may be high if the program is using culture examinations.

How to Measure It

The quarterly report on case registration provides the base data. If the result is not satisfactory (high proportion without smear results), the TB register, treatment cards, and laboratory register should be checked. If the transfer of data is correct, the medical practitioners who are not using the recommended diagnostic algorithm should be identified and retrained, or general information for practitioners can be developed and distributed.

Data Sources

- Quarterly reports on TB case registration
- TB register
- TB laboratory register

Frequency & Function

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

Strengths & Limitations

The indicator is very useful for monitoring trends in areas where medical practice relies mainly on radiological examination for diagnosis of pulmonary TB. A limitation is that exceptions are acceptable (particularly in children).

Indicator 2.4

NEW ADULT SMEAR-POSITIVE CASES

Definition

The percentage of new adult smear-positive TB cases out of all adult pulmonary TB cases.

$$\frac{\text{Number of new pulmonary smear-positive adult (age 15 and older) TB cases registered during a specified time period}}{\text{Total number of new adult pulmonary TB cases registered during the same period}} \times 100$$

What It Measures

The indicator assesses the adequacy of smear diagnosis for TB suspects, specifically the utilization of laboratory services by diagnosing clinicians for determining whether or not a TB suspect has infectious TB. It reflects the development of program screening of TB suspects with sputum smear microscopy, as well as the relative weight of medical diagnosis of pulmonary TB without microscopy examination or with negative smears. In program conditions in countries with medium or high TB burden, over two-thirds of pulmonary TB in adults should present with positive smears (the remainder being either culture-positive or culture-negative pulmonary TB). The proportion of children with smear-positive pulmonary TB is quite low. Although the diagnosis of TB can be made in smear-negative individuals (particularly in children and those who had never been treated), the absence of bacteriological examination is not an acceptable medical practice in the diagnosis of pulmonary TB in adults. Under program conditions, when microscopy laboratory services are available and diagnostic criteria are properly applied, pulmonary TB smear-positive cases represent at least 65% of the total pulmonary TB cases in adults and 50% or more of all TB cases. These proportions may be lower in populations with high HIV incidence.

How to Measure It

The indicator is calculated on the basis of information in the TB registers at diagnostic centers visited. A standard case-finding report for the most recent quarter should be prepared to determine the number of smear-positive adult (age 15 and older) pulmonary TB cases; this is the numerator. The total number of all adult pulmonary TB cases is the denominator. The indicator can be calculated for each center individually or for all centers visited.

Data Sources

- Quarterly reports on TB case registration
- TB register

Frequency & Function

This indicator should be collected and reported quarterly and annually for monitoring purposes.

Strengths & Limitations

The proportion of smear-positive cases should be interpreted in light of HIV prevalence, since in areas with a high proportion of HIV-associated TB, there will be comparatively more smear-negative cases than in areas with low prevalence. The indicator is somewhat dependent on the availability of X-ray facilities at the diagnostic centers. In locations where X-ray facilities are available, one would expect results at the lower end of the indicator range; where no X-ray facilities are available, results would typically be expected at the higher end of the range.

Indicator 2.5

RETREATMENT TB CASES

Definition

The percentage of TB cases classified as retreatment in the past year.

$$\frac{\text{Number of retreatment TB cases registered during a specified time period}^*}{\text{Total number of TB cases registered in the same period}} \times 100$$

**Retreatment includes all previously treated patients (treatment-after-default, treatment-after-failure, and relapse cases) who are newly registered for treatment.*

What It Measures

This indicator represents the percentage of TB patients who require more extensive treatment and should be suspected of having acquired drug resistance. Ineffective treatment or incorrect administration of medication may result in a large proportion of retreatment cases, which points to deficiencies in the medication used and/or nonadherence to D.O.T. on the part of patients and providers. This indicator indirectly reveals the effectiveness of the NTP, since under a well-functioning TB control program, retreatment cases should make up a smaller proportion than new cases. Additionally, relapse is more likely in patients with HIV, so the indicator should be interpreted in light of HIV prevalence. There are many reasons why retreatment is necessary, including nonadherence to D.O.T. on the part of patients and providers, low-quality anti-TB drugs, and the presence of drug-resistant TB. In newly implemented DOTS programs, a high proportion (up to one-third) of the cases can be retreatment cases due to failures in treatment quality in previous program strategies. This proportion is reduced in a few years to 10 to 20% with good program quality, particularly because of a reduction in defaulters.

How to Measure It

The numerator is the total number of retreatment TB cases, which can be obtained from the TB register or from the quarterly report on TB registration. The denominator, the total number of TB cases registered during a specified period, can also be obtained from the TB register.

Data Sources

- Quarterly reports on TB case registration
- TB register

Frequency & Function

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

Strengths & Limitations

This indicator relies on the accuracy of case definition at the time of diagnosis and subsequent reporting to the NTP. This indicator is useful for following trends within a country or region and for cross-country comparisons.

Indicator 2.6

NEW EXTRAPULMONARY TB CASES

Definition

The percentage of TB cases with site of disease defined as extrapulmonary in the past year.

$$\frac{\text{Number of new extrapulmonary TB cases registered during a specified time period}}{\text{Total number of new TB cases registered in the same period}} \times 100$$

What It Measures

Extrapulmonary TB is defined as a disease of organs other than the lungs (e.g., pleura, lymph nodes [including intrathoracic lymph nodes], abdomen, genitourinary tract, skin, joints and bones, meninges). Diagnosis should be based on one or more culture-positive specimens or on histological or strong clinical evidence consistent with active extrapulmonary disease accompanied by a clinician's decision to treat with a full course of anti-TB medications. When both pulmonary and extrapulmonary disease are present, the TB case should be classified as pulmonary. Cases of miliary TB should be classified as pulmonary because of the involvement of the lungs.

Typically, extrapulmonary TB cases should make up the minority of TB cases (10 to 15%). Treatment regimens are generally similar, regardless of disease site; therefore, the importance of defining disease site is for surveillance purposes and to monitor program coverage of patients diagnosed and managed by specialists other than pneumologists. Extrapulmonary TB is more common among individuals coinfecting with HIV; thus, a larger proportion of extrapulmonary cases may appear in areas of high HIV prevalence.

How to Measure It

The numerator, the number of new extrapulmonary TB cases during a specified time period, can be obtained from case-finding reports at the national level. Individuals diagnosed with both pulmonary and extrapulmonary TB should not be included in the numerator. The denominator, the total number of new TB cases registered in the same period, can also be obtained from case-finding reports.

Data Sources

- Quarterly reports on new cases and relapses of tuberculosis
- TB register

Frequency & Function

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

Strengths & Limitations

This indicator relies on the accuracy of disease site determination at the time of diagnosis and subsequent reporting to the NTP. This indicator is useful for following trends within a country or region and for cross-country comparisons.

Indicator 2.7

NEW TB CASES WITH NO SMEAR CONVERSION RESULT

Definition

The percentage of new smear-positive pulmonary TB cases registered in a specified period that were not examined by sputum microscopy at the end of the initial phase of treatment.

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that were not examined at the end of the initial phase of treatment}}{\text{Total number of new smear-positive pulmonary TB cases registered during the same period}} \times 100$$

What It Measures

Sputum smear conversion after 2 or 3 months of treatment is a good predictor of eventual cure if treatment is completed. This indicator also has treatment implications—in some countries, patients who have not converted their sputum smear after 2 months of treatment should extend the initial phase of therapy for 1 month. Lack of evaluation of the bacteriological (microscopy) status at 2 months impedes the decision to extend the initial phase of treatment; lack of evaluation at 2 or 3 months indicates poor staff compliance with the guidelines and/or loss of patients (through default, transfer, or death) during the initial phase.

How to Measure It

The numerator is the number of new smear-positive pulmonary TB cases registered in a specified period with no sputum results at the end of the initial phase of treatment (2 or 3 months). The denominator is the total number of new smear-positive pulmonary TB cases registered for treatment during the same period.

Data Sources

- Quarterly reports on smear conversion or program management
- TB register

Frequency & Function

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

Strengths & Limitations

If there are high levels of patients not evaluated, further investigation is required to determine the reason for this. For example, sputa may not have been collected, reflecting poor staff procedures or loss of patients; the results may not have been returned from the laboratory; or they may not have been registered.

Indicator 2.8

SPUTUM CONVERSION RATE AT THE END OF THE INITIAL PHASE OF TREATMENT

Definition

The percentage of new smear-positive pulmonary TB cases registered in a specified period that converted to smear negative at the end of the initial phase of treatment. The initial phase of treatment may be 2 to 3 months depending on national guidelines.

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that are smear negative at the end of the initial phase of treatment}}{\text{Total number of new smear-positive pulmonary TB cases registered for treatment in the same period}} \times 100$$

The same definition is used to calculate sputum conversion rate among other case types (e.g., relapse cases, retreatment-after-failure cases, treatment-after-default cases).

What It Measures

The majority of new smear-positive pulmonary TB patients should convert their smear to negative after 2 or 3 months of treatment. However, at 2 months, good laboratory technicians can often detect low grades of positivity, and the positivity rate can still be as high as 25%, even if the initial phase of treatment is well supervised and the drugs are of good quality. If adherence to treatment is poor or if sputum is not collected at the end of the initial phase, this indicator will be low. Other reasons for a low value could be a slow rate of progress with smear conversion because of extensive cavitation and a heavy initial bacillary load or, rarely, drug resistance that does not respond to first-line therapy. Sputum conversion has treatment implications since, in some countries, patients who have not converted their sputum smears after 2 months of treatment should extend the initial phase of therapy. Low rates of smear conversion after the initial phase of treatment among retreatment patients are an indication of possible drug resistance.

How to Measure It

The numerator is the number of new smear-positive pulmonary TB cases registered in a specified period (e.g., quarter or year) that had at least one negative smear result at the end of 2 or 3 months of treatment (initial phase). This number can be obtained from the quarterly report on smear conversion (or program management) or from the TB register. The denominator is the total number of new smear-positive pulmonary TB

cases registered for treatment during the same period, and this number can be obtained from the same sources.

Data Sources

- Quarterly reports on smear conversion
- TB register

Frequency & Function

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

Strengths & Limitations

This indicator relies on the capacity of the program staff to obtain sputa from patients at 2 and 3 months and the ability of the laboratories to provide accurate and complete results to the treatment centers. This indicator is useful for following trends within a country or region and for comparison between centers. Some of the patients who are still sputum smear positive at 2 or 3 months may be culture negative and already cured; this is an operational indicator, not a technical one.

Indicator 2.9

CURE RATE

Definition

The percentage of TB cases that were registered in a specified period and were cured. All TB cases recorded as cured must have a negative sputum smear result recorded during the last month of treatment and on at least one previous occasion during treatment. For the cohort of new smear-positive pulmonary TB cases, the definition is as follows:

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

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

What It Measures

Evaluation of treatment outcomes of patients is used to determine NTP quality and effectiveness. WHO has recommended that NTPs achieve at least 85% treatment success (defined as the proportion of registered patients who were cured plus the proportion who completed treatment) in order to curtail the TB epidemic (Indicator 1.3). Cured patients are the preferable contribution to the numerator of treatment success.

How to Measure It

At the end of the treatment course, each sputum smear-positive TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome “cured.” The denominator is the number of new smear-positive cases registered in the same period.

Data Sources

- Quarterly reports on treatment outcomes
- TB register

Frequency & Function

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

Strengths & Limitations

Sputum smear-negative results obtained at the end of treatment and once during treatment may hide a small proportion of patients who are culture positive and therefore not really cured.

Since HIV-associated TB is more likely to result in death, it is difficult to achieve a high proportion of cures in areas with high HIV prevalence. Additionally, in countries where D.O.T. is administered only in the initial phase, it may be challenging to obtain sputum during the last month of treatment, which can decrease the numerator. Likewise, where rifampicin is used throughout the continuation phase, it may be difficult to get a sputum sample, so cure rates may be low in countries that have adopted this treatment strategy. These factors should be considered when interpreting the value of the proportion cured during a specified time period.

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions.

Indicator 2.10

TREATMENT COMPLETION RATE

Definition

The percentage of TB cases registered in a specified period that completed treatment. For new smear-positive pulmonary cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that completed treatment and did not meet the criteria for cure or failure}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

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

What It Measures

Evaluation of treatment outcomes of new pulmonary smear-positive patients is used to determine NTP quality and effectiveness. This indicator measures the success of the NTP in ensuring that TB patients who cannot be classified as cured actually complete their course of treatment. Patients who have completed their treatment but do not meet the criteria to be classified as a cure or failure are designated as “treatment complete.”

This indicator should be examined in conjunction with the other treatment outcome indicators. When cure cannot be established, treatment completion is the best means of ensuring that patients have been adequately treated. However, cure is always a preferable outcome to treatment completion. Treatment completion may obscure the fact that the patient is still or again smear positive and therefore is a treatment failure.

How to Measure It

At the end of the treatment course, each sputum smear-positive TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome “treatment complete.” The denominator is the number of new smear-positive cases registered in the same period.

Data Sources

- Quarterly reports on treatment outcomes
- TB register

Frequency & Function

This indicator should be measured quarterly and annually.

Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons and can be used to monitor and evaluate the impact of specific interventions.

Indicator 2.11

DEATH RATE

Definition

The percentage of TB cases registered in a specified period that died during treatment, irrespective of cause. For new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that died during treatment, irrespective of cause}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

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

What It Measures

Evaluation of treatment outcomes of patients is used to determine NTP quality and effectiveness. Patients who died for any reason during their course of treatment are designated as “died.” Cause of death is not further specified (e.g., death due to TB versus other) in the basic reporting of treatment outcomes. For this reason—and because some unknown number of patients are lost because of death—the death rate from cohort analysis is not necessarily representative of the case fatality rate.

This indicator should be considered in the context of HIV prevalence, since a high proportion of HIV-associated TB will result in a greater number of deaths. In addition to coinfection with HIV, deaths during treatment may be a result of ineffective treatment or an advanced, severe state of TB at the time treatment is initiated. In situations where people do not seek care early, there may be a high number of TB deaths that are never recorded because a large number of individuals die before being diagnosed and starting treatment. In low-prevalence countries, deaths during treatment may be due to the advanced age of the patients. In the event of excess TB mortality (more than 5%) in areas of low HIV prevalence, deaths of patients should be reviewed to determine whether these deaths could have been prevented and/or whether programmatic interventions are warranted.

How to Measure It

At the end of the treatment course, each smear-positive pulmonary TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome “died.” The denominator is the number of new smear-positive cases registered in the same period.

Data Sources

- Quarterly reports on treatment outcomes
- TB register

Frequency & Function

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

Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions. This indicator includes patients who died for any reason during TB treatment; therefore, there may be related factors that can affect this calculation, in particular, HIV/AIDS. On the other hand, some deaths may not be reported and may be falsely counted as lost to follow-up.

Indicator 2.12

TREATMENT FAILURE RATE

Definition

The percentage of TB cases registered in a specified period that were treatment failures. For new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that are smear positive 5 months or later after initiating treatment}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

What It Measures

Evaluation of treatment outcomes of new pulmonary smear-positive patients is used to determine NTP quality and effectiveness. This indicator measures one of the possible outcome indicators for patients. Patients who are sputum smear positive at 5 months or later during the course of treatment are designated as “treatment failure.”

Treatment failure may be due to inappropriate treatment regimens or underlying primary resistance. If the number is too low, this indicates a measurement problem. No NTP can achieve a 0% treatment failure rate, but the goal is to attain the lowest failure rate possible. When treatment failure rates exceed 3%, case management should be reviewed to determine whether these failures could have been prevented and/or whether program interventions are warranted.

How to Measure It

At the end of the treatment course, each smear-positive pulmonary TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome “treatment failure” after the last control smear is taken and the results are recorded. The denominator is the number of new smear-positive cases registered in the same period.

Data Sources

- Quarterly reports on treatment outcomes
- TB register

Frequency & Function

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

Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions.

Indicator 2.13

DEFAULT RATE

Definition

The percentage of TB cases registered in a specified period that interrupted treatment for more than 2 consecutive months. For new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that interrupted treatment for more than 2 consecutive months}}{\text{Total number of new smear-positive pulmonary TB cases registered in the same period}} \times 100$$

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

What It Measures

Evaluation of treatment outcomes of patients is used to determine NTP quality and effectiveness. This indicator is one of the possible outcome indicators for patients. Patients whose treatment was interrupted for 2 or more consecutive months (e.g., patients who did not collect drugs for 2 or more months at any time after registration) are designated as “default.” Any default should prompt further investigation to determine whether the interruption could have been prevented and/or whether program interventions are warranted. It is very difficult to achieve a default rate of less than 2 or 3%. If the default rate is high (i.e., more than 15%), the success target of 85% is not achievable, and the causes of this defaulting need to be determined in order to take remedial action.

How to Measure It

At the end of the treatment course, each sputum smear-positive TB case has a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome “default.” The denominator is the number of new smear-positive cases registered in the same period.

Data Sources

- Quarterly reports on treatment outcomes
- TB register

Frequency & Function

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

Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions. This indicator does not provide any information about when or why a patient has defaulted, and therefore comparisons between regions or countries may yield invalid conclusions.

Indicator 2.14

TRANSFER-OUT RATE

Definition

The percentage of TB cases registered in a specified period that were transferred to another basic management unit from which there is no treatment outcome information. For new smear-positive pulmonary TB cases, the definition is as follows:

$$\frac{\text{Number of new smear-positive pulmonary TB cases registered in a specified period that were transferred to another basic management unit and for which there is no treatment outcome information}}{\text{Total number of new smear-positive pulmonary TB cases registered during the same period}} \times 100$$

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

What It Measures

Evaluation of treatment outcomes of patients is used to determine NTP quality and effectiveness. This indicator is one of the possible outcome indicators for patients. Patients who have been transferred to another reporting unit and for whom the treatment outcome is not known are designated as “transfer out.” Otherwise, transferring cases should normally have one of the other treatment outcomes. In the event of high transfer-out rates (greater than 3 or 4%), further investigation should be conducted to determine why the true outcomes are not being obtained and reported.

How to Measure It

At the end of the treatment course, each sputum smear-positive TB case is assigned a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of cases registered in a specified period (e.g., quarter or year) and assigned the treatment outcome “transfer out.” The denominator is the number of new smear-positive cases registered in the same period.

Data Sources

- Quarterly reports on treatment outcomes
- TB register

Frequency & Function

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

Strengths & Limitations

If the number of transfer-out cases is remarkably large, it may mean that:

- Transfer of care is such a common reality in this setting, and for a fairly large percentage of the transferring patients, the outcome is unknown.
- Transfer out includes a high proportion of patients who have actually defaulted but have been incorrectly evaluated as “transfer out.”

Transfer of care is not an event to be avoided. Patients should be accommodated by the program. A high rate of “transfer out” is really an indication of the quality of communication among health services units. It may be expected that a few very rare instances of transfer simply cannot be followed up (e.g., transfer out of the country).

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions.

Indicator 2.15

RETREATMENT FAILURE RATE (CHRONIC TB RATE)

Definition

Percentage of retreatment (treatment-after-failure, treatment-after-relapse, and treatment-after-default) sputum smear-positive pulmonary cases registered during a specified period that are smear positive at the end of the retreatment regimen.

$$\frac{\text{Number of retreatment smear-positive pulmonary TB cases registered in a specified period that are smear positive at the end of the retreatment regimen}}{\text{Total number of retreatment smear-positive pulmonary TB cases registered in the same period}} \times 100$$

What It Measures

Retreatment failure is an important indicator of possible drug-resistant strains in the community, which should be confirmed by the drug resistance surveillance. This indicator measures one of the possible outcome indicators for patients. Patients who are still sputum smear positive at the end of the retreatment regimen are designated as “chronics” and are noted as “treatment failure” in the TB register and in the quarterly report on treatment outcomes. The indicator is useful for program decisions regarding the adoption of treatment with second-line drugs. Treatment failure may be due to inappropriate treatment regimens underlying primary or secondary resistance, inadequate retreatment regimens, or misclassification of chronic patients.

How to Measure It

At the end of the treatment course, each smear-positive pulmonary TB case is assigned a treatment outcome, which is recorded in the TB register. The numerator for this indicator is the number of retreatment cases registered in a specified period (e.g., quarter) and assigned the treatment outcome “treatment failure” after the last control smear is taken and the results are recorded. The numerator and denominator can be obtained from the TB register. This indicator is reported routinely from district level upwards.

Data Source

- TB register

Frequency & Function

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

Strengths & Limitations

Cohort analysis of treatment outcomes is a major management tool for evaluating the effectiveness of the NTP. These indicators rely on the accuracy of treatment outcome determination and subsequent reporting to the NTP. These indicators are useful for following trends within a country or region and for cross-country comparisons, and they can be used to monitor and evaluate the impact of specific interventions. This indicator complements Indicator 2.12 for new cases.