

5. Case Management and Treatment

Introduction

Effective case management of TB is critical to achieving high cure rates and overall program success under the DOTS strategy. A cornerstone of case management is also one of the central DOTS elements: administration of short-course chemotherapy under direct observation by health workers or other trained individuals. A key to the success of case management is a patient-oriented environment and a supportive relationship between the patient and the treatment observer. The essential elements of case management and treatment that provide the foundation for this DOTS component include:

- Correct use of treatment protocols by diagnosing clinicians, including prescription of the correct medications at the appropriate dosages for the proper length of time for the initial and continuation phases of treatment (Indicator 5.2)
- Direct observation of therapy by regularly supervised health workers or other trained individuals (Indicator 5.1)
- Prevention of default and treatment interruption and follow-up of lost patients when necessary (Indicator 2.13)
- Recognition and management of adverse reactions to medication
- Monitoring response to treatment with smear examinations at the end of the second month, during the fifth month, and in the final month of 6- and 8-month regimens (Indicators 2.7 and 2.8)
- Determination of the treatment outcome for each patient (Indicators 1.2 and 2.9 through 2.14).

Additionally, some program models include elements of case management, such as provision of food supplements; nutritional counseling; infection control counseling to avoid transmission of TB to family members, friends, and/or coworkers; VCT for HIV; direct financial assistance for transportation to and from clinics for D.O.T.; and home visits to provide D.O.T. or follow-up care for severely ill patients.

Measurement of the provision of D.O.T. is challenging; it may be necessary to consult multiple sources of information to verify that treatment is routinely administered under direct observation. Likewise, facility-level measurement of some indicators can be burdensome. For example, review of individual medical records to check proper

dosage and duration of medication during the initial and continuation phases is time consuming when done correctly.

Several of the indicators for measuring effective case management should be measured at the facility level and are best suited for special surveys. Thus, they can be reported for an individual facility or used as summary indicators at the district or national level, depending on the scope of the survey. On the other hand, smear conversion and treatment outcomes are routinely reported to the NTP on a quarterly and annual basis at every level of the NTP.

Indicators

- Patients under direct observation of therapy
- New TB patients who were prescribed the correct regimen

Resources

An expanded DOTS framework for effective tuberculosis control. WHO report 2002. Geneva, World Health Organization, 2002 (WHO/CDS/TB/2002.297).

Enarson D et al. *Management of tuberculosis: a guide for low income countries.* Paris, International Union Against Tuberculosis and Lung Disease, 2000.

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

Quick J et al. *Managing drug supply.* Boston, MA, Management Sciences for Health, 1997.

Rational Pharmaceutical Management Plus Program. *Drug management for tuberculosis manual (DMTB).* Arlington, VA, Management Sciences for Health, 2003.

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

World Health Organization, International Union Against Tuberculosis and Lung Disease, Royal Netherlands Tuberculosis Association. Revised international definitions in tuberculosis control. *International Journal of Tuberculosis and Lung Disease*, 2001, 5(3):213–215.

Indicator 5.1

PATIENTS UNDER DIRECT OBSERVATION OF THERAPY

Definition

Percentage of TB patients whose therapy was directly observed by a trained, regularly supervised individual according to NTP guidelines.*

$$\frac{\text{Number of new smear-positive pulmonary TB patients who report observation of every dose of medication per NTP guidelines}}{\text{Total number of new smear-positive pulmonary TB patients interviewed regarding direct observation of therapy}} \times 100$$

**NTP guidelines should specify D.O.T. for at least the first 2 months of treatment. In some countries, the guidelines may specify direct observation for the full course of treatment if rifampicin is used in the continuation phase.*

What It Measures

This indicator measures an essential element of the DOTS strategy: direct observation of therapy to ensure patient and provider adherence to treatment. WHO recommends that a health care worker or trained and regularly supervised person observe the patient swallowing each dose of medicine and record the dose on the individual treatment card throughout the initial phase of treatment. Each facility should attempt to achieve 100% on this indicator, to comply with international guidelines and prevent drug resistance.

How to Measure It

The numerator for this indicator is determined through surveys of patients who are receiving treatment or who recently completed treatment. Ideally, these interviews should take place in private, as the presence of treating clinicians may discourage patients from admitting that any doses have not been directly observed. The patient should be asked to describe how the medication is distributed, and how or when it is taken. If patients are hospitalized during the initial phase, it should not be assumed that D.O.T. is practiced, and the same methods of treatment should be used to determine who has received D.O.T. All health facilities should aim to reach 100%.

Data Sources

- Surveys of TB patients (e.g., exit interviews with patients or at their household)
- Interviews with TB patients and treatment providers

Frequency & Function

This indicator should be measured on an annual basis for the purposes of quality monitoring.

Strengths & Limitations

This indicator reflects the degree to which the directly observed therapy component of DOTS has been implemented by the NTP; thus, it may help explain trends in poor treatment outcomes if the proportion of directly observed patients is low. However, the reasons for not achieving a high proportion of directly observed therapy are numerous, and it may be difficult to determine the specific problem area that results in a low value.

Indicator 5.2

NEW TB PATIENTS WHO WERE PRESCRIBED THE CORRECT REGIMEN

Definition

Percentage of new TB patients who were prescribed the correct regimen of medications, as described by NTP guidelines.

$$\frac{\text{Number of new TB patients who were prescribed the correct regimen of medications during a specified period}}{\text{Total number of new TB patients who completed treatment during the same period}} \times 100$$

What It Measures

This indicator measures the correct prescription of anti-TB drugs according to the NTP guidelines. Thus, it is important to measure adherence to protocols for the initial and continuation phases of treatment. To provide adequate treatment, facilities must have the correct drugs available in quantities to support the number of patients currently receiving therapy. Additionally, the prescribing physician must be familiar with treatment protocols, including the correct combination of medications, the proper dosage (according to body weight), proper frequency, and the appropriate duration. All facilities and districts should aim to reach 100% on this indicator.

How to Measure It

This indicator should be included as part of a facility survey, as correct measurement requires an in-depth review of individual medical records. At the district level, at least 20 treatment facilities should be selected randomly for measurement, and 30 individual medical records from each facility should be reviewed. The following data should be abstracted from each record: patient age and weight as well as the strength, dosage, and frequency of use for each medication prescribed to the patient. Additionally, the start and stop dates for each medication should be recorded. The numerator should include only those patients for whom the correct strength, dosage, and frequency of each medication were prescribed in accordance with NTP recommendations for the initial phase of treatment. The denominator should be the number of records reviewed of patients who completed treatment during the reporting period. This indicator may be calculated separately for initial and continuation phases of treatment.

Data Sources

- NTP treatment guidelines
- TB register
- Individual medical records, including treatment cards and prescriptions
- Facility survey

Frequency & Function

This indicator should be measured every 2 to 3 years as part of an in-depth facility survey. It can be modified to evaluate treatment procedures by private practitioners.

Strengths & Limitations

This indicator yields useful data for not only assessing the proportion of patients on the correct regimen, but also identifying any problems that may result in an incorrect regimen. For example, since data are collected for each medication, the information can be broken down by medication to see whether a shortage of a specific drug is the problem or whether the problem is due to provider mistakes in determining the correct dosage and frequency. However, data collection is time and labor intensive, which means that this indicator is not suitable for routine monitoring.