

# Assessing the quality of TB diagnoses

## Quality of TB diagnoses

*Objectives:* at the end of the field visit, reviewers should provide comments on –

- the procedures developed by the national programme to establish the diagnosis of TB;
- the quality of diagnostic protocols used for different types of TB;
- the measures necessary to improve the quality of diagnosis.

### *Background:*

Bacteriological tests should be used to diagnose TB (see *Assessing quality-assured diagnoses made by TB laboratories*); however in a significant proportion of patients, diagnosis may be based on a clinical evaluation that is supplemented by bacteriological evidence. Any protocol used to confirm the diagnosis of TB should involve adequate clinical assessment in order to avoid treating false TB cases. False diagnoses of TB primarily occur in the absence of bacteriological testing, such as in cases of non bacteriologically confirmed pulmonary TB, or in extrapulmonary TB or childhood TB. To diagnose these types of TB other investigations must be used.

*Location:* central unit of the national TB programme, the coordination unit at the intermediate level, the basic management unit, and health facilities providing TB care.

*Staff to be interviewed:* staff at the central unit of the national programme, staff at the coordination units at the intermediate level, staff at the basic management unit, and health-care staff providing clinical care.

### *Assessment*

- a. Are standards for the diagnosis and case-management of patients with TB available?
  - i. Have national guidelines been prepared by the central unit of the national TB programme to diagnose and manage patients with TB? If yes, do the guidelines specify the diagnostic process to be used to identify different types of TB (for example, smear-positive pulmonary TB, smear-negative pulmonary TB, extrapulmonary TB and childhood TB)?
  - ii. Are the guidelines for establishing the diagnosis of TB aligned with international standards?
  - iii. Are the HIV context and drug-resistance issues considered during the process of TB diagnosis?
  - iv. Are the guidelines available in the health facilities that were visited? In what proportion of the health facilities visited were the guidelines not available?

## Framework for conducting reviews of tuberculosis programmes

- b. Do the health professionals at the health facilities visited use the national guidelines to establish the diagnosis of TB? (It will be appropriate to discuss this with the staff and to look at the files of patients diagnosed with TB at the health facility.)
  - i. Is the diagnosis of smear-positive pulmonary TB established by following the procedures specified in the national guidelines?
  - ii. Is the criterion of positivity of a culture test or Xpert MTB/RIF test appropriately used to establish the diagnosis of bacteriologically confirmed TB?
  - iii. Are the criteria used to diagnose smear-negative pulmonary TB appropriate?
  - iv. What proportion of patients with pulmonary TB do not have bacteriological confirmation?
  - v. What procedures are used to establish the diagnosis of extrapulmonary TB?
  - vi. Are histopathology tests commonly used?
  - vii. For what proportion of patients with extrapulmonary TB was the diagnosis based on the results of histopathology?
  - viii. For what proportion of patients with extrapulmonary TB was the diagnosis based on the results of bacteriological tests?
  - ix. Is the initiation of TB treatment used as a criterion to establish the diagnosis of TB? If yes, how often is this criterion used? Under which circumstances is it used?
  - x. What criteria are used to establish the diagnosis of childhood TB? Are the criteria aligned with the national guidelines?
  - xi. Are the procedures to establish the diagnosis of TB clearly described in the patients' files?

## Framework for conducting reviews of tuberculosis programmes

Indicators for: <b>Assessing the quality of TB diagnoses</b>		
<i>Indicator</i>	<i>Calculation</i>	<i>Source of information</i>
Proportion of patients with bacteriologically confirmed pulmonary TB	<p>Numerator: number of patients with bacteriologically confirmed pulmonary TB</p> <p>Denominator: total number of patients with pulmonary TB</p>	TB treatment register, patients' files
Proportion of patients with extrapulmonary TB and diagnosis based on results of histopathology	<p>Numerator: number of patients with extrapulmonary TB and diagnosis based on results of histopathology</p> <p>Denominator: total number of patients with extrapulmonary TB</p>	TB treatment register, patients' files
Proportion of patients with extrapulmonary TB and diagnosis based on results of bacteriological testing	<p>Numerator: number of patients with extrapulmonary TB and diagnosis based on results of bacteriological testing</p> <p>Denominator: total number of patients with extrapulmonary TB</p>	TB treatment register, quarterly reports