



Diagnosis of smear positive pulmonary TB

New guidelines, effective from 1st April 2009

Identification of TB suspects

A pulmonary TB suspect is any person with cough for 2 weeks, or more.

At all outpatient clinics, hospitals and health facilities, both in the public and private sectors, all patients need to be systematically screened for cough by medical officers and health staff manning the health facilities. Additionally, in medical colleges and hospitals, in-patients also need to be screened for identification of TB suspects. Persons with cough for 2 weeks, or more, with or without other symptoms suggestive of TB, should be promptly identified as pulmonary TB suspects and steps taken to subject them to sputum smear microscopy for acid-fast bacilli, for diagnosis of TB.

Diagnosis of smear positive TB amongst TB suspects

Using the RNTCP laboratory form for sputum examination, the medical officer / health staff of the health facility sends the TB suspects for sputum examination to the laboratory of RNTCP designated microscopy centre (DMC). In the DMC laboratory the patient receives sputum containers with instructions to provide sputum specimens, which are then subjected for sputum examination. If the health facility is not a DMC then the patient may be referred to the nearest DMC, or else the patient's sputum is collected and transported to the nearest DMC.

The number of specimen required for diagnosis of smear positive pulmonary TB is two, with one of them being a morning sputum specimen.

Two sputum specimens are collected over one, or two consecutive days. Of the two sputum specimens, one is collected on the spot and the other is an early morning specimen collected at home by the patient. If the health facility is a DMC one spot specimen is collected immediately on the first day and patient is given a sputum container with instructions for collection of an early morning specimen which is brought to the DMC by the patient/attendant on the second day. If the health facility is not a DMC then the patient is given a sputum container with instructions to collect an early morning specimen and go with the sputum specimen to the DMC where the spot specimen can be

collected. In case the patient is not able to travel to the DMC then both the morning and the spot specimens could be collected at the nearest health facility or sputum collection centre and transported to the DMC. Results of sputum tests should be reported within a day.

One specimen positive out of the two is enough to declare a patient as smear positive TB.

Smear positive TB is further classified as a new or retreatment case based on their previous treatment history, and appropriate therapy is prescribed.

Patients in whom both specimens are smear-negative should be prescribed symptomatic treatment and broad-spectrum antibiotics for 10 - 14 days. In such cases antibiotics such as fluoroquinolones (ciprofloxacin, ofloxacin, etc.), rifampicin or streptomycin, which are active against tuberculosis, should not to be used. Most patients are likely to improve with antibiotics if they are not suffering from TB. If the symptoms persist after a course of broad spectrum antibiotics, repeat sputum smear examination (2 samples) must be done for such patients. If one or more smears are positive, the patient is diagnosed as having smear-positive pulmonary TB. If none of the repeat sputum specimens is positive, a chest X-ray is taken, and if findings of the X-ray are consistent with pulmonary tuberculosis, the patient is diagnosed by the physician as a case of sputum negative pulmonary TB.

The new diagnostic algorithm for diagnosis of pulmonary TB in adults and children is annexed.

Patients suspected of having extra-pulmonary TB, and patients who are contacts of sputum smear-positive patients, should have their sputum examined for AFB if they have cough of any duration.

Recording and reporting

For 2009, no changes are required in the recording and reporting formats. The spot sputum specimen, irrespective of whether it is collected prior or after the morning specimen, should be recorded as specimen “a” (first specimen) in the laboratory register and the laboratory form for sputum examination. The morning specimen is always recorded as specimen “b”, i.e. second specimen, in the laboratory form for sputum examination and the laboratory register. The space for the “c” specimen should be left blank.

Quality assurance of sputum microscopy

In view of these changes, it is of utmost importance to maintain the full range of External Quality Assessment (EQA) activities in all the RNTCP designated microscopy centres across all states and districts as per the existing guidelines. Each district should implement ‘on-site evaluation’ and ‘random blinded rechecking’ for all DMCs in the

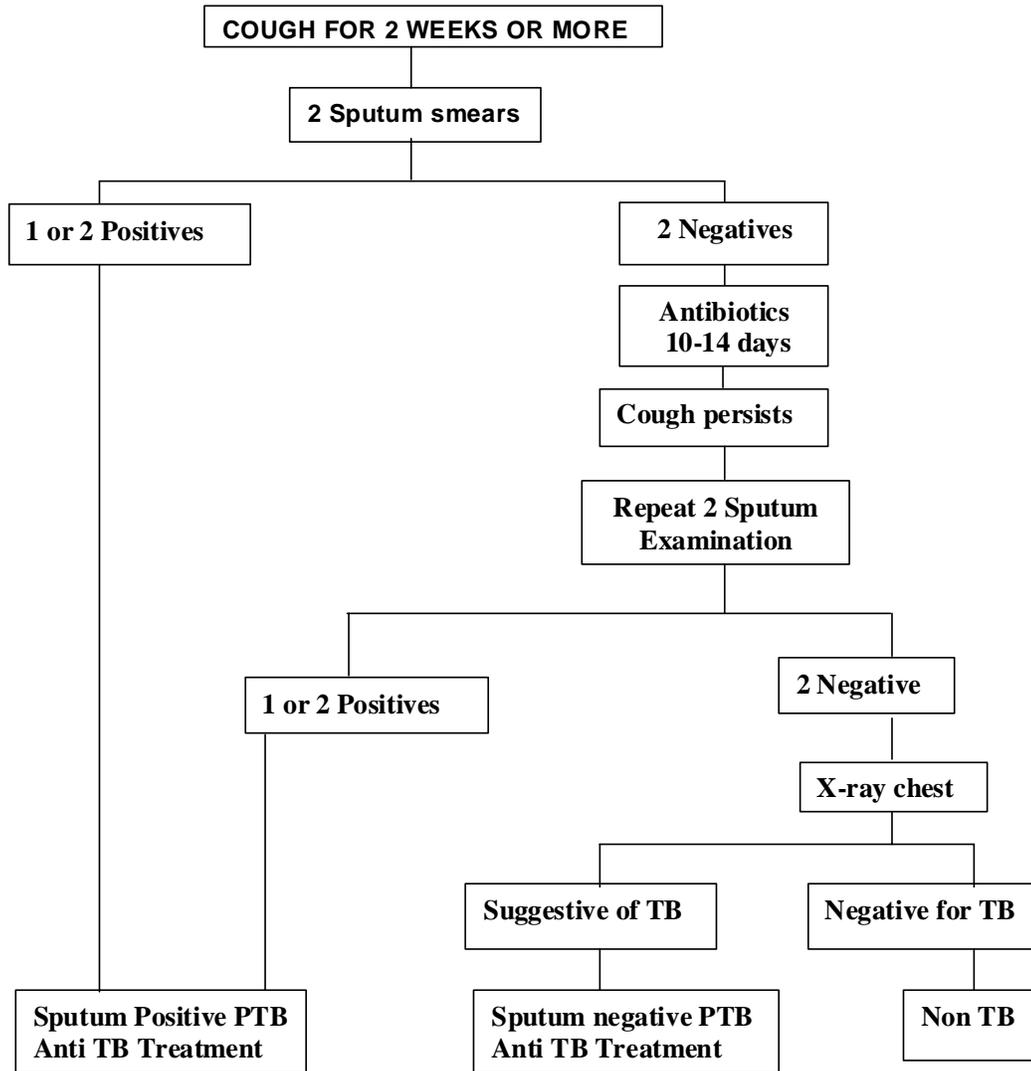
district. In addition, each district needs to undergo at least one ‘panel testing’ and one ‘on-site evaluation’ by the Intermediate Reference Laboratory. It is the responsibility of the STOs, DTOs and the IRLs to ensure that EQA is maintained across all DMCs under their jurisdiction. In addition to EQA, Internal Quality Control and Quality Improvement activities need to be carried out as per RNTCP guidelines.

For details of guidelines on quality assurance of sputum microscopy, please refer to “RNTCP laboratory network: Guidelines for Quality Assurance of smear microscopy for diagnosing tuberculosis”, published in 2005 by the Central TB Division, Directorate General of Health Services, Ministry of Health & Family Welfare, New Delhi, and available in downloadable format at www.tbcindia.org.

Training and communication

This change will be incorporated in the next version of all RNTCP training material. In the interim all concerned staff need to be briefed on the new policy. This change in policy needs to be communicated to all staff involved in identification of TB suspects, sputum microscopy and diagnosis of pulmonary TB, both in the public and private sector. All IEC material, on TB suspects and number of sputum samples for diagnosis, need to be changed to reflect the new policy. All partners of RNTCP, including PPM partners and TB/HIV partners at state and district levels need to be communicated the new policy.

Diagnostic Algorithms for Pulmonary TB



Diagnostic Algorithm for Pediatric Pulmonary TB

