



Tuberculosis (TB)

TB diagnostics and laboratory strengthening - WHO policy

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Definition of a new sputum smear-positive TB case, 2007

The revised definition of a new sputum smear-positive pulmonary TB case is based on the presence of at least one acid fast bacilli (AFB+) in at least one sputum sample in countries with a well functioning external quality assurance (EQA) system.

[Detailed background information](#)

pdf, 151kb

[Proposal for a revision of the case definition of "Sputum Smear-Positive Tuberculosis"](#)

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Background

As highlighted in the Stop TB Strategy, quality-assured bacteriological examination is an essential element for diagnosis and management of TB patients harbouring susceptible or resistant bacilli. During the last two years, an increasing number of countries are scaling up external quality assurance programmes for smear microscopy by means of blinded re-checking of slides. As a result, the quality of smear microscopy examination reached a satisfactory level in some countries. Evidence suggests that countries with a functional EQA system have very low frequency of false positive cases.

Key issues for WHO action

A number of key meetings and workshops were held where the TB case definition was discussed. These meetings included the Stop TB Partnership Laboratory Strengthening Subgroup (SLCS), an expert group meeting organized by the UNION held in Belgium and a technical expert workshop held in the Netherlands. Recent scientific evidence [Ref. 1,2] was reviewed and it was concluded that where a functional EQA for smear microscopy is in place, the finding of a single AFB in at least one single sputum smear examination in a TB suspect would satisfy the criterion to report a patient as having "sputum smear-positive tuberculosis" and to subsequently start treatment.

It should be noted that the definition of bacteriological failures has not been reviewed; hence, no change in definition of failure cases is proposed at this stage.

Given this policy revision, WHO will:

- guide and support countries in making country-specific plans of action for modifying all normative, training, and recording and reporting tools;
- provide technical assistance to countries to upgrade and fully expand functional external quality assurance (EQA) systems for TB laboratory services;
- provide guidance on study design, and sampling methodologies, in order to evaluate new diagnostic technologies (in collaboration with the Special Programme for Research and Training in Tropical Diseases (TDR));
- monitor and evaluate the impact of the change of policy on case detection at country level.

References

1. Mase S, Ramsay A, Ng N, Henry M, Hopewell PC, Cunningham J, Urbanczik R, Perkins M, Aziz MA, Pai M. Yield of serial sputum specimen examinations in the diagnosis of pulmonary tuberculosis: a systematic review. *Int J Tuberc Lung Dis* 2007;11(5):485-95)
2. Bonnet M, Ramsay A, Gagnidze L, Githui W, Guerin PJ, Varaine F. Reducing the number of sputa examined, and thresholds for positivity: An opportunity to optimize smear microscopy. Accepted for publication, *Int J Tuberc Lung Dis*



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Reduction of number of smears for the diagnosis of pulmonary TB, 2007

WHO recommends the number of specimens to be examined for screening of TB cases can be reduced from three to two, in places where a well-functioning external quality assurance (EQA) system exists, where the workload is very high and human resources are limited.

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Background

The WHO Stop TB Strategy and the Global Plan to Stop TB, 2006-2015 recognizes the weakness of the health system as one of the greatest challenges to TB control and indeed to the achievement of the Millennium Development Goals (MDGs) in general. The Global Plan also recognizes that patients, particularly poor patients, face economic barriers in accessing TB control services and that patients with TB in many resource-limited settings face long and sometimes costly pathways to diagnosis. In most of these countries, the laboratory services are often neglected and may be considered to be among the weakest components of the health system.

The challenge is particularly great in sub-Saharan Africa, where the direct and indirect effects of the HIV epidemic exacerbate the human resource crisis and compound the essential but neglected component of adequate TB diagnostic capacity within the health system.

Key issues for WHO action

The current international policy on TB case detection recommends the examination of three sputum smears for the diagnosis of pulmonary tuberculosis (PTB). The present definition of a smear-positive case states "*Tuberculosis in a patient with at least two initial sputum smear examinations (direct smear microscopy) positive for acid fast bacilli (AFB+)*". [Ref. 1,2]

A systematic review of 37 eligible studies that quantified the incremental diagnostic yield of serial sputum specimens was performed by Mase et al

and published recently. [Ref. 3] The results clearly demonstrated that the vast majority of TB cases (on average 85.8%) was detected with the first sputum specimen. With the second sputum specimen, the average incremental yield was 11.9%, while the incremental yield of the third specimen, when the first two specimens were negative, was 3.1%. [Ref. 3]

In a recent study conducted in Kenya, Bonnet et al. demonstrated that decreasing the number of smears examined for the detection of new pulmonary TB cases lead to a reduction of patient's visits to a clinic and the laboratory workload. Examining only two smears could therefore alleviate the workload of laboratories - particularly in countries with a high microscopy workload - by one third. [Ref. 4]

It is expected that microscopic analysis of two sputum smear samples will improve case findings through enhanced quality of service, decreased time for diagnosis and initiation of treatment and decreased number of patients dropping out of the diagnostic pathway.

However, the reduction of the number of specimens examined for screening TB patients from three to two specimens should only be recommended in settings with a well-established laboratory network, a fully functional EQA programme for smear microscopy including on-site evaluation with the feed-back mechanism and where the workload is very high and human resources are limited. [Ref. 5]

Given the new policy, WHO will:

- guide and support countries in making country-specific plans of action for modifying relevant normative, training, and recording and reporting tools;
- provide technical assistance to countries to upgrade and fully expand functional external quality assurance (EQA) systems for TB microscopy services;
- provide guidance on study design, and sampling methodologies, in order to evaluate new diagnostic technologies (in collaboration with the Special Programme for Research and Training in Tropical Diseases (TDR));
- monitor and evaluate the impact of the policy change on case detection at country level.

References

1. World Health Organization. Framework for effective tuberculosis control. World Health Organization Document 1994; WHO/TB/94.179:1-7.
2. World Health Organization, International Union Against Tuberculosis and Lung Disease, Royal Netherlands Tuberculosis Association. Revised international definitions in tuberculosis control. Int J Tuberc Lung Dis 2001;5:213-5.
3. Mase S, Ramsay A, Ng N, Henry M, Hopewell PC, Cunningham J, Urbanczik R, Perkins M, Aziz MA, Pai M. Yield of serial sputum specimen examinations in the diagnosis of pulmonary tuberculosis: a systematic review. Int J Tuberc Lung Dis 2007;11(5):485-95.

4. Bonnet M, Ramsay A, Gagnidze L, Githui W, Guerin PJ, Varaine F. Reducing the number of sputa examined, and thresholds for positivity: An opportunity to optimize smear microscopy. Accepted for publication, Int J Tuberc Lung Dis.

5. [External quality assessment for AFB smear microscopy \(CDC web site\)](#)
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