Definitions and reporting framework for tuberculosis – 2013 revision

(updated December 2014 and January 2020)

World Health Organization

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Contents

Abbreviations and acronyms

ADR	adverse drug reaction
AFB	acid-fast bacilli
ART	antiretroviral therapy
BMU	basic management unit
CPT	co-trimoxazole preventive therapy
DR-TB	drug-resistant TB
DST	drug susceptibility testing
EPTB	extrapulmonary TB
HIV	human immunodeficiency syndrome
HPF	high-power field
MDR-TB	multidrug-resistant TB
NTP	national tuberculosis programme
PTB	pulmonary TB
RR-TB	rifampicin-resistant TB
TB	tuberculosis
STAG-TB	Strategic and Technical Advisory Group on TB
WHO	World Health Organization
WRD	WHO-approved rapid diagnostics
XDR-TB	extensively drug-resistant TB

Background

Collection of tuberculosis (TB) data forms part of the general health information system, which aims to:

- ensure *high-quality patient care*, a continuum of care, information-sharing with patients and transfer of information between health facilities;
- *aid staff* in providing adequate services to individual patients;
- allow managers at different levels in the national TB programme (NTP) to *monitor programme performance* in a standardized and internationally comparable way;
- provide the basis for programmatic and *policy development*.

For data to be comparable within and between NTPs, standard definitions of key concepts captured by NTP information systems need to be used.

This document revises previous WHO standard case definitions[1] for TB and drug-resistant TB, the categories used to assign outcomes, and the standard reporting framework for TB.

The main reasons for these revisions are the following:

- WHO-approved rapid diagnostics (WRD) such as Xpert MTB/RIF,[2] which employ molecular or biomarker-based techniques for the diagnosis of TB, are being introduced globally and are expected to replace conventional bacteriology for diagnosis in many settings. However, WRD results do not always fit with the previous case definitions and treatment outcomes as envisaged by the 2006 WHO revision of paper-based reporting. Patients diagnosed with rifampicin-resistant TB using Xpert MTB/RIF need to be enumerated separately and the standard laboratory and TB treatment registers make no provision for this. Similarly, the standard laboratory test request form does not include these tests and makes no provision for reporting their results.
- The definition of a bacteriologically confirmed case needs to be more flexible to allow the incorporation of results from WRD.
- The definitions need to use less judgemental language, so the terms “defaulter” and “TB suspect” have been replaced by “lost to follow-up” and “presumptive TB”, respectively.
- The current treatment outcome definitions of “cured” and “treatment failed” in multidrug-resistant TB (MDR-TB) cohorts need simplification to allow their wider application to patients still on treatment.

The recording and reporting forms for paper-based systems needed revision to bring them into line with the revised case and treatment outcome definitions, as well as to address the following:

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[1] Previous definitions and recording and reporting formats were defined in:
Revised TB recording and reporting forms and registers – version 2006. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.373; available at http://www.who.int/tb/dots/r_and_r_forms/).
Guidelines for treatment of tuberculosis, 4th ed. Geneva, World Health Organization, 2009 (WHO/HTM/TB/2009.420; available at http://whqlibdoc.who.int/publications/2010/9789241547833_eng.pdf).
Guidelines for the programmatic management of drug-resistant tuberculosis: emergency update 2008. Geneva, World Health Organization, 2008 (WHO/HTM/TB/2008.402; available at http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf).
Those earlier definitions are now superseded by the definitions presented in this document.

[2] In this document, Xpert MTB/RIF refers to the currently available methodology that employs an automated real-time nucleic acid amplification technology for rapid and simultaneous detection of TB and rifampicin resistance. See*: Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF system. Policy statement.* Geneva, World Health Organization, 2011 (WHO/HTM/TB/2011.4; available at http://whqlibdoc.who.int/publications/2011/9789241501545_eng.pdf).

- Outcome reporting for drug-sensitive and drug-resistant TB (DR-TB) needs to be combined for countries where programmatic management of DR-TB is incorporated ("mainstreamed") in the NTP.
- Childhood TB reporting using paper-based systems was incomplete because age disaggregations were previously limited to sputum smear-positive TB, which is uncommon in children
- Using paper-based systems, there was a delay of two calendar years in the reporting of co-trimoxazole preventive therapy (CPT) and antiretroviral therapy (ART) because these were collected only in the treatment outcome reports and not in the case registration reports.

Revision process and acknowledgements

The revision of the definitions and reporting framework represents the collaborative work of staff at different levels of the World Health Organization (WHO) and its technical partners. The following milestones in the finalization of the process are highlighted:

- May 2011: expert consultation on updates to definitions of TB cases and treatment outcomes, Geneva, Switzerland.
- June 2011: WHO's Strategic and Technical Advisory Group on TB (STAG-TB), Geneva.
- July 2011: presentations and discussions with WHO regional and country staff, Geneva, and subsequent further consultation with WHO staff .
- October 2011: meeting of the DOTS Expansion Working Group, Lille, France.
- Extensive e-mail consultation with a wide range of countries and technical partners between November 2011 and March 2013.
- Twelve countries invited to test the definitions and forms in the second half of 2012, of which seven agreed (Belarus, Brazil, Cambodia, Djibouti, Estonia, Pakistan, Philippines); the definitions and forms were revised in the light of feedback received from these countries.
- December 2014: The reporting of TB/HIV (Block 4 of the "Quarterly report on TB case registration in the basic management unit" and Blocks 1 and 2 of the "Quarterly report on TB treatment outcomes in the basic management unit") was changed to focus on new and relapse TB cases only. This is to ensure consistency with the forthcoming 2015 revision of the guide to monitoring and evaluation for collaborative TB/HIV activities.
- January 2020: The definition of WHO-approved rapid diagnostics was extended to include biomarker-based techniques. This allows cases diagnosed using the lateral flow urine lipoarabinomannan assay (LF-LAM) to be recorded as bacteriologically confirmed subject to conditions defined in WHO guidelines[1].