Meeting Report

High-priority target product profiles for new tuberculosis diagnostics: report of a consensus meeting

28–29 April 2014

Geneva, Switzerland

World Health Organization

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The meeting was convened by the Global TB Programme of the World Health Organization on behalf of the Global Laboratory Initiative and the New Diagnostics Working Groups of the Stop TB Partnership.

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This document was finalized following consideration of all comments and suggestion made by participants of the meeting.

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Note to the reader

Because of the richness of the discussion and in an attempt to keep this report simple and readable, comments have not been attributed unless their content rendered attribution necessary. This report attempts to convey the themes addressed in each session, rather than attempting to provide a chronological summary of the dialogue.

Abbreviations

AG	aminoglycoside
CAP	capreomycin
DST	drug-susceptibility testing
EMB	ethambutol
FIND	Foundation for Innovative New Diagnostics
FQ	fluoroquinolone
HIV	human immunodeficiency virus
HRZE	isoniazid , rifampicin, pyrazinamide, ethambutol
INH	isoniazid
LAM	lipoarabinomannan
LVX	levofloxacin
MDR-TB	multidrug-resistant tuberculosis
MOX	moxifloxacin
NAAT	nucleic acid amplification test
NPV	negative predictive value
PaMZ	Pa824, moxifloxacin, pyrazinamide
PCR	polymerase chain reaction
PPV	positive predictive value
PZA	pyrazinamide
RIF	rifampicin
REMox	rifampicin, moxifloxacin, pyrazinamide, ethambutol
SNP	single nucleotide polymorphism
TB	tuberculosis
TPP	target product profile
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

Executive summary

Globally, one third of all tuberculosis (TB) cases are not notified, and many patients' samples do not undergo drug-susceptibility testing (DST). To achieve the targets for TB prevention, care and control that have been agreed for after 2015, new health-system strategies and diagnostic tools are critically important (1). The development of target product profiles (TPPs) helps to align the needs of end-users with the targets and specifications that product developers should meet for the performance and operational characteristics of a test. The meeting convened by the World Health Organization in April 2014 aimed to build consensus around four TPPs that were identified by stakeholders to be of high priority:

- a point-of-care non-sputum-based test capable of detecting all forms of TB by identifying characteristic biomarkers or biosignatures (known as the biomarker test);
- a point-of-care triage test, which should be a simple, low-cost test that can be used by first-contact health-care providers to identify those who need further testing (the triage test);
- a point-of-care sputum-based test to replace smear microscopy for detecting pulmonary TB (the smear-replacement test);
- a rapid drug-susceptibility test that can be used at the microscopy-centre level of the health-care system to select first-line regimen-based therapy (the rapid DST test).

Stakeholders were surveyed before the meeting to identify high-priority TPPs (2), and a Delphi-like process was used to facilitate consensus building around the TPPs. Shortened TPPs (including only key characteristics) were sent to invited participants (excluding industry representatives); participants were requested to provide a statement reflecting their level of agreement with each of the proposed characteristics for each of the TPPs. In total, 47 individuals were asked to participate in this process, of which 39 responded (response rate 83%). Prespecified agreement levels were achieved (that is, more than 50% of respondents gave a score of at least 4 (that is, mostly or fully agree)) for all characteristics. Characteristics for which less than 75% of the respondents agreed or with which a distinct subgroup disagreed were discussed at the meeting.

Further discussions at the meeting led to agreement on all key characteristics of the first three TPPs.