Score-TB Package ECHO session

André Trollip, FIND

Your presenter

Dr. André Trollip

Senior Technical Officer

FIND

QMS & TB laboratories

A **high-quality laboratory system** that uses **modern diagnostics** is a **prerequisite** for the **early, rapid and accurate detection of TB and drug resistance**.

Uptake of TB diagnostic technologies requires appropriate laboratory infrastructure, sufficient human resources, and adequate policy reform at country level to enable their effective use in TB screening and diagnostic algorithms.

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African Journal of Laboratory Medicine
ISSN: (Online) 2225-2010, (Print) 2225-2002

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Page 1 of 8 Original Research

Implementation of quality management systems and progress towards accreditation of National Tuberculosis Reference Laboratories in Africa

Authors:
Heidi Albert[1]
Jean de Dieu Ingeng[2]
Kebeletso Kao[3]
Donatella Erni[4]
Telen Mekonnen[5]
Phillip C. Onyebujoh[1]

Affiliations:
[1]FIND, Cape Town, Western Cape, South Africa

[2]World Health Organization, African Region Country Office, Brazzaville, Congo

[3]FIND, Campus Biotech, Geneva, Switzerland

[4]African Society for Laboratory Medicine, Addis Ababa, Ethiopia

[5]World Health Organization, African Region Country Office, Harare, Zimbabwe

Corresponding author:
Heidi Albert,
heidi.albert@finddx.org

Dates:
Received: 13 May 2016
Accepted: 07 Oct. 2016
Published: 31 Mar. 2017

How to cite this article:
Albert H, de Dieu Ingeng J, Kao K, et al. Implementation of quality management systems and progress toward accreditation of National Tuberculosis Reference Laboratories in Africa. Afr J Lab Med 2017;6(2), a490. https://doi.org/10.4102/ajlm.v6i2.490

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Background: Laboratory services are essential at all stages of the tuberculosis care cascade, from diagnosis and drug resistance testing to monitoring response to treatment. Enabling access to quality services is a challenge in low-resource settings. Implementation of a strong quality management system (QMS) and laboratory accreditation are key to improving patient care.

Objectives: The study objective was to determine the status of QMS implementation and progress towards accreditation of National Tuberculosis Reference Laboratories (NTRLs) in the African Region.

Method: An online questionnaire was administered to NTRL managers in 47 World Health Organization Regional Office for Africa member states in the region, between February and April 2015, regarding the knowledge of QMS tools and progress toward implementation to inform strategies for tuberculosis diagnostic services strengthening in the region.

Results: A total of 21 laboratories (43.0%) had received SLMTA/TB-SLMTA training, of which 10 had also used the Global Laboratory Initiative accreditation tool. However, only 36.7% of NTRLs had received a laboratory audit, a first step in quality improvement. Most NTRLs participated in acid-fast bacilli microscopy external quality assurance (95.8%), although external quality assurance for other techniques was lower (60.4% for first-line drug susceptibility testing, 25.0% for second-line drug susceptibility testing, and 22.9% for molecular testing). Barriers to accreditation included lack of training and accreditation programmes. Only 28.6% of NTRLs had developed strategic plans and budgets which included accreditation.

Conclusion: Good foundations are in place on the continent from which to scale up accreditation efforts. Laboratory audits should be conducted as a first step in developing quality improvement action plans. Political commitment and strong leadership are needed to drive accreditation efforts; advocacy will require clear evidence of patient impact and cost-benefit.

Introduction

The burden of tuberculosis in Africa remains high. The World Health Organization (WHO) reported 1 342 000 tuberculosis cases in the region in 2014; 28% of the global caseload. The region suffers from the highest per-capita burden; 281 cases per 100 000 population, more than double the global average. Despite meeting the Millenium Development Goal target of a falling tuberculosis incidence rate, the African region failed to meet the targets for 50% reduction in tuberculosis prevalence and mortality. Furthermore, the attainment of these targets varied among countries, with 40 countries achieving the Millennium Development Goal tuberculosis incidence target and only 18 countries achieving the 50% reduction in tuberculosis mortality target. Rates of multi-drug resistant tuberculosis vary across the continent, with average rates of 2.1% (0.5–3.7) among new cases and 11% (6.7–16) among previously-treated cases.[1]

High-quality laboratory services are an essential component of all stages of the tuberculosis care cascade, from diagnosis and drug resistance testing to monitoring response to treatment.[2,3] However enabling access to quality tuberculosis diagnostic services for populations in need is a major challenge in low-resource settings. The End TB Strategy calls for universal access to drug susceptibility testing (DST).[4] However, the WHO reported that only 6.4% of new bacteriologically-confirmed tuberculosis cases and 33% of previously-treated cases received DST in 2014.[1]

Laboratory services on the continent are known to suffer many challenges, including poor infrastructure, inadequate human resource capacity, and weak underlying health systems.[5]

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Page 1 of 8 Lessons from the Field

oping a customised approach for strengthening culosis laboratory quality management systems toward accreditation

Background: Quality-assured tuberculosis laboratory services are critical to achieve global and national goals for tuberculosis prevention and care. Implementation of a quality management system (QMS) in laboratories leads to improved quality of diagnostic tests and better patient care. The Strengthening Laboratory Management Toward Accreditation (SLMTA) programme has led to measurable improvements in the QMS of clinical laboratories. However, progress in tuberculosis laboratories has been slower, which may be attributed to the need for a structured tuberculosis-specific approach to implementing QMS. We describe the development and early implementation of the Strengthening Tuberculosis Laboratory Management Toward Accreditation (TB-SLMTA) programme.

Development: The TB SLMTA curriculum was developed by customizing the SLMTA curriculum to include specific tools, job aids and supplementary materials specific to the tuberculosis laboratory. The TB SLMTA Harmonized Checklist was developed from the World Health Organisation Regional Office for Africa Stepwise Laboratory Quality Improvement Process Towards Accreditation checklist, and incorporated tuberculosis-specific requirements from the Global Laboratory Initiative Stepwise Process Towards Tuberculosis Laboratory Accreditation online tool.

Implementation: Four regional training-of-trainers workshops have been conducted since 2013. The TB SLMTA programme has been rolled out in 37 tuberculosis laboratories in 10 countries using the Workshop approach in 32 laboratories in five countries and the Facility-based approach in five tuberculosis laboratories in five countries.

Conclusion: Lessons learnt from early implementation of TB SLMTA suggest that a structured training and mentoring programme can build a foundation towards further quality improvement in tuberculosis laboratories. Structured mentoring, and institutionalization of QMS into country programmes, is needed to support tuberculosis laboratories to achieve accreditation.

Introduction

The World Health Organization's (WHO) End TB Strategy calls for an end to the global tuberculosis epidemic. It aims to reduce deaths by 95% and new tuberculosis cases by 90% and to ensure that no family is burdened with catastrophic expenses due to tuberculosis by 2025.[1] Despite the fall in global tuberculosis mortality by 47% since 1990, the disease still claimed more than 1.5 million lives in 2014.[2] A cascade of events, including poor screening, failure to link screened patients to diagnostic services, and failure to link diagnosed patients to treatment, means that many people die from tuberculosis due to delayed diagnosis and treatment initiation.[3]

Quality-assured laboratory services are critical for the provision of timely, accurate and reliable results to support diagnosis, drug-resistance testing, treatment monitoring and surveillance of disease. Weak laboratory systems result in high levels of laboratory error that impact patient care and undermine the confidence healthcare providers have in laboratory services.[4] In recent years, the focus on improving laboratory quality management systems (QMS), and assuring the quality of laboratory services by working toward national or international laboratory accreditation has intensified.[5] Accreditation is the formal recognition of implementation of a QMS that adheres to international standards and has been shown to improve the quality of healthcare for patients through reduction in testing errors.[6]

The Strengthening Laboratory Management Toward Accreditation (SLMTA) programme was developed by the United States Centers for Disease Control and Prevention in collaboration with

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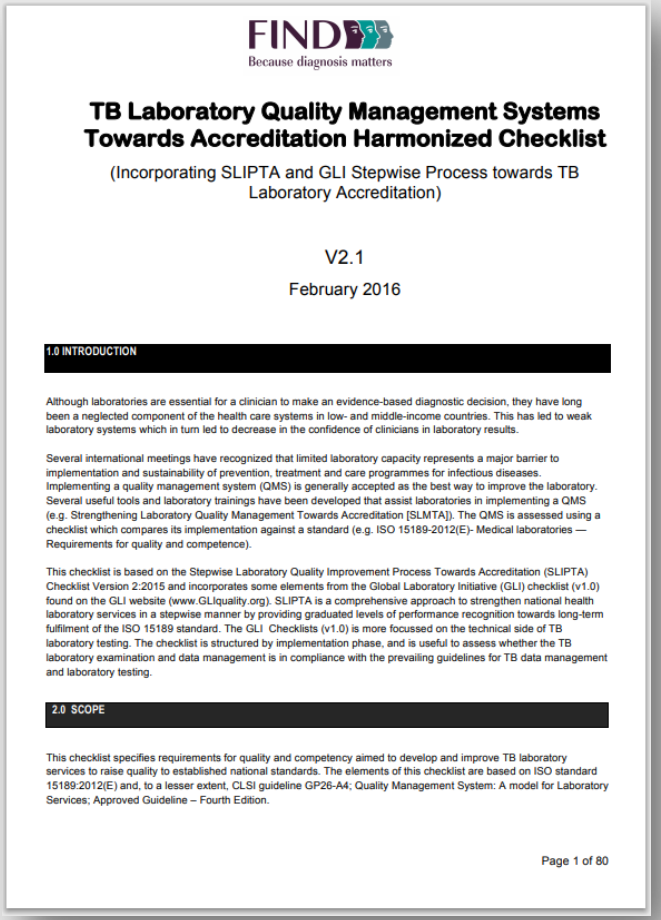
Albert *et al.,* Afr J Lab Med 2017:6(2)a490
Albert et al., Afr J Lab Med 2017:6(2)a576

Past efforts: *TB Harmonized Checklist*

- The TB SLMTA Harmonized Checklist was developed from the World Health Organisation Regional Office for Africa Stepwise Laboratory Quality Improvement Process Towards Accreditation checklist, and incorporated tuberculosis-specific requirements from the Global Laboratory Initiative Stepwise Process Towards Tuberculosis Laboratory Accreditation online tool.
- Launched in 2014



FIND
Because diagnosis matters

TB Laboratory Quality Management Systems Towards Accreditation Harmonized Checklist

(Incorporating SLIPTA and GLI Stepwise Process towards TB Laboratory Accreditation)

V2.1

February 2016

1.0 INTRODUCTION

Although laboratories are essential for a clinician to make an evidence-based diagnostic decision, they have long been a neglected component of the health care systems in low- and middle-income countries. This has led to weak laboratory systems which in turn led to decrease in the confidence of clinicians in laboratory results.

Several international meetings have recognized that limited laboratory capacity represents a major barrier to implementation and sustainability of prevention, treatment and care programmes for infectious diseases. Implementing a quality management system (QMS) is generally accepted as the best way to improve the laboratory. Several useful tools and laboratory trainings have been developed that assist laboratories in implementing a QMS (e.g. Strengthening Laboratory Quality Management Towards Accreditation [SLMTA]). The QMS is assessed using a checklist which compares its implementation against a standard (e.g. ISO 15189-2012(E)- Medical laboratories — Requirements for quality and competence).

This checklist is based on the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2:2015 and incorporates some elements from the Global Laboratory Initiative (GLI) checklist (v1.0) found on the GLI website (www.GLIquality.org). SLIPTA is a comprehensive approach to strengthen national health laboratory services in a stepwise manner by providing graduated levels of performance recognition towards long-term fulfilment of the ISO 15189 standard. The GLI Checklists (v1.0) is more focussed on the technical side of TB laboratory testing. The checklist is structured by implementation phase, and is useful to assess whether the TB laboratory examination and data management is in compliance with the prevailing guidelines for TB data management and laboratory testing.

2.0 SCOPE

This checklist specifies requirements for quality and competency aimed to develop and improve TB laboratory services to raise quality to established national standards. The elements of this checklist are based on ISO standard 15189:2012(E) and, to a lesser extent, CLSI guideline GP26-A4; Quality Management System: A model for Laboratory Services; Approved Guideline – Fourth Edition.

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Purpose of the Score-TB Package

To strengthen quality management in tuberculosis laboratories by providing a comprehensive approach for assessment based on SLIPTA and SLMTA and incorporating aspects of the GLI tool.

- Expansion of TB Harmonized Checklist
- Incorporates latest guidelines and testing techniques/assays
- Assesses technical TB testing competence and quality management system implementation
- Intended audience of the Score-TB Package: laboratory assessors + TB laboratory management & staff.
- Consists of three components →

User guide

Modular test-specific Scorecards

eTool

User guide

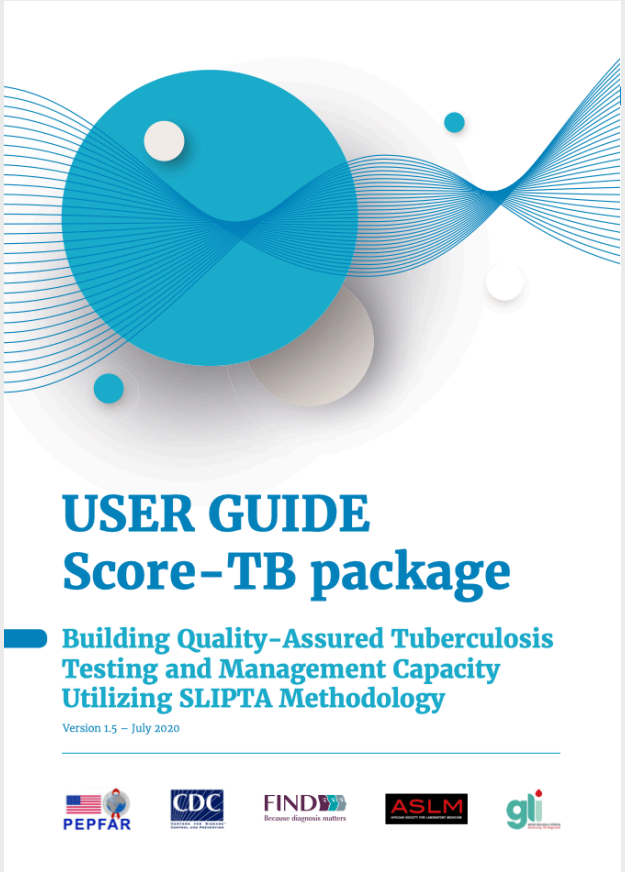
User guide

Main purpose:

- instruct assessors on using the scorecards
- provide a repository of relevant guidelines and recommendations for each TB test and for TB laboratory practice in general

Intro to using the Score-TB Package

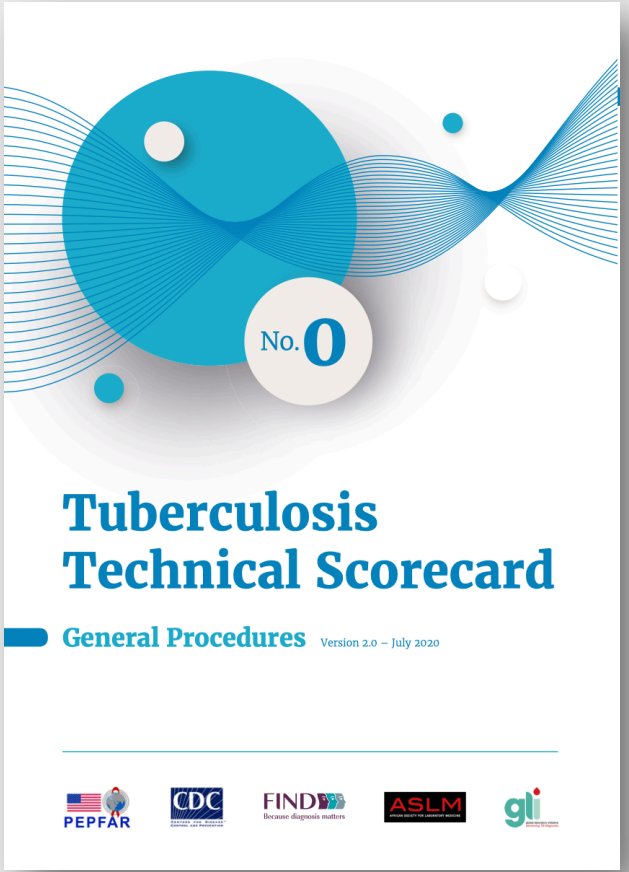
- Structure
- Assessor profile
- Conducting assessments
- Reporting
- References to technical resources



Scorecards

The Scorecards

0. General Procedures
1. Smear Microscopy
2. TB Culture for Detection and Identification of mycobacteria
3. Phenotypic Drug Susceptibility Testing
4. Xpert MTB/RIF and Xpert MTB/RIF Ultra
5. Line Probe Assay (incl. Genotype MTBDR*plus* and MTBDR*sl* & CM [for speciation])
6. Loop-Mediated Isothermal Amplification (TB-LAMP)
7. Lateral Flow Urine Lipoarabinomannan Assay (LF-LAM)
8. Truenat (incl. Truenat MTB, Truenat MTB Plus and Truenat MTB-Rif Dx)



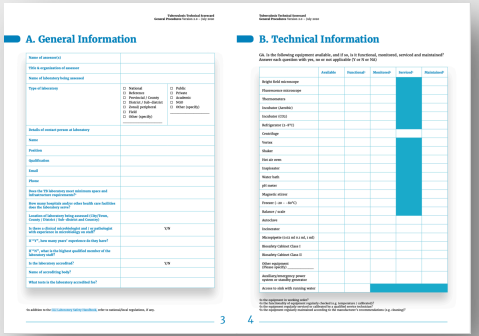
Scorecard outline

Score

A. General information

B. Technical information

- Quantitative data collection
- ‘Closed’/multiple-choice questions



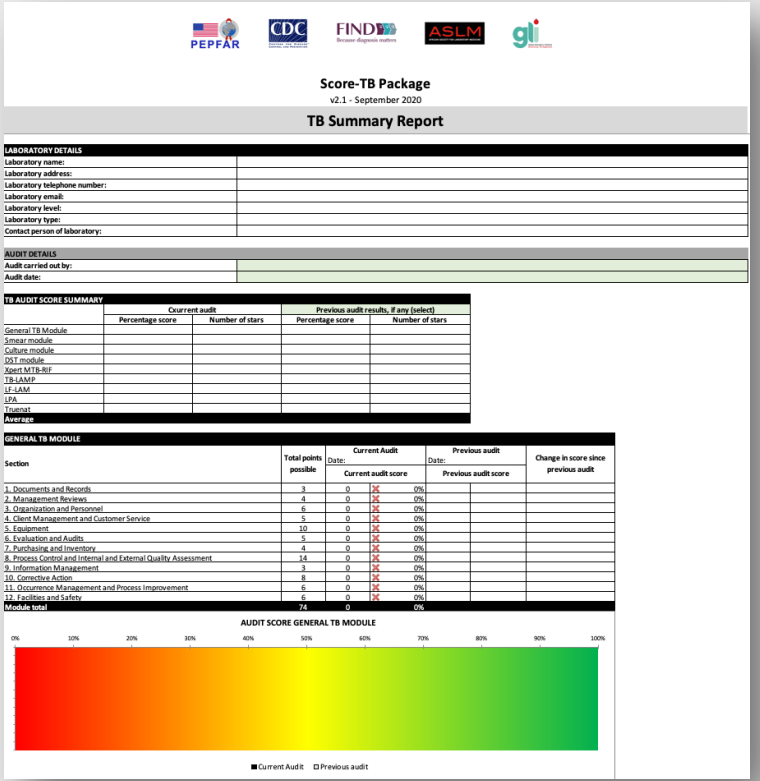
Aligned with SLIPTA sections:

1. Documents & Records
2. Management Reviews
3. Organization & Personnel
4. Client Management & Customer Service
5. Equipment
6. Evaluation & Audits
7. Purchasing & Inventory
8. Process Control
9. Information Management
10. Identification of Non-conformities, Corrective and Preventive Actions
11. Occurrence/Incident Management & Process Improvement
12. Facilities & Biosafety

eTool

eTool

- Digital version of the scorecards
- Includes SLIPTA checklist
- Excel-based
- Can be used for automated score-calculation and reporting
  - For TB scorecards alone
  - For SLIPTA alone
  - For TB scorecards combined with SLIPTA
- Will be discussed in-depth in webinar 3



Score-TB Package
v2.1 - September 2020

TB Summary Report

LABORATORY DETAILS	
Laboratory name:	
Laboratory address:	
Laboratory telephone number:	
Laboratory email:	
Laboratory level:	
Laboratory type:	
Contact person of laboratory:	

AUDIT DETAILS	
Audit carried out by:	
Audit date:	

TB AUDIT SCORE SUMMARY

	Current audit		Previous audit results, if any (select)	
	Percentage score	Number of stars	Percentage score	Number of stars
General TB Module				
Smear module				
Culture module				
DST module				
Xpert MTB-RIF				
TB-LAMP				
LF-LAM				
LPA				
Truenat				
Average				

GENERAL TB MODULE

Section	Total points possible	Current Audit Date: Current audit score			Previous audit Date: Previous audit score			Change in score since previous audit
1. Documents and Records	3	0	✗	0%				
2. Management Reviews	4	0	✗	0%				
3. Organization and Personnel	6	0	✗	0%				
4. Client Management and Customer Service	5	0	✗	0%				
5. Equipment	10	0	✗	0%				
6. Evaluation and Audits	5	0	✗	0%				
7. Purchasing and Inventory	4	0	✗	0%				
8. Process Control and Internal and External Quality Assessment	14	0	✗	0%				
9. Information Management	3	0	✗	0%				
10. Corrective Action	8	0	✗	0%				
11. Occurrence Management and Process Improvement	6	0	✗	0%				
12. Facilities and Safety	6	0	✗	0%				
Module total	74	0		0%				

AUDIT SCORE GENERAL TB MODULE

Score-TB Package

Building quality-assured TB testing and management capacity using SLIPTA methodology

Version 2.1 - September 2020

Introduction

Despite the fact that laboratory results influence 70% of medical diagnoses, laboratory services in low- and middle-income countries (LMICs) have long been a neglected component of health care systems. TB laboratories, which are an essential component in all stages of the TB care cascade, are no exception. A key intervention to strengthen laboratory services is the implementation of a quality management system (QMS). A QMS is defined by the International Organization for Standardization (ISO) as the "management system to direct and control an organization with regard to quality". Hence it is the system ("the set of interrelated or interacting elements") aimed at implementing and operationalizing quality management in an organization. Standardization of testing through implementation of a QMS has been shown to improve the quality of testing by reducing testing errors.

Several tools and initiatives to assist laboratories implement quality improvement activities have been developed. One of the most successful approaches to QMS improvement is the Strengthening Laboratory Management toward Accreditation (SLMTA) approach, first described by Yao *et al* . The SLMTA approach is often used in conjunction with the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) checklist. The SLIPTA checklist was developed by WHO Regional Office for Africa (WHO-AFRO) and partners in 2010 in recognition of the gap between the current state of laboratory quality and the requirements of the ISO 15189:2007 standard. In 2015, the SLIPTA checklist was adapted to incorporate the requirements of the ISO 15189:2012 standard and became known as 'SLIPTA v2:2015'.

The Foundation for Innovative New Diagnostics (FIND) has reported on the development of a TB laboratory-specific approach called TB Strengthening Laboratory Management toward Accreditation (TB SLMTA). The program is based on the existing successful SLMTA approach and utilized a revised checklist (TB Harmonized Checklist) based on SLIPTA, but incorporating some elements from the GLI tool with a focus on the technical side of TB laboratory testing.

In 2019, an additional technical revision was made to the TB SLMTA Harmonized Checklist to include TB testing methods not included in previous revisions. The current major revision concerns the incorporation of the TB SLMTA Harmonized Checklist into the 'Score-TB Package', which also includes an electronic version of the checklist referred to as the 'e-tool'. This e-tool substantially increases user-friendliness and reduces the risk for errors by automating the calculation of assessment scores and presenting these in a reporting worksheet to visualize strengths and weaknesses of a laboratory's QMS (the SLIPTA score) and TB testing methods.

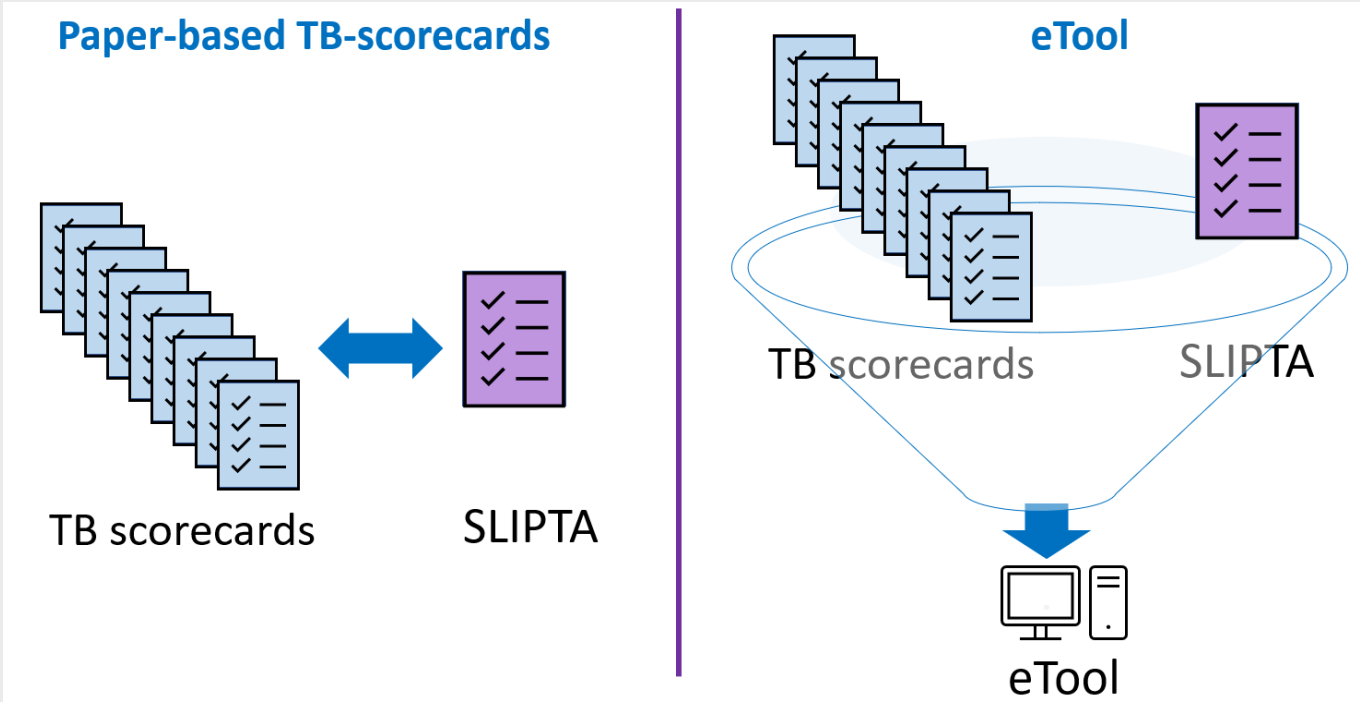
Target audience

The Score-TB Package is intended to inform Ministries of Health officials, health facility- and laboratory managers, donors, implementing partners, quality assurance personnel, program managers and supervisory staff at national, regional and facility level on requirements for delivering quality-assured laboratory testing for TB and ensuring effective use of laboratory resources as well as data for patient management and surveillance in LMIC.

Acknowledgements

The development of the Score-TB Package was led by FIND with contributions from Andre Trollip and Heidi Albert (FIND) and Tjeerd Datema and Linda Oskam (DATOS). The TB Lab Quality Scorecards draw from a number of existing tools, including CDC Laboratory Assessment of Antimicrobial Resistance Testing Capacity checklist, India Council for Medical Research (ICMR) TB Checklist, the WHO-AFRO SLIPTA checklist and FIND's TB Laboratory Quality Management Systems Towards Accreditation Harmonized Checklist.

Relation with SLIPTA



Performing the assessment

Score-TB Package ECHO session

Assessment process

Preparation → Assessment → Reporting

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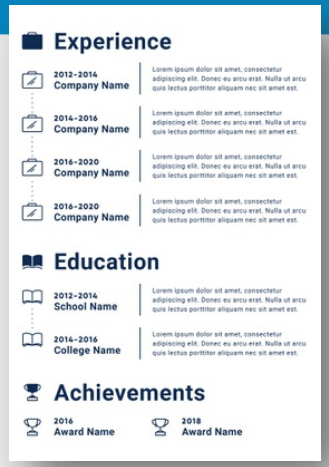

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Preparation

Assessment preparation

- Laboratory:
  - Provides access to data and necessary information
- Assessor:
  - Must use paper-based scorecards or eTool, or a combination of the two
  - Can do SLIPTA assessment first, then TB assessment, or vice versa

Assessment & Reporting

Conducting the assessment

- Introduce and explain assessment to laboratory team
- Combine horizontal with vertical audit, apply risk-based auditing

Reporting

- Debrief – positive constructive feedback is key
- Classify nonconformities into major and minor
- Report:
  - Summary: Major strengths and areas for improvement + suggestions on how to proceed
  - Summary sheets
  - Completed scorecards

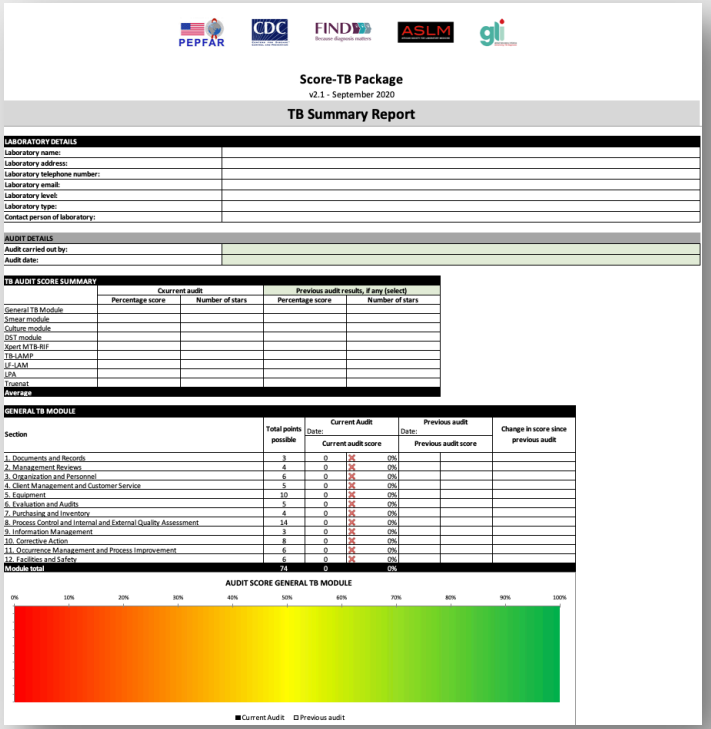
Score calculation

Recommendation: use the eTool for score calculation.

Manual score calculation is complex:

- Points for questions answered with N/A need to be subtracted from the denominator.
- Higher risk of errors

eTool directly visualizes scores for each scorecard and scorecard section and compares this with scores from previous audits.



Score-TB Package

v2.1 - September 2020

TB Summary Report

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Laboratory type:	
Contact person of laboratory:	

AUDIT DETAILS	
Audit carried out by:	
Audit date:	

TB AUDIT SCORE SUMMARY	Current audit		Previous audit results, if any (select)	
	Percentage score	Number of stars	Percentage score	Number of stars
General TB Module				
Smear module				
Culture module				
DST module				
Xpert MTB-RIF				
TB-LAMP				
LF-LAM				
LPA				
Truenat				
Average				

GENERAL TB MODULE

Section	Total points possible	Current Audit Date: Current audit score			Previous audit Date: Previous audit score		Change in score since previous audit
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11. Occurrence Management and Process Improvement	6	0	✗	0%			
12. Facilities and Safety	6	0	✗	0%			
Module total	74	0		0%			

AUDIT SCORE GENERAL TB MODULE

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

■ Current Audit ☐ Previous audit

Next steps

Score-TB Package ECHO session

Next steps

- The Score-TB Package has been translated into French & Portuguese
- The Score-TB Package will be available for download in early 2021
- Training webinar for assessors will be held in Q1 2021

Key messages

Score-TB Package ECHO session

Key messages

- Purpose of the Score-TB Package: to strengthen quality management in tuberculosis laboratories by providing a comprehensive approach for laboratory assessments based on SLIPTA and SLMTA and aspects of the GLI tool.
- The Score-TB Package consists of a user guide, modular test-specific paper-based scorecards, and an eTool.
- The Score-TB Package is aligned with SLIPTA so can be used in conjunction with SLIPTA.
- The Score-TB Package is used to assess the Tb laboratory following the PREPARATION | ASSESSMENT | REPORTING process

Acknowledgements

The development of the Score-TB Package was led by the Foundation for Innovative New Diagnostics (FIND), with contributions from Andre Trollip and Heidi Albert (FIND) and Tjeerd Datema and Linda Oskam (DATOS); and is funded by the African Society for Laboratory Medicine (ASLM) and U.S. Centers for Disease Control and Prevention (CDC) through the United States President's Emergency Plan for AIDS Relief (PEPFAR).

The TB Lab Quality Scorecards draw from several existing tools, including the WHO-AFRO SLIPTA checklist and FIND's TB Laboratory Quality Management Systems Towards Accreditation Harmonized Checklist (TB Harmonized Checklist). The TB Harmonized Checklist was developed by FIND, EXPAND-TB and CDC, with funding from PEPFAR under Cooperative Agreement 3U2GPS002746.

Thank you

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