Score-TB Package
ECHO session

André Trollip, FIND
Your presenter

Dr. André Trollip
Senior Technical Officer
FIND
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.

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
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

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 MTBDRplus and MTBDRsl & 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-RifDx)
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

- Digital version of the scorecards
- Includes SLIPTA checklist
- Excel-based
- Can be used for automated scorecalculation 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

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 (a set of interrelated or interacting elements) aimed at implementing and operating effective quality management in an organization. Standardisation 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 (SLIPTA) approach, first described by Yeo et al. The SLIPTA 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 2000 in recognition of the gap between the current state of laboratory quality and the requirements of the ISO 15189-2007 standard. In 2011, the SLIPTA checklist was adapted to incorporate the requirements of the ISO 15189-2012 standard and became known as “SLIPTA v1.0.1”.

The Foundation for Innovative New Diagnostics (FIN Diagnoses) has reported on the development of a TB laboratory-specific approach called TB Strengthening Laboratory Management toward Accreditation (TB SLIPTA). The program is based on the existing successful SLIPTA approach and utilizes a modified checklist (TB- Harmonized Checklist) based on SLIPTA, but incorporating some elements from the 15189-2012 standard as well as on the technical advice of TB laboratory testing.

In 2019, an additional technical revision was made to the TB SLIPTA Harmonized Checklist to include TB testing methods not included in previous revisions. The current major revision concerns the incorporation of the TB SLIPTA Harmonized Checklist into the “Score-TB Package”, which also includes an electronic version of the checklist referred to as the "e-tool". This tool substantially increases user-friendliness and reduces the risk for errors by automating the calculation of assessment scores and presenting them as a reporting worksheet to visualize strengths and weaknesses of a laboratory (QMS, 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 achieved with contributions from Andre Hottip and Heidi Albert (FIND) and Tjerd Adema and Linda Okomah (ERTDOS). The TB Lab Quality Scorecard draws from a number of existing tools, including CDC Laboratory Assessment of Technical Assistance 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.

Structure of the Tool

1. Introduction

2. Instructions

3. Set audit scope

4. General TB Module

5. Test specific module

6. TB Summary report

7. Previous audit information

8. SLIPTA summary

9. SLIPTA section

10. TB - specific section

11. SLIPTA
Relation with SLIPTA

Paper-based TB-scorecards

TB scorecards

SLIPTA

eTool

TB scorecards

SLIPTA

eTool
Performing the assessment

Score-TB Package ECHO session
Assessment process

Preparation

Assessment

Reporting

Score-TB Package ECHO session
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.
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

finddx.org