

Laboratory Tools

Worldwide the need for a well accessible, efficient and quality assured network for rapid diagnosis of TB cases is paramount. Reliable culture and drug susceptibility testing (C/DST) services and surveillance by national reference laboratories (NRL) are imperative for countries where MDR-TB and XDR-TB is prevalent.

TB CAP responded to these challenges by developing several laboratory strengthening projects.

It did so at three levels:

- 1 Globally through developing policy papers, guidelines and tools.
- 2 Regional by strengthening laboratory services and training.
- 3 At country level by strengthening the functioning of reference laboratories, expanding laboratory networks, quality control and application of modern technologies.

This TB CAP Focus highlights seven products recently developed to support countries in strengthening their laboratory services. These products have a generic character, for countries to adopt and adapt them to their local needs.



Laboratories have a pivotal role in the diagnosis of TB and treatment monitoring, in addition to surveillance and diagnosis of multi-drug resistance. Inequitable distribution and poor quality performance of laboratories are major barriers for DOTS expansion. Key issues affecting performance include: insufficient and inadequate human resources, crumbling or inappropriate infrastructure, lack of management and leadership capacity, inadequate equipment and supplies, and lack of appropriate tools. TB CAP has set up a group of laboratory experts, and in partnership with the Global Laboratory Initiative (GLI) developed a set of tools that focuses on strengthening management and technical capacity of laboratories.



Standard Operating Procedures

The purpose of Standard Operating Procedures (SOPs) is to ensure standardization of laboratory practice at a uniform level of quality throughout a country or region. TB CAP developed guidelines for the preparation and implementation of SOPs for countries with no written SOPs, but also for countries with SOPs available. The generic SOPs are user-friendly written instructions on all laboratory procedures, including test methods, operation of equipment, laboratory organization, quality control, safety practices and record keeping. All laboratories providing TB laboratory services from peripheral to central level can use these SOPs.

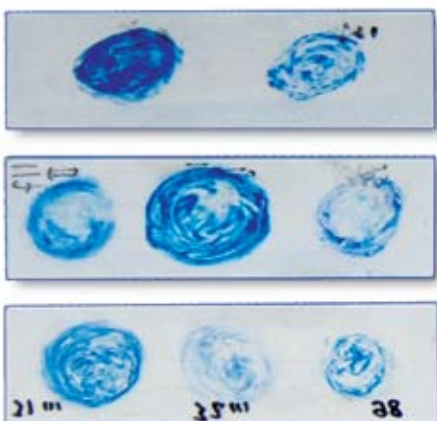
Logistics Management Tool

The Logistics Management Tool is a tool for procurement, logistics and management of laboratory equipment and other supplies that are required for TB microscopy and TB culture and DST. It provides guidance to countries and development partners on specifications and mechanisms for the efficient and timely procurement of quality laboratory equipment and supplies and the ongoing management of all TB-related laboratory commodities.

The tool consists of equipment specifications, recommendations on BSC installation, guidelines on laboratory commodity management, inventory control and algorithms, spreadsheets for calculating quantities and costs of consumables. The tool is developed for the National Tuberculosis Programs, NGOs, and agencies for tenders of laboratory equipment in low- and middle-income countries in order to implement or expand C/DST. Others responsible for the procurement, logistics and management of laboratory equipment and other supplies required for TB microscopy and TB culture and DST can also use the management tool.

External Quality Assurance package

This package provides standard materials for External Quality Assurance (EQA) training which allows countries to implement the guidelines correctly and efficiently. The package covers all main areas of AFB-microscopy EQA (rechecking, panels and supervision; newer developments, i.e. fluorescence; review of different AFB-microscopy techniques; complementary to EQA guide, AFB-microscopy training package). The package also facilitates training by providing various modules, presentations and exercises.





Panel testing as an EQA method.

Management Information System

A management Information System (MIS) will ensure standardized recording and reporting in laboratories. The system provides tools for reporting and monitoring of AFB-smears and supplies. It also promotes correct analysis, rechecking EQA important parameters and culture internal quality control. It improves efficiency of culture/DST bench records versus databases, it ensures correct data entry and easy and regular analyses and it ensures patient follow-up culture/DST. The MIS is provided both as printable hard copies and generic electronic software (dbase – Epi Info).

Culture & DST package

This package will provide countries with standardized training material to support the expansion of culture and DST techniques. The package consists of training material for trainers and participants (word documents, powerpoint presentations, exercises, reviews of modules). In total there are 12 modules (e.g. bio-safety, C/DST, use and maintenance of equipment, R&R, QM). The package is meant for laboratories providing C/DST services at national and country level.

Country roadmap

The country roadmap is a generic document to address the need for a coordinated and well-founded approach to country-level laboratory capacity development. This roadmap is a template for laboratory strengthening, encompassing the managerial, technical and operational processes required for developing and implementing a national TB laboratory strategy able to meet the needs of DOTS expansion, notably HIV-associated and drug-resistant TB. It is expected that NTPs and public and private national laboratory services will adapt the generic roadmap to suit country-specific needs, within their own epidemiological and resource context.

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Laboratory Tools in short

SOPs	Standard Operating Procedures on test methods, operation of equipment, laboratory organization, quality control, safety practices and record keeping
MIS	A Management Information System including a set of recording and reporting formats
EQA	A training package to strengthen AFB-microscopy External Quality Assurance
C/DST	A training package to strengthen capacity to provide TB Culture & Drug Susceptibility Testing
Bio-safety	A training package on bio-safety for laboratories
Logistics Management	A tool for procurement and management of laboratory equipment and other supplies
Country roadmap	A generic country roadmap document for laboratory strengthening

How to access TB CAP laboratory tools?

Contact TB CAP / PMU in The Hague, The Netherlands

Email pmu@kncvtbc.nl

Phone +31-70-416-7222

Website www.tbcta.org

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Bio-safety package

The bio-safety package consists of a manual on bio-safety for laboratories working with TB bacilli which fulfills the needs of low-income countries to design, organize and maintain safe working conditions in laboratories where TB microbiology procedures (microscopy, culture, DST, molecular tests) are carried out. It also contains a training package which explains how to work according to safe practice in laboratories where microscopy, culture and DST of *M. tuberculosis*, and molecular tests for the rapid detection of MDR-TB are carried out. The target audience for this package is the laboratory staff from high TB burden countries performing TB laboratory activities (microscopy, culture, DST, molecular tools).



Laboratory in Kenya.

What is TBCTA and TB CAP?

The Tuberculosis Control Assistance Program (TB CAP) is a USAID five year cooperative agreement (2005-2010) that has been awarded to TBCTA with KNCV Tuberculosis Foundation as the lead partner. The Tuberculosis Coalition for Technical Assistance (TBCTA) is a unique coalition of the major international organizations in TB control:

American Thoracic Society (ATS), Centers for Disease Control and Prevention (CDC), Family Health International (FHI), International Union Against Tuberculosis and Lung Disease (The Union), Japan Anti-Tuberculosis Association (JATA), KNCV Tuberculosis Foundation, Management Sciences for Health (MSH), World Health Organization (WHO).

The aim of TB CAP is to reach the following specific goals in the TB CAP countries with significant investment:

- 90% of public clinics implementing DOTS;
- At least 70% case detection rate;
- At least 85% treatment success rate and/or cure rate;
- 75% of countries meeting MDR TB quality standards defined by TB CAP;
- 100% of countries where nationwide TB and HIV programs effectively coordinated.

TB CAP focuses on five priority areas:

- Increasing political commitment for DOTS;
- Strengthening and expanding DOTS Programs;
- Increasing public and private sector partnerships;
- Strengthening TB and HIV/AIDS collaboration;
- Improving human and institutional capacity.

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Text PMU, Lynette Wijgergangs
Layout Chubaloo, Voorburg
Printing Marty Rengers BV, Koudekerk a/d Rijn