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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.

Acknowledgments

The following TBCTA partners have developed or contributed to the formation of the Laboratory Tools: CDC, MSH, KNCV Tuberculosis Foundation, JATA, The Union and WHO.
Introduction of 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 tools.

This TB CAP Lab Toolbox contains six products recently developed to support countries in strengthening their laboratory services:

1. A Roadmap for Laboratory Strengthening
2. Standard Operating Procedures (SOPs)
3. Logistics/Supply Management Tool
4. External Quality Assurance Training Package (EQA)
5. Management Information System (MIS)
6. Culture & DST Training Package

These products have a generic character so countries can easily adopt and adapt them to their local needs.

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Overview of Laboratory Tools

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1. A Roadmap for Laboratory Strengthening

Introduction

The purpose of the Roadmap for Laboratory Strengthening is to guide the development or updating of National Laboratory Strategic plans to incorporate the specific requirements for providing the laboratory services needed for TB diagnosis, treatment, and control. The roadmap is a document that matures and evolves to respond to issues such as:

- Disease burden and epidemiology
- New diagnostic tools
- Costs and benefits of technology advancement
- Government and donor support levels
- Clinical indications for diagnosis and monitoring
- Human resource requirement

Overview of Lab Tools
2. Standard Operating Procedures (SOPs)

Introduction

The purpose of the Standard Operating Procedures (SOPs) is to ensure the standardization of the quality of laboratory practices throughout a country or region. TB CAP developed guidelines for the preparation and implementation of SOPs for countries with no written SOPs as well as for countries with currently available SOPs. The generic SOPs are user-friendly, written instructions on 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.

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2. Standard Operating Procedures (SOPs)

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Module 4: Emergency procedure in case of major biohazard incident outside the biological safety cabinet
Module 5: Fumigation of a biological safety cabinet
Module 6: Emergency procedure in case of fire
Module 7: Use of personal protective equipment in an AFB microscopy laboratory
Module 8: Use of personal protective equipment for culture and drug susceptibility testing
Module 9: Use of disinfectants

Use and maintenance of equipment
Module 10: Use and maintenance of class I and class II biological safety cabinets
Module 11: Use and maintenance of an autoclave
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Module 21: Use and maintenance of a water distiller

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Module 25: Preparation of Löwenstein–Jensen drug-containing media

Procedures
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Module 27: Auramine staining
Module 28: Rechecking acid-fast bacilli smears for external quality assessment
Module 29: Sample conditions and transport for culture procedure
Module 30: Specimen processing for culture
Module 31: Drug susceptibility testing, proportion method
Module 32: Identification of *Mycobacterium tuberculosis*
Module 33: Niacin test
Module 34: Catalase test
Module 35: Nitrate reduction test
Module 36: Growth on PNB medium
Module 37: Maintenance of mycobacterial strains

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3. Logistics/Supply Management

Introduction

The Logistics Management Tool is used for the procurement, logistics and management of laboratory equipment and other supplies that are required for TB microscopy, and TB culture and DST (C/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, and spreadsheets for calculating quantities and costs of consumables. The tool was 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 this management tool.

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3. AFB Supplies Procurement Calculation Tool - User Guide
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5. Culture & DST Supplies Procurement Calculation Tool - User Guide

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4. External Quality Assurance Training Package

Introduction

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 AFBmicroscopy techniques; complementary to EQA guide, AFBmicroscopy training package). The package also facilitates training by providing various modules, presentations, and exercises.

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5. Management Information System

Introduction

A management Information System (MIS) ensures 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 the efficiency of culture/DST bench records versus databases, it ensures correct data entry and easy and regular analyses as well as patient follow-up culture/DST. The MIS is provided both as printable hard copies and generic electronic software (dbase – Epi Info).

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Note: In order to use the MIS Tools please read this readme file first: ReadMe

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6. Culture & DST Training Package

Introduction

This package provides countries with standardized training material to support the expansion of Culture & DST (C/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 (on topics such as: biosafety, C/DST, use and maintenance of equipment, R&R, QM). The package is meant for laboratories which are providing C/DST services at either the national or country levels.

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Trainer’s Manual

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Module 2:  Safety precautions for AFB culture and DST of *M. tuberculosis*
Module 3:  Use, calibration and maintenance of laboratory equipment
Module 4:  Preparation of solid media for culture and DST
Module 5:  Collection, transport and receipt of specimens
Module 6:  Processing the specimens and inoculation on solid and liquid media
Module 7:  Reading cultures
Module 8:  Identification of *Mycobacterium tuberculosis*
Module 9:  Recording and reporting culture results
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Trainers Guide
Customization Guide
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Epidata Software Install ReadMe

In order to use the Management Information System Tools you must complete the following steps:

1. If not already installed on your computer please install the Epidata software (English/Français):
   
   1.1 Epidata Entry Software (English)
   1.2 Epidata Entry English Introduction.pdf
   1.3 Epidata Entry English Help pdf
   1.4 Epidata Entry Logiciel (Français)
   1.5 Epidata Entry Français Fichier d’Introduction.pdf
   1.6 Epidata Entry Français Fichier d’aide.pdf

2. From the CD open the ‘Additional Materials For MIS’ folder and copy the whole ‘Installation’ folder to your computer

3. Open the copied ‘Installation’ folder and copy all the files to the following location on your computer:

   C:\epidata\reflab

4. Open the following linked files and save them to your preferred location on your computer but somewhere you can easily access them.

   2.1 Culture and DST Reporting Form
   2.2 Culture Analysis Workbook in EXCEL
   2.3 DST Analysis Workbook in EXCEL

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