TUBERCULOSIS LABORATORY NETWORK ASSESSMENT

Country:　　　___ _____

Year:　　　_____

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Introduction

Diagnosis and treatment monitoring by sputum smear microscopy are key components of the DOTS strategy. As DOTS is expanded to cover increasing portions of the population TB laboratory networks must be reinforced to meet these needs and with the ability to provide high quality and reliable laboratory services.

This document covers the minimum required information for a useful laboratory assessment. Depending on the specific circumstances in the country under assessment, additional data may be collected. This tool recommends the assessment focus on the following areas.

1. Structural, functional and policy profile of the TB laboratory network
2. Quality assurance programme
3. Laboratory performance analysis
4. Human resource development
5. Procurement of laboratory equipment and supplies
6. Safety measures and practices
7. Data management

This tool has been designed to gather a large amount of information, some of which may be difficult or impossible to obtain in certain settings. However, recommendations derived from biased or fragmentary information are often ineffective, not useful to improve the situation and even may be counterproductive. In this regard, this document should not be reduced, or used to focus on certain limited issues. A determined effort should be made to obtain the maximum available information, even if it concerns only a part of the country or a relatively short time period. Data should also be requested from NTP counterparts.

The summary report of constraints is an important aspect of this tool and will be very useful in determining the best approach to assist Laboratory networks both financially and technically. Though, the summary recommendations will be useful in the first stages of assistance the detailed information collected will be most useful in monitoring the progress in improvement. Attention should be given to both components.

Terminology in quality assurance

Quality assurance (QA): System designed to continuously improve the reliability and efficiency of laboratory services, including internal quality control, external quality assessment, and quality improvement.

Quality control (QC): A systematic internal monitoring of working practices, technical procedures, equipment, and materials, including quality of stains.

External quality assessment (EQA): A process which allows participant laboratories to assess their capabilities by comparing their results with those in other laboratories in the network (intermediate and central laboratory) through panel testing and blinded rechecking. EQA also includes on-site evaluation of the laboratory performance.

Reference: *External quality assessment for AFB smear microscopy. APHL, CDC, IUATLD, KNCV, RIT(JATA), WHO. Association of Public Health Laboratories, 2002.*

I. Basic information on the country to be assessed

1. The name of country:

2. Population: Rural population =

3. NTP manager & head of the National TB Reference laboratory (NTRL) or equivalents:

	NTP manager or equivalent	NTRL head or equivalent
Name		
Address		
Telephone		
Fax		
Email		

4. TB patients notified in the previous year: _____

Pulmonary tuberculosis					
Smear-positive			Smear-negative	Extra-Pulmonary TB	Total
New	Retreatment	Total			

If national level data is not available, it can be replaced with regional or local data with clear description of the source.

2. Structural and functional profile of the laboratory network for the NTP

TB laboratory services should be organized taking into account accessibility to the entire population and provision of all the necessary services for efficient TB case-management. The NTP of some countries has a built-in or fully integrated laboratory network, while in other countries TB laboratory services are integrated into the general health system or provided by completely independent organizations at some or all levels. When the laboratory network is independent from the NTP, coordination must be established to ensure functional integration of the network into NTP to provide comprehensive TB case-management.

(1) Structural profile (public sector): please write the number of health facilities in the table below

Level of the service	No. of functional facilities	No. doing AFB-microscopy
Central		
Intermediate		
Peripheral		
Total number		

Please describe the relationship of every level of laboratory with the NTP, according to the classification system described here below :
A= TB laboratory system fully integrated structurally (defined as budget, staff, and organization) and functionally (defined as operational) into the NTP
B= TB laboratory system separated structurally but functionally integrated through recording/reporting mechanisms, supervision & QA
C= TB laboratory system separated structurally from the NTP but reporting to the NTP with supervision & QA of laboratory services undertaken by another agency (describe the over-all system in which TB laboratory system is placed)
D= Other relationship – describe

D description

Are there problems with coverage for AFB-microscopy, even if only in some areas:
- over-decentralisation?
- poor accessibility?

Please describe possible existence, role and level of integration of specialised TB services (for TB diagnosis besides treatment):
- TB hospitals
- TB outpatient clinics
Is there a problem of referral / transfer of diagnosed patients from these facilities?
Is there a special hospital or wards for MDR-TB? If yes, describe the hospitalization policy for MDR-TB.

Is there already an important involvement of the private sector in TB (lab) diagnosis?

(2) Functional profile (public sector)

Please specify availability (level, number or names of institutions if few) and use of other bacteriological methods:
- culture:

- DST:

- fluorescence microscopy:

- molecular diagnosis of drug resistance:

(3) NTP Laboratory Guidelines

a) Is there a national TB laboratory manual? (please attach)

b) What are the NTP guidelines standard procedures for smear microscopy?
- Smear preparation: direct smear / concentrated smear / both
- Stains: Ziehl-Neelsen carbol-fuchsin / Kinyoun carbol-fuchsin / fluorescence
- Where are the staining solutions prepared? Peripheral laboratories? Intermediate laboratories? Central laboratory?
- Do those laboratories have equipment and supplies essential for preparation of stains?

c) What are the NTP guidelines for the use of culture: for diagnosis of smear-negative TB? only as first step for DST ? describe the indications in case a policy exists
- Media and culture system used?
- Decontamination technique used?
- How are samples neutralised? If repeated washing is performed, are centrifuges sufficiently powerful (3000 g, not just RPM)?
- Is incubation properly done (temperature, time)?

d) What are the NTP guidelines for use of DST, by type (slow culture-based methods; rapid culture-based methods; genetic methods)? In case a national policy exists, describe the indications for each group of methods (for diagnosis of MDR-TB / for resistance surveillance (DRS); define the drugs targeted by method and by objective (MDRTB diagnosis / DRS)
- Standard DST method(s) used: system for genetic testing? method and medium culture-based (specify for each if more than one)?
- Technical details culture-based DST:
  - drug concentrations (taking into account potency?); drugs used (origin, expiry, correct storage); antibiotic powder supply problems? Give medium inspissation details if applicable.
  - inoculum preparation: standardisation system; dilutions used for inoculation; are loops or pipettes used?
  - reading and interpretation

- Technical details genetic DST:
    - how are samples for genetic DST transported to the laboratory?
    - which measures are taken to prevent and detect cross-contamination?
    - DNA extraction method used?

3. Method and system for implementation of quality assurance

(1) Are there NTP guidelines (or protocol) for quality assurance of smear microscopy? Please attach.

(2) Describe measures of internal quality control for smear microscopy at each level. (specimen reception/handling; stains/staining; equipment function, etc)
Peripheral:

Intermediate:

Central:

(3) Method and system of external quality assessment (EQA) of smear microscopy:
  - Which methods are in use? for which level of laboratories / techniques?

  - Rechecking:
    - How are slides kept? Presence of identification number & absence of results on slides?
    - How many slides (positives / negatives / scanty) are sampled per microscopy unit per year? how is random sampling done, and by whom?
    - Is there a coordinator for rechecking at intermediate level?
    - How is first level blinded rechecking assured?
    - Is the second control on discordants done? By whom? Blinding?
    - Is restaining being used? At which level?
    - Does results analysis include a check on validity of the controls?
    - Are minimum performance targets clearly defined ?
    - Is there a different system for rechecking of fluorescence microscopy? In the affirmative, please describe. Also specify in case no rechecking of fluorescence microscopy is done.

(4) Results of smear microscopy EQA.
  a) Slide rechecking
    - no. of labs covered by rechecking; or approximate percentage of total microscopy labs covered (then also describe regularity)
    - no. of positive, scanty and negative smears rechecked in total for all labs (most recent report; please specify the year)
    - no. of labs with HFP (high false positives) detected
    - no. of labs with excessive FN (false negative) detected
    - corrective action taken?
    - numbers and error %: high false positive / positives rechecked; all false negative (high plus low) / all negatives rechecked

  b) Panel testing
    - describe type and constitution of panels used: manufactured for the purpose or from routine? Stained as well as unstained smears? Number of strong positives / scanty / negative smears, and total in the panel?
    - How are manufactured lots validated?

- Are tests taken during a supervision visit or unsupervised?
- Number of rounds done last year? Number of microscopy units covered?
- How are results analysed? How is feed-back and corrective action organised?
- Please give results of these rounds as detailed as possible

(5) Supervisory visits (last year)

Direction of supervision		No. of visits	
		Planned	Done
Intermediate to periphery	By laboratory person		
	By non-laboratory person		
Central to periphery			
Central to intermediate			

(6) Is supervisory visit (on-site evaluation) carried out with a check-list? If so, attach it. If not, what points are checked during supervisory visit?

(7) Describe the mechanism for feedback of the results of EQA or onsite supervision, from intermediate / national level

(8) Are there mechanisms to ensure that corrective actions (QI) are taken and sustained after the feedback?

(9) If culture examination is routinely performed, describe how QC and EQA for culture examination are implemented in brief. Also quote per cent fully contaminated and per cent negatives from smear-positive specimens of untreated cases (new and relapse) as per most recent data (specify year / quarter) at the NRL

(10) Describe how QC and/or EQA for DST are implemented, per method used.

4. Laboratory performance and workload analysis

(1) Smear microscopy done last year: _____

Result	Ziehl-Neelsen			Fluorescence microscopy		
	Number of smears examined			Number of smears examined		
	Diagnosis	Follow-up	Total	Diagnosis	Follow-up	Total
Positive						
Negative						
Scanty						
Total						

(2) Cultures done last year: _____

NRL	Year _____								
Microscopy result	Culture results				Culture results				Grand Total
	Not on treatment (new and relapse only)				Treatment follow-up / started treatment				
	Pos.	Neg.	Con.	Total	Pos.	Neg.	Con.	Total	
Positive									
Negative									
Scanty									
Total									
Intermediary level	Year _____ Number of labs included / total doing culture _____								
Microscopy result	Culture results				Culture results				Grand Total
	Not on treatment (new and relapse only)				Treatment follow-up / started treatment				
	Pos.	Neg.	Con.	Total	Pos.	Neg.	Con.	Total	
Positive									
Negative									
Scanty									
Total									

(3) DST performed last year: _____

Level	Slow culture-based		Rapid culture-based		Rapid genetic	
	No. done	MDR detected	No. done	MDR detected	No. done	MDR detected
National						
Intermediate						
Total						

(4) Workload of laboratory workers at different levels last year: _____

Averages		Central	Intermediate	Peripheral
Smear microscopy	Number staff per lab			
	No. of smears / year / staff			
Culture	Number staff per lab			
	No. of cultures / year / staff			
DST	Number staff per lab			
	No. of DST / year / staff			

5. Safety

(1) Microscopy laboratories
   Disinfectant(s) in use?
   Disposal of used sputum containers, sticks, other contaminated materials?
   Cleaning work place, how often? With what?
   Use of hand basin?
   Proper use of lab coats, gloves, etc?
   If safety cabinets are used: what is policy on installation? Type: local manufacture?
   Certified at factory? Properly maintained?

(2) Culture and drug susceptibility laboratory
   Laboratory layout designed to control the airflow? Negative pressure maintained?
   Use of centrifuges and their specification: aerosol containment?
   Use and maintenance of safety cabinet(s)?

(3) Is emphasis during training on safe laboratory practices correct? (transmission via air and not skin; untreated patient far more dangerous than his sputum; relatively low danger of smearing technique)

(4) Regular health check up of laboratory workers
   - Chest X-ray and sputum examination? If yes, how often?
   - Any documented laboratory infection during last 3 years?

6. Human resource development

(1) Is there a NTP training plan (describe and attach a copy).

(2) Give details of AFB-microscopy staff training
   Who provides the training?
   Where is it conducted?
   How often is it conducted?
   How long is the training: theoretical part / practical part?
   What is the curriculum (attach)?
   Are there training facilities and what equipment are used?
   Describe the training materials available e.g. laboratory manual? training modules?

(3) Approximate proportion of laboratory workers receiving refresher training each year.

(4) How many staff were trained overseas the last two years _____ (where, for how long, how funded)? Are they still involved in TB laboratory work?

(5) Describe the number and level of educational institutions for licensed laboratory workers. Can school-leavers do TB work independently: AFB-smears? Culture? DST?

(6) Approximate number of technicians newly licensed in a year.

(7) Describe turnover rates of laboratory staff at central, intermediate and peripheral levels.

(8) Is there a register of laboratory staff with training and experience in TB diagnosis?

(9) Describe the unmet resource requirements for human resources development at central, intermediate and peripheral levels.

7. Procurement and distribution of supplies and equipment

(1) Is there a plan for the procurement and distribution of supplies (laboratory reagents, consumables etc.) and equipment (microscopes, incubators, safety hoods etc.)? if available, please attach.

(2) Do NTP or Reference Laboratory expert(s) take part in the procurement system? For estimates of requirements? For choice of good quality materials?

(3) Describe the system for procurement and distribution at national and regional levels, including:
- At which level are funds made available for procurement?
- Who is responsible for estimated requirements at various levels?
- Who is making final decisions on quantities and suppliers?
- What is the storage and distribution system up to the periphery?

(4) Is the budget for procurement and distribution of supplies and equipment of the last 2 years sufficient? Consider central, intermediate and peripheral levels separately (attach)?

(5) Describe the system of recording and reporting for the status of supplies and equipment within the laboratory system. Is a standard used (if available, please attach)?

(6) Have there been interruptions in laboratory work at central, intermediate and peripheral levels due to shortages of supplies and equipment?

(7) Are buffer stocks of supplies and equipment kept? Please describe the system and give an indication of size of buffer stocks at different levels.

(8) Describe the maintenance system for equipment including availability of spare parts (especially bulbs & objectives) for microscopes.

(9) What is the average lifespan of microscopes? What are the major causes of malfunction?

Procurement and Distribution: Problems mentioned

8. Data management

(1) Are a standard TB microscopy request form and TB microscopy register book in use? (if yes, please attach both). Do the form and registry book conform to WHO/IUATLD format?

(2) Is there a culture/DST request form and registry book conform to WHO/IUATLD recommended format?

(3) On average, how long does it take for the laboratory report to be produced after the clinic has sent the patient or specimen to the laboratory (turnaround time): for smear microscopy; for culture; for DST? What is the average delay for the patients to be put on treatment?

(4) How often are laboratories required to report on their performance (monthly, quarterly, 6-monthly or annually) and to which authorities do they send their reports? Are there standard reporting forms (if yes, please attach) ?

(5) Is feedback on laboratory reporting, supervision and/or EQA data given regularly after proper analysis? if yes, how and from which level?

9. Summary of the major findings on constraints to adequate laboratory performance

	Findings and conclusions
Policy	
Organization (coverage/relationship with NTP)	
Human Resources (including training/supervision)	
Technical services (standard methods/operations)	
Procurement (equipment/supplies)	
Quality assurance Of services	

10. Recommendations

This part will be filled by the external assessors