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Microscopy network accreditation

Armand Van Deun
The Union &
Antwerp coordinating SRL

Rationale

- Current laboratory accreditation drive
 - complementary to reference lab accreditation
 - huge numbers (WHO 2009)
 - labs: India 13,000; Indonesia 5000, Brasil 4000, DR Congo 1500, ...
 - tests, e.g. DF Bangladesh 700,000 per year (165 labs, 1/6th of population)
 - not individual labs, but network organization and functionality
- Revive interest in microscopy
 - competing multitude of new laboratory priorities
 - no realistic replacement yet at the peripheral level
 - often unclear status, e.g. “100% EQA coverage”??
- Model for other point of care techniques organised as networks

USAID TBCARE I project

- In its second year
- Partners
 - Union lead
 - WHO, CDC, KNCV
 - consultants: Sabira Tahseen, Marijke Becx



Achievements

- Assessment tool version 1
 - policies questionnaire: national level
 - validation questionnaires: national, intermediate, peripheral levels
 - stratified random site sampling system
 - links to various GLI microscopy guidance documents
- First pilot test performed: Pakistan NTP
 - has confirmed the needs
- ISO does not address network management
 - proposed standards and measures drafted
 - for GLI endorsement

Standards for accreditation of an AFB-microscopy network

1. **The TB microscopy network structure, its services to the NTP, its management, future expansion and appropriate use (balanced with that of other available TB laboratory methods), must be defined in a strategic plan.**

Measure for standard #1 – A national strategic plan for TB laboratory services exists, either on its own or as part of the general NTP or laboratory services strategic plan. It clearly defines the place of microscopy as the first-line diagnostic and treatment monitoring test, except when Xpert MTB/RIF is available and indicated because of high prevalence of MDR-TB or HIV. The plan includes a gradual switch from Ziehl Neelsen to LED fluorescence technique where feasible.

2. **A national AFB-microscopy manual with standard operating procedures must exist, and be available in some format at all the microscopy labs.**

Measure for standard #2 - The national SOPs or guidelines are available and followed at all levels. Internal and external quality assurance policies and procedures are covered in this manual or separately, clearly stating the process and responsibilities at various levels. The operating procedures and policies respect global guidelines on the main points.

3. **There must be documented and recent evidence of complete coverage of the population by AFB-microscopy labs, organized as a network.**

Measure for standard #3 – There is at least one functional AFB-microscopy lab per 50,000 to 150,000 population, depending on population density. Except in the smallest countries, intermediate level laboratories assure an important part of the required training, external quality assessment (EQA) and supplies management for the peripheral level.



- 4. Qualifications and number of staff required for performing AFB-microscopy and its EQA must be appropriate and complemented by job descriptions and training curricula with sufficient emphasis on practice.**
- 5. EQA must target all labs, including regular supervision visits.**
- 6. Globally standardized recording and reporting formats for AFB-microscopy and its quality assurance must be used at all levels of the network.**
- 7. The NRL or lab specialist of the NTP must assure excellent control over microscopy network supplies and equipment, including estimates and specifications for procurement, balanced distribution, provision for buffer stocks and stock management at all levels.**
- 8. A policy regarding the place of the private sector and its microscopy labs within the NTP must exist and should be functional.**
- 9. There must be a dedicated budget for the microscopy network, assuring continuous and country-wide availability of free, quality assured AFB-microscopy.**
- 10. AFB-microscopy laboratories must be safe for the staff and the community.**



Planning

- Revise and finalise the assessment tool
 - endorsement by major TB organizations
- Have standards and measures approved
- Write business plan
- Announce the tool at Union conference 2012
- Third year proposed to USAID
 - to train surveyors
 - to perform few assessments leading to accreditation



Ultimately

- GLI accreditation scheme
 - administered by The Union
 - at the service of GLI members, SRL...
- Self-reliant: countries pay