

Proposal to Develop Accreditation for Smear Microscopy Networks

External Quality Assessment for AFB Smear Microscopy



TB laboratories under the supervision of National TB Reference Laboratories in
Tier 1 Countries

Country	Smear Microscopy			Culture		DST	
	No.	per 100,000 popn	% in EQA	No.	per 5M popn	No.	per 10M popn
<i>Routine Dx Min Req</i>		1			1		1
Afghanistan	545	1.9	72	1	0.2	0	0
Bangladesh	753	0.5	100	4	0.1	2	0.1
Brazil	4,044	2.1	45	232	0.6	38	2.0
Cambodia	205	1.4	93	5	1.7	1	0.7
DR Congo	1,545	2.4	85	1	0.1	1	0.2
Ethiopia	1,000	1.2	0	6	0.4	6	0.7
India	13,000	1.1	93	17	0.1	17	0.1
Indonesia	4,855	2.1	100	41	0.9	11	0.5
Kenya	930	2.4	4	5	0.6	1	0.3
Mozambique	252	1.2	100	3	0.7	1	0.5
Nigeria	1,138	0.8	44	9	0.3	9	0.6
Pakistan	1,131	0.7	32	5	0.1	1	0.1

Source: WHO Global Tuberculosis Report 2009

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<i>Routine Dx Min Req</i>		1			1		1
Philippines	2,374	2.6	100	3	0.2	3	0.3
Russia	4,048	2.9	0	965	34	280	20
South Africa	249	0.5	97	18	1.8	10	2.0
Tanzania	717	1.7	0	3	0.4	1	0.2
Uganda	741	2.3	100	4	0.6	2	0.6
Ukraine	-	-	0	-	-	-	-
Zambia	158	1.3	13	3	1.2	3	2.5
Zimbabwe	180	1.3	0	1	0.4	1	0.7
USAID Tier 1 Total	37,865	Yes=15 (75%)	66	1,326	Yes=4 (20%)	388	Yes=4 (20%)

Principles

- An accreditation scheme would be based on GLI/WHO guidelines for microscopy methods and Quality Management Systems (QMS), including EQA.
- Similar to modern QMS the countries would be required to have documented policies, plans, and procedures that address supervision, training, and support for the network. The accreditation program would review and assure that the country policy sufficiently addresses quality practices and that the policy is carried out throughout the system.
- External review of the plan, documentation, and a random sample of microscopy centers and EQA results will provide sufficient review to measure the quality of the network.
- An accreditation program must be self sustaining requiring that some combination of donor support and accreditation fees will be necessary to finance the administrative and technical development of the standards, pay for the trained surveyors, and support the country visits.

Benefits

- An accreditation scheme based on GLI/WHO guidelines will assure full implementation of quality standards in the microscopy network.
- Public notification of standards, requirements, and process along with a voluntary accreditation process will provide significant incentive to improve quality and increase case detection.
- A system accreditation scheme will also strengthen networks so that they are better positioned to implement new technologies such as fluorescence microscopy and molecular methods.
- An accreditation scheme with set standards and trained surveyors will significantly increase monitoring and evaluation of the laboratory network and improve on the current limited evaluation by individual consultants during WHO country TB programme reviews.

Process

- Develop the accreditation standards/requirements and process with representatives from partners and countries. The NTP/NRLs would be required to outline their network management policies and procedures in a plan, similar to a quality manual that addresses:
 - Clear organizational structure including who performs onsite supervision, their training and experience, and frequency of visits.
 - EQA methods and requirements, including the number of slides sampled by blinded rechecking, process for collection of slides, and methods to recheck, record and report results.
 - Methods to maintain equipment including protocol to determine when microscopes would be replaced.
 - Frequency of in-service microscopy training, methods of training, curriculum.
 - Protocols for distribution and inventory of supplies including where stains are produced and how the stains and components are quality controlled.

Process (cont)

- All components of the plan would be checked through documentation that might include records for training, EQA results, supervisory visit checklists, inventory, etc.
- A team would evaluate the extent of compliance with the country plan using tracer methods that would sample a sufficient number of microscopy centers or center records to provide assurance that the plan has been implemented and receives ongoing support.