

ACTIVITY: TB LABORATORY ACCREDITATION

Global laboratory Initiative (GLI) task force to develop a strategy and proposal for international accreditation of regional and country level TB laboratory networks.

Goal

To convene a task force of international experts and key partners to develop a consensus strategy and proposal for a voluntary laboratory accreditation program focused on TB regional and country level laboratory networks.

Background

There is a growing need to dramatically expand and strengthen TB laboratory services, including increasing access to high quality microscopy, culture, drug susceptibility testing (DST), and new diagnostics. A major barrier, however, is developing capacity and assuring quality in weak laboratory systems where there are little or no laboratory standards. The ready access to quality diagnostics in high resource countries is not simply a matter of greater resources for personnel, facilities, and supplies, but also reflects laboratory regulations and accreditation programs that clearly outline and enforce standards which ensure accountability and quality services. Even when resources are available in low resource countries there are often problems with the quality and efficiency of services, especially for culture and DST, which reflect the absence of consistent laboratory standards. Currently, there are significant new resources for TB laboratories, but the only externally administered system of laboratory requirements is the WHO drug resistance surveillance system which requires documentation of DST accuracy before country results are accepted and published as part of worldwide surveillance.

Accreditation programmes are usually voluntary, constructed and administered by laboratory peers, and relying on the incentives of peer pressure and prestige. There are many international organizations that provide external certification to the ISO standards (15189) which are rigorous and process-oriented. Although using existing ISO certification programs is one approach, there are concerns that these ISO standards might be unattainable and do not sufficiently address key technical requirements for TB NRLs in low and medium resource countries. What is needed is a programme that would promote implementation and compliance with consensus laboratory standards that include requirements for personnel, quality control/quality assurance, monitoring through consistent performance indicators and the mandatory enrollment and successful performance in external quality assessment (EQA) programs. Although strengthening quality systems for culture and DST and laying the groundwork for new diagnostics are a priority for accreditation, consideration might be given to also assessing the NRL responsibilities for managing a network of microscopy laboratories at all levels.

Process

A Task Force of international experts in TB laboratory practice, quality standards, and accreditation programs will be convened to discuss approaches and develop consensus on a strategy and possible organizational design for implementing an international program of TB laboratory accreditation. Developing broad consensus is vital in promoting acceptance in the international network of TB laboratories and assuring that any governance structure includes the representation and participation of those that are governed. The success of most accreditation programs is based on governance by steering groups in conjunction with broad review and consensus on specific standards. Additionally, many accreditation programs are administered through voluntary part-time laboratory evaluators who must be sufficiently trained to consistently assess compliance with the standards.