

Assessment of Tuberculosis Laboratory Quality: A Multi Centre Descriptive Cross Sectional Study in Sidama Zone, Southern Ethiopia

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ABSTRACT

Background: Tuberculosis laboratories play an imperative role to achieve the global goal for case detection of smear-positive pulmonary cases. However, tuberculosis laboratories in a low resource setting face numerous quality bottlenecks and hence, achieving the desired case detection target would only be a dream unless continuous monitoring and quality improvement mechanisms are put in place. Therefore, the objective of this study was to assess the quality of tuberculosis laboratory at public health facilities, Sidama zone, southern Ethiopia.

Method: A facility based descriptive cross-sectional study was conducted in fifty-six health facilities performing Acid-Fast Bacilli (AFB) microscopy. Data were collected using structured questionnaire and observation checklist. SPSS version 20.0 software was used for data entry and analysis. Descriptive summaries were used to describe the study variables.

Results: The overall performance of the tuberculosis laboratories was 48.9%. The lowest score was recorded on training status (19.7%) and the highest score was recorded on biosafety and waste disposal (69.4%). Inadequate performance also identified in infrastructure (28.1%), Standard Operating Procedure's (49.5%), reagents and equipment (43.5%), maintenance of microscope (42.9%), External Quality assessment (46.8%), internal quality control (25.6%) and data management (57.1%).

Conclusion and recommendations: The present study revealed a number of underperformance in the quality of tuberculosis laboratories. To ensure sustainable preventive maintenance of microscope, attention should be given for training and deployment of personnel trained in biomedical equipment maintenance. Laboratory technician should filter Carbol-fuchsin before use and check the quality of stains and staining technique. Training of the laboratory technicians on quality assurance of microscopy would be a good first step to enhance Standard Operating Procedure practice of tuberculosis laboratories.

INTRODUCTION

Tuberculosis (TB) remains one of the deadliest communicable diseases infecting over 9 million people in the world. In 2014, 28% of the world's cases were reported from African region ^[1]. Ethiopia continued to be among the 22 high TB burden and 27 high MDR-TB burden countries in the world ^[2]. In 2013, there were an estimated 210,000 (224 per 100,000 populations) incident cases of TB and prevalence of TB was estimated to be 310,000 (224 per 100,000 populations) ^[1].

The Sustainable Development Goal (SDG) target to reducing deaths from TB can be achieved if TB control efforts approach as closely as possible the global goals for case detection of smear positive PTB 70% and cure rate of 85% or above. Although

laboratories play a fundamental role in TB care and control, only 58% of the 4.9 million pulmonary TB patients notified globally in 2013 were bacteriologically confirmed using a WHO and International Union Against Tuberculosis and Lung Disease (IUATLD) recommended diagnostic methods ^[2,3]. Low coverage of laboratory confirmation may result in people without TB needlessly being enrolled on TB treatment, while true TB cases are being missed. Furthermore, the 5.7 million incident (new and relapse) TB patients diagnosed and notified to NTPs in 2012 represent only 64% of the estimated 9 million incident TB cases globally. The gap reflects both underreporting of diagnosed TB cases and failure to diagnose cases at all; the latter can be attributed in part to weak laboratory capacity in many countries ^[2].

Tuberculosis control requires a functional laboratory set-up with quality diagnostic services and a trained diagnostician and a microscopist. However, the performance of such laboratories depends on continuous monitoring and quality improvement mechanisms put in place. It is also important to understand the limitation of smear microscopy in the detection of tuberculosis. But the limited diagnostic capacity for TB in the countries remains a challenge to improving case detection rate ^[3].

Quality Assurance (QA) system for the sputum microscopy is aimed at minimizing the false positive and false negative results in the laboratory services. Failures to maintain the quality would result in loss of credibility and waste of precious resources, at individual laboratory level, and inaccurate data and poor performance of the programme, in terms of case detection, at the national level. According to the recommendations made by the national guideline, the quality assurance system for sputum smear microscopy for tuberculosis includes; Internal Quality Control (IQC), Quality Improvement (QI) and External Quality Assessment (EQA) ^[4].

On-site Evaluation (OSE) is one of the three components of External Quality Assessment (EQA) methods other than panel testing and blinded rechecking. It is the best method to obtain a realistic picture of the conditions and practices in the laboratory. The main purpose of the on-site visit is to observe the laboratory under routine conditions in order to check that it is operating in accordance with standards set down by the NTP/NRL in the manual for national tuberculosis laboratories guidelines and to identify potential problems underlying the substandard performance ^[5].

Although smear microscopy has its own limitations, the reduced sensitivity majorly raised from a problem associated with the stringent requirements of the test and technicians who perform it. Because of high workload and fatigue, they often make more mistakes in their routine more compared to laboratories processing moderate number with regular positives. False results in diagnosis either lead to unnecessary treatment of the patient with potentially toxic drugs and puts precious resources of the program to the drain, increasing the health care costs (false positive results); or deprive the potentially infectious TB patients from the benefit of treatment and cure (false negative results). Errors in reading follow-up of treatment smears can result in patients being placed on prolonged treatment or re-treatment or in treatment discontinued prematurely.

Therefore, quality assurance of AFB sputum smear microscopy is essential for any tuberculosis control program ^[4,5]. Even though quality laboratory services are mandatory for active pulmonary TB detection and monitoring purposes, it is not well studied and limited information was available in Ethiopia, particularly in the study area. Therefore, this study aimed to assess the quality of tuberculosis laboratories at public health facilities of Sidama zone, south Ethiopia. Information obtained from this study is valuable in providing evidence to improve laboratory quality and input for planning a focused quality improvement strategy.

MATERIALS AND METHODS

Study Design, Setting and Participants

A facility based cross-sectional study was conducted from February 1 to April 15, 2015, on 56 peripheral TB laboratories of Sidama zone, Southern Ethiopia. In the entire zone 3491 health professionals are providing health services and out of these laboratory personnel account 196 (5.6%). A total of 131 public health laboratories are found in the zone. Of this, all the 56 functional laboratories performing AFB microscopy during the study period were included in the study. The rest 65 laboratories not performing AFB microscopy were excluded from the study.

Data Collection Tools and Procedures

Data were collected using on-site evaluation checklist adapted from Hawassa Regional Public Health Laboratory (HRPHL) and different reviewed literature. The data collection checklist was prepared in English and then translated to Amharic for the purpose of data collection. Then the Amharic version was back-translated into English to check for any inconsistency in the meaning of the words and/or concepts. The checklist contains questions regarding the general laboratory infrastructure, Standard Operating Procedures (SOPs), equipment and reagents, training, biosafety and waste disposable, Internal Quality Control (IQC), External Quality Control (EQC) and data management. Three data collectors and one supervisor were involved in the data collection process.

Data Management and Analysis

The database was created based on data type, categories and ranges. Data were checked visually to identify errors and illogical values. The data was verified using distribution and frequency checks to look into the range of values and to identify

missing data or possibly miscoded data in each observation. Then descriptive analyses were performed using SPSS version 20 statistical software.

Data Quality Assurance

The data collection instrument was pre-tested in Tula Health center and Adare district Hospital TB laboratories. Data were collected by three medical laboratory personnel who are trained on Laboratory Quality Management System (LQMS) and AFB microscopy. One day training was also provided for data collectors and supervisors on the study objectives and data collection process. In addition, the supervisors were checked for the completeness of the filled checklists.

Ethical Considerations

Ethical clearance was obtained from Institutional Review Board (IRB) of Hawassa University, College of Medicine and Health Science. Permission was also obtained from Sidama zone health department. Verbal consent was obtained from each participant after they were informed about the purposes, procedures, and benefits of the study. Identification of study participants by name was avoided to ensure the confidentiality of the information obtained.

RESULTS

On-Site Evaluation Performance of the Health Facilities

A total of fifty-six peripheral tuberculosis laboratories which are found in three hospitals and 53 health centers were included in the study. The laboratories were assessed for standards of infrastructure, EQA, internal quality control, staining reagents, safety and waste disposal practices, SOP's, training status, microscope maintenance and data management.

The overall OSE performance was 48.9%. Only 1 (1.8%) TB laboratory had separated rooms for TB diagnosis. More than three fourth (80.4%) of the laboratories had no separate table for sample receipt, smear preparation, and microscopy. Forty-two (75%) of the laboratories had good ventilation inside the working room. Preventive maintenance for microscope was available in 3 (5.4%) of laboratories. Twenty-eight (50%) and 25 (44.6%) of the laboratories had slides, and sputum cups stock and supply according to the standard.

A total of 152 technicians were working in the 56 tuberculosis laboratories. Twelve (21.4%), 15 (26.8%) and 29 (51.8%) laboratories had one, two and three technical staff respectively. Within two years preceding the study, one out of fourteen (7.2%) TB laboratories had trained technician on AFB microscopy and/or External Quality Assurance. Only 12 (12.5%) of laboratories had assigned/responsible personnel for performing TB microscopy task. Majority of TB laboratories (60.7%) were examined 15-60 slides per week, 33.9% of them examined less than 15 slides/week and the remaining three (5.4%) were examined above 60 slides per week.

Regarding biosafety and waste disposal practice, most 54 (96.4%) of TB laboratories were disposed waste by disinfection/ autoclave/burial. However, only 25 (44.6%) of them had waste containers with lid for waste collection around AFB microscopy workstation. This study also showed that only 18 (32.1%) of TB laboratory personnel's had a practice of washing hand with soap after daily work (**Table 1**).

Table 1. On-site evaluation average score of fifty-six peripheral tuberculosis laboratories found in Sidama zone, Southern Ethiopia, 2015.

Checklist sub heads	Number of Checklist items	Average score * (Yes * # checklist items)	Percent
Infrastructure	4	16	28.5
Standard operating procedure	4	27.7	49.5
Reagents and equipment's	9	29.3	52.4
Maintenance of microscope	2	24	42
Biosafety and waste disposal	7	38.8	69.4
Training status	1	11	19.7
External quality assessment	4	26.2	46.8
Internal quality control	3	14.3	25.6
Data management	3	32	57.1
Average		27.4	48.9

Standard Operating Procedure and Quality Assurance

Majority 41 (73.2%) of public TB laboratories had no Standard Operating Procedures (SOPs) or NTLCP approved laboratory manual for AFB diagnosis, but 38 (67.9%) of them were posted AFB staining procedures in their working areas. EQA protocol/guideline was available only in 4 (7.1%) of the laboratories. The quality of smear within a standard was found in 10 (17.9%) of the laboratories. Smears with proper size, evenness, and thickness were examined in 32.1%, 46.4% and 26.8% of the facilities respectively. Less than half of TB laboratories (39.3%) had a practice of checking the quality of sputum before processing.

One out of seven (14.3%) laboratories always filtered Carbol-fuchsin before use. Only 7 (12.5%) of the laboratories were performed quality control for smears at least once a week and 14 (25.0%) checked the quality of stains and staining technique for each new batch of reagents. Three out of four (75.0%) were examined 100 or even more field per slide before reporting.

Forty-seven laboratories (83.9%) participated in external quality assurance activities. Nearly two third (62.5%) of the laboratories were stored slides in the slide box as per the laboratory register. Thirteen (23.2%) of TB laboratories had been supervised before 6 months but only 12 (21.4%) of the laboratories received EQA feedback (**Table 2**).

Table 2. Standard operating procedure and quality assurance practice of peripheral tuberculosis laboratories found in Sidama zone, Southern Ethiopia, 2015.

Checklist items for SOPs, IQC and EQA	Frequency Yes (N)	Percentage (%)
SOP or NTLCP manual is available	15	26.8
Posted smear preparation & staining procedure	38	67.9
Quality of smear	10	17.9
Quality of sputum checked	22	39.3
Carbol-fuchsin filtered always before use	8	14.3
Perform IQC for reagents	14	25
Perform IQC once a week for quality of stains	7	12.5
Examine 100 or more field before reporting	42	75
EQA Protocol/guideline available	4	7.1
Participate in EQA	47	83.9
Slides available in the slide box as per lab register	35	62.5
Supervised in previous 2 quarters	13	23.2
Receive EQA feedback	12	21.4

DISCUSSION

The overall on-site evaluation performance was 48.9%; and the lowest score (19.7%) was recorded on the training status of laboratory personnel and highest score (69.4%) were recorded on biosafety and waste disposal. In contrast to this, a study conducted in North Ethiopia showed 69.2% overall achievement of the tuberculosis laboratories quality [6]. Another study conducted in ten Intermediate Reference laboratories (IRLs) of India identified 44.1% errors in tuberculosis laboratory quality [7].

Separated TB laboratory room/area is recommended by WHO, and the national guideline of Ethiopia [8,9]. However, in this study only 1 (1.8%) TB laboratories had separated TB laboratory room. Findings on the structural quality of TB laboratory room below standard were also reported in studies conducted in North Ethiopia [8,10,11]. The reason for having separated TB laboratory from the main laboratory is to prevent TB transmission, increase its quality diagnosis and increase confidentiality. Since TB is a major public health problem, its diagnostic process must be done in maximum quality and with practices ensuring not to miss infectious cases [11].

This study showed preventive maintenance for microscope was available only in 3 (5.4%) of the laboratories. A study conducted in Eastern Ethiopia also showed that none of TB microscopy centers were applied preventive maintenance for microscope and resulting in microscope and equipment deposited in a storage room with minor problems [12]. In contrast, finding from the study conducted in Amhara region showed somehow improved practice of equipment preventive maintenance including microscope (33.3%) and much better microscope functionality status [13].

Regarding training access, only 11 (7.2%) of laboratory technicians took training at least once in the previous two years. This figure is very small compared to 80.2% trained staff reported in the studies from East Amhara [13]. Training of laboratory personnel plays vital role in order to ensure quality diagnosis. In this study checking the quality of sputum before processing was done only in 42.9% of TB laboratories. However, the national AFB microscopy laboratory guideline [14] emphasizes the importance of checking sputum quality before processing the sample. Processing none representative samples may result in missing active cases and resource wastage.

This study also found a prominent gap between standard operating procedures in facilities with regard to quality of smear, quality of smear staining and smear storage which were acceptable only in 10 (17.9%), 8 (14.3%) and 35 (62.5%) of laboratories, respectively. Although the importance of filtering Carbol-fuchsin before use during staining is recommended by national and international AFB microscopy guidelines [4,14], only few facilities were performed accordingly. The qualities of smear were deficient in size, evenness, and thickness in 32.1%, 46.4% and 26.8% of the facilities respectively.

The magnitude of error in smear was high compared with other studies conducted in India [10,11], where one out of 5 microscopy centers were found with maximum number of slides with poor quality of smear size (16.7%), 8% uneven smear and 14% slides with improper thickness on reading slides during OSE at each center [11]. Lack of refreshment training for laboratories personnel and supervision may be the most probable reasons for under-performance in smear preparation. The importance of

refreshment training was repeatedly described in different studies^[10,11]. For instance, marked improvements in smear preparation were achieved after training in the practical component of AFB in Kinshasa in 2008^[15]. In addition, regular on-job training together with supportive supervision was recommended, after a study conducted in southern Ethiopia showed a false positive reading of 3.2% which exceeded the recommended cut-off point of 2%^[16].

The present study also showed that only 47 (83.9%), 7 (12.5%), 14 (25%), 15 (26.8%) and 14 (25%) laboratory participated on external quality control, internal quality control for routine staining, internal quality control for new batch reagents, readily available Standard Operating Procedures and posted staining procedures in working place respectively. These figures are very low as compared to studies conducted in Ethiopia^[12,13,16,17] and other countries^[7,10].

Both national and international AFB microscopy guidelines emphasized the need for implementation of regular supervision (including, OSE) and timely feedback in order to achieve quality improvement and quality assurance in TB laboratories^[2,4,14]. In contrary to that, only thirteen (23.2%) and 14 (25%) of TB laboratories had been supervised at least once in the previous six months and get timely feed feedback for EQA, respectively. In fact, these problems were also identified in the studies conducted in East Ethiopia^[12], East Amhara^[13] and West Amhara^[17]. Incongruent to this, a study conducted in East Java, Indonesia showed frequent (4 times per year) supervision of laboratory technicians^[18]. This study focused on quality of input and process-related measures of tuberculosis laboratory. Output measures of tuberculosis laboratory quality like panel test and blind rechecking were not assessed and hence, interpretation of the findings should consider this limitation.

CONCLUSION AND RECOMMENDATIONS

The present study revealed a number of underperformance in infrastructure, standard operating procedure, reagent utilization, equipment maintenance, data management, training issue, internal quality control and external quality control practices. The absence of preventive maintenance for a microscope as seen in the majority of facilities will shorten equipment shelf-life. Functionality and maintenance status of microscopes require an urgent remedial action because it compromises the quality of laboratory performance mainly inaccuracy and delay in tuberculosis diagnosis. To ensure sustainable preventive maintenance of microscope, attention should be given for training and deployment of personnel trained in biomedical equipment maintenance. Training of the laboratory technicians on quality assurance of microscopy would be a good first step to enhance SOPs practice of tuberculosis laboratories along with early assessments of panel testing, blinded rechecking and onsite supervision. This study also highlights the need for improving TB laboratories performance (tracking and minimizing of error) as a prerequisite for an efficient implementation of TB control program. Quality is something of a moving target; with improvement interventions being repeatedly modified in response to outcome feedback. Therefore, program managers responsible for External Quality Assurance better to employ Plan-Do-Study-Act (PDSA) cycle to improve the overall performance of tuberculosis laboratories.

DECLARATION

Authors Contribution

AB conceived the study and was involved in the design, coordination, field supervision, analysis and report writing. BM was involved in proposal preparation, data analysis and report writing. DJ and LD participated in report writing, analysis and drafted the manuscript. All authors read and approved the manuscript.

Competing Interest

The authors declare that they have no competing interests.

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Hawassa University College of Medicine and Health Sciences gave ethical clearance for the study but have no role in the design, data collection, analysis, report writing and decision on the manuscript submission. The authors appreciate the participants (laboratory professionals) for their cooperation in providing the necessary information. We acknowledge the head of health facilities for their strong support during the study.

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