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External Quality Assessment (EQA) of Randomly Blinded Rechecking Slides on TB AFB Microscopy Laboratories: A Retrospective Study, Addis Ababa, Ethiopia

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Abstract: Tuberculosis (TB) is an infectious disease caused mainly by bacillus *Mycobacterium tuberculosis* and it remains a major public health problem. Globally, 9.6 Million people were ill and 1.5 million were died of Tuberculosis in 2014. In resource limited settings, tuberculosis diagnosis relies on sputum smear microscopy: with low and variable sensitivities, in adequately trained personnel, erratic reagent supplies, and poorly verified equipment. Thus there is a critical need for investment in laboratory capacity building and quality assured service. The objective of this study is to assess the performance and trend of Acid Fast Bacilli (AFB) smear microscopy external quality assessment program in Addis Ababa city Government. For this study a retrospective record review study was carried out among the participated AFB smear microscopy laboratories in Addis Ababa. The data was collected and summarized from 12 Jan. 2014 to March 20, 2015 in Addis Ababa Health research laboratory. The data entered in to EPI data V.3 and analyzed by SPSS version 20. Percentage of agreement for smear positive and negative results between periphery diagnostic health facilities and the regional laboratory was 95% and 99%, respectively. They have an observed agreement (Po) of 0.9918 and an expected agreement (Pe) of 0.8290. Moreover, Calculated kappa value was 0.95 which is almost perfect agreement. The trend of discordant slides decreases as participation in Regional External Quality Assurance System (REQAS) increases. This study concludes with evidences from the result that, Quality assured laboratory is the cornerstone for effective tuberculosis control programme. Continuous participation in REQAS and drilling of laboratory personnel accordingly at regular intervals plays an important role for improving the quality of TB laboratory services.

Keywords: EQA, Blinded Rechecking, AFB, Laboratory

1. Introduction

Tuberculosis is an infectious disease caused mainly by the Mycobacterium tuberculosis and it remains a major global public health problem. Globally, 9.6 Million people were diseased and 1.5 million were died of Tuberculosis, 12% of the 9.6 million new TB cases were HIV-positive in 2014 [1].

Despite Directly Observed Treatment Short-course (DOTs) strategy introduced in 1997, tuberculosis is still a leading cause of death in the developing world particularly in sub-Saharan Africa; it comprises 25% of avoidable adult deaths [2]. In countries with a high burden of TB, direct sputum

smear microscopy remains the most cost effective tool for diagnosing patients with infectious tuberculosis and monitoring their progress on treatment. Quality assured laboratory services for sputum smear microscopy is crucial to deliver accurate, reliable and timely AFB test results [3].

For a decade (1999-2008) Ethiopia registered a case detection rate (CDR) that remained within the ranges of 31-38%. The treatment success rate (TSR) of smear positive TB patients had increased steadily up to 84% during same period only 1%short of the global target. Based on the 2008 /09 report TSR of Addis Ababa region was 72% and CDR was 63%, which was below the WHO's targets for treatment success and case detection [4].

Accurate and reliable laboratory diagnosis will be provided if an efficient, excellent and quality assured system is maintained in the laboratory. Testing system must be monitored to ensure the quality of the overall process, to detect and reduce errors, and to improve laboratory performance across all the testing sites. External Quality Assurance (EQA) is a system designed to monitor the performance of laboratories in different methods by external body [5]. AFB smear microscopy is recommended in current TB control program due to its cost effective technology, capability to provide visual evidence of bacilli load and no need of confirmatory testing [6].

Reliable AFB laboratory result is essential for diagnosis of patients and proper categorization to follow their progress during treatment, including keeping them informed of the decision to start the continuation phase, and to declare them cured at the end of treatment [7]. The purpose of a quality assurance laboratory system is to improve the efficiency and reliability of AFB smear microscopy services. It allows for the identification of errors, causes of error and if performed regularly with feedback and corrective action, it can lead to increased motivation amongst the participated laboratories [8]. Hence, the implementation of EQA for AFB smear microscopy is important to strengthening laboratory networks and improves diagnostic quality [9].

Designing fast and accurate diagnosis is an important element of TB treatment and control because of the infectious nature of pulmonary TB [10]. By responding quickly and providing quality services, laboratories enable the early diagnosis of tuberculosis facilitating appropriate treatment and minimizing the risk of transmission and disease-related complications, including death [11, 12].

Quality assurance of sputum smear microscopy is adopted to implement at all public health laboratories to improve and sustain the quality of TB Program. EQA is a key component of quality assurance program to ensure the quality of sputum smear microscopy. In Ethiopia, like other country Onsite evaluation, panel testing and blinded rechecking are the methods to be followed for EQA. Blind rechecking is most widely practical and performed four times a year and sample slides are collected blindly by trained person or by TB supervisor using Lot quality assurance sampling (LQAS) method based on the Ethiopian national TB EQA guideline [13].

Early case detection and diagnosis through quality assured smear microscopy is indispensable. Presently, the laboratory infrastructure and quality assurance system remains weak in Ethiopia [14]. Therefore this study is intended to determine and update the current laboratories performance and the trends in the city government of Addis Ababa.

Furthermore, the finding of this study will be used as an input for program planner's federal ministry of health, Addis Ababa health bureau and other partners working on tuberculosis control programs. Researcher and practitioners will use this study as reference for further project.

2. Research Method and Design

2.1. Setting

The study was conducted in Addis Ababa city government, Addis Ababa, Ethiopia. It is the biggest city hosting population of 2, 854, 462 [15]. It has 6 regional, 2 NGO-supported, 30 private, 5 federal, 1 defense, 1 prison and 1 police hospitals laboratories; 70 (currently functional) public and 4 NGO-supported health centers laboratories, 7 public, 500 private and 31 NGO supported clinics laboratories [16]. In the city, Strengthening Laboratory Management Towards Accreditation (SLMTA) have been fully implemented on government Health facility Laboratories and this study was conducted on these SLMTA participated laboratories [17].

Research design and period: An Institutional based descriptive retrospective record review study was carried out among the participated Acid Fast Bacilli (AFB) smear microscopy laboratories from 12 January 2014 to march 20, 2015 in city government of Addis Ababa.

2.2. Source Population and Sample of the Study

The Source population of the study was all government health facilities in Addis Ababa which gives a tuberculosis treatment and diagnostic service to the community and the study population for this study was all government health facilities which are a diagnostic facility for tuberculosis and participated in AFB smear microscopy EQA in Addis Ababa.

Inclusion criteria: Government health institutions provide direct sputum AFB smear microscopy laboratory service using ZN method and which are participated in REQAS was included in the study.

Exclusion criteria: those health institutions which did not provide AFB laboratory service and did not participate in REQAS program at the time of study was excluded; private laboratories, facilities with incomplete data was excluded from the study.

For this study, purposive sampling technique was applied for those institutions meet the inclusion criteria. For the determination of sample size, all participated sites in REQAS were used for the analysis of trend analysis. In the region all the diagnostic eligible health facilities are extensively participated in Regional External Quality assurance scheme in city government of Addis Ababa. Therefore, we have a preference using the whole populations for this study which are fulfill the inclusion criteria.

2.3. Data Collection, Management and Analysis

Data was collected using standardized form adopted from Ethiopian TB-EQA guideline [13]. Previously performed blinded rechecking results were collected from paper based and electronic sources by trained and oriented data collector.

The Addis Ababa Health research laboratory practice LQAS method for sampling of rechecking slides, to eliminate the need to select positive slides separately from negative slides; Thus, all slides were stored in the provided slide boxes in the same order as they are listed in the laboratory register. The REQAS slides were collected by the regional lab in first month of quarter in order to provide sufficient time for completion of re-checking process by the end of the quarter as put into an envelope, the number of slides packed is written on the top of the envelope and clearly marked with the name of the respective laboratory, the quarter and year with sealed envelope.

The blinded rechecking assessment of the collected slides were primarily assessed by focusing on smear quality and this smear quality was based on six characteristics as *Table A1* (specimen quality, size, staining quality, thickness, evenness and cleanliness.

Regular feedbacks to the participating laboratory were provided for any essential improvements in performance by re-emphasizing that random blinded rechecking is not a method for validating individual patient diagnosis, rather assessing overall laboratory performance, detecting unacceptable levels of errors so that corrective action can be taken, and providing continuous motivation for good performers.

Analysis of the results, observations, conclusions, feedback and remedial action was performed at the end of each sampling period on a quarterly basis to the respective AFB performing laboratories. Discordant results were re-read by the testing facility laboratory personnel. Corrective action for the identified nonconformance and monitoring of the Potential sources of errors were investigated during the feedback visits by the regional lab personals at site level. Appropriate corrective actions and/or remedial training were provided within one quarter, which lead a continual quality improvement and these activities were performed in quarterly (four times a year) regularly.

Data entered by the principal investigators (PIs) using EPI data version 3. Data quality was checked by the PIs. Before doing the analysis, the entire data was cross checked for reliability and completeness. The data was exported and analysis performed using SPSS (version 20). Descriptive statistics including counts, percentage and means was calculated. Trend analysis was conducted by using the available data. The percentage of false positive and negative were calculated. Kappa (κ) statistic was used to calculate the rates of agreement, disagreement and reproducibility of microscopy reading results of Peripheral diagnostic health facilities and regional laboratory. The inter-observer variability was assessed on the basis of κ-values of <0.40, 0.40-0.60, 0.61-0.80 and >0.80 indicating respectively, poor-fair, moderate, substantial and almost perfect agreement between slide readers.

2.4. Data Quality Assurance

The data source for the study was the results of external quality assurance of randomly blindly rechecked slides on TB microscopy laboratory in Addis Ababa Health research Laboratory. In order to collect this information a standardized data extraction form or instrument was customized in English language (*Table A2 and 3*)

A one day intensive training was given for supervisor and Data collectors. Before utilizing these tools a pretesting was done on one health institution result and if any necessary indicators missed, was included based on the findings from pretesting. Instructions on how to the tools was made clearly at the data collection form. The principal investigators and the supervisor were supervising closely to follow the day-to-day data collection process and ensure completeness and consistency and if incomplete and inconsistent data identified, the necessary corrections was made.

Moreover, this blinded rechecking of slides was conducted in Addis Ababa Health Research Laboratory which had a good laboratory quality management system implementation and digital PT EQA performance.

2.5. Operational Definitions

I. Acid-fast: A condition of resisting decolorizing acid after being treated by 3% acid alcohol
II. Blinded Rechecking: A process, which involves collecting, smears from the microscopy center laboratory by using LQAS method for blinded re-reading at regional reference laboratory and providing feedback to the microscopy center for corrective actions. Rechecking must always be blinded, whereby the controller does not know the results from the peripheral laboratory.
III. Feedback: Process of communicating results of EQA to the participant laboratory, including suggestions for possible causes of errors and remedies.
IV. Peripheral Laboratories: Laboratories located at a Health center or Hospital, designed by regional and national laboratory and/or Health bureau as facility which will provide AFB smear microscopy service.
V. Quarter/cycle: a timing interval/round of one fourth of a year.
VI. Sensitivity: The expected performance in detecting positives, as compared to the controllers, means the detection of all positives, including low positives.
VII. Specificity: measure the proportion of negative slides that are correctly identified.

2.6. Ethical Considerations

Ethical clearance was obtained from the review and ethical committee of the Addis Ababa City government Health Bureau and the information that was collected by this study was stored in a file, without mentioning the name of the

study site (institution), but a code number was assigned to it.

3. Results

Random blind rechecking results were reviewed and available for 7220 of the collected slides from the periphery hospitals and health centers in city government of Addis Ababa. Percentage of agreement for smear positive and negative results between periphery diagnostic health facilities and the regional laboratory was 95% and 99%, respectively. They have an observed agreement (Po) of 0.9918 and an expected agreement (Pe) of 0.8290. Moreover, it have a calculating Kappa value of 0.95, which is almost perfect agreement (Table 1). The comparison of smear results between Periphery diagnostic health facilities and the regional laboratory show 0.95% and 0.99% sensitivity and specificity respectively.

Table 1. *Comparison of smear results between peripheral HF and AAHRL from the total slides of 7 Quarters (round) in Addis Ababa, 2015.*

Site Smear results	Smear results of AAHRL		
	Positive	**Negative**	**Total**
Positive	652 (95%)	25 (1%)	677 (9.4%)
Negative	34 (5%)	6509 (99%)	6543 (90.6%)
Total	686 (100%)	6534 (100%)	7220 (100%)

The numbers of participating health facility laboratories were initially small (From a total of 67 diagnostic laboratories which are eligible for Random blinded rechecking, 33 health facilities were participated in random blinded rechecking of TB AFB smear microscopy), even though, international and national guidelines recommend all eligible diagnostic facilities should be participated in a blinded rechecking program. The number of participating facilities steadily increased in each Cycle or quarter as illustrated in figure 1.

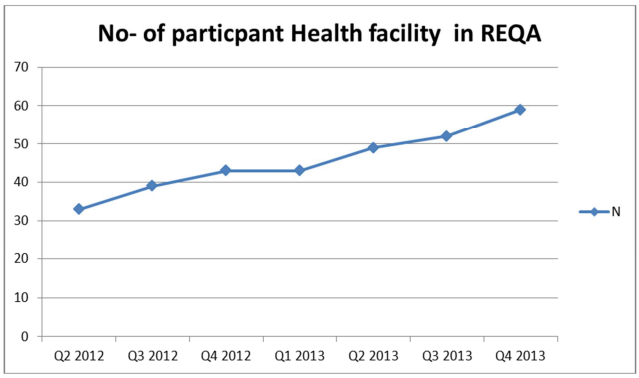

Fig. 1. *The number of Health facility laboratories participated in REQA in the seven Cycle or quarter in Addis Ababa, 2014.*

The trends of discordant slides from laboratories participated in REQAS in the seven Cycle or quarter in Addis Ababa as illustrated in figure 2, few labs (1%) were found reporting false positive and some labs (5%) still missing acid fast bacilli (false negative). Reporting of low false negative and quantification errors are expected especially if laboratory technicians are new but the number of discordant results decrease as the time of participation increases and it is recommend strengthening active participation in REQAS program. In general in city government of Addis Ababa as clearly indicated in figure 2, the discordance of results were decreased over time of participation because in quality assurance scheme commending corrective action for the identified nonconformance and monitoring the implementation is the primary objective.

The blinded rechecking assessment of collected slides was primarily assessed by focusing on smear quality and the results were almost all the laboratories meet good standard of smear quality according to 2013 EQA guideline in Ethiopia and they show steady improvement in their performances. The detail smear quality result is displayed on fig. 3.

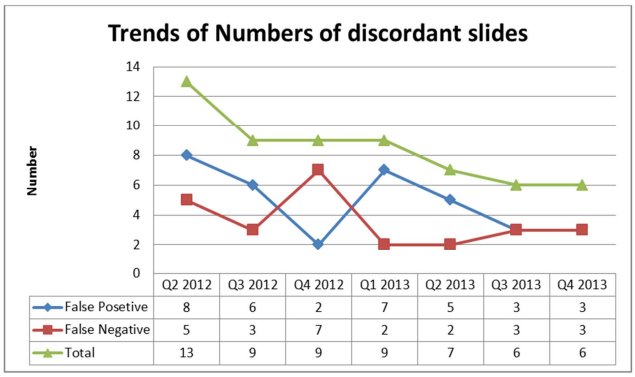

Fig. 2. *Trends of numbers of discordant slides from laboratories participated in REQA in the seven Cycle or quarter in Addis Ababa, 2015.*

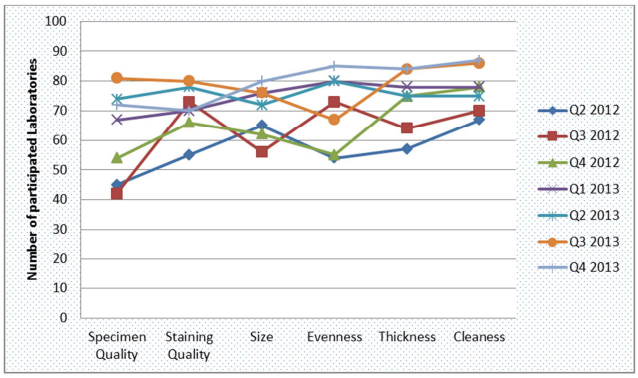

Fig. 3. *Smear quality of slides from laboratories participated in REQA in the seven Cycle or quarter in Addis Ababa, 2015.*

After the analysis of the finding from the random blinded rechecking of this research, higher discordance rates were seen in laboratories of overworked, technical problems such as poor stains, insufficient staining time or heating, bad microscopes or inadequate training of laboratory personnel and the results, observations, conclusions, feedback and remedial action was performed at the end of each sampling period on a quarterly basis to the respective AFB performing laboratories at facility level. Discordant results were re-read by the testing facility laboratory personnel. Potential sources of errors were investigated during the feedback visits by the regional lab personals. Appropriate

corrective actions and/or remedial training were provided within one quarter, which lead a continual quality improvement and these activities were performed in quarterly (four times a year) regularly.

4. Discussion

Record review was done on the participated health facility laboratory in the regional external Quality Assessment schemes (REQAS) in order to describe the external quality assessment of TB microscopy program and participation and discordance trends in Addis Ababa TB smear Microscopy quality assurance system is the improvement of efficiency and reliability of smear microscopy services. It allows for the appraisal of day-to-day performance and identification of some causes of error. Performed regularly with feedback, it can lead to increased motivation amongst the peripheral laboratory. Most of the laboratories were participated in SLMTA program, which have a positive impact on the EQA program by urging the facility maintain their TAT, exercising quality TB laboratory service and implementing an improvement project based on the identified gaps.

Maintaining the quality of tuberculosis laboratory services have major influence on patients and the monitoring and evaluation of tuberculosis control program [7]. In current study, the percentage agreement for smear positive and negative results between periphery diagnostic health facility laboratories and the regional laboratory was 95% and 99%, respectively which is higher finding than a study conducted in 2005, in India by N. Selvakumar and et al to assess the proficiency of technician on reading of AFB smear used 283 participants, with results available both at the start and at the end of the training shows that comparison of results of smear read before and after training with the reference results had sensitivity, specificity, PPV and NPV of reading smears were 75%, 88%, 93% and 63% respectively and also comparable with A. Van Rie study. This is as of an appropriate corrective actions were followed for the identified nonconformances and monitoring of the Potential sources of errors were investigated during the feedback visits by the regional lab personnel at site level by underlying the substandard performance at deficient laboratories and helped with the formulation of corrective actions and continual improvement over time of training [18, 19].

Comparing the current study finding with Laboratories at peripheral diagnostic centers in Dar es Salaam show inadequate performance in diagnosis of TB using smear microscopy and becomes a bad consequences and the most observed potential difference reason is that may be due to the difference in time of study, Number of participated health facilities (number of sample) and rechecked slides were too small comparing with this study; it includes private health institution. The current study also illustrate for seven Quarters while a study at Dar es Salaam, Tanzania performed at appoint of time [20].

The false positive and false negative results reviewed in this study were lower than that reported from a similar study in Malawi where false positive and negative rates for AFB microscopy were less than 2%. The overall results showed that about one of patients were misdiagnosed as non-cases and therefore not treated [21].

A similar study conducted in southern Ethiopia from October 2000 to June 2002, done by B. Estifanos and his colleagues to evaluate the level of agreement in the readings of sputum smears for AFB between the peripheral diagnostic centers and the reference shows that overall false reading was 3.2%. The false positive reading of 3.2% exceeds the recommended cut-off point of 2%. Showed little variations from the current finding and it will be because of the time of this study was almost after 6 years and study area difference, because the current study conducted in the capital city [22].

5. Limitation of the Study

This study was conducted only in public health facility so; it does not illustrate the private health situation.

6. Conclusion and Recommendations

Quality assured laboratory is the cornerstone for effective tuberculosis control programme. Continuous participation in regional External Quality Assessment scheme (REQAS) and drilling of laboratory personnel accordingly at regular intervals do play an important role for improving the quality of TB laboratory services.

The trends of discordant slides from laboratories participated in REQAS becoming to decrease as the time of participation increases and it is recommended strengthening active participation.

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Authors Contributions

Abay Sisay is the primary author of the manuscript, conceived and designed the study and collected data, performed analysis, interpretation of data and finalizing the manuscript. Adino Desale, Mulugeta Tsegaye and Abrham Tesfaye had assisted with the design, performed, analysis, interpretation of data, drafted and critically reviewed of this manuscript.

Appendixes

Table A1. *Assessment criteria of smear slide (source from Reference 3).*

Properties	Grading		
	Good	**Medium**	**Poor**
1. Sputum Quality	Presences of > 25 leucocytes/field at 100X.	Presence of < 25 Leucocytes/field but > 5 leucocytes/field. Less than 5 epithelial cells/ field.	Absence of leucocytes in the smear. Presence of unspecified cells and presence of more than 10 epithelial cells/ field.
2. Size	Smear size of 1x2cm. Oval in shape and smear centrally placed in the slide.	Acceptable size of approximately 1x2cm. Shape of smear round or oval and smear placed at sub-terminal end of slide.	Smear size smaller than 1x2cm and larger than 1x2cm. Irregular in shape. Smear placed at terminal end of slide.
3. Evenness	Sputum spread evenly on the glass slide not too thick and not too thin. Presence of leucocytes in every field screened at 100X for 100 to 200 fields.	Presence of leucocytes in 70% of smear screened at 100X for 100-200 fields.	Leucocytes present in 50% of smear screened at 100X for 100-200 fields. More than 50% empty fields of smear screened at 100X.
4. Thickness	Mono-layer smear on the glass slide Whole depth of the smear layer can be focused sharply in each field.	Few over-lapping cells seen. Whole depth of the smear layer can be focused sharply in 70% of field.	Smears too thick with over-lapping cells seen in entire smear. Too thin smear. Whole depth of the smear layer can be focused sharply in less than 50% of the field.
5. Cleanness	Clean smear. Smear free from stain deposit, crystals produced by overheating of stain and absence of debris.	Some portion of smear seen with stain deposits only but more than 70% of the smear is clean.	Dirty smear, cannot screen the smear on the slide. Smear found with stain deposits, crystals and debris.
6. Staining quality by microscopic observation	AFB and background clearly distinguished. AFB in bright red color. Leucocytes stained blue and absence of stain particles.	AFB and background clearly distinguishable in 80% of the smear. AFB light red in color. Presence of stain particles in some places of the smear.	Not able to distinguish AFB and background. AFB faintly red in color. AFB covered with methylene blue. Remaining of fuchsin color on the background. Remaining of methylene blue color on the un-smeared parts.

Table A2. *Evaluation and interpretation of errors between controllers and microscopist.*

Result of sites	**Result of controller /regional laboratory**				
	Negative	**1-9 AFB/ 100 fields**	**1+**	**2+**	**3+**
Negative	**Correct**	**LFN**	**HFN**	**HFN**	**HFN**
1-9 AFB/ 100 fields	LFP	Correct	Correct	QE	QE
1+	HFP	Correct	Correct	Correct	QE
2+	HFP	QE	Correct	Correct	Correct
3+	HFP	QE	QE	Correct	Correct

Table A3. *Blinded rechecking results collection forms /abstraction form/.*

Peripheral lab	Noof Slides	Participate health institution		Rereading result		No of discordant result	Discordant result	
		Pos	Neg	Pos	Neg		False Pos	False Neg
Code 1								
Code 2								
Code 3								
Code 4								
Code 5								
Code 6								
Code 7								
Code 8								
Code 9								

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