ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES



ASSESSMENT OF FEEDBACK QUALITY AND UTILIZATION ON TB MICROSCOPY EXTERNAL QUALITY ASSURANCE PERFORMANCE AT SELECTED PUBLIC HEALTH FACILITIES IN ADDIS ABABA, ETHIOPIA

BY:-YENENESH WONDWOSEN (BSC)

ADVISORS: FATUMA HASSEN (BSC, BA, MPH, PHD CANDIDATE)

ALEMAYEHU NIGATU (MSc, MPH)

A RESEARCH THESIS SUBMITTED TO THE DEPARTMENT OF MEDICAL LABORATORY SCIENCES, COLLEGE OF HEALTH SCIENCE, ADDIS ABABA UNIVERSITY, IN PARTIAL FULFILLMENT OF MASTER OF SCIENCE DEGREE IN CLINICAL LABORATORY SCIENCES (CLINICAL LABORATORY MANAGEMENT & QUALITY ASSURANCE SPECIALTY TRACK)

Mar, 2021

Addis Ababa, Ethiopia.

Research Examining board signature page

Name of the principal Investigator	**By: YeneneshWondwosen (BSc)** **Department of Medical Laboratory Sciences** **, College of Health Sciences, Addis Ababa University**
Advisors	**AlemayehuNigatu (MSc, MPH)** **Department of Medical Laboratory Sciences** **, College of Health Sciences , Addis Ababa University** **Tel: +251 29903436** **FatumaHasssen (BA, BSc, MPH, PhD Candidate)** **Department of Medical Laboratory Sciences** **College of Health Sciences, Addis Ababa University** **Tel: +251 911418062**
Full Title of the Project	**Assessment of feedback quality & utilization on TB microscopy external quality assurance performance at selected public Health facilities in Addis Ababa, Ethiopia**
Type of protocol	**Medical**
Duration of the project	**10 Months**
Total cost of the project	**20,000.00 Birr**
Address of the PI	**Email:emuwondesen@gmail.com** Tel:+251 **933 58 29 00**

Addis Ababa University

College of Health Science

Department of Medical Laboratory Technology

This is to certify that the thesis prepared by Yenenesh Wondwosen, entitled:

Assessment of feedback quality & utilization on TB microscopy external quality assurance performance at selected public Health facilities in Addis Ababa, Ethiopia and submitted in partial fulfillment of the requirements for Master of Science degree in medical laboratory management and quality assurance complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Signed by the Examining Committee:

External Examiner_____ Signature _____Date _____

Internal Examiner_____ Signature _____ Date _____

Advisor:-Alemayehu Nigatu Signature _____ Date _____

Advisor:-Fatuma Hassen Signature _____Date _____

_____

Chairman of the Department or Graduate Program Coordinator

Table of Contents

Table of Contents III
List of tables V
List of figures VI
Acknowledgement VII
Abbreviations/Acronyms VIII
Abstract 1
1. Introduction 2
1.1 Background 2
1.2 Statement of problem 4
1.3 Significant of the study 5
2. Literature review 6
2.1. Conceptual frame work 10
3. Objectives 11
3.1 General objective 11
3.2 Specific objectives 11
4. Material and methods 12
4.1 Study area 12
4.2 Study design and period 12
4.3 Population 12
4.3.1 Source population 12
4.3.2 Study population 12
4.4 Inclusion and exclusion criteria 12
4.4.1 Inclusion 12
4.4.2 Exclusion 13
4.5 Study variables 13
4.5.1 Dependent variable: 13
4.5.2 Independent variable 13
4.6 Sample size calculation and sampling method 14
4.6.1 Sample size calculation: 14

4.6.2 Sampling method: 15
4.7 Measurement and data collection 15
4.7.1 Data collection procedure 15
4.7.2 Measurement 15
4.8 Data quality assurance 16
4.9 Data analysis and interpretation 16
4.10 Operational definition 17
4.11 Ethical considerations 18
4.12 Dissemination 18
5. Result 19
5.1. Characteristics of study sites 19
5.2TB microscopy blinded rechecking performance 19
5.3Feedback quality 21
5.4Socio demographic characteristics of respondents 21
5.5Knowledge status of laboratory personnel 22
5.6Feedback utilization 22
5.7 Finding of Observational checklist 23
6. Discussion 25
7. Strength and limitation of the study 27
Conclusion 27
Recommendation: 27
8. References 29
9. Annexes 32
Annex I. Information sheet 32
Annex II. CONSENT FORM 33
Annex III. English version questionnaire 34
10. Declaration 38

List of tables

Table 1 Characteristics of the study sites in Addis Ababa, from February- March, 2020..... 19

Table 2Laboratory performances of TB microscopy on blinded rechecking retrospectively in Addis Ababa, between July 2018 and Dec 2019. 20

Table 3. Simple frequency distribution of TB EQA feedback utilization in Addis Ababa, from February- March 2020. 22

List of figures

Figure 1 Conceptual framework adopted for assessment of feedback quality & utilization on TB microscopy EQA program at selected public Health facilities in Addis Ababa, Ethiopia (22)..... 10
Figure 2 schematic presentation of sampling procedure for assessment of feedback quality & utilization on TB microscopy EQA program in Addis Ababa, Ethiopia 14
Figure 3 Graphical presentation of TB EQA blinded rechecking quality of slide performance from (Q1, 2011-Q2, 2012) E.C in Addis Ababa, Ethiopia. 21
Figure 4The basic challenge on TB laboratory EQA performancereport by percentin Addis Ababa, Ethiopia 24

Acknowledgement

I would like to thank Addis Ababa University Department of Medical laboratory Sciences forgive me this chance.

I would like to express my deep gratitude to my advisor Fatuma Hassen and Alemayehu Nigatu for their continuous support and giving their gold time during the study.

I would like to thank all sub city Health office in Addis Ababa, for supporting me to get Health centers with their specific address.

I would like to give my deep gratitude to all Addis Ababa city administration public Health centers laboratory professionals participated on this study.

Finally, I would like to give thanks for my family, my child and all my friends who give uncreditable supports and encouragement during study.

Abbreviations/Acronyms

AFB	Acid fast bacilli
AIDS	Acquired immune deficiency syndrome
DOTs	Direct observed treatments
EQA	External quality assurance
FM	Fluorescent microscopy
HBC	High burden countries
HC	Health centers
HF	Health facility
HFN	High false negative
HFP	High false positive
HIV	Human immune deficiency virus
IAR	Investigation, action and resolution
IQC	Internal quality control
LED	light-emitting diode
LFN	Low false negative
LFP	Low false positive
LQAS	Lots of quality assurance
LQMS	Laboratory quality management system
MDG	Millennium development goal

MDR-TB	Multi drug-resistance TB
MTB	Micro-bacterium TB
NPV	Negative predictive value
NTP	National tuberculosis program
PPM-DOTS	public private mix DOTs
PPV	Positive predictive value
QA	Quality assurance
QE	Quantitative error
REQAS	Regional external quality assurance
SOP	Standard operating procedure
TB	Tuberculosis
WHO	World Health organization
ZN	Ziehel nelson

Abstract

Background: Tuberculosis is an infectious disease caused mainly by the Mycobacterium tuberculosis and remains a major cause of ill Health and death worldwide. Ethiopia is one of the 30 highest TB burden countries in the world, Federal Ministry of Health of Ethiopia is implementing TB Prevention and control program at all level of the Health facility to reach 70% detection rate and to achieve sustainable quality TB service. The performance of TB smear microscopy quality of slide had no improvement in order to mitigate this the laboratories shall participate on continuous EQA and review the feedback by taking corrective action for sustainable performance.

Objective: To assess Feedback quality & utilization on TB microscopy EQA performance from Feb - March 2020.

Method: Institutional based retrospective and prospective cross sectional study design were conducted at 47 public Health centers which were selected by simple random sampling method from ten sub cities in Addis Ababa, Ethiopia. Data collection was conducted using semi-structured questionnaire to assess feedback quality & utilization on TB microscopy EQA performance from February- March 2020. The data was entered by EPI Info version 7 and analyzed by Microsoft Excel, SPSS version 23 and narrative form.

Result: The overall TB EQA feedback utilization of Addis Ababa public Health centers showed that only 15.9% of the facilities were using the feedback for improvement by identifying root cause, taking corrective action and follows the effectiveness. On TB microscopy blinded rechecking program feedback which was given for public Health centers from EQA centers have only 6.8% quality that is timely, accurate and reliable. Most of the laboratories have a challenge on competency, lack of commitment and lack of trained laboratory personnel on TB microscopy and quality management system.

Conclusion: The performance of Public Health facility laboratories on TB microscopy EQA quality of slide was poor in Addis Ababa, due to the facilities were not utilizing the feedback effectively for improving their achievement. And also regarding a quality feedback EQA centers had gap on timely distributing the feedback for Health facilities and overall feedback content.
Key word: EQA, TB microscopy, blinded rechecking, feedback quality and utilization

1. Introduction

1.1 Background

Tuberculosis (TB) is a communicable disease and it is included on top 10 causes of death worldwide and the leading cause of death from a single infectious agent (ranking above HIV/AIDS). It is caused by the bacillus *Mycobacterium tuberculosis*, which is spread from person to person through air due to TB expel bacteria from TB sick person by coughing and sneezing. Globally, estimations showed that two people from 10,000,000 get ill with TB in 2018,a number that has been relatively stable in recent years. The burden of disease varies enormously among countries, from <5 - >500 new cases per 100 thousand populations per year, with the global average being around 130 (1, 2).

The global TB control program progress followed the widespread implementation of the direct observed treatment (DOTS] strategy in countries with a high burden of TB. In 2006 at TB world day Stop TB Strategy launched, is designed to meet the TB-related MDG as well as the Stop TB Partnership targets set for 2015. The new Stop TB Strategy basis on stop TB, As a global plan in 2006–2015 (2).

External quality assessment (EQA) is a process to assure laboratory performance. EQA includes on-site assessments, panel testing and blinded rechecking. Quality control is internal monitoring of working practices, technical procedures, equipment and materials, including quality of stains by professionals. Quality improvement is a process of reviewing TB microscopy diagnostic service with purpose of decreasing or removing obstacle for future success (3).

Ethiopia is one of the Highest TB burden countries in the world, FMOH of Ethiopia is implementing TB Prevention and control program at all level of the Health facility. study conducted at 2018 on misdiagnosis of pulmonary tuberculosis and associated factors in peripheral laboratories in Addis Ababa showed that only 10.5% of the total AFB smear microscopy tests were positive slide and 89.5% were negative result at that time of study. This shows low number of detection rate which is much lower than the minimum target (70%).The

steady progress in case detection rate raised a question whether the previous estimate was reliable or not (4).

The ISO15189; 2012 clause 5.6.3.1 states that the laboratory shall participate in an inter-laboratory comparison program(s) such as an external quality assessment program or proficiency testing program(s) appropriate to the examination and interpretations of examination results. And also the laboratory shall monitor the results of the inter-laboratory comparison program(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled. So all laboratories participated on TB EQA program should participate and monitor the result or feedback.

1.2 Statement of problem

Direct sputum microscopy is the major diagnostic method for TB which is widely available in most laboratories at developing countries. This method has been shown to have low sensitivity (22 to 78%) and high specificity (93.3 to 99.9%). Inspite of the low sensitivity, direct sputum microscopy remains the cornerstone of laboratory diagnosis for TB because it is inexpensive, rapid and highly specific in settings where tuberculosis is endemic (5, 6).

The common causes of error in smear microscopy are too thick smear, washing out during staining, too thin smear, Poor staining quality, Cross-contamination, Red precipitates and others and this may lead the laboratory professional to diagnose false positive or false negative. Finally laboratory result will lead health provider to decide wrongly and from resource side unnecessary wastage of treatment for wrong person. Many smear microscopy laboratories have no separate TB room and Quality assurance programs including internal quality control and (EQAs) are often lacking (6, 7).

The result of error in reading sputum microscopy will lead to miss person with active tuberculosis and increase transmition rate and in other way false positive result for non TB cases lead to unnecessary anti-TB treatment decision of health care provider which predisposes the development of drug resistant tuberculosis (MDR-TB). Therefore quality assurance system for the sputum microscopy is basic to minimizing the false positive and false negative results in the laboratory services (8).

Most studies conducted on TB microscopy EQA program focus on acceptable rate of discordant result not on quality of TB microscopy slide this makes the participant laboratories to focus, only on discordant slides from the feedback. because of this as quarterly TB EQA report of Addis public health facilities showed that a quality of slide performance had no improvement during continuous assessment.so continues participation and feedback utilization on quality assurance program is basic for improving TB laboratory performance in the laboratory (6, 8).

1.3 Significant of the study

The purpose of a TB EQA program is for the improvement of the efficiency and reliability of smear microscopy services. As EQA one of quality management system activities the laboratories shall use for each part of TB smear microscopy diagnostic services with the aim of preventing the reoccurrence of errors in smear microscopy for better performance of TB detection this process is quality improvement (9).

As QI is part of quality assurance Process to analyze the quality of TB laboratory service and to continuously improve their reliability, efficiency and utilization. The reference laboratory must provide feedback to the test laboratory, including scoring for accuracy of the results as well as suggestions as to the likely explanations for any miss diagnosis and smearing errors (10).

The purpose of this study from the facilities participated on TB EQA program to identify how much of the facilities are using the feedback for identifying the gaps to prevent re-occurrence of non-conformance by taking effective corrective action for each poor performance TB EQA result and to determine the feedback quality at selected public Health facilities in Addis Ababa, Ethiopia. Furthermore, the finding of this study will be used as an input for training need assessment, referral linkage planner's federal ministry of health, Addis Ababa health bureau and other partners working on tuberculosis control programs.

2. Literature review

The DOTS strategy requires quarterly supervised by the district DOTS supervisor to each DOTS centre, where there will usually be a microscopy laboratory. The DOTS supervisor can undergo a limited assessment of the laboratory as part of other visit. The final report of supervision should be prepared for the NTP. Where significant errors are found, a technician from the intermediate to central level should visit the peripheral laboratory as a matter of priority. The other importance of visit is to select slides for blinded rechecking from peripheral laboratory. At the same time, results of the previous quarter visit should be delivered and discussed (3).

The global plan of to STOP TB strategy was increase access to quality-assured AFB microscopy with effective EQA performance. By the end of 2015, in the Global Plan, all of the 149 countries 35 considered should have at least one laboratory per hundred thousand populations able to perform AFB microscopy with effective EQA. More than 90 percent of AFB laboratories meet international standard and 20% of AFB laboratories replaced conventional light microscopes with LED microscopes. These LED microscopes enable enhanced diagnostic accuracy by increasing sensitivity (increased detection of true-positive cases of TB) by allowing laboratory staff to visualize TB bacilli much more easily emitted light on dark background (11).

A study conducted at 2006 in India determined the sensitivity of the ZN method for the centrifuged deposit smears. The observed sensitivity of 63% for the centrifuged deposit smears in the present study was almost similar to the sensitivity reported for direct sputum smears 47 to 65 percent. The failure to achieve the improved sensitivity for centrifuged deposit smears could be attributed to the exposure of sputum samples to cetyl-pyridinium chloride, as the physical & chemical injury to the integrity of the cell wall causes the bacilli to lose their acid fastness (12).

Another study conducted in India at 2005 suggests that fresh trainees can achieve the expected level of 85% sensitivity during the 15 days' training program recommended by World Health Organization (WHO) and IUATLD. It is very important that every laboratory technician should take training on sputum AFB smear microscopy. Hundreds of laboratories all over the world provide training programmes for laboratory professionals before implementing DOTS strategy to treat pulmonary tuberculosis patients (13).

Another study conducted in south Asia at 2012 on sputum microscopy at private facility indicates the frequency and percent of correct sputum smear classification at each laboratory. From the total of seven private facilities only two laboratories correctly identify all specimens, four laboratories correctly identifying less than 50% of submitted specimens. For several laboratories, only negative specimens for TB were correctly classified (14).

Study conducted in 22 Africa countries at 2012 shows several inadequacies have been identified in medical laboratory services on deficiencies in areas such as consumables, basic equipment, skilled personnel, training programs, logistical support, shortage or lack of appropriate reagents national standards and quality assessment have been emphasized (15).

Study conducted in western Amhara, Ethiopia at 2015 showed that the performance of site laboratories on blind rechecking and panel test reading showed good agreement with the reference laboratory. The overall false reading on blind rechecking and panel testing results were the same as the levels of PPM-DOTS site laboratories. The major problem in private DOTS laboratories for poor sputum smear microscopy was the quality and sources of AFB reagents were below the standards. This is supported by panel testing assessment because most errors were observed from unstained panel smears. And the others were the implementation of EQA and internal quality control was not regularly practiced (16).

Study conducted in selected Health center in Ethiopia at 2018 showed that out of the total 55 laboratories included in the study, 20 or 36.4 percent had major errors such as HFP and HFN results. The false positive results could lead patients to start unnecessary treatment, wastage of valuable medication, cause unnecessary stress to patients and their families. The high false positive results in this study were significantly higher among lacked IQC measures laboratories and poor staining procedures (17).

Study conducted at 12 hospitals in Addis Ababa, Ethiopia at 2017 on proficiency test feedback utilization at Public hospitals shows that from 20 test parameters throughout the 6 consecutive

quarters overall participation was 44.79 percent. The FGD and KII participant of the study agreed that the challenges for effective utilization of PT were knowledge gap on feedback utilization, development of quality improvement plan, gap identification and root cause analysis as well as poor staff commitment, on other hand equipment maintenance problem and shortage of TB reagent among identified challenges (18).

A study conducted at 2015 in Hawwasa, South Ethiopia conducted on laboratory professional showed that 13.6 percent correctly interpreted all PT slides, 23.5 percent made two discordant out of the ten PT slides and 86.4 percent committed at least one error among 10 slides. 63 percent participants correctly reported all four negative slides, 24.7 percent had at least one error among four negative slides and 12.3 percent misread all of the four negative slides. 22.2 percent of the participants reported all positive slides correctly, 27.2 percent had 2 errors among 6 positive slides and 3.7 percent reported incorrectly 5 of the 6 positive slides (19).

Also the study conducted at 2017 in Tigray on EQA performance of AFB microscopy suggests that on site evaluation result 13% of the laboratories have interruption of electric supply; most laboratories disinfect the sputum sample before disposal. On their findings 14% laboratories have shortage of AFB reagents and only 71 percent of laboratories performed IQC for new AFB reagents and routinely perform IQC in a weekly manner using known positive and negative control smear slides. 24 percent laboratories didn't filter AFB reagents and 29 percent laboratories didn't' use tissue paper for cleaning microscope lens due to unavailability of tissue paper. From blinded rechecking performance a total of 3246 slides were collected from the Health facilities using EQA guideline. Only 2 percent of slides from participated health facilities were score discordant result. The quality of most 80 percent slides was normal regarding the six quality indicators (20).

The major purpose of a rechecking program is to improve the overall quality of smear microscopy, therefore regular and timely feedback to the peripheral laboratory is very important if any improvements in performance are required. Annual reports should be sent to the regional Health bureau, district physician as well as the laboratory professionals. Although final analysis of the results and conclusions have to await completion of sample rechecking annually, gap

identification, feedback and preventive action will often be possible at the end of each sampling period. This will be practiced in laboratories which have very poor performance where immediate corrective action is most urgently needed (21).

2.1. Conceptual frame work

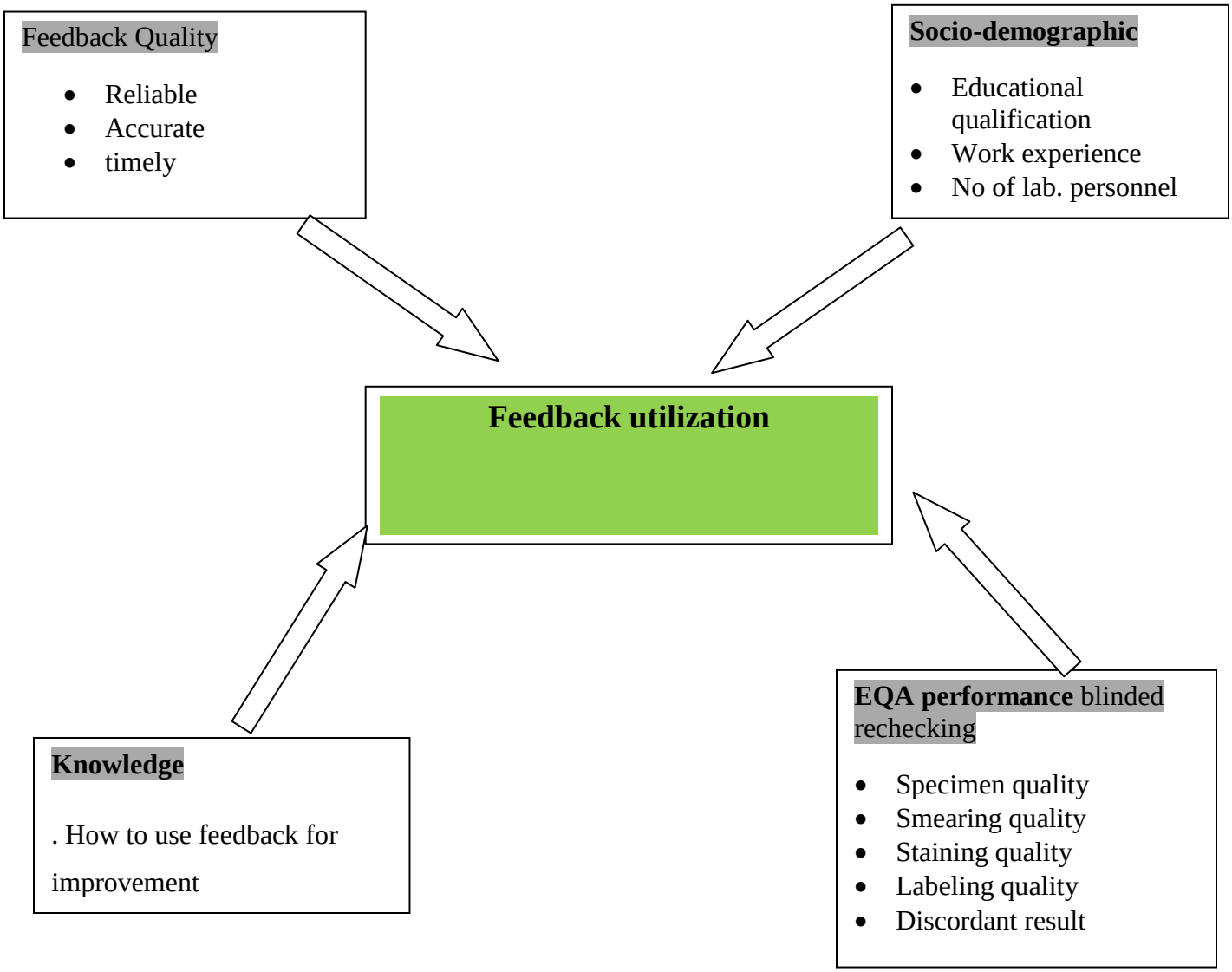


Figure 1 Conceptual framework adopted for assessment of feedback quality & utilization on TB microscopy EQA program at selected public Health facilities in Addis Ababa, Ethiopia (22).

3. Objectives

3.1 General objective

- To assess feedback quality and utilization on TB microscopy EQA performance at selected public Health facilities in Addis Ababa, Ethiopia from February- March 2020.

3.2 Specific objectives

- To assess of TB microscopy blinded rechecking performance at selected public Health facilities
- To assess TB microscopy EQA feedback quality at selected public Health facilities
- To assess TB microscopy feedback utilization for improvement at selected public Health facilities

4. Material and methods

4.1 Study area

The study was conducted in Addis Ababa, Ethiopia. Addis Ababa is the capital city of the country hosting population of 2, 854, 462according to the 2007 census in 10 sub cities (23). It has 94 Public Health Center, 6 Government Hospitals, 31 private Higher clinics, 19 private Hospitals, 8 NGOs HF and 3 Medical Center are participated on TB EQA program from this the study was focus on selected public Health centers at ten sub city in Addis Ababa.

4.2 Study design and period

Institution based prospective and retrospective cross-sectional study design was conducted using semi structured questionnaire focusing on assessment of feedback quality & utilization on TB microscopy External quality assurance program in Addis Ababa, Ethiopia.

Data were collected at selected Public Health facilities who participated on TB EQA program from February – March 2020 in Addis Ababa, Ethiopia

4.3 Population

4.3.1 Source population

The Source population of the study was all Public Health centers in Addis Ababa which were included in DOTs program providing tuberculosis treatment and diagnostic service to the community.

4.3.2 Study population

The study population for this study was Public Health centers which are a diagnostic facility for tuberculosis and participated in EQA program of AFB smear microscopy in Addis Ababa, Ethiopia.

4.4 Inclusion and exclusion criteria

4.4.1 Inclusion

Public Health facilities that provide direct sputum AFB smear microscopy laboratory service using ZN &FM method and which are participated in REQAS with in the study period was included in the study.

4.4.2 Exclusion

Those Health facilities which did not start to participate on DOTs program and REQAS at the time of study were excluded; 6 hospitals &AAPHREM which are EQA centers, gene xpert site Health centers and private Health facilities were excluded from the study.

4.5 Study variables

4.5.1 Dependent variable:

- Feedback quality and utilization of EQA on TB microscopy.

4.5.2 Independent variable

- EQA performance blinded rechecking
- Work experience
- Training status
- Educational status
- Knowledge of laboratory personnel

4.6 Sample size calculation and sampling method

4.6.1 Sample size calculation:

The sample size calculation for this study was 50% of the total 94 Health centers participating on TB DOTs and EQA program in Addis Ababa by making sub city based strata. Taking from each stratum a total of 47 public Health centers were included in this study.

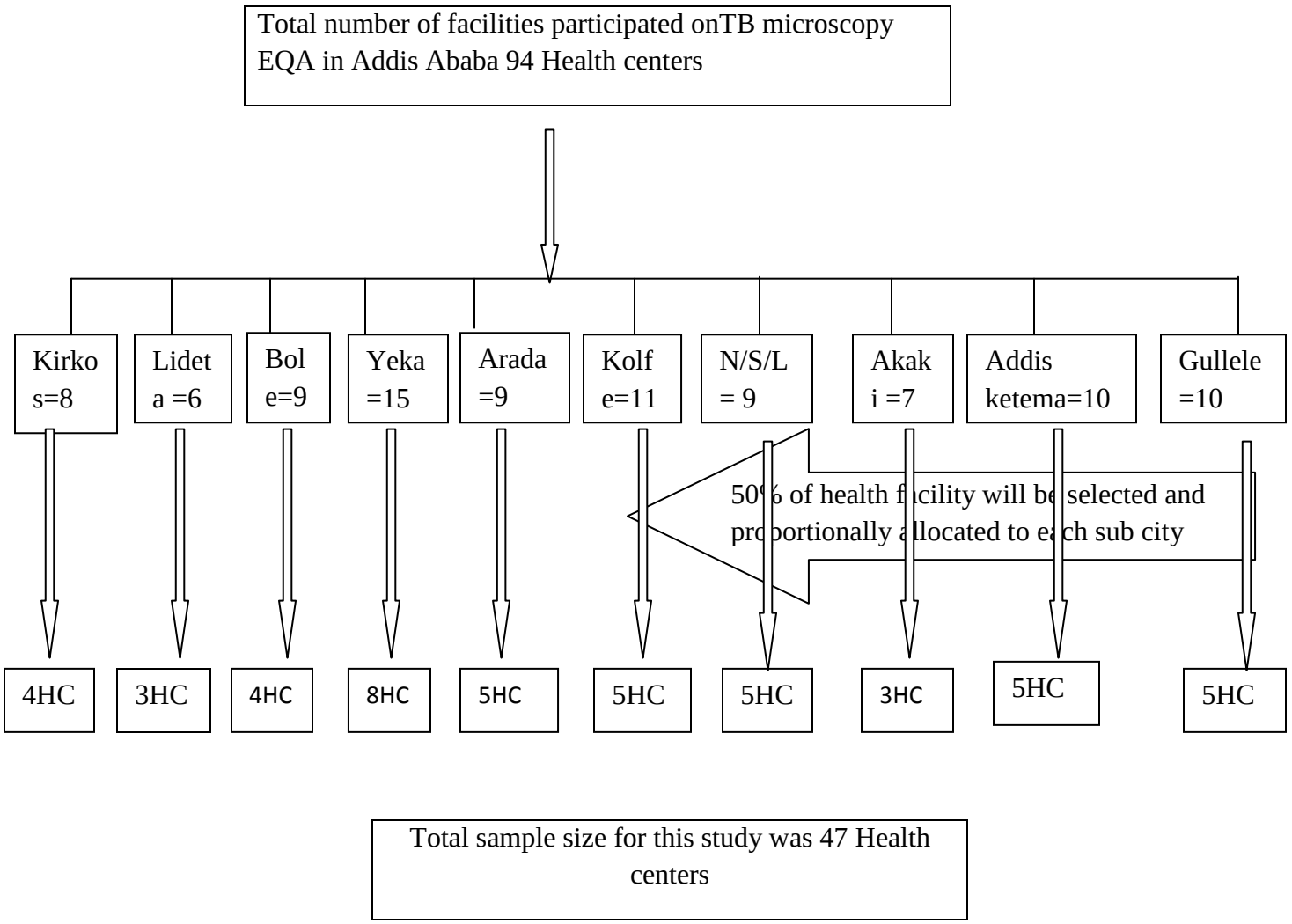


Figure 2 schematic presentation of sampling procedure for assessment of feedback quality & utilization on TB microscopy EQA program in Addis Ababa, Ethiopia

4.6.2 Sampling method:

Since the distribution of Health facilities were different in each sub cities. The study population was divided into 10 strata based on sub city. After making strata the sample were calculated by proportional allocation 50% from each stratum and the Health centers were selected by simple random sampling method, because there is no evidence from previous study how much of the facilities were using the feedback and because of similarities in infrastructure, manpower, method and procedure on TB microscopy there is no significant impact on the study.

4.7 Measurement and data collection

4.7.1 Data collection procedure

A one day orientation for data collectors were given for data collection on the objective of the study, data collection tool, time of data collection, timely collection and reorganization of the collected data. The data were collected from 47 Health centers which were selected randomly, 50% from each sub city total Health centers.

The data for feedback quality and utilization were collected using semi structured questionnaire developed from Guidelines for External Quality Assessment of Tuberculosis Smear Microscopy in Ethiopia and ISO 15189; 2012 Medical laboratories Requirements for quality and competence by making interview for laboratory head or quality officer and through observation by observational checklist..

The data for TB microscopy EQA performance on blinded rechecking were conducted using semi structured questionnaire developed by Guidelines for External Quality Assessment of Tuberculosis Smear Microscopy in Ethiopia retrospectively from July 2018- December 2019 by record review.

4.7.2 Measurement

Feedback utilization for this study was measured when a participant laboratories

- identifying non-conformance which had fewer than 80% performance of EQA result including quality of slide and discordant result,
- taking corrective action for identified gap and

- Follows the effectiveness of the corrective action

by taking response from Health facility laboratory Head or quality officer and also by looking investigation, action and resolution (IAR) record.

On this study feedback quality was measured when participant laboratories respond accurate (if the feedback they received include the same number of their slide that were send before), reliable (if the feedback is clear and concordant with each other) and timely (if the feedback delivered in one month after slide collection) by comparing their feedback which was given from reference laboratories with their performance.

4.8 Data quality assurance

All data collection instruments were pre- tested at two public Health centers, which were not included on the study to ensure its validity. The data collectors were oriented on how to collect the necessary data. The principal investigator was supervising data collectors closely to ensure data consistency and completeness.

4.9 Data analysis and interpretation

Completeness of the data were checked manually and, coded accordingly. The coded data were entered in to computer using Epi Data version 7 and transferred to SPSS version 23. After completion of data entering, it is cleaned before analysis. Description of frequency, minimum, maximum, mean and SD were done for EQA performance, quality of slide and feedback utilization. For open ended questions analysis was done by MS Excel. The Results were presented in text, table, figure and graphs.

4.10 Operational definition

- **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 rereading 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 from guidelines for EQA of TB smear microscopy in Ethiopian.
- **Feedback Quality**: accurate(the same number of their slide that were send before), reliable (clear and concordant with each other) and timely feedback delivered in one month after slide collection.
- **Feedback utilization**: reviewing the feedback immediately, identify the gap, take corrective action and follow the effectiveness of the action taken based on response and IAR record.
- **Feedback**: Process of communicating results of EQA to the participant laboratory, including suggestions for possible causes of errors and remedies.
- **Good:** means greater than or equal to 80% performance of TB microscopy from guidelines for EQA of TB smear microscopy in Ethiopia.
- **IAR:** A format use to identify and assess non-conformance in the laboratory, which include root cause analysis, corrective action and effectiveness measurement indicator from ISO 15189:2012 medical laboratory requirement.
- **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.
- **Poor:** means less than 80% performance of TB microscopy from guidelines for EQA of TB smear microscopy in Ethiopia.
- **Quarter/cycle**: a timing interval/round of one fourth of a year.
- **Smearing quality**: is the sum of size, thickness, cleanness and evenness of the slide performance on blinded rechecking TB EQA feedback.

4.11 Ethical considerations

Ethical clearance was obtained from Addis Ababa university department of medical laboratory sciences and Addis Ababa Public Health Research and Emergency Management Directorate. Then the selected Health facilities were informed about the purpose of the study, the importance of their participation, their right to withdraw at any time. Data were collected after getting informed consent from the facility and the study participants. Confidentiality of information given by each facility and individuals was kept appropriately and names of facility and study participants were not registered.

4.12 Dissemination

The results of this study will be disseminated to Addis Ababa Public Health Research and Emergency Management Directorate and will be presented to Addis Ababa University department of medical laboratory science as part of master of laboratory management and quality assurance specialty track. We will work further for publication and present the results on different national and international scientific conferences and peer reviewed journals.

5. Result

5.1. Characteristics of study sites

On this study 44 public health centers from ten sub cities at Addis Ababa, Ethiopia were selected proportionally and participated on this study to assess feedback quality and utilization of TBEQA performance. This is summarized on table 1.

Table 1 Characteristics of the study sites in Addis Ababa, from February- March, 2020.

S.no	Sub city	Number of participated health centers
1	kirkos	4
2	Lideta	3
3	Bole	4
4	yeka	8
5	Arada	5
6	Kolfe	5
7	NSL	5
8	Akaki	3
9	Addis Ketema	5
10	Gullele	5
Total		**44**

5.2TB microscopy blinded rechecking performance

A total of 47 Health centers in Addis Ababa, Ethiopia were selected on the study but only 44 Health centers were regularly participated on TB EQA program the rest of three Health centers did not regularly participate due to renovation of the laboratories.

The study showed that from the 44 sites included in this study 9 Health centers were not participated minimum one quarter and maximum two quarter per Health centers with in quarter 1, 2011 E.C and Q2, 2012 E.C.

In this study from all participated laboratories minimum 14.7% heath centers had good performance and maximum 36% Health centers had a good performance on specimen quality with the mean 28% and STD 0.078254 in six cycle. Labeling performance minimum 44.7% HC and maximum 100% HC had recorded good performance with a mean of 78.48% and STD 0.2468. Smearing quality minimum 33.3% HC's and maximum 90% HC's score good performance with the mean 57.37% and STD 0.233. Staining quality minimum 42.9% HC's and maximum 73.7% HC's score good performance with the mean of 52.27 and STD 0.1063. Within 6 cycle of performance in the Health centers a total number of 11(eleven) discordant results were delivered for customers (table 1, figure 3).

Table 2Laboratory performances of TB microscopy on blinded rechecking retrospectively in Addis Ababa, between July 2018 and Dec 2019.

Quarter /cycle E.C	No of facility participated	Good performance Health centers in percent				No of discordant result
		Specimen quality	Labeling	Smearing quality	Staining quality	
Q1,2011	40(90.9%)	16(36%)	34(91.9%)	20(46.5%)	21(56.8%)	1(2.7%)
Q2,2011	41(93.18%)	9(30%)	39(95.1%)	21(52.5%)	21(51.2%)	1(4.9%)
Q3,2011	43(97.72%)	5(14.7%)	39(90.7%)	15(35.7%)	23(53.5%)	2(4.9%)
Q4,2011	42(95.45%)	11(33.3%)	40(100%	11(26.2%)	27(67.5%)	1(2.6%)
Q1,2012	43(97.72%)	7(21.9%)	16(43.2%)	38(90.5%)	25(59.5%)	4(13.6%)
Q2,2012	43(97.72%)	5(15.2%)	20(48.8%)	36(83.7%)	17(51.2%)	2(14.8%)

Based on the study finding when we see the trend of Health facilities EQA performance from Q1, 2011 upto Q2, 2012 E.C with in six cycles except labeling almost all HF quality of slide performance were scored below 80% and also the trend of their performance was decreasing from quarter to quarter as it was showed on the Figure 3. On the last two quarter the numbers of discordant slides (False positive or False positive) were increasing based on EQA centers feedback.

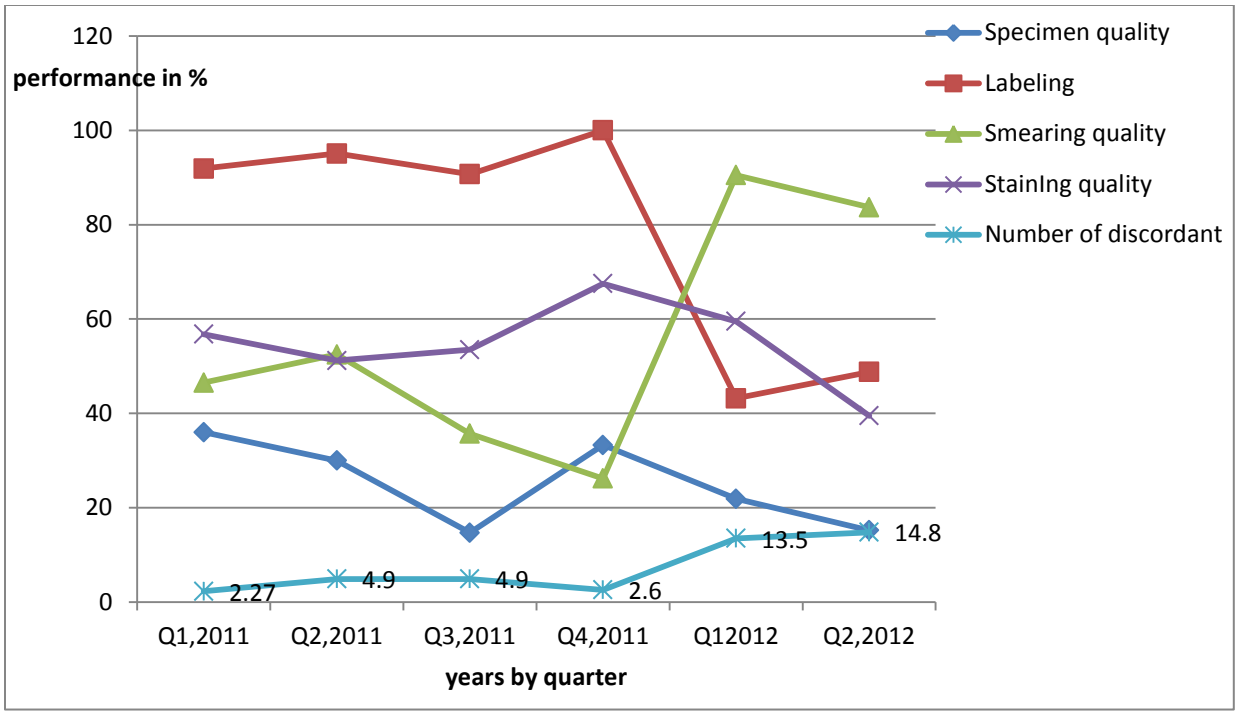


Figure 3 Graphical presentation of TB EQA blinded rechecking quality of slide performance from (Q1, 2011-Q2, 2012) E.C in Addis Ababa, Ethiopia.

5.3Feedback quality

The result of feedback quality assessment were done using self -structured questionnaire for 44 Health centers regularly participating Health facilities were 34(77.27%) Health centers. Majority of the Health centers 39(88.6%) respond that the feedback was not timely, only 5(11.36%) Health centers were responded it is timely. 50% of the Health centers respond the feedback reliable, 19(43.2%) Health centers respond the feedback were not accurate. Generally, Health centers who respond that quality feedback were given for our facility is 3(6.8%) Health centers, the other 41(93.2%) of the Health centers respond, it was not quality feedback.

5.4Socio demographic characteristics of respondents

The result of educational qualification, number of health centers who had≥2 laboratory technicians is 19(44.2%) and ≥5 laboratory technologist is 21(48.8%). Number of health centers who have ≥ 2 junior staffs are 14(32.6%) and ≥ 5 senior laboratory personnel's are 26(61.9%). Number of health centers who have ≤5 laboratory personnel's are 16 (37.2%).

5.5Knowledge status of laboratory personnel

The result of laboratory personnel knowledge status t shows that only 12(27.3%) of the health facilities respond that we have knowledge gap on TB microscopy and quality management practice and 32(72.7%) health facilities respond that we have no knowledge gap based on the response of laboratory head or quality officer using their daily practiceand annual competency test result of laboratory professionals. So as the study showed that there is no much gap on Knowledge on practicing feedback.

5.6Feedback utilization

The result of feedback utilization from the total of 44 Health centers only 11(25%) Health centers were identified root cause for each poor performance including quality of slides, 15(34.1%) Health centers set corrective action mostly for discordant result and only 7(15.9%) Health centers evaluate the effectiveness of corrective action. Generally from all participated laboratories only 7(15.9%) of the Health facilities utilize continuously TB EQA feedback for laboratory improvement effectively.

Table 3. Simple frequency distribution of TB EQA feedback utilization in Addis Ababa, from February- March 2020.

Variables	Value	Frequency	Percent
using feedback	0	21	47.7
	1	23	52.3
RC for each NC	0	33	75
	1	11	25
take corrective action	0	29	65.9
	1	15	34.1
follow effectiveness of CA	0	37	84.1
	1	7	15.9
update improvement plan	0	33	75
	1	11	25
Total feedback utilization	No	37	84.1
	Yes	7	15.9

5.7 Finding of Observational checklist

The result of observational checklist even if it did not had much difference on the previous result section but it showed that, the total of participated Health centers laboratories utilize feedback in different ways, number of Health facilities who identify root cause for each non-conformance including quality of slide was 7(15.9%), the rest 37(84.1%) didn't identify the root cause for each NC continuously. Similarly, number of Health facilities who set corrective action for identified NC was 11(25%) and who follow the effectiveness of CA was 5(11.4%).

On the assessment of feedback quality using observational checklist showed that Health facilities who gets feedback timely only 2(4.5%) the rest 95.5% of the feedback which was collected from EQA centers were not timely and also reliability were 14(31.8%) the other 30(68.2%) were not reliable or the measurement variables didn't contain all on the national TB guideline. And also in some EQA centers only the date were changed on the feedback. Generally feedback quality which was shown through observation was only 12.5%.

Regarding the open ended questions on this study from all participated public Health center 93.18% of Health centers laboratories had a challenge on TB microscopy as a general on personnel, equipment, supply & consumables, leadership & management and method of sample collection (Fig-2). From the total 26.68% of the Health centers had personnel problem like turnover of trained laboratory professionals, high workload, lack of competency & lack of commitment. Secondly supply, reagent and consumables like interruption of AFB/FM reagent, unavailability of consumables filter paper, tissue paper, lens cleaning solution and so on. Thirdly management and leadership problem likeHealth facilities were not included EQA performance on their plan, , not providing the right training for the right problem or Health facilities , poor communication with EQA centers. Fourthly, equipment problem no backup microscope, no FM microscope & Bunsen burner. Lastly, only 11.56% HC had a problem on environmental problem like safe and separate TB laboratory (Figure-3).

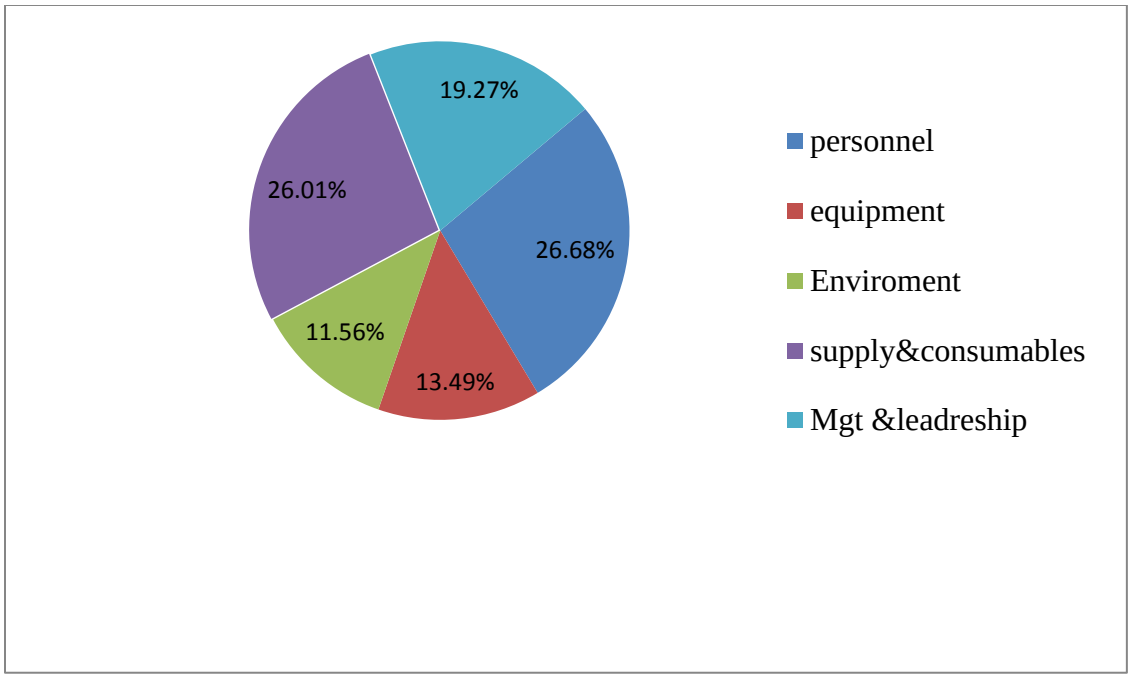


Figure 4The basic challenge on TB laboratory EQA performance report by percent in Addis Ababa, Ethiopia

In this study overall TB EQA feedback utilization of public Health centers only 15.9% were using the feedback for improvement by identifying root cause for each non-conformance including slide quality and taking corrective action to prevent re-occurrence and follow the effectiveness of corrective action and update performance value of the indicator. This was one of the root-cause for not improving the quality of TB slide performance during continuous assessment of blinded rechecking program.

6. Discussion

The overall TB EQA blinded rechecking quality of slide performance was poor (less than 80 %). The major error which was difficult to manage were specimen quality, the maximum achievement was recorded at quarter one 2011E.C were only 36%, this makes difficult to get a quality smearing and staining result. As the study showed the laboratories quality of slide performance were decreasing from quarter to quarter this will finally leads to failure to detect persons with infectious TB who will continue to spread infection in the community, or leading to unnecessary treatment for "non-cases." Errors in the reading of follow up smears may result in patients being placed on prolonged treatment, or in treatment being discontinued prematurely.

A similar study conducted on randomly rechecking slides on TB AFB microscopy laboratories at 2015 study shows that majority of the Health centers quality of slide performance were poor or less than 80%, when we see the minimum and maximum achievement of specimen quality at that time of the study was 40% and 80% respectively but as the finding of this study showed that the maximum achievement of specimen quality become 36%. Similarities of the study are study design and area of the study. But the difference for very low performance were due to lack of AFB smear microscopy training, not using the feedback effectively only use the feedback for discordant result and also the study period which was conducted before 6 year. The current study also illustrate the basic challenge on TB microscopy to get a good achievement and to increase the detection rate, the possible factors for decreasing TB EQA performance and related factors (25).

Another related study at 2015 conducted on Tuberculosis Laboratory Diagnosis Quality Assurance among Public Health Facilities at west Amhara region had a comparable poor performance of slide quality. The difference was study area and period. As this study showed that the basic challenge for getting good performance regarding personnel were their was high staff turnover, no refreshment training for the last two years on AFB microscopy, lack of commitment due to workload and other managerial dissatisfaction most Health facility laboratories were did not utilize the feedback effectively.If we cannot increase quality of slide it is difficult to increase detection rate up to 70%. So this need to identify root cause of the problem, take corrective action and follow the effectiveness (26).

The study conducted at 2018 on misdiagnosis of pulmonary tuberculosis and associated factors in peripheral laboratories: a retrospective study, Addis Ababa, Ethiopia showed that only 10.5% of the total AFB smear microscopy tests were positive slide and 89.5% were negative result at that time of study. From this 10.5% of positive slide 2.4% were false positive and from 89.5% negative slide 0.4% were false negative. The study shows that very low detection rate of TB on AFB smear microscopy were in Addis Ababa so as this study also showed that quality of slide performance were decreasing from time to time as one reason of low detection rate of TB microscopy because of poor utilization of Feedback on EQA program which is one way of the laboratory to assure their performance (27).

In this study the result of feedback quality showed almost all feedbacks were not timely and had many accuracy problems. These makes the health facilities to reject the non-conformance feedbacks and also during observational assessment of this study not a few numbers of Health center feedbacks were 100% the same performance at consecutive participation including recommendation, only the quarter year were updated.

Based on historical perspective of Addis Ababa public Health facilities laboratory performance assessment on quality management system by SLIPTA checklist especially Identification of Non Conformities, Corrective and Preventive Actions were had good result before 2018 evaluation as AAPHREM core process assessment report. After that evaluation as we know all, SLIPTA assessment was interrupted and motivation of laboratory professionals on performing quality management system was decreasing. As feedback utilization is one of the quality management practice it's also neglected because of lack of accountability at Health facilities by assessing their performance as previous by SLIPTA checklist.

As the finding of this study showed and other undetermined problems from the facilities participated on quality assurance program only 15.9% of Health centers utilize feedback effectively for improving the TB laboratory diagnostic performance. So if they cannot improve their performance it's difficult to decrease number of discordant slides and increase TB detection rate for achieving national TB strategy.

7. Strength and limitation of the study

Strength: -The strength of this study was including open ended questionnaire to express their feeling openly and taking the sample from all sub cities in Addis Ababa to get more representative result.

Limitation of the study: - the limitation of this study not including private health facilities who were participated on EQA program on the time of study due to budget shortage and extended study period due to Covid-19 pandemic in Addis Ababa, I was participating as laboratory professional on this pandemic. As our knowledge there were no study conducted before on this specific title this limits me to compare and contrast the study finding.

Conclusion

The performance of Health facility laboratories on TB microscopy quality of slide was poor in Addis Ababa, Ethiopia. Due to the health facilities were not utilizing the feedback effectively for improving their achievement and also the feedback which was send from EQA centers were not accurate, timely and reliable.

Unavailability of basic/ refreshment training (AFB smear microscopy), competency of laboratory personnel and commitment were additional problem from feedback quality the major problem on utilizing the feedback continuously every quarter with accountability for ensuring quality of TB service for their customers.

Recommendation:

To ensure sustainable performance it's mandatory to utilize every day feedback for improvement and also the facility leaders should follow & recognize their achievement and provide capacity building based on performance.

- Addis Ababa Health bureau TB program coordinator should follow strictly the effectiveness of the program by reviewing the performance of EQA centers Laboratories and their quality of feedback.
- All health facilities leaders should follow the TB laboratory performance and create accountability between laboratory personnel's.
- All participating laboratory should monitor and take action on every quarter feedback which is quality of slide and discordant result.

- Health facilities upper management should work on increasing number of trained laboratory personnel on TB microscopy and Decreasing staff turnover by giving recognition for good performer laboratories staff.
- Providing un interrupted supply, reagent and consumables regularly

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9. Annexes

Annex I. Information sheet

Good morning/good afternoon. My name is _____. We came from Addis Ababa University Medical Faculty. We are working for an investigator doing his thesis for the partial fulfillment of Master's degree in Clinical Laboratory Science. We would like to ask you few questions about feedback utilization of TB microscopy on EQA in your Health facility. This will help us to identify how much your facility is using the feedback for improvement of the service.

You have full right to refuse, withdraw or completely reject part or all of your participation in the study. But we encourage your full participation as the answers you give on this form are very important to this study and will help to develop recommendations for the improvement of quality of service. We need also to take some information from your files and records of Laboratory in the Health facility.

We would like to assure you that all of your responses to our questions will be kept confidential throughout the study process. Any of your information you provide will be used only by the research team and will, by no means, be revealed to a third party. We will ask you questions in a place where other people or conditions couldn't interfere. We would like to assure you that your participation on this research will not affect any of your service.

We would be thankful if you spend some time with us answering questions related to the issues described above. The interview will take 45 minute-1hour.

May I get your permission to continue my interview?

Yes 1

No 2_ Stop

Annex II. CONSENT FORM

I have read the information sheet above and clearly understood the purpose and anticipated benefit of the research. I hereby need to assure with my signature below that I, without any coercion or forceful act by the research team, have decided to voluntarily participate in the study to contribute my part in the effort being made for the improvement of TB EQA laboratory service.

Signature _____

Date_____

Name of Health facility_____

Data collector

Name _____ Signature _____

Supervisor

Name____ _____ Signature _____

Annex III. English version questionnaire

Assessment of feedback quality & utilization of TB microscopy External quality assurance performance at selected Public Health facilities in Addis Ababa, Ethiopia, 2020

Note: - put √ in front of your answer

Read the questions carefully and **circle** the number among the choices and **write an answer** to open questions in the space provided. Please circle on the number you select that best answers the question. Kindly make only one Selection unless otherwise instructed.

01. Questionnaire identification number (00) ----------

02. Interviewer code ---------- and name ----------

03. Date of interview ----------

04. Health center code ----------

PART I Socio demographic characteristics of TB microscopy laboratories in Addis Ababa, Ethiopia at 2020

S. No	Questions	Response	Remark
101	Educational qualification	1. MSc	
		2. BSC	
		3. Diploma	
102	Work experience	1. junior	
		2. senior	
		3. chief	
		4. expert	
103	Number of laboratory personnel	……..	

PART II Quality of slide samples (in percent and quantity) at selected Public Health facilities in Addis Ababa Ethiopia from July 2018- Dec 2019G.C (Q1,2011 – Q2 2012 E.C)

Code	Quarter	Quality	Specimen quality	Labeling	Smearing quality (size, thickness, evenness and cleanness)	Staining quality	Discordant result
201	2011, Q1	Good					

		Poor					
202	2011, Q2	Good					
		Poor					
203	2011,Q3	Good					
		Poor					
204	2011, Q4	Good					
		Poor					
205	2012, Q1	Good					
		Poor					
206	2012, Q2	Good					
		Poor					

Part IIIself- structured Feedback quality questions

Code	Questions	Response	Remark
301	Do the laboratory regularly participate on TB EQA program	1. Yes 2. No	
302	Do the laboratory receive the feedback regularly	1. Yes 2. No	
303	Does your laboratory receive the feedback timely in one month?	1. Yes 2. No	
	If not when? specify	……..	
304	Is the feedback received from reference laboratory reliable?	1. Yes 2. No	
	If not why?	…….	
305	Is the feedback given for your laboratory express your performance or accurate?	1. Yes 2. No	

PART IV knowledge related question on how to use feedback

Code	Questions	Response	Remark
401	Do you know about use of TB EQA feedback	1. Yes 2. No	
402	Do you know about good performance and poor performance on the feedback report	1. Yes 2. No	
403	Do you know poor performance are your laboratory non- conformance?	1. Yes 2. No	
404	Do you review the feedback immediately after received	1. Yes 2. No	
405	Do you know how to identify root cause and take corrective action	1. Yes 2. No	
406	Do you take TB microscopy, QMS training or other training related to the above	1. Yes 2. No	Specify

PART V Feedback utilization for improvement questions

Code	Questions	Response	Remark
501	Does your laboratory utilize EQA feedback for improvement? if your answer is yes go to the next questions	1. Yes 2. No	
502	Do you investigate root cause for each non-conformance on EQA feedback	1. Yes 2. No	
503	If not why?	1. Yes 2. No	
504	Do you take corrective action for identified gaps?	1. Yes 2. No	
505	Do you review regularly effectiveness of the corrective action?	1. Yes 2. No	
506	Do you investigate root cause for each non- conformance on EQA feedback	1. Yes 2. No	
507	If not why?	1. Yes 2. No	

Observational checklist

Code	Questions	Response	Remark
601	Do the laboratory utilize EQA feedback for improvement? if your answer is yes go to the next questions	1. Yes 2. No	
602	Do the laboratory investigate root cause for each non-conformance on EQA feedback	1. Yes 2. No	
603	Do they take corrective action for identified gaps?	1. Yes 2. No	
604	Do you review regularly effectiveness of the corrective action?	1. Yes 2. No	
605	Do the laboratory receive the feedback timely	1. Yes 2. No	
606	Is the feedback received from reference laboratory reliable or it seems copy paste?	1. Yes 2. No	

Please write the basic challenge on the blank space

1. Personnel

   _____ _____
   _____
   _____
   _____

2. Equipment

_____
_____
_____
_____-

2. Environment
_____
_____
_____
_____

3. Supply and consumables
_____
_____
_____
_____

4. Leadership or management
_____
_____
_____
_____

10.Declaration

I, the undersigned, declare that this M.Sc. thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been duly acknowledged.

M.Sc. candidate: YeneneshWondwosenReta (B.Sc.)

Signature: _____

Date of submission: _____

This thesis has been submitted with our approval as advisors.

Advisor: **AlemayehuNegatu (MSc, MPH)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: FatumaHassen(BA, BSc, MPH, PhD Candidate)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.