



EVALUATION OF QUALITY OF TUBERCULOSIS LABORATORY SERVICE
AT PUBLIC HEALTH CENTERS OF JIMMA TOWN, SOUTHWEST
ETHIOPIA

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Jimma, Ethiopia

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Abstract

Background: *The quality of Tuberculosis (TB) laboratory diagnosis in public health facilities is a direct reflection of the success of TB control programs and a key component of the Directly Observed Treatment Strategy (DOTS), yet it is one of the most neglected components of these programs.*

Evaluation objective: *To evaluate the quality of TB laboratory services in public health centers of Jimma town.*

Method: *The evaluation was conducted in Jimma town at four public health centers. A case study design with mixed method was used from April 1 to 30, 2018. The focus of the evaluation was process based on Donabedian structure-process–outcome model of health care quality with formative evaluation approach. Dimensions of the evaluation were availability, compliance and acceptability. By using structured questionnaire all 174 TB clients who were sent to laboratory in the study period interviewed consecutively; 24 provider client interaction sessions observation conducted, 174 NTP(National Tuberculosis Program) approved TB laboratory request papers were reviewed and resource inventory was conducted using resource inventory checklist. Key informant interview was conducted with eight laboratory professionals and one TB focal person working in the town health office. Quantitative data was entered in to Epi Data version 3.1 and exported to SPSS version 20.0 for descriptive analysis. Qualitative data were transcribed, translated, coded and analyzed in themes. The evaluation findings were interpreted based on pre- determined judgment matrix. Findings were presented using descriptions, tables and graphs.*

Result: *The result of this study showed that the overall quality of TB laboratory service was 79.76%. The structure, process and outcome quality were judged as good. According to the judgmental parameter the resources availability was 88.3%, compliance was 83% and satisfaction of TB clients was 68%. However, no isolated laboratory room, lack of checking the quality of sputum sample, and higher proportions of clients were dissatisfied with lack of respect from the providers and time for the result.*

Conclusion and Recommendation: *It was concluded that the three quality parameters as well as the overall quality of TB laboratory service at four health centers was good in relative to the pre-determined judgment criteria. But there were no isolated and ventilated laboratory rooms for TB lab. Likewise a relatively higher proportion of patients were not satisfied with time spent to receive the result. We recommend to concerned bodies to establish mechanisms to improve these.*

Key words: Quality, Laboratory, Evaluation

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Abbreviations

AFB	Acid Fast Bacilli
AFs	Acid Fast Smear
DMCs	Direct Microscopic Centers
DOTS	Directly Observed Treatment Strategy
EQ	Evaluation Question
EQA	External Quality Assessments
FMOH	Federal Ministry of Health
HCs	Health Centers
HEWs	Health Extension Workers
HFs	Health Facilities
HIV	Human Immunodeficiency Virus
IUATLD	International Union Against Tuberculosis and Lung Disease
MDR TB	Multi Drug Resistance TB
NTP	National TB Program
QA	Quality Assurance
QASs	Quality Assurance Systems
QC	Quality Control
QI	Quality Improvement
QMS	Quality Management Systems
SOPs	Standard Operating Procedures
TAT	Turnaround Time
TB	Tuberculosis
TCP	Tuberculosis Control Program
TTP	Total Testing Process
WHO	World Health Organization

Operational Definitions

Quality TB Laboratory service: measured by availability of resources, compliance of laboratory personnel to national guidelines and client satisfaction.

Program resources: refers to infrastructure like rooms, electricity and water supply, logistics and supplies (equipment's and AFB reagents, laboratory registration book, NTP approved TB lab request papers, guidelines, human resource and SOPs.

Compliance: In this context it refers to the compliance of laboratory professionals to TB laboratory program national guideline, like provision of information on sputum collection, keeping time for result or TAT, providing respect for clients, checking sputum sample quality and carbon fuchsin filtration as per standard.

Clients Satisfaction: This is clients' opinion or perception about the service readiness to provide quality TB laboratory after received the service.

Clients who are satisfied means: at time of exit interview answer either V. Satisfied or satisfied.

Clients who are not satisfied mean: those who answer V, dissatisfied or dissatisfied or neutral.

Full information for sputum: laboratory personnel's explain clearly to the clients how to collect the sputum specimen by actual actions as follows: Inhale deeply 2-3 times, Cough out deep from the chest during exhalation, open the container and spit the sputum into the container, avoid saliva or nasal secretions & close the container, using simple and easily understood words(1).

Proper heat fixing of slides: passing smeared slides only three or four times through flame.

Proper examining slides: Examining a minimum of 100 fields before the smear is reported as negative. For skilled microscopes this will take approximately five minutes.

Quality Control: means by which the laboratory personnel performing TB smear microscopy control the process, including checking of instrument, staining solutions smear preparation, grading.

Adequate: resources available in the laboratory for the last three months.

Presumptive Tuberculosis: refers to a patient who presents with symptoms or signs suggestive of TB, like night sweating, weight loss in particular cough of two weeks or more duration and sent to laboratory for sputum smear examination (1).

Bacteriologic ally confirmed TB case: refers to a patient who has at least one positive result by smear microscopy after provide spot-spot sputum sample (1).

Turnaround time (TAT): time from the client come to the laboratory until receives the result.

Functional microscope: Microscope which 100*(times) objective is useful for smear sputum examination at the time of observation.

CHAPTER 1: INTRODUCTION

1.1. Background

Tuberculosis (TB) is a chronic infectious disease caused by mycobacterium tuberculosis, an acid-fast bacillus. The main source of infection is untreated smear-positive pulmonary TB patient discharging the bacilli. It mainly spreads by airborne route when the infectious patient expels droplets containing the bacilli. It is also transmitted by consumption of raw milk containing mycobacterium bovis (2).

Tuberculosis (TB) remains a major public health problem worldwide. It causes ill-health in millions of people each year and in 2015 it was one of the top 10 causes of death worldwide, ranking above HIV/AIDS as one of the leading causes of death from an infectious disease. This is despite the fact that with a timely diagnosis and correct treatment, most people who develop TB disease can be cured (3).

In 2015, an estimated 10.4millionnew TB cases including 1.2million among HIV-positive and 1.4 million died from the disease, 0.4million of who were HIV-positive (3).

In Africa, at least one third of the population is already infected with Mycobacterium tuberculosis. Poverty, HIV/AIDS and poor general health status have shifted the odds in favor of TB, allowing over 1.6 million people to develop active tuberculosis each year (4). The World Health Organization (WHO) declared TB a global emergency and introduced the Directly Observed Treatment-Short course (DOTS) strategy for global TB control (4). Diagnosis and treatment monitoring by sputum smear microscopy are key components of the DOTS strategy and as DOTS is expanded to cover increasing portions of the population, TB laboratory networks must be reinforced to meet these needs and with the ability to provide high quality and reliable laboratory services (5).

Ethiopia is one of high TB endemic in the world, ranking 8th in the list of 22 high burden countries and 3rd in Africa. In 2011, the estimated annual incidence and prevalence of all forms of TB were 258 and 237 per 100,000 populations, respectively. A recent population based survey showed that the prevalence of new sputum smear-positive TB was 174 per 100,000 populations (6). The disease is well addressed in all four rounds of the health sector development program

(HSDP I-IV) as one of the major public health problems in the country. Efforts to control the disease began in early 1960's. In 1992, DOTS strategy was introduced nationwide and currently provided in almost all public hospitals and health centers as well as in private and NGO health facilities. Ethiopia now is focusing to reach people with tuberculosis through health extension workers throughout urban and rural communities. However, the numbers of tuberculosis cases remain high in the country; the burden of HIV/AIDS has complicated its management and the spread of drug resistance tuberculosis is becoming a challenge for tuberculosis control (6).

Accurate case detection is one of the DOTS strategies. The success of current concerted efforts to control TB will ultimately depend on our ability to detect patients early to institute curative therapy and interrupt the cycle of transmission. Smear microscopy is still the most crucial test for the diagnosis of pulmonary TB, especially in countries with limited resources like Ethiopia (7). It remains the mainstay of rapid TB case detection, especially for those patients who are most infectious to others, where the bacterial load involved often reflects the extent of the disease and the need for immediate treatment. Besides, it offers the triple advantages of speed, simplicity and low cost (7).

Laboratory plays a pivotal role in disease control and prevention programs by providing timely data or information for patient management and disease surveillance. Quality in laboratory has a huge impact on diagnosis and patient management as about 80% of all diagnosis is made on the basis of laboratory tests (8). International Organization for Standardization (ISO-15189) has recommended assessment and monitoring of quality management systems (QMS) in laboratory as quality improvement efforts towards quality laboratory services (9).

Quality laboratory management systems have main objectives which are timely, precise and accurate results and meeting patients' needs and satisfaction. Key measures for improving laboratory services are continuous monitoring of the total testing process, the use of quality indicators to identify improvement opportunities, and measurement of the efficacy of specific interventions (10).

Laboratory diagnosis of high quality is necessary to rapidly and accurately detect TB cases and antibiotic resistance, to start effective therapy and finally to stop the progression of disease and to prevent the spread of disease to healthy people (11).

1.2. Statement of the problem

Effective control of TB is dependent on a network of local laboratories that provide accurate and reliable direct acid fast bacilli (AFB) microscopy testing for diagnosis and treatment monitoring (13). Although this is the case, only 57% of the 4.6 million new pulmonary TB patients notified globally in 2012 were bacteriologically confirmed using AFB microscopy testing. This low coverage in 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 66% of the estimated 8.6 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 and quality in many countries (2).

It is obvious that there are many procedures and processes that are performed in the laboratory and each of these must be carried out correctly in order to assure accuracy and reliability of testing (10). The complexity of the laboratory system requires that many factors must be addressed to assure quality in the laboratory. Some of these factors include: the laboratory environment, quality control procedures, communications, record keeping, competent and knowledgeable staff, and good-quality reagents equipment (10).

In Ethiopia, 39% of estimated cases were missed; either not diagnosed, treated or reported to national tuberculosis program. Those missed cases remain infectious agents and sustain the transmission of disease within the community. Furthermore, different studies reported the high prevalence, even higher than global estimates of 108/100,000; it was 10.9% in south west of the country (12).

Due to poor quality of health care the consequence on clients were catastrophic expenses, loss of production and leads them to drug resistant. The quality of TB laboratory diagnosis depends on: the type of laboratory procedures, the availability of standardized operating procedures and other essential resources, presence of internal and external quality control programs, the time necessary for referring specimens, the volume of activity and the respect of biosafety precautions(14).

A low case detection rate is often associated with a lack of effective program awareness, lack of active cough identification and lack of quality-assured routine diagnosis (such as sputum quality, reagent quality, knowledge, and capacity of professionals). In Ethiopia, factors that are associated with low case detection rates have not been well studied. Assessing the quality laboratory services in the study area will identify the existing gaps and challenges, provide recommendations to tackle them timely.

Therefore, this study addressed the quality of TB laboratory service related issues with main focus on structure, processes and outcome parameters in the four health centers of Jimma town, Oromia regional state.

1.3. Significance of the evaluation

- ✓ For the improvement of TB program of Jimma town health office
- ✓ Provide valuable information for those working on TB control activities.
- ✓ A learning media for key stakeholders on some aspects of evaluation process of TB laboratory service.
- ✓ Serve as base line information for other similar studies that may be conducted in the future.

CHAPTER 2: PROGRAM DESCRIPTION

2.1. Stakeholders identification and engagement

Stakeholders are defined as individuals, groups, or organizations that can affect or are affected by program and an evaluation process or its findings(16).All stakeholder have their own role with respect to the operation of the program and use of finding .They have contribution in the evaluation and are likely to play unique roles during evaluation process. Different stakeholders actively involved in TB Laboratory service in Jimma town health office. The key stakeholders were identified during evaluability assessment in collaboration with Jimma town health office.

The following table shows different stakeholders with their role in program and evaluation, perspective on evaluation, way of communication and level of importance.

Table 1: Stakeholder analysis for evaluation of quality TB laboratory service at public health centers of Jimma town, 2018

Stakeholders	Role in the program	Interest on evaluation	Role in the evaluation	Way of communication	Level of importance H,M,L
Jimma town health office	<ul style="list-style-type: none"> ❖ Guidance, ❖ Decision maker, ❖ Resource allocation, ❖ planning, ❖ routine program monitoring ❖ Supportive supervision 	<ul style="list-style-type: none"> ❖ Use the result for Strength and gap identifying. ❖ Use the result for planning, ❖ Support the program to ensure accountability. 	<ul style="list-style-type: none"> ❖ Formulating evaluation questions ❖ Set judgment matrix ❖ Data source , ❖ Facilitating evaluation process, 	<ul style="list-style-type: none"> ❖ Formal letter ❖ Discussion ❖ Telephone 	H
Health centers laboratories & workers	<ul style="list-style-type: none"> ❖ Planning ❖ conducting all laboratory activities 	<ul style="list-style-type: none"> ❖ Using the finding & acting up on it for program improvement by discharging their responsibilities properly & reporting 	<ul style="list-style-type: none"> ❖ Providing data ❖ Defining indicators. ❖ Setting the matrixes of analysis 	<ul style="list-style-type: none"> ❖ Face to face ❖ Discussion 	H

TB clients	❖ Beneficiary	❖ Improvement in the provision of service	❖ Data source	❖ Face to face Interview	H
Nekemt regional laboratory	<ul style="list-style-type: none"> ❖ Planning ❖ supervising ❖ Logistic provision ❖ Rechecking slides ❖ Providing feedback 	<ul style="list-style-type: none"> ❖ Service improvement, ❖ Use the finding for logistic planning 	Source of information	❖ Telephone	H
NGOs(challenge TB)	❖ Technical, and materials support (microscopes)	❖ Use the result for planning	❖ Source of information	<ul style="list-style-type: none"> ❖ e-mail ❖ phone 	M

2.2. Program goal and objectives

2.2.1. Goal

To contribute for the reduction of TB related mortality and morbidity in Jimma town.

2.2.2. General objective

To provide quality TB laboratory services in public health centers of Jimma town, 2018.

2.2.3 Specific objectives

- ✓ To avail all the necessary resources needed for TB laboratory service quality consistently to Jimma town health centers in 2018.
- ✓ To reduce the chain of TB transmission rate from 90% to 70% by the end of 2018
- ✓ To increase TB cases detection rate from 65% to 95% by the end of 2018

2.3. Major strategies

- ✓ Strengthen laboratory infrastructure and maintenance.
- ✓ Improve laboratories human resource development.
- ✓ Develop and maintain laboratory quality management systems.
- ✓ Enhance management of laboratory commodities and supplies including equipment validation and maintenance.
- ✓ Improve laboratory information and data management systems.
- ✓ Avail continuous AFB reagent supply.

2.4. Program resources and activities.

The resources and activities of the program have been identified from the standard checklists of the NTP guideline of Ethiopia.

Resources

Major resources required to implement quality TB laboratory services are: human resource, financial, laboratory equipment's, infrastructure (Electricity, Water and Telephone...), guideline, registration books and recording formats, SOPs for different, AFB reagents such as Carbol fuchsin, methylene blue, acid alcohol, immersion oil, and laboratory materials and equipment's like microscope, frosted slides, wire loops, filter paper, staining racks, spirit lamp or Bunsen burner, lens tissue, microscopes, sputum containers, manuals, AFB request paper and performance report form. (17)

Activities

Patient management activities are; Reception of patients with respect, instructing patients properly on how to produce sputum rather than saliva and proper amount of sputum, checking the quality of sample and order patients to re bring proper sample in case of saliva.

Program activities: practicing safety measures, management, proper waste disposing, involving in EQA programs, smearing and staining of sputum, adherence to AFB procedures and manuals, collection of sputum samples, storage of slides for external quality assessment, on site reading, documenting, and filtering of carbon fuchsine and Methylene blue.

Program outputs

The immediate result of the activities after it is being provided to the presumptive TB patients.

Some of the outputs of the quality TB laboratory service are

- ✓ Number of TB presumptive investigated. .
- ✓ Number of patients received full information from laboratory personnel
- ✓ Number of clients with NTP approved lab request.
- ✓ Numbers of filtering carbon fuchsine and Methylene blue done on the time observation.

Program outcome

- ✓ Improved TB laboratory service quality.
- ✓ Increase client satisfaction.
- ✓ Improved Timely decision making
- ✓ Improved case detection rate.

Program impact

- ✓ Reduction of TB related morbidity and mortality.

Problem statements: Poor quality TB laboratory contribute to low detection rate and high missing results, this increases the transmission rate of TB in Jimma town and reinforces clinical irrelevance of diseases. In Oromia TB detection rate were 64% which is below the national target and 33% missing results. (18).

Goal: To contribute in reduction of morbidity and mortality caused by TB in Jimma town.

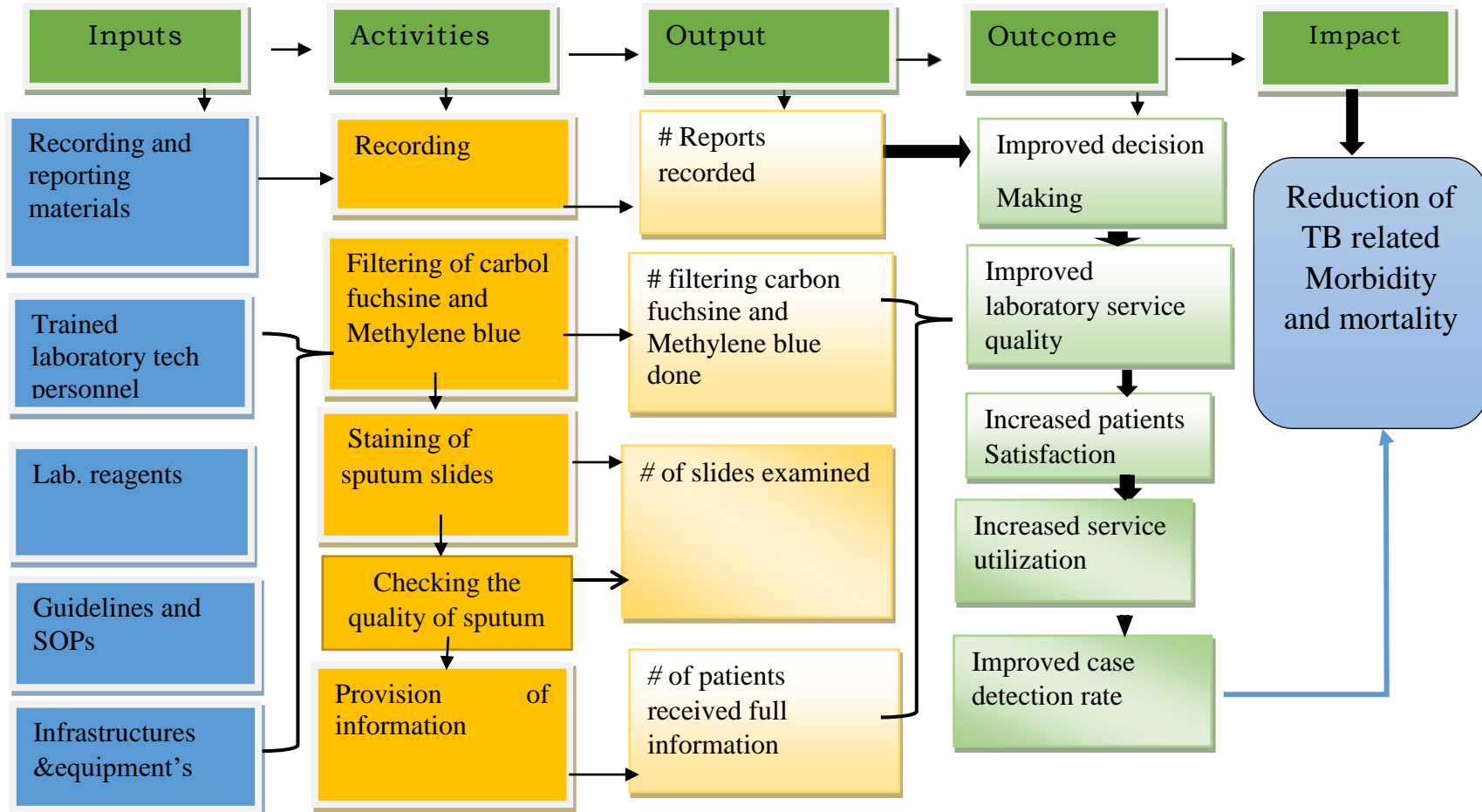


Figure 1: Logic Model for Evaluation of Quality of TB Laboratory Diagnostic service at Jimma town health centers, 2018.

2.5. Stage of Program Development

DOTS strategy launched by WHO in 1994, and subsequently endorsed by the WHO Stop TB Strategy in 2006 Ethiopia Adopted the DOTS strategy since 1997 Adopted the global STOP TB strategy in 2006 Ethiopia has achieved the millennium development goals for TB in 2015(6).Now adopted the new END TB strategy with aim of ending the TB epidemic by 2035.Recently public health laboratories in Ethiopia have begun to implement the international QMS to provide quality laboratory services (15).

The world Health Organization (WHO) recognizes quality laboratory services as key to improving global health and reaching Millennium Development Goals (15). Until recently, however, the majority of Ethiopian public health laboratories delivered suboptimal service and were not a direction to contribute to a quality health system. Now, through commitment and leadership by the Federal Ministry of Health (FMOH) the Ethiopian Health and Nutrition Research Institute (EHNRI), and the concerted effort of local and international partners, this has begun to change (15).

As far as TB laboratory is concerned, DOTs strategy still relies on a network of laboratories that provide AFB sputum smear microscopy. Therefore, establishment of a network of well-functioning peripheral laboratories within the health system and readily accessible to the population is a high priority for the TB control program because, provided that the laboratory diagnosis is unreliable, all other activities will be affected (19).

Despite the fact that assuring the quality of laboratory services is a complex issue, highly dependent on the available resources in the respective country or state, structure of the health system and laboratory network, and incidence of disease, effort to improve and expand TB laboratory capacity is currently under-way to some extent in our country.

Concerning Tuberculosis laboratory service in Jimma town evaluability assessment conducted in September, 2017, revealed as it was in its implementation stage and matured enough to be evaluated.

CHAPTER 3: LITERATURE REVIEWS

3.1. Overview of Quality

TB Laboratory Service

Sputum smear microscopy for acid-fast bacilli is of vital clinical and epidemiological importance in the diagnostic process for tuberculosis in both rich low- incidence countries and high burden countries with limited resources like Ethiopia. It remains the cornerstone for the diagnosis of pulmonary TB in adults because it identifies the most powerful sources of transmission of TB, and can be performed quickly and has high specificity in high-prevalence countries (20, 21).

No other established technique offers the same advantages of accuracy, speed, appropriateness and accessibility. However, its sensitivity may be reduced in HIV- positive cases or because of technical deficiencies, and it lacks specificity for viable bacilli in follow-up examinations. Its main problem is that sensitivity of the direct smear assay has been found to be dependent on staff that has been well trained so that sufficient time spent on preparing, staining, and reading each smear, with a well-functioning EQA program in place (22).

While it has a relatively low sensitivity in identifying all cases of pulmonary TB, correctly applied, it detected the transmitters of 83% of infections in San Francisco and 91% in British Columbia and Saskatchewan (23, 24).

Quality Assurance is a system designed to continuously improve the reliability and efficiency of laboratory services, and it has 3 main components which are internal quality control (laboratory continuously to control itself including test guides, staff training and supervision), improvement of quality (continuous improvement, error identification and correction) and external quality control (laboratory to control by the external quality control bodies and to compare the performance of inter-laboratories in terms of accuracy and proficiency) (25).

The sensitivity of sputum smear microscopy has been reported to vary (range, 20 to 80%), often depending on the diligence with which specimens are collected, smears are made, and stained smears are examined (26).

3.2. Quality Assessments

Donebodian developed the model to evaluate health care quality, which includes structure, process and outcome quality parameters and inference about the quality of care can be made by assessing these three parameters in detail. This model defines the tools and resources that providers of care have at their working classes, the general physical and organizational setting where they work or the way a health care system is set up and the condition under which it is provided as structure (27) whereas the set of activities that occur within the health service organizations, where judgment of quality could be made either by direct observation of what are being done or by reviewing recorded information of health care activities such as: diagnosis, treatment and prevention as process quality parameters and finally the effects of health care on patients or populations, including changes to health status, behavior, or knowledge as well as patient satisfaction and health-related quality of life as outcome. Outcomes are sometimes seen as the most important indicators of quality because improving patient health status is the primary goal of healthcare (28).

3.2.1 Structural quality assessment

Structural indicators that must be assessed in order to say TB laboratory quality are: structures of the services like governance and levels of tiered services, a availability of Infrastructure like buildings, Reagents and consumables and capital equipment like microscopes, Human resources which includes elements like capacity and training, Financial resources like financial systems of laboratories, technology like tests available at tiered laboratory levels, availability of Quality management and systems (29).

Successful DOTs expansion as well as programmatic management of drug-resistant and HIV-associated TB therefore requires at its core a robust network of TB laboratories with adequate biosafety, modern methods for diagnosis, standard operating procedures and appropriate quality assurance. Arguably the weakest component of health systems, laboratory services have historically been grossly neglected, under-staffed and underfunded. Diagnostic capacity is therefore a major bottleneck for scaling up management and control of drug-resistant and HIV associated TB (29).

Study conducted in India on qualitative and quantitative assessments of ten TB laboratories by 2006 on quality of sputum smear microscopy based on-site evaluation also showed infrastructure problems in almost 42% of the laboratories, lack of reagents and equipment's in 56.6% of them and lack of standard Operating procedure (SOP) in 40% of the TB laboratories (30).

Study conducted in Uganda on 48 laboratories from the fourth quarter of 1997 until the last quarter of 1998 using a standardized checklist to assess peripheral sputum smear microscopy laboratories for tuberculosis diagnosis showed that 75% of the 48 laboratories had shortage of laboratory reagents and other supplies. The most frequent missing items were: lens tissue (43.8%), filter paper and disinfectant (31.3%), sprit for spirit lamps and diamond pens/pencils (29.2%), Xylene and funnels (22.9%), sputum containers (16.7%), and wire loops and staining racks (12.5%). Twelve microscopes (25%) were either defective or had been stolen (31).

Study conducted in 8 zones of Oromia in public TB laboratory in 2008 showed that, 22% of laboratories had great biosafety problems, in which the laboratories had no ventilation and separate rooms for sputum smearing and among available laboratories' staffs during study periods, 50% were fresh and not trained on AFB microscopy (32).

Study done in three zones of Arsi of Oromia regional state on public and private TB laboratories by 2012 depicted that 75% of the TB laboratories had at least one laboratory technician that had been trained on TB laboratory diagnosis (33).

3.2.2. Process quality assessment

Process quality assessment is means of observing what are actually being done to and for the patients in giving services. It includes policy profile of TB laboratory network in the provision of care, safety measures and practices, laboratory performance analysis, quality assurance programs and data management. Studies of the process usually depend on direct observations or review of medical records (34).

World Health Organization suggests that there should be necessary cautions when establishing TB laboratories, since a direct relationship exists between workload, number of laboratory technologist required and the quality of microscopy of TB laboratories. The maximum number of AFB slides examined per microscopist per day should not exceed 20. If more examinations are attempted, visual fatigue well leads to a deterioration of reading quality (35).

Study conducted in three selected zones of Western Amhara Region of Ethiopia, showed that 66.7% of both public and private TB laboratories did not have and use standard Operating procedures (SOPs) for AFB diagnosis, about 66.7% of laboratories posted AFB staining procedures in their working areas. Adequate instructions how to bring representative samples were given to the patients in 90.0% of TB laboratories in the study area. Practice of checking quality of sputum before processing was done in only about 27 public & 12 private TB laboratories. Only 45.0% TB laboratories run quality control smears while performing routine AFB staining (36).

3.2.3 Outcome quality Assessment

Outcome quality in this context is assessment of the results found immediately out of health service delivery. Example: Client satisfaction with the service given. So, its parameter encompasses overall all satisfaction of the patient with: the TB laboratory services, respect provided to the client by the provider, and completeness and clarity of information given to the patient during sputum sample collection & timeliness of results (28).

Study conducted, in west Amhara region clearly showed that about 45.0% of patients preferred private TB laboratories for the reasons of timely services and respect ion given and 66.0%) patients were satisfied with service providers' impartiality, counseling and guidance to get additional services (36).

It is obvious that when insufficient attention is given to the quality of the work product, serious deficiencies in the laboratory operations will occur. (37) Measuring the quality of health care has paramount importance in continually improving the quality of care/services rendered and it considers the following assumptions: Quality is measured as a scale or degree rather than as a binary phenomenon, It has to be measured in terms of structure, process and outcome, which must be assessed in relation to the type and the specialty of the services (38).

This study was intended to evaluate the quality of the public laboratory diagnostic services by considering the structural, process and outcome quality assessment parameters in Jimma town health centers south west Ethiopia. By looking at different literature's, for this evaluation, quality of TB laboratory was conceptualize as the figure 2 below.

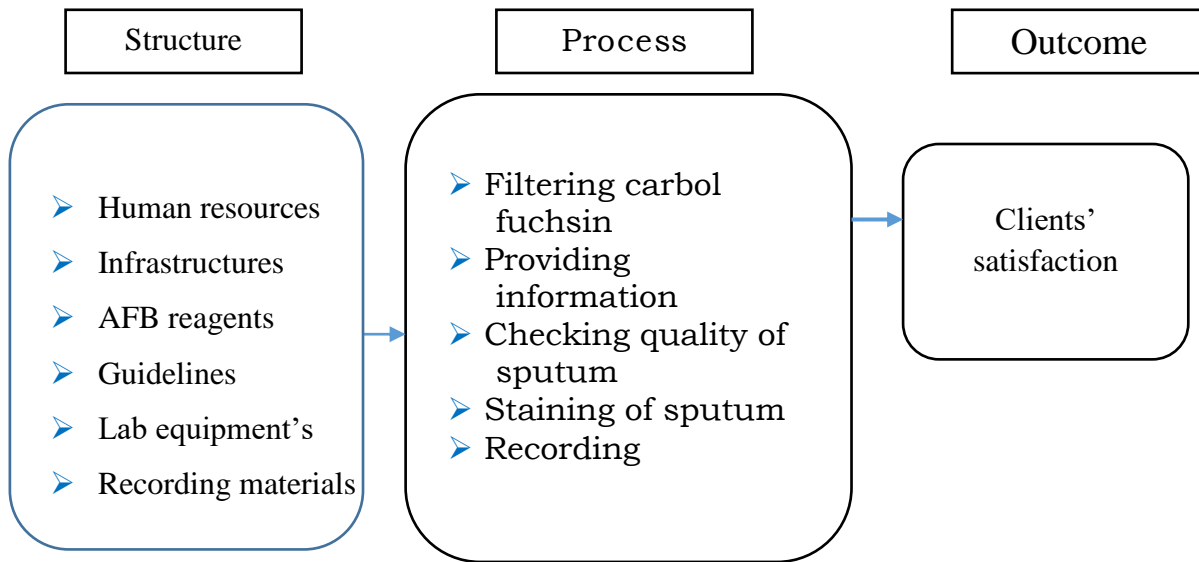


Figure 2: Theoretical framework for Evaluation of quality TB laboratory diagnostic services in Jimma town health centers (36).

CHAPTER 4: EVALUATION QUESTIONS AND OBJECTIVES

4.1. Evaluation questions

1. Are the necessary resources available for TB laboratory diagnosis? If not, why?
2. Are all TB laboratory-based diagnostic procedures implemented as per the national guidelines? If not, why?
3. Are the TB patients satisfied with the TB laboratory services? If not, why?

4.2. Objective

General objective

- To assess the quality of TB laboratory diagnostic services in Jimma town health centers, southwest Ethiopia.

Specific Objectives

- To assess availability of resources for TB laboratory diagnosis
- To assess whether TB laboratory based diagnostic procedures are implemented as per the national guidelines.
- To assess patients satisfaction with the TB laboratory services.

CHAPTER FIVE: EVALUATION METHODS

5.1. Study area

The evaluation was conducted in Jimma town which is one of the town administrations in Oromia region. This is located 352km southwestern direction of Addis Ababa. Approximately 199,575 populations it has 1 specialized, 1 district hospital and four health centers. Health centers are supported and supervised by town health office. All of these health care facilities provide TB laboratory services. According to town health office plan report of 2009, one thousand nine hundred ninety five presumptive TB were investigated annually (37).

5.2. Evaluation period

The evaluability assessment was conducted from October 10 to 20, 2017. Data collection of evaluation was conducted from April 1 to 30, 2018

5.3. Evaluation approach

Formative evaluation approach was used to evaluate quality of TB laboratory service in Jimma town. Formative evaluation was conducted for the purpose of improving program and it can be descriptive. It provides depth and detail about the programs strengths and weakness (38).

5.4. Evaluation Design

Case study design with mixed method of data collection was used to evaluate the process of quality TB laboratory service program. Qualitative and quantitative data was collected concurrently, analyzed separately, and integrated during interpretation of findings. This design was used to get deep and detailed source of information from real life context of quality of TB laboratory service program in Jimma town.

5.5. Focus and dimension of evaluation

The focus of the evaluation was process in which it provides information about resource to be used, activities to be accomplished and expected output and it also considers some immediate

outcome which was satisfaction of TB clients on TB quality laboratory services of Jimma town public health centers.

Dimensions of evaluation

Availability, compliance and acceptability of the service in bringing client satisfaction were the main dimensions of the evaluation.

Availability: The relationship of the volume and type of existing services and resources to the clients' volume and types of needs (27). It refers to the adequacy of the supplies like AFB reagents, frosted slide, disinfectants, laboratory technologist and technicians; and service delivering infrastructures like electricity, water, telephone and service rooms with their respective clients.

Compliance: Refers service provider adherence to the SOPs and the TB laboratory implementation guideline.

Satisfaction: clients satisfied in their perspective about the TB laboratory service they received. It is important to examine how the client views the services so that the immediate outcome of the service will be evaluated.

5.6. Evaluation Indicators

Indicators

The indicators will be assigned based on the dimensions of the evaluation and stakeholders need.

Availability indicators:

- ✓ Number of health center laboratories with adequate staining reagents for the last three month.
- ✓ Number of health center laboratories with adequate equipment's like, frosted slides, sputum cups and other consumables for the last three month.
- ✓ Number of Health center laboratories that have an incinerator to correctly dispose all hazardous materials (e.g. sputum cups, needles,, toxic materials)
- ✓ Number of health center laboratories with at least one trained professional on TB laboratory diagnosis at least one time.

- ✓ Number of health center laboratories having functional Microscopes.
- ✓ Number of health center laboratories that have national AFB microscopy manuals at the time of observation.
- ✓ Number of health center laboratories that have national SOPs on the date of survey.
- ✓ Number of health center laboratories with TB registration book on the date of survey
- ✓ Number of health center laboratories that have separate rooms for TB laboratory
- ✓ Number of health center laboratories with timer on date of survey
- ✓ Number of health center laboratories with running water supply on date of survey.
- ✓ Number of health center laboratories with electricity on date of survey

Compliance indicators

- ✓ Number of laboratories with in which carbol fuschin is filtered before use as per standard.
- ✓ Proportion of observation sessions which follow standard heating to fix the slide.
- ✓ Proportion of procedures which microscopic lens are cleaned after every slide examination as per standard.
- ✓ Number of laboratories within which AFB procedures job aids are posted.
- ✓ Proportion of clients who get full information by service providers on how to produce & bring adequate amount of sputum samples.
- ✓ Proportion of clients with NTP approved laboratory request formats.
- ✓ Proportion of TB client sputum containers are properly labeled as per standard.
- ✓ Proportion of TB client sputum smear staining time properly kept with timer.
- ✓ Number of laboratories in which infectious wastes were separated from general trash on date of survey
- ✓ Proportion of clients who received laboratory services within the recommended time.

Indicators of satisfaction

- ✓ Proportion of clients satisfied with clarity of information given by the provider on sputum collection & instruction given.

- ✓ Proportion of clients satisfied with providers respect at TB laboratory unit.
- ✓ Proportion of clients satisfied with keeping privacy by providers at TB laboratory unit
- ✓ Proportion of clients satisfied with the waiting time of laboratory services
- ✓ Proportion of clients satisfied with overall cleanliness of the waiting areas of laboratories.
- ✓ Proportion of clients satisfied with ventilation of the waiting areas.
- ✓ Proportion of clients satisfied with overall cleanliness of laboratory examination room.

Variables

- ❖ Clients' satisfaction
- ❖ Clients' socio demographic (age, sex, educational status, occupation and marital status)
- ❖ Health facilities factors (Amenities)
 - ♣ Cleanness of examination room
 - ♣ Cleanness of Waiting area
 - ♣ Waiting time

5.7. Population and sampling

5.7.1 Population and sampling

For quantitative part

- ✓ All presumptive TB clients within study period were included in this study
- ✓ All NTP approved laboratory request papers
- ✓ All Jimma town health center laboratory units,

For qualitative

- ✓ All laboratory professionals
- ✓ TB program coordinator

Sampling

For exit interview

All 174 TB clients TB presumptive and who were on follow up in Jimma town public health centers during data collection period.

Document review

NTP lab request paper of all TB presumptive and who were on follow up were reviewed.

Resource inventory

Laboratory reagents, equipment's, TB laboratory registration book and consumables in four health centers

Direct observation

Four TB laboratory service providers who were working in each health centers (4 health centers) were observed. Each health care provider was observed on six clients when providing TB laboratory service. A total of 24 observation sessions consecutively were conducted for one week. To minimize hawthorn effect the first one observation from all health care providers were excluded. So 20 observations were used for analysis purpose.

.For qualitative part

Key informant interview

Purposive sampling technique was used for in-depth interview based on their responsibility and experience. They were selected for the reason that they were more relevant information sources for the issues related to TB laboratory service such as availability of resources, and the strength and weakness of the implementation status of the program. Two laboratory professionals from each HC; Therefore 8(eight) Laboratory professionals, and 1(one) TB expert from town health office, a total of 9 interviews were conducted.

5.7.7. Inclusion and exclusion criteria

Inclusion criteria

Presumptive TB and TB case on follow up during data collection period. Laboratory professionals and TB focal person in the town health office working more than six months

Exclusion criteria

Client who are <18 years, those return back during study period, seriously and mentally ill were excluded from exit interviews.

5.8. Data collection

5.8.1. Development of tools

Interviewer administered questionnaire: a tool containing specific component on background characteristics of the respondent, information about visit, compliance of the health care provider with the type and time of services, availability of resources and health care provider- client interactions. The questionnaires were prepared first in English language and then translated to local language.

Key informant interview guide for service providers: a tool comprised of components like support system, training and preparation, services organization and delivery. It also assessed the availability of resources of program and barriers to program quality.

Document review checklist: a tool used to collect data from NTP approved result papers.

Observation checklist: a tool used to assess the compliance of service providers while delivering TB laboratory services and resources availability. It also assessed the availability of TB program resources.

Resource inventory: was conducted using resource inventory checklist. It was incorporated direct observation of resources.

5.8.2. Data collectors

Four laboratory technicians for data collection and two supervisors having BSc in medical laboratory technology were participated in data collection processes. The interviewer administer questionnaire collected by four diploma laboratory technicians after training. For observation,

key informants interview, and document review were conducted by principal evaluator. Furthermore, one supervisor (laboratory technologist) assigned. The data collectors and supervisors were given one day training on the evaluation objective, data collection instruments and techniques and ethical issues.

5.8.4 Data collection field work and data quality control

To assure data quality, the data collection instruments were properly designed, the tools were pre tested in 5% of the sample size in Serbo health centers which have similar contexts with the health centers before the actual data collected. Some terminological adjustment made accordingly, training for data collectors, continues supervision during data collection, data completeness, and consistency checked & immediate on site correction was given. Due care undertaken prior to data collection, in the process of data collection and analysis to ensure data quality

The data checked for completeness and consistency on daily base appropriate correction was given by supervisors and principal evaluator at any time during data collection field work and in each day the collected in-depth interview data transcribed, categorized in thematic area and narrated.

5.9. Data management and analysis

5.9.1. Data entry

The data was checked for completeness every day after data collection by principal evaluator together with data collectors and supervisors manually. Any problems encountered discussed among the evaluation team and solved immediately. Finally the data coded and entered to Epi data 3.1 for further processing then export to SPSS version 20.0 for statistical analysis.

For the qualitative data, for in-depth interview responses were transcribed, coded, categorized and analyzed using thematic analysis technique.

5.9.2. Data cleaning

Incomplete and invalid data were refined properly to get maximum quality of data before, during and after data entry. Corrections made according to the original data from questioners.

5.9.3. Data analysis

Using 7 satisfaction items with 5-point Likert scales ranging from vary dissatisfied to vary satisfied (1 to 5 points) were used for all the items. The responses of client were dichotomized in to satisfied and not satisfied; those who were satisfied and vary satisfied were simply categorized as "satisfied" and dissatisfied, very dissatisfied and neutral were categorized as "not satisfied". Descriptive statistics like frequency, proportion and mean of variables were used for reporting the descriptive results. The qualitative data was analyzed manually using thematic analysis with respective dimensions and results were presented in narrative form. The final interpretation of results was based on evaluation judgment criteria

5.11. Ethical considerations

Ethical clearance was secured from Jimma University Institute of Health, Public Health Faculty ethical committee before the beginning of data collection activity. Letter from Jimma town health office to the selected health facility received before data collection. Confidentiality and privacy of the participant was maintained by selecting appropriate place in the process of data collection. From all study participants oral consents were received before collecting data.

5.12. Evaluation dissemination plan

This evaluation report will be presented and submitted to Jimma University, Institute of public health, Department of Health Economics, Policy and Management, Health Program Monitoring and Evaluation unit and respective stakeholders. The evaluation findings and recommendations will also be communicated with Jimma university scientific communities, Jimma town health office and others stakeholders. Finally, this evaluation will be disseminated through hard copies and soft copies to stakeholders and publication on scientific journals will be considered.

Chapter 6: Results

Description of study participants

From four health centers a total of 174 TB clients responded the interviewer administered questionnaire. Eight key informants from health centers laboratory personnel, one from town health office TB program coordinator (Male=7, Female=2), 174NTP approved result papers, 20 client provider interactions observations and resource inventory was conducted in 4 HCs laboratory units.

6.1. Availability

The findings of this study showed that most of the laboratory supplies that are required for the service provision were available. Regarding availability of human resources in each laboratory there were two laboratory personnel. From eight laboratory personnel, 6were BSc holders 2 diploma all of them had taken training on TB laboratory diagnosis with in the last two years. In majority, 3 of TB laboratories had sets of reagents (carbol fuschin, acid alcohol and methylene blue), frosted slides, sputum cup, slide box, staining rack, and bunsen burner. One health center had shortage of acid alcohol (one of AFB reagent) before one month from study period.

All laboratories had two functional Olympus Microscopes. Concerning Laboratory safety, two laboratories, didn't have written guidelines on safety precautions such as: infection prevention, safe disposal of sharps (i.e., needles, etc.), safe disposal of biohazard medical and use of protective gear.

All laboratories had access to electric supply and access running water but no fuel generator in case of power interruption and also they didn't have neither distilled nor filtered water. This is supported by the key informant interview, where one key informant responded that.

“actually we have electric supply but sometimes there may be power interruption problem at that time we tried to examine sputum smear using lens or light This has effect on quality of the test and most of the time we don't have filtered or distilled water; so, we are forced to use water that comes from pipe sources which is sometimes turbid. We know as it compromises the quality of the tests, but we use it as we don't have any other alternatives. We have reported to different concerned bodies till now there is no result.”

(A 32 years old laboratory personnel)

All laboratories had no isolated room, all type of tests done in one room collection, staining and examination and also they were not ventilated. This is also supported by the key informant interview.

“Only one room designated for laboratory services for collection, smear and staining of sputum smear, which even not well furnished. The room is not ventilated and there is no isolated table for sputum collection and examination this have an effect on quality. One of our staff laboratory technologists was infected by TB. This might be due to the room he may acquire from the laboratory this might leads to poor quality services”.

[A 34 year old Lab. personnel]

All laboratories had incinerators to properly dispose all hazardous materials (e.g. sputum cups, needles, toxic materials).

Table 2: Judgment result of availability dimensions for evaluation of Quality of TB laboratory diagnostic services in health centers of Jimma town, south west Ethiopia,2018

Availability Indicators	Expected #	Observed #	Weight (W)	Score (S)	Achiv . (S/W *100)	Judgment parameters
Number of health center laboratories with adequate staining reagents for the last three months.	4	3	4%	3.00%	75.00 %	90-100= V. Good, 70-89.99 =Good 60-69.99= Fair < 60 = poor
Number of health center laboratories with adequate equipment's like, frosted slides, sputum cups for the last three months	4	4	4%	4.00%	100.00 %	
Number of Health center laboratories that have a incinerator to correctly dispose all hazardous materials	4	4	1%	1.00%	100.00 %	
Number of health center laboratories with at least one trained professional on TB laboratory diagnosis	4	4	3%	3.00%	100.00 %	
Number of health center laboratories having functional Microscopes.	4	4	4%	4.00%	100.00 %	
Number of health center laboratories that have national AFB microscopy manuals	4	4	1.5%	1.5%	100.00 %	
Numbers of health center laboratories have TB registration book.	4	4	2%	2.00%	100.00 %	
Number of health center laboratories that have isolated room for TB laboratory procedures	4	0	2%	0.00%	0.00 %	
Number of health center laboratories with timer on date of survey	4	2	1%	0.50%	50.00 %	
Number of health center laboratories with pipe water supply on date of survey	4	4	2%	2.00%	100.00 %	
Number of health center laboratories with electricity on date of survey	4	4	4%	4.00%	100.00 %	
Number of health center laboratories that have SOPs	4	4	1.5%	1.5%	100%	
Overall value	44	37	30.00%	26.50 %	88.30 %	

6.2. Compliance

The finding of observation indicated that provision of adequate instruction were provided for 18 (90 percent) clients by laboratory professionals and all observed sessions follow spot-spot method of sample collection. Regarding to sample collectors' profession; all were laboratory personals. Out of observed sessions 14 (70 percent) were check the quality of specimen visually.

In case of specimen quality, more than half 12 (60 percent) of laboratory personals check and offer the clients to repeated the specimen while saliva specimen collected. From observations all session procedures were label the cup, label slide and use lab request formats. Two laboratories were post NTP SOPs.

Two laboratories were observed on Carbone fusion and methyl blue filtration before use and slide staining time were 10 (50 percent) were keep time as the guidelines recommends. On sixty present of sessions professionals were clean the lens and eye piece of the microscope using tissue papers. In addition all of the observed lab personals were perform smear air dry and slide heat fix. Almost all of the lab personals were observed as to keep the examined slides for EQA purpose.

(Figure: 3)

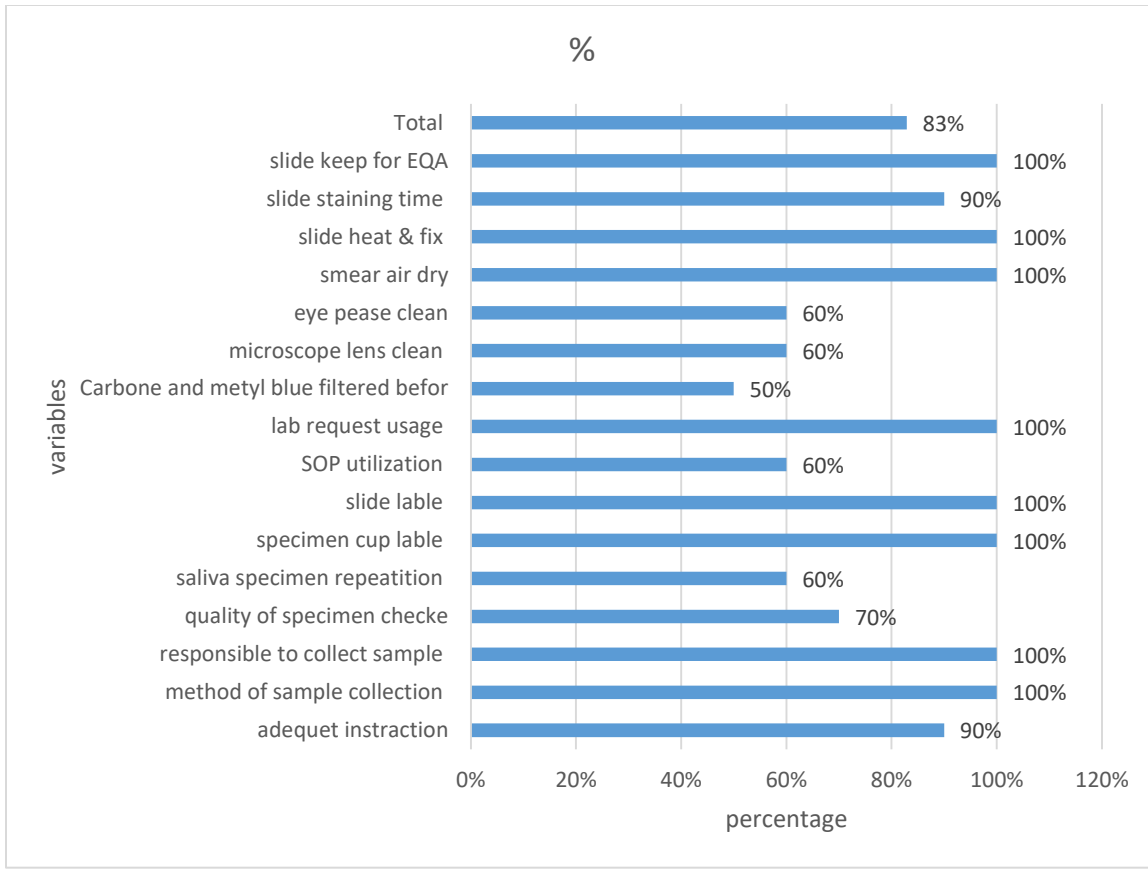


Figure 3: Compliance of laboratory personals on TB laboratory procedures quality standards, in Jimma town, Apr. 2018.

This finding is supported by response of one of the key informant.

“I was graduated from known university and also trained on TB laboratory at least 3 times. So, I have no technical deficiencies; but, I become negligent to post the TB SOPs and to filter carbon fuchsine and methylene blue”.

[29 years old laboratory technologist]

National TB program (NTP) approved laboratory request forms were used in all of laboratories as a result TB laboratory registers were properly filled in with all necessary data.

In addition, all of laboratories in the study, infectious wastes were not separated from general trash by clearly marking containers as infectious and non-infectious.

“Occasionally laboratory technicians would not orient patients about the type and amount of sputum specimen. Therefore sometimes patients bring saliva instead of sputum, and bring inadequate sputum, consequently resulting in incorrect laboratory diagnosis.”

[A 35 old male laboratory technologist]

Table 3: Judgment Matrix of laboratory Personnel's' compliance to guide lines for evaluating quality of TB laboratory diagnostic services at selected public health facilities of Jimma town ,2018.

S/ No	Indicators	Expected #	Observed #	Weight (W)	Score (S)	Achiv. (S/W*100)	Judgment parameters
1	Number of laboratories with in which carbon fuchsine is filtered before use as per standard.	4	2	4%	2.0%	50.0%	90-100=V. good, <div style="background-color: #008000; color: white; padding: 5px; display: inline-block;">70-89.99 =Good</div> 60-69.99=Fair < 60 = poor
2	Proportion of procedures which follow standard heating of to fix the slide	20	20	4%	4.0%	100.0%	
3	Proportion of procedures which microscopic lens are cleaned after every slide examination as per standard.	20	12	3%	2.4%	60.0%	
4	Number of laboratories within which AFB procedures job aids are posted.	4	2	3%	1.8%	60.0%	
5	Proportion of clients who get full information from service providers	20	18	4%	3.6%	90.0%	
6	Proportion of clients came to laboratory with	174	174	1%	3.0%	100.0%	

	NTP approved lab request forms.						
7	Number of TB client sputum containers is properly labeled as per standard.	20	20	3%	3.0%	100.0%	
8	Number of TB client sputum smear staining time properly kept with timer.	20	18	4%	3.6%	90.0%	
9	Number of clients who received laboratory services within the recommended time	20	12	3%	2.4%	60.0%	
10	Number of laboratories in which infectious wastes were separated from general trash on date of survey	4	0	1%	1.0%	0.0%	
All over performance				30%	24.9%	83%	

6.3. Acceptability of service

About 174 clients coming to TB laboratories to sputum smear laboratory services were interviewed using structured questionnaire to assess their acceptability on different aspects of laboratory services.

Among the study participants, 77(44.3%) were males, and 97(55.7%) were females. The age range of TB clients in this study was between 18 and 80 years. The mean age was 39.5 (SD \pm 14.08) years.

Table 4: Socio demographic characteristics of clients participated on exit interviews at Public Health centers of Jimma town April 2018(N=174). .

Characteristics	Category	Frequency	Percentage
Age	18-30	50	28.7
	31-45	74	42.5
	46-60	37	21.3
	>60	13	7.5
Gender	Male	77	44.3
	Female	97	55.7
Educational status	Unable to read and write	20	11.5
	Only read and write	52	29.9
	1-8 grade	33	19.0
	9-12 grade	39	22.4
	Above 12 grade	30	17.2
Occupation	Farmer	39	22.4
	Government employee	46	26.4
	Merchant	45	25.9
	Others	44	25.3
Religion	Muslim	68	39.1
	Orthodox	67	38.5
	Protestant	33	19.0
	Others	6	3.4
Marital status	Single	42	24.1
	Married	109	62.6
	Divorced	14	8.0
	Widowed	9	5.2

6.3.1. Satisfaction level on different aspects of Tuberculosis laboratory diagnosis

Client satisfactions were assessed using 7 satisfaction related questions. The responses of client were dichotomized in to satisfied and not satisfied; those who were satisfied and very satisfied were simply categorized as "satisfied" and dissatisfied, very dissatisfied and neutral were categorized as "not satisfied".

About 109(62.6%) of participants were satisfied with items which indicate waiting time for results, 143(82.2%) of participants were satisfied with overall cleanliness of waiting areas and 133(76.4) of participants were also satisfied with comfort and ventilation of the waiting areas. However, 67(38.5%) of participants were not satisfied with respect provided to them from laboratory professionals. About, 58(33.3%) of participants were also not satisfied with clarity of instruction given to them for sputum collection. And also 65(37.4%) of participants were not satisfied with time spent to receive the result. (See table 6)

Table 5: clients' satisfaction category on each satisfaction measuring items of TB laboratory services provided in Jimma town health centers April 2018.

S.no	Satisfaction items	Satisfaction category (N=174)	
		Not Satisfied N (%)	Satisfied N (%)
1	Proportion of clients satisfied with clarity of instructions given by the provider	58(33.3)	116(66.7)
2	Proportion of clients satisfied with providers respect at TB laboratory unit	67(38.5)	107(61.5)
3	Proportion of clients satisfied with the waiting time of laboratory services	65(37.4)	109(62.6)
4	Proportion of clients satisfied with overall cleanliness of the waiting areas	31(17.8)	143(82.2)
5	Proportion of clients satisfied with ventilation of the waiting areas	41(23.6)	133(76.4)

6	Proportion of clients satisfied with cleanness of laboratory room.	52(29.9%)	122(70.1)
7	Proportion of clients satisfied keeping privacy by service providers	79(45.4%)	95(54.6)

Table 6: Judgment result for client satisfaction levels to measure acceptability of clients on different aspects of the service at Jimma town health centers, 2018.

S/No	Indicators	Expected #	Observed #	Weight (W)	Score (S)	Achieve. (S/W*100)	Judgment parameters
1	Proportion of clients satisfied with information given by the provider on sputum collection	174	116	10%	6.7%	66.7%	90-100=V. good, 70-89.99=good 60-69.99=Fair < 60 = poor
2	Proportion of clients satisfied with providers respect at TB laboratory unit	174	107	5%	3.1%	61.5%	
3	Proportion of clients satisfied with the waiting time of laboratory services	174	109	7%	4.4%	62.6%	
4	Proportion of clients satisfied with overall cleanness of the waiting areas of laboratories	174	143	5%	4.1%	82.2%	
5	Proportion of clients satisfied with ventilation of the waiting areas	174	133	5%	3.8%	76.4%	
6	Proportion of clients satisfied with cleanness of laboratory room	174	122	5%	3.5%	70.1%	
7	Proportion of clients satisfied with keeping privacy by lab personals	174	95	3%	1.6%	54.5%	
Overall				40%	27.2%		68% (fair)

Overall judgments of evaluation of quality of TB laboratory program

Overall judgments of quality evaluation of TB laboratory diagnosis at Jimma town health centers was achieved good and the judgment result of 79.76% according to the stated indicators .

Table 7: Overall judgments of Dimensions for quality evaluation of TB laboratory diagnosis at Jimma town health centers, 2018

S/n	Dimension	Weight	Result	Judgment
1.	Availability	30	88.30%	Good
2.	Compliance	30	83%	Good
3.	Acceptability	40	68.%	Fair
All over		100%	79.76%	Good

Chapter 7: Discussion

This study has attempted to evaluate the process of quality of TB laboratory services in health centers of Jimma town, south west Ethiopia. The evaluation finding showed that the overall process of quality of TB laboratory of the four health center of Jimma town was 79.76 percent. The structure component measured by availability of resource was 88.3percent. The compliance of laboratory personals to the national guideline 83 percent and the satisfaction of clients 68percent. The status of process of the program needs some improvements according to the judgment parameter.

7. I. Availability of Tuberculosis Laboratory resources

Service providers are the most important laboratory resource; so, it is important to hire an appropriate number of staff to cover workload. This study revealed that, the average numbers of laboratory professionals were appropriate in terms quantity at each health facility's TB laboratory that means on average 2 professionals. This is as the national guideline stated that there should be at least 2 laboratory personnel in one health center. The study was also in concordant with study conducted in three zones of western Arsi in which the average numbers of laboratory technicians/technologists were satisfactory at each health facility TB laboratory i.e. on average 2 laboratory professionals in each health center's Tuberculosis laboratories. (33)

Tuberculosis control also requires a functional laboratory set-up with quality diagnostic services and a trained diagnostician (33). Concerning this all of laboratories had laboratory personnel that had taken training on TB laboratory diagnosis in the last two years. This finding was high when compared to the study conducted in Uganda in which Only 17 (35.4%) of the laboratory personnel had attended a refresher course in the last 2 years (31). This difference might be due to high training demands and its provision currently than the time when that study (study conducted in Uganda) was conducted.

Three laboratories there was no shortage of TB laboratory reagents but there was shortage of some laboratory consumables in most laboratories; the most frequent missing consumables were: Filter paper, spirit lamp, lens tissue, This result was also inconsistent with the study conducted in Uganda in which 75%of laboratory had shortage of laboratory reagents and other supplies and the most frequent missing items were: lens tissue, filter paper (31). These differences might be

due to better supply of these reagents and consumables by regional laboratories/other NGOs currently than the time when that study (study in Uganda) was conducted.

National Standard Manual for Laboratory Technicians on sputum smears microscopy recommends a good microscope and a comfortable work area to obtain excellence in smear examination (19). Regarding this all 4 laboratories had proper number and standardized microscopes (Olympus Microscopes) which was in accordance with this recommendation.

A laboratory safety program is important in order to protect the lives of employees and patients, to protect laboratory equipment and facilities, and to protect the environment (10). It is well documented that *M. tuberculosis* can cause laboratory-acquired infections (LAI) and commonly found in the top-ten list of hazardous agents for laboratory staff. The potential risks depend on the type of techniques used (42). This study revealed that 2 laboratories didn't have written guidelines on safety precautions such as: infection prevention, safe disposal of sharps (i.e., needles, etc.), safe disposal of bio hazardous medical and use of protective gear which were against the standard.

National tuberculosis programs (NTPS) laboratory standard manual for laboratory technician on sputum smears microscopy also recommends that rinsing after staining should be under gentle stream of clean and filtered water (19). Fifty percent of health facilities had neither distilled water nor filtered water. Finding from qualitative data also showed that laboratory professionals were forced to use water that came from pipe sources which even though they know as it compromises quality of the stain in turn affects the result leads to poor quality. This was completely against the standard (19).

In general adequate working space, clean running water, electricity, back-up power (generator or solar energy), ventilation, drainage systems, sanitation facilities and adequate furniture are some of the basic requirements in Smear microscopy laboratory (19). Contrary, all laboratories have inadequate work place (only one room to perform laboratory activities), no alternative electricity, no ionized or distilled, running water, no adequate infrastructure and no adequate sanitation and safety facilities. This was comparable with finding in other resource limited countries (43).

7.2. Compliance dimension (process)

Currently National tuberculosis programs' laboratory standard manual recommends collecting two sputum samples "on the SPOT - SPOT", preferably within one days from each person presenting at health center (1). Concerning this, it was reported and also observed that in almost all laboratories two sputum specimens were processed for diagnostic case which was in accordance with this guideline.

Sputum- submission instruction has been reported to improve detection of smear-positive TB, and client should be instructed, with demonstration by actual action as follows: inhale deeply 2-3 times ,cough out deep from the chest during exhalation, open the container and spit the sputum into the container, Avoid saliva or nasal secretions & close the container (19); and observation was conducted on each laboratories consecutively during the whole study periods to check wither these instruction were provided for clients by laboratory professionals and accordingly these instructions were given in only 3 of the laboratories. This finding was the same when compared to the study conducted in western Amhara in which adequate instructions were provided in majority (75%) of laboratories (44). The laboratories should be performed only by well-trained personnel (19). Regarding this sputum samples were collection from client by laboratory technicians/technologists in all of laboratories. International union against tuberculosis and Lung Disease (IUATLD) recommends as laboratory personnel should make sure that the specimen volume (3to5ml) and check the gross appearance of sputum whether it contains saliva (45). The study conducted in south Korea showed sputum gross appearance and volume were associated with smear positive and a volume of 4 ml seems to be the minimum sputum volume acceptable for smear microscopy in suspected of TB (46); as far as this procedure was concerned, among the 4 laboratories in the study it was in only 2 of them this procedure was being applied. This finding was low when compared to the study conducted in Uganda in which 39 laboratories (81.2%) claimed to visually check the quality of the specimens (31).

Adherence to standards is helpful in identifying problems and the improvement of quality in a systematic manner (19); there for, every procedure performed in the laboratory must be written out exactly as carried out and be kept in the laboratory for easy reference (1), in the study, health care providers followed job aids, manuals and standard operating procedure were followed in

only 3/4 of laboratories. This finding was also inconsistent with the study conducted in Western Amhara which elucidated as 40(66.7%) did not have these documents (44).

One of the most common causes of false positive result is failure of filter carbon fuchsin before use (40). This study revealed that, carbon fuchsin was not filtered in 2 of laboratories and this figure was high when compared to the study conducted in Uganda in which carbon fuchsin was not filtered in 18(37.5%) of laboratories (31) .

National tuberculosis programs (NTPS) laboratory standard manual recommends passing slide through a flame three or four times with the smear uppermost without overheating. Because care lessens in heating the fuchsin, allowing it to dry and crystallize on the smear are the main cause of false positive results (19), This procedure was applied as per standard in all four laboratories in the study area.

Failure to clean the immersion with lens tissue after each examination, especially after a smear is found to be positive is also one of the causes of false positive result (22); and national laboratory standard manuals recommend to clean immersion oil after slide. Regarding this 1/4 of laboratories immersion oil was not cleaned with lens tissues after every slide therefore very often did not get a clear a view of the smears.

One of major components of Good clinical laboratory practices (GCLP) is use of the requisition form the delineating the patient's identity, age gender, location, date time of specimen collection and its receipt as well as the investigation requested along with relevant clinical and treatment history (15).All laboratories in the study had national TB program (NTPs) approved laboratory request forms were used for every patient; This is as national TB laboratory manual recommends (31). Infection control in the laboratory must aim at reducing the production of aerosols (46). This study revealed that all of the laboratories in the study, infection waste were not separated from general trash in all around of laboratories by clearly marking containers as infectious and non-infection. These major problems which is against the standard that increases vulnerability of laboratory personnel to TB infection. This had been occurred mainly due to lack of enough waste bins in some laboratories and negligence of laboratory professionals.

7.3. Acceptability of TB clients on quality of Tuberculosis Laboratory Diagnosis

About 174 TB laboratory clients were interviewed about their acceptability or satisfaction with adequacy and clarity of instruction on sputum collection; out of these clients about 116(66.7%) were satisfied with adequacy and clarity instructions. This finding was high when compared to the study conducted in western Amhara in which about 62.45% of clients were satisfied with this service aspect (44).

Again regarding client satisfaction with respect provided to them by laboratory personnel during service provision, about 107(61.5%)of clients were satisfied with this service aspect and this finding was poor when compared to the study conducted in three zones of western Arsi in which only 62.24% of clients were satisfied with this service component (33). Concerning client satisfaction time (TAT) or waiting time for results, about109(62.6%) of clients were satisfied with this aspect and this finding was high when compared to the study conducted in western Amhara in which 57% of clients were satisfied(44).

5.13. Limitations of evaluation

Social desirability bias because of the interview conducted inside the health center. Information bias from TB clients based on their subjective judgments on perceived satisfaction towards TB laboratory service. During direct observation of TB laboratory service providers become aware that they are involved in a study or being observed the performance is different from what it would do other time (hawthorn effect).

Chapter 8: Conclusion and Recommendation

8.1. Conclusion

Overall quality of tuberculosis (TB) laboratory diagnostic service was judged to be good with good availability of necessary resource, good compliance and fair acceptability to laboratory guidelines, according to per-set judgments criteria. However, specifically all laboratories didn't have necessary infrastructures like separate table and rooms for TB works.

Again concerning compliance to standard laboratory procedures, there were laboratories with great compliance problems especially on: carbon fuchsine filtration, instructing patients properly on sputum collection, chalking appearance (purulent, bloody or saliva) and quality of sputum, respecting safety precaution and microscope lens cleaning labeling.

Overall satisfaction of clients on the quality of tuberculosis laboratory diagnostic service provided was good mentioned above. However, some were not satisfied with respect provided to them from laboratory professionals, clarity of instruction given to them on sputum collection, time for result (turnaround time TAT) and cleanness of laboratory and waiting area. These seem small but they have great implication for the laboratories to be accepted because patient expects to receive personal care keeping in mind comfort and privacy.

8.2. Recommendation

22 For laboratory professionals

- ❖ The quality of laboratory services in TB control programs is important for this success there should be appropriate sputum sample collection method, and functional laboratory set-up with quality diagnostic services.
- ❖ Greater emphasis should be given to those areas where patient dissatisfaction was observed like: respect given and keeping their privacy and not giving complete information to patients during sputum sample collection.
 - ❖ They should develop the habit of observe and evaluating the quality of samples received and order client to repeat when necessary.
 - ❖ They should post and follow standard procedures for consistency and accuracy.

- ❖ Should improve cleaning of microscope lens after examine positive slide.
- ❖ Should improve time for the result because many clients were dissatisfied.

For Jimma town health office and health centers

- ❖ Should provide infection prevention, job aid materials and standardized Guide lines
- ❖ They should construct laboratories which have isolated room and provide necessary furniture's for TB laboratory.
- ❖ They should avail alternative power sours (fuel generator or solar energy).

CHAPTER 9: META EVALUATION

9.1. Utility standards

To enhance use of the finding this evaluation the stakeholders were identified at the beginning and consulted throughout the process and the evaluation questions and a judgment criterion was set with stakeholders. Information was collected using different methods of data collections: documents review, interview, observation of consultations and facility readiness observations from all concerned bodies.

The evaluation process was conducted with a standard way by consulting advisors and different stakeholders. The evaluation questions were the needs of stakeholders and the finding at the end will be disseminated timely according to the interest of the stakeholders. This all will be assure the evaluation finding by the target beneficiary.

9.2. Feasibility standards

In order to make evaluation procedures practical, minimize disruption & obtain relevant and needed information; competent & qualified data collectors were recruited & trained. While planning and conducting the evaluation, different positions of various interest groups was anticipated so that their co-operation has been obtained. This evaluation was efficient and produces information of sufficient value to justify the use of resources.

9.3. Propriety standards

All data collection tools were designed by considering the ethical and legal issues for the rights and welfare of the study participant were considered. Ethical clearance planned to be taken.

There is no procedure that affects privacy, dignity, confidentiality, and rights of participants. Stakeholders agreed and consensus reached to do this process evaluation before starting the evaluation and conflict of interest was dealt with openly and honestly.

9.4. Accuracy standards

The evaluation process was focused from design to the end of evaluation to assure quality of data. The program was described in clear and understandable manner and the context in which

the program is being implemented is addressed. The sources of information were cited and the reliability and validity of the information produced were clearly described in method part. In order to address the evaluation questions in the evaluation, respective quantitative and qualitative analysis method was chosen and also data was triangulated to improve accuracy.

The Meta evaluation measured using 4 standards; 30 sub-standards and 96 criteria. The checklist was adapted from “*Meta evaluation Checklist*” developed by Daniel L. Stuffle-beam. It was conducted by program stakeholders ([Annex 13](#))

Table 8: summary of Meta evaluation standards and specific criteria, Apr. 2018

Standard	#of specific criteria	Criteria met	present	Judgement
Utility	29	23	79.3	>=90%=V. Good 70-89.99= Good 50-69.99= Fair <49.99= poor
Feasibility	10	8	80.0	
Propriety	20	16	80.0	
Accuracy	37	29	78.4	
Total	96	76	79.2	
Total judgement parameter		$(76/96)*100= 79.2\%$: the value is b/n 70 &89.9; Judged as Good		

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ANNEXES

Annex 1: Consents forms for all TB Laboratory diagnostic service providers

HF's.-----

Dear sir/madam

My name is _____ I came from Jimma University. I am conducting the process evaluation of quality of TB laboratory diagnosis at this facility. The purpose of the study is to find ways of improving the quality of TB Laboratory diagnosis by providing information generated from this study to concerned stake holders so that they may contribute all necessary ingredients for the program enhancement. I am interested to know your experiences so far in providing TB laboratory services. May I ask you some questions about this? Please be assured that this discussion is strictly confidential and your name will not be recorded.

Also, your participation is voluntary and you are not obliged to answer any question you don't want to, and you may withdraw from the interview at any time.

Do I have your permission to continue? Yes _____ No _____

Name and signature of the data collector: _____

Name and signature of the supervisor: _____

Annex 2: Questioners prepared to assess the structure of TB laboratories of jimma town health centers.

Facility name: -----Name of Laboratory Technologist/technicians Collecting data-----

Date: _____ month _____ 2018.

S.NO	Questions	Answers	Code
1.1	The current working staff at this facility	1.M.Sc----- 2.B.Sc----- 3.Diploma -----	
1.2	Number of laboratory personnel Trained on TB laboratory diagnosis in the last 2 years.	1. One 3. Three 2. Two 4. Not at all.	
1.3	Does the laboratory have:		
	a. Separate areas for TB work	1 / yes 2 / No	
	b. Separate tables for specimen receipt/smear preparation/ microscopy.	1 / yes 2/ No	
1.4	Does the laboratory have:		
	a. Access to Running water?	1/yes 2.No	
	b. Access to filtered water.	1/Yes 2.No	
1.5	c. Distilled or deionizer water	1 / Yes 2.No	
	Are the following items available?		

	a Frosted Slides	1.Yes	2.NO	
	b .Wire loops	1.Yes	2.NO	
	c. Filter paper	1.Yes	2.No	
	d. Funnel	1.Yes	2.NO	
	e .Staining racks	1.Yes	2.No	
	. Sprit lamp or Bunsen burner	1.Yes	2.NO	
	g. Fuel for spirit lamp	1.Yes	2.No	
	h. Lens tissue	1.Yes	2.No	
	I. functional Microscope(s)	1.Yes	2.No	
	j. Slide boxes	1.Yes	2.No	
	k, Sputum containers	1.Yes	2.No	
	l. Diamond pen or pencil in case of frosted slides	1. Yes	2.NO	
1.6	Are the following TB reagents available?			
	a. Carbon fuchsine	1.Yes	2.No	
	b. Methylene blue	1. Yes	2.No	
	c. Sulphuric acid (25%) Or acid alcohol (3%)	1.Yes	2.No	
	d. Immersion Oil	1.Yes	2.No	

	e. Xylene /ethyle ether	1.Yes 2.N0	
1.7	Does the laboratories have national AFB microscopy manual or at minimum SOPs and job aides?	1 Yes 2.No	
1.8	Are written guidelines on safety precautions available in this laboratory? (Check all that apply.)	1. Infection prevention 2. Safe disposal of sharps (i.e., needles, etc.) 3. Safe disposal of bio hazardous medical waste. 4. Use of protective glove other.	
1.9	Are written guidelines for storage of laboratory products available in this laboratory?	1. Yes 2.N0 3. Don't know	
1.10	Does the laboratory have a set minimum stock level for TB reagents and consumables?	1.yes 2.No 3.Don't know/not sure	
1.11	How often is the stock level of TB reagents and supplies reviewed?	1. Each time an issue is made 2. Monthly 3 Every two months 4. Quarterly 5.other 6.Never	

Part II: Questionnaire to be completed by trained laboratory staff in public health centers of Jimma town, southwest Ethiopia, 2018.

S.NO.	Questions	Answers	Code
2.1	How many sputum specimen(s) do you process for new patients to diagnose pulmonary TB?	1.One 2.Two 3.Three	

2.2	Patient receive adequate instruction produce sputum rather than saliva(try to observe)	1. Yes 2.No	
2.3	Which Sputum specimens routinely collected for diagnosis, follow ups?	A. Spot-spot. B. spot -morning -spot C. Spot- morning-morning	
2.4	Who is responsible for the collection of sputum sample?	1 Laboratory technologists/technicians 2.Supportive staffs 3.others-----	
2.5	Is the quality of specimen checked visually? [Ask and observe!]	1.Yes 2.N0	
2.6	If saliva is obtained, is collection repeated?	1. Yes 2. No	
2.7	Are sputum containers labeled properly (on the side of the container)?	1. Yes 2. No	
2.8	Are slides marked properly (district number, laboratory number, and suspect number, with diamond pen or pencil)?	1.Yes 2.No	
2.9	Do they display and follow smear preparation, staining procedure &grading chart? (Ask and observe!)	1. Yes 2. No	
2.10	When did this laboratory receive the last supervisory visit?	1/ Never 2/ Within the last month 3/ More than one month 4/ More than three months 5/ More than six months ago.	
2.11	To which authorities do you send your reports?	1. Woreda health 2. Zonal 3. Regional bureau 4. FMOH	

Part III: questionnaire prepared to assess the process quality of selected TB laboratories in public health center of Jimma town south western Oromia regional state, 2018.

Health facility name: -----

S.N	Questions	Answer	Code
3.1	Does NTP approved lab. Request form are used for every patient?[observation]	1. Yes 2. No	
3.2	Does the sputum request and report form is correctly used?(observation)	1. Yes 2. No	
SMEARING AND STAINING			
3.3	Is carbol fuchsin and methylene blue filtered before use?(observe for records)	1. Yes 2. No	
3.4	Is the lens of the microscope cleaned with lens tissue after every slide?	1. Yes 2. No	
3.5	Are the eyepieces of the microscope cleaned regularly?	1. Yes 2. No	
3.8	Are smear air-dried before fixing?	1. Yes 2. No	
3.9	Are slides properly heat fixed (three times through flame)?	1. Yes 2. No	
3.10	Does the exact time slides stained for Carbofuchsin, Methylene blue and staining with 3%HCL kept with timer as per standard?	1. Yes 2. No	
3.12	Are your results consistent with NTP recommendations for grading and reporting?	1. Yes 2. No	
3.13	Are all slides kept as required by the NTP EQA program?	1. Yes 2. No	
3.14	Are there standard reporting forms?	1. Yes 2. No	

,Annex 3: Clients consent form

Dear sir/ madam

My name is _____ I came

From _____ I am a member of an evaluation team of process evaluation of quality of TB Laboratory diagnosis at this health centers. It is believed that provision of quality tuberculosis laboratory diagnosis increases clients' satisfaction, which contributes to increase case detection and good treatment outcome. The purpose of this study is to evaluate the quality of TB Laboratory diagnosis service provided in health Facilities and level of satisfaction of Tuberculosis patients, and finally to give important comment to the providers as well as other concerned Stakeholders that will help to strengthen and improve quality of service. To do this, your information is very important. I would like to ask you a few questions about your visit to the health facility toward out your experience today. I would be very grateful if you could spend a few minutes to answer questions related to the service. This will not put your name registration number in the format. All the information you give will be kept strictly confidential. Your participation is voluntary and you are not obliged to answer any questions you don't want. But your honest participation will contribute to generate information that can be used to improve the quality of TB Laboratory diagnoses is at this health center.

Do I have your permission to continue? Yes _____ No _____

Name and signature of the data collector: _____

Name and signature of the supervisor: _____

Annex 4: Questionnaire prepared to assess TB client's satisfaction level in the laboratory

Diagnostic service in the selected public Health facilities of Jimma town, south west Ethiopia, January, 2018.

Name of the health facility-----

S.No.	Questions	Response category	Code
	General information		
5.1	Sex of the patient	1 Male . 2 Female	
5.2	Age of the patient		
5.3	Marital Status	1. Single 2. Married 3.Divorced 4.Widowed	
5.4	Educational status	1. Illiterate 2. Read & Write 3. 1-6grade 4. 6-12 grade 5. Above 12 grade	
5.5	Religion	1. Orthodox Christians 2. Muslim 3.Protestant 4. Other (specify)	
5.6	Occupation	1. Farmer 2. Gov't employee 3. Merchant 4. Other (specify)	
5.7	Do you incur cost for your visit?	1. Yes 2. No-skip to next	
5.8	If yes, for what purpose?	1. Transport 2. Food & Reception 3.Laboratory services 4.Other(specify)	
5.9	Have you ever visited this TB Laboratory services before?	1. Yes 2. No	
5.10	How long (minutes/ hours) do you normally go to get this TB laboratory services?	1 10-30min 2/ 30-60min 3/ 2hours 4/ 3-4hours	

5.11	By what means you nominally get to the TB Laboratory?	1/ On foot 2/ by Car 3/ on horse(mule) 4/ Other (specify)	
Organizational issues:			
5.12	After arriving at the TB laboratory, how satisfied are you with the time spent waiting to receive your result	1. Vary dissatisfied 2. dissatisfied 3. Neutral 4. Satisfied 5, Vary satisfied	
5.13	How long do/did you wait for the results?	-----Time -----days	
How satisfied are you with:			
5.14	The overall cleanliness of the waiting Area of laboratory & its set up?	1. Vary dissatisfied 2. dissatisfied 3. Neutral 4. Satisfied 5, Vary satisfied	
5.15	The overall comfort & ventilation of the waiting area as well as laboratory	1. Vary dissatisfied 2. dissatisfied 3. Neutral 4. Satisfied 5, Vary satisfied	
5.16	The overall cleanliness of the laboratory Room/place where you received service?	1. Vary dissatisfied 2. dissatisfied 3. Neutral 4. Satisfied 5, Vary satisfied	
Interpersonal qualities of service providers:			
5.17	How are satisfied with the respect provided to you by laboratory personnel - Your visits?	1. Vary dissatisfied 2. dissatisfied 3. Neutral 4. Satisfied 5, Vary satisfied	
5.18	How are satisfied with the method of Keeping your privacy?	1. Vary dissatisfied 2. dissatisfied 3. Neutral 4. Satisfied 5, Vary satisfied	
Professional competence and skill of the laboratory workers			
5.19	How are satisfied with the completeness & of the information Over to you about Sputum sample collection?	1. Vary dissatisfied 2. dissatisfied 3. Neutral 4. Satisfied 5, Vary satisfied	

Annex 5.Key informant interview

Consent forms for all service providers

Dear sir/madam my name is

I came from Jimma University. I am conducting evaluation of quality of TB laboratory service. The purpose of the study is to find ways of improving the quality of TB laboratory services. I am interested to know your experiences so far in providing TB services. May I ask you some questions about this? Please be assured that this discussion is strictly confidential and your name will not be recorded. Also, you are not obliged to answer any question you don't want to, and you may withdraw from the interview at any time.

Do I have your permission to continue? Yes_____ No_____

Name and signature of the data collector: _____

Name and signature of the supervisor: _____

Name of health center _____ Date of data collection_____

Annex 6 Interview guide to laboratory personals.

Background information of service provider.

- I Work experience _____
- II Profession _____
- \
- III How long you have been in this health center _____

1. Have you ever been received AFB microscopic examination training? When ?

2. What procedures do you follow for sputum collection and examination for suspected cases? Why?

3. In your opinion what could be the factors which affect quality of TB diagnosis?

3. Who do you think is/are responsible for the improvement of this service?-

4. In your opinion how quality TB laboratory service can be improved?

Annex 7. Interview guide to TB focal person in town health office

Background information of service provider.

I Work experience _____

II Profession _____

\
III How long you have been in this health center

1. What are the general problems related to TB laboratory service.

2. In your opinion how TB laboratory service can be improved?

3. How do you provide TB laboratory reagents and equipment's?

Annex 8. Resource Inventory Checklist.

Consent form for: I want to thank you for taking time to meet with me today. My name is _____ from Jimma University and I am hereby to observe the TB laboratory service provision at this unit. This is part of the overall evaluation and it will help to improve the implementation of quality of TB laboratory services delivered at this health center. The observation will be conducted while the service providers delivering services and all findings of the observation will be kept confidential. Furthermore; we will ensure that any information we include in our report does not identify you as the respondent. Are you willing to participate in this observation?

1. Yes 2. No (if yes continue. If no END)

S. no	Questions	Answers
	Does this facility have clear signs indicators for different service areas? (Lab. Waiting area, toilet)	1. Yes 2. No 3. Some have
	The facility staffs are easily identifiable to patients.	1. Wear Both gown & name tag 2. Have name tag 3. Neither gown or name tag
	Does the facility have separate room for TB lab?	1. Yes 2. No
	Is the waiting area and the lab room clean	
	Is there adequate number of chairs for the number of patients present at waiting area?	1. Yes 2. No
	Is there separate area for TB laboratory work?	1. Yes 2. No

	Are there separate tables for specimen receipt / smear preparation / microscopy?	1. Yes 2. No
	Is the laboratory room ventilated	1. Yes 2. No
	Power supply	1. Yes 2. No
	Running water supply	1. Yes 2. No
	Manuals, Standard Operating Procedure, Job Aids	1. Yes 2. No

	Laboratory supplies	Comments/Remarks
	Functional Binocular light Microscopes Slide Frosted slide Slide box Sputum containers approved Wire loops or sticks Funnel Filter paper Staining rack	

	Sprit lamp/Bunsen burner Lens tissue Red pen Recording for positive result Carbol fuchsine Methyl blue 3% acid alcohol Oil immersion Forceps for holding slide and fixing Alarm clock 5% phenol or 10% Sodium hypo chloride	

Annex 9: Provider client interaction observations Checklist

Consent

My name is _____ from Jimma University I am conducting evaluation of quality TB laboratory service for this study, you are chosen by chance. I do not put your name or registration number on this questionnaire. The observation will contribute to generate information, which can be used to improve the quality of TB laboratory service.

Do you agree to participate in this study?

Yes _____ Go to the next page.

No _____ Acknowledge and ask the reason then go to the next-----

I appreciate your co-operation very much

Code No of health institution----- Questionnaires No. -----

Date ----- Signature of observer-----

	Does the patient politely greeted?	Yes	no
	Do the service providers show respect for the clients?		

	Does the patient participate in part of decision-making?		
	Does the health worker speaks the same language with the Patient?		
	Does the health worker explain how to bring sputum sample.		
	Does the provider keep staining procedure Or use sops and guidelines		
	Does the provider tell the patent turnaround time(TAT)		
	Does the provider keeps Staining Procedures		

Annex 11 Documents review.

Permission requested form My name is _____ from Jimma University I am conducting evaluation of quality TB laboratory service in order to capture information related to the process of quality TB laboratory service program implementation.

This will help to improve the implementation status of quality TB program in the future. During the review, the confidentiality of the information will be kept and the information will be utilized for evaluation purpose only.

May I continue to review the all NTP approved requests of the cliants? 1. Yes 2. No (if yes continue if No END)

Instruction: this questionnaire will be used to conduct document review in order to assess the TB laboratory services received by TB presumptive and cases on follow up in the past six months.

Document review checklist

	Is the following information recorded on TB request papers	yes	no
	Name of health post		
	Age /sex of pts		
	Patient's unit TB Number Recorded ?(Cod)		
	Name and address of contact person recorded?		
	Category of the patient		
	Date of sample collection(dd/mm/yy)____/____/____		
	AFB result recorded?		
	Completeness of the registration form		
Reporting	Reports are complete or incomplete		

Annex 12 , Translated Questioner

Uunka Walligaiteen Maamilarraa ittiin fuudhamu

Maqaa Dhaabbatichaa

Obboo/Aaddee

Maqaan koo _____ jedhama kanin dhufe Jimma Yuunivarsitii Dame Gamaaggamaa fi Hordoffii Fayyaarraati immoo (-pi-ad-mu kanan barbaade waa'ee qulqullinaa Laaboraatorii dhukkuba Sombaati; akkuma beekamu tajaajilli quiquilina qabu yoomiyyuu tajaajilamaa ni ammachiisa jedhamee amanama kunimmoo karaa biraan tajaajilamaan dhufee akka itti thyyaclamu, namoonni dhukkuba kanaan qabaman da•aan hordofa.manii akka dafanii fayyanii fi nama biraattis akka isaan bin dabarsineef gargaara. Irratti dabalatees dandeettiin addabaasuu cilvibee kanaa sadarkaa Hundatti akka dabaluu taasisa.

Kaayyoon gorannoo kanaa inni guddaan waa'ee quiquilina tajaajila kanaa gorachuu fi firii gorannoo kanaa immoo qaama dhimmi isaa ilaallatu mara faana mari'achuun akka tajaajilli kun irra caalaatti fooyya'u gochuudha; kana keessatti iddoo guddaa kan taphatu odeeffannoo isin nuuf laattanidha. Odeeffannoo isin laattan kunis karaa kamiinuu iccitiin isaa kan eeggamee –fi feclha keessan guutuunatti kan hundaa'edha.

Kanaaf naaf eeyyamtuu? 1. Eeyyee 2. Lakki

Maqaa fi mallattoo odeeffannoo fudhataa:

Maqaa fi mallattoo Supervaayizaraa:

Kolleejjii Faysyaa Universitii Jimmaa dipaartimentii :Ikon omiksii fityyaa fayyaa

Manaajimantii fi Hordoffii fi gamaaggama fayyaatti.Bay-gaaffii itti quufinsi maamila tajaajila qorannoo labooraatorii dhukkuba sombaa gat ii dhaabbilee fayyaa magaalaa Jimmaa Kibba –lixa Itoophiyaa qo'annoodhaaf filataman Bitootessa,....., bara 2018

	[Gaaffiilee	Deebilee	Koodii deebilee
	Odeeffannoo dinishaashaa tajaajilanzaa		
5.1	Saala tajaajilanzaa	1.dhiira 2.dhalaa	
5.2	Unnzrii tajaajilantaa(waggaadhaan)	
5.3	Sada•kaa bultii	Lican bultii hin godhanne 2.Ican	

		buitii godhate/tte 3.kan hifte/te 4.kan falaa du'elduute	
5.4	Sadarkaa barnootaa	1. kan hitt ba•anne 2. bar•eessuu fi dubbisuu gofa kan dun cla'uleessu 3. 1-6 tiofa kan barateitte 4.6-12 km baratette 5. kutaan ol kan baratente	
5.5	Amantaa	Liciristaana Ortodoksii 2.Musliima 3.Proteestaantii 4.kan biraa yoo jiraateblaa ibsanzu	
5.6	Ifojii	1. Ootee bulaa 2 illojjetaa mootummaa 3. Daldalaa 4. kan biroo yoo fi•aate [yaa ibsamu]	
5.7	Tajaajila kanaaf baasiin isin baastan nifiraa? - -	1. Eejyee 2. Lakki (yoo lakkii ta 'e gaaffii isa ittaanutti haa darbanzu)	
5.7.1	Yoo fi•aate kamiifi?	1. Taf. geejiibaaf 2. Nyaataafi sired' 3. Taj. Laabo•aatorilf 4.Ican biroo(yaa ibsamu)	

5.8	Kanaan dura laabo•aatorii kanattifajyadamtanii beektuu ?	1. Eeyyee 2. Lakki	
5.9	Tajaajila (loran/zoo Italia	I.Daqi.10-30 4.Sa'aatii lamaa	

	Argachuuf daqiiqaa/sa'a meeqa deemtu	Oli 2. daqi. 31-60 3. sa'aatii 2	
5.10	Tajaajila qorannoo kanaaf yeroo dhuftan geejjiba maaliin dhuftu?	1. Miillaan 2. Konkolaataan 3. Fardaan (gaangeen) 4. Kan biro (yaa ibsamu	
Dhimmoolee tajaajila dhaabbilee keessaa			
5.11	Eega laaboratorii geessanii waa'ee turtii yeroo firii laaboratorii keessaniirratii haalli itti quufinsa keessanii maal fakkata?	1. Baay'ee itti hin quufne 2. Itti hin quufne 3. Giddu galeessa 4. Itti quufeera 5. Baay'ee itti qufeera	
5.12	Firii laaboratorii keessanii hagamiif eegaa turtan?guyyaan	
5.13	Haala qindoominaa fi qulqullina waliigalaa iddoo turmaataa laaboratorii kanaa ilaalchisee itti quufinsi keessan maal fakkaata	1. Baay'ee itti hin quufne 2. Itti hin quufne 3. Giddu galeessa 4. Itti quufeera 5. Baay'ee itti qufeera	
5.14	Mijaa'inaa fi haala qilleensa galchiinsa bakkee turmaata tajaajilamaa laaboraatorii irratti haalli itti quufinsa keessaniimaal fakkaata?	1. Baay'ee itti hin quufne 2. Itti hin quufne 3. Giddu galeessa 4. Itti quufeera 5. Baay'ee itti qufeera	
5.15	Qulqullina waliigalaa laaboraatorii kanaarratti haalli itti quufinsa keessani maal fakkaata?	1. Baay'ee itti hin quufne 2. Itti hin quufne 3. Giddu galeessa 4. Itti quufeera 5. Baay'ee itti qufeera	
Waa'ee hariioo tajaajilaa fi tajaajilamaa gidduu			
5.16	Yeroo gara laaboraatorii tajaajilaaf dhuftanirratti haala kabajaa fi simmannaa hojjetaan isin keessumeeerratti hagam itti quuftan	1. Baay'ee itti hin quufne 2. Itti hin quufne 3. Giddu galeessa 4. Itti quufeera	

		5. Baay'ee itti qufeera	
5.17	Yaalii isaan iccitti keessan eguudhaaf taasisanirratti hagam itti quuftan?	<ol style="list-style-type: none"> 1. Baay'ee itti hin quufne 2. Itti hin quufne 3. Giddu galeessa 4. Itti quufeera 5. Baay'ee itti qufeera 	
5.18	Yaalii ogeesi laaboraatorii waa'ee akkee fiduurratti issiniif laaterratti hagam quu	<ol style="list-style-type: none"> 1. Baay'ee itti hin quufne 2. Itti hin quufne 3. Giddu galeessa 4. Itti quufeera 5. Baay'ee itti qufeera 	

Annex 12: Information judgement Matrix

Table 9: Information judgments Matrix of availability, compliance and acceptability dimension's.

Evaluation Questions	Indicators	Source of data	Data collection methods	Data collection tools
Are the necessary resources available for TB laboratory diagnosis? If not, why?	<ul style="list-style-type: none"> ✓ Number of health center laboratories with adequate staining reagents. ✓ Number of health center laboratories with adequate equipment's like, frosted slides, sputum cups and other consumables. ✓ Number of Health center laboratories that have a incinerator to correctly dispose all hazardous materials (e.g. sputum cups, needles,, toxic materials) ✓ Number of health center laboratories with at least one trained professional on TB laboratory diagnosis in the last 6 months. ✓ Number of health center laboratories having functional Microscopes. ✓ Number of health center laboratories that have national AFB microscopy manuals or SOPs job aids on the date of survey. ✓ Number of health center laboratories with TB diagnosis 	<ul style="list-style-type: none"> Health center Documents Health center Staffs 	<ul style="list-style-type: none"> Interview Document review Observations 	<ul style="list-style-type: none"> Interview and document review checklist

	<p>TB registration book on the date of survey</p> <ul style="list-style-type: none"> ✓ Number of health center laboratories that have separate tables and areas for TB laboratory procedures within health center laboratory room on the date of survey ✓ Number of health center laboratories with functional timer on date of survey ✓ Number of health center laboratories with functional running water supply on date of survey. ✓ Number of health center laboratories with functional electricity on date of survey 			
<p>Are all TB laboratory-based diagnostic procedures working to standardized operating procedures in appropriately equipped and safe laboratory? If not why?</p>	<ul style="list-style-type: none"> ✓ Number of laboratories with in which carbol fuschin is filtered before use as per standard. ✓ Number of laboratories with in which slides are properly heat fixed as standard. ✓ Number of laboratories within which microscopic lens are cleaned after every slide examination as per standard. ✓ Number of laboratories within which AFB procedures' job aids are posted and being used. ✓ Proportion of clients who get sufficient instructions by service providers on how to produce & bring adequate amount of sputum samples. ✓ Number of laboratories with in which NTP approved lab. 	<p>service providers</p> <p>documents</p> <p>Store man</p>	<p>Document review, Interview and Observation</p>	<p>Interview and document review and Observation checklist</p>

	<p>Request forms are used for every patient.</p> <ul style="list-style-type: none"> ✓ Proportion of TB client sputum containers are properly labeled as per standard. ✓ Proportion of TB client sputum smear staining time properly kept with timer. ✓ Number of laboratories in which infectious wastes were separated from general trash on date of survey ✓ Proportion of clients who received laboratory services within the recommended time. 			
<p>Are the TB patients satisfied with the services? If not, why?</p>	<ul style="list-style-type: none"> ✓ Proportion of clients satisfied with clarity of instructions given by the provider on sputum collection & instruction given. ✓ Proportion of clients satisfied with providers respect at TB laboratory unit ✓ Proportion of clients satisfied with the waiting time of laboratory services ✓ Proportion of clients satisfied with overall cleanliness of the waiting areas of laboratories ✓ Proportion of clients satisfied with comfort & ventilation of the waiting areas 	<p>Service providers TB presumptive and Clients</p>	<p>Interview Observation</p>	<p>Interview and Observation checklist Client provider interaction observation</p>

Annex 13: Meta evaluation check list

The Requirements for Utility Standard

Sub-Standards and checkpoints	Met criteria			Elaboration
	Yes (1)	No(0)	NA	
U1: Stakeholder Identification	5			
Did potential stakeholders consulted to identify their information needs	1			
Did an arrange made to involve stakeholders throughout evaluation period	1			
Were stakeholders' evaluation needs addressed	1			
Did the information to be provided allow necessary decisions about the program to be made?	1			
Did stakeholders Used to identify other stakeholders	1			
U2: Evaluator credibility	4			
Could the evaluator address stakeholders' concerns?	1			
Did the evaluation plan responds to key stakeholders' concerns?	1			
Did evaluator helped stakeholders understand the evaluation plan	1			
Did information on the evaluation plan's technical quality and practicality was given to stakeholders	1			
U3: Information scope and selection	5			
Were client's evaluation requirements understood?	1			
Did Assign priority to the most important stakeholders?	1			
Did the stakeholders' questions addressed?	1			
Did different stakeholders Interviewed to determine their different perspectives	1			
Did the design flexible for adding questions during the evaluation	1			
U4: Values identification	3			
Did alternative sources of values consider for interpreting findings	1			
Were a clear, defensible basis for value judgments provided	1			
Did the stakeholders' values take into account?	1			
U5: Report clarity	4			
Did reports focused on contracted questions	1			
Did the program and its context described	1			

Did the evaluation's purposes, procedures, and findings describe conclusions and recommendations Supported	1			
U6: Report timeliness and Dissemination	0			
Were timely interim reports made to intended users?		0		
Did the presentations appropriately briefed?		0		
U7: Evaluation Impact	2			
Did contact with audience Maintained during evaluation	1			
Were stakeholders Involve throughout the evaluation	1			
Make arrangements to provide follow-up assistance in interpreting and applying the findings		0		
	23/29=79.3%			

The Requirements for Feasibility Standards

Sub-Standards and checkpoints	Met criteria			Elaboration
	Yes(1)	No(0)	NA	
F1: Practical Procedures	4			
Did data burden minimized?		0		
Did competent staff appointed?	1			
Did Methods and instruments tailored to information requirements	1			
Did a realistic schedule Made	1			
F2: Political Viability	2			
Did different positions of different interest groups anticipated ?	1			
Did cooperation encourage?	1			
F3: Cost Effectiveness	4			
Did program improvement encouraged?	1			
Did accountability information provided?	1			
Did new insights generated?	1			
Did effective practices spread?		0		
	8/10=80%			

The Requirements for Propriety Standards

Sub-Standards and checkpoints	Met criteria			Elaboration
	Yes(1)	No(0)	NA	
P1: Service Orientation	3			
Assess needs of the program's customers	1			
Were program strengths Identified to build on	1			
Were program weaknesses Identified to correct	1			
P2: Formal Agreement	1			
Did written agreement reached on evaluation procedures and schedule?		0		
Did written agreement reached confidentiality/anonymity of data?	1			
P3: Rights of Human	3			
Did clarity made to stakeholders that the evaluation will respect and protect the rights of human subjects?	1			
Did the evaluation free of harm?	1			
Were participant values understood ?	1			
P4: Human Interactions	3			
Was evaluator Consistently relate to all stakeholders in a professional manner	1			
Was evaluator alert to and address participants' concerns about the evaluation	1			
Did effective communication with stakeholders maintained?	1			
P5: Complete and Fair Assessment	2			
Did account given for the evaluation's process?	1			
Did the draft report reviewed?		0		
Was evaluation's limitations on the overall judgment of the program estimated ?	1			
P6: Disclosure of Findings	3			
Did balanced conclusions and recommendations reported	1			
Did basis for the conclusions and recommendations showed	1			
Did evaluation's limitations disclosed	1			
P7: Conflict of Interest	1			
Were potential conflicts of interest identified	1			
Were independent parties to assess the evaluation engaged		0		
	16/20=80.0%			

The Requirements for Accuracy Standards:

Sub-Standards and checkpoints	Met criteria			Elaboration
	Yes(1)	No(0)	NA	
A1:ProgramDocumentation	2			
Did descriptions of the intended program from various written sources collected	1			
Did how the program actually functioned described	1			
Did a technical report produced that documents the program's operations		0		
A2:ContextAnalysis	1			
Did multiple sources of information used to describe the program's context?	1			
Did context of program outcomes effects estimated?		0		
A3:Described Purposes and Procedures	2			
Did points of agreement among stakeholders regarding the evaluation's purposes identified	1			
Did the actual evaluation procedures record	1			
A4:DefensibleInformation Sources	3			
Were variety sources of information obtained?	1			
Did a variety of data collection methods employed?	1			
A5:Valid Information	5			
Do the evaluation focus on key questions	1			
Do the data collectors train and calibrate	1			
Assess and report what type of information each employed procedure acquires		0		
Document how information from each procedure was scored, analyzed, and interpreted	1			
A6:ReliableInformation	3			
Did the unit of analysis specify?	1			
Did levels of reliability of measuring devices acceptable?	1			
Were the consistency of scoring, categorization, and coding checked and reported?	1			
A7:SystematicInformation	2			
Did protocols established systematically for quality control of information?	1			
Was the accuracy of scoring and coding checked?	1			
A8:AnalysisofQuantitative Information	3			
Was chosen procedures for evaluation questions and nature of the data appropriate	1			
Were statistical interactions Identified and analyzed	1			
Were statistical significance and practical significance assessed	1			
A9:AnalysisofQualitative Information	3			
Did the boundaries of information defined	1			

Did appropriate analytic procedures and methods of summarization chosen	1			
Did the derived categories for reliability and validity tested	1			
A10:JustifiedConclusions	2			
Did conclusions focus directly on the evaluation questions?	1			
Did accurately reflect the evaluation findings?	1			
A11:ImpartialReporting	3			
Did appropriate plans for releasing findings to all audiences established and followed ?		0		
Did reports Safeguarded from deliberate or inadvertent distortions	1			
Did steps taken to control bias described	1			
A12:Meta-evaluation	5			
Did the standards used to judge the evaluation defined?	1			
Did responsible body assigned for documenting and assessing the evaluation process and products?	1			
Did both formative and summative met evaluation Employed		0		
Did the instrumentation, data collection, data handling, coding, and analysis against the relevant standards evaluated	1			
	29/37=78.4%			
Total	76/96=79.2%			