ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH

Quality Assessment of Tuberculosis Laboratory Diagnosis in Selected Health Facilities of Public & Private Laboratories in Oromia Regional State.

By

Desalegn Ararso (B.Sc)

A Thesis submitted to School of Graduate Studies, Addis Ababa University in Partial fulfillment of the Requirements for the Degree of Masters in Public Health

Advisor: Ababai Zergaw (MPH, PHD)

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Abbreviations and acronyms

AFB: Acid Fast Bacilli

EQA: External Quality Assessment

FMOH: Federal Ministry of Health

DOTS: Directly Observed Treatment Short Course

HIV: Human Immuno Deficiency Virus

NTLP or NTP: National Tuberculosis and leprosy Control Programme

PPM-DOTS: Private-public-Mix Directly Observed Treatment Short Course

TB: Tuberculosis

TLCP: Tuberculosis and Leprosy Control Program

PTB: Pulmonary Tuberculosis

PSP: Private Sector Programme

PPM-DOT: Public-private-Mix Directly observed treatment Short Course

SPR: Slide Positivity Rate

SOP: Standard Operating Procedure

WHO: World Health Organization

RTLC: Regional TB & Leprosy Coordinator

QA-PPML: Quality Assessment of Public-Private-Mix Laboratories

ABSTRACT

***Introduction*:** In the new Millennium, the quality of TB laboratory diagnosis in both public and private health facilities was often a direct reflection of the success of TB control programmes and a key component of the DOT strategy, yet it was one of the most neglected components of these programmes.

***Objective*:** To assess the quality of TB Laboratory Diagnosis in selected public & private Health Facilities in Oromia Region.

Methodology: Crossectional survey design was conducted out in 60 randomly selected public & private TB laboratories between 3rd January –12 th May 2011, in purposively selected 3 zones of Oromia Region. Sixty TB laboratory department heads were interviewed, 270 patients records were reviewed, 384 TB laboratory clients were interviewed and panel testing for 20 laboratory technicians were done.Odd ratios and logistic regression were employed to see if any association exits among the three quality parameters. Data were entered and analyzed using SPSS version 15.0 software and findings at 95% Confidence interval and p value of 0.05 were used for statistical significance.

***Result*:** The study shows that staff training is a neglected issue in most private TB laboratories which are separated structurally from NTP, high false negative discordant rate of AFB result, weak supervision mechanism, and lack of checking the quality of sputum sample. Higher proportions of patients visited the TB laboratories were dissatisfied with lack of respect from the providers. Statistically significant association was observed between structure and process quality (OR =2.9(1.46-5.7; P=0.01) and between process and output quality parameters (OR=3.2(3.13-10; P=0.02).

***Conclusion and Recommendations* :**The quality of TB laboratory diagnosis in both public and private TB laboratories in Oromia region were poor in that laboratory technicians training was not satisfactory, high false negative discordant rate of AFB result and the pattern of supervision was weak and unplanned. So mechanisms of improving the different stages of TB laboratory diagnosis especially staff training, displaying and follow smear preparation and sticking to the National TB laboratory manual were strongly recommended.

INTRODUCTION

1.1 Background information

Tuberculosis (TB) is one of the world's leading causes of infectious disease morbidity and mortality (1) .The World Health Organization (WHO) estimated that there were 9.27 million new cases of TB in 2007, of which 3.9 million were sputum smear positive (2). Each individual with untreated smear positive TB infects 10-15 persons per year, making the identification of these infectious patients one of the key aspects of TB control (1).

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. Of the six WHO regions, five have TB incidence that is falling or stable, but Africa has an incidence that keeps increasing at almost 10% per year, offsetting the gains in the rest of the world (3).

The estimated incidence, smear positive cases and prevalence of all forms of TB in Ethiopia in 2007 were 314/100,000 population, 152/100,000 population and 546/100,000 population respectively(4).Mortality rate was estimated as 73 per 100,000 and the prevalence of HIV positivity in TB incidence cases of all ages was reported as 19% (4).

Case detection by sputum smear microscopy among patients self reporting to health facilities is one of the five tuberculosis Control Strategy under DOTS programme (3).The WHO report on global tuberculosis control for the year 2007 noted that although, a case finding by DOTS programmes was increasing, the increase was small. The report went on to add that to reach the global target 70% case detection, most countries would have to find innovative methods to find and treat cases (3) .

Avery low detection rate of 36% in our country (5) and 35.8 % in Oromia (6) implies that significant proportions of TB patients were not getting the service or did seek and receive outside of the National TB programme (4).

So improving the DOTS coverage and increasing TB case detection rate called for engaging all care providers in the country, i.e the Public-Private-DOT-Mix (PPM-DOTS) was included as one of the National TB control programmes along with good quality Acid Fast Bacilli (AFB)

examination. PPM-DOTS programme in Ethiopia has been implemented after holding policy dialogue with different partners and stakeholders including the private sector (7).

The current role of the private practioners is not limited to the diagnosis of TB and referring them to the public health facilities for treatment, Now in the era of DOTS expansion the strategy to successful TB control is related to different standards of diagnosis and care, such as sputum smear case detection; treatment of TB patients by both public and private health institutions which will help to maximize Public-Private Mix Directly Observed Therapy–Short Course (PPM-DOTS) coverage and more efficient use of existing resources (8) .

The ultimate goal of Public-Private Mix Ethiopia is encouraging efforts to achieve PPM-DOTS in diverse settings, i.e. to ensure that large numbers of TB patients under private care can access care and are managed as recommended for DOTS (7). Despite the interest in PPM-DOTS, very little is known about the quality of both public and private sector in detecting and reporting TB laboratory results in accordance to the National standards (6).

DOT relies on smear microscopy for diagnosis, categorization of patients and assessment of treatment progress. On the other hand the credibility, success and sustainability of the TB Control Programme depends on the strength of the laboratory network (8).The establishment of a well functioning laboratory network that provides the population with easy access to high quality smear microscopy services is of the highest priority for TB Control Programme (8).

Poor quality microscopy services have serious implications for the programme, including failure to detect persons with infectious TB who will continue to spread the infection in a community, or leading to unnecessary treatment“non-cases and ”errors in reading of follow up smears may result in patients being placed on prolonged treatment, or in treatment being discontinued prematurely (9) .

1.2 STATEMENT OF THE PROBLEM

The quality of laboratory services in TB control programs is important given that the diagnosis and treatment of the disease is entirely dependent upon the laboratory investigation (6). Case finding through quality assured sputum microscopy is one of the five elements of the-Directly Observed Therapy Short course (DOTS) strategy (8).

In Ethiopia TB laboratories have integrated structurally and functionally in to NTP in public health facility TB laboratories such as as budget, staff, training, operations and organization in all public health facility TB laboratories However, some private TB laboratories are separated structurally from NTP but functionally integrated through reporting mechanisms, supervision and quality assessments (4,7)

Thus, TB control requires a functional laboratory set-up with quality diagnostic services, trained diagnostician, continuous monitoring and quality improvement mechanisms for proper performance in these laboratories (9). However, many laboratories in developing countries did not fulfill all the above pre-requisites and face numerous constraints in providing quality laboratory results (10).

In our country Ethiopia (5), particularly in Oromia (6) Regional State the low smear positive TB case detection rate in both public and private health facilities is not to the standard expected.

Therefore, this study has assessed the quality of TB laboratory diagnosis using the Donebodians quality assessment parameters in purposively selected three zones of Oromia Regional states using the Donebodian's quality assessment parameters of structural, process and output quality parameters. Staffing, training, necessary equipments and reagents and budget were included under structural quality parameter (12).

Policy profile of TB laboratories, Safety measures and practices, laboratory performance analysis, quality assurance programmes and data management were included as the process quality assessment tools (11,12).

Overall satisfaction of the patient by the TB laboratory service, respect provided to the client by the provider, and completeness of information given to the patient during sputum sample collection were included as output quality assessment parameters(10,11).

This study has potentially had important contributions in assessing the structural, process and output quality parameters of TB laboratory diagnosis of both public and private randomly selected TB laboratories in East Shoa,Arsi and West Arsi Zones, Oromia region, during January 3– May 12,2011

1.3 SIGNIFICANCE OF THE STUDY

The global case detection target of smear positive Pulmonary tuberculosis 70%, is one of the Millennium Development Goal (MDG) of reducing death from TB in TB control efforts (2) .Diagnosis and treatment monitoring by sputum smear microscopy are key components of the DOTS (3).The quality of laboratory services in TB control programs is important given that the diagnosis and treatment of the disease is entirely dependent upon the laboratory investigation (6).

The lowest case detection rate of TB smear positive in Oromia Regional State which is 35.8 % (6) and 36% in Ethiopia (5) calls for an attention to study quality assessment of TB laboratory diagnosis in randomly selected health facility TB laboratories. More over there was no study done in the region in order to fill the lowest case detection rate focusing on assessing the quality TB laboratory diagnosis.

Therefore this cross-sectional study was conducted to assess the status of quality TB laboratory diagnosis in selected three zones of Oromia Regional State (E.Shoa Zone,West Arsi Zone and Arsi Zone).The study was hoped to provide valuable information for stake holders working on TB control and policy makers to alleviate the problems in this region.

2. LITERATURE REVIEW

Case detection by sputum smear microscopy among patients self reporting to health facilities is one of the five tuberculosis Control Strategy under DOTS programme (3).Sputum microscopy is the most efficient way of identifying sources of tuberculosis infection, and the primary tool for diagnosing TB, monitoring and defining cure; it is the easiest method to perform even at peripheral laboratories (3).

WHO and the "Stop Tb" partnership recommended case detection rate of new smear-positive pulmonary Tb to be at least 70% of the estimated incidence, where the case detection rate is primarily passive and should primarily be based on sputum microscopy, which is the most reliable and important one (**2)**.

During sputum microscopy, three sputum specimens must be collected and examined in two consecutive days (spot-early morning-spot):a first spot specimen – when the patient presents him/herself; an early morning specimen- consisting of all the sputum raised in the first 1-2 hours and a second spot specimen when the patient returns with the early morning specimen (3).

2.1 Quality Assessment:

Expansion of DOTS strategy requires reinforced tuberculosis laboratory services because diagnosis and treatment monitoring by sputum smear microscopy are key components of the DOTS (11). To provide good quality laboratory services, the laboratories should be organized efficiently and the procedures should be carefully selected, taking account programme efficiency, and performed only by well-trained workers under a systematic, effective, and sustainable quality assurance programme (11).

The WHO tuberculosis laboratory assessment tools used together with the Donebodian quality assessment model as: staffing, training, necessary equipments and reagents and budget were included under structural quality parameter and Policy profile of TB laboratories, safety measures and practices, laboratory performance analysis, quality assurance programmes and data management were included as the process quality assessment tools (10,11,12).

2.2 Donebodian Quality Assessments:

The first model to evaluate health care quality, which was developed by Donabedian, includes the element of: structure, process and output quality parameters from which inferences can be drawn about the quality of care (12).According to this model structure is defined as the tools and resources that providers of care have at their disposal and the 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 (12)

Whereas Process quality parameter also defined as, the set of activities that occur within the health service organizations, where judgment of quality may be made either by direct observation or by reviewing recorded information (the activities that constitute health care like diagnosis, treatment, prevention) and outcome as the change in patient's current and future health status (10,).

2.2.1 Structural quality assessment

Structural quality assessment characterizes resources in the health care system, structural and functional profile of TB laboratory and the capacity of that setting to produce quality. It includes: staffing of laboratory, training, and budget, availability of equipments, reagents and supplies (11, 12).

TB laboratory services should be organized taking account of accessibility to entire population and provision of all the necessary services for efficient TB case-management .The NTP of some countries has built in or fully integrated structural laboratory network (defined as budget , staff and organization) and functionally (defined as operational) in to the NTP,while in some countries TB laboratory services are integrated in to the general health system or provided completely independent organizations at all or certain levels (11).

Availability of the corresponding laboratory services or activities such as TB smear microscopy, TB quality assurance are components of functional profile of TB laboratories (11). Early laboratory diagnosis of tuberculosis still relies on the examination of stained smears. Microscopy of sputum smears makes a particularly important contribution since the technique

is simple, inexpensive and detects those cases of pulmonary tuberculosis who are infectious, ie. those responsible for maintaining the tuberculosis epidemic (9).

Moreover, TB laboratory services are an essential component of health care delivery and play a vital role in improving the accuracy of clinical diagnosis and the investigation of disease outbreaks (13).

In Ethiopia TB laboratories face numerous constraints in providing quality services, including poor selection of techniques, difficulties in equipment availability and maintenance, and shortages of supplies, staffing and supervision (9). In order to TB laboratories functioning effectively, motivated and dedicated staffs are crucial, i.e. laboratory personnel must be fully aware of their important role in tuberculosis control and must become full partners in National Tuberculosis Programmes.Training laboratory technicians in the microscopic diagnosis of tuberculosis is, accordingly, an essential activity under the revised tuberculosis control strategy (9).

Study done in 8 zones of Oromia in public TB laboratories in 2001 showed that 22% of laboratories have working space problem, which is the laboratory is neither ventilated nor has separate room for sputum smearing and 50% of the available laboratory staff are fresh and not trained on AFB microscopy (14) .

An assessment of 20 health facilities in Addis Ababa and Oromia pilot projects of Private Sector Projects during 2007 for the overall evaluation of performance of the PPM-DOT's laboratories showed that all the pilot facilities had the basic diagnostic investigation (sputum AFB) test in their laboratory, Eighteen (90%) of the clinics had a functional sink with running water in the laboratory. Four (20%) of laboratories had a covered dustbin for sputum cups and syringe disposal (7).

Qualitative and quantitative assessments of ten TB laboratories in India by 2006 for quality of sputum smear microscopy based on-site evaluation showed that: problems of infrastructure in 42% of the laboratories, lack of reagents and equipments in 56.6% of them and lack of Standard Operating Procedure (SOP) in 40% of the TB laboratories (16).

2.2.2 Process quality assessment

Process quality assessment means what is actually done to and for the patients in giving and receiving care. It includes policy profile of TB laboratory network (availability and use of protocols or guidelines) in the provision of care, safety measures and practices, laboratory performance analysis, quality assurance programmes and data management. Studies of the process of care can lie on direct observations or review of medical records (11)

The availability of standardized NTP TB laboratory manual, availability of national policy on Standard Operating Procedures (SOPs) of smear preparation, stain AFB using Ziehl-Neelsen method and the national policy on TB culture, quality assurance programmes or TB drug susceptibility testing are most components of process quality assessments of TB laboratory diagnosis based on the status of the laboratory (11,12).

Additionally the World Health Organization reminds the necessary cautions when establishing TB laboratories, since a direct relationship exists between workload, number of microscopists required and the quality of microscopy performed TB laboratories. The maximum number of AFB slides examined per microscopist per day should not exceed 20. If more examinations are attempted, visual fatigue will lead to a deterioration of reading quality (2)

According to the National Tuberculosis and Leprosy Control Programme (NTLCP) manual of Ethiopia, which strongly recommends, TB control activities has to be recorded daily and reported quarterly (4). On-site evaluation in Ethiopia of the five year, 1996-2001, program development plan of the NTLCP of Federal Ministry of Health (FMOH) indicted that lack of laboratory manuals and formats and absence of adequate training and IEC materials at the regional levels as the main problems in Tb control activities (17).

Major findings from supportive supervision of 22 PPM-DOTS laboratories carried out by the regional research laboratory in Amahara Region in 2009 showed that only 54% had Standard Operating Procedure (SOP) in microscopy, 77 % staff trained in AFB and quality assurance (15).

In a study conducted in Afar region, the quality of patients record was very poor in that the majority, 239 (88.5%) patient records were found incomplete; that is treatment for some

patients were initiated and continued without recording full information needed to start and commence patient monitoring (18). However, study conducted in Tigray region indicated that about 6.8% of Tb patients were put on treatment without any documented evidences (19).

2.2.3 Output quality Assessment

Output quality assessment is the results we found out of health service delivery. For example, whether a client is satisfied with the service he/she got after visiting health facility or not. The output quality parameter encompasses overall all satisfaction of the patient by the TB laboratory service, respect provided to the client by the provider, and completeness of information given to the patient during sputum sample collection (10).

Effective control of TB is dependent on a network of local laboratories that provide accurate and reliable AFB microscopy testing for diagnosis, treatment, and monitoring through the availability of adequate resources and services, technical competence of the health care personnel, interpersonal relations between the patient and health care provider. The availability and quality of AFB microscopy relies on national programs that support, train, and monitor the testing performance of individual laboratories (9).

It is well known that serious deficiencies can occur in the laboratory operations when insufficient attention is given to the quality of the work product (8).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 (12) .

So far, no study has attempted to assess the quality of microscopy diagnosis of tuberculosis in Ethiopia. This study was therefore, important to assess the quality of both the public and private TB laboratory diagnosis, by considering the structural, process and output quality assessment parameters in selected TB laboratories of Oromia region.

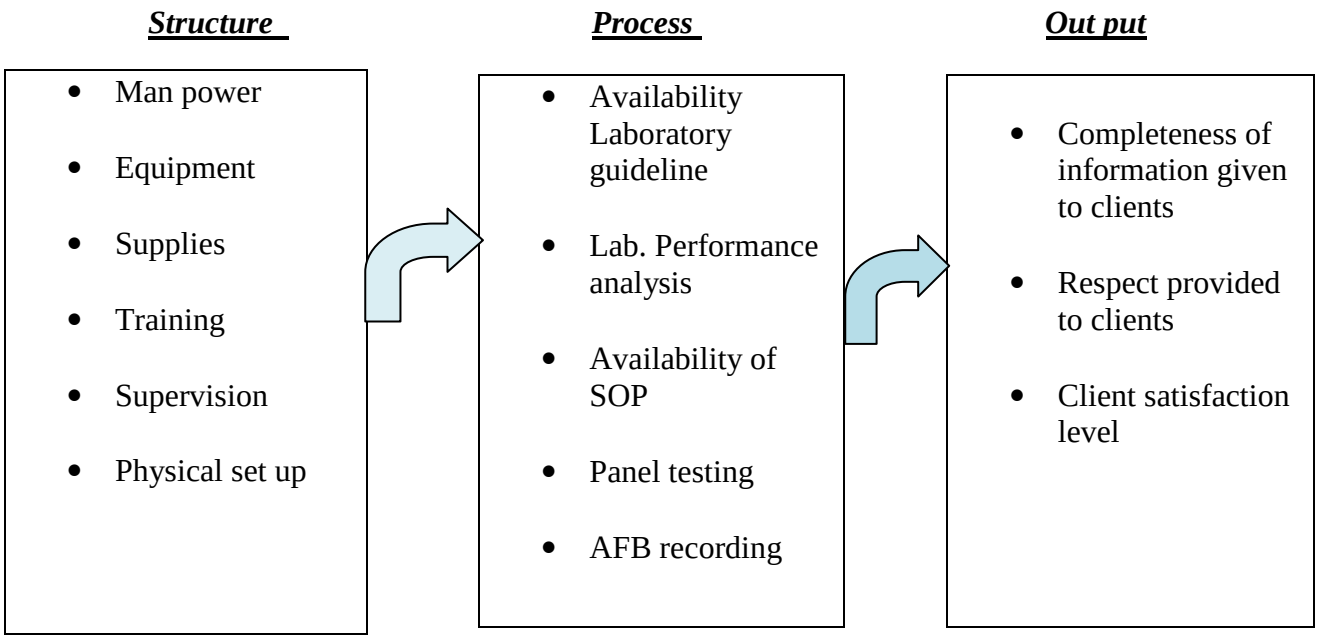


Fig.1 A systems based model as applied to TB laboratory Diagnosis.

3. OBJECTIVE

3.1 GENERAL OBJECTIVE:

- To assess the quality of TB laboratory diagnosis in randomly selected public and private TB laboratories in Oromia region.

3.2 Specific Objectives

- To assess structural qualities of TB laboratory diagnosis in randomly selected public and private TB clinics with regard to structural and functional profile of TB laboratory, staffing, budget, availability of materials, reagents .
- To assess process qualities of TB laboratory diagnosis focusing on availability and use of guidelines, laboratory performance analysis, quality assurance and data management of TB laboratory diagnosis in randomly selected public and private health facilities.
- To assess patients' satisfaction level in the given TB laboratory diagnosis services.
- To assess the association among the three quality parameters of TB laboratory diagnosis in selected TB laboratories of Oromia region.

4. *METHODS AND MATERIALS*

4.1 Study area and Period

The study was carried out in 60 randomly selected health facility TB laboratories in purposively selected 3 zones of Oromia Regional State between 3 rd January–12 th May 12, 2011

Regarding health infrastructure and delivery, Oromia has 22 hospital laboratories, 342 health center laboratories owned by Government and 46 higher clinic laboratories, 134 medium clinic laboratories and 715 lower clinics owned by the private sector (private sector data from S.West Shoa, E.Wollega, W.Wollega and Horro Guduru Wollega were not available & not included (6) .

In Oromia Region DOTS has now expanded to all zones, all woredas and in 69% of existing health facilities. The regional case detection is 36% which is still far below the national target of 60% (9). But slight improvement was seen in Oromia Regional State, as it increased from 32% in 1999 to 36% in 2000 (6).All the public health facilities were supplied with all materials and reagents, manuals and recording books from the Regional Tuberculosis Programme. Similarly staffs training on TB laboratory diagnosis and external quality assurance progammes were given by the Oromia Regional research laboratory (14).

Generally TB laboratory system in Oromia region as well in Ethiopia was either fully integrated structurally (defined as staff, budget and organization) and functionally (defined as operational) in to the NTP in public TB laboratories or separated structurally but functionally integrated through reporting mechanisms, supervision and quality assurance programmes in some private TB laboratories (4,6,8) .

4.2 Study Design

The study was descriptive cross-sectional facility based survey, which has employed standardized questionnaire for interview, record review and checking AFB microscopy reading status of laboratory technicians for assessing the quality of TB laboratory diagnosis in selected TB laboratories of both public and private health facilities in Oromia Regional state .

4.3 Source Population

- All Public and private TB laboratory units in purposively selected three Zones of Oromia region were the source population.

4.4 Study Population

- The study populations were randomly selected public and private TB laboratories from three zones of Oromia Region.

4.5 The Inclusion criteria

- The inclusion criterion was running TB laboratory diagnosis in all public or private TB laboratories

4.6 Unit of Analysis

- Public and private TB laboratories, laboratory technicians, Patients records,TB patients constituted the study unit

4.7. Sample Size Determination

4.8.1 Health facility TB laboratories

Sample size calculation was based on a suggested rule of Thumb (21) in determining the number of health facilities for quality of care study, which states: if numbers of units are large, i.e. 500-1000, take a 10% sample. If it is medium size 100-500, take 20-30% sample and if it is very small, <50, take 30-50% sample (21).

Based on the number of TB laboratories i.e. one hundred seventy seven in these purposively selected Zones of Oromia Region, sample size was determined using the rule of Thumb which is 30% of the total numbers of health facility and become sixty health facility TB laboratories (annex 4)

4.8.2 Record review

- Based on estimation of proportion from a finite population of size N.

$$N=\frac{Z\alpha^2\, p\,(1-p)}{d^2}$$

Where, P = proportion of desirable behavior.

In this case P of 6.8 % was taken, as study conducted in Tigray (19) indicated that 6.8 % of TB patient's documents were not properly recorded before their treatment .

d= allowable error of 3%

CI=Confidence interval at 95%

$$\text{Hence } N=\frac{(1.96)^2 \times 0.068 \times .932}{(0.03)^2}$$

$$N_1=270$$

So the 270 TB patients of new and follow up cases record were reviewed for checking its completeness (complete for age,sex and AFB result) or recorded in standard National TB laboratory recording books.

4.8.3 TB Patients Interview

In this case P =0.5 was used, since no similar study was done concerning TB patients interview to assess the output quality of TB laboratory diagnosis, d = allowable error of 5% and CI=Confidence interval at 95%. So the required sample size for interviewing TB patients for their satisfaction level on the overall laboratory service, respect offered by the provider during TB laboratory visit was $N_2 = 384$ as an output quality parameter.

4.8.4 AFB Panel Slide Preparation and testing

Panel testing is a method of External Quality Assessment (EQA) that is used to determine whether laboratory personnel can adequately perform AFB smear microscopy. This method evaluates individual performance in reading AFB slides (9).

Standard smears with known results were prepared and stained by the laboratory technologist as principal investigator and dispatched to TB laboratories.

A Minimum of five slides per set is required, covering the full range from negative to strongly positive, as follows (9):

- Negative: Two slides
- <10 acid-fast bacilli (trace): One slide
- 1+: One slide
- 2+ or 3+: One slide

These AFB Panel test slides were distributed to each 20 voluntary laboratory technicians (10 from public and 10 from private health facility TB laboratories) workings on TB laboratory on day of laboratory visit were included in the stud

4.5 Sampling Method

4.8.1 TB laboratories Sampling Method

Sampling of sixty TB laboratories of different kinds in both public and private health facilities (health centers, medium clinics) and was done by the simple random sampling. All hospitals and higher clinic TB laboratories were included, since they were few in number. Accordingly 21 health facility TB laboratories, 19 health facility TB laboratories and 20 health facility TB laboratories were selected from East Shoa Zone, West Arsi Zone and Arsi Zone respectively (annex 4). TB laboratory activities in all selected health facilities were observed and all heads of the respective TB laboratories were interviewed.

4.8.2 TB patients Record Sampling

TB patients record review was done by distributing the sample size of N_1=270 proportionally in to 60 health facilities based on the number of TB patients recorded on the daily basis. (Annex 5). The sampling interval for TB laboratory record review was 5. Then the first patient record was selected randomly and the others by systematic random sampling every 5^{th} of the patients records followed. So 169 patients from hospitals, 50 patients from health centers, 34 patients from higher clinics and 17 patients from medium clinics records were reviewed.

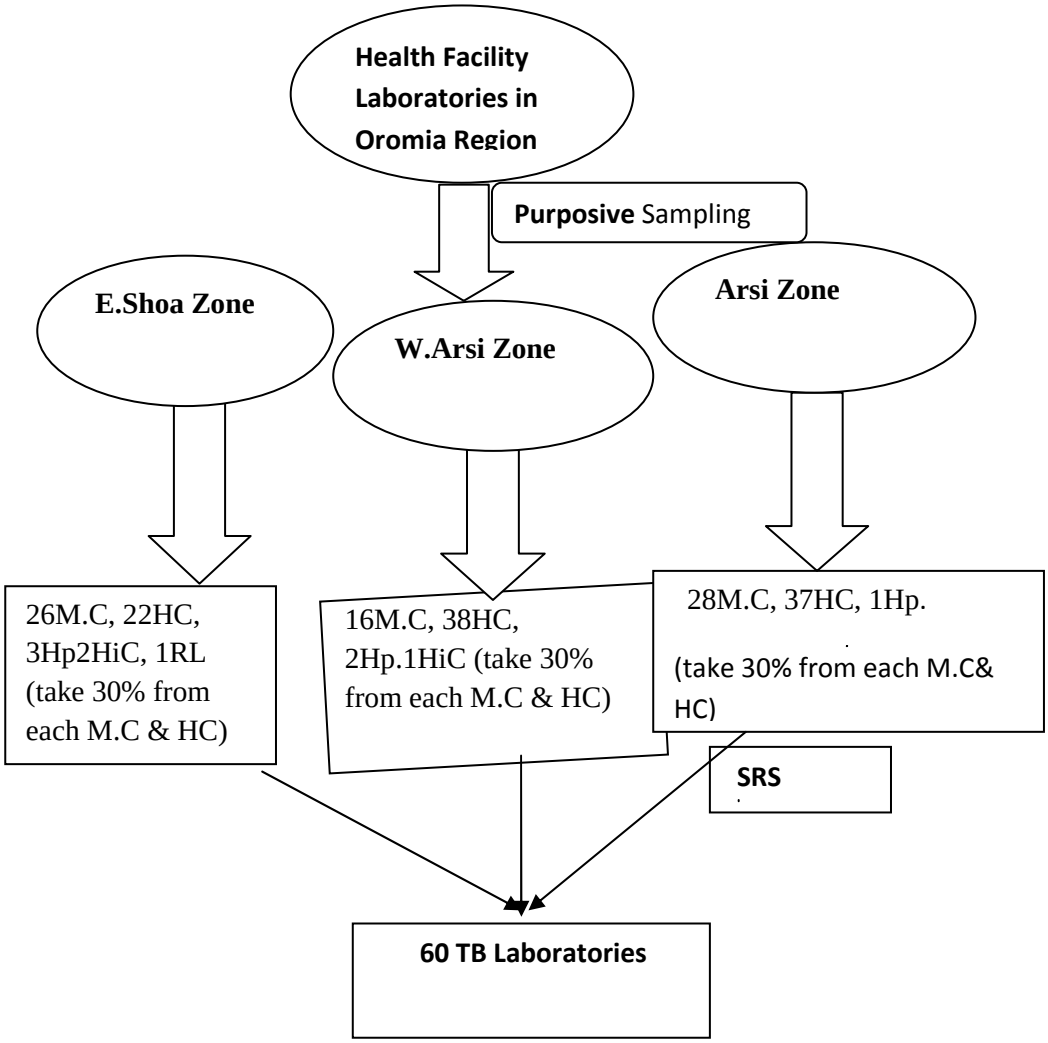
4.8.3 TB patient's interview

TB patients interview was done by distributing the sample size N_2=384 proportionally in to 60 health facility TB laboratories based on the average number of TB patients visiting these facilities on the daily basis. So 240 TB patients from hospitals,72 TB patients from health centers,48 patients from higher clinic and 24 TB patients from medium clinic were interviewed.

TB patients were interviewed based on the availability of the patient on the day of interview.

Panel test slides were distributed to each health facility TB laboratory and laboratory technician working on TB laboratory on the day of laboratory visit was included in the study. Accordingly 20 health facility TB laboratory technicians (10 public and 10 private TB laboratories) which were voluntary to participate in the panel test were included.

Figure-2 Schematic presentation of sampling procedure among TB laboratories in 3 zones.



Hp=Hospital, HC=Health Center,MC=Medium Clinic, HiC=Higher Clinic, RL=Regional Laboratory

SRS=Simple Random Sampling.

NB.All hospitals (6) & Higher Clinics (3) will be taken, since they are few in number.

4.6 Data Collection tools and Procedures

For the purpose of data collection (patient and laboratory department heads interview) an anonymous self-admintered structured questionnaire was prepared after reviewing relevant literatures of WHO TB laboratory assessment tool and the Donebodian quality assessment model (11,12).

Data was collected by two laboratory technicians using pre-tested, structured and interviewer-administered questionnaire on TB patients interview, laboratory head interview, record review and panel testing of already prepared TB slides. Initially a questionnaire was prepared in English language and then was translated in to Amharic language and back to English for checking its consistency.

The Laboratory technicians were trained for two days by the principal investigator prior data collection. Then data collections were proceeded after giving introduction on the aim of the study to TB patients and laboratory technicians.

4.10.1 Structural assessment

Structural data i.e. availability of staff, supplies , reagents , equipments , training ,budget were collected by two laboratory technicians using WHO TB laboratory assessment tool monitoring checklist and Donebodian quality of health care model .

The underlying concept in structural assessment is to decide whether TB laboratory diagnosis is provided under conditions favorable for good quality AFB diagnosis or not and it is actually relatively the easiest method of quality assessment of TB diagnostic laboratories (11, 12).

4.10.2 Process Quality assessment

Policy profile of TB laboratories, safety measures and practices, laboratory performance analysis, quality assurance programmes and data management were included as the process quality assessment tools. Process quality assessment denotes what is actually done by the TB diagnostic laboratories in giving the diagnostic services (11,12).

Observation and interviewing of laboratory heads in each TB laboratory were done by two laboratory technicians on procedures followed in the laboratory during sample collection, smearing, staining AFB microscopy, completeness of TB laboratory records and dispatching AFB slides for panel testing at each laboratory was done by the principal investigator (laboratory technologist) who was for proper quality of TB laboratory diagnosis.

4.10.3 Output quality parameters

To asses the output quality parameters: TB patient satisfaction level on the overall laboratory service, respect offered by the provider during TB laboratory visit and level of information they get during the laboratory diagnosis for the proper collection of sputum sample were included as output quality assessment tools (12).

4.11 Measurements

Donabedian's structure–process–outcome model of health care quality and WHO TB laboratory assessment tool were employed as a framework for the study (11, 17). Data on the structure, processes and outcomes of care was collected cross-sectionally on: Availability of resources required to provide TB laboratory diagnosis, structural and functional profile of TB laboratory, availability and use of protocols or guidelines, record review of TB laboratory and satisfaction level of the patient on the interpersonal qualities of service provider and the service provided to patients(11,12)

Resource availability & adequacy was assessed, including trained laboratory staff, laboratory facilities, laboratory chemicals and reagents. An inventory tool prepared based on the resource requirements of the national program TB laboratory diagnosis was used for this purpose (9).

The process indicators were assessed by reviewing 270 systematically selected TB patient records, which was based on the actual proportion of TB patients based on records of patients on adaily bases in each sixty health facility TB laboratories. In addition; an interview was conducted with 384 patients visiting the TB laboratory during data collection period to assess satisfaction level of patients as an outcome quality parameter. Interviews were conducted by trained data collectors using a satisfaction questionnaire adapted from the Donebedian quality assessment parameters and panel slide reading by the laboratory technicians working in TB laboratory room on the day of visit. .

4.12 Variables of the Study

4.12.1 Dependant Variable

- Status of Quality of Public and Private TB Laboratories.

4.12.2 Independent Variables

- Policy profile of TB laboratories
- Availability of laboratory guidelines.

- Availability and use of laboratory equipements, chemicals.
- Laboratory workload analysis
- Laboratory technicians training
- Examination of TB Panel slides
- Record of TB laboratory result

4.13 Data Quality Control

The questionnaires were pre-tested on TB patients and laboratory technicians, who were not included in the study. Data collectors were laboratory technicians who had more experiences on TB laboratory diagnosis. Two days training was given to the data collectors on the procedure. The data was checked for completeness, accuracy clarity and consistency by the supervisor on the daily bases. Data were intensively cleaned up by double data entry before analysis.

Data was then collected by two laboratory technicians working in Shashemene Referral Hospital TB laboratory on procedures followed in the laboratory during sample collection, smearing, staining,AFB microscopy, completeness of TB laboratory records ,on TB patient satisfaction level on the service of TB laboratory and one laboratory technologist /the primary investigator collect data from the dispatched AFB panel tests .

Data collectors had prior experience in sputum smear examination and on-site evaluation. Data collectors were trained both theoretically and practically using a training material prepared by the principal investigator (and TB experts, on how to ask permission for participation during the onsite evaluation and interviewing patients.

4.14 Data Processing and Analysis.

SPSS version 15.0 for windows statistical software application was used for data entry and analysis. Descriptive statistics (frequency tables) were used to describe the structural, process and output quality assessment results. Binary regression analysis was used to explain the dependent variable in terms of the independent variable and was employed to see if any association exits among the three quality parameters (structure, process and output) quality parameters. Findings at P value of 0.05 and confidence interval of 95% were used as statistically significant.

4.15 Ethical Considerations

Ethical approval and clearance was obtained from the Faculty's Institutional Review (IRB) of College of Health Sciences, Addis Ababa University. Then at all levels, officials were communicated through formal letters from the school of public health, College of health sciences, Addis Ababa University and permission was secured. The necessary explanation about the purpose of the study,assurance of confidentiality was attached to the cover page of the questionnaire.

Finally the respondents were informed of their right to refuse or agree to participate in the study, or discontinue their participation whenever they feel the need.

4.16 Dissemination of Findings

The findings of this study will be distributed to different stakeholders of TB control programmes.Including Oromia TB control, Oromia Regional laboratory and West Arsi Zonal Health Bearu.Based on the scientific merit of this thesis it may be published in Scientific Journals.

4.17 Operational Definitions

External Quality Assessment (EQA): Is the process to assess laboratory performance by an outside agency and includes on-site evaluation, panel testing and blind rechecking.

DOTS: Directly Observed Treatment, Short course chemotherapy which is internationally/Nationally recommended strategy for TB control.

Interpersonal Relations; It refers to the relationship between laboratory providers and our clients and communities, between health mangers and their staff.

Process Quality parameter: This refers to what is done and the way things are done. An example is the activities for outpatient care including TB laboratory diagnosis.

Output quality parameter: It is the results we get out of health service delivery. For example, is the client satisfied with the service he/she gets after visiting TB laboratory.

Supervision: Involves observation, discussion, and support and guiding the staff while carrying out the work, review registers and interview the focal person using standardized check list

TB laboratory system integrated structurally to NTP: defined as budget, staff and organization in these TB laboratories are fully integrated in to NTP and functionally.

TB laboratory system separated structurally: TB laboratories dissociated from the NTP by budget, staff, and organization, but integrated through reporting mechanisms, supervisions and quality assurance.

TB laboratory workload: Volume of work done at different levels of TB laboratory. Example: numbers of AFB slides examined, TB cultures and drug susceptibility tests done per one laboratory technician per day.

Quality of laboratory diagnosis:Are systematically developed frame works that can be used to assess the appropriateness of specific laboratory services through WHO TB laboratory assessment tools and the Donebodian health care quality parameter.

5. RESULT

TB laboratory Characteristics

Among 60 TB laboratories included in the study; 33 were private medium clinic laboratories, 18 Governmental Health Centers laboratories, 5 Governmental Hospital laboratories and 4 private Higher Clinic laboratories were included. Generally 18 TB laboratories were from W.Arsi Zone, 22 from E.Shoa zone and 20 TB laboratories were from Arsi Zones. There was hundred percent response rates of health facility TB laboratories.

Patient Characteristics

An interview of a total of 384 patients attending TB laboratory unit from public & private health facilities: 240 patients from hospitals, 72 patients from health centers, 48 patients from private higher clinics and 24 patients from private medium clinics were interviewed.

Record reviews of 270 patients: 169 TB patients record from hospitals, 50 TB patients from health centers, 34TB patients from higher clinics and 17TB patients record from medium clinic health facility TB laboratories were reviewed between 3rd January and 12th May, 2011 based on the number of patients visited each health facility TB laboratory and number of patients recorded in TB laboratory registration book in one day. (Annex 5).

Laboratory Technicians Characteristics

Generally there were 100 laboratory technicians and technologists in all TB laboratories. Sixty five (65 %) were diploma, thirty three (33%) were B.Sc and two (2%) were M.Sc level were interviewed for assesssement of structural and process quality parameters between 3 rd January and 12 th May 12, 2011. All heads of health facilities TB laboratories were willing to participate in the study and verbal consent was obtained from each of them before starting data collection.

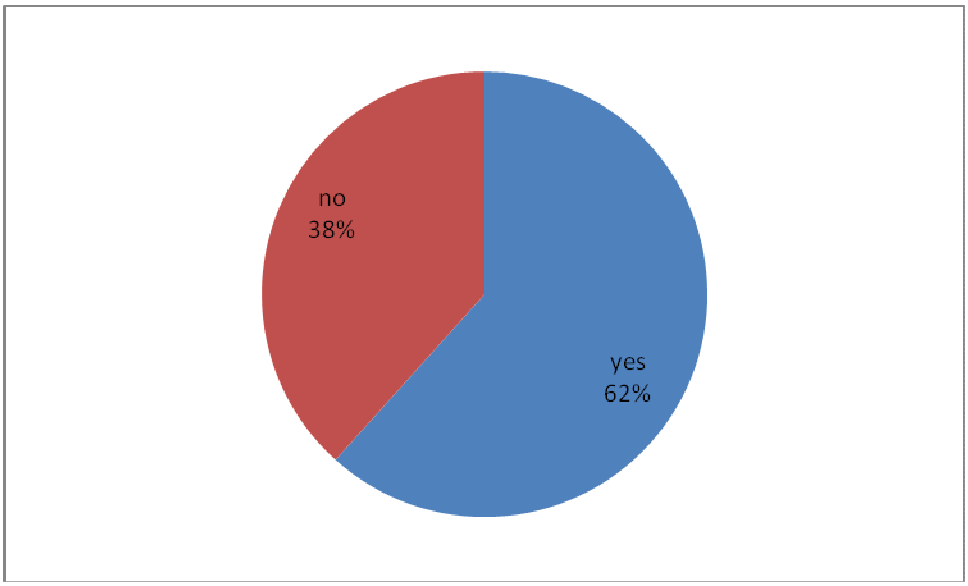
5.1 Structural Quality Assessment

Structural and Functional profile of TB laboratories network with NTP

Thirty seven (62%) of public and private TB laboratories in three Zones of Oromia Regional State were fully integrated structurally through budget, staffing, training and functionally as operational activities in to the National TB programme, where as twenty three (38%) of TB

laboratories were separated structurally but functionally integrated through reporting system (Table 1).

Fig.3 Structural and functional profile of TB laboratories in relation to Oromia Regional TB control Programme May 2011



Staffing: Sixty laboratory technicians: two of them were M.Sc, fifteen were B.Sc level and fourty three were diploma levels were included in the study. Fifty were males and ten were females working as department head in TB laboratory .Forty (75%) of the TB laboratories had at least one laboratory technician that had been trained on TB laboratory diagnosis (Table 1)

Materials, reagents and supplies: Almost all of the TB laboratories had sets of reagents (carbolfuschin, acid alcohol and methylene blue), microscope, slides, sputum cup, slide box, staining rack, and bunsen burner for AFB test (annex 5).

Table 1: Description of Structural and Functional profile of public and private TB laboratories network for NTP in Oromia Region (N=60), May 2011.

S.no	Variables Category	Response	Number	Frequency (%)
1	TB laboratory staff:			
		M.Sc	2	3.3
		B.Sc	15	25
		Diploma	43	71.7
2	Sex	Male	50	83.3
		Female	10	16.7
3	TB Laboratory fully integrated structurally and functionally with NTP			
		Yes	35	58.3
		No	25	41.7
4	TB laboratory system separated structurally but functionally integrated through reporting			
		Yes	25	41.7
		No	35	58.3
5.	TB laboratories doing Smear microscopy			
		Yes	59	98.3
		No	1	1.7
6.	TB laboratories participating in EQA	Yes	41	68.75
		No	19	31.25

Supervision: Majority of TB laboratories: thirty four (57%) had supervisory system for the last one year. About fifteen (25%) of the health facility TB laboratory had no any training for the last one year (Table 2).

5.2 Process Quality Assessment:

Policy profile of TB laboratory: Standard Operating Procedures (SOP) for AFB laboratory diagnosis was not available in fifty one (85%) of public and private TB laboratories. Only fourty five (75%) of both public and private TB laboratories had National Tuberculosis Programme

(NTP) approved laboratory manual and thirty eight (63%) of the TB laboratories had NTP approved request forms (Table 2).

Laboratory workload analysis: In fifty five (91.7%) of public and private TB laboratories, the number of Acid Fast Bacilli slides examined per a laboratory technician per day didn't not exceed 20 (Table 2).

Table 2: Description of certain variables of Structural and Process Quality in Public and Private TB laboratories in Oromia Region (N=60), May 2011

S.No	Variables Category	Response	Number	Frequency (%)
1.	Lab. tecn.training	Yes	45	75
		No	15	25
2.	Supervision with in 12 month	Yes	34	57
		No	26	43
3.	Availability of SOP	Yes	9	15
		No	51	85
4.	NTP laboratory manual	Yes	45	75
		No	15	25
5.	NTP laboratory request forms	Yes	38	62.5
		No	22	37.5
6.	workload per techn/ day > 20 slides	Yes	5	8.3
		No	55	91.7
7.	Display and follow staining procedure	Yes	40	66.7
		No	20	33.3
8.	instruction for patients for sample	Yes	54	90
		No	6	10
9.	Checking quality of sputum for AFB	Yes	39	65
		No	21	35
10.	Control AFB smears included in staining	Yes	27	45
		No	33	5

AFB Panel testing: From the dispatched six AFB slides prepared for panel testing (two negative slide, one positive (trace), 1+ positive, 2+positiveand 3+ positive slides) for twenty laboratory technicians in twenty TB laboratories to assess the AFB microscopic reading status of the laboratory tecnicians: 2 (10%) of the laboratory technicians poorly reported on positive (trace) AFB slide reporting as Negative. These reports were from Private medium clinic TB laboratories (Table 3).

Table 3: Microscopic reading status of laboratory technicians through dispatched AFB as Process Quality assessment in Oromia Regional State (N=20), May 2011.

Panel slides	Slides in a panel	Number of slides read	% of discordant result	
			Public TB laboratory	private TB laboratory
Stained	**No AFB**	2	No	No
	AFB positive	4	**No**	2* (10%)

2*= refers the laboratory technicians report only from the trace (<10 acid-fast bacilli per slide

Recording and Reporting: A total of 270 records of initial and follow up TB patients were reviewed: 136 (50.4%) were male, 114 (42.2%) were females and 20 (7.4%) were not recorded by their sex category. Majority of the age group were in 35-44 years, i.e 113 (41.85%). Initial diagnostic AFB tests were done for 238 (88%) patients, where 46 (19.3%) were positive for AFB and 159 (66.8%) were Negative for AFB. (Table 4)

Table 4: Description of patient's unit TB laboratory record in the selected public and private TB Laboratories in Oromia region (N=270), May 2011

S.no	Variable category	Number	Frequency (percent)
1.	Sex(n=270)		
	Male	136	50.4
	Female	114	42.2
	Unrecorded	20	7.4
2.	Age group(270)		
	5-14	11	4
	15-34	98	36.3
	35-44	113	41.85
	55^{+}	36	13.3
	Unrecorded	12	4.55
3.	Initial AFB(N=238)		
	Yes	56	23.5
	No	182	76.5
4.	Initial AFB result positive	46	19.3
	No AFB	159	66.8
	Not recorded	33	13.9
5.	Follow up result (N=32)		
	Positive	1	3.1
	No AFB	29	90.6
	Not recorded	2	6.3
6.	AFB positive written in ı ink (N=47)		
	Yes	46	97.8
	No	1	2.2

5.3 Output Quality assessment

The socio-demographic characteristics of the respondents were shown in table (5). Among the study participants, one hundred ninety (49.5 %) were in the age group of 35-44, two hundred one (52.35%) were females, one hundred nineteen (30.97%) were illiterate; one hundred fifty three (39.84%) were Muslims and one hundred thirty five (35%) were farmers in occupation (Table 5).

Table 5: Socio-demographic characteristics of patients in Selected TB laboratories of Oromia Regional State (N=384), May 2011.

No	Variable	Number	Frequency(Percent)
1.	Age (N=384)		
	5-14	26	6.8
	15-34	125	32.5
	35-44	190	49.5
	45-54	37	9.7
	≥ 55	6	1.5
2.	Sex (N=384)		
	Male	183	46.65
	Female	201	52.35
3.	Marital Status		
	Single	75	19.5
	Married	254	66
	Others	55	14.5
4.	Educational Status		
	Illiterate	119	30.97
	1-6 grade	59	15.36
	7-12 grade	102	26.56
	12^{+}	104	27.1
5.	Religion		
	Muslim	153	39.84
	Orthodox	138	35.93
	Protestant	93	24.23
6.	Occupation		
	Farmer	135	35
	Government employee	86	22.4
	Merchant	58	15.2
	Others	105	27.4

Binary regression analysis for overall satisfaction level of patients by laboratory service received versus certain Socio-demographic variables showed that patients in the age group of 35-44, farmers and illiterates were more satisfied than an employee, educated and other age groups. The association is statistically significant at P<0.05 (Table 6).

Table-6 Patients overall satisfaction level with the laboratory service versus certain Socio-demographic Variables in the selected health facilities of Oromia Regional State (N=384)

Variable category	**Satisfaction level**		**COR(95CI)**	**AOR(95CI)**	**P value**
	Satisfied	**Not satisfied**			
1 Sex					
Male	130	53	1.00	1.00	
Female	143	58	1.32(1.0-1.93)	1.03(0.66-1.44)	0.45
2.Religion					
Muslim	110	43	1.00	1.00	
Christian	165	66	2.33(0.93-4.5)	1.42(1.0-1.89)	0.15
3.Age Group					
5-14 yr	15	11	1.2(0.43-3.5)	1.2(0.43-3.35)	
15-34 yr	41	84	0.48(0.17-1.34)	0.58(0.28-1.18)	
35-44 yr	183	7	4.43(2.01-9.76)	3.67(1.64-8.2)	0.003
45-54 yr	34	3	0.53(0.29-1.2)	0.49(0.17-1.42)	
≥55	4	2	1.00	1.00	
4 Educational Status					
Illiterate	78	41	2.35(1.26-4.39) *	1.90(1.06-3.75)*	0.002
Grade 1-6	40	19	2.13(1.02-4.45) *	0.83(0.486-1.43)	
Grade 7-12	72	30	1.86(0.97-3.59)	0.73(0.41-1.31)	
>=12	73	31	1.00	1.00	
5 Occupation					
Farmer	85	50	3.2(1.19-4.53) *	2.21(1.6-3.9) *	0.004
Govn't	65	21	1.07(0.55-2.08)	0.65(0.32-1.29)	
employee	63	23	0.96(0.45-2.05)	0.78(0.46-1.133)	
Others	84	21	1.10(0.86-1.4)	1.08(0.79-1.47)	
Merchennt	48	10	1.00	1.00	

Binary regression analysis for certain structural and process parameters versus patient's overall satisfaction level on the TB laboratory service showed that: two hundred fifty nine patients (62.45%) who had got complete information on sputum sample collection and two hundred thirty nine patients (62.24%) who had visited TB laboratory providers being respected were more satisfied than those patients who had no complete information on sputum sample collection and those patients who were not being respected by their providers. The Association is statistically significant (P<0.05) (Table 7)

Table-7: Patients overall satisfaction versus certain structural and process attributes in Selected public & private TB laboratories in Oromia Regional state (n=384) May 2011.

Variables	**Overall satisfaction level**		**COR(95% CI)**	**AOR(95% CI)**	**p-value**
	satisfied	**Not satisfied**			
1-Lab tech. received training:	249	135	4.38(1.05-5.8) 1.0	2.34(1.27-3.12) 1.00	0.71
2- Staff take part in regular QA	297	87	2.17(1.31-7.00) 1.0	1.90 (1.51-4.62) 1.00	0.01
3- Supervision with in 12 month period	315	69	1.7(0.34-8.8) 1.0	0.83 (0.45-1.50) 1.00	0.20
4- Checking the quality of sputum sample	276	108	1.27(0.034-48) 1.0	1.19 (0.21-6.68) 1.00	0.12
5- Respect offered to pt's from TB lab.	239	145	2.34(1.12-2.25) * 1.00	2.21(1.34-2.24) * 1.00	0.04
6- Pat's get complete infon. on sputum colln.	259	125	2.49(2.47-2.99)* 1.00	2.53(2.46-2.73) * 1.00	0.03
7-Long Stay period at TB lab.	275	109	1.43(0.896-2.287) 1.00	1.23(1.00-2.17) 1.00	0.051

5.4 Quality Parameters analysis

Logistic regression analysis among the three Quality parameters for TB laboratory diagnosis was done between structure versus process quality parameter, structure versus output quality parameter and process versus output quality parameters. The quality parameter indicated that there was a statistically significant association between the structural qualities (training of lab. Technicians) and process quality parameters i.e. display and follow smear preparation procedure (OR **2.9(1.46-5.7; P=0.01)** and also significant association between process quality parameter (display and follow smear preparation procedure) and output quality parameter (OR **3.2(3.13-10; P=0.02)**. However, there was no a statistically significant association between structure quality and output quality (patient satisfaction) (P >0.05) as seen in table 8.

Table 8: Logistic Regression analysis of the three Quality Parameters in Selected TB Laboratories in Oromia Regional State (n=60), May 2011

Quality parameter	**Description**	**Out put**	**process**
structure	**Odd ratio**	**0.56(0.43-2.14)**	**2.9(1.46-5.7)**
	P value	**0.52**	**0.01**
process	**Odd ratio**	**3.2(3.13-10)**	
	P value	**0.02**	

**Correlation is significant at the 0.01 level (2-tailed).

6. DISCUSSION

Laboratories have a central role in controlling the spread of tuberculosis by providing high quality TB laboratory results from testing sputum samples (9).This study has attempted to assess the quality of TB laboratory diagnosis of public & private health facility laboratories in purposively selected three zones of Oromia Region. Donabedian's quality assessment model in health care (structural, process and output quality assessments) and WHO TB laboratory assesement were used in this study as a tool of quality measurement (11, 12).

Availability of laboratory technicians/technologists, structural and functional profile of TB laboratory with NTP, staff training and availability of materials, reagents, and supplies were used for structural quality assessment While policy profile of TB laboratory, TB laboratory work load analysis, recording and reporting of AFB results, panel testing of dispatched AFB slides and use of equipments and supplies, and reviewing records were used as process quality measures (11, 12).

Overall satisfaction level of TB patients on the laboratory services, satisfaction level on the completeness of information given to TB patients during sputum sample collection and respect offered by service provider during patient visit were included under the output quality assessment (12).

The average numbers of laboratory technicians/technologists were satisfactory at each health facility TB laboratory i.e on average 2 laboratory technicians in each Health Center TB laboratories, and 7 laboratory technicians in each Government hospital TB laboratories and 1 laboratory technician in private medium clinic laboratories and 2 laboratory technicians in each private higher clinic TB laboratories.

Thirty seven (62%) of TB laboratories in three Zones of Oromia Regional State were were fully integrated both structurally in budget, staff, procurement and functionally i.e. in operational activities in to the Oromia Regional TB programme, where as twenty three (38%) of TB laboratories were separated structurally but functionally integrated through reporting system structural and functional profile.

In twenty three (38%) private TB laboratories which are separated structurally from the Oromia TB control are lacking majority of the training opportunists, quality assurance programmes and interruption of the AFB testing in the respective TB laboratories.

From these, eleven (22.9%) of them were from the private medium clinic laboratories.Although,Training of laboratory technicians has a strong influence. on the quality of TB laboratory diagnosis provided to patients, little attention was given to the training of laboratory technicians in private medium clinic laboratories which are separated structurally from the Oromia regional TB programme.

This was against the revised WHO's, Quality assurance of sputum microscopy in DOT's programme which states: training of laboratory technicians in the microscopic diagnosis of tuberculosis is, accordingly, an essential activity in tuberculosis control strategy (9, 23).

The finding was different from with that of study done in eight zones of Oromia in 2001 which showed 50% of the available laboratory staffs were fresh and not participated in any training of TB laboratory diagnosis. The difference might be explained by training gap might be filled with those two previous years.

To maintain quality in implementation, laboratory technicians must be appropriately trained to provide the best level of diagnosis. For some TB clinic health facilities, outdated knowledge and skills must be updated to current evidence-based information. Training is also necessary to encourage adherence to national protocols and guidelines introducing some degree of standardization in TB laboratory diagnosis (8,9).

Almost in twenty six (43%) of the health facility TB laboratories there was no any supervision system within one year period of time at all and ninteen (31.25%) of health facility TB laboratory staffs had no any regular quality assessment mechanism. In some, even though, there was supervision mechanism, the system was weak, not had any feedback mechanisms, which was against the recommendation of WHO and the National Tuberculosis programme guide line (23), which recommended strong and supportive supervisions.

In practice the TB laboratory supervision system should be monitoring the day-to-day activities of the TB laboratories and the Supervisors must also ensured the laboratory activities were carried out as planned once every four to eight weeks .In this study, the supervision mechanism was not as per the national scheduled period which was inconsistent and had no any feedback mechanism (4, 17).

Majority of the health facility TB laboratories had materials, reagents, power supply and water supply in the TB laboratory as per the National guideline of Ethiopia (4). How ever there was a

problem in the utilization of some materials, especially posters of AFB staining were not displayed in visible areas and some even, were not displayed it at all.

Although three Sputum specimens must be collected and examined in two consecutive days (spot-morning-spot) to diagnosis TB efficiently, in this study 6 (10%) of the health facility TB laboratories did not give adequate information for patients to follow standard sputum collection of spot-moring-spot. But according to the latest recommendation of WHO and the national AFB microscopy laboratory manual: every individual suspected of having TB must have an examination of three sputum smears, to determine whether or not they had infectious TB.These report were mainly from the private medium clinic TB laboratories, in which majority of them were not included under the National TB prevention and control programme.

Thirty three (55%) of the health facility TB laboratories, didn't use control slides with each batch of stains for checking the quality of stains prepared and twenty one (35%) of the health facility TB laboratories didn't check the quality of sputum sample during collection of spot-morning-spot sputum sample

From the dispatched Known AFB Slides of different smear status: negative, positive(trace), positive(1+), positive(2+), positive(3+) to twenty laboratory technicians working in different health facilities of TB laboratories: to assess the microscopic reading ability of laboratory technicians, 2(10%) of the laboratory technicians from private medium TB laboratories committed error as false negative. This reading was from positive (trace) slide (1-9 AFB/100 Fields).

This finding was found to be higher than the nationally accepted discordant rate of 5%.The difference might be explained in terms of small number of laboratory technicians were assessed and lack of training in private medium clinic TB laboratories.

According to the national guideline for quality assurance of smear microscopy for TB diagnosis in Ethiopia, panel testing was used as a measure of individual performance in reading AFB microscopy (9)

According to the National Laboratory EQA of Ethiopia, panel testing of AFB slide serve as a process of effective and systematic monitoring of the performance of bench work in the tuberculosis laboratory against established limits of acceptable test performance. It ensures that the information generated by the laboratory is accurate, reliable and reproducible and serves as a

mechanism by which tuberculosis laboratories can validate the competency of their diagnostic services (9).

The quality of patients rescored was very poor in that thirty three (13.9%) of the initial AFB result was not recorded and twenty (7.4%) of patient's sex and twelve (4.5%) age of the patients were not recorded. This was smaller than the finding from Afar region in which 26.8% of patient's records was incomplete. This difference might be in terms of the data in this study was only from the laboratory record book and infrastructure difference. This finding was totally opposed the national TLCP manual of Ethiopia, which strongly recommends, TB laboratory results had to be recorded daily and reported quarterly(4,17).

Laboratory Supervisors should assess the quality, review the specimen request forms, laboratory register, and reporting of the laboratory results for completeness, consistency and credibility (8)

Majority of the patients who had got complete information on sputum sample collection were more satisfied than who were not and similarly patients who were greeted politely and had got respect during TB laboratory visit were more satisfied than those not greeted politely and had got respect (9, 23).

In this finding the emotional response of patients is found to be as important as their cognitive judgment of the laboratory service used. Satisfaction with care also related to communication, responsiveness & reliability as well as having expectations met (24).

Patients are the best source of information about health facility TB laboratory diagnosis and they are the only source of information about whether they were served with dignity and respect. Their experiences often reveal how well TB laboratories are operating and can stimulate important insights into the kinds of changes that are needed to close the gap between the laboratory diagnosis provided and the laboratory service that should be provided (24). In this study, patients satisfaction with utilization of TB laboratory is defined as the patient's opinion of the service received from TB laboratory and is acknowledged as an output indicator of the quality TB laboratory diagnosis.

Logistic regression analysis among the three Quality parameters for TB laboratory diagnosis was done . The quality parameter indicated that there was a statistically significant association between the structural qualities (training of lab. Technicians) and process quality parameters i.e. display and follow smear preparation procedure (OR 2.9(1.46-5.7; P=0.01) and also significant association between process quality parameter (display and follow smear preparation procedure)

and output quality parameter (OR 3.2(3.13-10; P=0.02). However, there was no a statistically significant association between structure quality and output quality (patient satisfaction) (P >0.05). So focusing on structural quality like staff training on TB laboratory diagnosis and measures to improve process quality parameters like displaying and follow smear preparation procedures of TB should be considered.

6.1 Strengths of the Study

- Data were collected from all the three components of the program i.e. structure, process and output (triangulation methods were employed to collect data)
- Combination of different data collection techniques were used
- Carefully designed questionnaires and pre-tested data collection tools were used for data collection

6.2 Limitations of the study

- Existing TB record books from private TB laboratories were poor.
- Lack of similar study done
- As it was cross-sectional study, difficult to establish cause-effect relationship or difficult to generalize the exact causes for the poor qualities of the TB laboratory diagnosis.

6.1 CONCULUSION AND RECOMMENDATION

Currently available TB laboratory refreshment trainings, most designed for use in the public sector, but not adapted to meet the needs of most private TB laboratory providers. Poor supervision mechanisms in both the public and private TB laboratories and lack of regular quality assessment of laboratory technicians in private TB laboratories were the most common problems for producing AFB results of good quality. Also a single 'spot' sputum sample collection, incomplete instruction and lack of checking the quality of sputum sample collection, high discordant rate in reading AFB results by the laboratory technicians and poor quality of AFB records or lack of reporting AFB results were the main problems encountered TB laboratories in Oromia Region. In addition lack of patients respect and lack of appropriate information were the main concern for the patients' dissatisfaction which can lead to service rejection.

Therefore, we recommend to the concerned stakeholders on the following main points:

- Service Providers

  - The quality of laboratory services in TB control programs is important given that the diagnosis and treatment of the disease is entirely dependent upon the laboratory investigations. For this success there should be appropriate sputum sample collection method, regular quality assessment and functional laboratory set-up with quality diagnostic services and microscopist.

  - Accurate record-keeping and reporting of AFB laboratory results were an essential for the proper management of TB control programme strategy. So TB laboratory record books should be complete and the responsible body should report AFB results, analyze the reports and act upon them accordingly before forwarding to the Government health department office.
  - Greater emphasis should be given to those areas where patient dissatisfaction was observed like: discouraging and not giving complete information to patients during sputum sample collection.

- Regional TB Co-ordiators

    - Outdated knowledge and skills must be updated to current evidence-based information through training which was adapted to meet the needs of PPM-DOT laboratory diagnosis.

    - There should be regular supervision mechanisms and feedback should be sent back.

    - There should be regular quality assessment and functional laboratory set-up with quality diagnostic services and microscopist.

    - Further study should be made.

REFERENCES

1. Guideline for the Prevention of Tuberculosis in health care settings in resource limited settings World Health Organization, Geneva 2000;WHO/TB/99,269-270
2. World Health Organization; Global Epidemiological TB report : 2009,1-2
3. World Health Organization News: Bulletin of the WHO. 2007; 83(3): 168-169
4. Federal Minstry of Health : Tuberculosis, Leprosy and TB/HIV Prevention and Control Programme manual.4th ed. Addis Ababa: Ethiopia, 2008:135-137
5. Federal Minstry of Health: Planning and programming Department, Health and Health Related Indicators. Addis Ababa: Ethiopia, 2007/8
6. Oromia Regional Health Bureau, Annual performance report. Addis Ababa,Ethiopia,2007/8:27-28
7. Federal Ministry of Health of Ethiopia, Private Public Mix-DOTS Implementation Guidelines. Addis Ababa: Ethiopia, 2006:7
8. Private Sector Partnership, USAID-From the American People, Expanding TB Services to the Private Health Sector in Ethiopia ,2009,10-11
9. Federal Minstry of Health: Guidelines for quality assurance of smear microscopy for Tuberculosis diagnosis. Addis Ababa: Ethiopia, 2009,(1),23-30
10. Performance Measurement in Health care. Baldrigeplus,2003 ,115-116
11. World Health Organization; TB laboratory Assessment Tool; 2002, 3rd edition. 2-11
12. Donabedian A. An Introduction to Quality Assurance in Health Care. Oxford: Oxford University Press; 1988
13. Shargie E,Ahmed M,Lindtjorn B. Quality control of sputum microscopic examinations for acid fast bacilli in southern Ethiopia. Ethiopian Journal of Health Development, 2005; 19(2):104-108
14. Oromia Referral & Research laboratory, External quality assessment report of AFB microscopy laboratories in government health institutions,2009
15. Amhara Regional research laboratory report of quality assessment of TB laboratory diagnosis in PPM-DOTS,Bahirdar:Ethiopia,2009
16. Ajaykumar T,Shyni S, Shijut S.Assesement of quality of sputum smear microscopy in India. P.NTI Bulletin, 2006; (42):74-94.

17. Federal Minstry of Health: Report on Evaluation of five-year program development plan, 1996-2001, TB and Leprosy control program ,2001; Addis Ababa, Ethiopia.

18. Girma A. Quality Assessment of Directly Observed Treatment Short-Course of Tuberculosis in Afar National Regional State.EPHA Masters extract5,2008:(5);19-25,
19. Mengiste M Mesfine, Tesfaye W Tasew and Madley Richard. The quality of Tb diagnosis in destrict of Tigray Region of Northern Ethiopia. Ethiopian Journal Health Development Journal. 2005; 19 (1-34) :12-20
20. Arah O, Westert GP,Hurst J,KlazingaA .Conceptual Framework for the OECD Health Care Quality Indicators. International Journal for Quality in Health Care, 2005,35-38
21. Beaufort B. Longest, Jonathan S, Rakich and Kurt Darr. Managing Health Service Organizations and Systems.3rd edition. Health professionals press, inc. 2003 ,Maryland,97-99
22. The Aga Khan Foundation. Assessing the Quality of Service & Primary Advancement Program Module 6.USA, 1993
23. Mengiste M Mesfine, Tesfaye W Tasew and Madley Richard. The quality of Tb diagnosis in destrict of Tigray Region of Northern Ethiopia. Ethiopian Journal Health Development Journal. 2005; 19 (1-34) :12-20
24. World Health Organization; Laboratory Services in Tuberculosis Control Organization and Management 1998;1 (1):21-22
25. Michael Oerlemans, Terry Mills and Jenni Ham, Measuring Patient Satisfaction, Last Updated by Bill Fawcett, 5 June 2004, Internet source.
26. Linder S. Social psychological determinants of patient satisfaction: test of five hypothesis. Soc. Sci. & Med; 1982; 16: 583-589.

10.Annex

10.1: Introduction to the Interviewer

Questionnaire to conduct Quality Assessment of Tuberculosis Laboratory Diagnosis in selected Health Facilities of Public & Private Laboratories in Oromia Regional State**.** At each of your visits, Please greet and make respondent at ease. Ensure as much Privacy of the respondent as possible. You can use a separate room or a quite place the respondent prefers. Then, notify to the respondent that this study will being carried on in the health facility TB laboratory, with the objective to make Quality assessment of public & Private TB in the context of structur,process and output quality assessment parameters. Read all the information in the informed consent.

After you discussed the necessary information and obtained his/her full consent, continue to complete the questionnaire. If the candidate refuses to participate in the study despite adequate discussion and explanation, fill your reason on your visit (response) status checklist format and go to the next facility. For each question, make a circle around the number that corresponds to the answer, fill the blanks with the answers, or put a figure (number) as appropriate. Carefully read and follow the instructions indicated in each part and for each questions, observations and record review

Informed consent

(Greetings) My name is Desalegn Ararso, final year student of Master of Public Health in Addis Ababa University. I am conducting Quality assessment of public & private TB laboratory diagnosis in selected health facilities in three zones of Oromia region, and your laboratory is one among the randomly selected health laboratories to be included in the study. (Show a letter of permission written from AAU and Oromia Regional Health Bureau).

The purpose of this study is Quality assessment of public & private TB laboratory diagnosis in selected health facilities of three zones of oromia region.

The questions are designed to assess the Quality assessment of public & private TB laboratory diagnosis observing using the questionarreie to assess the structural and process of public and private TB laboratories. The process and output quality parameters assessed by the record review and interviewing the TB patients on the level of satisfaction of the service.

We would like to assure your confidentiality of the data collected. We will not be referring to individual facilities in our report, but rather are looking at the overall picture for all Laboratories of the same type. The data collected won't be used for purposes other than what I mentioned

now. I expect the interview will take about 30 minutes with you, Your honest and genuine participation is highly appreciable and very important to attain the study objective. The information you will provide me is extremely important and valuable.

However, you and your staff have all the right not to answer to the interview. Refusal to participate or to answer any specific question will have no effect on benefits or services of the facility and interviewees.

Do you have any questions thus far?

May I proceed? 1. Yes, 2. No, thank you any way.

Addis Ababa University Faculty of Medicine, School of Public Health. Questionnaire prepared For Partial fulfillment of Master of Public Health (MPH) on Quality Assessment of Tuberculosis Laboratory Diagnosis in selected Health Facilities of Public & Private Laboratories in Oromia Regional State.

10.1 Part I: Questionnaire prepared to assess the structure of selected Tb laboratories in three zones of Oromia regional State.

Zone_____HealthfacilityName:_____Name of Laboratory Technician Collecting data_____ Date_____ ***May 2011***

S.No	Questions	Answers	Code
1	**TB laboratory staffing (Hospital, Health center, clinic)**		
1.1	Number of laboratory workers in the TB laboratory	1. Junior lab. Technician___ 2.Diploma_____ 3.B.Sc_____4.M.Sc_____	/---/
1.3	How long are you providing service in this facility?	_____Month(s)	/---/
1.4	Number of laboratory workers trained onTB laboratory diagnosis since 2 years.	1. One 2. Three 3. Two 4. Not at all.	/---/
1.5	If the above answer is yes, on which area is training given most?	1.Sputum sample collection 2.Training on reporting AFB results 3.slide keeping for blind rechecking	/----/
1.6	Staff takes part in regular quality assessment & and receives retraining as required.	1.yes 2.No	/---/
	Questionnaire to be filled by TB laboratory staff of the Oromia regional research center		
S.no	Question	Answers	Code
2.5	Research run by the regional TB quality officer	1.yes 2.No	/--/
3.3	Is there adequate % safe ventilation TB lab. Safety requires?	1.yes 2.No	/--/
3.4	What is the NTP approved disinfectant active against TB used in your laboratory?	1.Ether 2.Alcohol 3.NaOH	/--/
3.6	How do you dispose infected used materials like sputum containers?[Try to confirm]	1. By burning 2. By burning after disinfecting 3. By burial	/--/

4.0	Sputum Collection		
4.1	How many sputum specimen(s) is/are required to diagnose pulmonary TB?	1.One 2.Two 3.Three	/-/
4.2	Patient receive adequate instruction to produce sputum rather than saliva	1. Yes 2. No	/--/
4.3	Which Sputum specimens routinely collected for diagnosis, follow ups?	A.spot-Moring-spot B.moring-spot-morning C.moring-moring moring	/--/

Questionnaire to be completed by trained head laboratory staff in selected health facilities of public and private TB laboratories in Oromia region.May 2011

S.No	Questions	Answers	Code
4.5	Who is responsible for the collection of sputum sample?	1.Lab.technician 2.Nurse 3.Others_____	/---/
4.6	Is the quality of specimen checked visually?	1.Yes 2.No	/---/
4.7	Display and follow smear preparation, staining procedure & grading chart?check	1.Yes 2.No	/---/
4.8	NTP laboratory manual available? Check.	1.Yes 2.No	
4.9	How often are laboratories required to report on their performance?	1.Monthly 2.quarterly 3.By 6month or annually	/---/
4.10	to which authorities do you send your reports?	1.woreda health 2.Zonal bearu 3.Regional bearu 4.FMOH	/---/
4.11	Are there standard reporting forms?	1.Yes 2.No	/---/

Part II: Questionnaire prepared to assess the Process Quality of selected Tb laboratories in three zones of Oromia regional State, May 2011

Health facility Name: _____

S.No	Questions	Answers	Codes
5.1	Does NTP approved lab. Request forms are used for every patient	1.Yes 2.No	/---/
5.2	TB laboratory results entered to the registration book	1.On daily basis 2.In 2 days days 3.Weekly	/---/
5.3	What is the maximum number of days that all the 3 results sent back?	1.One day 2.Two days 3.Three day	/---/
7.0	Staining Procedures	1. smear-air dry-carbolfuschin-heat fix-methylene blue-acid alcohol. 2.smear-carbolfuschin-methylene blue-acid alcohol	/---/
5.4	What type of slides can be used for AFB	1.New slides 2.Re used slides 3-New slides with cover slide	/--/
5.5	Are AFB slides labeled with laboratory code	1.Yes 2.No	/--/
5.6	For how much time slides fixed under flame	1.for 1-2min 2.for 10min 3.for 3-5min.	/--/
5.8	How much fields of microscope would you see before reporting the AFB result of the patient	1)10 field 2)50 fields3)100 fields 4)Others____	/--/
5.9	How much time would it take for you to report the AFB result of the patient?	1. max. 1minute 2.max.2 minute 3.min.5 minute	/--/
5.10	Are your results consistent with NTP recommendations for grading and reporting	1.Yes 2.No 3.Other_____	/---/
5.11	Are control smears included during staining?	1.Yes 2.No	/---/
5.12	Are all slides kept as required by the NTP EQA programme	1.Yes 2.No	/---/

Part III: Record review of TB Laboratory AFB result of the selected health facilities of public & private laboratories in Oromia region. May 2011

S.No	Variable by Category	Number	percent
6.0	Sex of the patient .Male		

	.Female .Unrecorded		
6.1	Age group in years 0-4 5-14 15-54 55+ Unrecorded		
6.2	Initial diagnostic AFB tests done 1.yes 2.No 3. Unrecorded		
6.3	Initial diagnostic AFB result 1.Positive 2.Negative 3. Unrecorded		
6.4	Follow up AFB microscopy done on 2nd month of Rx. 1.Yes 2.No		
6.5	Result of 2nd month follow up AFB microscopy 1.Positive 2.Negative 3.Unrecorded		
6.6	Follow up AFB microscopy done on 5/7th month of Rx. 1.Yes 2.No		
6.7	Result of AFB microscopy done on 5/7 th month of Rx. 1.Positive 2.Negative 3.Unrecorded		
6.8	Completeness of information on Tb registry 1.Complete 2.Incomplete		
6.9	Positive AFB results written in red pen 1.Yes 2.No		

Part IV: Questionnaire prepared to assess TB client's satisfaction level in the laboratory diagnosis service in the selected Health Facilities of Oromia.May 2011

Name of the health facility_____

S. no	Questions	Response Categories	code
	General information		
7.0	Sex of the patient	1 Male___. 2 Female____	/---/
7.1	Age of the patient	__(in years& in months for children)	/---/
7.2	Marital Status	1. Single 3.Divorced2. Married 4. Widowed	/---/
7.3	Educational status	1. Illiterate 2. Read & Write 3. 1-6 grade 4) 6-12 grade 5) Above 12 grade	/---/
7.4	Religion	1. Orthodox Christians 2. Muslim 3.Protestant 4. Other (specify)_____	/---/
7.5	Occupation	1. Farmer 2. Gov't employee3. Merchant 4. Other (specify)	/---/
.67	Do you incur cost for your visit?	1. Yes 2. No-skip to next	/---/
7.7	If yes, for what purpose?	1. Transport 2. Food & Reception 3. Laboratory services 4. Other (specify)	/---/
7.8	Have you ever visited this Tb laboratory services before?	1. Yes 2. No	/---/
7.9	How long (minutes/ hours) does it normally take you to the Tb clinic?	1. 10-30min 2.30-60min 3.2hours 4.3-4hours	/---/
7.10	By what means you normally get to the Tb Laboratory?	1. Walking 3. Car 2. Camel 4. Other (specify)	/---/
	Organizational issues:		
8.0	After arriving at the Tb laboratory, how satisfied are you with the time spent waiting to receive your result?	1. Satisfied 2. Dissatisfied 3. Neutral/ I don't know.	/---/
8.1	About how long (hours) did you have to Wait?	_____ Days	/---/
	How satisfied are you with:		

8.2	The overall cleanliness of the waiting area?	1. Satisfied 2. Dissatisfied 3. Neutral/ I don't know.	/---/
8.3	The overall comfort of the waiting area?	1. Satisfied 2. Dissatisfied 3. Neutral/ I don't know.	/---/
8.4	The over cleanliness of the laboratory room/place where you received service?	1. Satisfied 2. Dissatisfied 3. Neutral/ I don't know.	/---/
8.5	Have you ever experienced shortage of reagents during your laboratory visit period?	1. Yes 2. No	/---/
	Interpersonal qualities of service provider:		
	How are satisfied with:		
8.6	The respect offered by the provider during your visit?	1. Satisfied 2. Dissatisfied 3. Neutral/ I don't know	/---/
8.7	The measures taken to assure privacy during your laboratory examination?	1. Satisfied 2. Dissatisfied 3. Neutral/ I don't know	/---/
	Professional competence and skill of the Health workers**:**		
	How are satisfied with:		
8.8	The completeness of the information given to you about sputum sample collection?	1. Satisfied 2. Dissatisfied 3. Neutral/ I don't know.	/---/
8.9	How satisfied are you with the cost you incur during your laboratory diagnosis?	1. Satisfied 2. Dissatisfied 3. Neutral/ I don't know.	/---/

10.2: Curriculum Vitae

1. Personal information

- NAME:Desalegn Ararso
- Birth date 17/1/75 E.C
- Place of Birth:Wollega
- Nationality: Ethiopian
- Marital Status: Married
- Religion: Christian

2. Qualifications

- Diploma in Medical laboratory Technician from previous Gonder College of Health sciences in 1990 E.C
- B.Sc in Medical Laboratory Technology from Jimma University 1998

3. Work experiences

- Laboratory technician in Chiro Hospital ,West Harerghe zone 1990-1995
- Laboratory school instructor in Shashemene Health Science College 1999-2002

Referances

- Ato Worku Dugasa;Dean of Shashemene Health Science College

  09-11-99-16-47
- Ato Efrem Raga:V/Dean of Shashemene Health Science College

10.3: Sampling Method of TB laboratories

First selecting 30% of TB laboratories of different categories from each three Zones of Oromia Regional state by the rule of thumbs (21), then TB laboratories of different kinds in both public and private health facilities have been selected by simple random sampling. Accordingly 21 health facility TB laboratories were selected from East Shoa Zone (8 medium clinic TB laboratories,7 health center TB laboratories , 3 hospital TB laboratories ,1 higher TB laboratory and 1 regional laboratory) ,19 health facility TB laboratories from West Arsi Zone (5 medium clinic TB laboratories ,11 health center TB laboratories ,2 hospital TB laboratories and 1 higher TB laboratory) and 20 health facility TB laboratories from Arsi Zone (8 medium TB laboratories , 11 health center TB laboratories and 1 hospital TB laboratory). All hospitals and higher clinic TB laboratories were included, since they were few in number.

10.3.1 Sampling Method of

- **TB patients and**
- **Record review**

TB patients record review and interviewing of TB patients were done by distributing the sample size of N_1=334 for record review and N2 = 384 for interview of patients , proportionally in to 60 health facilities based on the number of TB patients recorded and the number of TB patients visiting these TB laboratories in one day. The sampling interval for TB laboratory record review was 5. Then the first patient record was selected randomly and the others by systematic random sampling every 5^{th} of the patients records followed and TB patients were interviewed based on the availability of the patient on the day of interview.

On average 10, 3, 2, and 1 patients were visited hospital TB laboratory, Health center TB laboratory, higher clinic laboratory and medium clinic laboratory respectively after checking pilot study.

So based on the proportion of patients recorded on the daily bases and the number of patients visiting of different public and private TB laboratories ,the N1=334 were divided proportionally in to different TB laboratories and N2=384 also divided in to all TB laboratories included in the the study. Generally 208,62,42 and 22 patients record were reviewed from hospitals, health centers, higher clinics and medium clinic TB laboratories respectively.

Also 240, 72, 48 and 24 patients were interviewed from hospitals, health centers, higher clinics and medium clinic TB laboratories respectively.

10.4 List of Tb laboratory Materials and reagents

1. Microscope- Binocular
-Electrical/Daylight
2. Xylene (toluene)
3. Immersion oil with a dropper
4. Sputum cups
5. Glove
6. Cotton wool swab
7. Cotton/gauze
8. Pen-blue/red
9. Slides
10. Slide holder
11. Wire loop/Wooden applicator
12. Bunsen burner/Spiral Lamp Burner
13. Forceps for holding slide and fixing
14. Staining reagent
15. Filter paper and glass flasks
16. Slide rack for staining
17. Basin if their is no Sink
18. Water filter can with a tap if no running water
19. Alarm clock
20. Waste receptacle (metal with lid)
21. Box for keeping examined slides
22. Bucket for water
23. Disinfectant-5% phenol or 10% sodium hypo chloride.

10.5 : DECLARATION

I, the under signed ,declared that this thesis is my original work, and has not been presented for a degree in any other university and that all source of material used for this thesis and all people and institution that gave support for this have been duly acknowledged.

Name: Desalegn Ararso

Signature_____

Place: Addis Ababa

Date of Submission_____

This Thesis work has been submitted with my approval as university Advisor.

Advisor's Name Signature

Dr Ababi Zergaw