

Assessing the Quality of Tuberculosis Laboratory Services in Selected Public and Private Health Facilities in Western Amhara, Ethiopia

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Abstract

Introduction: Quality of TB laboratory services in both public and private health facilities is a mandatory component in detecting active pulmonary TB cases and treatment follow-up. Even though it is one of the key components of DOTs strategy, a very low TB detection rate (36%) in Ethiopia and 37.5 % in Amhara Region was observed. The quality of TB laboratory services was very low (6.8%) in Ethiopia.

Methodology: Institutional based cross sectional study was conducted among 60 randomly selected public and private TB laboratories in Western Amhara, Ethiopia. Data were collected by interviewing 120 laboratory personnel and 384 TB suspected patients, reviewing 270 patient records and panel testing among 20 laboratories. Data entered in to computer via Epi Info version 3.5.4 for editing and analysed using SPSS version 19. Findings at 95% Confidence interval and p value < 0.05 were considered as statistical significant.

Results: The presence of quality laboratory services in the study areas was reported by 53.0% of the study participants. Supportive supervision and timely feedback, internal and external quality assurance practices, equity in training and resource distribution were issues given less attention in the study areas. Poor documentation from record reviewing and about 10% false negative discordant report on panel testing were observed. Shortage and unfair distribution of inputs can compromise service quality by 79% and 76% (OR=0.21, CI=0.08-0.57 and OR=0.24, CI=0.07-0.81) respectively. Patient's age, sex, religion, residence & educational status were none significant on TB laboratory services satisfaction. Farmers were 2.25 [1.26-4.05] times satisfied on TB laboratory services than their counter parts.

Conclusion: About 53.2% patients reported the presence of quality TB laboratory services. Documentation and microscopic diagnosis or reading problems were observed from record reviewing and panel testing. Equity in inputs, training access, standard operational procedures, supervision, quality control activities, informing patients and checking sputum quality were most important determinants to improve the quality of TB laboratory services.

Keywords: TB; Quality assessment; Quality assurance; Patient satisfaction; TB laboratories; Quality control

Abbreviations

AFB: Acid Fast Bacilli; BSc: Bachelor of Science; DOTs: Direct Observed therapy of treatment; EQA: External Quality Assurance; FMOH: Federal Ministry of Health; HIV/AIDS: Human Immune Deficiency Virus/ Acquired Immune Deficiency Syndrome; Lab: Laboratory; NGOs: None Governmental Organizations; NTP: National TB Programme; QC: Quality Control; SOPs: Standard Operating Procedures; TB: Tubercle Bacillus; WHO: World Health Organization

Introduction

Background

Tuberculosis (TB) is one of the world's leading cause of infectious disease morbidity and mortality. It affects all age, sex and human body parts [1,2]. According to World Health Organization's (WHO) 2010 estimation, there were 8.5-9.2 million new cases and 1.2-1.5 million deaths including deaths from TB among HIV-positive people [2-5]. Every untreated smear positive TB patient can infect 10 - 15 persons per year. Identifying and following-up of those infectious patients is the primary objective of TB control strategy [1].

In Africa, at least one third of the population is already infected with Mycobacterium Tuberculosis [4]. Over 1.6 million people developed active tuberculosis each year in relation to Poverty, HIV/AIDS and poor health status [4-5]. Even though TB incidence is falling or stable among five out of six WHO regions, the incidence keeps increasing at almost 10% per year in Africa [4-6].

The estimated incidence, smear positive cases and prevalence of all forms of TB in Ethiopia in 2009 were 163/100,000, 284/100,000 and 585/100,000 population respectively [3,7]. A very low detection rate (36.0%) in Ethiopia [8] and 37.5 % in Amhara Region [9] implies that significant proportions of TB patients were not getting the service as stated by National TB control Programme [7].

Currently, federal ministry of health gave greater attention to TB detection and treatment services in both governmental and private health sectors in order to achieve millennium development goals [4,10]. Formerly, the role of private health sectors was limited to the diagnosis of TB and referring them to the public health facilities for treatment, but now, the majority have gotten permission from government to provide all the services including treatment (DOTs) freely with supportive supervision and accessing supplies/imputes [5,11].

One of the backbone components in TB controlling programme is the presence of uninterrupted quality laboratory services for the

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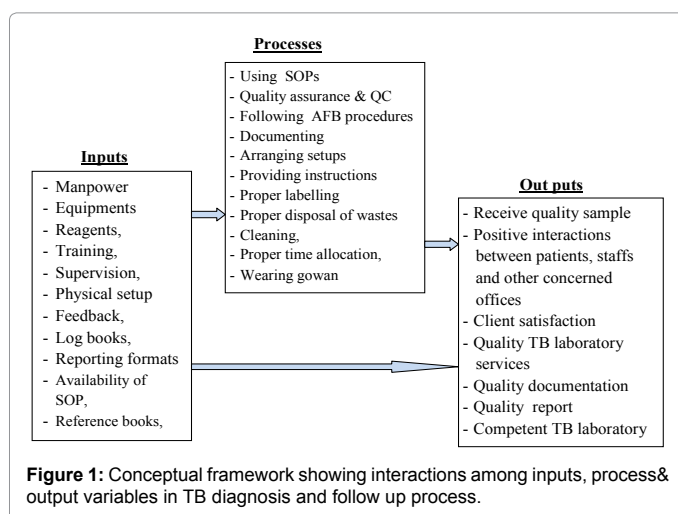
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detection and follow-up of the treatment [7]. The golden standard method of active pulmonary TB detection mechanism in poor countries, where there is no access to culture is microscopy [9-11]. Errors during diagnosis, reading and recording of results will lead in missing real infective cases and miss treatment that will result in unnecessary complications on patients and spreading of the case to the community [11-14].

Even though quality laboratory services are mandatory for active pulmonary TB detection and monitoring purposes, it is not well studied and no adequate policy recommendations were given in Ethiopia, particularly in the study areas [15-17]. Therefore, knowing level of quality of TB laboratory services and major determinants interms of inputs, processes and output variables in selected zones was the primary objectives of this study (Figure1).



Methods

Institutional based cross-sectional descriptive study design was conducted using standardized questionnaire, record reviewing and panel testing techniques to assess the overall quality of TB laboratory services in both public and private health facilities in three selected zones of Western Amhara Region, Ethiopia from 1st October/2012 to 20th April / 2013. The study was conducted among 60 randomly selected health facility TB laboratories in east Gojjam, West Gojjam and Awe zones. The selected zones are woina-dega in climate and agriculture is the major income source for more than 90% of their population. East Gojjam zone has two public hospitals, more than 95 health centres, about 345 health posts, 5 higher clinics, 25 medium clinics, and 5 medium diagnostic laboratories. West Gojjam zone has 01 public hospital, 90 health centres, 337 health posts, 01 private hospital, 03 higher clinics, 18 medium clinics and 07 small laboratory diagnostics, whereas Awi zone has 75 health centres, 290 health posts, 04 higher clinics, 19 medium clinics and 08 small diagnostics laboratories [18].

Number of laboratory technicians in each governmental health facilities across three zones was adequate as compared to national TB guide line derived from WHO guide line [19]. The guideline stated that there should be at least 6, 11, 2, 4 and 2 laboratory personnel in district hospitals, zonal hospitals, health centres, higher and medium clinics respectively.

Sample size determination for health facility TB laboratories was done based on a suggested rule of Thumb [20]. According to this rule, if number of units/facilities is large (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.

There were about 200 (70 from east Gojjam, 67 from West Gojjam & 63 from Awi) private and public health facilities having DOTs program in the study area. Based on the above rule, the maximum sample size of health facilities in the study area was 30% of the total number of health facility since 200 is within 100-500. Therefore, 30% of 200 became sixty health facilities having TB laboratories. About 21 TB laboratories from east Gojjam, 20 from west Gojjam and 19 from Awe zone were selected proportionally. Then, sixty TB laboratories were selected randomly from the three zones.

Thirty public (3 hospitals & 27 health centres) and thirty private clinics (1 hospital, 12 higher and 18 medium clinics) were involved in the study. All hospitals and higher clinics were included in the study purposively since their number is few. All laboratory technicians working at TB laboratories during the study period (120) were included in the study since their number is small.

The objective of record reviewing in this study was to evaluate the overall quality of TB laboratory services. When we say there is a quality TB laboratory service, there should be appropriate information provision, handling, processing, examining, recording and reporting of results. Quality processing and examination activities will not have meaning unless there is quality documentation. Single proportion formula for the finite population N was applied to determine sample size for record reviewing:

$$N = \frac{Za^2p(1-p)}{d^2}$$

Where, p=proportion of quality of TB documents' and it is 6.8% taken from study conducted in Tigray [21], which is highest prevalent and directly related to this study. P=6.8% means, 6.8 % of TB patients' documents were not properly recorded before treatment in the study area.

d=3%, the precision or maximum tolerated error in this study and 95% confidence level was considered to calculate Za2 by assuming the distribution of documents is normal. Based on the above givens, the sample size for records became 270 new and follows up records. The size for each site was determined proportionally and selected randomly. Therefore, 169 patients' records from hospitals, 50 patients' records from health centres, 34 patients' records from higher clinics and 17 patients' records from medium clinics were reviewed.

In the case of TB patient interview, the purpose of interviewing patients was to assess their satisfaction on information given on sampling, respectation, timely result dispatch, quality of laboratory results and showing the concerned departments after result dispatch for the next services. To say a patient is satisfied, he/she should answer 2/3 or 5 and above out of 7 satisfaction/quality related questions (Table 3). Single proportion formula was also applied by considering proportion p=0.5 since no similar study was done concerning TB patients interview to assess TB Laboratory quality; d=0.5 and CI=95%. Then, 384 patients (240 from hospitals, 72 from health centres, 48 from higher clinics and 24 from medium clinics) who visited TB laboratories were selected for interview. Sample for each facility was determined proportionally and selected randomly.

For the case of AFB panel slide preparation and testing, five slides (2 negative, one <10 acid fast bacilli, one +1 and one +2) from known sample were prepared by the principal investigator with the consultation of quality officers of Amhara regional laboratory office as AFB panel

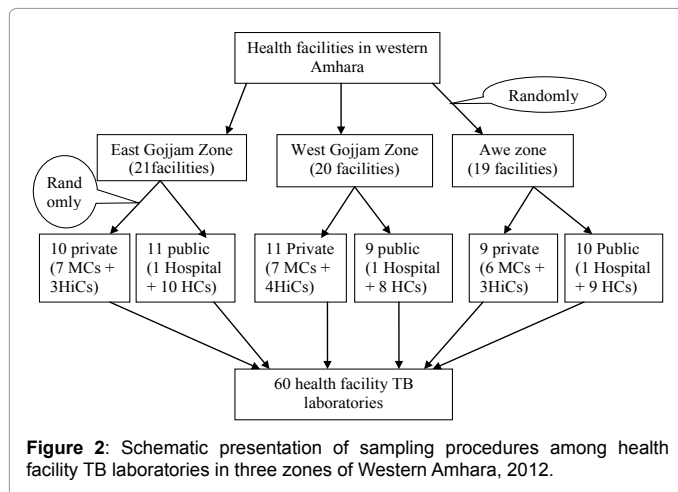


Figure 2: Schematic presentation of sampling procedures among health facility TB laboratories in three zones of Western Amhara, 2012.

testing slides and dispatched to test the quality of laboratory technicians among 20(10 private & 10 public) randomly selected TB laboratories. Due to the presence of resource shortage (slides & reagents), we selected only 20 laboratories for panel testing (Figure 2).

Data were collected using pre tested structured questionnaire which was prepared after reviewing relevant literatures regarding to TB laboratory quality. Four laboratory technicians and two supervisors having MSc in medical laboratory were participated in data collection process. The questionnaire was pre-tested among TB patients and laboratory technicians of health facilities having similar setups. One day training was given to data collectors and supervisors prior to data collection date. Data were checked for its completeness, accuracy and consistency by supervisors and investigator daily.

Manually edited data entered in to computer for editing and analysis using data entry template created on Epi Info version 3.5.4. The edited data were exported in to SPSS version 19 for farther editing and analysis. Frequencies, proportion and summary statistics were used to describe the study population in relation to relevant variables. Binary logistic regression was done to see the impact of each studied variable on an outcome variable. Those variables having impact on an outcome variable were further confirmed with multivariate logistic regression analysis. Findings at P-value of ≤ 0.05 and confidence interval of 95% were considered as statistically significant. Then, findings were presented using text, tables and figures accordingly.

Ethical clearance

Ethical clearance for this study was taken from Amhara Regional Health Bureau before starting the actual research. Letter of acceptance was obtained from East Gojjam zone, West Gojjam zone and Awe Zone Health offices after explaining the objective of the study. Verbal consent was also obtained from heads of each public and private health institutions who were involved in the study. Interviewed patients were informed well before data collection date. Maximum care was done to keep the confidentiality of collected data.

Results

TB laboratory technicians and structural characteristics

The response rate for TB laboratories, patient interviews and laboratory personnel was 100%. From 120 laboratory personnel in the study area (73 public & 47 private), 78 (65.0%) were diploma, 40 (33.3%) were BSc and 2 (1.7%) were MSc holders. The majority of

laboratory personnel were within the age group of 25-35 years and the mean SD age was 28 ± 5 years. Slightly more than half; 35 (58.3%) TB laboratories were integrated structurally and functionally with National TB Program (NTP). The rest 25 (42.0%) TB laboratories had system separated structurally, but functionally integrated with reporting NTP. From above 25 TB laboratories, majority (76%) were from private clinics. Almost all TB laboratories, 59 (98.3%) reported as they perform smear microscopy.

The majority, 110 (92.0 %) of both private and public laboratory personnel examined ≤ 20 slides per day. Ninety (75.0%) of laboratory personnel had taken training related to TB case detection at least once. From those who took training, majority (80.0%) were from public health facilities. Almost all, 38 private laboratory technicians reported as they did not get regular supportive supervision and feedback from governmental health offices. This problem was also a problem for the majority of public health facilities. More than half, 80 (67.0%) laboratory personnel from public and private reported the presence of unfair distribution of reagents, trainings, reporting formats, registration books, manuals, equipments and incentives among health institutions, especially in private clinics and in some public health centres. Thirty laboratory technicians considered shortage of reagents and equipments as major determinants to the quality of TB laboratory services (Table 1).

Quality assessment

A majority, 40 (66.7%) of both public and private TB laboratories did not have Standard Operating Procedures (SOPs) for AFB diagnosis, but 45 (75.0%) of them had NTP approved laboratory manual. About 40 (66.7%) of laboratories posted AFB staining procedures in their working areas. Adequate instructions how to bring representative samples were given to the patients by the majority, 54 (90.0%) of TB laboratories in the study area. Practice of checking quality of sputum before processing was done in about 27 public & 12 private TB laboratories.

Only 27 (45.0%) TB laboratories run quality control smears while performing routine AFB staining. From studied private health institutions, only one TB laboratory from hospital had a habit of running quality control smears parallel to routine staining activities (Table 1).

Of 60 TB laboratories, 32 (53.3%) were participated in external quality assurance (EQA) activities. From the above figure, only one hospital and 2 higher clinics were from private. Thirty-four (57.0%) of TB laboratories had been supervised before one year. In regarding to AFB panel testing, the majority (90.0%) performed correctly, but 2 laboratory technicians from private medium clinics reported slides of trace positive as negative. The majority of TB laboratories (75.0%) gave adequate information to their patients on sputum sample collection and time required to dispatch the result. Most of the public laboratories had assigned responsible laboratory personnel for running tasks and accessing requirements in TB laboratories. Of 60 studied laboratories, only 40 (27 public & 13 private) had separated and equipped rooms for TB diagnosis (Table 1).

Table 1: Association between input, process & structural variables and improvement on quality of TB laboratory services in three Zones of Western Amhara Region, Ethiopia, 2012.

Variables	Improved lab. Quality		COR (95%CI)	AOR (95%CI)
	Yes (%)	No (%)		
Took training on TB diagnosis at least once:				
Yes	67(55.8%)	23(19.2%)	3.81[1.48 -9.91]	4.00[1.61-9.97]
No	13(10.8%)	17(14.2%)	1	1

Supportive supervision & timely feedback:				
Yes	24(20%)	20(16.7%)	3.36[1.43 -7.95]	2.53[1.23-5.92]
No	20(16.7%)	56(46.6%)	1	1
Having separated TB rooms:				
Yes	55(45.8%)	25(20.8%)	2.69[1.15 -6.35]	2.15[1.05-4.12]
No	18(15.0%)	22(18.4%)	1	1
Participated in quality assurance activities:				
Yes	44(36.6%)	20(16.7%)	3.40[1.50 -7.77]	2.92[1.25-5.84]
No	22 (18.4%)	34(28.3%)	1	1
Running QC slides parallel with routine tasks:				
Yes	37(30.8%)	17(14.2%)	2.31[1.02 -5.26]	2.10[1.01-3.95]
No	32(26.7%)	34(28.3%)	1	1
Having SOPs & standard manuals:				
Yes	32(26.7%)	10(8.30%)	3.37[1.36 -8.51]	2.50[1.22-6.32]
No	38(31.7%)	40(33.3%)	1	1
Shortage of reagents, equipment:				
Yes	9(7.5%)	21(17.5%)	0.21[0.08 -0.57]	0.17[0.05-0.45]
No	60(50%)	30(25.0%)	1	1
Information Provision on sputum collection:				
Yes	88(73.3%)	20(16.7%)	4.40[1.11-17.6]	2.85[1.08-11.5]
No	6 (5%)	6(5.0%)	1	1
Patient respect/proper handling :				
Yes	55(45.9%)	40(33.3%)	1.27[0.48 -3.35]	1.18[0.22-2.43]
No	13(10.8%)	12(10.0%)	1	1
Impartiality & patient guiding				
Yes	68(56.7%)	37(30.8%)	1.23[0.35 -4.16]	1.31[0.5- 5.95]
No	9 (7.5%)	6(5.0%)	1	1
Unfair distribution of inputs :				
Yes	6(5.0%)	74(61.7%)	0.24[0.07 -0.81]	0.19[0.05-0.62]
No	10(8.3%)	30(25.0%)	1	1
Posting staining procedures in working place :				
Yes	61(50.8%)	21(17.5%)	3.99[1.65 -9.80]	3.68[1.59-8.73]
No	16(13.4%)	22(18.3%)	1	1
Checking quality of sputum:				
Yes	58(48.3%)	20(16.7%)	3.19[1.35 -7.61]	3.72[2.01-9.42]
No	20(16.7%)	22(18.3%)	1	1
Assigning responsible lab. Technician				
Yes	30(25.0%)	22(18.3%)	3.27[1.44 -7.52]	2.14[1.18-5.66]
No	20(16.7%)	48(40%)	1	1

* **NB.** Results shown with red are statistically significant at $p < 0.05$.

Record reviewing

Of the total 270 follow up and new TB records, 136 (50.4%) were males and 20 (7.4%) & 12 (4.4%) were incomplete for sex and age categories respectively. About 113 (42.0%) had age between 35-44 years. About 119 (31.0%), 198 (73.3%) and 135 (35.0%) were illiterate, Orthodox and farmers respectively. Thirty-three (14.0%) patients were recorded on TB registration book without AFB examination results. About 60 (22.2%) of records did not have patient addressee and contact persons. Fifty-one records were lacking registration date, year and signature of laboratory technicians who reported that result. In the case of positive results, no any indicator to identify weather the cases are new or follow up. Some of the records were poorly handled and difficult to read (Table 2).

Table 2: Record reviewing results in three zones of Western Amhara Region, Ethiopia, 2012.

Variables	Number	Percent (%)
Patients' age from record reviewing (n=270):		
≤ 24 years	17	6.3
25- 34 years	80	29.6
35-44years	113	41.9

>44 years	48	17.8
Sex of patients (n=270):		
Male	136	50.4
Female	134	49.6
Religion (n=27 0):		
Orthodox	198	73.3
Muslims	52	19.3
Others	20	7.4
Educational status (n=270):		
Literate	119	44.1
Illiterate	151	55.9
Patients category (270):		
Employed	55	20.3
Farmers	135	50
Merchants	80	29.7
Patients' age record (270):		
Complete	258	95.6
Incomplete	12	4.4
Patients' sex record (n=270):		
Complete	250	92.6
In complete	20	7.4
Patients' result record (n=270):		
With result	237	87.8
Without result	33	12.2
Patients' address & contact person (n=270):		
Complete	210	77.8
Incomplete	60	22.2
Recording date, year & signature (n=270):		
Presence	219	81.1
Absence	51	19.9

Patient interviewing

About 384 randomly selected patients coming to TB laboratories to get TB related services were interviewed using structured questionnaire. Among the study participants, 204 (53.1%) were >32 years with the mean SD age of 32 ± 4 years and 201(52.35%) were females. One hundred seventy (44.3%), 153 (39.84%) and 130 (35.2%) were illiterate, Muslims and farmers respectively. From the total respondents, majority (69.0%) were from rural areas and more than 120 (31.2%) were from private health institutions (Table 3).

About 45.0% of patients preferred private TB laboratories for the reasons of timely services and respect given. More than half, 57.0% study participants had received TB laboratory services timely. Study participants were also asked whether they got adequate information on sputum sample collection and about 259 (62.45%) of them reported as they got adequate information before sample collection. More than half, 239 (62.24%) patients had given respect or proper patient handling services from TB laboratory technicians. About two-third, 254 (66.0%) patients were satisfied on service providers' impartiality, counselling and guidance to get additional services (Table 3).

Binary regression analysis for overall patients' satisfaction on TB laboratory services versus certain Socio-demographic variables showed that occupation, facility type, time, information provision, patient respect, impartiality & guidance, overall quality and service interruption showed significant association with patient satisfaction. Farmers were more satisfied on TB laboratory services compared to none farmers (OR=2.25, CI=1.26-4.05). About 212 (55.2%) patients

were 1.97 [1.06-3.69] times satisfied with governmental TB laboratory services compared to their counter parts. Their mentioned reasons were presence of improved quality (53.2%), confidentiality (85.0%), resource availability (90.0%) and relatively uninterrupted services (46.6%) compared with private clinics. Around 219 patients were satisfied with timely services compared to the rest groups (OR=3.54, CI=2.54-5.89) (Table 3).

The majority, 204 and 254 respondents were satisfied in overall TB laboratory services and service impartiality with good guidance given compared to their counterparts (OR=1.73, CI=1.13-2.65 & OR=3.19, CI=1.99-5.13) respectively. Patients who said there was absence of service interruption were more satisfied with the current service than those who said there was service interruption (OR=2.06, CI=1.22-3.47). However, sex, age, religion, residence and educational status were none

significant variables for patients' satisfaction on TB laboratory services in the study area (Table 3).

Based on the binary logistic regression analysis for certain structural and process parameters versus overall laboratory personnel' insights on TB laboratory service quality improvement; training, participating on quality assurance, supportive supervision, timely feedback, having separated TB rooms, running QC slides parallel to routine tasks, having SOPs and information provision on sputum collection were significant variables to increase TB laboratory services (Table 1).

Laboratory personnel who took training perceived as training would increase the quality by 3.81 [CI=1.48-9.91] times than those who did not take it. They also said that supportive supervision with timely feedback and participating in quality assurance activities could improve quality of TB laboratory services (OR=3.36, CI=1.437.95 and OR=3.40,

Table 3: Associations between socio demographic, process & output variables and patient satisfaction in three Zones of Western Amhara Region, Ethiopia, 2012 (n=384).

Variables	Patients' satisfaction		COR (95%CI)	AOR (95%CI)
	Yes	No		
Age :				
≤ 32 years	140(36.5%)	40(10.4%)	1.42[0.87 – 2.33]	1.21[0.34-2.11]
>32 years	145(37.8%)	59(15.3%)	1	1
Sex :				
Male	170(44.3%)	13(3.4%)	1.53[0.70 – 3.34]	1.82[0.53-4.21]
Female	180(46.9%)	21(5.4%)	1	1
Educational status:				
Literate	110(28.4%)	104(27.1%)	0.44[0.28 - 0.69]	0.28[0.15-0.47]
Illiterate	120(31.4%)	50(13.1%)	1	1
Religious:				
Christians	180(46.9%)	51(13.2%)	0.62[0.35 – 1.11]	0.74[0.43-2.13]
Muslims	130(33.9%)	23(6.0%)	1	1
Residence:				
Rural	170(44.3%)	84(21.8%)	1.45[0.90- 2.32]	1.16[0.32-2.05]
Urban	70(18.2%)	50(13.0%)	1	1
Occupation:				
Farmers	115(30.0%)	20(5.2%)	2.25[1.26 - 4.05]	1.85[1.18-3.45]
None farmers	179(46.6%)	70(18.2)	1	1
Types of services:				
Public	190(49.5%)	22(5.7%)	1.97[1.06 – 3.69]	1.42[1.02-2.54]
Private	140(36.5%)	32(8.3%)	1	1
Good timely services:				
Yes	185(48.1%)	34(8.9%)	3.54[2.54 - 5.89]	2.23[2.19-3.57]
No	100(26.0%)	65(17.0%)	1	1
Information obtained on sputum collection:				
Yes	124(32.3%)	135(35.2%)	2.36[1.45 – 3.84]	1.55[1.28-2.95]
No	35(9.1%)	90(23.4%)	1	1
Respection from providers:				
Yes	123(32.0%)	116(30.2%)	2.78[1.75 – 4.45]	2.02[1.58-3.86]
No	40(10.4%)	105(27.4%)	1	1
Service impartiality & guidance:				
Yes	149(38.8%)	105(27.4%)	3.19[1.99 – 5.13]	3.24[2.52-5.95]
No	40(10.4%)	90(23.4%)	1	1
Overall quality of lab services:				
Improved	115(30.0%)	89(23.2%)	1.73[1.13 – 2.65]	1.56[1.09-2.52]
Not improved	77(20.0%)	103(26.8)	1	1
Service interruption:				
Absence	100(26.0%)	79(20.6%)	2.06[1.22 – 3.47]	1.48[1.12-2.99]
Presence	40(10.4%)	65(17.0%)	1	1

*NB. Results shown with red are statistically significant at p < 0.05.

CI=1.50-7.77) respectively than their counter parts. Shortage of reagents and unfair distribution of inputs can compromise the quality by 79.0% and 76.0% (OR=0.21, CI=0.08-0.57 and OR=0.24, CI=0.07-0.81) respectively (Table 1).

Discussion

Laboratories have a central role in controlling the spread of TB epidemics worldwide [12]. Nearly all, 92.0% of laboratories performed ≤ 20 AFB slides/ about 8 patients per day. According to WHO and national TB program manual which allowed a minimum of 15 slides per day [12,14], this result is relatively acceptable. The most probable reasons for this may be low patient screening at OPD level, shortage of inputs like slide, reagent, manpower and low-suspected patients flow. When we examined laboratory personnel proportion in private and public facilities, it was below the standard [10,19] in private clinics. This may be due to presence of low recruitment habits, poor follow up from government and monthly salary related issues.

Regarding to training access, only 90 (75.0%) of laboratory technicians took training at least once. From this figure, only 10 were from private which is unfair and opposite to national guideline and supported with study from Tigray region [10-12,20]. This may be due to less attention given to professional development in private clinics from private owners, government and NGOs. In the case of frequent follow up and timely feedback activities, which is vital for quality improvement in TB services [21-23], almost all (38) private clinics did not practice it. It was also a problem for most public health facilities. Study findings from Ethiopia national TB survey [24], Amhara, Afar and Tigray Regions [16-17,21] also support it. The probable reasons could be less attention given, giving primary emphasis for collecting reports, transportation and limited manpower with limited knowledge.

In the case of basic inputs distribution, more than 80 laboratory personnel mentioned the presence of unfair distribution of inputs (reagents, equipments, training, manuals, registration books, sputum caps...) across health facilities, especially in private clinics. This result was in line with study findings from WHO report, Amhara, Afar, and Oromia region [6,16-17,25].

A majority, 108 laboratory personnel informed their patients how to bring sputum sample, which was supported by FMOH guideline, studies from Addis Ababa & Oxford University [7,12,15].

Forty two (35.0%) and sixty eight (56.7%) laboratory personnel did not check sputum quality before receiving and assigning responsible lab technician only for TB laboratory duties respectively. It was highly different from the latest WHO manual [23] and the national AFB microscopy laboratory manual [7]. Assigning responsible body in TB laboratory is highly recommended by WHO to be responsible and accountable for everything concerning TB.

Checking sputum quality before receiving is vital to change/accept the sample. If laboratory technicians process none representative samples, they will miss active cases and at the same time they will waste their time & resources. Possible reasons for this might be high patient flow & over load, giving less attention to quality and limited manpower.

Around 80 laboratory respondents reported as they had separated TB laboratory rooms which is highly recommended by WHO [1]. The reason for having separated TB laboratory from main laboratory is to prevent TB transmission, increase its quality and increase confidentiality. Since TB is a major public health problem, its diagnostic process must be done in maximum quality not miss infectious cases.

Based on this, 64, 54, 42 and 82 laboratory personnel participated on External quality assurance, internal quality control activities, preparing SOPs and posting staining procedures in working place respectively to validate their reagents, equipments and personal skills. These figures are very low as compared to WHO [1,14,23] and FMOH [12] guidelines. It is also lower /poor compared to study findings from Oxford University [22], southern Ethiopia and Oromia regional research centre [15,25]. This might be due to less attention to QC, reagent shortage, skill gaps, daily workload, limited manpower and poor supportive supervision & timely feedback.

Regarding patients' record reviewing (N=270); 12 (4.4%), 20 (7.4%), 33 (12.2%), 60 (22.2%) and 51(19.9%) patient records were incomplete for age, sex, AFB result, address and date/year respectively (Table 2). This issue is critical and higher figure compared to WHO [23] and TLCP guidelines [7,24], which stated that "recording daily and reporting each activity when needed is mandatory for every laboratory personnel." It was also higher compared to study findings from Amhara and Oromia regions [16,25], but slightly smaller than findings from Afar region [17] where 26.8% of patients' records were incomplete. The possible reasons for the above higher figure might be workload of laboratory personnel, absence of supervision and feedback, poor habit of reporting and less attention to data quality.

Based on the findings from bivariate & multivariate logistic regression analysis (Table1) of laboratory personnel perceptions, training, supervision, participating in EQA & QC activities, having SOPs, informing patients on sample collection, & checking sputum quality before processing were found significant variables for improving TB laboratory services. This finding was supported by WHO [23] & Ethiopian TLCP [7] guidelines, study from Amhara, Afar, Tigray, Oxford University, Oromia regions and India, [16,17,21,22,25,26].

Regarding to patients' satisfaction (Table 3), farmers were 2.25 [1.26-4.05] times more satisfied/ answer 2/3 of 7 satisfaction related questions on quality of TB laboratory services than none farmers. Reasons for this may be the presence of impartiality, good guidance and respectation given to patients. Over 212 (55.2%) patients were 1.97 [1.06-3.69] times more satisfied with governmental TB laboratory services compared to their counter parts. This result was supported by binary regression results obtained from laboratory personnel's perception of this study. Based on overall results of this study and reality, the most probable reasons may be the presence of relatively poor quality, confidentiality, resource availability, poor supportive supervision and feedback and service continuation in private clinics. More than half of the patients, 57.0% and 53.2% were also 3.54 [2.54-5.89] and 1.73 [1.13-2.65] times more satisfied on timely services and overall quality improvement than their respective groups respectively. Even though the figure is lower, it is slightly in line with study findings from Amhara, Oromia regions & India, [16,25,26].

Conclusion

According to this study, variations in laboratory personnel proportion, service quality, inputs and training access, service continuity, patient satisfaction, confidentiality, quality control activities and infrastructures were identified between governmental and private health institutions. Even though slight improvements in TB laboratory quality, patient handling, information access, documentation, service interruption, inputs availability and training access were reported by respondents, it is very low compared to national standards, millennium development goals and other study findings. Results of

this study also showed that there were clear gaps in communication, supportive supervision, timely feedback, equity in accessing inputs and on job trainings and conducting operational research. Poor quality of documentation, confidentiality and reporting were observed from record reviewing. The most determinants of TB laboratory services quality in the study area could generally be grouped as governmental, service providers/technical, patients, organizational and resource related.

Strong communication, supportive supervision, timely feedback and equity in inputs and training access from governmental and other responsible bodies in both public and private health institutions are important to increase TB laboratory quality. Researchers should also explore effective ways of increasing quality of TB laboratory services in the study area, other regions and at national level to do policy recommendations at large.

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