Addis Ababa University

College of Health Sciences

School of Clinical Laboratory Science

Assessing the outcome of Strengthening Laboratory Management Towards Accreditation (SLMTA) on laboratory quality management system in city government of Addis Ababa.

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Approved by the Examining Board

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Acronyms and Abbreviations

AA	Addis Ababa
AAHRL	Addis Ababa Health Research & Laboratory
ASM	American Society for Microbiology
ASCP	American Society for Clinical Pathology
BPR	Business processing reengineering
CAP	College of American Pathologists
CLSI	Clinical and Laboratory Standard Institute
COHSASA	Council for Health service Accreditation of Southern Africa
EHNRI	Ethiopia Health Nutrition Research Institute
EQA	External Quality Assessment
IQC	Internal Quality Control
ISO	International organization for standardizations
JCAHO	Joint Commission on Accreditation of Healthcare
JCI	Joint Commission International
KLAP	Korean Laboratory Accreditation program
KSLM	Korean Society of Laboratory medicine
LAP	Laboratory Accreditation Program
LQMS	Laboratory Quality Management System
MOH	Ministry of Health
NGOs	Non Governmental Organizations
NSL	Nefas Silk Lafto
PPS	proportional probability Sampling
SANAS	South African National Accreditation System
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SPSS	Stastical Package for Social Science
USA	United States of America
WHO	World Health Organization
WHO AFRO	World Health Organization Regional Office for Africa

SUMMARY

Background; Medical laboratory services are an essential component of health systems. Strengthening these services can combat the major infectious diseases**.** Laboratory accreditation system is found to be essential to have national and international acceptance of various laboratory test results. Poor quality laboratory services guide to massive cause of over-treatment, overuse of drugs which leads to the emergence of drug resistant and laboratory errors guide the patients at risk of inappropriate care and potentially of adverse events .By recognizing this gaps of the current state of laboratories and the requirements of ISO 15189 particular requirements for quality and competence in Africa, Ethiopia, in 2009, WHO-AFRO established SLMTA in order to help laboratories with stepwise recognition of evolving fulfillment of the ISO 15189 standard instead of a grading of pass-fail.

Objectives: To assess the outcome of Strengthening Laboratory Management Towards Accreditation (SLMTA) on laboratory quality management system in Addis Ababa.

Methods: The study used an Institutional based cross sectional study design that employed a retrospective and prospective data collection approach on the participated institution of medical laboratory in SLMTA in Addis Ababa city government. The study was conducted in Addis Ababa city government and the data was collected from February –April 2014 and data was interred in to EPI-data version 3.1 and was analyzed by SPSS version 20.

Results; The assessment finding indicate that there was a significant improvement in average scores (141.4; range of 65-196, 95%CI =86.275-115.5, p = 0.000) at final with 3 laboratories become 3 star, 6 laboratories were at 2 star, 11 were at 1 star .76% of the respondents respond that their facilities have no work plan and budget for laboratory specific purpose and lack of resources accounts 24% is the reason for this which is followed by absence of System. Laboratory facilities which get adequate and timely manner mentorship were found 2.5 times more likely to get good success in the final status of improvement project (AOR= 2.501, 95% CI= 1.109-4.602) than which did not get it and those laboratory which didn't perform their customer satisfaction survey were 2.261 times more likely to get less final result than laboratory which are conducting their customer satisfaction survey (AOR= 2.261, 95% CI= 1.851-6.007).

Conclusion: At the end of SLMTA 3 laboratories become 3 star, 6 laboratories were at 2 star, 11 were at 1 star .The most important contributing factor for not scoring star in the final outcome

of SLMTA were not conducting their customer satisfaction survey, shortage of resource, poor staff motivation, and lack of regular equipment service maintenance. Mentorship, onsite and offsite coaching and training activities had shown that a great improvement on laboratory quality management system in most district laboratories.

Keywords:-SLMTA, WHO-AFRO, Mentorship, Accreditation.

1. Introduction

1.1 Background of the study

Medical laboratory services are an essential component of health systems. Strengthening these services can combat the major infectious diseases **(1).**Thus there is a need for increased direct investment in laboratory services to avoid compromising patient care **(2**).This also include quality management system to maintain and continuously improvement on the quality of laboratory processes **(3**).Accreditation is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks, it is an autonomous process **(4)**.

Accredited clinical laboratory is standard laboratory processes are in place and the effectiveness of the overall process is checked and acknowledged by external assessors or organization **(5**).

Accreditation provides a way whereby a laboratory may meet international standards and provide assurance to the patients that the laboratory is providing high quality results **(6).** Quality system is about people, for people with people. Accreditation provides verification that laboratories are adhering to established quality and competence standards deemed necessary for accurate and reliable patient testing and staff safety **(7).**

As parts of the quality assurance system accreditation is extremely beneficial in supporting an achievable and efficient health-care system and it is an emerging as a preferred framework for building quality medical laboratory systems in limited resource settings. Laboratory service with higher quality ,related with accreditation is expected to improve patient care by advancing the accuracy of medical decision making and reducing the frequency of laboratory errors and this have a positive effect on other health care system**(8)**.

In Ethiopia, EHNRI Polio laboratory (by WHO), international clinical laboratories (ICL)(by JCI) and AAHRL,ALERT,Hema Dx laboratory, and Medical Biotech laboratories (by ENAO) are the laboratories accredited internationally**(9,10)**

1.2 Statement of the problem

Laboratory accreditation system is important for the acceptance of test results nationally and internationally. All medical services need reliable laboratory support for taking proper action,

formulating policies and making decisions **(11**).Poor quality laboratory services guide to massive unnecessary expense in human lives and inability to determine the correct episode of disease; and these may cause over-treatment, overuse of drugs which leads to the emergence of drug resistant **(12**).In USA study indicates that 6% to 12% of laboratory errors guide the patients at risk of inappropriate care and potentially of adverse events, and from 26% to 30% of errors have a negative impact on other aspects of patient care **(13)**.

By recognizing this gaps of the current state of laboratories and the requirements of ISO 15189 particular requirements for quality and competence in Africa, Ethiopia., in 2009, WHO-AFRO established Stepwise Laboratory Quality Improvement Process, Strengthening Laboratory management Towards Accreditation (SLMTA) in order to help laboratories with stepwise recognition of evolving fulfillment of the ISO 15189 standard instead a grading system of pass-fail (14). This model is not proposed to replace the established ISO 15189 accreditation process, rather to provide an interim pathway for monitoring, measuring and recognizing improvement toward the realization of international laboratory standards and subsequent application to full ISO 15189 accreditation system(15).SLMTA is a task-based curriculum which helps countries in the training of laboratory managers to implement the quality management system requirements of the WHO–AFRO–SLIPTA process, by the aim of giving way them international accreditation ultimately**(16).**The WHO-AFRO accreditation program create a framework to establish an effective quality management system for medical laboratory testing.

Following assessment, laboratories will be recognized on a 0 to 5-star ascending scale. Laboratories will not be awarded a star ranking score below 55% points. After assessment, laboratories are expected to maintain their star status and work toward the next star **(17**).

Moreover, SLMTA is a new practice and in process of development in our country. Therefore there is a gap in knowledge and availability of data, thus an urgent need to strengthen data and to make accessible evidence based information to the professional and the community is the cornerstone of this study.

1.3 Rationale and significance

After the launching of WHO-AFRO Stepwise Laboratory Accreditation Process in Ethiopia 2009, from the laboratories selected for accreditation program Addis Ababa Health research and Laboratory were the only lab score four star based on WHO AFRO assessment checklist (November 2011) up from a baseline of 0-star**(18)**.

After this the health bureau heads and officials of Addis Ababa city government take a direction to cascade this program to the health institutions (Hospitals and health centers). At base line, laboratories were at the SLMTA zero star rating, all the 31 laboratories assessed and were found below 1 Star-level (minimum for 1 Star: 55% of Standard), measured based on the WHO-AFRO checklist from this one could infer that there might be more problems with maintaining laboratory quality management system in the capital city of Ethiopia, Addis Ababa.

Literatures recommend that future study is crucial for further investigation to improve laboratory quality management system (6,15) and this study was intended to assess the outcome and factor affecting or challenges of SLMTA in city government of Addis Ababa after Mentorship & couching and to gives some pictorial display on the current status of medical laboratory services. For giving useful baseline information to policy and decision makers, program managers for all efforts that will be made to improve laboratory quality in future. Moreover; it will be an entry point or base line data for further study in this subject matter.

2. Literature review

2.1. Accreditation and WHO approach

Different literatures states that SLMTA is an alternative training approach in laboratory management and quality management systems aimed at producing measurable improvement and preparing laboratories for accreditation **(6, 15**).

Accreditation officially started by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in 1951 in USA ,reached in Australia & Canada in 1960 and 1970s and in 1990s this program extend to all over the world. After World War II by increasing world trade in manufactured goods led to an introduction of the International Standards Organization (ISO) in 1947**(19).**

Higher quality laboratory service related with accreditation is expected to improve patient care by advancing the accuracy of medical decision making and reducing the frequency of laboratory errors and this have a positive spillover effect on other health care systems**(20**).The Strengthening Laboratory Management towards Accreditation (SLMTA)is a laboratory management frame work prescribing managerial job tasks, the starting point of the hands on activities based curriculum and begins with base line assessment with checklist and put into operation with multiple workshop, training, coaching and mentoring b/n each improvement project. The program equipped laboratory professional to improve their laboratory by using existing resources and support laboratory by improving managements and building preparedness for accreditation. To assess the effectiveness, the WHO Regional Office for Africa /WHOAFRO/ developed and adopted the lab accreditation checklist for developing countries (**21**).

*2.*2. Outcome of accreditation

A quasi-experimental design study was conducted to determine the impact of a management training program in Mexico, Colombia, and El Salvador on health managers' job performance, where in the baseline study an intervention group of 85 district health managers in the 3 countries was compared with a control group of 71 managers who did not receive the training program. After an 18-month of implementation training program (which included 5-day training workshops and a series of tasks to be carried out between the workshops), the job performance improvement (i.e. use of predefined management techniques) was measured through twelve management indicators. The control group showed 8.3, 3.6 and 2.4times weaker management

performance compared to the intervention group in Mexico; in Colombia and in El Salvador respectively **(22)**.

A longitudinal study was conducted in Australia on 23 hospitals for more than 2 years to observe their response to accreditation requirements and the general changes through accreditation in the hospital's environment were monitored and the result indicates that an improvement in the structure of nursing organization, medical staff organization, and physical facilities and safety(**23)**.

In another study conducted in Copenhagen on 51 units (13 anesthetic &38 surgical) to assess the effects of accreditation, significantly more accredited units had guidelines in place compared to non-accredited units and the improvement on the Systematic Development Scale was significantly higher than in non-accredited units **(24**).

A randomized controlled trial on 20 selected public hospitals in the South African. 10 of these hospitals were randomized to the accreditation program in 1998 and the other 10 used as controls. After accreditation began with in 2 years; intervention hospitals significantly improved their average compliance with Council for Health Services Accreditation of Southern Africa (COHSASA) accreditation standards from 38% to 76%, but no considerable increase was observed in the control hospitals from 37%-38% **(25**).

A study conducted on impact of accreditation , and the results were accreditation was associated with significant improvement in compliance with standards in the overall scores, and in 7 out of 13 important functional areas in a large investigation of the Zambia Hospital Accreditation Program (n=79 hospitals) (**26**).

A study conducted at Rwanda to determine the baseline quality of laboratory services at the sites using the WHO-AFRO checklist, to help sites to identify gaps that needs to be addressed to meet the requirements for accreditation and to help the laboratories in mounting quality improvement project ,the accreditation process of the 5 satellite laboratories has been begin in November 2011,The results were improved from the baseline assessment (average score of 37.6 %) to second assessment (average score of 66.92 %).One Laboratory has 3 stars (Nyagatare), one has two stars, (Gihundwe) and other 3 hospital laboratories score 1 star (Byumba, Kibungo, Gisenyi).The study team recommend that the Continuous Training on SLMTA and Mentorship is

important for those district hospital Laboratories being participated in the process of accreditation to sustain what they archived and improve on weaknesses ***(27).***

A study conducted in Burkina Faso national center for research and Training on Malaria to see the impact of SLMTA on Quality Management System to comply with international standard requirements. In 5 laboratories an internal audit was conducted using the WHO stepwise SLMTA checklist and was organized through the twelve quality system essentials from the WHO checklist, filling the gap. The laboratories have reached 3 or 4 stars after 1 year implementation of the quality system, starting from 0 stars according to WHO classification **(28).**

An initial assessment was conducted on 5 public hospitals in August 2011 in Kenya for the SLMTA program and the end term assessment conducted after one year later. The results were during the initial assessment, four of the five laboratories scored Zero SLIPTA star rating while one laboratory scored 3 Stars. After addressing the nonconformities identified from the initial assessment, two laboratories improved from zero to three stars, one laboratory improved from (Díaz-Monsalve 2004)three to four stars while the remaining two laboratories improved from zero to one star. The average percentage improvement was 25% with the best improved lab having improved by 46%. There was remarkable progress particularly in the two labs that improved from zero to three stars, even if there was no statistically significant difference (p=1.439) in the average scores between the initial (120.8) and the end term (182.8) assessment result. Laboratory that achieved poorly did not address the gaps identified from the initial assessment **(29).**

Similar Study conducted at Lesotho to determine the improvement of the quality of testing services in public laboratories by implementing of two mentorship at eight laboratories from June 2009 to December 2010 after a series of two mentoring and coaching conducted at four and six week of initial and follow up. Quality improvements were measured at baseline and at intervals during the mentorship using the WHO-AFRO Strengthening Laboratory Quality Improvement Process towards Accreditation (SLIPTA) checklist and scoring system. At the base line all laboratories were at the SLIPTA zero star rating and After the initial six weeks of mentorship, two of the three district laboratories had improved from zero to one (out of five) star even though the gaps between their baseline (107.7) and the end of the six weeks (136.3) average scores was not statistically significant(p=0.25).After mentorship there was a significant

improvement in average scores (182.3; p = 0.034) with one laboratory achieving WHO-AFRO three out of a possible five star status and the two remaining laboratories achieving a two star status **(30**).

2.3. Challenges on the ways Towards Accreditation

A study done in Thailand showed that factors that influenced laboratories' readiness for quality improvement are shortage of staff, lack of knowledge, shortage of budget and poor staff commitment to the program**(31**).

The major determinate factors for providing quality laboratory services in developing countries were shortage of trained and skilled personnel; lack of equipment maintenance, poor supply-chain management systems, lack management commitment, shortage of laboratory standards poor infrastructure, inadequate supply of electricity and water (**32**).

Study in the Korean Laboratory Accreditation Program (KLAP) by the Korean Society of Laboratory Medicine (KSLM) by analyzing and summarized history and achievement of KLAP for 8 yr data (1999-2006) trends of the laboratories, and scores according to the impact of the question to the outcome of the tests. And the accredited laboratories was increased 2.4 times in 2006 (n=227) than in 1999 (n=96) and the average accreditation rate was 99.6% during these periods and the 2-yr accreditation rate was 32.4% in 2000, 45.6% in 2001, 53.3% in 2002, 47.3% in 2003, 68.5% in 2004, 37.7% in 2005, and 47.7% in 2006. Finally the study sum up efforts for improvement of quality control and inspector training workshops appeared to be in the main determinate factors (**33**).

Wertheim and colleagues analyzed the major challenges of developing effective laboratory capacity in resource limited setting, including lack of infrastructure, failure to create and/or implement national laboratory policies, weak national regulatory and laboratory networks system, weak procurement and supply systems, variable quality of laboratory performance due to lack of standardization and quality standards, lack of equipment maintenance, and the inability to follow manufacturers' recommendations to ensure proper operational capacity of laboratory instruments (***34***).

Study done in Libya in order to identifies the factors which affect the establishment of accreditation program in industrial laboratories indicates that commitment of top management, organizational effort, lack of knowledge and skill or expertise and expenses are the main

determinate factories for implementation of quality program (***35***).Shortage of staff is the main determinate factors of errors and longer turnaround times ***(36***).

Similarly in Kenya point out minimized wastage of laboratory supplies and reagents and other unnecessary cost and efforts in laboratory by put into action of quality standards based on accreditation requirements. The wastage of laboratory reagents and supplies were a considerable drop off from the time of base line to final assessment by increased competency and effective inventory system and sample rejection was also decreased from 4.5% to less than 1% (***37***).

3. OBJECTIVES

3.1 General Objective:

To assess the outcome of Strengthening Laboratory Management Towards Accreditation (SLMTA) on laboratory quality management system in Addis Ababa.

3.2 Specific objectives:

To describe the outcome of Strengthening Laboratory Management Towards Accreditation with base line assessment.

To identify factors associated with the outcome of SLMTA.

4. Methodology

4.1 Study Setting

This study was conducted in Addis Ababa, Ethiopia. Located at the heart of the country with the area of about 540 square kilo meters, it is the biggest city in the country and a chartered city having three layers of government namely, city government at the top, 10 sub cities in the middle and 116 woreda, hosting population of 2, 854, 462, (**38**).It has 34% primary health coverage and 100% geographical health coverage, there are 6 regional, 2 NGO-supported, 30 private,5 federal, 1 defense ,1 prison and 1police hospitals laboratories; 70 (currently functional) public and 4 NGO-supported health centers laboratories, 7 public, 500 private and 31 NGO supported clinics laboratories (**39**).

SLMTA were implemented on Thirty one health facility laboratories (6 Hospital and 25 health centers), among them 29 facility laboratories were eligible for this study by using exclusion /inclusion criteria ,4 hospital laboratory and 25 district health center laboratory namely Zewuditu memorial hospital, Ghandi Memorial hospital ,Yekatit12 Hospital , Tirunesh bejing hospital and 25 public Health center laboratory,namely, Addis Ketema ,Meshualekia ,N/S/Lafto W-09,Kotebe ,Kirkos ,Entoto No. 1 ,Kality,w-7 ,T/Haimanot ,Arada ,N/S/Lafto W-03 ,Bole 17/20 ,Semen ,Kolfe ,Kolfekeranio w-09 ,Saris ,Kebena ,Selam, Akaki ,W-17, Beltshachew, Kazanchis ,Yeka ,Lideta ,Shiromeda health centers which are found under city government of Addis Ababa and have been providing the clinical laboratory service for the People of the city and surrounding areas were assessed their status of the Quality System Essential before and after implementation of SLMTA at each Laboratory Facility by (based on) WHOAFRO SLIPTA checklist

4.2 Study period and design

The study used an Institutional based cross sectional study design that employed a retrospective and prospective data collection approach on the participated institution of medical laboratory in Strengthening Laboratory Management Towards Accreditation (SLMTA) in city government of Addis Ababa. The study was conducted at Addis Ababa, Ethiopia and the data was collected from February-April 2014.

4.3 Source population

All health institution laboratories which is found in city government of Addis Ababa, Ethiopia.

4.4 study population.

The study population of this study was all the participated institutional medical laboratories in Strengthening Laboratory Management Towards Accreditation (SLMTA) program on laboratory quality management system which are located in Addis Ababa city government.

4.5 Inclusion and Exclusion Criteria

The participated institutional medical laboratory in Strengthening Laboratories Management Towards Accreditation (SLMTA) program having base line and final assessment result/data was included in this study while, the institutional medical laboratory which is not participated in Strengthening Laboratories Management Towards Accreditation (SLMTA) program, participated laboratory having insufficient data and who are not willing to participate in the study, Laboratory professional who are not at there during SLMTA program & Professional who have less than one year service experience were excluded.

4.6 Sample size

All the participated institutional medical laboratory facilities in SLMTA program which full fill the Inclusion Criteria was included in this study and the sample size of the study participant for questioner respondent was 144.

4.7 Sampling Procedure

4.7.1 Purposive sampling technique was applied for the secondary data and the study was conducted on all the participated institutional medical laboratories in Strengthening Laboratory Management Towards Accreditation (SLMTA) program which full fill the Inclusion Criteria.

4.7.2 The respondents of the questioner was selected based on the following sample size determination and the respondents, the laboratory department head and the quality officer was selected by purposively and the rest was based on simple random sampling by the data collector. The sample size of the study participant for questioner respond and aiming to point out the determinate factors for the outcome of SLMTA was determined by using single population proportion formula by considering: because of the absence of previous study take p=50 % Level of significance = 0.05 Marginal of error (d) = 5%

Sample size = n Z (a/2) = Z-score at 95% confidence interval = 1.96

The formula for calculating the sample size (n) was:

$$n = \frac{Z_{\alpha/2}{}^2 P(1-P)}{d^2} \; ; \qquad n = \frac{1.96^2 \times 0.5 \times 0.5}{0.05^2} = 384$$

Based on the profile of the health institution laboratory professional, there are 6 laboratories professional in the health center and 18 laboratory professional in the hospital based on BPR. In Addis Ababa there were 25 health centers and 6 government hospitals participated in SLMTA program. In each of the health centers there are six laboratories professional where as there are 18 professionals in the hospitals which account a total 108 of 258 laboratory professionals. Since the calculated sample size is greater than the total population, correction factor was done based on the finite population formula (nf), therefore the sample size was reduced to;

$$nf = \frac{n}{1+n/N}, nf = 154$$

After adding 10% for missing non response, the sample size will be 154 + 15 = 169, but because of exclusion criteria the sample, respondents become 144.

4.8 Data collection and Quality control method

The data source for the study was the results of base line & final assessment and questioner survey of the participated institution of medical laboratories on Strengthening Laboratory Management Towards Accreditation (SLMTA) program in Addis Ababa city government. In order to collect this information a standardized data extraction form (modified WHO AFRO SLMTA checklist) or instrument was prepared in English language (annex 1) and the form was contained baseline data and all the 12 quality system essential. A pretested questioner (anex2) was used to collect the factors associated with the outcome of SLMTA and this questioner is prepared by reviewing different literatures. A one day intensive training was given for supervisor and Data collectors .Before utilizing these tools a pretesting was done at Minillik II Hospital and NSL woreda 06 Health Center prior to the actual data collection period. Instructions on how to the tools was made clearly at the data collection form. The principal investigator and the supervisor were supervising closely to follow the day-to-day data collection process and ensure completeness and consistency and incomplete and inconsistent data identified, the necessary corrections was made.

4.9 Data collectors and supervisors

One day intensive training was given for supervisor and Data collectors. The supervisor was a laboratory professional with a BSC degree Holder having greater than five years work experience in clinical laboratory service and having Laboratory Quality Management training and SLMTA training certificate and the two data collectors are laboratory professionals with work experience greater than three years and having hands on experience in data collection.

4.10 Operational Definitions

1. Accreditation-procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.
2. Outcome -The 'end' that is being sought by a program, organization, policy or other intervention, an end result, which is the Star level.
3. Quality-degree to which a set of inherent characteristics fulfils requirements.

4.11 Study Variables

4.11.1 Dependent variables

The star level of outcome of SLMTA

4.11.2 Factors/independent variables

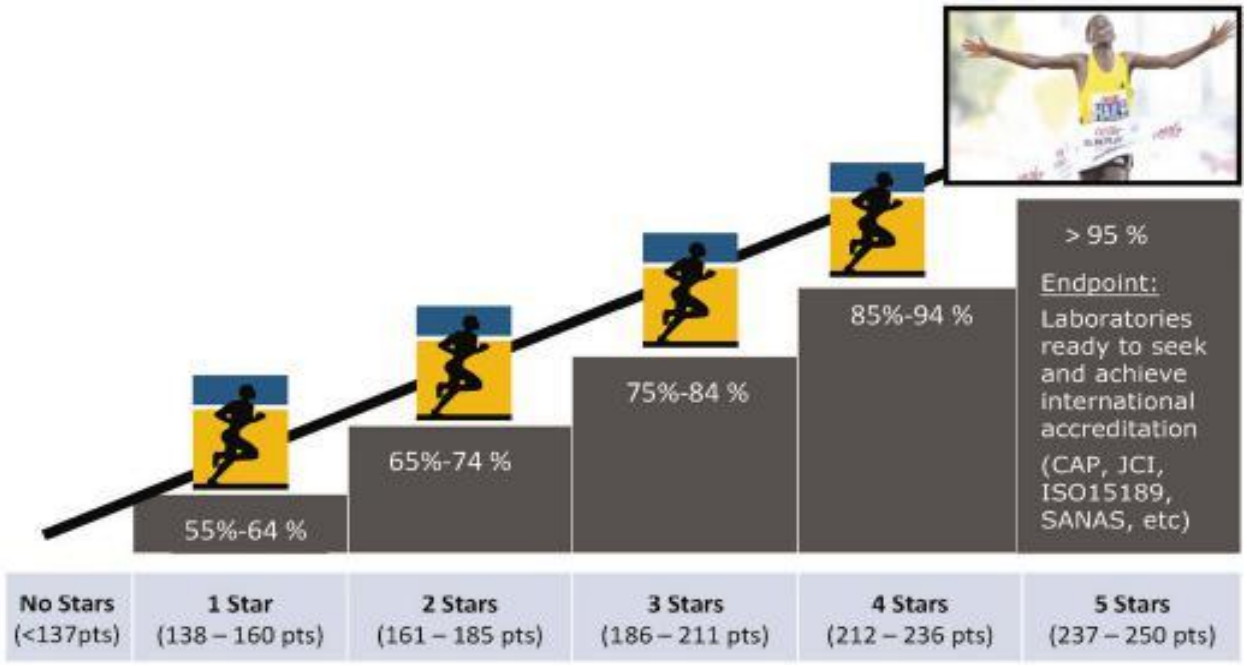
- Work load
- Management Commitment
- Staff motivation
- Training
- Number of staffs
- Laboratory equipments

4.12 Data Management

Data was entered by the principal investigator (PI) using EPI-Data version 3.1. Data quality was check by the PI, supervisor and data collectors. Before doing the analysis, the entire data was cross checked for reliability and completeness on the collected hard copy data and soft copy of the entered data.

4.13 Data Analysis procedures

Data was exported and analysis performed using SPSS (version 20). Descriptive statistics including counts, percentage, means and standard deviations was calculated. The SLMTA Checklist has 12 sections which provide assessment on the basis of 110 clauses and 250 total possible points. Each item has been assigned a weighted value of 2, 3, or 5 points based on complexity and/or relative importance. Incomplete fulfillment of an item can be scored as "partial" and awarded a single point, with written explanation (13).



Adapted from original graphic by Guy-Michel et.al

Figure 1 WHO/AFRO Accreditation Staring rate

At the end of the improvement project the laboratories were assessed to see the significance change on Laboratory Quality management system. After the training and mentorship by using similar checklist with baseline assessment done i.e. the WHO-AFRO SLMTA checklist (2010),which is based on the ISO 15189:2007(E) standard and the CLSI guideline GP26-A, quantitatively measures adherence to accreditation requirements for quality and competency, was

used to collect and measure improvement performance and the final improvement project assessment was conducted using the external assessors (who were not participating as the mentors), who were trained as Technical assessor by Ethiopian National Accreditation Office (ENAO), made all measurements in order to avoid biased

Paired T-test was done to compare the mean of the baseline and final assessment and Logistic regression models was used to examine factors which are associated with the outcome of SLMTA on Laboratory quality management and to see the association b/n the variables by using Odds Ratio (OR) with a 95% Confidence Interval (CI). P-Value less than 0.05 was considered as statistically Significant. Variables with a statistically significant association ($p<0.05$) at univariate logistic analysis were entered and analyzed by multiple logistic regression analysis to control the confounding variables.

Based on the checklist the minimum score for the star level is 138 (55%) points of the standard, based on the final scores of 12 quality system essential elements were transformed the data in to two groups which is those laboratories which scored 138 (55%) and above as good status (assigned as 1) and those laboratories which scored 137(< 55%) points and less as poor status (assigned as 0).

4.14 Ethical consideration

Ethical clearance was obtained from the ethical committee of the Addis Ababa university, school of Clinical laboratory science, An official letter of cooperation was also collected from the university to the study sites and the Permission was also obtained from the AA Regional Health Bureau, The information that was collected by the study were stored in a file, without mentioning the name of the study site (institution), but a code number was assigned to it. Such information's was not be revealed to anyone except the principal investigator and was kept locked with key.

4.15 Dissemination of results

Final result of this paper will be given to Addis Ababa University, school of Clinical Laboratory science. The results of this paper will be also disseminated to all /relevant bodies/stakeholders including the AA Regional health Bureau, AAHRL and NGOs working on the study subject matter in the area and will reached to the community through Publishing and peer reviewed journals and by Presenting in scientific conference.

5. Results

5.1 Laboratories Baseline and final assessment results

In this study ,29 health institution laboratory were participated which full fill the inclusion criteria, among them 20 were health center and 4 were hospitals ,the detail was illustrated in table 1.

Table 1. Characteristics of health institution which are participated in the study .Addis Ababa, 2014

	Health institution with star		Health institution without star	
	Number of Health center	Number of Hospital	Number of Health center	Number of Hospital
	17	3	8	1

Record review was done on the baseline and final assessment of SLMTA on 29 health Laboratory and the reviewed data indicate that the base line score of these 29 laboratory facilities ranges from 23 (9.2%) to 85 (34%) and indicate that all 29 laboratory facilities were in zero star level .

The assessment finding indicate that there was a significant improvement in average scores, this proved to be true using paired T-test (141.4; range of 65-196, 95%CI =86.275-115.5, p = 0.000). as illustrated in table 2

Table 2. Paired Test result b/n *Average Total baseline and final SLMTA result of laboratory based on the 12 LQMS, in AA, 2014*

Paired Differences					t	df	Sig. (2-tailed)
Mean	Std. Deviation	Std. Error Mean	95% CI				
			Lower	Upper			
100.89	38.439	7.138	86.275	115.518	141.35	28	0.000

Finally 3 laboratories become 3 star (2 health centers and 1 Hospital), 6 laboratories were at 2 star (1 hospital &5 health center), 11 were at 1 star (1 hospital, 10Health center) and the rest were at zero star out of a possible five star. The average base line and the final result comparing with the scored star were displayed on table 3

Table 3 Average Total baseline and final SLMTA result of laboratory based on the 12 LQMS, in AA, 2014

Serial No.	code no-	Baseline Result			Final result		
		Total	Achievement	Star level	Total score	Achievement	Star
1	01	40	16%	0*	196	80.32%	3*
2	02	28	11.2%	0*	191	78.72%	3*
3	03	50	20%	0*	189	77.45%	3*
4	04	39	15.6%	0*	182	74.0%	2*
5	05	61	24.4%	0*	180	73.17	2*
6	06	39	15.6%	0*	170	69.1%	2*
7	07	63	25.2%	0*	168	68.299%	2*
8	09	31	12.4%	0*	163	66.2%	2*
9	10	30	12%	0*	161	65.85%	2*
10	11	39	15.6%	0*	159	65.16	1*
11	12	36	14.4%	0*	158	64.75	1*
12	14	31	12.4%	0*	154	63	1*
13	15	37	14.8%	0*	154	63	1*
14	16	43	17.2%	0*	150	61.4	1*
15	17	43	17.2%	0*	149	61	1*
16	18	36	14.4%	0*	144	59.01	1*
17	19	40	16%	0*	141	57.7	1*
18	20	40	16%	0*	141	57.7	1*
19	21	28	11.2%	0*	138	55	1*
20	22	44	17.6%	0*	138	55	1*
21	23	56	22.4%	0*	132	54	0*
22	24	36	14.4%	0*	124	49.9	0*
23	25	44	17.6%	0*	117	46.8	0*
24	26	31	12.4%	0*	111	43.02	0*
25	27	23	9.2%	0*	107	42	0*
26	28	44	17.6%	0*	90	39.34	0*
27	29	41	16.4%	0*	91	37.29	0*
28	30	85	34%	0*	73	29.9	0*
29	31	49	19.6%	0*	65	27.45	0*

The total standard score is 250,*=star

At the end of the improvement project most health laboratories have star level change in the average of 12 quality management system essential. In contrast to this there were no significant changes in nine health laboratory which means unable to score the minimum standard for eligible of star level, the star level of status of the laboratory and their frequency is illustrated in table 4.

Table 4.star level status and frequency of health laboratory based on the 12 quality system essential of laboratory in Addis Ababa, 2014

Star level	Frequency	Percent
0	9	31.0
1	11	37.9
2	6	20.7
3	3	10.3
Total	29	100.0

Performance of Laboratory on Quality Management System Essential

Based on the finding of this study after the mentorship, most district laboratories improved their scores in client management with an average of 58% from 20% of baseline result and organization and personnel achieved more than 64% scores. In management reviews, facilities and safety and occurrence management from baseline scores of 40%, 70% and 23%, respectively. Average scores for implementation of corrective actions was 30% and in case of occurrence & process control improved an average of from 0% to 23, 15%to 53% respectively. Corrective action, occurrence management and internal audits showed the highest percentage change compare to the base line results.

Moreover, among the SLMTA participated health institution laboratory the highest score were achieved in document and record& facility and safety as illustrated in Figure1.

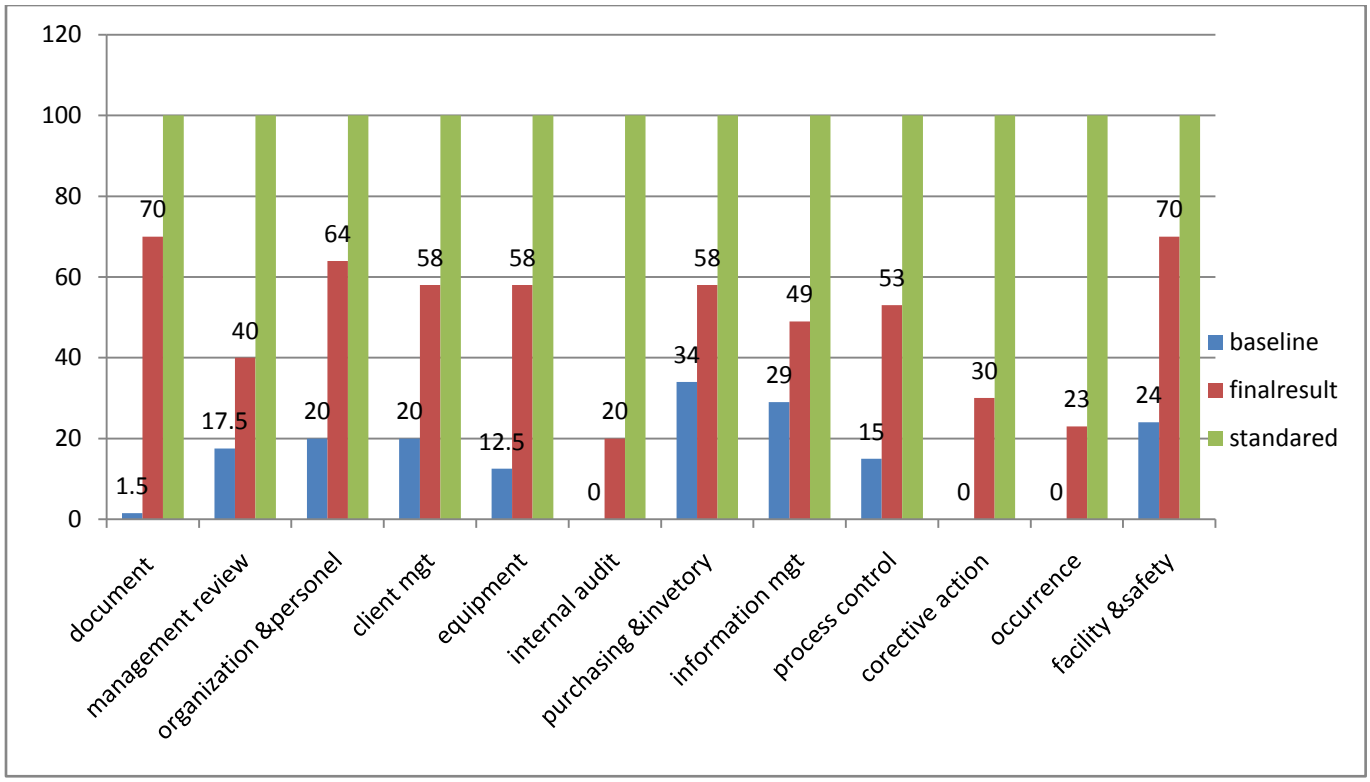


Figure 2. *The average total assessment scored of 29 laboratories in 12 Quality management systems Essential in government health facilities of Addis Ababa using WHO-AFRO Checklist, 2014*

5.2. Factors associated with the outcome of SLMTA

Socio demographic characteristics of the participants

In this study a total of 144 laboratory professional working in the 29 health facility were participated. About 61.1% of participants were male, the mean age of the participants were 29.21 (SD, 3.71). About 54.2% of participants were married followed by never married. One hundred four (72.2%) of them were Bsc degree in their educational status and 26.4% were Diploma. Thirty nine point six percent of respondents had 6-10yrs work experience in the health facilities. When we come to the current position of the respondents in the health institution 46.5% was Laboratory bench worker and only one respondent 1(0.7%) was satisfied in his salary payment. The detail of Socio demographic character sticks of the participants is shown in table 3

Table 5.Socio demography characteristics of laboratory professionals who was participating in this study in Addis Ababa, 2014

VARIABLE	Frequency	Percent
S EX		
Male	88	61.1
female	56	38.9
Educational status		
Diploma	38	26.4
BSC	104	72.2
MSC	2	1.4
Current professional of the respondents		
Laboratory technician	38	27.1
Laboratory Technologist	104	71.5
Others	2	1.4
Work experience in the current health institution		
1-2years	10	6.9
3-5years	43	29.9
6-10years	57	39.6
>10years	34	23.6
Current position in the health institution		
Laboratory head	29	20.1
Quality officer	29	19.4
Safety officer	20	13.9
Laboratory bench worker	67	46.5
Salary satisfaction		
Ye	1	0.7
No	143	99.3

5.3 The Reason for not fully implement LQMS in their Laboratory

In this study there is a chance to evaluate the reason behind that the laboratory professional for not exercising the laboratory quality system essentials in their laboratory. Based on the finding, 76% of the respondents disclosed that their facilities have no work plan and budget for laboratory specific purpose and lack of resources accounts 24% which is followed by absence of system in the health system.

105(73.4%) of the participant respond that there is no enough equipment in their laboratory and 115 (79.9%) of the lab equipment did not serviced according to the scheduled in the laboratory because of poor resource allocation and 53.9% the available equipment don't conduct preventive maintenance in the laboratory. According to the participants' response, 91.7% replayed that their laboratory lay out and size was not adequate enough for laboratory operation due to the poor engineering lay out and followed by lack of knowledge and training on laboratory requirement during building construction.

Generally, 52.4% of the participated professional agreed that their laboratory did not deliver their result within the established turnaround time. The detail is displayed in table 4 below.

Table 6.factors affecting LQMS Essential in their laboratory in Addis Ababa, 2014

Variables	Freq.	%
Availability of work plan and budget for laboratory		
Yes	34	23.6
No	110	76.4
Communication with the upper mgt regularly		
Yes	85	59
No	59	41
Timely manner and adequate coaching and mentoring (n=143)		
Yes	80	55.6
No	63	43.8
Customer satisfaction assessment activities		
yes	89	61.8
no	54	37.5
Has enough equipment to provide lab service (143)		
yes	38	26.6
no	105	73.4
Laboratory provide uninterrupted testing service (143)		
yes	22	15.4
no	121	84.6
Laboratory deliver client results within the established TAT		
yes	68	47.6
no	75	52.4
Adequate Size and layout of the laboratory		
yes	12	8.3
no	132	91.7

Due to the lack of motivation 27(18.8%) the laboratory didn't communicate regularly with upper management and 54(37.5%) of the laboratory professionals did not conduct their customer satisfaction survey because of poor staff communication and poor recourse allocation. Participated professional agreed that their laboratory did not deliver their result within the established turnaround time and the main reason was shortage of reagents and supplies which account 47.9% followed by equipment down time. The detail is displayed in table 5 below.

Table 7. The Reason for the laboratory professional not exercise the laboratory quality system Essential in their laboratory in Addis Ababa, 2014

The reason for No work plan and budget in place that support the laboratory (n=107)		
Lack o resource	13	24.3
Lack of knowledge	35	11.8
Poor communication with the management	17	13.9
Poor management commitment	20	15.3
Absence of system in the health system	22	15.3
The reason for No communication with the upper mgt regularly (n=60)		
Lack of knowledge	8	5.6
Lack o f motivation	21	14.6
Poor communication with the management	27	18.8
Workload	4	2.8
The reason for did Not, perform customer satisfaction assessment activities in (n=55)		
Poor resource allocation	6	10.9
Poor staff communication	28	50.9
lack of knowledge	14	25.5
workload	7	12.7
The reason for interrupted testing service (118)		
Workload	9	7.6
Equipment downtime	28	23.7
Shortage of reagents and supplies	81	68.6

5.4 Association between outcome of SLMTA with different Factors

This study explores the association of the outcome of Strengthening Laboratory Management Towards Accreditation (SLMTA) with different variables. The bivariate analysis showed that, there are a statically significant association between the outcome of Strengthening Laboratory Management Towards Accreditation(SLMTA) with regular staff meeting , getting adequate training how to implement SLMTA, coaching and mentoring, assessment of customer satisfaction, availability of enough equipment, equipment routinely serviced, workload, as illustrated in table 8.

Based on the finding of this study none of the socio demographic variables were found to be statically significant association with the outcome of SLMTA. However, the variables that were found to be significantly associated with the outcome of star level of SLMTA by the bivariate analysis were entered in to multiple logistic regression model to be regressed simultaneously. The multiple logistic regression model analysis made evident that performing customer satisfaction survey, timely and adequate mentorship, enough and routinely serviced equipment were statically significantly associated with the outcome of star level of SLMTA at P-value less than 0.05 .the detailed was indicated in table 8.

Regarding to timely and adequate mentorship, laboratory facilities respondents which thought getting adequate and timely manner mentorship were found 2.5 times more likely to get good success in the final status of improvement project (AOR= 2.501, 95% CI= 1.109-4.602) than which did not get it and concerning to customer satisfaction survey , those laboratory which didn't perform their customer satisfaction survey were two point two six one times more likely to get less final result than laboratory which are conducting their customer satisfaction survey (AOR= 2.261, 95% CI= 1.851-6.007).the detail is shown in table 8.

Table 8 factors associated with outcome of SLMTA in laboratories of Addis Ababa, 2014

VARIABLE	Dependent variable Outcome of SLMTA		COR, (95% CI)		P-Value	AOR, (95% CI)	P-Value
	STAR	No star					
Staff meeting							
Yes	**12**	**31**	**8.761**	**(3.887- 19.745)**	**0.00**	**1.3(0.298-5.957)**	**0.580**
No	**78**	**23**	**1**			**1**	
Adequate training*							
Yes	**6**	**67**	**11.824**	**(4.537-30.810)**	**0.00**	**2.40(0.846-6.813)**	**0.390**
No	**36**	**34**	**1**			**1**	
Timely and adequate ıtorship							
Yes	**6**	**69**	**13.297**	**(5.096-34.695)**	**0.00**	**2.501(1.109-4.602)**	**0.038***
No	**37**	**32**	**1**	**1**		**1**	
Conducting ustomer satisfaction							
Yes	**11**	**78**	**10.314**	**(4.486-23.714)**	**0.00**	**2.261(1.651-6.007)**	**0.019***
No	**32**	**22**	**1**	**1**		**1**	
Laboratory has enough equipment							
Yes	**11**	**69**	**6.273**	**2.810-14.004)**	**0.00**	**0.421(0.124-1.972)**	**0.642**
No	**32**	**32**	**1**	**1**		**1**	
Equipment serviced timely							
Yes	**10**	**68**	**6.800**	**2.993-15.449)**	**0.00**	**2.123(1.231-5.667)**	**0.011***
No	**33**	**33**	**1**	**1**		**1**	
Vaccination							
Yes	**3**	**11**	**1.543**	**1.012-4.831**	**0.00**	**0.649(0.171-2.460)**	**0.525**
No	37	88		1		1	

*@-indicate statically significant level and reference categories are indicated by 1. *=LQM S and SLMTA*

6. Discussion

This study has been conducted in twenty nine district laboratories in city government of Addis Ababa with the aim of assessing the outcome of SLMTA and factors associated with it according to WHO /AFRO SLIPTA checklist (2010). According to base line assessment result the mean baseline score were 41.7 which means at baseline, all laboratories scored zero stars on the WHO-AFRO SLIPTA star scale, which is similar with studies conducted in Burkina Faso national center for research and Training on Malaria to see the impact of SLMTA on Quality Management System and Study conducted at Lesotho to determine the improvement of the quality of testing services in public laboratories (**29, 30**).

When we look at the impact of training and mentorship activities that had been given in this 29 district health facilities, the finding indicate that there was a significant improvement in average scores (141.4; ranging from 65to196 , p = 0.004). Which is similar with studies conducted in Copenhagen on 51 units, South African, Zambia &Lesotho, (**23,24,25,26**). In final assessment 3 laboratories had got 3 star (2 health centers and 1 Hospital), 6 laboratories got 2 star (1 hospital 5 health center) and 11 got 1 star(1 hospital,10Health center) out of a possible five star.

The associated factors were regular staff meeting, satisfaction with current salary, getting adequate training how to implement SLMTA, coaching and mentoring, assessment of customer satisfaction, availability of enough equipment, equipment routinely serviced, staff motivation like vaccination and is comparable with Wattanasri N et al study in Thailand(**40**).

Based on the reviewed data as indicated as in figure 2 Corrective action ,occurrence management and internal audits showed a competency gap among laboratory professionals prior the SLMTA training and This study have also a comparable finding with abdosh (**41**).

105(73.4%) of the participant respond that there is no enough equipment in their laboratory and 115 (79.9%) of the lab equipment did not serviced according to the scheduled in the laboratory because of poor resource allocation and 53.9% the available equipment don’t conduct preventive maintenance in the laboratory which is comparable study with study done in developing country

laboratory, where services had the lack of adequate resources and necessary equipments **(42)**and study done by Peti CA et al state that the major determinate factors for providing quality laboratory services in developing countries were shortage of trained and skilled personnel; lack of equipment maintenance, poor supply-chain management systems, lack management commitment, **(32)** and similar study done in Asia **(34).**

The current study revealed that 143 (99%) of respondents were not satisfied by their salary payment and the finding was comparable with the findings of Lyons et al, where the study found laboratory technologists were less satisfied on their job than other health professionals and the common dissatisfaction factors were low wages, poor working conditions, and lack of recognition **(43)**.

Based on this study, 52.4% of the participated professional agreed that the final result of their client logout beyond the established turnaround time and the main reason were shortage of reagents and supplies which account 47.9% followed by equipment down time and it was more higher compared to study conducted in USA by Steindel et al which is 11% tests results were reported out of turnaround time **(44)**.

A study conducted in Thailand explained that factors that influenced laboratories' readiness for quality improvement were shortage of staff, lack of knowledge, shortage of resource and poor staff commitment **(31)**which is concordant with the finding of current study which is due to the lack of motivation 27(18.8%) the laboratory didn't communicate regularly with upper management and 54(37.5%) of the laboratory professionals did not conduct their customer satisfaction survey because of poor staff communication and poor recourse allocation.

In the regression model doing their customer satisfaction have a direct relationship with improving the outcome of strengthening laboratory management Towards Accreditation to achieve good quality system essential through management reviews and customer survey was able to continuously review and self-evaluate its quality management system. The identified opportunities for improvement need the laboratory to have the ability to implement and evaluate their progress.

7. Strength and Limitation of this study

7.1 Strength of the study

This study can be used as a spring board for further study because this is the first study in the city.

To strengthening the secondary data a primary data collection method was employed.

7.2. Limitation of the study

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

Lack of similar study in the city to compare the results.

8. Conclusions & Recommendation

8.1 Conclusions

At the end of SLMTA improvement project the finding indicate that there were a significant improvement in average scores (141.4; range of 65-196 , 95%CI =86.275-115.5,p = 0.000) comparing from the baseline.

Finally 3 laboratories become 3 star (2 health centers and 1 Hospital), 6 laboratories were at 2 star (1 hospital &5 health center), 11 were at 1 star (1 hospital, 10Health center) and the rest were at zero star out of a possible five star.

The most important contributing factor for not scoring star in the final outcome of SLMTA were not conducting their customer satisfaction survey , shortage of resource, and lack of regular equipment service maintenance.

According to the findings of this study mentoring, onsite and offsite coaching and training improve the laboratory quality management system. The current study become into conclusion with mentorship activities had shown that a great improvement in most district laboratories.

8.2 Recommendation

Based on the findings of this study, the following recommendation was drawn;

Mentorship be incorporated into laboratory quality improvement and management training program , in order to accelerate the progress of laboratories towards achieving accreditation and mentorship is an effective mechanism to assist progress towards accreditation

To address the paucity of accredited laboratories in Addis Ababa, Ethiopia all concerned body especially program managers prioritize the SLMTA and doing with the newly established Accreditation office, ENAO.

To achieve more, every laboratory should conduct their customer satisfaction survey and stakeholders and health managers be exercise that equipment service is a routinely service agreement.

Further detailed study should be conducted in the national and regional level including the private health sector

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11. ANNEXES

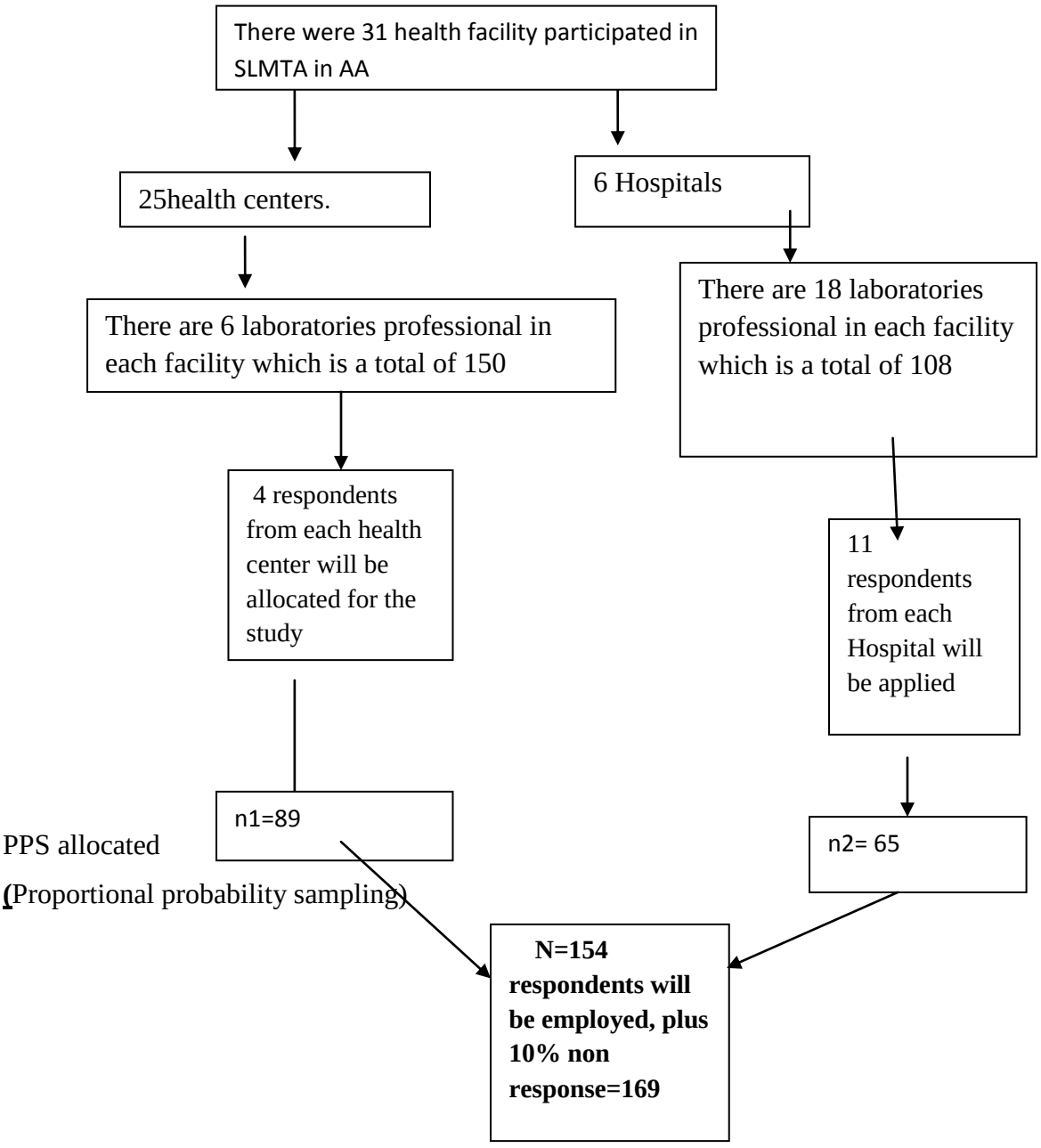
ANNEXE I Data abstraction form

Data abstraction form, *adapted from WHO AFRO Accreditation Checklist, Ethiopia, March, 2010.***Note;**this abstraction form contains the 12 quality management system essential base line and final assessment of SLMTA result corresponding with excepted standards

Assessment Score Sheet			
Section/quality system essential/	*Standard results*	*Baseline result*	*Final result*
Section 1: Documents & Records(11 items)	**25**		
Section 2: Management Reviews(3 items)	**12**		
Section 3: Organization & Personnel(7 items)	**20**		
Section 4: Client Management & Customer Service(1 item)	**10**		
Section 5: Equipment(14 items)	**32**		
Section 6: Internal Audit*(1 item)*	**5**		
Section 7: Purchasing & Inventory*(15 items)*	**31**		
Section 8: Information Management*(6 items)*	**14**		
Section 9: Process Control and Internal & External Quality Assessment *(17 items)*	**43**		
Section 10: Corrective Action*(4 items)*	**8**		
Section 11: Occurrence/Incident Management & Process Improvement*(3 items)*	**10**		
Section 12: Facilities and Safety*(23 items)*	**40**		
TOTAL SCORE	**250**		

0 Stars (0 – 137 pts) *< 55%*	**1 Star** (138 – 160 pts) *55 – 64%*	**2 Stars** (161 – 185 pts) 65 – 74%	**3 Stars** (186 – 211 pts) *75 – 84%*	**4 Stars** (212 – 236 pts) *85 – 94%*	**5 Stars** (237 – 250 pts) >95%

Annex 2 proportional allocation of sampling for study



Annex 3, English version questionnaire

DEPARTMENT OF CLINICAL LABORATORY SCIENCE

COLLEGE OF HEALTH SCIENCES

ADDIS ABABA UNIVERSITY

QUESTIONNAIRE to identify factors associated for the outcome of strengthening laboratory management towards accreditation /SLMTA/in Addis Ababa.

Identification

Health institution name _____Code No. _____

Verbal consent form before conducting interview

Greeting

Hello, I am_____. I am working with Abay Sisay who is from Addis Ababa University, College of Health Sciences, Department of Clinical Laboratory Sciences to conduct a research for partial fulfillment of Masters Degree in clinical laboratory management and Quality Assurance specialty track with the research title of ***assessing the outcome of strengthening laboratory management towards accreditation (SLMTA) on laboratory quality management system in Addis Ababa***. I would like to ask you a few questions about strengthening laboratory management towards accreditation (SLMTA) program. This will help the PI to identify factors which are affecting this program and improve the quality of laboratory service based on your answer to my questions. Your name will not be written in this form and will never be used in connection with any information forwarded by you; moreover these information's will be kept strictly confidential. Your participation is voluntary and you are not obliged to answer any questions you do not wish to answer. However, your honest answers to the questions will help me in identifying the factors.

Do I have your permission to continue? If yes, continue.

Date of interview _____

Interviewer's name……..Signature_____

Supervisor's name……...Signature_____

Note; the *questionnaire were used interviewed to the laboratory professional so that no need of translating this questionnaire in to Amharic version because they considered well understand this English version.*

Part 1: socio demography information			
No	Questions	Code classification	Remark
101	Sex	1.male 2.female	
102	Age in year		
103	Marital status	1. Never married 2. Married 3. Divorced 4. Separated 5. widowed	
104	Educational status	1. Diploma 2. BSC 3. MSC	
105	What is your profession?	1. Lab Technician 2. Lab Technologist 3.other	
106	What is your position in this health Institution?	1. Laboratory head 2. Quality officer 3.safety officer 4. Laboratory bench worker	
107	How many years have you been working in this institution as this position?	1.1-2 years 2. 3-5 years 3. 6-10 years	

		4.>10 years	
108	What is Your monthly income /salary?	1.<1000 birr 2. 1001-2000 birr 3.2001-3000birr 4. 3001-4000birr	
Part 2:Motivation and Communication			
201	Are you satisfied with your current salary?	1.yes 2.No	
202	Is a work plan and budget in place for the laboratory that supports the laboratory's testing operations and maintenance of the quality system?	1.yes 2.No	
203	If the answer/response for Q 202 is no, what is the reason	1.lackof resource 2.lackof knowledge 3.poorcommunication with the management 4.poor management commitment 5.absence of system in health structure. 6. others(specify----------)	
204	Does the laboratory communicate with upper management regularly regarding personnel, facility, and operational needs?	1.yes 2.No	

205	If the answer/response for Q204 is no, what is the reason	1. lack of knowledge 2. lack of motivation 3.poor communication with the management 4.work load 5. others(specify----------)	
206	Are staff meetings held regularly?	1.yes 2.No	
207	If the answer/response for Q206 is no, what is the reason	1. lack of knowledge 2.lack of motivation within the staff 3.poor communication with the management 4.work load 5. others(specify----------)	
Part 3:Training			
301	Do you participate on continuing education program?	1.yes 2.No	
302	Do you think that your laboratory have adequate training or refresher training for how to implement SLMTA?	1. Yes 2. no	

303	Do you think that your laboratory get a timely manner and adequate coaching and mentoring during SLMTA program?	1. Yes 2. no	
304	If the answer for question 401 is No, what is/are the reason ?	1. Poor staff communication staff with the mentor 2..poor staff motivation 3.lack of knowledge 4.Work Load 5. lack of knowledge and skill of mentor 6.its not important 7. others(specify----------)	
Part 4:Client management and management commitment			
401	Did you perform customer satisfactions assessment activities in your lab ?	1.yes 2.no	
402	If the answer for question 401 is No, what is/are the reason?	1. Poor resource allocation 2..poor staff motivation 3.lack of knowledge 4.Work Load 5.its not important 6. others(specify----------)	

403	Are collaborative laboratory and patient care improvement projects implemented between organizations, work groups, or relevant professions?	1.yes 2.no	
404	If the answer/response for Q403 is no, what is the reason	1.Workload 2.poor communication within staff 3. poor staff knowledge 4.poorresourceallocation 5.poormanagement commitment 6. others(specify----------)	
Part 5:Laboratory Equipments			
501	Do you believe that your laboratory has enough equipment to provide laboratory services efficiently?	1.yes 2.no	
502	Is routine preventive maintenance performed on all equipment according to the manufacturer claim?	1.yes 2.no	
503	If the answer/response for Q502 is no, what is the reason	1. Poor resource allocation 2..poor staff motivation 3.lack of knowledge 4.Work Load	

		5.its not important 6. others(specify----------)	
504	Is equipment routinely serviced according to schedule at your laboratory?	1.yes 2,no	
505	If the answer/response for Q504 is no, what is the reason	1.Poor resource allocation 2.poor staff motivation 3.lack of knowledge 4.Work Load 5.its not important 6. others(specify----------)	
506	Has your laboratory provided uninterrupted testing services during the last one year or the program?	1.yes 2,no	
507	If the answer/response for Q506 is no, what is the reason	1.work load 2.equipment down time 3.shortageof reagents, supplies 4.personel 5. others(specify----------)	
508	Is there a system for accurately forecasting needs for supplies and reagents?	1.yes 2.No	
509	If the answer/response for Q508 is no, what is the	1.purchasing system,	

	reason	2.knoweledge gap 3.work load 4.poor supply-chain management systems 5.others(specify----------)	
Part 6:human Resource and work load			
601	Do you believe that your laboratory has enough human resources to provide laboratory services efficiently?	1.yes 2.No	
602	Have you actively participated in the SLMTA program in order to improve the quality/star level of your laboratory ?	1.yes 2.No	
603	If the answer/response for Q602 is no, what is/are the reason	1.Poor resource allocation 2.poor staff motivation 3.lack of knowledge and training 4.Work Load 5.its not important 6. others(specify----------)	
604	How do you rate your laboratory workload based on your human resource and available service ?	1.Very high 2.High 3.Faire 4.Low 5. I don't know	
605	Did your laboratory deliver your client results within the established turnaround time?	1.yes 2.No	

606	If the answer/response for Q605 is no, what is/are the reason	1.work load 2.equipment down time 3. shortage of reagents, supplies 4.poor staff motivation 5. others(specify----------)	
Part 7: Facilities/size of the laboratory &safety			
701	Is the size of your laboratory adequate and is the layout of the laboratory, as a whole, organized so that workstations are positioned for optimal workflow, Is the physical work environment appropriate for testing?	1.yes 2.No	
702	If the answer/response for Q701 is no, what is/are the reason	1. Poor resource allocation 2..poor engineering lay out 3.lack of knowledge and training on lab. requirement during building construction 4.poor knowledge on laboratory service requirement in management body 5. others(specify----------)	

703	Is standard safety equipment *(lab coat,eye wash,…)* available and in use in the laboratory?	1.yes 2.no	
	If the answer/response for Q702 is no, what is/are the reason	1.resource shortage 2.lack of knowledge 3.poor management commitment 4. others(specify----------)	
704	Did you use the available standard personal protective equipments in the laboratory	1.yes 2. No	
705	If the answer/response for Q704 is no, what is/are the reason	1. Poor resource allocation 2.the available equipment is not fit with us 3.lack of knowledge 4.Work Load 5.its not important 6. others(specify----------)	
706	Are your laboratory personnel offered appropriate vaccination/s?	1.yes 2.no	
707	If the answer/response for Q706 is no, what is/are the reason	1.Resource shortage 2. Lack of knowledge 3.absence of management commitment 4.staff is not volunteer 5. others(specify----------)	

Thank you for your participation!

Annex 4 -Declaration

I, the under Signed, declare that this is my original work and has never been presented for a degree in this or any other university and that all the source material used for the thesis has been duly acknowledged.

Name Abay Sisay

Signature_____

Place _____

Date of submission_____

This thesis has been submitted for examination with my approval as a university advisor:

Name Tedila Mindaye (PhD fellow)

Signature_____

Date _____