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Assessment on the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) Implementation Progress in Public Health Facility Laboratories from 2013 to 2015 G.C Addis Ababa, Ethiopia

By

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Abbreviation

BDHL	Bungoma district America pathologists
CAP	College of America pathologists
CDC	Central disease control
CEO	Central Executive Officer
CHAI	Clinton health access initiative
ENAO	Ethiopia National Accreditation Office
I-TECH	International Training and Education Center for Health
KENAS	Kenya accreditation service
LQMS	Laboratory quality management system
QSE	Quality system essential
SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
SLMTA	Strength of laboratory management towards Accreditation
WHO	World health organization

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Definition of Terms

1. **Audit-** A systematic and independent examination to determine whether quality activities and related results comply with an agreed standard.

2. **Star level**- WHO ranking (stratum) from 0-5 star instead of recognition of laboratory according to final average audit achievement or score of the standard.

3. **Staff commitment**- When the laboratory staff to perform SLMTA activity to achieve the final goal and to sustain quality management system.

4. **Management commitment-** When health facility management devoted to support the laboratory on SLMTA activity.

5. **Good communication-** A process by which information is exchange between facility management and laboratory staff.

6. **Implementation-** A process of moving an idea of SLMTA from concept to reality.

7. **Progress-** The laboratory advanced to a better stage than the previous status of SLMTA

8. **Implementation progress-**A process of moving an idea of SLMTA from concept to reality for a better stage it.

Abstract

Background: Strengthening Laboratory Improvement Process Towards Accreditation recognizes laboratories where they are in the process of quality improvement; through audits and direct on technical assistance.

Objective: The aim of this study was to assess the implementation progress of SLIPTA in selected public health laboratories in Addis Ababa, Ethiopia.

Methods*:* Retrospective study design was used to assess the implementation Progress of SLIPTA in 31 public health laboratories in Addis Ababa, Ethiopia. The facilities were selected using convenient technique. Their implementation status was assessed using SLIPTA standard checklist, and a semi-structured questioner to identify factors that affect during the implementation phases. The current and the last audit scores of the facilities had compared against the SILPTA score level. This study wasconducted from Marchto August 2015.

Results: This finding indicated that number of laboratory those have zero star level decrease from nine to three,Number of health facility in 2013 those are13(41.9%),6(19.35%) and 3(9.67%), have 1,2,3 stars levels respectively, result of 2015 audit shows presence of good SLIPTA progression than two years ,(number of lab 5(16%) have 4 star,[8(32%),3] and [11(29%),2], only one lab have 5 star,2(6%) have one star and 3(13%) have zero star level. The audit finding shows that assessed in 2013 and 2014 before the current audit) was 71(27.5%) point score zero stars to 207(80.3%) point score three stars and 85(33%) point score zero stars to 246(95.6%) point score five stars , respectively from a possible 258 points.There were have regular follow up on LQMS implementation activities in the laboratory, make good communication with laboratory staff, having financial Support, facilitation of training program andhire additional staff had an impact on having good progress on SLMTA implementation. And also, here was challenge to implement the system like staff turnover;staff resistance and misunderstand of the system.

Conclusion: Improvements were seen with 31public health laboratory which in level of star score and each quality essential element.

Chapter One

1.1 Introduction

Medical laboratories form the backbone of health systems, as test results are critical for diagnosing diseases, guiding treatment, determining drug resistance and identifying diseases of public health significance through surveillance (1).

National health laboratories should work for improving laboratory quality systems and attaining accreditation to improve Laboratory practice. Accreditation gives formal recognition of the technical competence of a laboratory to perform specific tests (2).

WHO and the US Centers for Disease Control and Prevention (CDC) held joint conference on laboratory quality management systems (LQMSs) in Lyon, France in April 2008 and issued the following statement in support of a stepwise, standards-based process towards internationally-recognized accreditation: "It is recommended that countries with limited resources consider taking a staged approach, where principal requirements for all are stated in the national laboratory standards as a minimum requirement, while more advanced and national reference laboratories are encouraged to aim at meeting internationally accepted standards such as ISO 15189"(3).

Following the 2008 Lyon conference In Kigali, Rwanda, July 2009, the WHO Regional Office for Africa, in collaboration with CDC, theClinton Health Access Initiative (CHAI), the American Society for Clinical Pathology (ASCP) andother partners, launched SLIPTA in the presence of government health officials from 13 Africancountries. The Strengthening Laboratory Management towards Accreditation (SLMTA) training program was also introduced in Kigali as a preparatory initiative to ready laboratories forSLIPTA. Nine countries in sub-Saharan Africa are implementing SLMTA since 2009 (3).

World Health Organization (WHO) recognizes quality laboratory services as key to improving global health and reaching Millennium Development Goals. Strengthening the horizon of laboratory services accessible to clients and ensuring that results as accurate, reliable,

reproducible, and rapid enough to be useful is crucial to improved health outcomes by SLIPTA. SLMTA grounded in its ability to identify deficiencies in a laboratory, improve them and measure the outcomes (4).

SLIPTA provides a pathway that recognizes conformity over time by breaking down the process into a series of specific implementation-friendly stages.The process is expected to have a catalytic effect by encouraging quality improvement in individuallaboratories and Laboratories will be audited against laboratory standards outlined in the WHO SLIPTA Checklistfor the African Region and will be recognized as operating at one of the levels of performancedemonstrated by a star rating (3).

The emphasis of SLIPTA was on intervals for audit, planning, and tools for conducting an audit in objective manner using documented guidelines or procedures to identify the extent of compliance with the requirements and the competence of personnel. This took the participants through developing the audit and corrective action plan to help the laboratory address the gaps. WHO-AFRO step-wise progress goals meet standards used worldwide but the step-wise approach recognizes that improvement takes time and often occurs in increments especially in resource-limited settings (4).

In response to these challenges, laboratory assessments were conducted on a national scale within Ethiopia and the first laboratory strategic plan was set in 2005 and mandating the Ethiopian Public Health Institute (EPHI) to lead laboratory programs nationwide. However, because of reforms within the Ethiopian health sector, the second strategic plan was revised in 2010, to focus on three goals: establishing and strengthening laboratory quality systems, laboratory capacity building and laboratory accreditation (3).

The first (Cohort I) national SLMTA program was implemented between June 2010 and October 2011on 24 public health laboratories and; the second (Cohort II) program, implemented between January 2011 and May 2012.One of the objectives of the second strategic plan of the national laboratory (EPHI) (2nd draft) for the year of (2015/16 to 2019/20) was the implementation of Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) (1, 4).

As a national laboratory improvement strategy, SLIPTA was implemented at all tiers of the national laboratory network whereby the national and regional reference laboratories, all hospital laboratories and those of Health Centers with high test volumes were given priority (4).

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. 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)(5).

The aim of this study is to investigate the SLIPTA implementation status in Addis Ababa public health facilities and to identify major factors contributing for SLIPTA under achievement.

Statement of the Problem

Quality laboratory services are critical for ensuring optimal patient care and comprehensive public health response and quality laboratory services are essential for the decision-making capacity of clinicians, health workers and public health authorities(6, 7).

The laboratories encountered challenges linked to the lack of reliable laboratory support, disease diagnosis, and management of patient care (8, 9). Among many areas of concern in laboratory services poor laboratory infrastructure, poor quality control practices, no strong proficiency practice, limited test menus, poor turnaround time, and low diagnostic accuracy was seen (5).

In Addis Ababa there were three governmental laboratories which were accredited. These laboratories are one government hospital laboratory, Public Health laboratory and research Center and government health center(10).

Even if SLIPTA was implemented in more than 72 public health facility i.e. hospital and health center laboratories in Addis Ababa. Despite all SLIPTA enrollment and recourses mobilized, the progress stepand primarily factors that contributing for implementation or to have under achievements value not well studied.

Significance of the Study

This research revealed the implementation status and improvement challenges. It will indicate the factors that contribute for SLIPTA under achievements and improve SLIPTA implementation in the country. In addition, the research could be used as a baseline for further studies.

Chapter Two

Literature Review

2.1. SLIPTA Audit Results on Quality Management System Essential

The study conducted in Caribbean region in five national reference laboratories in May 2011 with 18 month interval reveals**,** at the baseline audits the laboratory scores ranged from 19% to 52%, corresponding to 0 stars. Scores increased steadily throughout the program and by 18 months each laboratory had improved, with three of the laboratories more than doubling their baseline scores. One laboratory reached four stars on the five-star scale, two attained three stars and the remaining two laboratories each attained two stars. Of this group, one laboratory achieved accreditation through the College of American Pathologists (CAP) in September 2013; meanwhile three others have applied for accreditation and are preparing for the assessment within the next few months. The greatest improvements were in corrective action (66%), organization and personnel (55%) and purchasing and inventory (54%). The sections showing the least improvement were process control (18%), occurrence management (25%), internal audits (30%) and equipment (36%) (12).

The study conducted in Hong Kongin27 laboratories analyzedin tow periods, from 2004 to 2006 and 2009 present the frequency of nonconformities to requirements of the ISO 15189 accreditation standard encountered during the assessments of medical laboratories. For management requirements, nonconformities were most frequently reported against quality management system, quality and technical records and document control; whereas for technical requirements, they were reported against examination procedures, equipment and assuring quality of examination procedures. There was no major difference in types of common nonconformities reported in the two study periods 2004 and 2006. The total number of nonconformities reported in the second reassessment of 27 laboratories in 2009 was almost halved compared to their initial assessments(5).

Another study performed in Ghana in 2011, 2012 and 2013, Building local human resources to implement SLMTA with limited donor funding .The local SLMTA team successfully implemented three cohorts of SLMTA in 15 laboratories. Seven out of the nine laboratories that underwent follow-up audits have reached at least one star. Three out of the four laboratories that underwent official ASLM audits were awarded four stars. Patient satisfaction increased from 25% to 70% and sample rejection rates decreased from 32% to 10% (17).

The study conducted in Bungoma District Hospital Laboratory (BDHL) in Kenya, Creating a sustainable culture of quality through the SLMTA program from 2011 to 2013. BDHL improved from base line score zero stars (38%) to four stars (89%) after 16 months in the SLMTA program. Over a period of two to three years, external quality assessment results improved from 47% to 87%, staff punctuality increased from 49% to 82%, clinician complaints decreased from 83% to 16, rejection rates decreased from 12% to 3% and annual equipment repairs decreased from 40 to 15. Twelve months later the laboratory scored three stars (81%) in an external surveillance audit conducted by Kenya Accreditation Service (KENAS) (11).

The study conducted in Kenya on progressing beyond SLMTA show internal audits and corrective action are the key drivers of quality improvement to analyzed the performance of individual QSEs, to identified the key areas of progress and challenge in implementation of QMS and examine non-conformities at the exit and surveillance audits with a focused on identification of common issues. Any nonconformity identified at both the exit and surveillance audits in the same laboratory was classified as recurring nonconformities. Ten nonconformities were common to all five laboratories, lack of critical procedure, lack of or incomplete management review records, incomplete personnel files, lack of equipment calibration records, deficient internal audit, inconsistence internal quality control monitoring, unacceptable proficiency testing result, ineffective corrective action and deficiency of quality indictor monitoring. At the exit audits, two laboratories had the most non-conformity. However, these laboratories develop corrective action plans that covered most of the nonconformities, so that by the surveillance audit their nonconformities were reduced by more than half (16).

Four public health Hospital based study which was conducted in Ethiopian finding indicated that two laboratories were improved from zero stars [82(31.78%) and 102(39.5%) points] in pervious audit result to two stars [175(67.8%) and 182(70.5%) points] in current audit result respectively. The other two laboratories had no changes that score zero stars with pervious audit result [94 (36.4%) and 82 (32.56%)] to current audit result [95 (36.8%) and 104 (40.31%)] respectively. All (16/16) key informants responded that they had no written plan, follow up, report of the SLIPTA program; and with staff attrition rate, no written duties and responsibilities (4).

Another assessment in Ethiopia by Tilahun M. et al. on the 44 laboratories shows that participated in both the baseline (on June 2010 for cohort I and on January 2011 for cohort II) and exit audits (on October 2011 for cohort I and lower scores were observed for internal audit (6% baseline and 18% exit), occurrence management and process improvement (14% and 29%) corrective action (31%and 41%) and management reviews (32%and 44%), client management and customer service (42% and 59%), organization and personnel (44% and 59%), information management (58%and 63%) and facilities and safety (51% and 71%). Documents and records improve (32%), facilities and safety (22%) and client management and customer service (17%), Information management (5 %), equipment (6 %) and process control and internal and external Quality assessment (9 %) (14).

The study in Ethiopia by Luile on Perceptions and attitudes toward SLMTA amongst laboratory and hospital professionals revealed that all SLMTA had improved communication between Laboratory staff and management and had led to measurable quality improvements. They reported that the most dramatic improvements were seen in reduced turnaround times, decreased Equipment down times, new and functional data management systems and minimized supply lead times. Additionally, laboratory logistics information systems had been implemented and storage conditions improved (15).

The study conducted in Ethiopian on laboratory system strengthening and quality improvement stated assigned improvement project based on common gaps identified during the base line audit and components of the quality management system. Improvement project includes customer satisfaction, External quality assurance, and Turnaround time and equipment utilization rate (23).

2.2. Factors contribute SLPITA Implementation progress

The study on SLMTA program in developing country stated that the most common challenge such as attribution of SLMTA trained staff, encouraging the entire laboratory to work as a team, engaging hospital management and site support and insufficient mentorship capacity. Program disruption during SLMTA implementation, presence of highly staff turnover, Non- SLMTA staff involvement and program sustainability were another challenge (18).

Mentoring in Lesotho at four hospital laboratories from June 2009 to Dec.2011 shows, in the beginning of the mentorship all laboratories was at the SLIPTA zero star rating. After the initial six weeks of mentorship two of the three district laboratories had improved from zero to one star although the difference between their baseline (107.7) and the end of the six weeks (136.3) average scores was not statistically significant ($p = 0.25$). After 10 weeks of 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. Implementation of corrective actions improved from 25% to 67%. Management reviews and internal audits showed the highest percentage change, 46% and 43% respectively (13).

The study which was on a comprehensive review of the SLMTA literature measuring success stated that at base line the weakest area overall were in the improvement management stage of the quality cycle was included internal audit (5%) and occurrence management (16%), corrective action (25%) and management review (29%). None of the 12 QESs had mean baseline score above 55%, the highest scores were in information management (51%), facility and safety (47%), purchase and inventory (42%) and process control and internal and external quality assessment (41%). At the exit audit, the four-improvement management QSEs still showed the lowest scores, ranging (42%). The resource management and process management stage had higher scores (65%) and (63%) respectively. The greatest improvements were in document and records (34%), Client management (29%), and facility and safety (27%). The greatest overall score increase had focused on internal audit and corrective action and can hypothesize that an improvement in these areas may be a catalyst for overall improvement in other areas (16).

In Kenya SLMTA implementation followed the standard three-workshop series, mentorship site visits and audits were done in Bungoma District Hospital Laboratory in 16 month interval. They had indicated that without hospital management support, sustainable changes are difficult to achieve. In order to sustain the gains achieved, SLMTA was integrated into daily routines, building a foundation for continuous improvement. Discussions of improvement projects have to include contain in regular laboratory staff meetings; the laboratory conducts weekly hands-on continuous medical education sessions; and all staff members are involved in budget and planning discussions. The changes were designed in order to improve the laboratory staff's customs, beliefs and attitudes in the workplace, leading to widespread and lasting staff support of laboratory quality improvement activities (20).

The study which was focused on, study based on a comprehensive review of the SLMTA that analyzes the challenge at both the facility and program levels. At the facility level, the difficulty was engaging non-SLMTA –trained laboratory staff as well as hospital management and regional health bureaus on QSM program. Commitment and consistent support was noted. In addition, documentation in providing sufficient site support to ensuring the staff understanding on the requirement of QSM and ISO15189 standard and how to conduct internal audit were another challenge. Implementation of QMS was a difficult process- particularly noted on balancing the requirement of multiple functions within a laboratory, establishing root cause analysis for nonconformities, equipment maintenance and outage, development of method validation, space shortage, document review and maintenance, insufficient time to implement improvement project (19).

The study that conducted in Egypt based on root cause analysis for medical equipment calibration stated that two non -conformities that Customer complaint and Internal audit with their cause-and-effect root cause analysis tool to analyze the problem. Reason for non-conformity on Customer complaint and internal audit are on Calibration & work instructions and quality management & procedure, respectively (22).

The study on I-TECH-supported laboratories in Ethiopia workplace-based, accreditation-focused on laboratory mentorship by Mamo.W recommended that SLMTA implementation helped to engage hospital and senior management, creating a strong commitment to ensure ownership and accountability of the program, team spirit among lab staff and willingness to build a culture focused on quality and problem solving. He had also stated about the challenge which narrated to high turnover of laboratory staff, especially among staff trained in quality-management and SLMTA procedures, and in bio-safety, often caused inconsistency in the quality of mentorship and delays in the SLMTA process (21).

Chapter Three

Objectives

3.1. General Objective

To assess SLPITA implementation progress and identify contributing factors in public health laboratories from 2013 to 2015 Addis Ababa, Ethiopia.

3.2. Specific Objectives

1. To assess score star level with in three years in public health laboratories.
2. Toassess progress of the quality score in 12 quality essential elements in public health laboratories.
3. To determine factor that contributing for SLPITA implementation progress in public health laboratories.

Chapter Four

Methodology

4.1. Study Design

Retrospective and cross sectionalstudy design was employed to assess SLIPTA improvement progress in public health facility from 2013 to 2015, Addis Ababa ,Ethiopia and factors associated with SLPITA implementation status that contribute for SLPITA progress.

4.2. Study Period

Study was conducted in Medical laboratories those in SLIPTA Addis Ababa, Ethiopia from March 2015 to August 2015.

4.3. Study Area

The study was conducted in Addis Ababa, the seat of government of the Federal Democratic Republic of Ethiopia. It is also home to the African Union, the Economic Commission for Africa and other international organizations with the population of 3,384,569 according to the 2007 population census. For administration purposes Addis Ababa is divided into 10 Sub-cities and 99 wards. 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; 76 (currently functional) public and 4 NGO-supported health centers laboratories, 7 public, 500 private and 31 NGO supported clinics laboratories(7).According to Addis Ababa City Administration Health Bureau public Health Research and emergency management core Process laboratory information SLIPTA implemented 31 health facilities laboratories (6 hospital and 25 health centers) from 2013 to 2014, 26 additional new health center on 2015.

4.4. Population

4.4.1. Source of Population

The source population for this study was all hospitals and health centers laboratories under Addis Ababa city administration Health Bureau in Addis Ababa.

4.4.2. Study Population

The study population was Laboratories enrolled and implemented SLIPTA during the study period.

4.5. Sample Size Determination and Sampling Procedure

The sample size was determined based on SLIPTA implementation period, conveniently select 31 health facility (26 health center and 5 hospital under city administration),according to information for implementation of SLMTA program on health facility and the key informants interview were, Laboratory managers; the Quality officers, and/or the Medical Directors and head of regional laboratory were selected to get the detailed responses since they are being as lead focal persons in SLIPTA enrollment.

4.6. Inclusion and Exclusion

4.6.1. Inclusion Criteria

All laboratories that participated in SLMTA program and having assessment results were included in the study.

4.6.2. Exclusion Criteria

Laboratories which are participated but having insufficient data,which are not willing to participate in the study and those are on renovation were excluded from the study.

4.7. Data Collection Tools

Data collection using self-administered questionnaire was used. It was organized into four main categories (socio-demographic, staff commitment, Management Commitment and Training on SLMTA**(Annex I & II)**. The WHO SLIPTA Checklist **(Annex III)** is compliant with ISO 15189/17025. The Checklist has 334 questions and a possible 258 points. The questions are organized in 12 sections. While the checklist has been constructed to prepare laboratories for international accreditation, the headings are derived from the quality system essentials (QSEs) contained in the quality management system (QMS) of the renowned Clinical and Laboratory Standards Institute (CLSI). Each item has been assigned a weight 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. Some clauses in the checklist are

*tick lists*required the satisfactory presence of all sub item listed below the main heading to receive full credit.

4.8. Data Collection Method and Procedures

This study will be crucial to address factors that affecting the SLIPTA program in areas of human resources management; process management and improvement management by engaging interview with health facility laboratory and management members. Principal investigator was involved in data collection and overall controlling activities of data collection. The Principal investigator was already known about checklist (already trained on SLMTA and mentor/ auditor) and questioner. During data collection period the investigator explain the study objective and got oral informed consent from participant health facilities before conducting of data collecting.

4.9. Study Variables

4.9.1. Dependent (outcome) Variable

- SLIPTA Implementation Progress in Public Health Facility Laboratories.

4.9.2. Independent (Exposure) Variable

- Twelve (12) quality essentials element

4.10. Method of Measuring Variables

Variable include in this study was SLIPTA implementation progress and major factor that contribute for SLPITA implementation progress in Public Health Laboratories and there were report in assessments based on WHO Afro checklist was analyzed from 2013 to 2015. The performance of 31 laboratories initially assessed (base line assessment)andstart from 2013 and on 2014, and continued to their performance in the third reassessment in 2015.

The implementation progress value of essential element and major factors to have effect on for implementation was assessed.

4.11. Data Quality Assurances

Completeness, accuracy and consistency of the collect data was check on daily based during data collection by principal investigator, where those checklists found incomplete, inaccurate and inconsistency was recheck to fill again. Data was clean and code before entry and then recode after analysis.

4.12. Data Management and Analysis

Data was export and analysis performs using SPSS (version 20). Descriptive statistics are compute for analysis of current data that might be associated factor for implementation of SLMTA.

4.13. Ethical Consideration

Ethical approval was obtain from the department of research ethical review committee (DRERC) Addis Ababa University (AAU) department of medical laboratory science and An official letter of cooperation was also collect from Addis Ababa City administration health bureau and the Permission was also obtain from sub city of the study sites. The information that collects by the study was store in a file, without mentioning the name of the study site (institution), but a code number was assign to it. Such information's was not revealed to anyone except the principal investigator.

4.14. Dissemination and Utilization of Result

The result of this study will delivered to Addis Ababa University department of Clinical Laboratory, relevant bodies or stake holders to respective regional health Bureau and regional laboratory. For the Community it would be reached through publishing and peer reviewed journals and by presenting in local and international symposiums.

5. Chapter Five

Result

5.1. SLIPTA progress against number of lab with star score

Overall, for the 31 laboratories that participated SLIPTA in 2013 to 2015, there was a 20 percentage point average increase in SLIPTA audit score, with 68% as the average 2015 score and 11 percentage point average increase in audit score with 59% as the average 2014 score. The range of all (31) laboratories of the previous audit score (that assessed in 2013 and 2014 before the current audit) was 71(27.5%) point score zero stars to 207(80.3%) point score three stars and 85(33%) point score zero stars to 246(95.6%) point score five stars , respectively from a possible 258 points. At the assessment time, 9 of them have averagely 29% scored zero stars in 2013,.when we compare the result with 2015 audit result it is more better than two years and it is ranges from 109(42.5%) to 246(95.7%) three zero star score. The number of laboratory with their level of score stars in 2013 is 13(41.9%),6(19.35%),3(9.67%), have 1,2,3 stars levels respectively, result of 2015 audit shows presence of good SLIPTA progression than two years ,(number of lab 5(16%) have 4 star,[8(32%),3] and [11(29%),2], only one lab have 5 star which was achieved accreditation through Ethiopia National Accreditation Office (ENAO) ,2(6%) have one star and 3(13%) have zero star level.

Table 1:- Number of score stars against number of health facility

Variable =Number of health center with their star level

	2013			**2014**			**2015**	
No. of HC	(%)	Star	No. of HC	(%)	Star	No. of HC	(%)	Star
9	(29)	0	10	(32.3)	0	3	(13)	0
13	(41.9)	1	6	(19.3)	1	2	(6)	1
6	(19.4)	2	3	(9.6)	2	11	(29)	2
3	(9.67)	3	11	(35.4)	3	8	(32)	3
0	(0)	4	0	(0)	4	5	(16)	4
0	(0)	5	1	(3.2)	5	1	(3)	5

Table 2:- Average assessment audit value of health facility

Year	Audit point range	Audit percentage range
2013	71-207	27.5% - 80.3%
2014	85 - 246	33% - 95.6%
2015	109-246	42.5% - 95.7%

5.2. SLIPTA progress against star level (2013 and 2015)

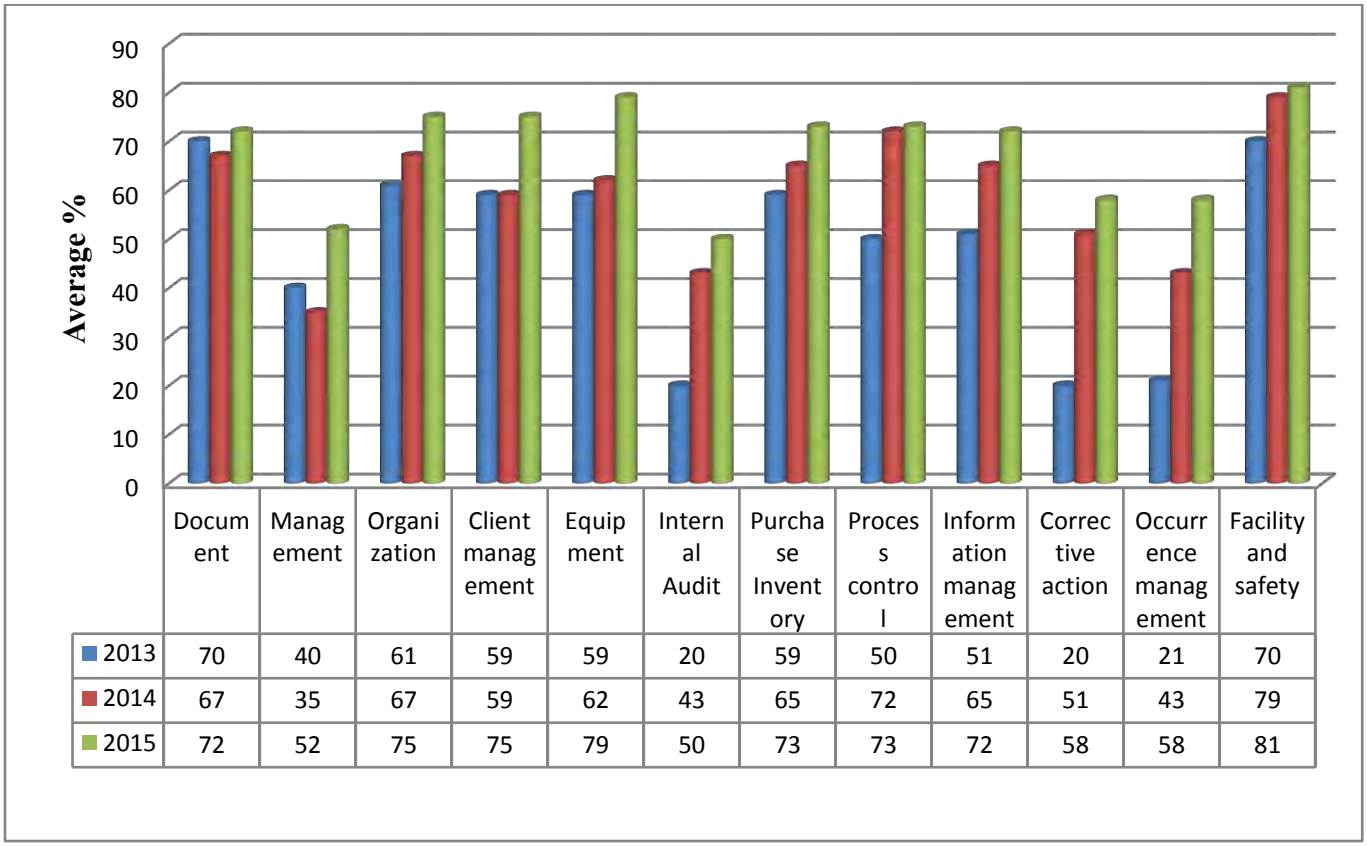
In 2013 audits, 9 laboratories scores less than 55% correspond to 0 stars. Six of them show the progress and stars scores increased steadily throughout the programme and by two years, at 2015. One laboratory reached four stars, two attained three stars and the remaining three laboratories each attained two stars. In the other way those laboratories (13) scores 55% to 64% which correspond to one stars, from this nine laboratories are changed their status to, two of them score four stars, the other two scores three and the remaining five laboratories scores two stares. One of the laboratories that score three in 2013 attained five stares in 2015 and also achieved accreditation through Ethiopian national accreditation office (ENAO) November 2015.

Table: 3 Number of health facility those show SLIPTA progress against stars scores levels (2013 and 2015)

Variables:- SLIPTA progress against stars levels (2013 and 2015)		
Score stars levels	**No of health facility**	**No of lab average percentage**
0 to 4	1	3%
0 to 3	2	6%
0 to 2	4	13%
1 to 4	2	6%
1 to 3	2	6%
1 to 2	5	16%
2 to 3	4	13%
3 to 5	1	3%
3 to 4	1	3%

5.3. SLMTA implementation against quality essential element

Table 4 shows the average percentage improvement across 31 laboratories for each of the 12 sections of the checklist (i.e., the 12 quality system essentials), measured as the difference between the 2013 and 2015 audit result after two years The greatest improvements were in corrective action (58%), Occurrence management (55%), customer service(75%) ,equipment(79%) and process control(73%). The sections showing the least improvement were internal audit (50%) and management review (52%). Average final absolute scores were > 55% for all areas except management review and internal audits.



	Document	Management	Organization	Client management	Equipment	Internal Audit	Purchase Inventory	Process control	Information management	Corrective action	Occurrence management	Facility and safety
2013	70	40	61	59	59	20	59	50	51	20	21	70
2014	67	35	67	59	62	43	65	72	65	51	43	79
2015	72	52	75	75	79	50	73	73	72	58	58	81

Figure 1 Average achievement of essential element within three years (2013, 2014, and 2015)

5.5. Current performance of the laboratories (2015)

Thirty one laboratories fulfilled the inclusion criteria for the current assessment from a total population of 31health facility laboratories. Of 30 laboratories, one of them scored five star ,five laboratories scored four stars, eight laboratories scored three stars, eleven laboratories scored two stars , two laboratories scored one stars and three laboratories scored zero stars in 2015 SLIPTA audit. The total percentage score of the laboratories ranges from 109(42.5%) to 246(95.7%)point from a total possible point of 258 (100%). The best performing laboratory scored 246 points or 95.7% that positioned in five stars in SLIPTA score scale. The best points from those score four stars is 242(94%) ,from score three stars is 215(83.6%) , from score two stars is 186(72.4%) and from score one star is 158(61.4%)points. The least point 109(42.5%) score zero stars.

Table 4: **Laboratory performance with their star level (2015),Addis Ababa**

Variables (n=31)			
No of laboratory	**Score star**	**Best points**	**Percentage**
1	5	246	95.7
5	4	242	94
9	3	215	83.6
11	2	186	72
2	1	158	61.4
3	0	109	42

5.6. Factors Contribute for SLIPTA implementation

5.6.1. Training

Currently the types of training for implementation of SLIPTA are SLMTA,QMS and Safety. As presented in table 5, from laboratory interviewer 25(40.3%)and 21(63.6%) of facility manager have SLMTA training. SLMTA was difficult to implement for only 2(3.1%) laboratory respondent,62(96.9%) can be implement easily. 32(50%) laboratories and only 1(2.9%) facility management respondent have safety training. From the total number laboratories professional (300) in 31 health facility (152) in health center and (148) in hospital, 91(45.5%) taken SLMTA training.

Table: 5Type of training that related with SLIPTA implementation

Variables (n=95)

Laboratory respondent training (62)

		Frequency	percentage
SLMTA	Yes	25	(40.3)
	No	37	(59.7)
Safety	Yes	31	(50)
	No	31	(50)

Management respondent have training (31)

		Frequency	Percentage
SLMTA	Yes	19	(61.2)
	No	12	(38.7)
Safety	Yes	3	(9..6)
	No	28	(90.3)

Variables (total laboratory professional in 31 health facility=300)

SLMTA	91	(45.5)

Sample size (n) varies due to missing values

5.6.2. Staff Commitment

From the total number laboratories professional (300) in 31 health facility (152 in health center and 148 in hospital) 99% of them are fully participated during SLIPTA implementation. It is because of 98.8% of staff have responsibility or focal person on twelve quality essential element. From the total of 64 respondents 36(56.2%) & 17 (26.5%) of them responded Equipment and Purchasing and inventory section as difficult essentials respectively and Information management and customer service were the least difficult essentials 1(1.5%) & 2(3.1%) responded respectively.

5.6.3. Management commitment

From the total of sixty four respondent 43(67.2%) health facility management fulfilling the laboratory need for implementation of laboratory quality management system(LQMS).From those,24(68.6%) have regular follow up on LQMS implementation activities in the laboratory,

45(70.3%) make good communication with laboratory staff,18(51.4%) provide financial Support,10(27.2%) facilitate training program and 4(11.4%) hire additional staff. And also, here was challenge to implement the system like 11(31.4%) financial, 15(42.9%) staff turnover, 6(17.1%) staff resistance and only one (2.9%) misunderstand of the system.

Table:-6 Laboratory professional response for management commitment for laboratory to implement SLIPTA

Variables (62)		
Number of respondent about management activity for implementation of SLIPTA in the laboratory		
	Frequency	Percentage
Fulfilling the laboratory need	43	67.2
Regular follow up	24	68.6
Good communication	45	70.3
Financial Support	18	51.4
Facilitate training program	10	27.2
Hire additional staff	4	11.4

Chapter Six

6. Discussion

This study mainly focused on assessing the implementation status and progress of SLIPTA performance in public health facility within three years. Comparing average performance of 12 essential element result and identifying factors affected Stepwise Laboratory Improvement Process Towards Accreditation Program in 31 public health laboratory.

In this study as the citation of all (31/31) medical directors and laboratory professional of the study hospitals and health center described SLIPTA played great role to have continuous quality improvement, and patients 'satisfaction; and better results on achievement communication and continuous follow-up activity. Laboratory professionals gained knowledge and experience from SLIPTA program on quality management system.

According to pervious assessment, results of all the laboratories scored zero stars during baseline assessment on the WHOAFRO SLIPTA star scale. It is similar with the studies conducted in the Caribbean region in five national reference laboratories, Lesotho and Ghana but my study laboratories based on three years dates. In addition to this different results were seen in three years assessment, it shows 31 laboratories which scores zero stars are nine laboratories in 2013 but in 2015 three laboratories score zero stars and the number of laboratory with their level of score stars in 2013,22 laboratories have one and more than that stars levels in 2015 and it shows presence of good SLIPTA progression than two years.

The greatest improvements during 18 month were in corrective action (66%), organization and personnel (55%) and purchasing and inventory (54%).and the least improvement were process control (18%), occurrence management (25%), internal audits (30%) and equipment (36%) shows studies conducted in the Caribbean region in five national reference laboratories (12). In my study within three years the greatest improvements were in corrective action (58%), Occurrence management (55%), customer service(75%) ,equipment(79%) and process control(73%) and the least improvement were internal audit (50%) and management review

(52%) discordant with Leseto study. Average final absolute scores were > 55% for all areas except management review and internal audits.

Improvements in the areas of management reviews, internal audits, and corrective actions were important, as these areas are critical in the continual improvement process. This assessment finding is concordant with the study by Guevara G et al in the Caribbean Region and by Tilahun M. et al in Ethiopia (12,14),based on the findings of this study, there was a measurable improvement on the laboratories. These improvements were continued and increased with number of lab decrease from nine to three those have zero stars at the WHO SLIPTA audit result in three years. There were no laboratories that score four stars on the first two years and five laboratories get four stars and only one lab score five star in 2015.

Based on current prevalence finding using Quant-qual data collection (Interviewing) presence of training based on SLMTA, QMS and Safety has a factor to have good progress for facility manager, Lab head and quality officer. Only 2% of lab head and quality officer get a challenge to implement SLMTA. This indicates that there were have regular follow up on LQMS implementation activities in the laboratory, make good communication with laboratory staff, provide financial Support, facilitate training program and hire additional staff. And also, here was challenge to implement the system like financial, staff turnover; staff resistance and misunderstand of the system. The study conducted in Kenya based on SLMTA implementation and study on I-TECH-supported laboratories in Ethiopia support the above finding. (19,20,21).

The study on SLMTA program in developing country stated that the most common challenge such as attribution of SLMTA trained staff, encouraging the entire laboratory to work as a team, engaging hospital management and site support and insufficient mentorship capacity. Program disruption during SLMTA implementation, presence of highly staff turnover, Non- SLMTA staff involvement and program sustainability were another challenge(18).

Another finding show staff commitment one of the factor to implement SLMTA and Equipment and Purchasing and inventory section as difficult essentials and Information management and customer service were the least difficult essentials to implement. The main identified factors or challenge for implementation based on each essential elements were ,Documents and records are not properly maintained and not easily in an up-to-date Master List with Archived records and results are not easily retrievable in a timely manner.

Absence of annually management review meeting and not routinely perform a documented review are a gap on management section. Absence of system for competency assessment of personnel that include planning and documentation of retraining and reassessment and regularly evaluating client satisfaction and feedback received to improve services are found in organization and personnel and client satisfaction essential element.

The study conducted in Egypt likely with finding that is absence of equipment and methods validated/verified, service information and routinely serviced according to schedule are major problem (22).The reason why internal audit, corrective action and Occurrence management do not show best progress when compare with other, not conducted at intervals with corrective/preventive actions made based on audit findings and do not documented occurrence reports indicating the root cause of the problem(s) and corrective & preventive actions taken to prevent recurrence.

Chapter Seven

7. Strength and Limitation of the study

7.1. Strength

- Key informant interviews were used to explore facts in depth to strength the SLIPTA assessment finding and to get the root of the factors that affect SLIPTA.

- All data except pervious SLIPTA results was collected by principal investigator

7.2. Limitation

- This study was conducted only in Addis Ababa and include only 31 health facility laboratory even if currently more than 56 laboratories join SLMTA program.

- This study not separate health center and hospital finding.

- There may be minor assessors' bias with pervious audit and current audit of SLIPTA results.
- Because of presence of less sample size could not analyze some test statics.

- This study could not address the strength or the achievement of the SLIPTA program and improvement tools that used by those site during SLIPTAimplementation.

Chapter Eight

8. Conclusion

Over all 31 laboratories participate in the study have final assessment audit result based on WHO Afro Checklist on 2013 to 2015.

The range of all (31) laboratories of the previous audit score (that assessed in 2013 and 2014 before the current audit) was 71(27.5%) point score zero stars to 207(80.3%) point score three stars and 85(33%) point score zero stars to 246(95.6%) point score five stars , respectively from a possible 258 points.

At the assessment time, 9 of them have averagely 29% scored zero stars in 2013,.when we compare the result with 2015 audit result it is more better than two years and it is ranges from 109(42.5%) to 246(95.7%) three zero star score. The number of laboratory with their level of score stars in 2013 is 13(41.9%),6(19.35%),3(9.67%), have 1,2,3 stars levels respectively, result of 2015 audit shows presence of good SLIPTA progression than two years ,(number of lab 5(16%) have 4 star,[8(32%),3] and [11(29%),2], only one lab have 5 star,2(6%) have one star and 3(13%) have zero star level.

Also there were seven laboratories that score zero star on 2013 changed to two to four star level likely nine laboratory those have one star level change their status to two- four star level, four laboratories from two star level change to three star level,one lab from three to five and another laboratory from three star level change to four star level.

Quality essential element implementation had progress within three years but for management review, internal audit, corrective action and preventive action did not show radical change within three years.

The gaps or factors that affect the program corresponding to staff attribution rate, limited laboratory budget, no strengthen motivational package of the laboratory and staff turnover were seen.. The laboratory staffs including the laboratory head and quality officer and facility management had commitment and responsibility that helps to involve, to participate, to implement and to follow quality management system

Chapter Nine

9. Recommendation

Health facility management

- With the regional health bureau and /or regional laboratory has to set vision and leadership in operation and advocacy; and invite partnerships or allocate resources by Considering effectiveness and long-term viability depend on country leadership, Ownership and commitment for the program.

- Together with the laboratory management has to develop clear plan, follow up, report of laboratory's program for process design and quality measurement, analysis, and improvement systems.

- Have to give attention to human resource management and development (technical and management level) and give consideration on identification of required qualification, skills (technical, computer and supervisory management) and competency during hiring Or delegation and on job follow-up.

❖ **The Laboratory management and laboratory staffs should to have**

- Active engagement
- integrate SLIPTA on daily laboratory activities not handle as separate program
- Continues improvement plan and follow up
- Integrated planning and coordination of tasks
- Internal motivation, courage, and strong team sprit

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Annex I.

Questioner for laboratory director and quality office

This questionnaire is prepared for collecting of information on factor associated on the implementation of SLMTA in the laboratory.

Number of page = 3

ADDIS ABABA UNIVRSITY COLLEGE OF ALLIED HEALTH SCIENCES SCHOOL OF CLINICAL LABORATORY SCIENCE

Introduction;
My name is_____. I am working as data collector in a survey conducted by the Collaboration of Addis Ababa University,Medical faculty/Department of clinical laboratory. Your name will not write on this form and will never use with any information you may tell me. You don't have to answer any questions that you don't want to answer and you may end this interview at any time you want. However, your honest answer to these questions is very Important for the purpose of the study. I would very much appreciate your participation in this Survey by genuinely responding to theinterviews. Would you be willing to participate?
It would take _____ minutes to complete the questionnaire

1. If" yes" Continue to answer
2. If "No "skip to the next participant by writing the reason her or his for refusal

Date_____

Result of interview- 1.completed 2.Respondant not available 3.Refused 4. Partially completed

Checked by- Supervisor Name _____ Signature_____

Put circle on your response for choice given and write your response for those open-ended question

Part 1 Organizational factors			
S. No	Question	Response Coding Categories	skip
101	What is the level of your health facility?	1. Hospital 2. Health center	
Part 2 Socio Demographic Characteristics			
S. No	Question	Response Coding Categories	skip
102	Service year of respondent?	1. less than three years 2. Three years 3. More than three years 4. Other(specify)	
103	What is your educational level on your profession?	1. Diploma 2. BSC 3. Certificate 4. MSC	
104	Current professional of respondent?	1. Laboratory technician 2. Laboratory Technologist 3. Others (specify)	
105	What is your responsibility in organization?	1. Facility Manager (CEO) 2. Lab manager 3. Quality Manager	
Part 3 Management Commitment			
S.No	Question	Response Coding Categories	skip
106	Is your facility management body fulfilling the laboratory need for implementation of LQMS?	1. Yes 2. No	
107	Does your facility management body have regular follow up action to maintain LQMS?	1.yes 2.No	
108	Is there effective supportive supervision by the responsible bodies, (Laboratory itself, Management and	1.yes 2.No	

	AAHRL)?		
109	Is the organization infrastructure appropriate to implement LQMS?	1.yes 2.No	
110	Does the laboratory Communication with the upper mgt regularly?	1. Yes 2. No	

Part 4 Staff Training			
S. No	Question	Response Coding Categories	Skip
111	The type of "**TRAINING"** that you taken related with laboratory system strength? (if more than one, you can circle all training taken)	1.SLMTA 2.QMS 3. Safety 4. other (specify)	
112	Is activity based SLMTA program understand able to implement in your laboratory?	1. yes 2. No	
113	If "No" (for Q 012) what are the reasons?	1. Knowledge gap 2. Conflict of interest with in laboratory professional 3. Negative recognition of the program 4. Other(Specify)	
114	How many laboratory professional taking SLMTA training?	1.one 2.two 3. three 4. more than three	
115	Is there turn over on SLMTA trained personnel?	1. Yes 2. No	
116	If "yes" for Q 015, is your laboratory have got opportunity to participate gap filling (retraining) program?	1. Yes 2. No	
117	Is there a system to share after having training based on SLMTA or QMS?	1. Yes 2. No	

Part 5 Staff Commitment			
S. No	Question	Response Coding Categories	skip
118	Do all laboratory personnel fully participate on implementation of LQMS?	1. Yes 2. No	
119	Does the laboratory management delegate focal person for each essential element?	1.Yes 2.No	
120	Is there conflict of interest in your laboratory on SLMTA implementation activity?	1.Yes 2. No	
121	Which one of the following essential element difficult to implement?	1.Document and record controlling system 2.Management review 3.organization and personnel 4.cliient management 5.Equipment 6.Internal Audit 7.purchase and inventory 8.process control 9.Information management 10.corretive action 11.preventive action 12 Safety and Facility	

Annex II.

Questionnaires for Facility Manager

To assess associated factor based on management activity for implementation of SLMTA

Number of page = 1

ADDIS ABABA UNIVRSITY COLLEGE OF ALLIED HEALTH SCIENCES SCHOOL OF CLINICAL LABORATORY SCIENCE

Introduction;

My name is_____. I am working as data collector in a survey conducted by the Collaboration of Addis Ababa University, Medical faculty/Department of clinical laboratory. Your name will not write on this form and will never use with any information you may tell me. You don't have to answer any questions that you don't want to answer and you may end this interview at any time you want. However, your honest answer to these questions is very Important for the purpose of the study. I would very much appreciate your participation in this Survey by genuinely responding to the interviews. Would you be willing to participate?

It would take _____ minutes to complete the questionnaire

1. If" yes" Continue to answer
2. If "No "skip to the next participant by writing the reason her or his for refusal

Date_____

Result of interview- 1.completed 2.Respondant not available 3.Refused 4. Partially completed

Checked by- Supervisor Name _____ Signature_____

Put circle on your response for choice given and write your response for those open-ended question

S.No	Question	Response Coding Categories	skip
301	Respondent responsibility in the organization?	1.Medical Director 2. CEO 3.Other(specify)	
302	The type of "**TRAINING"** that you taken related with laboratory system strength? (if more than one, you can circle all training taken)	1.SLMTA 2.QMS 3. Safety 4. other (specify)	
303	Did you believe in SLMTA program to improve quality laboratory system?	1. Yes 2. No	
304	In what level the management supports the laboratory for quality laboratory system.	1.Finacially 2.In training program 3.By hiring additional staff 4.other(specify)	
305	Did the management perform follow up activity on laboratory to assess the effectiveness of Quality management system?	1. Yes 2. No	
306	Does the management give the recognition for the laboratory founded on quality laboratory system?	1.yes 2.No	
307	Challenge for implementation of quality management system?	1.Finacially 2.staff turn over 3.staff resistance 4.Misunderstanding 5.other	

Annex III.

WHO - AFRO Checklistto identify non-Conformities Encounter during the Assessment of Medical Laboratory.

Annex IV:

Declaration

I, the undersigned, declare that thisis my original work, has not been presented for a degree in Addis Ababa University or any other universities. I also declare that all sources of materials used for the proposal have been duly acknowledged.

Name of the candidate: YemsirachReta (BSc)

Signature_____

Place: Addis Ababa University School of Medical Laboratory Sciences, Ethiopia

Date of submission_____/_____/_____

This work has been submitted with my approval as university advisor.

Name of advisor:

Signature _____

Place: Addis Ababa University School of Medical Laboratory Sciences, Ethiopia

Date of submission_____/_____/_____

Name of advisor:

Signature _____

Place: Addis Ababa University School of Medical Laboratory Sciences, Ethiopia

Date of submission_____/_____/_____

Name of advisor:

Signature _____

Place: Ethiopian Public Health Institute (EPHI)

Date of submission_____/_____/_____