
COLLEGE OF HEALTH SCIENCES, SCHOOL OF ALLIED HEALTH SCIENCES,
DEPARTMENT OF MEDICAL LABORATORY SCIENCE

# *Assessment on the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) Implementation in Selected Public Hospital Laboratories in Ethiopia.*

By

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RESEARCH PAPER SUBMITTED TO THE DEPARTMENT OF MEDICAL LABORATORY SCIENCES, SCHOOL OF ALLIED HEALTH SCIENCES, COLLEGE OF HEALTH SCIENCES, ADDIS ABABA UNIVERSITY IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN CLINICAL LABORATORY SCIENCE (LABORATORY MANAGEMENT AND QUALITY ASSURANCE)

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**Assessment on the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) Implementation in Selected Public Hospital Laboratories in Ethiopia.**

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## List of abbreviations

ASLM= African Society for Laboratory Medicine

CAP= College of American Pathologists

CEO= Chief Executive Officers'

CLSI=Clinical Laboratory Science Improvement

DRERC=Departmental Research and Ethics Review Committee

EQA=External Quality Assessment

HIV= Human Immune Virus

ISO= International Standard Organization

JCI= Joint Commission International

MGT=Management

NGO=Non-Governmental Organization

NLTWG= National Laboratory Technical Working Group

PDCA= Plan–Do–Check–Act

PI=Principal Investigator

PPE=Personal Protective Equipment

QMS= Quality Management System

QSEs= Quality System Essentials

SANAS=South African National Accreditation System

SLIPTA= Stepwise Laboratory Improvement Process Towards Accreditation

SLMTA=Strengthening Laboratory Management Towards Accreditation

SSA=Sub-Saharan Africa

TQMS= Total Quality Management System

WHO= World Health Organization

WHO-AFRO= World Health Organization Regional Office for Africa's

## Definition of Terms:

**1. Accreditation**: Accreditation is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

**2. Accreditation bodies:** Accreditation bodies are organizations or agencies with the authority to inspect a facility and provide written evidence of its competence with regards to a standard. Many of them accredit medical laboratories using ISO 15189/17025 standard with or without national adaptation.

3. **Assessment:** is the process of gathering and discussing information from multiple and diverse sources in order to develop a deep understanding.

5. **ISO 15189:2007**: It is standard of Medical Laboratories for quality and competence," for use by medical laboratories in developing their quality management systems (QMSs) and assessing their own competence, and for use by accreditation bodies in confirming or recognizing the competence of medical laboratories.

4. **Quality Management System:** The organizational structure, responsibilities, policies, procedures, processes, standards, and resources required; it is not a static model, but a dynamic and evolving activity.

5. **Standard:** A standard is an authoritative "document" setting forth criteria for performance and characteristics. It may be issued by national, regional, or international standards bodies. The most widely accepted international standards are issued by the International Organization for Standardization (ISO), a federation of national standards bodies.

## 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 status of SLIPTA in selected public hospital laboratories in Ethiopia.

**Methods*:*** Hospital based cross sectional study design was used to assess the implementation status of SLIPTA in four public hospital laboratories in Ethiopia. The facilities were selected using purposive technique. Their implementation status was assessed using SLIPTA standard checklist, and a semi-structured questioner to identify factors during the implementation phases. The current and the last audit scores of the facilities had compared against the SILPTA score level. Interview based exploratory discussion for the key informants were used. This study was conducted from April to October 2015.

**Results:** This finding indicated that two laboratories (lab.3 and lab.4) 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 (Lab.1 and Lab. 2) 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.

**Conclusion:** Improvements were seen with Lab.3 and Lab.4 which reaching two stars from zero stars at the WHO SLIPTA audit result within one year. These laboratories had better partnership support that initiate or drive the laboratories and better management style when it is compare to the other two laboratories. The factors that affect the SLIPTA program were mainly in human resources and development part that corresponding to lack of concern, commitment, dedication, managerial skill; and resistance to new approach, staff attrition rate, no written duties and responsibilities and demotivation.

**Key Words**: SLIPTA, WHO-AFRO, Transcription, Key Informants, Quality Management System

## 1. Introduction

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 using Stepwise Laboratory Improvement Towards Accreditation (SLIPTA) (1). Strengthening Laboratory Management Towards Accreditation (SLMTA) grounded in its ability to identify deficiencies in a laboratory, improve them and measure the outcomes (2).

Starting from 2008, several landmark events have drawn attention to the poor state of public health laboratories and have pushed for strengthening of laboratory systems and networks. (3,4) In 2008, in Mozambique, African Caribbean and Pacific Group of states leaders joined in the Maputo Declaration. As part of a larger set of health goals the declaration included global efforts to strengthen laboratory systems and services in resource-limited countries. Later that year, in Senegal, the WHO African Regional Office (AFRO) laboratory network called for the establishment of a "step-wise" accreditation process. In July 2009, in Kigali, Rwanda, WHO-AFRO, Unit State partners and a group of health experts and policymakers from 13 African countries launched the WHO-AFRO step-wise laboratory accreditation program (5, 6).

SLMTA is a task-based hands-on training program aimed at effecting tangible laboratory improvements in developing countries. It includes a series of workshops that are supplemented by assigned improvement projects and supportive site visits or mentoring. To evaluate its effect, an audit is performed before (baseline) and after (exit) SLMTA implementation using the World Health Organization Regional Office for Africa's (WHO AFRO) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist (7).

SLIPTA is a framework for improvement of laboratory quality system in developing countries to fulfill ISO 15189 standards in a stepwise process to achieve accreditation and was designed based on ISO 15189/17025 Standards and the 12 QSEs of CLSI. The checklist was developed to monitor and check the progress and improvement of laboratory quality management system and award laboratories certification of recognition for quality improvement in an incremental process.

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 (8).

The 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. The five-step quality improvement process prepares laboratories for international accreditation. Using the number of accredited laboratories as a quality metric, a 2013 survey showed that 37 out of the 49 countries in SSA had no medical laboratories accredited to any internationally-recognized standards. Of the 380 accredited laboratories in that region, 91% were in South Africa and only 17% were public health laboratories (9, 10).

The national laboratory strategic plan was developed in Ethiopia in 2010 to strengthen laboratory QMS and prepare laboratories to earn accreditation (11,12). 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 (22).

One of the objectives of the second strategic plan of the national laboratory (EPHI) (2$^{nd}$ draft) for the year of (2015/16 to 2019/20) was the implementation of Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA). As a national laboratory improvement strategy, SLIPTA will be 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 will be given priority (13).

Hence, the aim of this study is to investigate the implementation status and the factors affecting in the process of moving towards accreditation using SLIPTA checklist and with key informants interview for the SLIPTA program.

## 2. Statement of Problem

The laboratories encountered challenges linked to the lack of reliable laboratory support, disease diagnosis, and management of patient care (14, 15). Among many areas of concern in laboratory services clinical misdiagnosis, inadequate health care, poor laboratory infrastructure, poor quality control practices, no strong proficiency practice ,limited test menus, poor turnaround time, and low diagnostic accuracy was seen (16).

In Ethiopia there were only two laboratories which were accredited. These laboratories are one government-owned or public clinical laboratory (National polio laboratory) by WHO and one private owned clinical laboratory by Joint commission International. In addition, Ethiopian National Accreditation Office recognizes some laboratories in country on different disciplines. SLMTA/ SLIPTA was implemented since June, 2010 but there were no laboratories which reached five stars and/or applied for accreditation internationally or nationally (17, 18).

Previously, researchers assessed the improvement status and outcome of SLIPTA/ SLMTA program. They were indicated the star levels and the 12 quality management system (QMS) of different laboratories in different times. Similarly this study assessed the study hospital laboratories' stars level and the 12 QMSE. In addition, the study showed the gaps or factors that affect the program corresponding to staff attrition rate, laboratory budget, motivational package, time utilization, partnership situation, training accessibility, clear duties and responsibility, staff involvement to the program and continuous improvement monitoring plan and supervisory management system style in detail with description in qualitative.

## 3. Significance of the Study

This research revealed the implementation status (improvement and challenges) of SLIPTA program in study areas. It would show the factors or gaps that help to indicate the way forward for these study laboratories and other related laboratories. In addition, the research could be used as a baseline for another wide or vast study in the future. As different previous study indicated many laboratories were participated in SLIPTA program.

However there were a challenge and laboratories could not improve as expected as of their long time involvement in the program. For this reason, key informant interviews were used to explore these facts in depth and to strength the SLIPTA assessment finding. The give and take of these interviews can result in the discovery of information. It revealed in a survey which might disclose strategic points for intervention.

This study will be crucial to address the root of the factors that affecting the SLIPTA program in areas of human resources management; process management and improvement management by engaging an interview with hospital and laboratory management members. It indicated the actual SLIPTA features of the study areas that would help to suggest or to establish improvement plan by themselves or with different SLIPTA contributors.

## 4. Literature Review

### 4.1SLIPTA Baseline and Exit Audit Results on Quality Management System essential

The study conducted in Caribbean region in five national reference laboratory in May 2011 with 18 month interval reveals**,** the baseline audits of the laboratory scores ranged from 19% to 52%, corresponding to 0 stars. Scores increased steadily throughout the program and by18 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 sections showing the least improvement were process control (18%), occurrence management (25%), and internal audits (30%) (19).

Another 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 (20).

The assessment in Botswana by Mokobela KO, et al in July 2010 (bassline) and November 2011(Exit) ; in July 2012 to February 2013 using SANAS described that one of the keys to success of the roll-out of SLMTA in the laboratories was strong staff commitment and involvement. During the training sessions, staff involvement was cultivated by the formation of teams that brainstormed improvement projects and outlined specific implementation tasks. This practice fostered a culture of problem solving and boosted confidence amongst laboratory staff, who felt empowered to implement improvement projects previously considered beyond their

capability. These projects were developed by the trainees and responsibility was shared across the laboratory team. The audit result at baseline was four of the seven laboratories had a zero-star rating, two had one star and one had two stars. At exit, two laboratories remained at zero stars, four laboratories were rated at two stars and one laboratory was rated at three stars (21).

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 %) (22).

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 (23).

### 4.2 Factors affecting Step wise Laboratory Improvement Process Towards Accreditation

CLIA regulations which was published and become effective on April 24, 2003 stated that laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel. It is his/her responsibility to develop and to ensure the laboratory polices on use of a quality management system approach which helps to provide accurate and reliable patient test results (24).

An international standard (ISO15189) of medical laboratories requirements for quality and competence stated that the responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory. The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory. The duties and responsibilities of the laboratory director shall be documented. The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard (25).

The survey conducted in laboratories in upper South Carolina hospitals were done to determine job satisfaction and stress levels by Rogers DA indicated that of 27 (47%) technologists who reported job satisfaction, 3 (5%) were neutral and 29 (48%) were dissatisfied with their jobs. About half (48%) of those surveyed reported that there is job dissatisfaction. The results of this study indicate that management should implement strategies to increase the job satisfaction and decrease the job stress of clinical laboratory scientists (26).

The study by Ketchum SM. in 1991 on overcoming the four toughest management challenges: Increase your effectiveness by using situational leadership revealed that the high-pressure work environment of the clinical laboratory presents significant challenges for managers. Often thrust into supervisory roles without formal management training, laboratory managers un able to find

ways to delegate tasks, mediate conflict, minimize office politics, and build effective teams out of employees who may be quite diverse in their experience levels, motivation levels, and cultural backgrounds (27).

Another study by Pfeiffer IL and Dunlap JB. in Athens, on empowered employees- a good personnel investment cited that clinical laboratory managers are facing the challenge of having to do more with less. This "pressure-cooker" environment requires clinical laboratory managers to find new ways to motivate their teams to perform at peak levels at all times; the key to doing this is empowerment. By empowering employees, managers create a nurturing environment in which their staffs can learn, grow, improve, and function effectively. This type of environment is created when managers are honestly concerned about their employees and exhibit a true "partner" attitude. This article describes specific actions that clinical laboratory managers can take to empower their employees to work together to do better jobs (28).

The study in Kuwait by Al-Enezi N. et al on the overall job satisfaction of medical laboratory scientist graduates of one Kuwaiti University from the years 1982 to 2001 concluded that a high percentage of laboratory technologists were not satisfied overall with their jobs or with specific aspects of their jobs. Particularly important in this respect were whether technologists felt that their work appropriately used their knowledge, feelings of technical competency, work related rules/procedures, and presence of unhealthy competition. These issues of health worker dissatisfaction need to be addressed by the health authority managers responsible for these services and by academics who train Medical Laboratory Scientist workers (29).

The study in Mozambique in 2011 by a national laboratory technical working group (NLTWG) to integrate SLMTA within the existing structure of the ministry of health laboratory system was developed a self-sufficient quality program. This implementation framework of this group was established and a dedicated coordinator hired. The Ministry of health provided the vision and leadership in operation and advocacy, coordinated and financed the program with partner support and pressed for SLMTA activities to be included in provincial and hospital annual plans and

budgets. Decentralizing the program management to the provincial level has enabled them to increase program coverage and lower the costs (30).

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 (31).

An innovative training approach to accelerate laboratory accreditation in Uganda pilot testing by Yao et al on the efficacy of the SLMTA program which was aim to assess the efficacy of the SLMTA program, specifically the task-based approach and multi-workshop delivery model, capture lessons learned, refine the curriculum, and guide future program rollout. The assessment revealed that the SLMTA program increased communication, among laboratory staff and between laboratory staff and hospital administration (32).

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 biosafety, often caused inconsistency in the quality of mentorship and delays in the SLMTA process (33).

# 5. Objective

## 5.1 General Objective

- To assess the implementation status of Stepwise Laboratory Improvement Process Towards Accreditation in selected Public hospital laboratories in Ethiopia.

## 5.2 Specific Objectives

- To evaluate the current performance of the laboratories
- To compare the current performance with the previous audit result
- To identify factors affecting Stepwise Laboratory Improvement Process Towards Accreditation program

# 6. Materials and Methods

## 6.1 Study Design

A cross sectional study design was used in selected public hospital laboratories in Ethiopia.

## 6.2 Study Site,

**Yirgalem General Hospital** inaugurated in 1968 G.C and previously run by Norwegians. It has 200 beds, serving for 4 million peoples. It is far from Addis Ababa 300 k.m to Southern Nations, Nationalities and Peoples Region

**Queen Eleni Mohammed Memorial Hospital** found in Hosanna town. It is one of the zonal hospitals of Southern Nations, Nationalities and Peoples Region

**Gambella Regional Hospital** found in Gambella National Regional State. It is one of the major hospitals which located in the region and Gambella town.

**Debrebirhan Referral Hospital** provides services to approximately 2.4 million people in North Shoa, East Amhara Zone.

## 6.3 Population

### 6.3.1 Source of Population

All hospital laboratories which are participated in the first three SLIPTA cohorts in Ethiopia were the sources of population.

### 6.3.2 Study Population

The study populations were Yirgalem general hospital, Queen Eleni Mohammed Memorial general hospital, Gambella Regional hospital and Debrebirhan Referral Hospitals' Laboratories

## 6.4 Inclusion and Exclusion Criteria

### 6.4.1 Inclusion Criteria

Hospital laboratories that the participated in SLIPTA program and having previous assessment results were included in the study.

### 6.4.2 Exclusion Criteria

Hospital laboratories which are participated but having insufficient data and which are not willing to participate in the study were excluded from the study.

### 6.5 Sampling Procedure

Purposive sampling technique was used to select the study facilities that full fill the inclusion criteria. They were selected from the first three cohorts of SLIPTA program to see their long time progress and suitability. The study area were selected to ensure representation of various levels of hospital laboratories in distances and supports that include, one federal, one regional, one referral, one general, one zonal/general hospitals and one district hospitals from four regional state and one city administration. The key informants for the semi-structured questioner interview were the Laboratory managers; the Quality officers, the Medical Directors, and/or the Chief Executive officers of the facilities were selected to get the detailed responses since they are being as lead focal persons in SLIPTA enrollment. A total of 16 key informants were interviewed in the four hospitals.

### 6.6 Data Collection Strategies

#### 6.6.1 Data Collection Tools

Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) checklist, which was the same version with pervious checklist (SLIPTA Checklist that contain 111 main sections, a total of 334 questions for a total of 258 points). It had been used to evaluate and to compare the current status with the previous one on the twelve quality management system essential elements, and each item has a value of 2, 3, 4 or 5 points. Laboratory Profile about their prior audit status, staff profile, and basic infrastructure were recorded on the SLIPTA checklist allowed spaces. Semi-structured questionnaire were used to assess the factors affecting throughout the implementation phases. It is adapted from ISO15189 medical laboratories requirements for quality and competence and from the SLIPTA checklist Annex 13.3.(25) Triangulation method had been used to get valuable findings as indicated in figure 1.

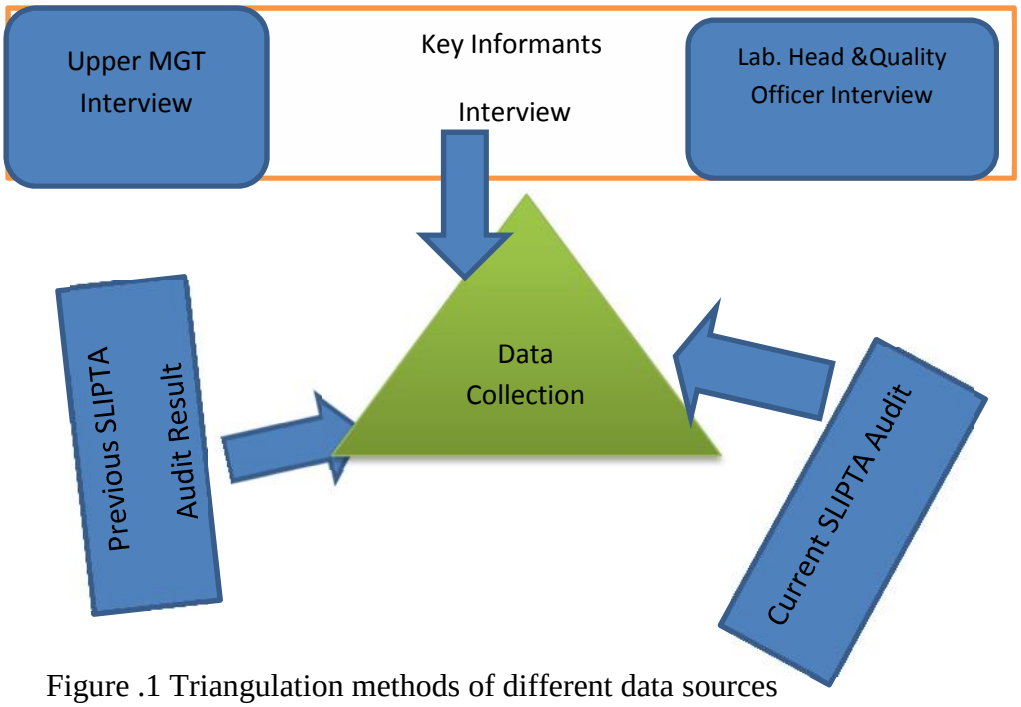


Figure .1 Triangulation methods of different data sources

### 6.6.2 Data Collectors

Data were collected by the principal investigator, to assemble the qualitative data using the above mentioned data collection tools.

### 6.6.3 Data Collection Period

The data were collected from May to June 2015**.**

### 6.7 Data Analysis and Interpretation

Data of SLIPTA-checklist entered and analyzed using Microsoft® Excel; and simple descriptive statistics were used to present the findings. SLIPTA scores were summarized and presented as range. Percentage scores were determined by dividing the respective scores of the sum of each QMS and total scored points by the maximum possible points and expressing the results as a percentage (Figure 2). Relative point distribution of the SLIPTA checklist over different sections, subdivided over the three quality cycle stages ( Figure 3).

The semi- structured (key informants) data were analyzed by transcribing the data or gathering techniques to generate narrative expression of the key informant responses.

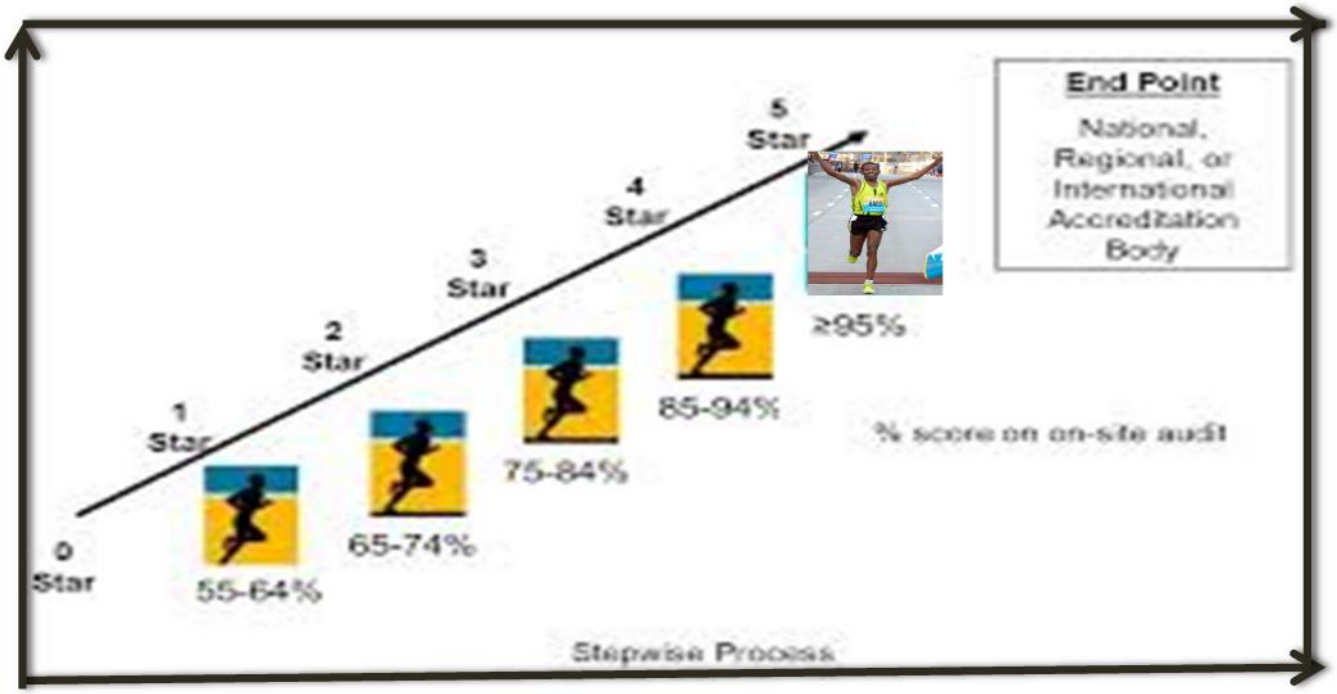


**Figure 2: SLIPTA Tiers of Recognition of Laboratory Quality Management [Adapted from original graphic by Gershy-Damet et al]**


**Figure 3: SLIPTA Tiers of Recognition of Laboratory Quality Management [Adopted from: T. A. M. Datema et al. Critical review of the SLIPTA]**

### 6.8 Data Quality Assurance

To collect the information in a standardized data extraction form; SLIPTA checklist was used which was originally developed by WHO-AFRO and were used for all the 12 quality system essential. Semi-structured questioner for open-ended question was used to collect data on factors that affecting SLIPTA. This Semi-structured questioner was developed and reviewed by supervisor and trained personnel.

Discussion on the use of semi- questioner and SLIPTA checklist was made clearly with trained personnel and with the supervisors. Participant laboratories were well oriented on the objective of the study, thereby encouraged to provide genuine information. In order to enhance the quality of data each facility were monitored and assessed the relevant documents during interview.

The principal investigator was in close to do on the strategies of the data collection, flow of work on the day-to-day data collection process and ensure completeness and consistency. Answers and audit results were supported with witness or observation.

The data of SLIPTA checklist points was entered in Microsoft® Excel and before doing the analysis; the entire data was cross checked by PI and supervisors for reliability and completeness on the collected hard copy data and soft copy of the entered data. The final result of the laboratory were conducted and rechecked by the supervisor.

## 6.9 Ethical Consideration

Ethical clearance paper was collected from departmental research and ethics review committee (DRERC) of the medical laboratory sciences, school of allied health sciences, College of Health Sciences; Addis Ababa University. Concerning the confidentiality of the result, since all laboratories that were willing to participate had unique code for confidentiality. This code had kept well throughout the study. The results of each laboratory findings were provided and communicated with the respective hospital laboratories. Information with regard to the overall laboratory status was forward only to the respective health facility higher management body, and during publication, synonymous code would be used.

### 6.10 Dissemination of Results

The result of this study was 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.

# 7. Results

## 7.1 Current performance of the laboratories

Four laboratories fulfilled the inclusion criteria for the current assessment from a total population of six laboratories. Of the four laboratories, two of them (Lab.1 and Lab.2) scored zero stars and the other two laboratories (Lab.3 and Lab.4) scored two stars in current SLIPTA audit. The total score of the laboratories ranges from 95 to 182 points from a total possible point of 258. The best performing laboratory (Lab.4) scored 182 points or 70.54% that positioned in two stars in SLIPTA score scale. The next laboratory was Lab.3 which attained two stars with a total point of 175 or (67.8%). Lab.1 and Lab.2 achieved 95 (36.8%) and 104 (40.3%) respectively.

The best performance of Lab.4 (attained two stars) was resources management that achieved more than 80% (except equipment) from a total expected point in areas of facility & safety, organization & personnel and purchasing & inventory. Performance of process management and improvement management was less than 80% in all areas of quality management system. The least performances were information management (<40%), client management & customer service (50%) and management review (<60%).

The performances of Lab.3 which attained two stars in current audit result were better in resource management and in document & records it scored 24 points from 25 possible points. Another best performances of this laboratory were organizational & personnel, purchasing & inventory and internal audit that scored =< 80%. The weakest areas were occurrence & incident management (25%), client management & customer service (38%) and information management (50%).

The performances of the two laboratories (lab.1 & Lab.2) which scored zero stars in current audit were better in resource management when compare to process and improvement management but in all quality management systems except facility and safety both laboratories scored which was less than 60%. The weakest areas were improvement management (internal audit 0 points, management review 17%, for both laboratories; and occurrence/incident management & process (25% & 17%) and corrective action (8% & 0%) for Lab.1 and Lab.2 respectively.

### 7.2 Comparison of Laboratories with previous and current audit results

The range of all (4) laboratories of the previous audit score (that assessed in a time of eight to twelve months before the current audit) was 82-102 points from a possible 258 points. At that assessment all of them scored zero stars on the WHO-AFRO SLIPTA star scale. The current mentorship of the two laboratories (lab.3 and lab.4) improved with a total score of 175(67.78%) and 182 (70.54) points from 82(31.8%) and 102(39.5%) correspondingly that positioned in two stars on SLIPTA score scale. (Table 1)The previous audit result of the other two laboratories (Lab.1 and Lab.2) were 94 (40.3%) and 84 (32.6%) points respectively. They had no shift from zero stars on current audit of SLIPTA score scale which score 95 (36.8%) and 104 (40.3%). (Figure 2)

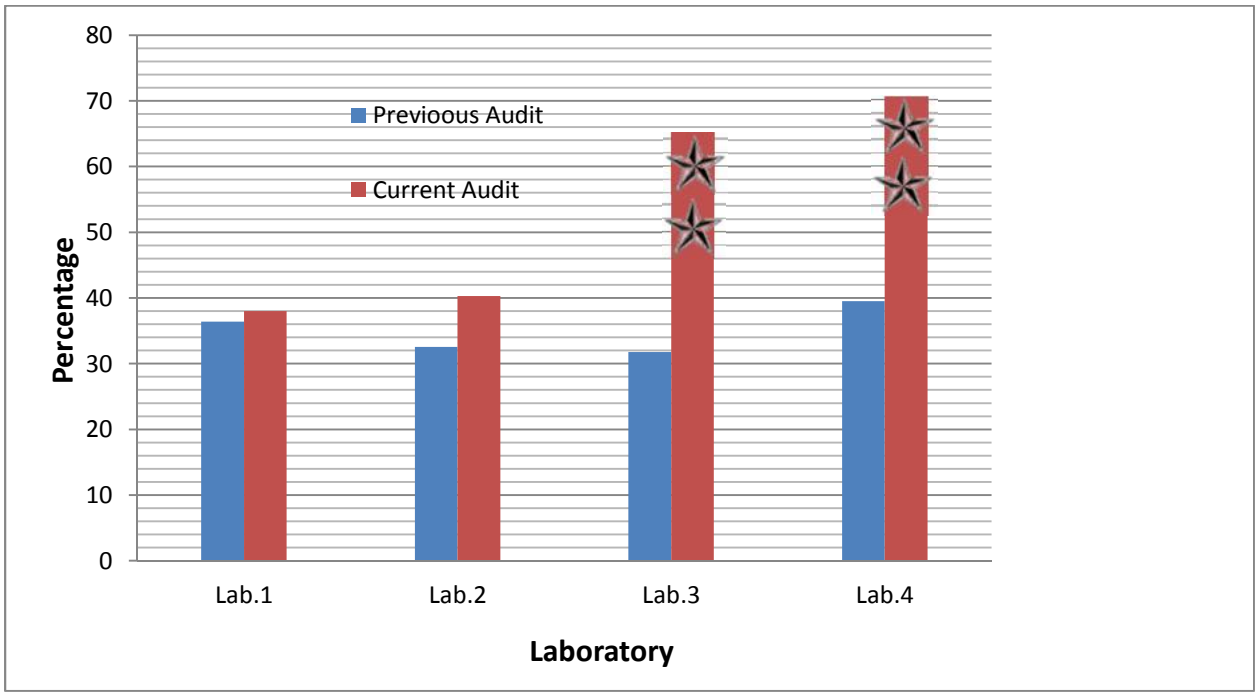


Figure 4: SLIPTA scores and star levels at the previous and current audits of the four laboratories.

Table.1 SLIPTA assessment result that show total score, percentage and star level of the pervious and current audits of the laboratories.

| | Possible score | Lab.1 Audit result | | Lab.2 Audit result | | Lab.3 Audit result | | Lab.4 audit result | |
|---|---|---|---|---|---|---|---|---|---|
| | | Pervious | Current | Pervious | Current | Pervious | Current | Pervious | Current |
| Total Score | 258 | 94 | 95 | 84 | 104 | 82 | 175 | 102 | 182 |
| Percentage | 100% | 36.4% | 36.8% | 32.6% | 40.3% | 31.8% | 67.8% | 39.5% | 70.5% |
| Star Level | Five | Zero | Zero | Zero | Zero | Zero | Two | Zero | Two |

For these laboratories (Lab 3 & lab 4) which scored two stars with the greatest point improvements were in areas of Documents & Records (16/25 & 14/25); Purchasing & Inventory (18/30 & 15/30) and Equipment (11/30 & 11/30) points which gained in the current audit respectively to each laboratories.

No improvements were seen in areas of client management & customer service that score 4 points from 8 points; facilities and safety scored 26 points for Lab.3 in both audit; and previous audit 33 points & current audit 34 points from 43 possible points for Lab.4. All laboratories scored zero pints in previous audit in internal audit except lab.4 that scored 2 points; and 8 points in current audit for Lab.3 and Lab.4 from possible 10 points. The other low scored point in all laboratories was Occurrence/Incident Management & Process Improvement. In this quality management system all laboratories scored a maximum 3 points in both audit except Lab.4 that score 6 points form a point of 12 in current audit. Form 258 total possible points almost no changes in Lab.1 but Lab.2 increased 10 points only in current audit. They remained almost in the same points in all 12 quality management system essentials. (Figure 5-8)

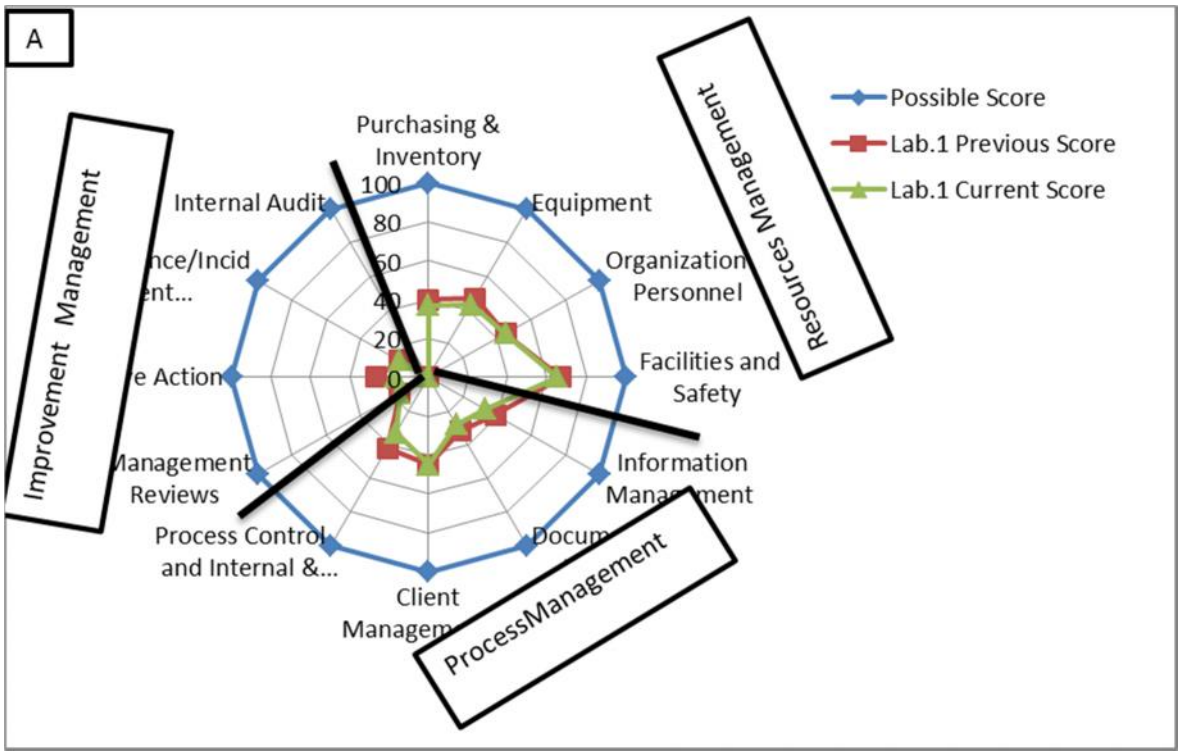


Figure 5: Performance of Lab.1 on 12 QMSE

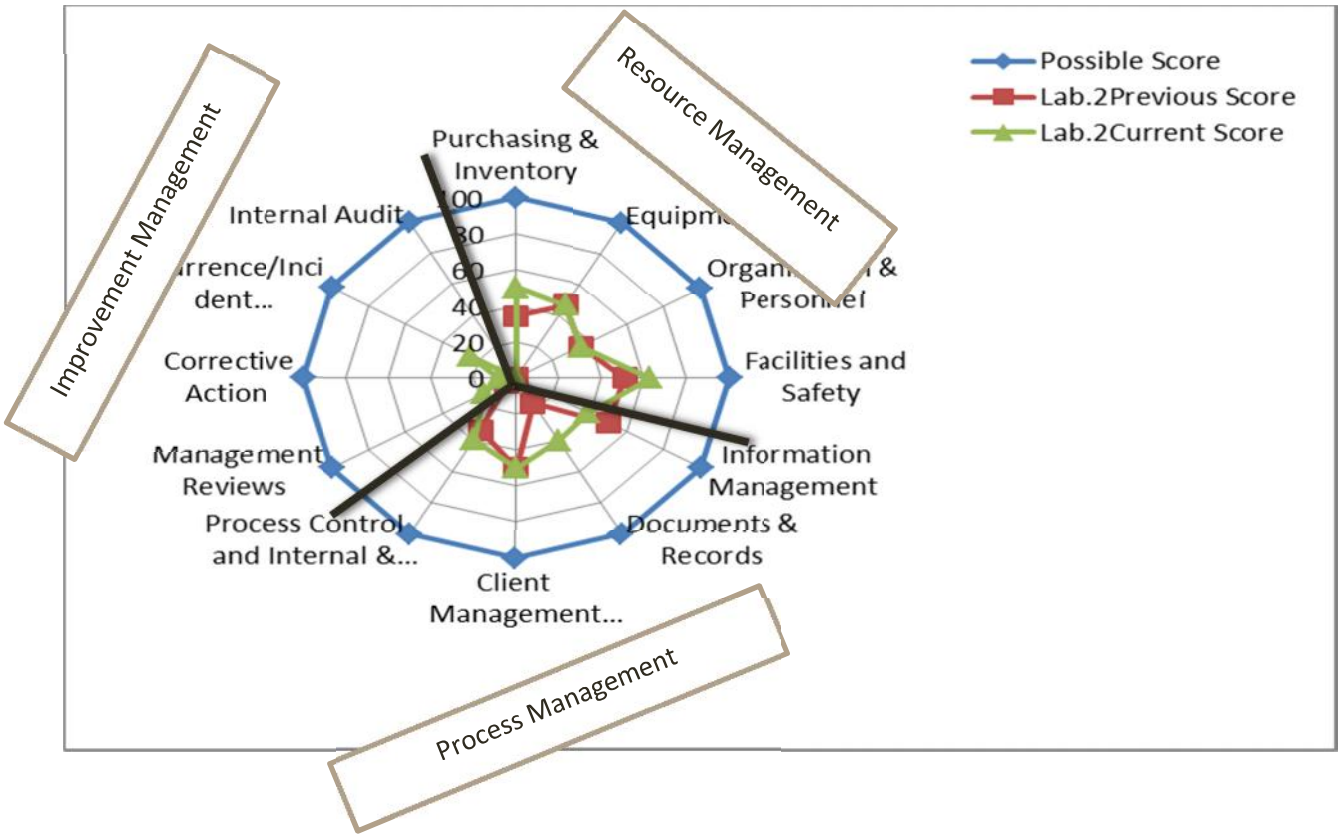


Figure 6: Performance of Lab.2 of 12 QMSE

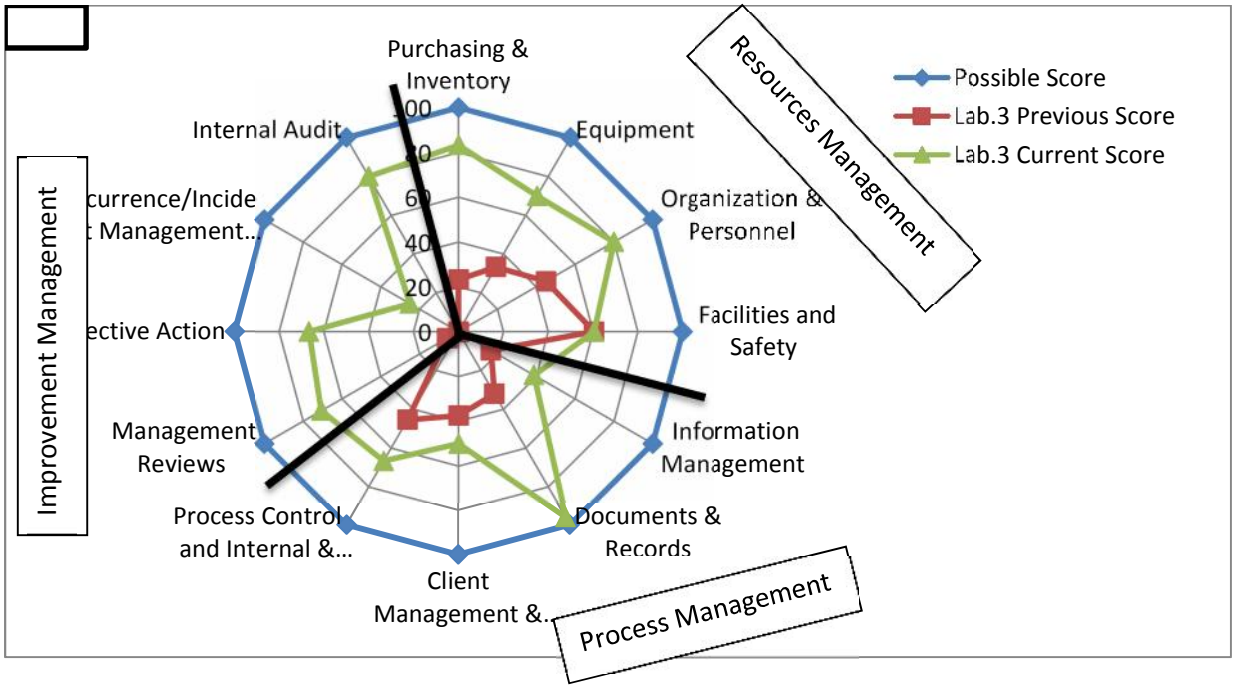


Figure 7: Performance of Lab.3 of 12 QMSE

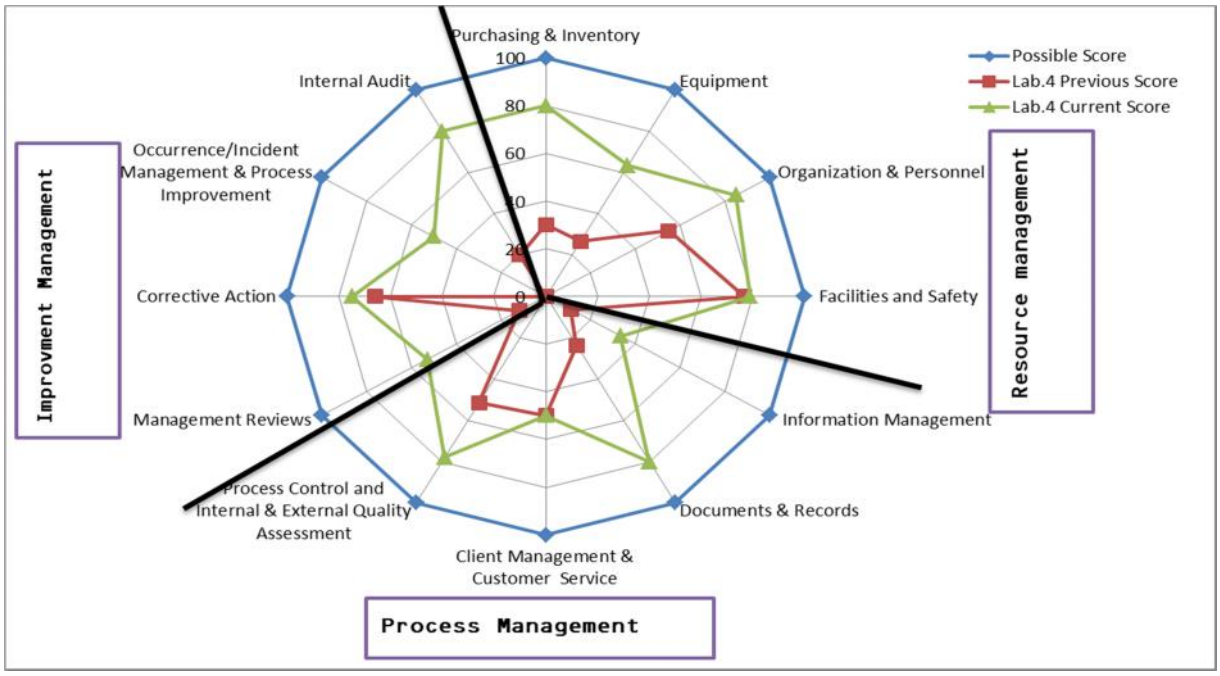


Figure 8: Performance of Lab.4 of 12 QMSE

### 7.3 Factors affecting SLIPTA

This finding shows the factors that affecting SLIPTA on different quality management system for each study laboratories. The result was integrated from current SLIPTA audit and from interview of a total of 16 key informants. From these key informants eight of them were laboratory management and eight of the others were hospital upper management members.

Table 2: Factors affecting the performance of the 12 QMS essential elements of Lab.1

| Quality management system | Score | Main identified factors or challenges |
|---|---|---|
| **Purchasing & Inventory** | 11/30 | No request and specification, lack of concern |
| **Equipment** | 13/30 | No validation verification , maintenance, |
| **Organization & Personnel** | 9/20 | Lab. MGT focuses in routine task, no written duties and responsibility , turnover ,no training ,Weak team spirit, unstructured |
| **Facilities and Safety** | 28/43 | Patient can enter in the lab, the lab not managed the available space |
| **Information Management** | 6/18 | communication (informal), lack of concern |
| **Documents & Records** | 7/25 | Lack of focus, lab MGT engaged in routine task, skill gap |
| **Client Management & Customer Service** | 2/8 | lack focuses, concern |
| **Process Control and Internal & External Quality Assessment** | 12/33 | Result was not secured due to inattention, EQA not done as the standard due to delay, |
| **Management Reviews** | 3/17 | Resistance for new approach, No budget & work plan, |
| **Corrective Action** | 2/12 | Resistance , skill gap, no motivation to do, SLIPTA not integrated with routine activities by all staff, lack of concern |
| **Occurrence/Incident Management & Process Improvement** | 2/12 | Resistance , skill gap, no motivation to do, |
| **Internal Audit** | 0/10 | Resistance , skill gap, no motivation to do, |

As the description of key informants of the Lab.1 and the result of current SLIPTA assessment; there was no seated motivational package from hospital management and the laboratory management that encourages the laboratory staffs for inspiration.

*''The numbers of staffs were enough but there was a skill gap and a person could not contribute his/her time, effort, skills, knowledge, and work behaviors by keeping quality due to demotivation. This is due to low salary, no risk payment, no overtime payment; and no good laboratory equipment and no enough training.''* Laboratory head

Mentoring and coaching (managerial activities) for technical staff:

*''We were discussed with the laboratory manager to do their managerial activities but they continuously involved in technical operation ''* medical director

*''We have mentoring and coaching but it is not strong because we are involved in many duties including the routine''* laboratory head

Staffs are not engaged in their daily activities.

*''Staffs will absent due to social background, demotivation, personal behavior, family issue; and it is difficult to warn and advice since the staffs feel and response…..* Laboratory head

Communication with upper management:

*''There is no awareness on the SLIPTA program, no fast responses and it is hard to convince the upper management''* Qualiy officer

*''The laboratory mostly communicated verbally''* CEO

Partnership:

*''There is limited support from regional laboratory only on supervision and EQA but is not as scheduled''* medical director

*''We don't have any partner currently but last time NGOs innovated the laboratory''* laboratory head

Maintenance of equipment:

*''Maintenance price is so expensive after completion of contract''* laboratory head

*''We have limited budget for maintenance and for others''* medical director

**Table 3: Factors affecting performance of the 12 QMS essential elements of Lab.2**

| Quality management system | Score | Main identified factors or Challenges |
|---|---|---|
| **Purchasing & Inventory** | 15/30 | lack of concern, no supply request |
| **Equipment** | 14/30 | Maintenance, no focuses and practice, no verification |
| **Organization & Personnel** | 7/20 | No training, turn over, Lab MGT involved in operation activities, way of employment, no written responsibilities and duties |
| **Facilities and Safety** | 27/43 | No chair, table, no monitoring of temperature |
| **Information Management** | 7/18 | No commitment ,Informal communication |
| **Documents & Records** | 10/25 | lack of commitment and concern |
| **Client Management & Customer Service** | 4/8 | Lack of initiation ,lack of focuses , |
| **Process Control and Internal & External Quality Assessment** | 13/33 | EQA not done as the standard,( external factors), no verification reagents and equipment |
| **Management Reviews** | 3/17 | Resistance, lack of commitment , no identified indicators |
| **Corrective Action** | 1/12 | SLIPTA not integrated with routine activities by all staff |
| **Occurrence/Incident Management & Process Improvement** | 3/12 | No monitoring practice, resistance , |
| **Internal Audit** | 0/10 | Resistance, no motivation, |

According to the cited of key informants of the laboratory management of Lab.2, they were not engaged in employment. They had added that recruiting, interviewing, orientation and training or continuous professional development of new staff were not conducted as the standard.

*''Requirement of laboratory professionals for the specific operation was not responded as the need of the laboratory. Transfer of the staffs from another health facility took place in the case of different concerns which is not in case competency''* Laboratory head

*''We do not have a strengthened competency assessment during employment and on job''.* Medical Director

*''No strong summarized and compiled periodic and routine monitoring; because we are resistance for new approach but we believed it is very important.''* Quality officer

*''High turnover of trained laboratory professionals, especially who had a skill in quality-management, SLIPTA, in biosafety and dedicated staffs had high attrition rate that cause a delay in the SLIPTA process. Therefore the remaining staffs including me and the quality officer would be stretch due to more assignment that make too thin; and lost engagements that tend to disengage and lose productivity''.* Laboratory head

Partnership:

*''At this time we do not have partner, ideally regional health bureau together with regional laboratory have a responsibility to support SLIPTA but no support from both side''* laboratory head

*''We do not have any support for SLIPTA''* medical director

Delegation letter of Quality officer: *''Mr X… .. you are doing in the hospital as laboratory technologist; … starting from this date you are delegated as quality officer of the laboratory in addition to your current activities''*

Table: 4 Factors affecting performance of the 12 QMS essential elements of Lab.3

| Quality management system | Score | Main identified factors or challenges |
|---|---|---|
| **Purchasing & Inventory** | 25/30 | - |
| **Equipment** | 21/30 | Maintenance, late response for purchasing, no verification |
| **Organization & Personnel** | 16/20 | Staffs not adequate, turn over, no written duties and responsibility, hospital MGT not involved in SLIPTA, no training, employment , lack of structured man power, |
| **Facilities and Safety** | 26/43 | Staffs did not use of PPE (gown, N-95) during operation, physical structure and space of laboratory |
| **Information Management** | 7/18 | No attention ,Late response of hospital MGT |
| **Documents & Records** | 24/25 | No challenge due to NGO provision |
| **Client Management & Customer Service** | 4/8 | No way of follow of client concern, no focus |
| **Process Control and Internal & External Quality Assessment** | 22/33 | EQA not done as the standard, no verification |
| **Management Reviews** | 12/17 | No improvement plan, so no follow up… |
| **Corrective Action** | 8/12 | Good in follow up due to support of the NGO |
| **Occurrence/Incident Management & Process Improvement** | 3/12 | Record of occurrence started ,no monitoring of indicators |
| **Internal Audit** | 7/10 | No challenge. NGO supports to do |

Organization and personnel:

*''Carrier development and new required professional were not considered by performance evaluation, competency and qualification.''* Laboratory head

*''There is no written job description from the hospital for each staff; it is developed from civil service in general ''* laboratory head

*''In our hospital, management was not involved in quality assurance program and had no much awareness since there was a lot of turnover of medical directors that had be new for the program .''* Quality officer

SLIPTA (accreditation) not integrated in routine task:

Minute of the meeting agenda: *''….resistance to do especially for accreditation''*

Partnership:

*''We have good support from partner''* medical director *''We have good support from partner on mentorship, in day to day paper work including developing laboratory manual, laboratory hand book , logs, forms and others.''* laboratory head

Number of adequate qualified staffs:

''The *number of staffs are not adequate and we need SLIPTA training ''* laboratory manager

*''Since the numbers of staffs are few in number we want to employee more laboratory professionals.''* Medical director

During SLIPTA audit we observed:

Many laboratory professionals did not wear gown and glove. They were doing the laboratory work with their own normal cloth during any procedure.

The hospital laboratory did not do any chemistry test for more than three years due to maintenance problem and they could not access a new automation. The laboratory partner was following and asking any quality activities of the staffs regularly.

Table: 5 Factors affecting performance of the 12 QMS essential elements of Lab.4

| Quality management system | Score | Main identified factors or challenges |
|---|---|---|
| **Purchasing & Inventory** | 24/30 | no request and specification |
| **Equipment** | 19/30 | Maintenance, no Validation & verification, no calibrations indicated |
| **Organization & Personnel** | 17/20 | Turnover, no orientation, no written duties and responsibilities lack of structured man power, |
| **Facilities and Safety** | 34/43 | No challenge (excellent facilities and safety practices) |
| **Information Management** | 6/18 | |
| **Documents & Records** | 20/25 | - |
| **Client Management & Customer Service** | 4/8 | No separate client concern follow up |
| **Process Control and Internal & External Quality Assessment** | 26/33 | EQA not done as the standard, skill gap interpreting of quantitative IQC, no verification of reagent |
| **Management Reviews** | 9/17 | No work plan with the management ,lack of concern |
| **Corrective Action** | 9/12 | No focus, |
| **Occurrence/Incident Management & Process Improvement** | 6/12 | No monitoring on quality indicators |
| **Internal Audit** | 8/10 | No challenge It is done together with the support of |

Organization & Personnel:

*''Responsibilities and duties of each staff was developed by civil service and it is common for each qualification''* medical Director

*'No clear measuring approach for new staff competency and they will transfer from another health facility as promotion''* medical Director

*''There is lack of commitment and involvement quality management due to knowledge gap or negligence''* quality officer

*''There is no structured man power''* quality officer

Partnership:

*''There is no commitment to support SLIPTA since it is not implemented as part of regional health bureau and as a point of comparison for the hospitals''*

*‘‘Currently, there was no enough support from different partners for SLIPTA program and it was not implemented by regional health Bureau as a program. It should be assumed as part of the hospital duties. The implementation disregarded from previous experience which is handled with national program and different NGOs. So the program had to be handled with regional health bureau as one indicator to compare one hospital with the other. Follow up as well as allocation of the budget had to be done by hospital CEOs for the SLIPTA activities.’’* Quality officer

Purchasing and inventory:

*‘‘We were not develop specification for purchasing instead it is selected/supported by NGOs and pharmacy department’’* Laboratory head

*‘‘No detail plan, report of laboratory’s program for process design and quality measurement, analysis, and improvement system due to work load’’* medical director

## 8. Discussion

This study mainly focused on assessing the implementation status of SLIPTA along with the current performance of the laboratories, comparing the current performance with the previous audit result and identifying factors affecting Stepwise Laboratory Improvement Process Towards Accreditation program in four hospital laboratories in Ethiopia.

In this study as the citation of all (8/8) medical directors and CEO of the study hospitals described SLIPTA played great role to have continuous quality improvement, and patients' satisfaction; and better results on achievement of TAT and documentation. Laboratory professionals gained knowledge and experience from SLIPTA program on quality management system. This is concordant with the finding of the study which is done by Lulie AD et al in Ethiopia (23).

According to pervious assessment, results of all the laboratories scored zero stars on the WHO-AFRO SLIPTA star scale. It is similar with the studies conducted in the Caribbean region in five national reference laboratories and another study in Lesotho but our study laboratories stayed in the program more than four years. In addition to this different results were seen in exit (current) assessment of this study which scores two stars in two laboratories but the remaining two laboratories score zero stars which are not comparable with the exit assessment of the above study. They had scored two and more than two stars in all laboratories in 18 months and in 10 weeks of time respectively. This may be due to the follow up and support of the program . But the finding of the study by Mokobela K. had similar results in exit audit with our current audit results (19, 20, 21).

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 had lowest points in these QMEs areas with no improvement unlike the finding of the, a study by Maruta T. et al in Lesotho; but this finding is concordant with the study by Guevara G et al in the Caribbean Region and by Tilahun M. et al in Ethiopia (20,19 ,22).

Based on the findings of this study, there was only a measurable improvement on the two laboratories. These improvements were continued and increased, with the Lab.3 and Lab.4 which reaching two stars from zero stars at the WHO SLIPTA audit result in less than one year. But Lab.1 and Lab.2 remained in the same move in each 12 QMS. This indicated that it is possible to get progress towards accreditation using the SLIPTA program if there is an initiation of the partnership support and good laboratory management style that can conduct better supervisory management. This is finding concordant with the study in Botswana by Mokobela KO, et al (21).

As indicated in table 5-8 all (8) laboratory management members were not engaged in hiring of new laboratory staffs; and no written duties and responsibility for laboratory management but as CLIA regulations and ISO 15189 clearly stated the laboratory director responsibility ‘‘as laboratory director, he/ she is responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel’’.There for gaps may be seen in the demand of the laboratory; and it may be difficult for the laboratory manager in managing of staffs (24,25).

As the respondent of all (16/16) key informants high turnover of trained laboratory professionals, especially who had a skill in quality-management, in SLIPTA, in biosafety and dedicated staffs had high attrition rate that cause a delay in the SLIPTA process. Due to this reason the remaining staffs including the laboratory head and quality officer may be stretch due to more assignment that make too thin; and lost engagements that tend to disengage and lose productivity. This finding is similar with the studies which were conducted by Mamo W. in Ethiopia (33).

The key informants of Lab.1 which score zero stars expressed that the numbers of staffs are enough but there was a skill gap; and a person cannot contribute his/her time, effort, knowledge, and work behaviors by keeping quality due to demotivation. The laboratory management believed that this is due to low salary, no risk payment, no overtime payment; and no good laboratory equipment and no enough training. This finding is similar with the findings of Rogers DA in upper South Carolina hospitals and another study in Kuwait by Al-Enezi N. et al (26, 29).

As indicated in all hospital laboratories there was no clear plan, follow up, report of laboratory’s program for process design and quality measurement, analysis, and improvement system in periodic and routine time using identified indicators. This indicates that there were no work plans that reflect the findings of management review, process improvement, objectives and action of the laboratory that support for the improvement. This may be due to the gaps in human resources and development in skill gap, lack of concern, resistant to new approach, engagement of laboratory management in routine activities (due to no written and understand responsibility and duties). The study conducted in Kenya in Bungoma District hospital laboratory expressed that without hospital management support, sustainable changes are difficult to achieve; and plans had designed in order to improve the laboratory staff’s customs, beliefs and attitude of laboratory quality improvement activities (31).

The laboratory management indicated that there was a challenge in communication with hospital management due to late response and in convincing of question for every inquiry. But in another side the hospital upper management stated that the communication was informal and not evidence based to hospital higher management regularly or at any time that focuses on personnel, facility and other operational needs. Unlike this study in Uganda pilot testing on SLMTA training showed that increased communication, among laboratory staff and between laboratory staff and hospital administration, was reported during SLMTA approach (32).

Maintenance was another main challenge of all hospitals. They had stated that response from federal level (national laboratory) was too late. They had recommended that maintenance activities have to be decentralized to regional or zonal level to get better reply.

In this study the laboratory manager and QA officer were involved in many different routine tasks rather than doing the managerial supervision and paper work. At the time of assessment at all hospital laboratories there were no laboratory managers and QA officers who were tending more time in managing overall laboratory operations; administrative and management matters; consulting with principal investigators; and monitoring the daily activities but there is no similar study in this area. However, ISO 15189 and CLIA regulation described the duties of the laboratory manager as ‘‘the responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory’’ (24,25).

Laboratory head and quality officer duties, responsibility and authorities were not designed or well-known clearly by top management of the hospital so that they could not follow the activities accordingly. This had also made a gap on required competency, qualification and supervisory management style on planning, organizing, staffing, leading (directing), and controlling activities toward the achievement of predefined goals and objectives of SLIPTA. So that the hospital managements may not know initially at the time of delegation of laboratory head and quality officer if there were no clear duties and responsibilities. Therefore there would be challenging to supervise, to handle the task of the management and could not meet what is anticipated for SLIPTA program. This finding is supported by the study by Ketchum SM. on overcoming the four toughest management challenges. Increase your effectiveness by using situational leadership and the study by Pfeiffer IL, Dunlap JB. (27,28).

Support on SLIPTA program from different partnership on budget or financial resources, maintenance, mentoring is not as required except Lab.3. It was not sustainable and integrated with the routine activities of the laboratories; and was done as one time- on provision. Unrelated finding of this study by Masamha J. et al, in Mozambiques stated that the Ministry of Health provided the vision and leadership in implementation and advocacy, coordinated and financed the programme with partner support and pressed for SLMTA activities to be included in provincial and hospital annual plans and budgets. Decentralizing programme management to the provincial level has enabled them to increase programme coverage and lower the costs (30).

# 9. Strength and Limitation of the study

## 9.1 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 with the principal investigator

## 9.2 Limitation

- This study was conducted only in three regional sate in four hospitals in Ethiopia so it did not illustrate all type of laboratories in the country.

- There may be minor assessors' bias with pervious audit and current audit of SLIPTA results.

- This study could not address the strength or the achievement of the SLIPTA program in deep as it is more focus on the factors affecting the program and current performance.

## 10. Conclusion

The two laboratories (lab.3 and lab.4) improved from zero stars to a total score of 168 and 182 or (65.12% and 70.54%) respectively that positioned in two stars on SLIPTA score scale. But the other two laboratories (Lab. 1 and Lab. 2) remain in the same situation in their audit results of the previous and current SLIPTA audit. The improved laboratories had better partnership support that initiate or drive the laboratories and better management style when it is compare to the other two laboratories.

It is clear that to do process and improvement management, resources management especially skilled and concerned human resources were very important. This study indicated this as we see the results of improvement management which scored least points. The gaps or factors that affect the program corresponding to staff attrition rate, limited laboratory budget, no strengthen motivational package of the laboratory were seen. Currently, there were no strong and integrated partnerships from different stake holders except Lab.3; no enough SLIPTA training with practical approach.

The laboratory staffs including the laboratory head and quality officer had no written duties and responsibility that helps to involve, to participate and to follow in the program accordingly. There was no continuous improvement monitoring plan which supports for progress. There was also a challenge on supervisory management system style (the action of overseeing and managing employees in the workplace) which was seen in laboratory management. They were involved in every activity rather than invested on employees.

## 11. Recommendation

- **The hospital 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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# 13. Annexes

## 13.1 Annex-I. Questionnaire for Key Informant (Laboratory Head Quality Officer) to identify factors affecting Stepwise Laboratory Improvement Process Towards Accreditation program

Date Prepared =April, 2015

Number of Pages= 4

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

Identification

Name of the Facility _____Code_____

Dear Sir/Madam;

My name is Kefelegn Beyene. I am currently a postgraduate student of Addis Ababa University, department of medical laboratory sciences in the track of Clinical laboratory Management and Quality Assurance. I am going to conduct a research study on the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) in Selected Public Hospital Laboratories in Ethiopia.

The objective of this study is to assess the implementation status of SLIPTA in selected Public hospital laboratories in Ethiopia.

The benefit of the study will be identifying the gaps which affecting SLIPTA in the 12 QMS that helps to indicate the recommendations for improvement. This will have an input for better health care service for the specific study site by inviting for direction from the finding. It will not have risk since the confidentiality will be kept strongly. If you are volunteer, your valuable opinion will be treated with highest privacy. You will be required to respond to an interview which takes one and half hour to complete this survey.

Your participation is voluntary and you are not obliged to answer any question that you do not want to answer. If you are not comfortable with the study, please feel free to stop in any time you like.

Thank you for participating in the study!

Please give the answer for the following questions by ticking √ in the given space (Yes or No) and continue asking the key informant to brief the given answer until obtaining deep, meaningful, and thoughtful answers. (Use attached paper to write the answer).

**I-Part One: Human Resource Management**

| | Laboratory Personnel focuses | Yes | No | Note |
|---|---|---|---|---|
| 1 | Does the staff have responsibilities and duties in written form? For Yes: how and for No: why? | | | |
| 2 | Does the assigned personnel are allotted adequate amounts of time to fulfill their duties for the program? | | | |
| 3 | Do you assured the laboratory have provided adequate knowledge-based training consistent with their roles in the program (SLIPTA)? | | | |
| 4 | Do you facilitate orientation of new employees and providing ongoing in-service training and continuing education? For Yes: how and for No: why? | | | |
| 5 | Do you see gap for SLIPTA program due to turn over of trained /experienced personnel/? For Yes: how and for No: why? | | | |
| 6 | Do you have mentoring and coaching approach for technical staff? For Yes: how and for No: why? | | | |
| 7 | Do you assume a person contributes his/her time, effort, skills, knowledge, and work behaviors by keeping quality? For Yes: how and for No: why? | | | |

**II-Part Three: Resource Management System**

| No. | Laboratory Resource Management System | Yes | No | Note |
|---|---|---|---|---|
| 1 | Do you have budget or financial resources in separate for the laboratory? For Yes: how and for No: why? | | | |
| 2 | Do you have laboratory department request on laboratory equipment's? | | | |
| 3 | How the laboratory equipment selected and purchased? | | | |
| 4 | Are equipment specifications and maintenance needs routinely communicated to upper management? | | | |
| 5 | Do you assume physical structure and space in the laboratory to facilitate efficient and effective delivery of laboratory services? | | | |
| 6 | Can you say there is adequate resources are provided for the quality management and improvement program (to meet the goal of SLIPTA)? For No: Why? | | | |
| 7 | Do you have supply requests clearly and documented? For Yes: how and for No: why? | | | |
| 8 | Do you assume the personal protective equipment (safety items) enough for use? For No: which? | | | |

**Part-III: General Questions and Suggestions**

1. Do you have periodic and routine monitoring of quality management system?

_____
_____
_____
_____
_____
_____
_____.

2. Please suggest your remark on factors affecting SLIPTA in your laboratory?

_____

_____

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3. Do you assume the hospital laboratory has enough support on SLIPTA program from different partner?_____

_____

_____

_____

_____

_____

4. Final comment/suggestion

_____

_____

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**13.2 Annex-II Questionnaire for Key Informant (Hospital Upper Managements) to assess the involvement of upper management on Stepwise Laboratory Improvement Process Towards Accreditation**

**Date Prepared =Feb, 2015**

**Number of Pages= 5**

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

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Your participation is voluntary and you are not obliged to answer any question that you do not want to answer. If you are not comfortable with the study, please feel free to stop in any time you like.

Thank you for participating in the study!

Please give the answer for the following questions by ticking √ in the given space (Yes or No) and continue asking the key informant to brief the given response until obtaining deep, meaningful and thoughtful replies for each question. (Use attached paper to write the answer).

**I-Part One: Human Resource Management**

| No | Laboratory Personnel focuses | Yes | No | Remarks |
|---|---|---|---|---|
| 1 | Does the management have laboratory heads' responsibilities and duties in written form? For Yes: how and for No: why? | | | |
| 2 | Does the assigned personnel are allotted adequate amounts of time to fulfill their duties for the program? How? | | | |
| 3 | Does other supervisors' responsibilities are clearly defined in written form? | | | |
| 4 | Dose the management assured the laboratory personnel's provided adequate knowledge-based training consistent with their roles in the program (SLIPTA, ART others)? | | | |
| 5 | Does the management have the way of determining the qualifications and competence of laboratory staff? For Yes: how and for No: why? | | | |
| 6 | Does the management facilitate orientation of new employees and providing ongoing in-service training and continuing education? For Yes: how and for No: why? | | | |
| 7 | Does the management assume there is an adequate number of qualified competent staff? | | | |
| 8 | Does the hospital set retaining mechanism for valuable employees from leaving their jobs? For Yes: how and for No: why? | | | |

**II-Part Two: process management**

| No | Management and Leadership Issues | Yes | No | Remarks |
|---|---|---|---|---|
| 1 | Do the management have plan, report of laboratory's program for process design and quality measurement, analysis, and improvement system? For Yes: how and for No: why? | | | |
| 2 | If No.1 is yes; is the work plan reflect the findings of management reviews in its goals, objectives and action? | | | |
| 3 | Does the laboratory management annually perform a review of all quality systems at a management review meeting? For Yes: how and for No: why? | | | |
| 4 | Does the management check safe use maintenance, and supervision of space, equipment and other environmental element such as required utilities? | | | |
| 5 | Does the management support on developing plans, managing processes, and setting priorities to measure, assess, and improve the quality of laboratory services in the implementing of quality management and improvement system on SLIPTA? | | | |
| 6 | Does the laboratory have communication tool with upper management regularly or at any time regarding personnel, facility and other operational needs? | | | |
| 7 | Do Leaders communicate to laboratory staff the priority of meeting the needs of clinicians, patients, and other users of laboratory services? | | | |
| 8 | How do you handle client satisfaction, clinicians and patients regarding its services, either on an ongoing basis or through episodic solicitations? | | | |

**III-Part Three: Resource Management System**

| No. | Laboratory Resource Management System | Yes | No | Remarks |
|---|---|---|---|---|
| 1 | Does the management assume a budget or financial resources is enough to operate for the laboratory services? For Yes: how and for No: why? | | | |
| 2 | Do you have laboratory department request on laboratory equipment's? For Yes: how and for No: why? | | | |
| 3 | How the laboratory equipment selected and purchased? | | | |
| 4 | Are equipment specifications and maintenance needs routinely communicated to upper management? (How?) | | | |
| 5 | Do you assume physical structure and space in the laboratory to facilitate efficient and effective delivery of laboratory services? | | | |
| 6 | Does Management Review the Supply Requests? | | | |
| 7 | Does management review the finalized supply requests? | | | |
| 8 | Do you assume the personal protective equipment (safety items) enough for use? | | | |

**IV-Part Four: General Questions and Suggestions**

1. Please suggest your remark on the impact of SLIPTA for your laboratory on quality improvement?

_____

_____

_____

_____

_____.

2. Do you assume the hospital laboratory has enough support on SLIPTA program from different partner?_____

_____

3. Final comment/suggestion

## 14. Statement of declaration

By my signature below, I declare and affirm that this thesis is my own work. I have followed all ethical principles of scholar in the preparation, data collection, data analysis and completion of this thesis. All scholarly matter that is included in this thesis has been given recognition through citation. I affirm that I have cited and referenced all sources used in this document. Every effort has been made to avoid any plagiarism in the preparation of this thesis. I sincerely declare that this thesis has not been submitted to any other institution anywhere for the award of any academic degree, diploma or certificate.

Name: Kefelegn Beyene / MSc Candidate /

Signature: _____

Date of submission: _____

This thesis has been submitted with my approval as University advisor.

Name: _____

Signature: _____

Date of submission: _____