PERCEIVED DETERMINANTS OF ADHERENCE TO STANDARD OPERATING PROCEDURES AMONG LABORATORY PERSONNEL AS PER THE STAFF IN THE DEPARTMENT IN BOMET COUNTY, KENYA

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A Thesis Submitted to the Institute of Postgraduate Studies of Kabarak University in Partial Fulfillment of the Requirements for the Award of the Master of Medicine in Family Medicine Degree

KABARAK UNIVERSITY

NOVEMBER, 2022

DECLARATION

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   i. This research is my own work and to the best of my knowledge, it has not been presented for the award of a degree, diploma and certificate in any university or college.

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RECOMMENDATION

To the Institute of Postgraduate Studies:

The research thesis entitled **"Perceived Determinants of Adherence to Standard Operating Procedures among Laboratory Personnel as per the staff in the department in Bomet County, Kenya"** written by **Sifora Fanta Chaleabo** is presented to the Institute of Postgraduate Studies of Kabarak University. We have reviewed the research thesis and recommend it be accepted in partial fulfillment of the requirement for award of the degree of Master of Medicine in Family Medicine.

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ACKNOWLEDGEMENT

Above all I would like to thank my almighty Father who has held my hand through this journey. Praise, honor and glory be to your Holy name. I would like to express my gratitude to my beloved family Fanta Chaleabo, Akalat Chemo, Tamirnat Fanta, Tigist Fanta, Tsegaab Fanta and Mehereteab Fanta.

I would like to thank my supervisors Dr. Joy Mugambi and Dr. Matthew Loftus thank you for the encouragement and continuous support.

DEDICATION

I would like to dedicate this research to Tenwek and Longisa laboratory staff and management. All things are possible through Christ!

ABSTRACT

Laboratory errors are a major burden in health care systems. To decrease laboratory error and increase laboratory quality international health organizations such as the World Health Organization developed laboratory quality management systems (QMS). One of the QMS essentials (Documents and Records) contains Standard Operating Procedures (SOPs). SOPs are step-by-step instructions that laboratory personnel use as a guide in performing laboratory procedures. Thus, adhering to SOPs ensures consistency, accuracy, and quality of laboratory procedures, thereby increasing laboratory data quality and reducing errors. However, studies in Kenya have shown low percentage results in evaluating documents and records, which means low adherence to SOPs. This study aimed to identify the determinants of adherence to SOPs. A qualitative phenomenological study was conducted in two conveniently selected hospitals (Tenwek Mission Hospital and Longisa County Referral Hospital) in Bomet County, Kenya. Four focused group discussions and eight key informant interviews were done. Based on the objectives, collected data were analyzed using manual coding and thematic analysis. The study identified themes that determine adherence to SOPs which mainly is the working environment, factors that promote adherence to SOPs are professional education, leadership factors, and work environment. Key areas that needed intervention on SOPs adherence are personal reasons, professional education, and quality equipment. Professional education and leadership have been suggested for the sustenance of intervention. Recommendations to hospitals to increase opportunities for professional education and to increase the number of staff to help lower workload are made.

Keywords: Laboratory error, standard operating procedures, Laboratory personnel

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ABBREVIATIONS AND ACRONYMS

ASCP	American Society for Clinical Pathology
CDC	Center for Disease Control and Prevention
CLSI	Clinical Laboratory Standards Institute
EQA	External Quality Assessment
FGD	Focused Group Discussion
GCLP	Good Clinical Laboratory Practice
HIV	Human Immunodeficiency Virus
ISO	International Organization for Standardization
KENAS	Kenya Accreditation Service
LM	Laboratory Manager
LT	Laboratory Technicians
MOH	Ministry of Health
NACOSTI	National Commission for Science, Technology & Innovation
PARIHS	Promoting Action on Research Implementation Health Services
PGH	Provincial General Hospital
QMS	Quality Management Systems
QO	Quality Officer
RIDDOR	Reporting of Injuries, Diseases & Dangerous Occurrences Regulation
SLMTA	Strengthening Laboratory Management toward Accreditation
SOPs	Standard Operating Procedures
TB	Tuberculosis
TRH	Teaching and Referral Hospital
WHO	World Health Organization
WHO AFRO	World Health organization's Regional Office for Africa

OPERATIONAL DEFINITION OF TERMS

Laboratory Error: is defined as any paucity that occurs during a laboratory procedure.

Laboratory Personnel: are laboratory professionals that are supervising or managing laboratory procedures as well as supervising or managing the laboratory. Laboratory personnel and laboratory technicians are terminologies that will be used interchangeably in this study.

Adherence to SOPs: is compliance of the laboratory personnel to standard operating procedure while performing any given laboratory test.

Leadership Support: is behavior, attitude and action of laboratory personnel and hospital managers that influence adherence to SOPs.

Culture: refers to are potential contextual barriers that influence adherence to SOPs.

Evaluation Capabilities: are reflections given to laboratory personnel and laboratory technician that may affect performance.

Receptivity to Change: is openness, responsiveness and readiness of laboratory technician and laboratory personnel to improvement.

CHAPTER ONE

INTRODUCTION

1.1 Introduction

This chapter will discuss the presence of laboratory errors in different parts of the world, and how it has affected health care systems. Elaboration about interventions done in international and national settings to reduce laboratory error and provide quality laboratory data will be made. Laboratory Quality Management Systems (QMS) has been developed by World Health Organization's Regional Office for Africa (WHO AFRO), the Centers for Disease Control and Prevention (CDC), and the American Society for Clinical Pathology (ASCP) to improve laboratory quality and reduce error. This study focuses on Standard Operating Procedures (SOPs) which are a portion of QMS essentials, further discussion on the importance of SOPs, deficiency in the implementation of SOPs, and advantages of adherence to SOPs will be discussed. This chapter will reflect on several studies in Kenya that display low scores on SOPs evaluation, including adherence. This study seeks to discover the determinants that affect adherence to SOPs in Bomet County Kenya. Finally, the aim, specific objectives, and assumptions will be discussed in this chapter.

1.2 Background of the Study

Laboratory errors have become a major burden in the health care system. In developed countries such as the United States of America (USA) and the United Kingdom (UK), despite advanced laboratory technologies, laboratory errors are highly prevalent (Mohammedsaleh & Mohammedsaleh, 2015). According to Wagar, Tamashiro, Yasin, Hiborne, and Bruckner (2006) 0.92 per 1000 pre-analytical laboratory errors have been reported in 147 laboratories in the USA. In Africa, several countries have documented tremendous laboratory errors. For example, one of the main government hospitals in

Ethiopia, Addis Ababa, reported up to 33.1% of overall laboratory errors and in Kenya, Kenyatta National Hospital reported up to 42% (Tadesse, Desta, Kinde, Hassen, &Gize 2018; Kimengech, Waithaka, Onyuka, &Kigondu 2017). Despite the importance of laboratory data, in clinical practice errors occur.

Laboratory data is important in the health care system. About 60-70% of clinicians make important decisions such as diagnosing, admitting, discharging, and treating based on laboratory data (Plebani, 2006). Petti, Polage, Quinn, Ronald, and Sande (2006) reported that the limiting factors of laboratory test use could be associated with unavailability and low laboratory quality, which may lead to clinicians' over-reliance on clinical signs and symptoms for diagnosis. This might lead to misuse of antimicrobials further contributing to global drug resistance and increased morbidity/ mortality (Petti et al., 2006; Reyburn et al., 2004). Therefore quality laboratory data is crucial in the healthcare system, as it has a great influence on clinical decision-making in the healthcare system.

In order to provide quality laboratory data, international health organizations such as World Health Organization's Regional Office for Africa (WHO AFRO), the Centers for Disease Control and Prevention (CDC), and the American Society for Clinical Pathology (ASCP) have developed laboratory Quality Management Systems (QMS) as one of the systems used to provide laboratory quality (World Health Organization, 2011). QMS is a system that assures the accuracy, reliability, and timeliness of laboratory tests by reducing laboratory errors. QMS uses 12 quality system essentials that are developed by Clinical Laboratory Standards Institute (CLSI) namely,

i. Document and records
ii. Management reviews
iii. Organization and personnel
iv. Client management and customer service

v. Equipment
vi. Internal audit
vii. Purchasing and inventory
viii. Process control and internal and/or external quality assessment
ix. Information management
x. Corrective action
xi. Occurrence and/or incident management and process improvement
xii. Facilities and safety (World Health Organization, 2011)

These essential elements must be addressed in order to improve laboratory quality. In addition to improving the laboratory quality, these same essentials are used for national and international accreditation of a laboratory (Schneider, Maurer, & Friedberg, 2017). For a certain laboratory to be internationally accredited; it has to fulfill the International Organization for Standardization (ISO) 15189, ISO/IEC 17025, and ISO 9001, which are international standards utilized for medical practices (World Health Organization, 2011; Yao, Maruta, Luman, & Nkengasong, 2014).

Internationally accrediting laboratories has been a challenge in Africa. There are several challenges that occur particularly in developing countries, causing poor quality laboratory data. Some of these challenges include a lack of available and well-maintained materials, a lack of well-trained professionals, and poor water and electricity supply (Nkengasong et al., 2010). As of July 2009, 340 laboratories in Sub-Saharan Africa have been internationally accredited, of those, 312 (91.8%) were from South Africa (Gershy-Damet et al., 2010) and only 28 (8.2%) were from other countries.

When a certain laboratory applies for accreditation, it goes through the process of evaluation, then the result is given as a pass or fails according to ISO 15189. In

developing countries considering the above challenges (a lack of available and well-maintained materials and well-trained professionals, poor water and electricity supply) different approach to the accreditation system was developed by WHO AFRO. This accreditation system approach provides gradual progress to international accreditation by using certain programs (Gershy-Damet et al., 2010). Some of the programs are Good Clinical Laboratory Practice (GCLP) and Strengthening Laboratory Management toward Accreditation (SLMTA). These programs are used to improve laboratory quality by providing a stepwise approach to implementing ISO 15189 (Gumba et al., 2018; Luman, Yao, & Nkengasong, 2014).

SLMTA and GCLP are training curriculums and laboratory quality improvement implementation programs in developing countries. They use Stepwise Laboratory Improvement Towards Accreditation (SLIPTA) checklists divided into 12 sections, based on 12 laboratory quality system essentials, hereby leading laboratories in developing countries towards national and international accreditation and quality assurance (Gumba et al., 2018). Prior to GCLP and SLMTA, external quality assessment (EQA) programs (which are programs that use a review of a certain laboratory by an external peer group to improve the quality of service) were being used as a quality improvement of laboratories. EQA review comprises several parameters including compliance with SOPs (Makokha et al., 2014).

In our country Kenya, national laboratory accreditation is done through Kenya Accreditation Service (KENAS). The Ministry of Health (MOH) in Kenya has the aim of accrediting all of the public laboratories in Kenya (Luman et al., 2014). Once a certain laboratory applies for accreditation, the process of accrediting is done guided by ISO 15189, and ISO/IEC 17025 accreditation standards specifically for medical laboratories (Kenya Accreditation Service, 2019). According to Barbé, Yansouni, Affolabi, and

Jacobs (2017), asof 2017, only 31 laboratories in Kenya have been internationally accredited. Inour county, Bomet, out of five major hospitals which are Longisa County Referral Hospital, Ndanai Sub-County Hospital, Sigor Sub-District Hospital, Kaplong Hospital, and Tenwek Mission Hospital some of them have gone through SLMTA programs steps toward accreditation and one of them Tenwek Mission Hospital has been provided national accreditation by KENAS. Once a certain laboratory is nationally accredited, reassessments on the sustainability of the laboratory quality are done by KENAS, which assists the progress to international accreditation. This research will focus on a section of the essential QMS- Documents and Records. Documents are written guides of all laboratory test procedures. They are available and accessible for every laboratory personnel or any other person foruse. They are safely kept and updated yearly or whenever there is a need to update. Examples of documents are- SOPs, Job aids, and quality manuals. Records are collected data upon performing laboratory tests, they include information such as patients' results (World Health Organization, 2011). Furthermore, this study will focus on SOPs.

"SOPs are step-by-step instructions the laboratory personnel uses as a guide in performing laboratory procedures." (World Health Organization, 2011).

These SOPs are meticulous guides of all laboratory procedures that laboratory personnel use. They are used to confirm the competence, reliability, safety, and accuracy of laboratory tests done. They contain information about managing samples, maintaining the quality, and actions to be taken in case of unfavorable incidences and reporting (World Health Organization, Regional Office for South-East Asia. & World Health Organization. Regional Office for the Western Pacific. 2011).

SOPs are to be followed at all phases of the laboratory testing process. This means that laboratory personnel has to comply with SOPs during the pre-analytical (specimen handling and labeling prior to being received in the laboratory), analytical (the actual laboratory testing or diagnostic procedures) and Post-analytical (resulting and interpretation of the test) (World Health Organization, 2015).

SOPs are either given internationally by organizations such as WHO or developed/adopted from machine templates (guides prepared by the machine company) by laboratory personnel. WHO is responsible for the development of SOPs of certain laboratory tests, such as malaria smear and rapid malaria test, TB Gene X-pert, and rapid HIV tests. These SOPs provided by WHO give policies that serve as templates for some common laboratory procedures and they are distributed to laboratory facilities. Even though national policies are provided, all laboratories have to develop their own policies using available resources. This means that in addition to the WHO, laboratories make their own SOPs adopted from the policies provided and also templates of certain laboratory equipment. SOPs need to be adapted to the local standard and be relevant to the functions appropriate for the level in each laboratory setting (Barbara Barbé et al., 2016).

SOPs should include manuals, instructions for machines, and test kits used. After the adaptation, written SOPs are finalized, reviewed, and approved by the organization's head of department and the laboratory manager. Once a SOPs is written, everyone performing work should read it carefully and sign at the SOPs training documentation page at the end of the SOPs template (Barbara Barbé et al., 2016).

Adherence to SOPs assures quality laboratory service. Manghani, K. (2011) reported that adherence to SOPs has several benefits to laboratory personnel, patients, and health facilities/ laboratory.

Benefits to laboratory personnel: Laboratory personnel will have confidence in the service he/she is providing, he/she will provide quality and reliable data, he/she will provide timely service and he/she will improve the quality of overall laboratory service.

Benefits to Patients: Patients will have satisfaction with the turnaround time of laboratory service provided additionally they will benefit from quality laboratory service.

Benefits to Health facility/Laboratory: The laboratory will increase the reliability of laboratory service, progress toward national and international accreditations, and increase laboratory business.

Systematic adherence to SOPs significantly improves laboratory data accuracy and precision, allowing for consistent interpretation and reliance upon laboratory results. In doing this, laboratory personnel will synchronize laboratory practices, reduce laboratory errors, and ensure quality laboratory data (Barbara Barbé et al., 2016). Barbosa, Mauro, Cristóvão, and Mangione (2011) reported that adherence to SOPs gives quality, harmonious results, hence it is recommended that laboratory leaders give instructions and teachings on adherence to SOPs. Though SOPs have great advantages that improve laboratory quality it also has some detriments. According to Amare (2012), SOPs limit one's ability to generate new ideas, use creative skills to improve quality or be restricted to a particular guideline. This reduces the freedom to work as one desire. In other ways, SOPs may be time-consuming, especially in areas where number of tests to be done, it may cause a delay.

In order to have quality laboratory data and further internationally accredit laboratories, Kenya started implementing SLMTA in 2010 and GCLP in 2014. These programs utilize the SLIPTA checklist guide based on the 12 QMS essentials. The SLIPTA checklist for Documents and Records monitors descriptions of the roles and responsibilities of all

laboratory personnel. It measures adherence to SOPs, properly maintained, accessible and updated documents and records among other checklists (World Health Organization Regional Office for Africa, 2011).

Several studies done in different laboratories in Kenya in the evaluation of the 12 QMS essentials show a low level of audit evaluation on documents and records, which includes SOPs. For example, Maina et al. (2014) implemented the SLMTA program in five laboratories in Kenya. They saw that all five laboratories in their study improved in all 12 quality essentials at the exit audit. Among the 12 quality essentials, documents and records (SOPs) were one of the low points in the initial audit that showed a marked improvement at the exit audit (from 33% to 77%). Another study done among 315 laboratory staff on malaria test quality assurance found that only ten percent of the facilities initially were recording quality assurance activities by complying with SOPs; after a refresher course, the activities increased to 61% (Wanja et al., 2017). The low scoring on evaluation has been observed in several laboratories in Kenya. Makokaha et al (2014) implemented SLMTA in Kenya through Kenya's Ministry of Health (MOH). They selected eight laboratories that were balanced in the geographical and regional sites of Kenya. These are Kakamega PGH, Oginga Odinga TRH, Nakuru PGH, Nyeri PGH, Embu PGH, Garissa PGH, and Mbogathi DH. All of the laboratories were previously running the EQA to improve the quality of service. They found low scores in some of the 12 essentials, including documents and records (SOPs). The study implemented the SLMTA mentorship project by training and partnering laboratory personnel (twinned) and training without partnering (un-twinned) program. The programs are implemented in separate laboratories for both programs. For both programs, the initial audit of the study showed a low result of documents and records (7% for twinned and 9% for un-twinned) after the implementation of the project the percentage increased significantly (71% for

twinned and 79% for un-twinned). This study is regionally balanced data that shows a low evaluation level of documents and records or SOPs in these regions. Kakamega PGH is about 136km away from Bomet County, where this study's site is. The SLIPTA checklist that was done in Tenwek Hospital laboratory in 2015 scored 71% in documents and records, after internal audits and quality improvements the scores increased significantly to 82% in 2019. This has led to national accreditation of the laboratory by KENAS. In view of this, the determinants affecting adherence to SOPs remain unknown.

In conclusion, the studies presented so far have illustrated the prevalence and seriousness of laboratory errors in Kenya. To reduce error and improve quality, QMS has been implemented. Despite the importance and benefit of SOPs, studies show low evaluation results. Other studies have even indicated minimal improvement despite training (Maina et al., 2014; Makokha et al., 2014; Wanja et al., 2017). Therefore, this study seeks to elucidate the determinants that affect adherence to SOPs among laboratory personnel in Bomet County, Kenya.

1.3 Statement of the Problem

The problem of laboratory errors in Kenya has become critical. Kimengech et al. (2017) reported a significant number of errors at all stages of laboratory testing: pre-analytical error is 42.8%, an analytical error is 32.9% and post-analytical error is 24.3%. Additionally, the study urged laboratory management, health care facilities, and policymaker action on the development of studies to increase laboratory quality. Quality laboratory data is important for clinical decision-making. The quality of a certain laboratory is achieved and maintained through QMS (World Health Organization, 2011). Documents (SOPs) which are one of the essentials of QMS are an important parameter that can determine the quality of laboratory data. Non-compliance to SOPs reduces quality laboratory data here by increasing laboratory error (Barbara Barbé et al., 2016).

Number of studies statistically indicates a low percentage of score on evaluation of documents (SOPs) and records in Kenya (Maina et al., 2014; Makokha et al., 2014; Wanja et al., 2017). Additionally, Makokha et al. (2014) study done in regionally balanced clinical laboratories in Kenya reveal a low percentage score in Documents (SOPs adherence) unfortunately the reason for low adherence to SOPs in Kenya has not been studied so far. Therefore, this study intends to inquire the perceived determinants of adherence to SOPs as per the laboratory personnel in Bomet County, Kenya. The results of this qualitative study can be used to generate hypotheses for further interventional programs. These findings will guide the design of subsequent policies and programs to improve adherence to SOPs in Bomet County, Kenya, and beyond.

1.4 Purpose of the Study

The purpose of the study is to identify the perceived determinants that influence adherence to SOPs among laboratory personnel in Bomet County, Kenya.

1.5 Objectives of the Study

i. To identify the perceived determinants that affect adherence to SOPs, by the laboratory personnel.
ii. To explore factors that promote adherence to SOPs.
iii. To identify key areas requiring further intervention on SOPs adherence.
iv. To inquire further ideas to sustain interventions.

1.6 Significance of the Study

This study seeks to identify the perceived determinants that affect adherence to SOPs. This subsequently may improve laboratory quality, reduce laboratory error, and increase reliability of clinicians on laboratory data. Identified determinants impacts laboratories by improving the adherence of laboratory technicians to SOPs, health facilities by

improving the over-all laboratory quality, it may assist clinicians receive quality laboratory data which subsequently promotes better treatment of patients, the identified determinants also impacts health service providers, provides information for additional research, it will impact policy makers, county government and the country Kenya. Understanding the adherence to SOPs highlights areas for further research in the area. Addressing the determinants leads to laboratory quality improvement and hence improves health care system. Additionally, addressing the determinants helps in national and international accreditation of laboratories. This supports the progress toward Sustainable Development Goal 3 which is to ensure healthy lives and promote well-being for all at all ages.

1.7 Assumptions of the Study

The assumptions of this study are:

i. Laboratory personnel will give information about determinants that are affecting their compliance to SOPs.
ii. Laboratory personnel will give their opinion on areas that need further intervention in relation to SOPs.
iii. Laboratory personnel will provide their opinions on how to better sustain a quality improvement change.

1.8 Limitations of the Study

There are some limitation encountered in this study. There is response bias which was noted during interviews. Though this was mitigated by setting out the mood, orienting participants and answering questions, verbally consenting and reassuring confidentiality prior to data collection. Additionally a research assistant who is not a staff of either facility was recruited, trained and sworn to confidentiality.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

There is limited literature regarding laboratory quality and SOPs. This chapter will be highlighting review of literature based on the three specific objectives listed in chapter one. Further discussion on the conceptual framework will be made.

2.2 Literature Review

The purpose of the study is to identify the perceived determinants that affect adherence to SOPs by using thematic approach. A study done by Bates and Holroyd (2012) looked into the human determinants that lead to non-compliance with SOPs. They identified different types of human determinants, procedures, and violations that may affect the compliance as well as reasons for "cutting corners" or non-adherence in the laboratory. Barbe et al. (2016) did a study that reviewed the standards and guidelines about writing and implementing laboratory SOPs, in doing this they have also identified areas that needed further studies to improve the writing of SOPs.

2.2.1 Determinants that Affect Adherence to SOPs

The first objective of this study was to elucidate the determinants that affect adherence to SOPs by the laboratory personnel. A study done by Bates and Holroyd (2012) in Great Britain conducted six focus group discussions in containment level three laboratories. The aim of the study was to identify human determinants that influence the non-compliant behavior of staff working in laboratories or why they fail to follow the SOPs. They also looked into the barriers that can be applied to reduce such behaviors. By doing this, they commented on three areas that would cause non-adherence:

1. **Human Determinants**- These are determinants that affect adherence to SOPs namely individual, job and organizational determinants.
2. **Procedures**- Written procedures or SOPs are guides to provide harmony, consistency and safety to the laboratory tests done. They are there to prevent accidents and provide safety to the laboratory personnel.
3. **Violations**- Infractions that happen caused by laboratory personnel and management due to non-compliance to SOPs. These violations have sub-themes:

   -**Routine Violations**: Behavior in opposition to the rule, procedure or instruction. It is workers personality, attitude and complacency. These were described as key contributors to non-adherence to SOPs.

   -**Situational Violations**: These occur because of determinants dictated by the employee's immediate work or environment. These could include time pressure, workload, or staffing levels.

   -**Exceptional Violations**: Defined as the flexibility of the laboratory personnel to change.

   -**Optimizing Violations**: Caused through a need for interest in jobs which are considered repetitive, unchanging or boring, a desire to explore the boundaries for a system which are thought to be too restrictive.

Routine violations are personal factors affecting SOP adherence is reported as laboratory personnel's personality or attitude towards SOPs. If a laboratory personnel has a negative perception toward SOPs it affects the adherence hence poor laboratory result (Bates &Holroyd 2012). Similar report has been reported in Iran where refusal to improve practice by non-adherence to updated SOPs is reported (Safadel et al. 2012).

Workload is one of the major factor that affects adherence to SOP. Bates and Holroyd (2012) stated that workload might alter laboratory personnel's attention hence affecting

the step to step adherence to SOP. Similar result is reported in Ethiopia, Addis Ababa where performance of laboratory personnel is affected by high burden of work among laboratory personnel in public and private hospital laboratories (Mesfin et al. 2017).

Furthermore time pressure and staffing levels have been identified as determinants that affect adherence to SOPs (Bates &Holroyd 2012). Improvements suggested to address non-adherence included workload and time management, booking timeslots in the facilities, and challenging the work pressure from management. Forecasting peaks in demand and planning a realistically achievable workload. Additionally training and open culture, communication and the recruitment and selection process where suggested.

2.2.2. To Explore Factors that Promote Adherence to SOPs

The second objective of this study was to identify factors that promote adherence to SOPs. SOPs have to be available to be read, accessible, easily understandable and to be utilized when laboratory personnel is performing a procedure. According to Barbe et al. (2016) lack of clarity in SOP guide might affect the technician's ability to perform efficiently. Therefore clear, available and easily understandable SOP guide quality laboratory service.

In addition to SOP guide, skilled and knowledgeable laboratory personnel well trained to follow and apply SOP promotes adherence to SOP. Mesfin et al. (2017) conducted a study in Ethiopia to evaluate the factors affecting quality laboratory service. They have identified professional education, motivation (being motivated at work) and effective communication as factors that improve laboratory quality. Education is one of the key areas that increases laboratory quality. According to Marinucci et al. (2013) low educational levels have been noted in most Sub- Saharan countries therefore education might increase adherence to SOP hence quality of laboratory result.

2.2.3 Key Areas Requiring Further Intervention

The third objective of this study was to identify key areas requiring further intervention on SOPs adherence. Barbe et al. (2016) did a study that reviewed the standards and guidelines for writing and implementing laboratory SOPs. In the art of writing SOPs, legibility (the ease with which a reader can recognize the characters and words in a text) should be ensured. This is determined by looking at the font and size of the SOPs. Readability is the complexity of the words and sentence length. Comprehensibility refers to whether the reader understands the SOPs and is able to have a correct assumption from it. According to QMS 02-A6 there are guidelines recommended in writing SOPs to insure the legibility, readability, and comprehensibility.

Barbe et al. (2016) have suggested best practices for writing and implementing laboratory SOPs. They have found that language and terminology could be a barrier to adherence of SOPs and this needs special attention. Culturally, certain language and symbols can be interpreted differently; this also depends on training, educational level, and professional experience. Barriers to correct use and application of SOPs include misunderstandings due to language and terminologies, lack of familiarity with guidelines, lack of belief that SOPs will improve practice, and lack of motivation to change practice. Number, length and complexity of SOPs also affect adherence. To overcome the barriers, Barbe et al. (2016) have suggested ownership by and discussion with local users in SOP development. They have also suggested a collaborative partnership to engage in local researchers to share the responsibilities within a study. Adequate budget and staff should be allocated to pretest the draft SOPs and to implement once finalized. Training period should be conducted and continuous support should be available. Regular exchange with local users and supportive site visits are indispensable for guaranteeing correct use of SOPs.

2.2.4 Ideas to Sustain Interventions

Once a laboratory has made a quality improvement change on previous practice, that change must be sustained. According to Silver et al. (2016) methods to sustain quality improvement require openness, straightforwardness and activeness. This means once a problem is identified solution will be paved then an action to improve the quality will be taken. Quality improvement interventions are to be evaluated in several ways one of them is process control board. This is an evaluation tool that weighs the work needed to be done and work done in certain period of time. In doing this, deficiencies are identified then strategic improvement are made. Then timely evaluation of the quality improvement is made daily, weekly and monthly. A performance board evaluates the performance of staff by management. This is to provide an open reward or constructive criticism on performances. Both process control board and performance board increases the sustainability of quality improvement (Silver et al., 2016).

According to Barbeet al. (2017), laboratory personnel should be involved in writing, implementing as well as reviewing an error of SOPs. By doing this, the laboratory personnel will be accountable to maintain make quality changes made and add more improvements. Quality improvement should be adopted and implemented to a local set up, while the quality of laboratory is maintained.

In addition to involving staffs on quality improvement process training staffs, giving an open constructive evaluation, and documented starting point are important for quality improvement and sustaining a quality improvement (Silver et al., 2016).

2.3 Conceptual Framework

This is a qualitative study that will look into determinants that affect laboratory personnel adherence to SOPs. Promoting Action on Research Implementation Health

Services (PARIHS) frameworkis a framework designed for continuous quality improvement used for research (Stetler et al., 2011:Laycock et al., 2018). PARIHS framework will be used to systematically approach determinants influencing adherence to SOPs. PARIHS is a validated conceptual framework that uses key interacting elements to influence successful implementation of evidence based practices. These elements are Evidence, Context, Facilitation and Successful implementation (Stetler et al., 2011). Evidence is information systematically or non-systematically collected; these are studies, clinical practices, and guidelines(Stetler et al., 2011). In application to this study there is evidence showing that there is a low adherence to SOPs (Maina et al., 2014; Makokha et al., 2014; Wanja et al., 2017).Context includes leadership support, culture, evaluation capabilities and receptivity to the targeted change. This study will focus on context where by the determinants affecting laboratory personnel adherence to SOPs would be assessed through the four themes. Facilitation is attainment of specific goal towards implementation. Successful implementation is where the interventions comes to action (Stetler et al., 2011). The last two elements of the framework facilitation and successful implementation are to be implemented in future studies.

The following conceptual framework (figure 2) is developed based on the PARIHS theoretical framework. As stated on chapter one there is evidence that show low adherence to SOPs, the importance of SOPs and improvement of quality with adherence to SOPs. The next step to follow is context to answer why there is a low adherence to SOPs, what practices could be encouraged to promote adhesion to SOPs, interventions that could be done to promote adherence and further ideas to sustain adherence. Specific contexts are discussed further below:

a. Leadership support- According to Stetler et al., (2011) is to identify behaviors, attitudes and actions of leaders. Bates and Holroyd (2012) expanded the

definition human determinants (affect adherence to SOPs in individual, organizational and job levels) and procedures (available and clearly written procedures or SOPs are guides to provide harmony, consistency and safety).

b. Culture- Identify potential contextual barriers that may need to be better understood or be addressed in the implementation strategy (Stetler et al., 2011). Bates and Holroyd (2012) has grouped violations into routine, situational and exceptional violations to identify the reasons for non-adherence to SOPs.

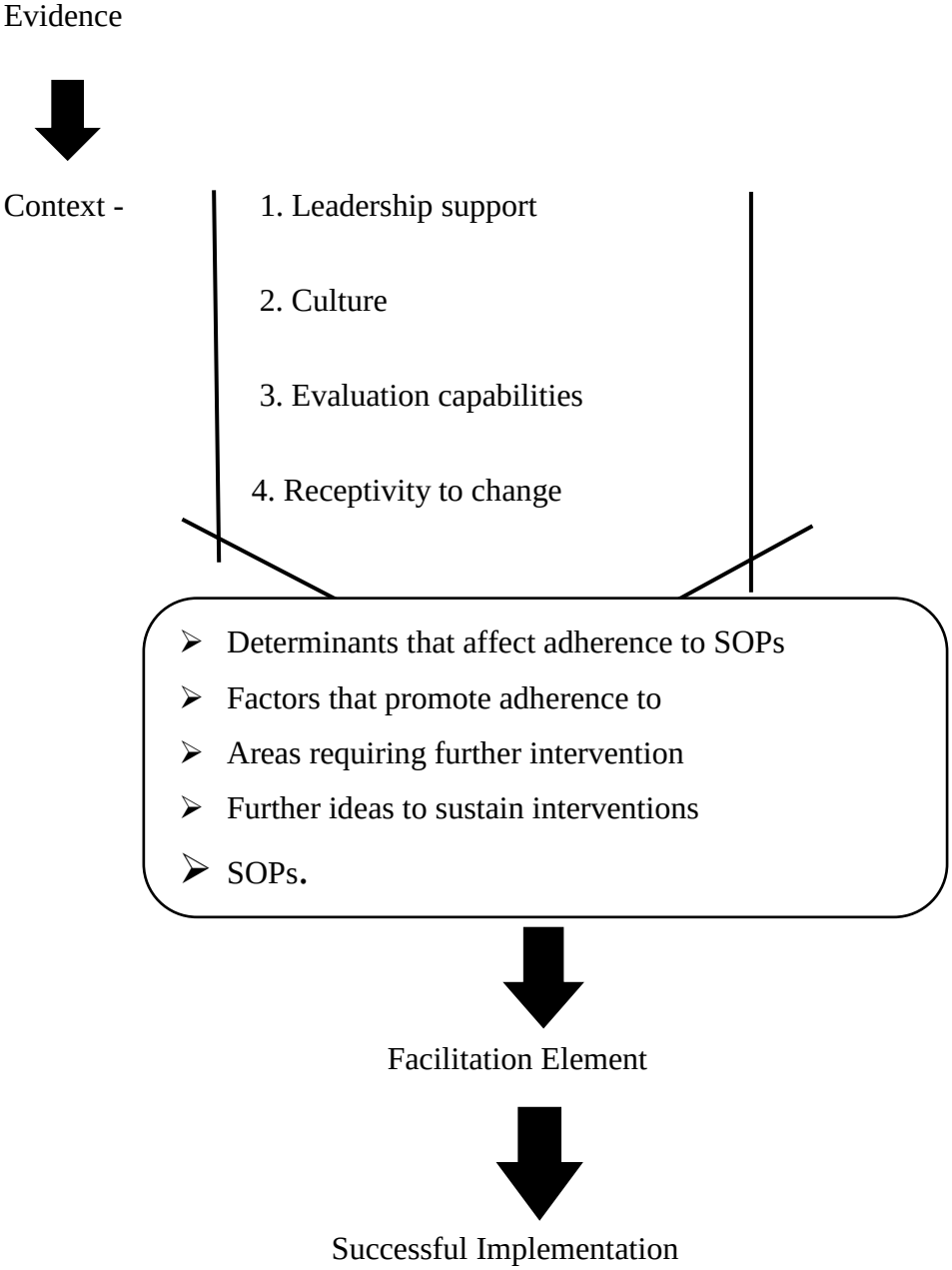
c. Evaluation capabilities- According to Stetler et al., (2011) this are reflections given to laboratory personnel and laboratory technician that may affect performance.

d. Receptivity to target change- These are openness, respectability and readiness to improve quality.

2.3.1 Conceptual Framework of Determinants of Adherence to Standard Operating Procedures

Figure 1

Conceptual Framework Developed from PARIHS



CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

This research was carried out at two conveniently selected hospitals, Tenwek Mission Hospital and Longisa County Referral Hospital from Bomet County, Kenya. This chapter will discuss the research design, location of the study, methods, sampling, instruments used, analysis and ethical considerations.

3.2 Research Design

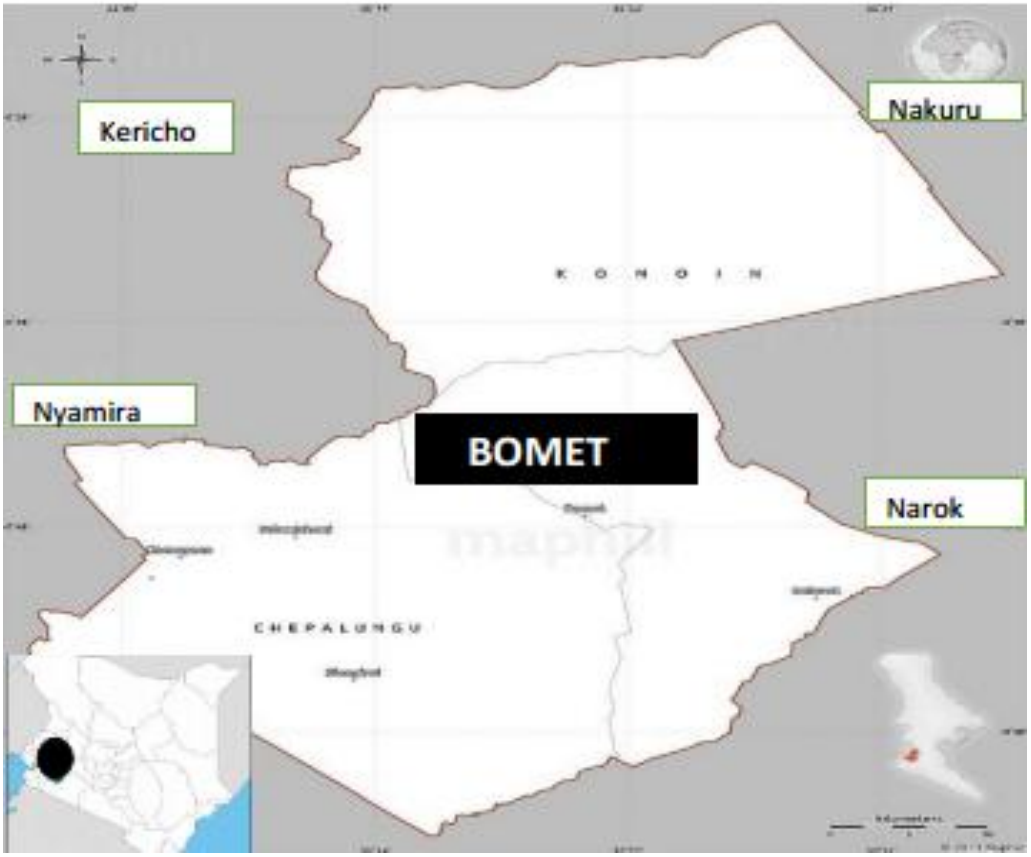
A qualitative phenomenological research design was used in two conveniently selected hospitals in Bomet County, Kenya namely Tenwek Mission Hospital and Long is a County Referral Hospital.

3.3 Location of the Study

The study was carried out in selected facilities in Bomet County Kenya. Bomet County is located in the Great Rift Valley and borders Kericho County to the North and Northeast, Nakuru County to the East, Narok County to the East and Southwest and Nyamira County to the Northwest (County Government of Bomet, 2016).

Figure 2

Map of Bomet County



Source: Maphill, 2011

Bomet has 78 health facilities serving a total population of 846,012 population according to the County Government as of 2016. It has two district hospitals, one sub-district hospital, 61 dispensaries, 10 health centers, one medical clinic, one voluntary counseling and testing center and one privately owned institution(County Government of Bomet, 2016).Among these institutions two major hospitals (Longisa County Referral Hospital and Tenwek Mission Hospital) are referral hospitals utilized in Bomet County. This research was done in two conveniently selected hospitals, which are Long is a County Referral Hospital and Tenwek Mission Hospital. Long is a hospital is a public hospital while Tenwek hospital is a private hospital. Long is a County Referral Hospital is a level four hospital while Tenwek Mission Hospital is a level five hospital.

The reason why the principal investigator selected the study sites was because both of the hospitals are referral hospitals in Bomet County. Therefore, the laboratories of both hospitals receive a large number of laboratory test samples per day. Additionally, Long is a is a government referral hospital while Tenwek is a private referral hospital. Therefore the finding of these selected hospital could be representative of the county. The study acknowledges a possibility of not representing different socio-economic strata of Bomet County.

Longisa County Referral Hospital laboratory and Tenwek Mission Hospital laboratories have the following departments: Blood transfusion, Hematology, Serology, Biochemistry, Parasitology, Microbiology, and Histology. Additionally, Longisa laboratory has a virology/immunology department while Tenwek has cytology department. Longisa County Referral Hospital laboratory receives average of 800 samples per day for all laboratory procedures, while Tenwek Mission Hospital receives about 600 samples per day. Therefore, depending on both hospitals being referral hospitals, type of departments and number of samples per day at both laboratories both study sites are comparable.

3.4 Population of the Study

Tenwek Mission Hospital and Longisa County Referral Hospital are both main referral hospitals in Bomet serving 846,012 population. According to Kenya medical counsel, Tenwek Mission Hospital is a level six (b) teaching and referral hospital with a bed capacity of 361. Tenwek provides several medical services including causality, accident and emergency services, general outpatient clinic services, diagnostic services, eye services, dental services, maternity services, pediatrics services, inpatient medical services, surgical services, intensive care unit services, and oncology services. Tenwek's laboratory service is a core unit that supports the overall hospital services. Tenwek's

laboratory has gone through several quality screening SLMTA and is granted national accreditation by KENAS as of 2020.

Longisa County Referral Hospital has a bed capacity of 144. It gives several medical services including emergency services, general outpatient clinic services, eye services, dental services, maternity services, pediatrics services, inpatient medical services, surgical services, intensive care unit services and renal and dialysis services. Longisa laboratory service is a main department in supporting these services of the hospital. In doing this Longisa laboratory has gone through SLMTA quality screening.

The total population size of all laboratory personnel in the two selected hospitals is N=51. One laboratory manager, one deputy laboratory manager, one quality officer, one deputy quality officer, one safety officer and one deputy safety officer at both hospitals. In addition to these Tenwek has 24 laboratory technicians and Longisa has 15 laboratory technicians.

In this study laboratory managers, quality managers and laboratory technologists were targeted. Laboratory quality officers and laboratory managers are in charge of ensuring the quality of overall laboratory. In doing this they monitor adherence of laboratory technician to SOPs. Given their positions, knowledge and experience all laboratory quality officers and laboratory managers in both institutions were subjected for key informant interviews (Stalmeijer, McNaughton, & Van Mook 2014).

Additionally, FGD was conducted among the laboratory technicians. Laboratory technicians are expected to perform laboratory procedures such as hematology, chemistry, parasitology and so on. They are expected to ensure and apply quality protocols while performing laboratory tests (World Health Organization, 2011).Since

they actively engage in performing laboratory procedures, they were able to disclose their feelings and experiences related to SOPs adherence.

3.5 Sample Size and Sampling Procedure

3.5.1 Sampling Procedure

One day prior to data collection, the laboratory manager was approached by the principal investigator with an invitation to the study. The day, time and venue of data collection was clarified. Non-probability purposive maximum variation sampling was used for selection of participants in FGD. This is to ensure heterogeneous focused group by composing participant from different departments of the laboratory (Blood transfusion, Hematology, Serology, Biochemistry, Parasitology, Microbiology, and Histology).At least one participant from each department was selected. This has supported gathering rich and diverse data from different departments (Stalmeijer et al 2014). On data collection day principal investigator ensured heterogeneous focus group by inquiring the department of participants verbally.

For key informant interviews, non-probability purposive and convenience sampling was used to select participants. Given their positions and responsibilities all laboratory quality officers and laboratory managers at both institutions were subjected for key informant interviews (Lopez & Whitehead 2013).

3.5.2 Sample Size

Interview was conducted until saturation is achieved. Theoretical saturation was used to determine saturation. Two rounds of data collection was made. The first round of data collection was done May 31- June 11, 2021. At Tenwek Mission Hospital, FGD was conducted among eight laboratory personnel and key informant interview was conducted with one laboratory manager and one quality officer. At Longisa County Referral

Hospital, FGD was conducted among eight laboratory personnel and key informant interview was conducted with one laboratory manager and one quality officer. Then after analysis to achieve saturation second round of data collection was done in the same manner as the first round from July 7th, July 19th and July 22nd, 2021 at both hospitals.

Theoretical saturation was evaluated by using the five steps of analysis. Transcription of raw data was done by research assistant, since Swahili language was not used translation was not applicable. Familiarizing of the interview was done by both the principal investigator and the research assistant by rehearing and following the transcribed data. Then codes were manually allocated to subthemes by grouping correlating codes that are directed to similar subjects. After the subthemes analysis, the principal investigator in collaboration with research assistant identified five major themes. After these identified themes second round of data collection was done to achieve saturation. The second round of data collection was done in similar manner of first data collection. FGD was conducted on seven participants in both study site. Additionally key informant interview was conducted among deputy laboratory managers and deputy quality officers at both study sites. Saturation was achieved by absence of new theme after three interviews (two key informant interviews and one FGD) following an identified themes stated above (Nascimento et al., 2018; Francis et al., 2010). Total population size of participant is 38 (First round FGD-8 participants at both study sites, second round of FGD- 7 participants at both study sites, all the laboratory managers, deputy laboratory managers, quality officers and deputy quality officers are included in the key informant interview. Total of 8 participants for key informant interview).

3.6 Study Subjects

3.6.1 Inclusion Criteria

All laboratory personnel working as laboratory manager, quality officer, safety officer and laboratory technologist at both Longisa and Tenwek hospital were recruited. Laboratory personnel were holding at least a certificate in laboratory technology and certified and accredited by their accrediting body.

3.6.2 Exclusion Criteria

Laboratory personnel who were undergoing disciplinary action were excluded from the study. To allow freedom of discussion among laboratory technician during FGD, laboratory managers and quality officers were not allowed to attend FGD, neither were laboratory technicians allowed to attend key informant interviews.

3.7 Data Collection Instrumentation

3.7.1 Pre-Test

Hypothetical cases were prepared based on Bats and Holyord (2012), after seeking consult from the hospital medical superintendent and laboratory manager, the principal investigator was provided with incidences and occurrences that have happened in a hospital to utilize and design to a hypothetical case and use for FGD. Key informant question guide was prepared based on PARIHS frame work by Stetler et al., (2011). Since the questioners for key informant interview and hypothetical cases prepared for the study have not been tested hence, semi-structured pretesting was done at Litein AIC Hospital laboratory on May 17-19, 2021.

Litein AIC hospital is located in Kericho County, 43 kilometers away from Bomet, the study site. The aim of pretesting was to evaluate problems on participant recruitment, possible change of researcher engagement, acceptability of interview protocol

(methodology of the research) and mainly overall evaluation of the study tools (Janghorban, Latifnejad, &Taghipour, 2014; Majid et al. 2017). According to Majid et al. (2017) five stages were followed during pretesting.

1. **Determine Clearly Interview Questions**- This study aims to identify the determinants that affect laboratory personnel adherence to standard operating procedures (SOPs). Interview questions are prepared based on PARIS conceptual framework of quality improvement. This framework utilizes leadership support, culture, evaluation capabilities and receptivity to change therefore questions are prepared based on these themes. Additionally, hypothetical cases for FGD were prepared based on incidences and occurrences that occurred in a hospital.
2. **Have the Initial Interview Questions Reviewed by Experts**- This is to evaluate if questions are applicable to the system as well as to evaluate if the questions are open and expressive as opposed to leading. Therefore the proposal and study tools were emailed to laboratory professional (Biochemist) to comment on the study tools. Then corrections on the questions were done according to the response.
3. **Selecting the Participants**- The study sites (Tenwek Mission Hospital and Longisa County Referral Hospital) have to be in accordance to pretest site. Therefore up on evaluating Litein hospital laboratory; Litein Hospital has 23 Laboratory personnel working in the laboratory. It has six laboratory departments namely, chemistry department, blood transfusion department, hematology department, parasitology department, serology/CD4 department, and microbiology department. These departments receive an average of 670 samples per dayEven though Litein laboratory is not nationally accredited, it has gone

through QMS/SLMTA training and evaluation. For this reason, Litein laboratory is in accordance with the study sites.

4. **Pre-ting for Interviews**- The pre-test aimed to test the appropriateness of the questions which will provide researcher the viability of the research. In doing so; the exact methodology as the proposal will be used for the presesting study in Litein AIC hospital laboratory. After a permission was granted from Litein hospital superintendent and the laboratory manager pre-test was done on May 17-19, 2021.
5. **Pre-data Collection-** Five days prior to data collection, the laboratory manager was communicated to via email and then information was linked to medical superintendent before verbal permission was granted to do the pre-test. Arrangement was done with the laboratory manager to help select participants from each department to ensure a heterogeneous focus group. A day prior to data collection participants were informed about the pre-test data collection venue and time.
6. **The Setting-** The data collection site was at a conference room, a quiet room about 100 meters away from patients or working environment. The room was well ventilated, with a meeting table in the center that allowed an adequate 2 meters social distancing.

Table 1

Pre-test Study Demographic Data

Demographics	Characteristics	Number of participants
Gender	Male	5
	Female	3
Position	Laboratory manager	1
	Quality officer	1
	Laboratory Technologist	6
Educational level obtained	Certificate	0
	Diploma	8
	BSc	0
Duration in current job/ position	6 months	2
	1-5 years	4
	More than 5 years	2

The focus group discussion was held among laboratory personnel who actively engage in performing laboratory tests. Volunteers were selected from each laboratory department to ensure a heterogeneous focused group. Six laboratory personnel participated in FGD. Participants were informed about the pre-test a day prior to the data collection. They were informed to arrive to the conference room at 8:00 am. FGD was held away from working area in a conference room. Participants arrived at 8:15am; upon entrance they were provided with hand sanitizer and face masks. The conference room sitting arrangement was done with social distancing. An introduction was given; participants were informed that the information they provide will be kept confidential. It will be utilized to evaluate the validity and reliability of the data collection instrument and method of the study. Questions and clarifications were made. Then participants were requested to fill out the demographic data form.

After introduction, hypothetical cases were read to participants, followed by discussion questions. Participants discussed cases according to the question guides. The

hypothetical cases were clearly understood and participants assured the researchers that this is a common problem they face. Stated by one volunteer, *"This is a common challenge we face almost every day."*

During discussion, participants were able to introduce new themes such as turnaround time, training, and cultural challenges as determinants that influence adherence to SOPs. Overall, participants responded well to the discussion. FGD took one hour from 8:30 am to 9:40am. After FGD session, refreshments were served.

Key informant interviews were done among laboratory managers and quality officers on the same day of FGD. Interviews were done in two separate sessions for each individuals. Interview with laboratory manager was done from 10:00-10:40am away from the working area in a conference room. Upon entrance, participant were provided face mask. Sitting arrangement was done with social distancing. An introduction and clarification on the aim of the study was given. Participants were informed that the information he/she provide will be kept confidential. This was utilized to evaluate the validity and reliability of the data collection instrument and method of the study. Laboratory interview questions were answered thoroughly and additional themes were raised during the interview, hence, principal investigator explored these additional ideas. After interview, refreshments were served.

An interview with quality officer was done from 11:00-11:30am in a similar manner as laboratory manager.

Challenges Inquired and Modifications Made on FGD,

i. There have been challenges obtaining participants from each department to ensure a heterogeneous group since some of the workers have been on leave.

Modification made: for study sites the heterogeneity of volunteers will be confirmed before FGD session by selecting volunteers a day before FGD.

ii. Additional themes of factors that influence adherence to SOPs were raised that made the principal investigator explore more. These additional discussion questions were added to the questionnaire. Added questions are: turnaround time, education, training, and cultural challenges as possible determinants that influence adherence to SOPs.

3.7.2 Data Collection

One research assistant and one information technologist were recruited for this study. Research assistant was recruited for FGD data collection to serve both selected hospitals. He was trained and certified by the principal investigator on the objectives of the study and data collection tools. An information technologist was recruited for purpose of voice distortion of audio recoded data.

Hypothetical cases for FGD guide was prepared from incidences and occurrences that have happened in hospitals. Question guides were used to guide the discussion in view of the hypothetical cases. FGD question guide was categorized as opening, key and ending question based on Kruger and Casey (2009). For unclear answers of questions research principal investigator or assistant asked for clarification. Audio recorder was used for specific recoding of the data.

Key informant interview was guided by the principal investigator at both hospitals. Key informant question guide was developed according to the four validated themes (leadership support, culture, receptivity to change and evaluation capabilities) by Stetler et al., 2011: Laycock et al., 2018. Interview guide was conducted using open and closed-

ended questions. If answers to the interview were not clear, further elaboration was requested. All key informant interviews was audio recorded.

Credibility of the study is ensured by assessing the true value, consistency, neutrality, and applicability of the study. This is done by recognizing possible biases in the method, data collection and analysis. Credibility was ensured by data triangulation, investigator triangulation, and theory triangulation is utilized for this study (Ghafouri & Ofoghi 2016).Data triangulation is done among the laboratory managers, quality officers and laboratory technicians defined by job- positions held by the participants. (Hsieh & Shannon 2005).Investigator triangulation is made by using more than one researcher to collect data, analyze and interpret the data. Additionally theory triangulation is done by utilizing two methods for data collection which is FGD and key informant interview (Ghafouri & Ofoghi 2016).

3.8 Data Collection Procedure

After National Commission for Science, Technology & Innovation (NACOSTI) permit was granted, data collection was planned at both Tenwek Mission Hospital and Longisa County Referral Hospital on two separate weeks. On the first week, the laboratory manager of Tenwek Mission Hospital was approached by the principal investigator. Orientation about the purpose of the study was done. Questions were answered and clarifications were made. The next day during morning meeting, the principal investigator approached the laboratory technicians for orientation of the study and clarification of the purpose of the study. Questions were answered and clarifications were made. Since a heterogeneous focused group is needed for the FGD, volunteers from different departments of the laboratory were selected during orientation. Then, appointment for first FGD was made for the next day. FGD and key informant interviews were done in two separate days.

FGD was conducted among eight laboratory technicians. The setting was in a meeting room, COVID precautions were observed with masks kept on at all times and social distancing. After a verbal consent, participants were served with demographic data forms to be filled prior to the discussion. Since the discussion was to be audio recorded, quick orientation on handling and passing the dicta phone was made, then discussion was started. Hypothetical cases were read by research assistant who consented for privacy. After the cases were read, discussion questions were asked and discussion was conducted by the research assistant and the principal investigator. During discussion additional questions and clarifications were made by the participants as well as the investigators (research assistant and principal investigator). This is to reduce possible misinterpretation of the provided answers (Ghafouri and Ofoghi, 2016). After discussion, refreshments was served.

Key informant interviews were made among laboratory managers and quality officers. It was conducted on the following day after FGD was conducted. The interview was done away from the working area in a quiet meeting room led by the principal investigator. COVID precautions were observed with social distancing and face masks. After obtaining verbal consent, demographic data form was provided to be filled. After the interview, refreshments were served.

FGD and key informant interviews were conducted in similar schedule in both study sites. After the data collection, all possible identifiers were removed as soon as possible. Then data analysis was made by both research assistant and principal investigator. Data was transcribed by the research assistant. Since Swahili language was not used during data collation, translation was not applicable. Familiarizing of the interview was done by both the principal investigator and the research assistant by rehearing and following the transcribed data. A total of 24codes were identified by both the principal investigator and

research assistant separately. Then these codes were manually allocated to subthemes by grouping correlating codes that are directed to similar subjects. After the subthemes analysis identified five major themes namely leadership factors, working environment, professional education, quality equipment and personal factors.

Proceeding from this analytical framework, principal investigator and research assistant went back to collect more data based on theoretical saturation (Nascimento et al., 2018; Francis et al., 2010). An additional two FGDs were conducted among seven laboratory personnel in both facilities and four key informant interviews were conducted among deputy laboratory manager and deputy quality officer. The second round of data collection was done in similar manner as the first round of data collection. During and after the second round of data collection additional themes were not identified and repetition of previously identified codes was noted, hence, interview was ceased.

After the second round of data collection, analysis was done. Identifiers were removed as soon as possible. Collected data was transcribed by the research assistant. Familiarizing of the interview was done by both the principal investigator and the research assistant by re-listening and following the transcribed data. Codding of the transcribed data was done however a new code or theme was not identified hence identified themes were set to analytical framework. Then the framework was charted and interpretation of the data was made according to the objectives.

3.9 Enhancing Rigor

Rigor is maintained by ensuring credibility, reliability and by collecting thick and rich data. Credibility is confirmed by using data triangulation, investigation triangulation and theory triangulation. Data triangulation was applied when data was collected from laboratory managers, quality officers and laboratory personnel. Investigation

triangulation was applied when data was collected and analyzed by principal investigator and research assistant. To further reduce intrinsic bias additional second research assistant who has a training certificate in qualitative study was recruited to assist in coding of collected data. Theory triangulation was applied when FGD and key informant interview was used as a data collection method (Ghafouri and Ofoghi, 2016). Additionally, credibility was ensured by reviewing findings of the study with participants. This was done after data was analyzed. Laboratory managers and some laboratory personnel who participated in the study were approached to review interpreted analysis. This is to avoid bias of misinterpretation and increase credibility of the analysis. Reliability of the data collection was done by structurally collecting data by two investigators, and reliability of data analysis is done by extracting codes from collected data by two individuals separately (research assistant and principal investigator) (Ghafouri and Ofoghi, 2016). Additionally thick and rich data was collected. This is achieved by conducting key informant interview among laboratory managers and quality officers and FGD was conducted heterogeneous group of laboratory technician (Morse J.M. 2015).

3.10 Data Management and Analysis

Data analysis was done by principal investigator in collaboration with research assistant. Framework method is used to analyze the collected data. They are manually coded according to the framework data analysis steps (Gale, Heath, Cameron, Rashid, & Redwood 2013).

1. **Transcription-** Voice distortion was done by recruited information technology assistant. Audio recordings that are difficult to transcribe such as two people talking at the same time or distant voice that cannot be heard was not transcribed. The audio recorded and written data was transcribed by principal investigator collaboration in

collaboration with research assistant. Since data was collected in English and no Swahili was used translation was not applicable.

2. **Familiarizing with the Interview-** After transcription data was familiarized by reading, rereading, as well as re-listening to the interviews relating data to transcribed data. This was done by principal investigator and research assistant.

3. **Coding-**This is an inductive study that identifies codes and themes from data collected. After familiarization, coding was done by two separate individuals to reduce bias and increase reliability. Collected data was manually coded by principal investigator and research assistant separately. Research assistant identified 10 codes, principal investigator identified 24 codes and second research assistant identified 24 codes. After discussion and elaboration codes were joined together to make a total of 24codes.

4. **Developing a Working Analytical Framework-** The 24 codes were grouped to subthemes by identifying grouping similar codes together. This was done by the principal investigator and research assistant by setting similar codes into groups here by making subthemes. After subthemes were made further grouping was made on similar subthemes that relate to each other making themes namely- working environment, professional education, personal reasons, quality equipment, and leadership factors.

5. **Applying the Analytical Framework-** After the themes were identified second round of data collection was done to achieve saturation. This was done by conducting two FGD one at each study sites and four key informant interviews. This was done according to theoretical saturation three interviews (one FGD and two key informant interview at each facilities) was done. During the second round of data

collection, no additional theme was identified and a repetition of the previous codes was noted.

6. **Charting Data into the Framework Matrix-** This is done by reviewing analysis and refining the specifics of each theme. Themes and subthemes are refined and analyzed by principal investigator by reading and re-analysis of codes, subthemes and themes.
7. **Data Interpretation-** The analyzed data was related back to the main objectives and specific objectives. Then analysis produce a report by- compelling extract examples, analysis of extracts in themes, relating back the final analysis to the research question and objectives.

3.11 Ethical Consideration

Ethical approval was granted from Kabarak University Research Ethics Committee on May 11, 2021. A permit for data collection was granted National Commission for Science, Technology and Innovation (NACOSTI) on May 27, 2021. Ethical permit and clearance to conduct research was granted from Tenwek and Longisa hospital on May 28, 2021 then data collection was done May 31- June 11, 2021. To achieve saturation second round of data collection was done on July 7th, July 19th and July 22nd, 2021.

This study aimed to identify determinants affecting adherence to SOPs in doing this, laboratory personnel discloses the situations that affect their adherence. This disclosure might cause fear of job security. Therefore orientation and clarification on the objectives of the study was done one day prior to data collection. Participants asked questions for clarity hence clarification was made. There are no laboratory personnel who refused to participate in the study. On the data collection day, participants gave a verbal consent and confirmed that by placing a check mark (✓) on a consent form and demographic data was collected. Recruited research assistant signed a written consent prior to data

collection. Since the FGD and key informant interview is going to be audio recorded participants were informed not to use names but pronouns if necessary. After data collection any identifier was anonymized on the same day by deleting audio recording with names or names on consent forms. After removing any identifiers, collected audio recorder was kept with principal investigator locked with password. Hand written data was kept locked in a cabinet accessible only to the principal investigator. Voice distortion of the audio recording was done. Transcription was done by research assistant who consented to confidentiality. Transcribed data was kept confidential locked with password. Data will be stored up to 5 years after publication and will be destroyed by deleting from the password locked file.

CHAPTER FOUR

DATA PRESENTATION, ANALYSIS AND DISCUSSION

4.1 Introduction

This chapter incorporates the findings, interpretation and discussion on the objectives of the study. In the general information, through explanation on how the data was collected and how it was analyzed, difficulties and challenges faced is presented. Then, specific findings according to the objectives are discussed.

4.2 General and Demographic Information

4.2.1 General Information

The data collection was done with cooperation of the laboratory managers and laboratory personnel. The FGD sessions were vibrant discussions. On average, the FGDs took 1 hour each and an average of 42 minutes was used for key informant interviews. Key informant interview and FGD discussion questions were answered with elaboration.

Table 2

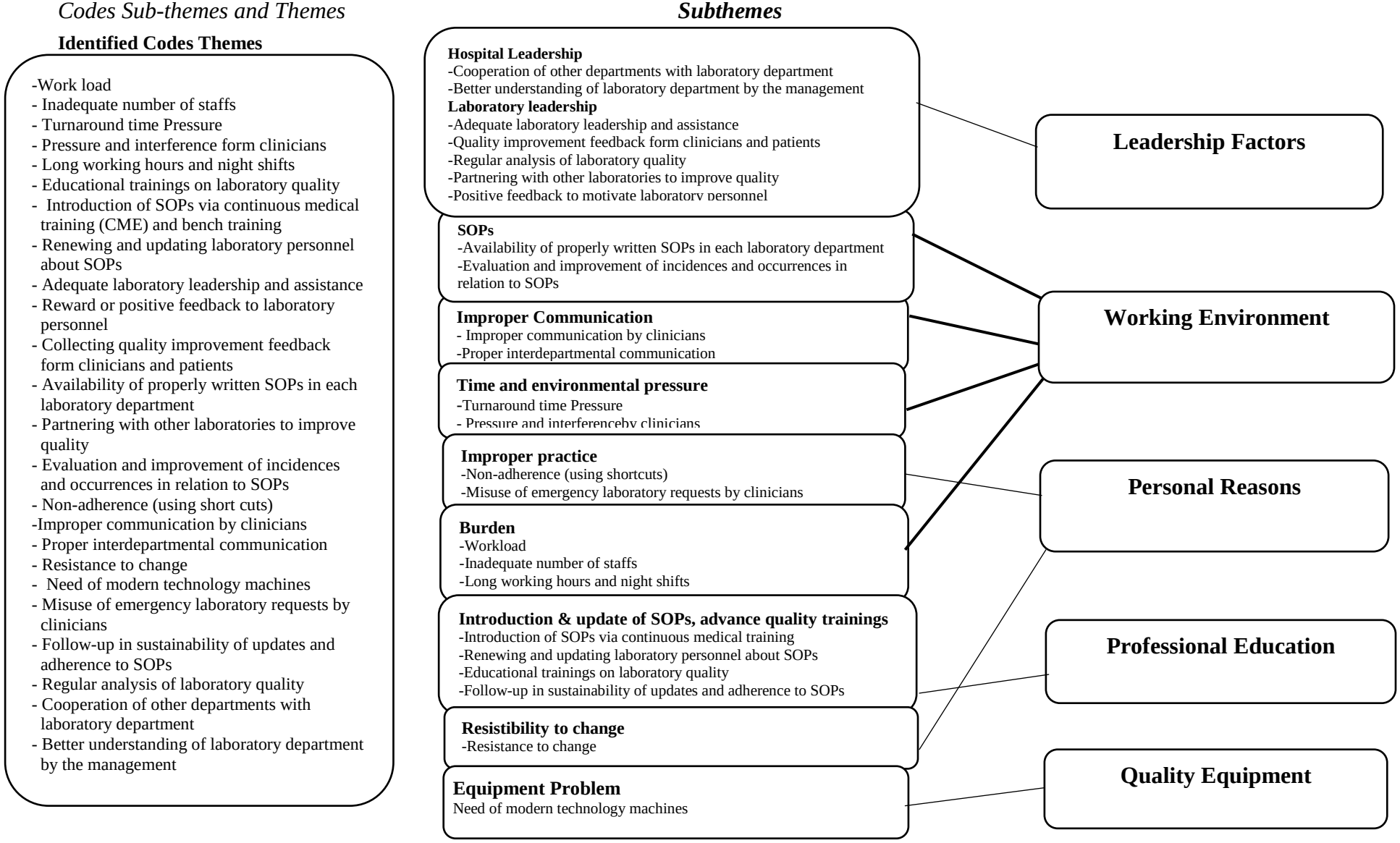
Demographic Data of Study

Demographic Variables	**Number of Participants**
Gender	
Female	19
Male	19
Position	
Laboratory manager /deputy lab. manager	4
Laboratory quality officer/deputy quality officer	4
Laboratory technician/technologist	30
Educational Level	
Certificate	2
Diploma	32
BSc	4
Duration in Current Position	
6< months	3
1-5 years	22
More than 5 years	13

There were an equal number of male and female participants. Thirty laboratory technicians participated in FGDs. Two laboratory managers, two deputy laboratory managers, two laboratory quality officers and two deputy quality officers participated in key informant interview. The educational level of majority of the participants was diploma level. Majority of the participants have worked one to five years in their current position.

Figure 3

Codes Sub-themes and Themes



4.3 Findings for Objectives

4.3.1 To Identify the Determinants that Affect Adherence to SOPs by the Laboratory Personnel

The theme working environment has been identified as the major determinants that affect adherence to SOPs. The subthemes and descriptions are discussed below.

A. Working Environment

i. Burden

Participants reported determinants that affect their capability to adhere to SOPs. The most common determinant reported was high workload followed by inadequate number of staff and long working hours. Most of the laboratory personnel reported that there is workload that determines the adherence to SOPs. When there is a workload the laboratory person will be focused on the load of tests that he/she needs to run compared to adherence to SOPs for quality result. Some laboratory personnel have reported that this could be the reason why a laboratory personnel uses non-adherence (short cuts). One of the participant reported facing a lot of task alone by itself could be exhausting. Other participant reported, when there are a lot of samples to run and an additional emergency test is being requested, it could be overwhelming.

> *"The problem comes in initially at high workload, usually someone would say, take like 15 minutes for the sample to be done and you have 100 samples so multiply that and its 1500 minutes so somebody will be like this is much, this is now the issue with workload and then now you'd want a short cut." KI2*

This overwhelming workload have pushed laboratory personnel to either be distracted to adhere to SOPs or use non-adherent method for faster outcome.

The other determinant that affect adherence to SOPs is inadequate number of staffs. Participants reported that they are affected by work coverage that he/she have to do. Sometimes two to three tasks can be given to one laboratory technician that might alter their focus hence affect their adherence to SOPs. Some participants have suggested an increase in number of staff for a better quality outcome of the laboratory.

> *"Exactly at the moment we don't have enough staffing to manage our lab. Currently in hematology we are running up to 250 samples a day but we have two personnel .This personnel have to run INR, they have to run the malaria test, and they have to prepare pdf's. The work load of this technology is very high. This are the times you have high chances of deviation from the SOPs. So you realize that they overwork and they have that pressure at the end of the day at least at some point there is a deviated sample." KI8*
>
> *"A solution could be, I think one is to increase the number of staff to do the night shift…"FGD2*

Long working hours have been reported to show some exhaustion on the laboratory personnel. This might affect the focus of the laboratory personnel hence affecting the quality of the test. Some laboratory personnel have reported that long working hours may cause non-adherence to SOPs.

"I think the manager of the lab should know the workload in the section, if the workload is too much, so they can calculate if there can be a long shift maybe the morning or day shift should be pushed or shorten…"FGD2

"I think the time frame, if somebody is exhausted for three night shifts it should be reduced to two, according to the time schedule and the staff who are available. so you should rotate and even we should have some time off...."FGD4

ii. Time and Environmental Pressure

Laboratory personnel have reported a pressure to meet the turnaround time (TAT) and clinician pressure are other environmental determinants that affect adherence to SOPs. When laboratory personnel are under pressure to meet a certain time, steps in the SOPs can be missed or over looked.

> "*It really affects if someone doesn't know how to meet the TAT then the procedure is fully guess work so if I know of a way to do a shortcut to test the result and help to reduce the TAT, someone would prefer that than following the procedure of the SOPs and the TAT that's where complains arise as the clients receive results in 10 minutes and feel served well yet it's not quality results…" KI6*

Additionally pressure and interference from clinicians in laboratory has a negative effect on adherence to SOPs. This pressure influences the step by step adherence to SOPs in providing quality laboratory results. For example, in one of the FGD a participant noted that a clinician had interfered with the procedure process because they wanted quick results. This affected adherence to SOPs.

> *"I think another thing was the disturbances from the intern, she came most of the time now disturbing her, because she was a bit late because she had to listen from the intern all the time" FGD1*

The other type of interference is overriding the queue of samples for a hospital staff. Laboratory personnel reported that they are usually approached by a hospital staff for a faster result hence intervening the routine procedure. This interferes with the SOP that a laboratory personnel needs to follow.

"you see for a colleague the nature of work we do in the hospital you expect when you go to the pharmacy you get assisted you go to casualty you get assisted you go to anywhere within the hospital you are supposed to have that relationship, now a situation comes where, you know the lab work is different, it has procedure. So many times the other staff cannot understand that proper procedure to follow in the laboratory." FGD3.

iii. Improper Communication

Participants have reported challenges of miscommunication on some laboratory tests by clinicians affecting quality of service provided. Misunderstanding or lack in knowledge of some laboratory tests would lead to unnecessary laboratory procedure that risks waste of time and contamination of samples.

"...you come to realizes nurses don't even know the difference between cross match, CBC and blood grouping so if you're not careful you'll end up doing CBC the whole process of cross match and that blood remain in the lab. You will be creating more risk by risking contaminating the same blood. So Doc., I was explaining to them that nurses mostly don't know the difference between blood grouping and cross match." FGD2.

Lack of privacy at laboratory working site is another cause of destruction that affects adherence to SOPs. When laboratory personnel is being approached by a clinician inside the private working area, it affects the normal routine of SOPs more than a phone call. Additionally participants emphasized the importance of using a call to inform the laboratory personnel in case of an emergency request.

"Communication is key…. when it is an urgent thing I think the doctor or clinician who is responsible should also make a call to say that I have sent an emergency case like this so it will really help" FGD1

4.3.2 To Explore Factors that Promote Adherence to SOPs

Laboratory personnel have identified three major themes namely, professional education, leadership factors, and working environment as factors that promote adherence to SOPs. The subthemes and descriptions are discussed below.

A. Professional Education

i. Introduction & Update of SOPs and Advance Quality Trainings

The importance of proper introduction of SOPs through either personal training or continuous medical training (CME) and quality trainings has been reported. SOPs are drafted according to ISO: 15189 standard that is adjusted to fit the local standard. This draft is made by the quality officer and interdepartmental leaders. Once drafted it will be evaluated by the laboratory manager. After an evaluation the SOPs are introduced to laboratory personnel who actively engages on performing the test through CME and training. The introduction of SOPs will be signed by the leadership of the laboratory and the laboratory personnel after the training. This training is followed up by competency evaluation prior to exposure to work with supervision proceeded with working without supervision. The participants have emphasized that these introduction steps promotes laboratory personnel's adherence to SOPs hence providing quality result.

"SOPs are written by all lab leadership that is the laboratory manager, the deputy, the quality officer, and also the section head".KI2

"Guided by an ISO standard, 15189, of a standard they give direction on when to update the SOPs. When you change the reagent that you are using you have to

update the SOPs. That is one, the other one is that aaah, the standard procedures requires that a developed standard should be actually guided by a given map, you have to review your own standards".KI1

"Performing competency test to the newly staffed, the newly trained staff, the newly adopted standard procedure….. we actually approve that this person is truly competent they can then perform test by their own. Otherwise before we agree that this person is competent there is someone who guiding and actually following his procedure until such a time that we see that this man or woman is competent to run the test alone."KI7

Renewal and updates of SOPs are done in similar manner as introduction of SOPs. It is done by laboratory management, quality officers and interdepartmental leaders. After an update is drafted it is provided to laboratory personnel through CME by the quality officer or interdepartmental leaders. Training of the renewed SOPs will be done followed by competency evaluation of the laboratory personnel who will be engaging on performing the test. In addition to the updates the importance of regular CME by laboratory leaders, expert training, or machine providing companies has been emphasized.

"We normally after change of standard procedure you expect the entire tech to follow the standard, but the requirement is that there should be a continuous medical training on the same so they fully adopt the procedure and this is to disseminate in form of CME and inform of one on one training or in form of an expert bench training. And then once that one has been done there is supposed to maybe a given standard that a technologist who has happened to have the

information and has been trained on the same owns the procedure by timing a given standard procedure and actually adopting." KI5.

The importance of educational trainings on quality management system has been reported by the laboratory personnel. They have expressed the interest for professional education and quality trainings. Participants also have reported the challenge of workload affecting the time of training or education.

"Training is everything, the option of training is also dependent on the passion of worker to train you to be as much as similar to him or her. We have very good people to disseminate information. So we have people who are potential lecturers they can teach you until you know everything, but those are dependent on time factor the work, the workload so it is also dependent on that, now there is the external training where you get someone from outside to teach. We appreciate the chance". FGD4.

B. Leadership Factors

i. Laboratory Leadership

Laboratory leadership and assistance is provided by the laboratory managers, quality officers, safety officers and interdepartmental leaders. Leadership incorporates availability of leaders for assistance, training, mentorship, provision of equipment and reagents. Key informants interviewed reported adequate assistance is provided based on the need of the laboratory personnel.

'The assistance that we give to a colleague that is working in a section, we usually do mentorship,… we usually provide mentorship and also we can do a CME and then when a patient is presenting we can also assist them maybe correcting issues before the presentation." KI3

"... we help them air out their views and equip them by assessing the objective and help them now to meet the SOPs and also for leadership we provide enough quality reagents and make sure that the machines are okay and are serviced and working at any time."KI2

Collecting positive and negative feedback on laboratory service is important for further quality improvement. This is done by collecting service feedback form clinicians and patients who benefit from laboratory services. After proper analysis of these feedback, improvement on quality laboratory services will be done in response to the feedback. Then based on the analysis an action will be taken to improve the quality of the laboratory. It was reported that feedback is collected quarterly, which promotes laboratory quality.

"We did it yesterday on a questionnaire we gave out to our clinicians and again as I said according to the standard we need to get a survey from the clinicians and a survey for the lab research which actually are the patients, the clinicians, the nurses and many other people who we interact with in our lab. Those are the feedback that we require to actually analyze them and come up with what we need to improving at a given time and know whether we are actually failing. this is what we normally do at least quarterly and we get the results and we disseminate the result and when we reflect on the result, we compare the results with previous ones whether we are improving, where we are as now, where we need to do to close the gaps to close the complains, so those are the things we do."KI7

Furthermore, FGD participants reported at least being verbally rewarded promotes inspiration to work. Though being rewarded for good performance has not been reported,

respondents have stated the significance of such rewards for creating a conducive and encouraging environment. Laboratory personnel who actively engage in performing laboratory procedures reported that appreciation or positive feedback gives them motivation in the work environment.

> *"We normally receive our salary at the end of the month but the motivation part I think it doesn't happen, I've never encountered one. So if we're working here appreciating us will make us happy. I think that is a collective answer."FGD1*

After discussing the hypothetical cases during FGD, participants elaborated the importance of appreciation for the hard work they do.

> *"We build teamwork for a quality result there should be something like an initiative even like an incentive for the staff .when I work like for night shift like he had said, it is not easy there are many challenges coming through maybe even travelling to home when you from work reaching home you are tired so they have to appreciate the work of the staff. Number two, when most of the staff are working hard the way John and Maureen (from hypothetical cases for FGD) have done tomorrow or the following day or next the lab management cannot pay you or the quality manager it is not easy to say 'thank you have done good' instead what they do is to fight that John or Maureen….they have to understand the staff and how they are working, It's good for the lab managers to honor and appreciate their staff…"FGD3.*

C. Working Environment

i. Improper Communication

Proper interdepartmental communication is emphasized especially during change of shifts. Proper handing over of laboratory tests when shifts end is important because it

helps the incoming laboratory personnel organize, focus and work on samples handed over as well as newly collected samples.

> *"Proper handing over means is being a medical set up you cannot just make a phone call to your colleague that am leaving when you get to work you do a,b,c,d…, proper handing over means you find the next person working in shift you discuss if there more work to do he or she can still help you do that…" FGD4*

ii. Standard Operating Procedures

According to participants, available, clear, and understandable SOPs are placed in each department of the laboratory. This availability of SOPs for revision in case of uncertainty provides and promotes adherence to SOPs. They also reported the importance of early audit and correction of incidences and occurrences in relation to SOPs promotes a better adherence to SOP.

> *"…On top of that we provide these standard procedures in all the departments, across it actually found in writing in soft copy and hard copy in each department. So there is a freedom of revising or revisiting the given standard procedure if you are not sure."KI6*

> *"…we currently have an internal auditor and we have two auditors including the QA officer and some of the head of sections, we audit our system in a given time... So we actually have the auditors auditing the lab here, every 3 months write a report and give us the feedback from the results so that we know what is happening and we intervene on the incidences…"KI4*

4.3.3 To Identify Key areas requiring Further Intervention on SOPs Adherence

Laboratory personnel have identified personal reasons, professional education, and quality equipment themes as key areas that require further intervention. The subthemes and descriptions are discussed below.

A. Personal Reasons

i. Improper Practice

Non-adherence (using shortcuts) is one of the key areas where improvement is needed. Laboratory personnel might use shortcut due to increased workload, pressure given by patients or clinicians, or pressure to meet the TAT. Participants have reported the importance of balance between the work demand and the ability to provide that service.

> *"…In general I would say, balance between the workload and following the procedure, now when someone gains experience and knows that there's short cuts here follows the shortcut and not the procedure…." KI5*

Participants have stated the importance of proper use of specific requests. One of them is use of emergency requests for routine laboratory requests. This would distract the routine laboratory setup for a focus on the emergency which affects adherence to SOPs.

> *"I don't have any obligation running the emergency test if someone finds that I have initially started running a test there should be a reason and the urgency for interfering the test I started, there should be a reason why they need this test the only challenge that we experience at the same time the… when you try to get someone sample and they call it an emergency I think, aaah,… So eventually you get frustrated because you get almost five samples on your desk are emergencies and this are being handled by one technician….." KI5*

ii. Resistibility to Change

Laboratory leaders have reported occasional resistance to change of previous practice. This could be due to resistance to leave comfort zone and introduce new practice. This means there will be non-adherence to SOPs that are updated. This resistance might affect the quality of laboratory service hence need improvement through proper education.

> *"Once in a while we face such challenges and when we get resistance it is actually abbreviated to the kind of training, maybe the training was not exclusively done when the staff were training. Then there are expectation that you expect when running the standard procedures."KI8*

B. Professional Education

i. Introduction & Update of SOPs and Advance Quality Trainings

Participants have reported the need for further quality management system training. Quality management system trainings are provided by KENAS once or twice a year for which certain number laboratory personnel are given the chance to attend. However the chance of attending these quality management system trainings is minimal given the need of work coverage.

> "*Maybe once in a while they are a bit rare. Maybe once or twice but it depends because opportunities for training do not match the number of staffs. For example if there is a training somewhere you will only be requested to give one or two persons to attend meaning at the end of the year it could be only one or two persons who have attended the training." FGD3*

Laboratory personnel stated that without proper training, they face challenges to provide quality laboratory test result.

"We don't have much quality training, it is very rare and if it is there then it is personal of course …. With very low training we continue struggling in the lab trying to give out a quality reliable result." FGD4

C. Quality Equipment

i. Equipment Problems

Laboratory personnel have reported the importance of having modern machines that can run several samples at the same time, as opposed to having a manual machine that might require more human power and more focus on controlling. This exposes results to more error while being more time consuming. They have suggested the utilization of a modern machine that is more specific and timely that provide reliable results.

"The results we're using like if the work load is much and you're using the manual results maybe you are incubating some results and you are going to do another one. You tend to forget another one or it will just take some time because if something is manual and it takes around 20 minutes to finish on sample it will really take your time and affect the turnaround time. So, for the workload we should be having the machines that are better." KI3

4.3.4 To Inquire Further Ideas to Sustain Interventions

Laboratory personnel gave ideas on professional education and leadership factors themes to sustain interventions. The subthemes and descriptions are discussed below.

A. Professional Education

i. Introduction & Update of SOPs and Advance Quality Trainings

Sustenance of quality improvement by adhering to SOPs is stated as an important factor of quality improvement process. It was stated that follow-up of sustainability is done by the quality officer and laboratory interdepartmental leader.

"…*We have tasked the quality officer with that work, every day he has to make sure that he's checking he adherence of the SOP and incase of non-conformity he relay that this has not been done and then we check who was responsible what was the reason and why." KI2*

Regular education on laboratory quality, revision of SOPs and CME was reported as parameters for continuous and sustained laboratory quality improvement.

"We have continuous monthly education, and each department we help them to comprehend on the procedure happening in the department and that helps even the staff working in other department to understand that this is what is happening and it should be adhered to and that's what to follow when you are allocated in that department and the CME has been of help."KI2

B. Leadership Factors

i. Hospital and Laboratory Leadership

The quality of a certain laboratory is a result of cooperative effort of those involved in the work. This includes other departments of the hospital, nurses and clinicians who are involved in sample collection and storing, laboratory personnel who will be running the test, computer system that is used to report results and cleaner who is involved on sanitation and disposal. Quality result is a summation and cooperation of other departments with laboratory department. Furthermore they reported the importance of administration support for quality result.

"We should also have a track of system whereby we know as lab we're not working alone we need the support of other departments. From the administration to the clinicians, every one of us for the quality of the results… we should all support one another, like when we have something to install or take a

new machine it's the support of our administration and also for the quality results like maybe a clinician is bringing a sample the identification of the patient and giving the right sample and the right queue will also help improve the quality of our results."KI4

This cooperation requires a better understanding of the laboratory department by the management as well as other departments. According to the participants, there have been some collaboration of the management with the laboratory however, they cited a need to be understood and heard well at the same level as other departments.

"I think we are getting support so far, but I would push to ensure that laboratory is part of the management, in the same way the nursing have a part in it by the nursing officer. It would be good to put lab at the same point as the nursing. To ensure that , yes I know we are well preceded by the medical team, like the doctors but once its doctors representing us, it easy to bring doctors issues first and then bringing others as AOB but if there is a lab person in the table the decision made are made for the lab. And now we can bring issues of the lab to be addressed directly since most people don't understand why and what we need in the lab our own person in the management can understand and that would be of help to us."KI7

Partnering with nationally or internationally accredited laboratories opens opportunity for learning and implementing national quality management system in our setup.

"*We actually expect more changes that lead to really improve on our personnel like external interaction with them see how people do things in these other performing labs like Nairobi hospital, Moi Referral Hospital in Eldoret. This are the things we need to borrow from other facilities. The way they do it is better,*

the way we can incorporate into our lab to make it better than them or actually interact with them and get more educative resources from them .those are the things we want to do and focus to do at the same time."KI1

CHAPTER FIVE

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

5.1 Introduction

This chapter elaborates the discussion of the findings based on the major themes, conclusion, and recommendations. Discussion is made based on the major themes. Under themes, the objectives are expounded. At last conclusion and recommendations are made based on study findings.

5.2 Summary

5.2.1 Working Environment

The aim of this study is to identify determinants that affect adherence to SOPs among laboratory personnel in Bomet county Kenya. The study identified workload, time pressure, and improper communication as the main determinants affecting adherence to SOP. Additionally, inadequate number of staff, and long working hours are reported as determinants that affected their ability to adhere to SOPs. These findings are reflected in other studies, Bates and Holroyd (2012) reported that workload and low staffing are one of the major reasons for non-adherence to SOP in Great Britain. Similarly, Mesfin et al. (2017) reported that high workload is one of the major determinants of laboratory quality among private and public facilities in Addis Ababa, Ethiopia. The inadequate number of staff and Workload affect once ability to perform efficiently. It influences an individual's decision to use an easier way (short-cut) to perform a task (Diwas et al. 2017). Other studies reported the importance of workload and employee balance for timely quality laboratory service (Stotler& Kratz2012). Workload and inadequate number of staff have been identified as a key area that requires intervention. Mesfin et al. (2017) reported that either increasing the number of staff or improving the quality of the machines might improve the outcome. Another determinant that affects adherence to SOP is long

working hours. Long working hour affects an individual's decision making and performance. This in a laboratory setup not only might affect the quality but also the health of laboratory personnel (Vallo & Mashau 2020). The findings of this study showed long working hours as one of the determinants of adherence to SOP however, the duration of 'long working hours' have not been elaborated. According to labor laws in Kenya, standard working hours per week is 52 hours and 60 hours for night shifts (Wage indicator 2021). Evaluating working hours in relation to the standard hours and personnel performance might be beneficial for future intervention.

Every laboratory test has turnaround time (TAT); this is a time given for a certain laboratory test to take from the time it is collected, tested, and reported (Stotler & Kratz 2012).This study also identified time pressure or the haste to meet the TAT as a determinant that affects adherence to SOP. The expedition to meet TAT with workload or understaffing might influence a laboratory personnel to skip a step or not adhere to SOP, hence affecting laboratory quality. Similar, studies have identified time pressure as one of the factors affecting adherence to SOP (Bates & Holroyd (2012); Stotler & Kratz (2012).

SOPs require laboratory personnel to follow a standard procedure with clear and specific interdepartmental (with in laboratory department) and hospital departmental (other departments in the hospital) communication. This study has identified a lack of proper communication at both interdepartmental and hospital departmental levels. Communication from clinicians must be reasonable, realistic, clear, and specific, especially for emergency laboratory test requests. Some laboratory requests are made to result in lesser time than the TAT. This is an emergency setup that increases the risk for error. According to Jayalakshmi, Devi, and Kumar, (2020) proper communication is

related to the quality performance of tasks among hospital departments. Therefore it is important to have proper communication with other departments of the hospital.

Interdepartmental communication has been emphasized during change of shifts where important information might be handed over to the laboratory personnel in the next shift in a rushed manner exposing them to possible errors. Bates and Holroyd (2012) identified that proper communication among laboratory personnel reduces non-adherence to SOP and increases laboratory quality. Therefore proper and clear communication from other departments and among laboratory personnel is important for adherence to SOP. In addition to being determinant that affects adherence to SOP improper communication has been identified as a key area that needs an intervention.

SOPs documents are the other identified sub-theme that promotes adherence to SOP. These SOPs have to be detailed, understandable, available, and concise for quick reference while performing a test (World Health Organization, 2011). This study identified that SOPs are accessible for reference, clear and understandable up on performing tests. This promotes the laboratory personnel to adhere to SOP. In relation to this, Barbe et al. (2016) stated that the simplicity and easily accessibility of SOPs need to be reinforced for better adherence to SOP. Additionally, early improvement of incidences and occurrences halts the problem from reoccurring and promotes smooth adherence to SOPs.

5.2.2 Professional Education

Education is one of the main determinants identified to promote adherence to SOPs. The majority of the participants in this study are trained only until diploma level. Similar results are noted in other studies, Mesfin et al. (2017) reported that the majority of laboratory personnel in Ethiopia own a diploma level of educational attainment. This

shows that there is a need in increasing the educational level among laboratory technicians not only in Bomet County, Kenya but also in other African countries. Furthermore, Marinucci et al. (2013) reported that laboratories in sub-Saharan countries are in need of professional growth and departmental training to implement quality laboratory performance. This confirms the demand that is not only in our country Kenya but also in Sub-Saharan countries. Additionally, laboratory technicians and leaders in this study have expressed their enthusiasm for advanced educational opportunities. This signifies that there is a passion for self-improvement and growth. Therefore, attention to increasing educational level or knowledge among laboratory personnel is crucial not only for adherence to SOP but also for overall laboratory quality performance. In relation to advancing educational level, continuous medical education (CME) and training are important identified factors that promote adherence to SOPs. SOPs are procedures that are frequently revised and updated. These updates and revisions are introduced to the laboratory personnel via CME sessions and training, which are important informative sessions that promote adherence to SOP (Barbe et al. 2017). The data from this study elaborated that CME sessions and training are routinely offered in the laboratories. When there is a new update of SOP, CME and training are given by the laboratory management team then trained laboratory personnel is supervised until competent enough to perform alone. This is a standardized introduction of SOP, according to Barbara Barbé et al., (2016) newly introduced SOPs require training and competency assessment of laboratory personnel prior to utilization.

This study has identified advanced quality training as a key area that requires further intervention in SOPs adherence. Quality training is provided by the Kenya Bureau of Standards either annually or once in two years. The training encompasses QMS for laboratory personnel based on ISO/IEC 17025 & ISO/IEC 15189. It nurtures laboratory

skills, improves overall laboratory knowledge, and enhances laboratory leadership and management methods (Kenya Bureau of Standards, 2017). This laboratory quality training enables the laboratory personnel to update their practice and perform based on the QMS which are international standard for quality laboratory practice. According to the participants in this study, only one or two of the laboratory personnel have been participating in these quality trainings. Increasing the participants in this quality trainings might improve performance, increase the quality of the laboratory and further increase the possibility for national and international accreditation.

5.2.3 Leadership Factors

Good laboratory leadership is one of the identified factors that promote adherence to SOP. According to WHO laboratory leadership competency framework (2019), a laboratory leader is a person with skills and knowledge to motivate a team of laboratory technician toward a common goal. Laboratory leadership includes training, equipment provision, assistance on performing procedures, and mentorship. In this study laboratory technicians reported adequate supervision and assistance from laboratory leaders and this has contributed to better adherence to SOP. They also reported the importance of motivational words or act of encouragement that could influence their performance positively. Other studies reported similar results Mesfin et al. (2017) reported that lack of motivation affects quality laboratory performance negatively. Therefore motivation might be an encouragement to a better performance which would make the work environment more conducive. According to Necochea et al. (2015) verbal motivation or incentives are recommenced as part as an intervention to improve performance among health care service employees.

Further improvement of laboratory quality in relation to SOP or other QMS essentials is assessed by regular quality improvement feedback from clinicians and patients. This

enables the laboratory quality team to identify the factors that affect adherence to SOP and either intervene or indorse a feedback to improve adherence to SOP. Additionally laboratories partake in benchmarking which is to partner with other laboratories compare and share performances. This enables laboratories to improve quality and introduce national or international accreditation requirements to a local setup (Valenstein & Schneider, 2008).

Collaboration and cooperation of the hospital leadership in laboratory quality improvement has a great influence in adherence to SOP. In this study several concepts have been raised to improve adherence to SOP and increase overall laboratory quality. Collaboration of hospital leadership in providing opportunity for professional education and training is one of the key areas discussed. Additionally the importance of modern technology laboratory machine by the management has been raised. Cooperation of other departments such as nurses, doctors and administration to improve the laboratory quality service has been reported. This is done especially during sample collection and sample labeling, proper request of laboratory tests and so on. Therefore better understanding of laboratory department by hospital management, by other departments and hospital administration to ward a better goal might improve SOP adherence. The lack of cooperation and collaboration of other department is a new finding that is not stated as a determinant in other literatures.

5.2.4 Personal Reasons

Personal reasons for non-adherence to SOPs are reported as attitude or negative perception toward SOPs (Bates & Holroyd 2012). In this study occasional resistance to a new change in SOPs has been reported among laboratory personnel. Given that SOPs are updated and reviewed frequently change is expected to occur often. A resistance to an SOP improvement or change causes non-adherence to improved SOP and this might be

an obstacle to increase the standard of laboratory tests. Similar finding has been reported in Iran. According to Safadel et al. (2012) resistance to change is identified as a barrier to standardized laboratory service. Therefore regular teaching sessions such as CME and quality improvement trainings are recommended to improve resistance to change and have positive perception toward SOP updates.

5.2.5 Quality Equipment

Modern technology laboratory machine are essential for timely and quality result. Lack of these modern technology laboratory machines are reported as one of the areas requiring further intervention that assist on adherence to SOP (Mesfin et al. 2017). These modern machines not only would improve the quality but will reduce the workload by testing several samples at the same time. According to the Institute of Medicine (2000) new technology machines are associated with timely result, reduced error and improved overall quality of the laboratory. Owning a modern technology laboratory machine in our setup might reduce the workload which is one of the major determinants that affect adherence to SOP identified in this study.

5.3 Conclusion

Laboratory errors are common but preventable. In this study determinants of adherence to SOPs in Bomet County, Kenya are elucidated. This study was conducted in faith based and public facility. The findings indicate similar results at both facilities where work environment is the common determinant of SOP adherence followed by professional education, leadership factor, personal reasons and quality equipment. Improving this determinants assists toward adherence to SOP. Adherence to SOP for better quality laboratory result requires a multidisciplinary approach.

5.4 Recommendations

5.4.1 Policy and Hospital Recommendations

i. There is a high workload that demands for skilled man power. To solve this problem there should be effort to increase professional education. According to MOH (2014) there is a plan to increase number of health training opportunities due to increased demand. This study further emphasizes increase in professional training.

ii. Low number of staff is a factor that increases work burden, increasing number of staff based on MOH norm could be beneficiary for effective and quality performance.

5.4.2 Recommendation for Further Research

i. A quantitative study to assess impact of adherence to SOP in laboratory quality.

ii. Qualitative study to identify what kind of leadership promotes adherence to SOPs.

iii. Qualitative study to identify the causes of resistibility to SOPs.

iv. Quantitative study to compare performance and professional educational level.

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APPENDICES

Appendix I: Research Participant Consent Form

Principal Investigator -Sifora Fanta Chaleabo

Affiliation -Kabarak University

Title- Perceived Determinants of Adherence to Standard Operating Procedures among Laboratory Personnel as perthe Staff in the Department in Bomet County, Kenya

Information Sheet

Introduction

My name is Sifora Fanta Chaleabo. I am a Family Medicine Masters student in Kabarak University. The proposed study seeks to identify determinants influencing adherence to standard operating procedures (SOPs) among laboratory personnel in Bomet County, Kenya. I am interested to do this study because recent studies have revealed significant rates of laboratory error even in laboratories with advanced technologies. In Kenya we have advanced to implement quality management system through the implication of Good Clinical Laboratory Practice (GCLP) and Strengthening Laboratory Management toward Accreditation (SLMTA) programs. Upon implication of these two programs in Kenya some studies reported low levels in Documents and records evaluation which includes adherence to SOPs. Other studies have demonstrated a correlation between adherence to SOPs and the increased accuracy and precision of laboratory data. Adhering to SOPs increases laboratory quality and decreases error. This study intends to identify the determinants influencing adherence to SOPs which will improve laboratory quality subsequently reduces error.

This study aims to identify determinants that influence laboratory personnel adherence to SOPs in Bomet County, Kenya. My specific objectives are to identify determinants influencing laboratory personnel adherence to SOPs, identify areas requiring further intervention on SOP adherence and inquire further ideas to sustain interventions.

This study will involve two conveniently selected Tenwek and Longisa Hospitals in Bomet County, Kenya. The principal investigator and trained research assistant will conduct key informant interview among laboratory managers and quality officers.

Focused group discussion (FGD) will be conducted among laboratory technicians. FGD led by research assistant will be held among eight laboratory technicians and key informant interview on one laboratory manager and one quality officer. Thus said the participants in this study is determined by saturation.

Risk

Laboratory personnel who participates in this study will be asked to disclose determinants that affect their adherence to SOPs. Discussion and interview questions are categorized in themes which are leadership support, culture, evaluation capabilities and respectability to change. This disclosure might cause fear of job security. Therefore the study will collect a verbal consent and not written consent this is to ensure security for all participants. Volunteering participants as well as trained research assistant will provide verbal consent for confidentiality. Data will be collected by audio recording and writing or documenting important points.

Confidentiality of interviewed data is secured by removing any identifiers from audio recorded data and written data. Interview data will be anonymous and records will be kept in a password locked safe available only to the principal investigator. This means written notes will be kept in a locker key and audio recorded files will be locked with a password available only to the principal investigator. Your participation in this research is entirely voluntary.

Benefits

During the interview, you will help me identify determinants affecting laboratory personnel adherence to SOPs. Identifying the determinants will be used to create recommendations, programs and policy change to improve adherence to SOPs by the laboratory personnel in Bomet County, Kenya and beyond. I believe that the data from this research will improve laboratory quality which improves health care system. Improving SOPs adherence benefits laboratory personnel increase confidence in service, provide reliable data and provide timely service. Additionally improving adherence to SOPs benefits the laboratory facility by increasing the reliability of the service, increase laboratory business and improvement toward national and international accreditation. Overall improving laboratory quality will support the progress toward sustainable developmental Goal 3 which is to ensure healthy lives and promote well-being for all at all ages.

If you agree to volunteer and participate in this study, you will be asked to give a verbal consent. By putting a check mark (✓) on the consent form this will be acknowledged with audio recording. The interview session will be conducted outside your work place before working hours. During the key informant interview and the FGD, the interviewer will be taking notes while audio recording for 30 minutes to 1hour. Key informant question guide are focused on the determinants that affects adherence to SOPs categorized in themes which are leadership support, culture, evaluation capabilities and respectability to change. FGD are guided by three hypothetical cases and question guide for discussion. You might be asked to give an information that you may not feel comfortable answering, if you are not comfortable answering them, you have a right to remain silent.

Your participation is highly appreciated in addition to the interview there is no additional activity that this study requests. If you have questions I will be glad to answer now or later. You can contact me by this number 0741468042 or Email -siforaf7@gmail.com . This proposal has been reviewed and approved by the Tenwek hospital Institutional Ethics Review committee and Kabarak University Research Ethics Committee.

Appendix II: Certificate of Consent

If you agree to participate as a volunteer in this study, please place a check mark (✓) the consent form below.

Consent to Participate in Study

I have read (or had read to me) the information above describing the interviews, benefits and risks of participating in this study titled- "Determinants o Adherence to Standard Operating Procedures among Laboratory Personnel in Bomet County, Kenya"

I agree to participate as a volunteer in this study.

_____	_____
Date	Check Mark of Participant
_____	_____
Date	Signature of Person Obtaining Consent

Appendix III: Certificate of Consent for Research Assistant

If you agree to assist the principal investigator on the research titled "Determinants of adherence to standard operating procedures among laboratory personnel in Bomet county Kenya", you are expected to keep every information or data collected strictly confidential. Written or audio recording are not to be shared except for analysis of this study. Name or any identifier of participants in this study are to be kept strictly confidential. If any collected data or identifier of participants is identified outside this study the principal investigator will be forced to question you legally.

Consent to Participate in Study

I have read (or had read to me) the information above the risk and benefit of assisting in this study titled- "Determinants of Adherence to Standard Operating Procedures among Laboratory Personnel in Bomet County, Kenya"

I agree to participate as a research assistant in this study.

_____	_____
Date	Name and signature of a research assistant
_____	_____
Date	Name and signature of Person Obtaining Consent

Appendix IV: Interview and Focus Group Discussion Guide

QO= Quality Officer

LM= Laboratory Manager

Demographic Data

Gender	□ Male □ Female
Position	□ Laboratory Manager □ Laboratory Quality Officer □ Technician/ Technologist
Educational level obtained	□ Certificate □ Diploma □ BSc □ Master □ Other
Duration in current job/ position	A) less than 1 month B) 6 month; C) 1-5 years; D) more than 5 years

Interview Guide

SOPs Basic Information 1. How do the SOPs fit with your understanding of good laboratory practice? 2. Is there consensus amongst your colleagues about SOPs? 3. From your experience what could be the reason for not adhering to SOPs? 4. How often are the SOPs updated, kindly elaborate on the updating process? 5. How do you update the laboratory technicians about changes in procedure? 6. What are the institutional policies regarding implementation of new SOPs? 7. How often are the laboratory machines and equipment calibrated according to the SOPs?
Leadership Support 1. How are SOPs written and who writes them?

2. Once SOPs are updated, how do you follow up adherence of the new improvement?
3. Once SOPs are updated, how do you follow up the sustainability of the new improvement?
4. What are the most common complaints you get from laboratory personnel in relation to SOPs?
5. How do you provide assistance to laboratory technicians?
6. As a laboratory manager/ quality officer what would you change to have good adherence to SOP?

Culture

1. In the laboratory environment are there any practices done culturally?
2. Do you think some cultural practices could be barrier to adhering to SOPs?
3. Are there some cultural practices that improve laboratory quality?

Laboratory Personnel Staffing and Waiting Time

1. Would you say that you have enough staffs to thoroughly adhere to SOPs?
2. Would you have adequate opportunity for the supervision and orientation of new laboratory staff members?
3. How would you describe the pressure to meet the waiting time of laboratory tests?
4. How does the waiting time pressure affect adherence to SOPs?
5. In your opinion what are the reasons why you think laboratory personnel might use short cuts during specific tests?
6. In your own opinion what would you suggest for better adherence to SOPs and also meet the waiting time?

Educational Training

1. How does training or educational sessions improve adherence to SOPs?
2. Does your department participate in further professional training?
3. How do you get additional educational training?
4. How do you promote the importance of adhere to SOPs?

Work Environment

1. What makes your work environment conducive?
2. What makes you eager to work?
3. Are you or other laboratory personnel rewarded when performing well?
4. Do you have any disciplinary measure for inconsistent practice?
5. If you can what will you change or introduce to make your work environment more

conducive?
Evaluation Capabilities 1. Do you routinely (and systematically) collect physician's experiences with the lab data? 2. Do you have regular staff- meetings? 3. How do you improve quality from previous occurrences? 4. If you can what would you change or introduce to avoid reoccurrences of previously occurred problems? 5. Do you share and critically review your laboratory work experience in relation to the SOPs?
Receptivity to the Targeted Change 1. Have you ever experienced resistance to SOPs among laboratory personnel? 2. Have you experienced a challenge when you introduce a change on current practice? 3. When you criticize or receive criticism do you or they take it positively? 4. What can be done to improve the respectability of new practice? 5. How do you interfere before problems become serious, how do you avoid reoccurrence of problems?

Thank you for your feedback. Finally, are there any additional comments about barriers and facilitators to implementing the program that you would like to mention?

Hypothetical Cases for FGD

Case 1

Maureen is a laboratory technologist working in the hematology department. She came into her shift a bit exhausted because this is her 3rd day of night shift and the previous nights were busy. She went to the machine and was told that she has five samples to run. As she sits to start her shift an intern approached her and told her that he has a bleeding patient 'X' therefore he needs hemoglobin result as soon as possible (ASAP) then he left. Maureen responded to the emergency immediately and started to run the complete blood test (CBC) for patient 'X'. As she was running the test the machine stopped working hence Maureen started to become anxious. She immediately started trouble-shooting the machine. As she was trouble-shooting the intern returned and told her since patient 'X' is losing a lot of blood he needs a type and crossed blood for transfusion immediately.

Maureen now started to type and cross the sample given to her. As she was doing that the intern kept on coming and telling her that she needs to hurry up. Maureen told the intern that she needs some time and worked on the blood ASAP then gave it to the nurse to transfuse. The nurse received the blood and before transfusing she noticed that the blood was expired hence returned the blood back to the laboratory. Maureen was approached by the intern again to do another type and cross match.

Discussion question for case 1

a. What are the determinants that affected Maureen from adhering to SOP (checking the expiration day)?
b. What do you suggest to be done to reduce the pressure from Maureen?
c. What can be done make her work more conducive and enjoyable?
d. What kind of support do you get in case you face such difficulty?
e. Have you received such kind of pressure without the situation being emergency? e.g.- sample of a staffs relative, colleague
f. Is there any thought you would like to add?

2. Case 2

John is a laboratory technologist that works in chemistry section. One day as he was working, a nurse approached him to run a creatinine test ASAP for a known kidney failure patient awaiting dialysis. John knowing that it is a sample of a kidney failure patient he run the test according to SOPs. Before reporting the result john noticed that the result was normal as other creatinine results he did that day. He decided to calibrate and run the sample again but the result was the same. Since this is a wrong result John approached the quality officer who came and checked the machine. The quality officer noted that the collaboration disc was old and that the external quality result was only 40%. This was not a news to the quality officer, he has noted that there was a problem and has requested for new collaboration disc but there was a delay on the process. The quality officer appreciated the Johns hard work.

Discussion questions for case 2

a. What are the determinants that affected John and the quality officer to adhere to SOPs?
b. What can the quality officer do to improve the quality of laboratory result?

c. From your experience, what are the process that delay provision of quality laboratory service? e.g.- Financial reasons, delay on request, long process…etc
d. How does this affect the turnaround time (waiting time)?
e. What additional thing would you add or wish to have to improve the above case?
f. How often are you rewarded at your work area?

3. Case 3

Joy is laboratory technologist who worked at the front disk by receiving samples and doing phlebotomy. One day as she was receiving samples she noticed one of the sample given to her by casualty nurse had two names "Donald Kibet" but no identification number. Since the information was not complete, she kept the sample aside and continued working. Few minutes later an intern approached Joy asking for results for Donald Kibet. Joy told the intern that she couldn't run the test because the sample has no identification number. The intern immediately gave the identification number to Joy and the test was done. The laboratory technologist noticed that Donald's potassium was elevated K-7.1meq/L that needed an immediate action. According to the protocol the laboratory technician communicated the intern therefore the intern started treating the patient accordingly. Few minutes later a nurse from the casualty approaches Joy asking for result for Donald Kibet. Joy told the nurse that the samples were not labeled correctly but then an intern gave her the identification number. The casualty nurse apologized for the mistake but said that the patient is not being treated and there is no result for Donald Kibet. Joy immediately called the intern and asked where the patient is only to find out that it was a different Donald Kibet.

Discussion questions for case 3

a. What are the determinants that affected Joy form adhering to SOPs?
b. What can Joy do to improve the laboratory quality?
c. What can the nurse or the intern do to improve the quality of care?
d. How do professional trainings and fit into your practice? How do they affect SOP adherence?
e. How often to you go for professional trainings?
f. What additional thing would you add or wish to have to improve the above case

Appendix V: University IPGS Letter

KABARAK UNIVERSITY

BOARD OF POST GRADUATE STUDIES

Private Bag - 20157
KABARAK, KENYA
http://kabarak.ac.ke/institute-postgraduate-studies/

Tel: 0773265999
E-mail: directorpostgraduate@kabarak.ac.ke

13th May, 2021

The Director General
National Commission for Science, Technology & Innovation (NACOSTI)
P.O. Box 30623 – 00100
NAIROBI

Dear Sir/Madam,

RE: SIFORA FANTA CHALEABO – GMMF/M/1402/09/17

The above named is a candidate at Kabarak University pursuing Master's degree in Family Medicine. She is carrying out a research entitled "**Factors Influencing Adherence to Standard Operating Procedures among Laboratory Personnel in Bomet County, Kenya**". The student has defended her proposal and has been authorised to proceed with field research.

The information obtained in the course of this research will be used for academic purposes only and will be treated with utmost confidentiality.

Please provide the student with a research permit to enable her to undertake the research.

Thank you.

Yours faithfully,

KABARAK UNIVERSITY
DIRECTOR
POST GRADUATE STUDIES
13 MAY 2021
RECEIVED
PRIVATE BAG - 20157

Dr. Wilson O. Shitandi
DIRECTOR, INSTITUTE OF POST GRADUATE STUDIES

Appendix VI: KUREC Authorization Letter

KABARAK UNIVERSITY RESEARCH ETHICS COMMITTEE

Private Bag - 20157
KABARAK, KENYA
Email: kurec@kabarak.ac.ke

Tel: 254-51-343234/5
Fax: 254-051-343529
www.kabarak.ac.ke

OUR REF: KABU01/KUREC/001/03/04/21

11th May, 2021

Sifora Fanta,
Kabarak University,

Dear Fanta,

SUBJECT: ETHICS REVIEW DECISION

Kabarak University Research Ethics Committee (KUREC) received application for a protocol titled "FACTORS INFLUENCING ADHERENCE TO STANDARD OPERATING PROCEDURES AMONG LABORATORY PERSONNEL IN BOMET COUNTY, KENYA" on 18th April, 2021. The protocol was reviewed and discussed during a virtual meeting held on 3rd May, 2021 at 1000 Hours. The committee considered the application in accordance with the Kabarak University procedures on review of research protocols for ethical clearance and decided as follows:

1. **PROPOSED STUDY SITE**

   Logisa Level Four Hospital and Tenwek Mission Hospital-Bomet County, Kenya

2. **KUREC DECISION**

   Approved for data collection for a minimum period of ONE year from 11th May, 2021

This approval is subject to the following conditions:

i. The researcher shall obtain a RESEARCH PERMIT from NACOSTI before commencement of data collection & submit a copy to the Kabarak University Institute of Postgraduate Studies (IPGS);
ii. The researcher shall immediately notify KUREC in case of any adjustments to the protocol;
iii. The researcher shall within 7 days of occurrence notify KUREC of any adverse events associated with the conduct of this study;
iv. The researcher shall apply for extension of the study period at the end of the initial 1 year;
v. The researcher shall submit study progress reports to KUREC after every 6 months and a full report at completion of the study/project

Thank you.

Sincerely,

KABARAK UNIVERSITY
INSTITUTIONAL RESEARCH ETHICS COMMITTEE
11 MAY 2021
APPROVED
P O. PRIVATE BAG - 20157, KABARAK

Prof. Jackson Kitetu PhD.
KUREC-Chairman
Cc Vice Chancellor
DVC-Academic & Research
Registrar-Academic & Research
Director-Research Innovation & Outreach
Institute of Post Graduate Studies

Appendix VII: NACOSTI Research Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **613625**

Date of Issue: **27/May/2021**

RESEARCH LICENSE

This is to Certify that Dr.. sifora Fanta Chaleabo of Kabarak University, has been licensed to conduct research in Bomet on the topic: FACTORS INFLUENCING ADHERENCE TO STANDARD OPERATING PROCEDURES AMONG LABORATORY PERSONNEL IN BOMET COUNTY, KENYA for the period ending : 27/May/2022.

License No: **NACOSTI/P/21/10694**

613625

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

Appendix VIII: List of Publication

Kabarak Journal of Research & Innovation
www.kabarak.ac.ke

RESEARCH ARTICLE

Perceived Determinants of Adherence to Standard Operating Procedures among Laboratory Personnel as per the Staff in Bomet County, Kenya

Sifora Fanta CHALEABO*[1], Joy MUGAMBI[2], Matthew LOFTUS[3]

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Submitted 28th June, 2022, Accepted 2nd July 2022 and published 29th November 2022

ABSTRACT

Laboratory errors are a major burden in health care systems. To decrease laboratory error and increase laboratory quality international health organizations such as the World Health Organization developed laboratory quality management systems (QMS). One of the QMS essentials (Documents and Records) contains Standard Operating Procedures (SOPs). SOPs are step-by-step instructions that laboratory personnel use as a guide in performing laboratory procedures. Thus, adhering to SOPs ensures consistency, accuracy, and quality of laboratory procedures, thereby increasing laboratory data quality and reducing errors. However, studies in Kenya have shown low percentage results in evaluating documents and records, which means low adherence to SOPs. This study aimed to identify the determinants of adherence to SOPs. A qualitative phenomenological study was conducted in two conveniently selected hospitals (Tenwek Mission Hospital and Longisa County Referral Hospital) in Bomet County, Kenya. Four focused group discussions and eight key informant interviews were done. Based on the objectives, collected data were analyzed using manual coding and thematic analysis. The study identified themes that determine adherence to SOPs which mainly is the working environment, factors that promote adherence to SOPs are professional education, leadership factors, and work environment. Key areas that needed intervention on SOPs adherence are personal reasons, professional education, and quality equipment. Professional education and leadership have been suggested for the sustenance of intervention. Recommendations to hospitals to increase opportunities for professional education and to increase the number of staff to help lower workload are made.

Keywords: laboratory error, laboratory personnel, standard operating procedures

Appendix X: Evidence of Conference Participation

KABARAK UNIVERSITY

Certificate of Participation

Awarded to

Dr. Sifora Fanta

for successfully participating in the Kabarak University School of Medicine and Health Sciences & School of Pharmacy International Research Conference from 20th – 21st October 2021 and presented a paper entitled ***"Determinants of adherence to Standard Operating Procedures Among laboratory personnel in Bomet County, Kenya."***

Conference Theme

Transforming Healthcare In Africa

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