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

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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

I. INTRODUCTION

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). However, several African countries have documented tremendous laboratory errors. For example, a hospital in Ethiopia, Addis Ababa, reported up to 33.1% overall laboratory errors and in Kenya, Kenyatta Hospital reported up to 42% (Tadesse, Desta, Kinde, Hassen, & Gize 2018; Kimengech, Waithaka, Onyuka, & Kigondu 2017). In order to provide quality laboratory data, international health organizations such as World Health Organization's Regional Office for Africa (WHO AFRO), Centers for Disease Control and Prevention (CDC), and 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).

One of the QMS system essentials is documents and records that incorporates of SOPs. "SOPs are step-by-step instructions the laboratory personnel uses as a guide in performing laboratory procedures." (World Health Organization, 2011). Adherence to SOPs assures quality laboratory service. Manghani, K. (2011) reported that adherence to SOPs has several benefits to laboratory personnel, patients and health facility/ laboratory. Despite the importance several studies done in Kenya show low level of audit record on document and record which also audits adherence to SOPs (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.

II. THE PROBLEM

The quality of a certain laboratory is achieved and maintained through QMS (World Health Organization, 2011). Documents (SOPs) which is one of the essentials of QMS is 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). Studies stated as background statistically indicate low percentage 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 low percentage score in Documents (SOPs adherence) unfortunately the reason for low adherence to SOPs in Kenya have not been studied so far. The question why there is low adherence to still stands.

Therefore, this study was done to identify the determinants of adherence to SOPs 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 by the laboratory personnel in Bomet County, Kenya and beyond.

III. LITERATURE REVIEW

A. Determinants that affect adherence to SOPs

A study done by Bates and Holroyd (2012) in Great Britain looked into the barriers that can be applied to reduce adherence to SOPs. The study reported the following themes and results as reasons for non-adherence.
Routine violation- The personality and attitude of the laboratory personnel.
Situational violation- Time pressure, workload and staffing levels.
Exceptional violation- Flexibility of the laboratory personnel to change (Bates & Holroyd 2012).
Improvements suggested to address situational violations included workload and time management, booking timeslots in the facilities, and challenging the pressure from management.

B. To Explore 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 guides quality laboratory service.

In addition to SOP guide, skilled and knowledgeable laboratory personnel well trained to follow and apply SOP promotes adherence to SOP. According to Mesfin et al. (2017) education, being motivated at work and effective communication are 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.

C. Key Areas Requiring Further Intervention

Barbe et al. (2016) did a study that reviewed the standards and guidelines for writing and implementing laboratory SOPs, implementing them in low resource settings that have showed areas for intervention. Another area that needed an intervention was analyzing an error that has happened. According to Barbe et al. (2017) errors that happened during any stage of laboratory procedure should be tracked back and reviewed for feature quality improvement. Additionally, language and terminology have been identified as a barrier to adherence of SOPs.

D. 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 in a timely manner. This is to provide an open reward or constructive criticism on performances (Silver et al., 2016).

IV. METHODOLOGY

A qualitative phenomenological study that was conducted in two conveniently selected hospitals in Boment County Kenya namely- Tenwek Mission Hospital and Longisa Level Four Hospital. These are main referral hospitals that serve about 846,012 population in Bomet County. The study was conducted after ethics approval granted by Kabarak University ethics committee

and National Commission for Science, Technology & Innovation. Question guide for focused group discussion (FGD) was prepared by utilizing hypothetical cases prepared from incidences and occurrences that happened in a department (Bats & Holyord., 2012). Key informant interview (KII) question guide was prepared guided by Promoting Action on Research Implementation Health Services (PARIHS) frame work by Stetler et al., (2011). Prepared question guides are tested at Litein AIC hospital and corrections were made. Data collection was done by conducting FGD among laboratory technicians who actively engage on performing laboratory tests and KII was done among laboratory managers and quality officers. Non-probability purposive maximum variation sampling was used to select participants for FGD. Non-probability purposive and convenience sampling was used to select participants for KII. Data collection was done in two rounds; on the first round- four KII and two FGD was conducted then collected data was analyzed. At this point the study identified five themes then second round of data collection was conducted to achieve saturation (Nascimeto et al., 2018). After the second round of data collection, data was analyzed and no new theme was noted, hence data collection was ceased (Gale et al., 2013). Theoretical saturation was used to determine saturation achievement. Data was analyzed by trained and certified two research assistants and principal investigator separately. Manual thematic coding was used based on framework data analysis steps (Gale et al. 2013).

Credibility was assured by data triangulation, investigation triangulation and theory triangulation. Misinterpretation bias was reduced by reviewing findings with participants. To reduce intrinsic bias additional research assistant for codding was recruited. Reliability was assured by data being collected by two investigators and codding being done by three individuals separately (Ghafouri & Ofoghi., 2016; Morse J.M., 2015). The participants' gave a verbal informed consent for the interview and audio recording. Research assistant was sworn to confidentiality. Collected interview data was anonymized on the same day of data collection by removing all identifiers. Recoded data was distorted by IT professional and locked with a password accessible only to principal investigator

V. RESULTS

A. To Identify the Perceived Determinants that Affect Adherence to SOPs by the Laboratory Personnel

Working environment theme have been identified as the major determinant that affect adherence to SOPs.

Working Environment

The most common determinant reported was workload followed by inadequate number of staff and long working hours. 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 participants reported facing a lot of task alone by itself could be exhausting.

"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, then now you'd want a short cut." KI2

Additionally, 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. 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). 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…" KI2*

Participants have stated the importance of proper and specific communication from the clinicians about laboratory procedures. They have reported that there are some improper communications by clinicians on laboratory requests; an example of this is, emergency laboratory requests for non-emergent cases. This would distract the routine laboratory setup for a focus on the emergency which affects adherence to SOPs.

B. To Explore Factors that Promote Adherence to SOPs

Professional Education

The participants have emphasized the importance of introduction of SOP to laboratory personnel via personal training or continuous medical training (CME) and bench training followed by performance test, working with supervision and without supervision. These processes of educational training promote laboratory personnel's adherence to SOPs hence providing quality result. Additionally, laboratory technicians and leaders in this study have expressed their enthusiasm for advanced educational opportunities.

Working Environment

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. Participants reported the significance of the availability and renewal of SOPs done by laboratory management, quality officers and interdepartmental leaders. 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.

Leadership Factors

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

"….appraisal 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.

C. To Identify Key areas requiring Further Intervention on SOPs Adherence

Personal Reasons

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 turnaround time. Participants have reported the importance of balance between the work demand and the capability 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…." KI 2

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.

Professional Education

Participants have reported the need for further quality management system training. Quality trainings are provided by Kenya Bureau of Standards either annually or twice a year for which certain number laboratory personnel are given the chance to attend. However the chance of attending these quality 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." FGD2*

Quality Equipment

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, which 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.

D. To Inquire Further Ideas to Sustain Interventions

Professional Education

Sustenance of quality improvement by adhering to SOPs is stated as an important factor of quality improvement process. Participants have stated that regular revision of SOPs on CME was reported as a parameter for continuous and sustained laboratory quality improvement.

Leadership Factors

Participants reported that quality result is a summation and cooperation of other hospital departments with laboratory department. 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 or 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.

VI. DISCUSSION

The aim of this study was to identify determinants that affect adherence to SOPs among laboratory personnel in Bomet county Kenya. 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.

Working Environment

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.

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.

Leadership Factors

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.

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.

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

VII. CONCLUSIONS

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 these determinants assists toward adherence to SOP. Adherence to SOP for better quality laboratory result requires a multidisciplinary approach.

VIII. 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.

Areas for Further Study

i. Quantitative study to assess the effect of the five identified determinants.
ii. A quantitative study to assess impact of adherence to SOP in laboratory quality in Bomet County.

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