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Factors Affecting the Sustainability of ISO 15189:2012 Medical Laboratory Accreditation Programs in Kenya

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Abstract:- This study sought to investigate the factors affecting the sustainability of ISO 15189:2012 medical laboratory accreditation programs in Kenya. Specifically, the study focused on the challenges medical laboratories go through on their ISO 15189:2012 accreditation journey and factors affecting the sustainability of ISO 15189:2012 medical laboratory accreditation in Kenya. The research utilized an exploratory study methodology. Structured questionnaires were used to gather data from senior laboratory managers from twenty accredited county referral hospitals in Kenya. Face-to-face interviews were also held with hospital management for the accredited hospitals. The study concluded that the major challenges are the cost of the accreditation process, the cost of a yearly subscription, and the cost of proficiency testing. Other challenges are huge documentation requirements, lack of senior management support, reagent stock-outs, and poor laboratory equipment maintenance schedules. The study also concluded that the high turnover of laboratory personnel as a result of successive county government policies where qualified and trained officers on quality management systems are transferred to other facilities or demoted is a major challenge in the sustainability of ISO 15189:2012.

***Keywords*:-** *Accreditation, ISO 15189, Laboratory Quality, Quality of Service, Sustainability, Quality Management Systems.*

I. INTRODUCTION

The reason for seeking international accreditation is driven by the aspiration to meet worldwide benchmarks, achieve global acknowledgment and acceptance, build trust and confidence among medical professionals and patients, improve the quality of healthcare, and enhance the capacity to evaluate performance and optimize operations (Tanasiichuk et al., 2023). The achievement of universal health care requires low- and middle-income countries to focus on accreditation and the development of high-quality health systems.

An effectively organized and executed healthcare system can lead to improved health outcomes, decreased disparities in health, and lower rates and costs of hospitalization (Beyene, 2015). World Health Organization has found that despite substantial global investments in the health sector, including medical laboratories, there are still significant challenges facing health systems and laboratory practices (Mtotela, 2020). In the region of sub-Saharan Africa, a number of endeavors aimed at enhancing medical laboratory capabilities have yielded limited tangible and enduring results (Bahati et al., 2021). Several factors hurt the accreditation process. These include the absence of prioritization of accreditation, insufficient allocation of resources for achieving and sustaining accreditation, limited understanding of the significance of accreditation among laboratory personnel and health authorities, and the substantial cost associated with the process. Medical laboratories offer essential services to patient care and therefore have to be available to meet the needs of all patients. The laboratory personnel are responsible for offering these services. Such services include examination of patients' laboratory request forms, collection of samples, examination of patient samples, test reporting, and interpretation of the results.

The ISO is a global organization made up of representatives from various national bodies. Its main objective is to establish standards that ensure the quality of service in different industries worldwide (Clapp, 2017). ISO 15189 is sector accreditation specifically designed for medical laboratories. The International Organization for Standardization (ISO) has established a global standard that outlines the necessary criteria for ensuring quality and competence in medical laboratory settings (Dequeker, 2017). In essence, this standard necessitates laboratories to create a strong and dependable quality management system (QMS) to demonstrate their proficiency. Quality refers to the extent to which a collection of inherent characteristics meets specific requirements, whereas competence refers to the capacity to apply knowledge and skill (World Health Organization, 2016).

The ISO 15189 standard was initially released in 2003 and has subsequently undergone two evaluations, one in 2007 and another in 2012. Consequently, the present iteration is recognized as ISO 15189:2012. In recent years, international donors have provided support to numerous government medical laboratories in obtaining ISO 15189:2012 accreditation (Kalra & Kopargaonkar, 2016). Accreditation is a formal process through which an organization receives authoritative recognition of its competence to perform specific tasks. Additionally, the certification of ISO 15189 holds significance for laboratories as it plays a crucial role in guaranteeing the provision of precise and dependable test outcomes to their clientele. This,

in turn, enhances confidence in the laboratory and ensures high-quality service for patients or customers (Bahati et al., 2021).

Obtaining accreditation to the ISO 15189:2012 standard is commonly seen as a guarantee that a medical laboratory fulfills the essential criteria for delivering a high standard of service that promotes excellent patient care (Dequeker, 2017). Laboratory accreditation offers official acknowledgment to capable laboratories, thereby offering a convenient method for customers (patients and doctors) to recognize and choose a dependable medical laboratory testing facility.

The process of accreditation involves application, document review, assessment, accreditation, and follow-up visits. This process costs not less than USD 10,000.00 to complete and has a period ranging from 12 to 24 months to be accomplished (KENAS, 2021). Furthermore, there is a yearly accreditation maintenance fee of USD 2,000.00 for surveillance to identify gaps and monitor non-conformity. As a result, many health facilities have either opted out of the accreditation status or dropped some scopes due to either non-conformity or yearly maintenance costs. Despite the important role played by these particular accreditation programs in health care delivery, their acquisition and maintenance offer a significant challenge, especially in resource-limited settings like county referral hospitals.

The study aims to establish the challenges that medical laboratories go through during the process of accreditation. It also gives an insight into the factors affecting the sustainability of the accreditation status. The study will be beneficial to healthcare decision-makers, pathologists, and laboratory managers as it will unearth the factors they will need to put in place in order to sustain and retain their accreditation status.

The results of the study will be beneficial to the county's healthcare decision-makers as will provide an outline of the challenges experienced during and after the accreditation process. If the decision-makers are fully aware of the challenges, then they will prepare early enough in order to be able to sustain the accreditation status for the benefit of providing quality healthcare,

II. LITERATURE REVIEW

Laboratory accreditation refers to the official acknowledgment by a competent external entity that a laboratory has the capability to perform designated services and is responsible for consistently and reliably producing precise and quantifiable outcomes that fall within acceptable industry standards (Wallace & McCulloch, 2021). According to Kalra and Kopargaonkar, (2016), medical laboratories play a crucial role in ensuring patient safety and have a significant impact on 70% of medical diagnosis. In order to obtain accreditation, a medical laboratory must adhere to the various criteria outlined in the internationally recognized standard ISO 15189 (Antonelli et al., 2017). Enhancing the quality of testing services in medical laboratories is a significant focus in numerous countries. Laboratory standards are confirmed by means of accreditation. However, the task of obtaining laboratory accreditation that is both practical and sustainable, while also ensuring patient safety, poses a significant challenge. This challenge is primarily attributed to a lack of effective leadership, insufficient attention to detail, limited resources, and a lack of commitment to achieving excellence (Sciacovelli et al., 2017). Hence, it is important for accreditation standards to promote enhanced performance, while also being attainable and avoiding excessive prescription.

Accreditation is necessary to ensure effective laboratory management, competent staff through training, and the enhancement of purchasing and supply chain processes, as well as instrument calibration and maintenance. Accreditation plays a crucial role in ensuring the long-term establishment of high-quality healthcare service interventions (Khadambi-Morokane et al., 2021). Africa has a total of 396 medical laboratories that have received international accreditation (SLMTA, 2023). The medical laboratories that are officially recognized meet certain criteria. One of the criteria is to participate in a proficiency testing (PT) program. Additionally, accredited laboratories should have well-documented internal quality control (IQC) policies and the laboratory's test methods should be verified (Okezue et al., 2020).

The research conducted in Iran by Tashayoei et al., (20200 demonstrated that the current accreditation system is widely utilized as a means of auditing health laboratory activities worldwide. However, there are significant challenges to maintaining accreditation in hospitals. These challenges include difficulties in implementing quality management systems, a lack of evaluators and evaluations, limitations in the content of the standards, issues related to the psychological readiness of staff, and managerial problems (Tashayoei et al., 2020). Training and competency assessment are fundamental activities for implementing a quality management system. Providing training according to established standards ensures the development of capable personnel, thereby preventing any decline in the quality of service in healthcare laboratories. This, in turn, helps to maintain accreditation.

A study conducted in Denmark revealed that medical professionals hold varying attitudes towards accreditation, with clinical attitudes playing a significant role in shaping public decisions regarding its utilization (Ehlers et al., 2017). The attitude displayed may be more influenced by political motives rather than a focus on providing high-quality service. This could potentially undermine the long-term viability of the accreditation system. The quantity and seriousness of non-conformities identified during an evaluation of a testing laboratory are indicative of its degree of adherence to quality standards. Laboratory test reports rely on quality standards to ensure their reliability. By promoting the advantages of laboratory accreditation, it is possible to assist additional countries in sub-Saharan Africa in overcoming current obstacles and attaining accreditation and strong quality systems aligned with ISO 15189. This

would contribute to the sustainability and effectiveness of their operations (Okezue et al., 2020).

Healthcare services in developing countries face significant limitations and are vulnerable to various obstacles. Therefore, the implementation of an accreditation service is necessary in order to assess and disclose the potential risks involved and ensure the delivery of high-quality outcomes. Accreditation enables conformity assessment bodies (CABs) to effectively allocate resources, establish robust quality management systems, meet customer expectations, and implement sound quality processes (Adane et al., 2019). There is a lack of understanding between international and local/regulatory actors regarding the customization and transfer of accreditation policies. Therefore, low and middle-income countries have adopted accreditation standards from developed countries. The main challenges in regards to the standard are its implementation and long-term viability, which are faced by both CABs (Conformity Assessment Bodies) and ABs (Accreditation Bodies) (Beyene, 2015).

The primary obstacles that impact the utilization of accredited medical laboratory services include limited resources, insufficient management collaboration, inadequate equipment utilization, and personnel incompetence in terms of knowledge (Mesfin et al., 2017). Accreditation has the capacity to decrease errors in medical laboratories. According to a recent study by Khadambi-Morokane et al. (2021), participating in proficiency testing (PT) was found to reduce errors in CD4 testing.

The drawbacks and difficulties related to the use of accreditation encompass resistance to change within organizations, a rise in staff workload, limited awareness about continuous quality improvement, insufficient training and support for staff in implementing continuous quality improvement, absence of accreditation standards that are applicable at the local level, and a lack of performance outcome measures (Mesfin et al., 2017). Several factors can impede the utilization of accreditation. The factors mentioned in the study by Tanasiichuk et al. (2023) encompass external quality assessment, root cause analysis, laboratory equipment maintenance, competency of lab personnel, evaluation of measurement uncertainty, audits, trained staff, turnover, and method validation and verification.

Accreditation status offers several advantages. These include obtaining recognition on a global and national scale for demonstrating a strong commitment to quality. It signifies that the laboratory adheres to internationally recognized standards, facilitating the exchange of crucial information on a global level (Hussein et al., 2021). Additionally, accreditation assures clients that the laboratory possesses the necessary technical expertise to provide accurate results and that its systems align with international standards (KENAS, 2019). Accreditation provides a competitive advantage to the accredited laboratory, serving as a potent strategic asset. Accredited public health laboratories receive a certificate that serves as a valuable tool for advertising and demonstrates their dedication to providing high-quality services, effective management, and improved service quality (KENAS, 2019).

A. Research Objective

This research investigates the factors affecting the sustainability of ISO 15189:2012 medical laboratory accreditation programs in Kenya.

B. Research Questions

- What challenges do medical laboratories go through on their ISO 15189:2012 accreditation journey?
- What are the factors affecting the sustainability of ISO 15189:2012 medical laboratory accreditation in Kenya?

III. METHODOLOGY

The research utilized an exploratory study methodology. An exploratory study is a useful method for understanding current events, gaining fresh perspectives, posing inquiries, and evaluating a phenomenon from a different perspective (Saunders et al., 2019). This method was well-suited for this study as it aided in comprehending the essence of the problem being examined.

The research focused on senior laboratory managers who are employed in county referral medical laboratories in Kenya. To ensure a thorough representation, twenty accredited county referral hospitals were selected for our study. The questionnaires were then distributed to each of these hospitals. The study employed purposive sampling to select respondents who contributed significant information. Structured questionnaires were preferred because they place less cognitive burden on the participants and allow for easier analysis using descriptive and other statistical methods (Saunders et al., 2019).

The process of collecting data started by creating and improving the questionnaire. After that, a group of medical laboratory professionals evaluated its validity. Once the final questionnaire was created, it was distributed to a group of 20 county referral medical laboratories in Kenya for completion. A total of 16 senior laboratory employees participated in the survey, providing information about their experiences and challenges in ISO 15189:2012 medical laboratory accreditation.

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IV. RESULTS

In this chapter, the quantitative data that was collected was analyzed and the findings were obtained from the data analysis.

A. Demographic analysis

The respondents were asked to indicate the number of years they have worked as senior laboratory managers in their particular hospitals. Their responses are shown in table 1.

Table 1Years worked as a senior laboratory manager in this hospital

Years	Frequency	Percentage
Below 1 year	2	12.5
1-5 years	3	18.75
6-10 years	5	31.25
Above 10 years	6	37.5
Total	**16**	**100**

Source: Author (2023)

The findings suggest a diverse range of experienced senior laboratory managers in the surveyed hospitals, with a substantial number (68.75% having significant laboratory experience of more than six years. This suggests that a significant proportion of senior laboratory managers have experience in their roles and are therefore suited to provide reliable answers in this survey.

The researcher conducted an assessment of the educational background of the respondents. Consequently, the participants were requested to specify their level of educational attainment. The participants' answers are presented in Table 2.

Table 2 Level of education

	Frequency	Percentage
Secondary certificate	0	0
Diploma	0	0
Bachelor’s degree	1	6.25
Masters	11	68.75
Postgraduate	4	25
Total	**16**	**100**

Source: Author (2023)

The results indicate that all participants possessed the necessary qualifications to serve as laboratory officers, enabling them to have a foundational knowledge of the ISO 15189 application in the quality of laboratory diagnosis. The fact that a significant portion of the respondents (25%) have completed postgraduate education indicates that they possess a skill set focused on practical applications, which could be highly beneficial for carrying out routine laboratory tasks.

B. Challenges of ISO 15189:2012 Accreditation

The study examined the challenges encountered by participants during their pursuit of ISO 15189:2012 accreditation. A range of potential challenges were identified and participants were asked to indicate whether they considered them to be significant, minor, or not a challenge at all.

Challenges	Not a challenge		Minor challenge		Major challenge	
	F	%	F	%	F	%
Lack of Senior Management support	0	0	4	25	12	75
Detailed documentation of laboratory processes, quality management systems, document control, and procedures.	1	6.25	5	31.25	10	62.5
Lack of Training on quality management systems.	2	12.5	5	31.25	9	56.25
Lengthy Gap Analysis Process	1	6.25	7	37.5	8	50.0
Cost implications	0	0	0	0	16	100

Table 3: Challenges of ISO 15189:2012 Accreditation (Table provided by the author)

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The findings of the study indicate that the majority of the respondents, 75% (n=12), indicated that lack of senior hospital management support is a major challenge. The findings also show that 62.5% (n=10) of the respondents indicated detailed documentation of laboratory processes, quality management systems, and procedures as a challenge in the accreditation journey. Moreover, the lengthy gap analysis process which forms the foundation for the accreditation journey in every laboratory presents a challenge to 50% (n=8) of the respondents. Finally, lack of necessary quality management systems was noted to be a challenge by 56.25% (n=9) of the sampled officers.

The implementation of ISO 15189:2012 necessitates substantial resources, such as human capital, time, and financial commitments. Laboratories might be required to recruit extra personnel, offer additional training programs on quality management systems, and make investments in infrastructure and equipments in order to comply with the standards' demands. These findings align with the studies conducted by Tashayoei et al. (2020) and Sciacovelli et al. (2017), which similarly identified limited resources as the primary challenge

C. *Factors affecting the sustainability of ISO 15189:2012 medical laboratory accreditation*

The study investigated the factors affecting the sustainability of ISO 15189:2012 medical laboratory accreditation in Kenya. The respondents were given a list of factors and asked to indicate whether in their opinion they considered them not a factor, a minor factor or a major factor in sustainability of ISO 15189:2012 accreditation. The results were recorded in table 4.

Table 4: Factors affecting the sustainability of ISO 15189:2012 medical laboratory accreditation

Factors	Not a factor		Minor factor		Major factor	
	F	%	F	%	F	%
Yearly Financial subscriptions.	0	0	3	18.75	13	81.25
Hospital leadership and management Support.	1	6.25	4	25	11	68.75
Cost of the Periodic Proficiency Testing	4	25	2	12.5	10	62.5
Periodic Preventive Equipment Maintenance.	0	0	7	43.75	9	56.25
Continuous Training on QMS	3	18.75	5	31.25	8	50.0
Reagent Stock-Outs	0	0	2	12.5	14	87.5
Employee Turnover	5	31.25	3	18.75	8	50.0

The findings of the study indicate that the majority of the respondents, 81.25% (n=13), believe that the yearly subscription for the maintenance of the ISO 15189 status is a major challenge. Moreover, 68.75% (n=11) of the respondents agree that strong hospital leadership and management commitment play a major role in the sustainability of ISO 15189:2012 accreditation in medical laboratories. Training on Quality Management Systems (QMS) was reported by 50.0% (n=8) as a factor that would sustain the accreditation status. Finally, periodic equipment maintenance (56.25%, N=9), frequent reagent stock-outs (87.5%, N=14), and employee turnover (50%, N=8), were noted to influence the sustainability of ISO 15189:2012 medical laboratory accreditation status in county referral hospitals.

V. CONCLUSIONS

The study sought to find out the challenges medical laboratories go through on their ISO 15189:2012 accreditation journey. The findings of the study concluded that the major challenges are the cost of the accreditation process, huge documentation requirements, lack of hospital management support, lack of training on quality management systems, and the lengthy gap Analysis.

The second objective of the study was to determine the factors affecting the sustainability of ISO 15189:2012 medical laboratory accreditation in Kenya. The findings of the study concluded that yearly financial subscriptions, hospital management support, cost of periodic proficiency testing, reagent stock-outs, and employee turnover affect the sustainability of the accreditation status.

The study recommends that the government should allocate adequate financial resources, human capital, and time to county referral hospitals to support the accreditation process. They should also invest in the training and development of laboratory staff to ensure they have the necessary skills and knowledge to meet accreditation requirements. The study also recommends that county referral hospitals consider implementing quality management software systems to streamline processes, document control, and quality management.

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