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Strategies for Implementing the International Organization for Standardization 15189 for Medical Laboratories

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Abstract

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MBA, University of Zimbabwe, 2010

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Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Inadequate quality management systems (QMS) in medical laboratories result in errors, which cost the United States healthcare industry approximately $29 billion per year. Healthcare managers who fail to implement the International Organization for Standardization (ISO) 15189 QMS are at high risk of managing costs. Grounded in Lewin's 3-step organizational change model and the force field analysis, the purpose of this qualitative multiple case study was to explore strategies healthcare managers use to design, develop, and implement an ISO 15189 QMS using a mentorship approach. The participants comprised 5 healthcare managers from the United Republic of Tanzania, East Africa, who implemented the ISO 15189 QMS up to international accreditation using a mentorship approach. Data were collected using semistructured telephone interviews and company documents and reports. Thematic analysis was used to analyze the data; 4 themes emerged to include unfreezing phase-preparation for change, changing phase-implementation of QMS, refreezing the new behavior, and maximizing the forces for change. A key recommendation is to structure mentorship programs into 4 stages, including a gap assessment, documentation of the QMS, implementation of the process, and continuous improvement activities. The implications for positive social change include the potential to promote reliance on ISO 15189 accredited medical laboratories by the people served and help the population engage in correct health-seeking behavior.

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Section 1: Foundation of the Study

Implementing quality management systems (QMSs) in the healthcare industry is one of the top three goals that healthcare managers across the globe struggle to achieve (Al-Shdaifat, 2015). The other two goals in the healthcare industry are to reduce the cost of healthcare services and to improve accessibility to the general populace (Ngo, Gandhi, & Miller, 2017). Medical errors, which are often a result of inadequate QMSs, cost the healthcare system in the United States of America more than 29 billion dollars per year (Zineldin, Zineldin, & Vasicheva, 2014). Medical laboratories can reduce medical errors by implementing an International Organization for Standardization (ISO) 15189 QMS based on the adoption of industry best practices (Schneider, Maurer, & Friedberg, 2017). ISO 15189 is an international standard specific for medical laboratories wishing to demonstrate quality and competence. However, some medical laboratory managers lack knowledge of strategies to implement ISO 15189 QMSs cost-effectively in their laboratories (Nasser, M'hamed, Badrane, Bencheikh, & Omaima, 2018).

Background of the Problem

Globally, the key challenge facing healthcare organizations is how to deliver value to customers. To create value, healthcare leaders should address three policy goals, namely, cost reduction, improved access, and improved quality of health care services (Al-Shdaifat, 2015). Improving the quality of healthcare involves the adoption and implementation of quality management programs, such as ISO certification and accreditation standards (Johannesen & Wiig, 2017). Medical laboratory services are critical to today’s healthcare system, and some studies claim that more than 70% of

medical decisions involving diagnosis requires clinical pathology data (Ngo, Gandhi, & Miller, 2017). Healthcare managers may implement an ISO 15189 QMS for medical laboratories to improve service quality, reduce errors, and ultimately reduce costs.

The World Health Organization (WHO), in collaboration with the Centers for Diseases Control (CDC), introduced the Strengthening of Laboratory Management towards Accreditation (SLMTA) program to train medical laboratory managers to implement the ISO 15189 QMS (Andiric, Chavez, Johnson, Landgraf, & Milner, 2018). The SLMTA program includes mentoring laboratory management on the ISO 15189 QMS but does not define strategies managers can use to implement the quality system. Similarly, although Perrone et al. (2016) and Maruta, Rotz, and Trevor (2013) discussed a structured mentoring program for ISO 15189, they did not elaborate on the strategies a mentor may use to implement the QMS. Therefore, a gap exists in the literature regarding the strategies of implementing ISO 15189 based QMSs by using a mentoring approach. The reason for conducting this qualitative multiple case study was to explore the strategies that healthcare managers used to structure and implement ISO 15189 QMSs through a mentoring approach.

Problem Statement

Inadequate QMSs in medical laboratories result in errors, which cost the United States healthcare industry approximately 29 billion dollars per year (Zahar, Barkany, & Biyaali, 2016; Zineldin, Zineldin, & Vasicheva, 2014). Implementing ISO 15189 QMSs in medical laboratories improves patient safety and reduces errors by approximately 80% (Schneider, Maurer, & Friedberg, 2017). The general business problem was that the lack

of QMSs in some healthcare organizations results in poor organizational performance and has negative consequences for business sustainability. The specific business problem was that some managers in the healthcare industry in developing countries lacked strategies on how to design, develop, and implement ISO 15189 based QMSs through a mentoring approach to improve organizational performance.

Purpose Statement

The purpose of this qualitative multiple case study was to explore strategies on how managers in the healthcare industry in developing countries used to design, develop and implement ISO 15189 based QMSs through a mentoring approach to improve organizational performance. The targeted population comprised of five healthcare leaders located in East Africa (United Republic of Tanzania) who implemented and attained international accreditation in ISO 15189 standard through a mentoring approach. The selected population was appropriate because the participants experienced the phenomenon of implementing an ISO 15189 QMS through the assistance of a mentor and attained international recognition. The significant contribution of this study to social change was an improvement in the economic and health conditions of the populations served by ISO 15189 accredited laboratories. Furthermore, the study results have the potential to improve people's perceptions about healthcare services, leading to increased usage and desirable health outcomes.

Nature of the Study

The qualitative research method was the appropriate method for this study to explore the strategies and processes that laboratory managers and mentors used to design,

develop, and implement ISO 15189 QMSs to attain international accreditation. The three most common types of research methods are qualitative, quantitative, and mixed. Quantitative research involves statistical analysis and is a means of testing scientific theories through an examination of the relationships among variables or groups' differences (Daley, Martin, & Roessger, 2018). Qualitative research involves an exploration of a study area with little information known and is typically accomplished by using open-ended questions and observation (Jonsen, Fendt, & Point, 2018). Mixed methods research involves a combination of both qualitative and quantitative research methods (Doyle, Brady, & Byrne, 2016). Neither the quantitative nor mixed methods approach were appropriate because the study did not involve the testing of hypotheses, examination of variable relationships, or groups' differences using statistical analysis nor gathering of data for inferential purposes.

I used the case study research design in this study. In a case study research, the researcher conducts an in-depth exploration of a program, event, activity, process, or individual, and the case is time-sensitive and is situationally specific (Yazan, 2015). The case study design is appropriate in situations where the focus of the study is to answer questions about *what, how*, and *why* (Marshall & Rossman, 2016). In ethnographic design research, the researcher addresses questions about *when, where,* and *how* about the cultural experiences of groups or individuals (Marshall & Rossman, 2016). I also considered a phenomenological study, where the researcher identifies the essence of lived experiences of a phenomenon by participants. Since the purpose was to explore mentoring strategies for successful implementation of ISO 15189 QMS, the best design

for this study was a multiple case study design. The results of a multiple case study may provide the researcher with a deeper understanding of the phenomenon and offer an opportunity to understand differences and similarities (Yazan, 2015).

Research Question

The overarching research question for this qualitative case study was: What strategies did managers in the healthcare industry in developing countries use to design, develop, and implement ISO 15189 QMSs through a mentoring approach?

Interview Questions

1. How did your organization's mentor structure a mentorship program from the initial engagement phase up to the time the laboratory attained ISO 15189 accreditation?
2. Based upon your experience, what key issues positively affected the success of the mentorship program for implementing the ISO 15189 QMS?
3. What strategies did the laboratory mentors and management use to overcome ISO 15189 implementation barriers?
4. How did your organization's mentor effectively transfer the ISO 15189 knowledge to their protégés during the mentorship program?
5. How did your organization's mentors prioritize activities to conduct during each ISO 15189 mentorship engagement?
6. How did your organization's mentors inspire or influence the laboratory management and staff to adopt and implement the ISO 15189 QMS?

7. What strategies did your mentor apply to manage resistance to change within your organization when implementing ISO 15189 QMS?
8. How did your mentor catalyze a new organizational culture that supported the implementation of your ISO 15189 QMS?
9. How did your mentors influence their mentees to implement ISO 15189 QMS in situations when the mentor was not physically at the site?
10. Based on your experience, how did the mentor-mentee relationship affect the success of the mentoring program?
11. What else can you share with me about the strategies and processes your organization's mentor used to achieve ISO 15189 accreditation?

Conceptual Framework

The conceptual framework of this study was organizational change management. Lewin (1946) influenced the study of organizational change management and implementation of change management programs, of which quality improvement is an example. Lewin is the founder of organizational change management and has two significant contributions to the change management theory, that is, the force field analysis and the 3-step change model (Burnes, 2004). Concerning the force field analysis, Lewin proposed that group behavior is a complex interaction of forces that affect group structures and modify an individual's behavior. Lewin proposed that individual behavior is a result of the group environment or *field,* and consequently, changes in behavior is because of changes in the forces within the field (Burnes, 2004). To influence a situation, management should work towards improving the two types of forces, that is, forces for

change and forces preventing change. In an ISO 15189 QMS implementation, healthcare management should be able to identify both the forces positively impacting on achieving international accreditation and forces working against achieving international accreditation.

Lewin also contributed to the 3-step model for organizational change, where he proposed that a successful change process involves three phases, which are, unfreezing, moving, and refreezing (Burnes, 2004). The unfreezing phase consists of preparing the organization to accept the coming change; the change phase involves people implementing the change programs, and the refreezing phase involves perpetuating the successes of the change program as a new paradigm (Burnes, 2004).

Lewin's conceptual framework for organizational change applied directly to my study, as the implementation of ISO 15189 QMSs requires the application of a planned change. A vital aspect of Lewin's conceptual framework of force field analysis is that it could verify my assumption that the successful implementation of an ISO 15189 QMS requires dealing with forces acting for and against organizational change.

Operational Definitions

Mentoring: Mentoring is a workplace process in which an older, more experienced person acts as a guide, counselor, coach, and friend to a younger and inexperienced person with the purpose of developing certain skills (Son, 2016).

ISO 15189 standard: The ISO 15189 standard is an international standard detailing the requirements for management and technical competences of a QMS for medical laboratories (ISO, 2012).

Strengthening Laboratory Management towards Accreditation (SLMTA): A medical laboratory management training program that uses a series of three workshops interspersed with on-site mentoring and supervision projects designed to improve laboratory quality (Ndihokubwayo et al., 2016). SLMTA is a WHO and CDC designed program for the accreditation of medical laboratories in resource-limited settings.

Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA): SLIPTA is a framework for assessing or auditing medical laboratories implementing the SLMTA process developed in line with the ISO 15189 standard and the Clinical and Laboratory Standards Institute's (CLSI) 12 quality system essentials (Ndihokubwayo et al., 2016). The process allows the regular evaluation and awarding different star ratings based on the level of implementation of the QMS (Ndihokubwayo et al., 2016).

ISO 15189 Accreditation: An international recognition, seal of approval by an accrediting body in which a particular medical laboratory satisfies both the management and the technical requirements for the ISO 15189 standard and that it can perform specific tasks related to the examination of patient samples in a consistent manner (Wilson, Smye, & Wallace, 2016).

Quality Management System (QMS): A formalized system that documents policies, processes, procedures, plans, and responsibilities for achieving laboratory objectives regarding quality (Sabbagha, Rahman, Ismail, & Hussain, 2016).

Assumptions, Limitations, and Delimitations

Assumptions

Study assumptions form the foundation of any research and are the aspects of the study that the researcher takes for granted (Leedy & Omrod, 2015). Assumptions are the things that the researcher accepts as real or plausible and are issues that are potentially influential to the study for which the researcher has no empirical evidence or verification (Leedy & Omrod, 2015). I had four assumptions in this study. The first assumption was that the qualitative research methodology was the most suitable for the exploration of strategies that healthcare managers use during mentoring of medical laboratories. The second assumption was that the case study was the most appropriate research design because interviews provide an in-depth understanding and explanations of the strategies suitable for implementing QMSs. The third assumption was that the participants would give honest, truthful, and comprehensive responses to the interview questions. The final assumption was that the sample of participants represented the population of the healthcare managers involved in the implementation of the ISO 15189 QMS using the mentoring approach.

Limitations

Limitations of a study are potential weaknesses that the researcher identifies before embarking on the study and are outside their control (Ozkan & Kaya, 2015). The primary method of data collection in this study was telephone interviews, which generally have a limitation of bias. Participants may have answered the interview questions based on their perspective and may have failed to remember accurately past

events or experiences, thereby introducing bias. Another limitation of this study was the purposive sampling method used, which is prone to researcher bias. Thus, it may be difficult to generalize the research findings. The other limitation was that the study only covered a single geographical area, that is, East Africa, and therefore participants from different geographical regions could have provided different responses.

Delimitations

Delimitations refer to boundaries or restrictions of a study set by the researcher, limiting the scope of the study so that it becomes more manageable (Yin, 2014). The first delimitation was the selection of research participants from healthcare institutions that successfully underwent mentorship for their ISO 15189 QMS and attained international accreditation. People who served as laboratory management and had experience working with a mentor in developing and implementing an ISO 15189 QMS qualified as research participants. Another delimitation of the study was that I restricted this study to a geographical area in East Africa (United Republic of Tanzania). Therefore, findings from this study may not apply to health care organizations from other geographical regions.

Significance of the Study

Contribution to Business Practice

Findings from this study may provide insights on successful strategies for implementation of ISO 15189 QMSs in the healthcare industry, thereby explaining the implementation process for a successful QMS. The possible result of this study is that more healthcare institutions can adopt and implement quality systems and thus improve performance and reduce costs associated with poor service quality and healthcare errors.

The findings of this study may guide policymakers and laboratory managers through a defined structure and model for implementing ISO 15189 QMSs. The strategies identified for medical laboratories could positively impact the speed of implementation of quality systems, thereby reducing time wastage. The results of the study may benefit healthcare managers by providing them with knowledge and strategies for effective implementation of quality systems to improve the performance of their healthcare institutions.

Implications for Social Change

ISO 15189 accreditation has the potential to improve the quality of health care for patients by reducing misdiagnosis and decreasing inappropriate treatment (Sisay, Mindaye, Tesfaye, Abera, & Desale, 2015). Through the increased implementation of ISO 15189 QMSs, more people may access quality health care services, thus promoting their health, worth, and dignity. Some potential long-term benefits of implementing ISO 15189 QMSs include improvement of the patient care experience, improvement of the population's health, and reduction of healthcare costs (Zima, 2017). Implementation of ISO 15189 QMSs results in better analytical performance and, as a result, fewer laboratory errors, which may then result in healthier communities (Butcha et al., 2018).

A Review of the Professional and Academic Literature

I reviewed the literature on medical laboratory ISO 15189 QMSs, the role of medical laboratories, and mentoring methods. I used peer-reviewed articles, books, reports, and other scholarly resources to review the literature. I used *Ulrich's Periodical Directory* to verify that articles are from recognized peer-reviewed journals. I used 218 sources, of which 192 are peer-reviewed articles, which represent 88% of the sources,

189 had a publication date less than 5 years (2016-2020), which was 86.7% of the total references.

The leading search topics considered under mentoring included mentorship approaches and models, benefits of mentoring, characteristics of mentor and mentees, challenges of mentoring, and relationships between mentor and mentees. The search topics under QMSs included total QMS (TQM), Lean, Strengthening Laboratory Management Towards Accreditation (SLMTA), Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA), and International Organization for Standardization (ISO). Under ISO standards, topics searched included ISO 15189 QMSs, implementation of QMSs, benefits of ISO 15189 QMSs, success factors for the implementation of QMSs, and impact of QMSs. The academic databases used included Google Scholar, Business Source Complete, ABI/INFORM Collection (ProQuest), Emerald Insight, Science Direct, and Sage Journals. Other sources reviewed included articles in PubMed and a review of archives from the African Journal of Laboratory Medicine.

The purpose of this qualitative multiple case study was to explore strategies used by managers in the healthcare industry in developing countries to design, develop and implement the ISO 15189 QMS through a mentoring approach to improve organizational performance. The targeted population comprised of five healthcare managers located in East Africa (United Republic of Tanzania) who implemented and attained international accreditation in ISO 15189 through a mentoring approach. The selected population was appropriate for this study because the participants experienced the phenomenon of

implementing an ISO 15189 QMS through the assistance of a mentor and attained international recognition. The significant contribution the study may add to social change is improving the economic and health conditions of the populations of people served by ISO 15189 accredited laboratories.

The conceptual framework used was Lewin's organizational change model. Lewin proposed the earliest organizational change model known as the 3-step-change as well as the force field analysis (Cummings, Bridgman, & Brown, 2016). The 3-step change model broke organizational change into three phases, which are unfreezing, moving (changing), and refreezing (Burnes, 2004). Cummings, Bridgman, and Brown (2016) provided detail to the model by explaining the different phases. Unfreezing is the process of changing the present stable state of equilibrium, which supports the current organizational behaviors and attitudes (Cummings, Bridgman, & Brown, 2016). The unfreezing phase involves preparing the organization to accept the coming change and considers the inherent threats that the planned change presents to the staff and how to motivate those affected to achieve a natural state of equilibria through accepting the change (Cummings, Bridgman, & Brown, 2016). Schein (1996) identified three processes required to achieve the unfreezing phase, which is, disconfirmation of the validity of the present status, induction of guilt or survival anxiety, and creation of psychological safety. Moving or changing is a transition phase, where the organization introduces new behaviors, values, and attitudes through structural and process changes and developmental techniques (Cummings, Bridgman, & Brown, 2016). The refreezing phase involves stabilizing the change through reinforcement of the new ways of conducting

activities. The staff within the organization may return to the original methods of doing things if management fails to reinforce the latest changes (Cummings, Bridgman, & Brown, 2016).

Cummings, Bridgman, and Brown (2016) summarized the various arguments against Lewin's organizational change model. The first argument was that the model was a simplistic representation of change, which presented organizational change in a linear and static conception. The second argument was that the freeze-change-refreeze model was not appropriate in today's complex world, which requires flexibility and adaptation (Al-Haddad & Kotnour, 2015). The third argument was that Lewin's change model was a mechanical approach similar to Taylor's scientific management concept, which prescribes one best way of management. Hussain et al. (2016) noted that Lewin's model of change did not involve the employees who play an essential role in bringing change. Hussain et al. (2016) observed that transformational leadership was a crucial factor in the organizational change process, and Lewin's model did not consider those. Despite all the criticisms, the Lewin model provides a pragmatic approach to organizational change programs. Healthcare managers in developing countries who may have little training in management can adopt and use the simple change management approach to implement an ISO 15180 QMS.

Lewin also proposed the force field analysis model, where he suggested that individual behavior was a result of the group environment or *field*. Therefore, human behavior changes are a result of changes in the forces within the field (Burnes, 2004). Lewin defined a *field* as an entirety of coexisting facts, which are mutually

interdependent and in a continuous state of adaptation (Burnes, 2004). Therefore, the force-field analysis involves three steps defined below.

The first step involves the identification of the restraining (forces against change) and driving forces (forces for change) that affect the transition to the future state (Al-Haddad & Kotnour, 2015). Restraining forces include the adverse reactions of those who see change as not necessary or as a threat to their interests. The second step involves assessing both the driving or restraining forces and taking note of those that are critical. The third step involves deliberately increasing the vital forces in support of the change while decreasing the forces against the change (Al-Haddad & Kotnour, 2015). Implementing an ISO 15189 QMS requires an organizational change strategy; therefore, some healthcare managers can adopt Lewin's three steps as a simple model for organizational change.

The definition of the word quality in the healthcare sector is subjective and thus depends on the perspective of the person defining it. Quality is the standard of a product or a service, the degree of excellence that a service possesses (Nylenna, Bjernaes, Saunes, & Lindahl, 2015). In the context of health care, the Institute of Medicine (IOM) defined quality as the degree to which health care services for people are consistent with current professional knowledge and how they increase the likelihood of desired health outcomes (Lohr, 1990). Nylenna et al. (2015) noted that healthcare quality is complex to define because of the different perspectives of the individuals defining the term. For example, patients emphasize the importance of short waiting time and sufficient time in consultations more so than the caliber of the physician (Agarwal & Ganesh, 2017).

Healthcare managers emphasize efficiency, distribution of resources, and sustainability more than other healthcare professionals and patients (Nylenna, Bjernaes, Saunes, & Lindahl, 2015). The critical component in the implementation of the ISO 15189 QMS in medical laboratories is having a clear understanding of what healthcare quality means and the associated benefits of international accreditation.

Recent events in research indicate an increase in interest in quality improvement initiatives in the healthcare sector. Sun, Perla, and Davies (2014) reviewed the frequency of studies about the commonly used quality improvement initiatives in the healthcare setting and noted a significant increase in the total number of publications regarding quality improvement in healthcare beginning in 1991. Agarwal and Ganesh (2017) attributed the increased interest in health care quality because of the fast-growing nature of the healthcare industry and the considerable investment by both the private and public sectors. Hussey, Friedberg, Price, Lovejoy, and Damberg (2017) observed the growth in health care quality measurements in response to the increase in demand by the customers and policymakers to hold providers accountable for high quality and lower costs. Therefore, understanding market demands and satisfying the requirements of the clients are driving forces healthcare managers can use to design, develop, and implement QMSs.

Healthcare service quality is more critical for healthcare organizations primarily because of increased competition. Customers are aware of the importance of the service quality they receive, and the rapid growth of internet communication technology facilitates the easy dissemination of negative comments on poor healthcare service quality (Sumaedi, Yarmen, & Bakti, 2016). Balasubramanian (2016) attributed the

increase in the importance of quality in healthcare to the improvement of governmental regulations, the influence of customers and public pressures, and the rise in hospital management initiatives. Considering that several outside factors are pushing healthcare managers to adopt quality services, healthcare managers should, therefore, invest in understanding the market forces and be at the forefront of the fulfillment of the demands of the customers.

Total Quality Management

Total quality management (TQM) is a quality philosophy or point of view that evolved over decades (Albert et al., 2017). TQM is a set of management tools consisting of aspects such as quality assessment and continuous quality improvement, which are part of a systematic approach with both positive and negative feedback loops (Bajaj, Garg, & Sethi, 2018). TQM is a powerful tool useful in creating a quality culture since it includes principles such as leadership, communications, training, and continuous improvements (Albert et al., 2017). Organizations are adopting TQM as a business strategy to reduce costs and improve customer satisfaction (Patyal & Maddulety, 2015). Knowledge and understanding of the principles of TQM by healthcare managers in developing countries may result in a positive impact on the overall implementation of the ISO 15189 QMS.

Mosadeghrad (2014) identified several critical success factors for implementing TQM in the healthcare sector, some of which are good leadership, effective planning, and education and training. Regarding good leadership, healthcare managers should consider a program for the sensitization of all the leaders who have a direct impact on the success

of the ISO 15189 QMS. Since decisions about resource allocation are the privilege of most senior leaders, leaders should appreciate the benefits accrued by investing in the QMS implementation. Mosadeghrad recommended the recognition of quality as a strategic goal and making quality visible within the organization's vision and mission statements. Therefore, effective planning and the addition of TQM into the strategic objectives of the organization helps to avail resources for implementation. A deliberate action to train and educate the medical laboratory staff in TQM is critical to the success in the implementation of the ISO 15189 QMS. Asking personnel to implement QMSs they do not understand may lead to failure. Education and training help management to establish a common language within the organization, and that helps to secure commitment to implementing quality practices and change the behavior of the staff.

A search of the academic literature reveals several methods for the implementation of QMSs. Martins, Pinheiro de Lima, and Gouvea da Costa (2015) described the use of the process approach applied for a medical equipment manufacturing company in Brazil. The process approach consisted of nine different phases, namely: gap analysis, development of objectives, development of performance indicators, identifying primary and support activities, process mapping, implementation planning, management, process audit, and critical analysis. Breaking down the implementation phases, as is done in the Lewin’s model may help healthcare managers and staff implementing the ISO 15189 QMS to keep track of the progress and understand the specific actions required at each stage. A critical component in the implementation of the ISO 15189 QMS is training and education in the system, which is missing in the process approach described above;

the primary assumption with the process approach is that healthcare managers have knowledge and understanding of the ISO 15189 QMS, which may not always be the reflection on the ground.

In contrast to the Martins et al. (2015), process approach to implementation of the QMS, Al-Shadaifat (2015) identified the essential principles helpful in the QMS implementation. Al-Shadaifat (2015) identified the five most critical tenets of TQM implementation in healthcare institutions as continuous improvement, teamwork, training, top management commitment, and customer focus. The essential principles approach is vital because healthcare managers can identify and have more time to work on forces that work against the ISO 15189 QMS implementation. Another critical aspect of the QMS essential principles approach is that teamwork and training are easy to implement and are every manager's responsibility. However, having fundamental principles alone may not lead to a successful QMS implementation without the processes as identified by Martins et al. (2015).

Bouranta, Psomas, and Pantouvakis (2017) studied the implementation of total QMS in a Greek hotel industry by determining the underlying structures or latent factors of TQM practices and their impact on company performance outcomes. Bouranta et al. concluded that the TQM factors in the hotel industry are the quality practices of top management, employee quality management, customer focus, strategic quality planning, employee knowledge, and education. The findings by Bouranta et al. are in line with those made by Al-Shadaifat (2015). Successful implementation of the ISO 15189 QMS in

the healthcare sector will, therefore, require that healthcare managers initially put in place the underlying structures, the right attitude, and the right environment.

Success factors for the implementation of QMSs

Several researchers reported the success factors for implementing QMSs. Braithwaite, Marks, and Taylor (2014) reviewed more than 57 peer-reviewed articles about the implementation of the QMS and identified eight key success factors. The eight key factors are: (a) preparing for the change, (b) capacity for implementation-people, (c) capacity for implementation-setting, (d) types of implementation, (e) resources, (f) leverage, (g) desirable implementation enabling features, and (h) sustainability. Braithwaite et al. noted that the obstacles to QMS implementation are the mirror image of the success factors. Yeh and Lai (2015), and Aquilani, Silvestri, Ruggieri, and Gatti (2017) conducted similar studies and discovered that top management involvement, inter-departmental communication, and coordination, teamwork, hospital-wide participation, continuous internal auditing were the key factors for the successful implementation of a quality management program. The eight factors identified by Braithwaite et al. are an expanded Lewin's organizational changes model, although it adds the underlying principles as identified by (Al-Shdaifat, 2015). Therefore, the basis for the successful implementation of the ISO 15189 QMS depends on the understanding of Lewin's change model.

A distinct factor for the success of the implementation of any QMS is the leadership of the organization. Mosadeghrad (2014) noted that the success or failure of any QMS largely depends on the management of any organization. Top healthcare

managers should demonstrate commitment and direction for the successful implementation of the ISO 15189 QMS (Day et al., 2018). Almeida, Pradhan, and Muniz (2018) noted that top management has the responsibility of providing moral support and advocating for the setting up and communication to all the members on the importance of implementing the QMS. The burden of the mentor is not only to ensure the implementation of the ISO 15189 QMS but also to influence the attitude of the organizations' leaders to advocate and support all efforts of the ISO 15189 QMS implementation.

Krajcsak (2018) explored the drivers and the challenges of a quality improvement program and discovered that organizational culture and a self-evaluation system contributed significantly to the success or failure of the quality improvement program. Krajcsak noted that the organizational structure, the operating environment, and employee commitment are the most decisive factors related to the organization. Other factors Krajcsack noted included employee morale, empowerment, training, management support, and involvement. Internal staff training on ISO 15189 standard and the laboratory's QMS is a strategy that healthcare managers and staff can consider ensuring smooth adoption of the QMS. Mentors should have a basic understanding of the drivers and challenges for the ISO 15189 QMS implementation and consider strengthening the success factors and, at the same time, reduce the severity of challenges during the mentorship.

Hussein, Abou-Nassif, Aridi, Chamas, and Khachfe (2017) explored the barriers to the successful implementation of the QMS in a higher education sector. Hussein et al.

identified barriers in the implementation of any QMS as (a) resource availability, (b) commitment of top management, (c) resistance to change, and (d) lack of awareness. Limited resource allocation reflects the lack of commitment by healthcare managers in the QMS implementation. Therefore, mentors should consider advising the healthcare managers of the importance and benefits of ISO 15189 accreditation to the healthcare system. Raising awareness and increasing the advocacy in the benefits of the ISO 15189 QMS should be part of the mentor's role when in contact with healthcare leaders.

Approaches for Implementing Healthcare Quality Improvements

Different methods are in use worldwide to achieve health care quality improvements. Examples of methods in use for the implementation of quality systems are Lean and ISO 9001 standards (Al-Qatawneh, 2017). Albert et al. (2017) noted that none of the approaches is superior but combining these methods might better serve the healthcare industry. Each QMS implementation approach serves a particular advantage over the other; therefore, combining the different aspects of each system helps to ensure a quicker adoption and implementation of the quality systems.

Lean. Lean involves analysis and standardization of work processes, eliminating waste, and creating value. Based on the Toyota model of quality, Lean focuses on the efficient use of resources by considering the value-added for the customer in every process (Daultani, Chaudhuri, & Kumar, 2015). Yaduvanshi and Sharma (2017) noted that Lean is not a suitable method for evaluating the financial aspects of a process but is essential in the identification of inefficiencies in a process flow. Bacoup, Michel, Habchi, and Pralus (2018) noted that the main objective for implementing a Lean system is to

reduce waste by cutting out steps that do not create value. Overall, Lean fundamentally changes organizations thinking and value, which leads to a transformation of the organization's behavior and culture (Daultani, Chaudhuri, & Kumar, 2015).

A basic understanding of Lean principles by the organization's mentors can help in the implementation of the ISO 15189 QMS. Hussain and Malik (2016) analyzed the application of the Lean principles in private and public healthcare institutions and noted a significant reduction in patient waiting time, an increase in productivity, and a lowering of inventory costs. Healthcare processes in developing countries may have several steps, which are considered as waste in terms of Lean principles. Adoption and application of the Lean principles by mentors in implementation of the ISO 15189 QMS in medical laboratories will help in the identification of wasteful processes, which require optimization. ISO 15189 QMS documentation process is a potential area that requires Lean principles as most documents are bulky and contain unnecessary information.

ISO standards. The increasing international focus on improving the quality of health care services has led to a focus on the adoption of the ISO 9001 standard for evaluating healthcare organizations and for implementing certification and accreditation programs in the sector (Al-Qatawneh, 2017). The International Organization for Standardization (ISO) has the responsibility for developing the ISO 9001 standard and other versions like ISO 17025, ISO 15189, and many others supporting different industries (Díaz & Martínez-Mediano, 2018). Founded in 1947, ISO includes standardization for technical specifications for products and services traded in the international marketplace (Al-Qatawneh, 2017).

The ISO standards are generic in that the primary standard is ISO 9001, and the other versions are the equivalent field-specific versions. ISO 17025 is specific for the technical requirements of testing and calibration laboratories, while ISO 15189 is specific for technical requirements for quality and competence in medical laboratories (Barradas & Sampaio, 2017). A laboratory that fundamentally fulfills the requirements of ISO 17025 or ISO 15189 meets the management requirements of ISO 9001 (Nasser, M'hamed, Badrane, Bencheikh, & Omaima, 2018). As with any other quality systems, the ISO standards evolve with time as ISO revises all the standards after specific periods; for example, the first publication of ISO 15189 was in the year 2003, and the current revision of ISO 15189 was in 2012, which replaced the 2007 version (Bouchet, 2015).

ISO 9001 and related standards apply to any organization working on improving the quality of its goods or services (Bacoup, Michel, Habchi, & Pralus, 2018). The standards are generic, which means that a single standard may apply to different types of organizations, and that is the reason healthcare institutions have adopted them within the healthcare industry (Olkiewicz & Bober, 2015). The ISO standards establish minimum requirements for organizations in the design and implementation of a QMS that provides confidence in the conformity of its goods and services (Díaz & Martínez-Mediano, 2018). In the healthcare industry, QMSs complying with ISO 9000 standards, like ISO 15189, are the most widespread management systems in use as compared to other methods like Lean or Six Sigma (Olkiewicz & Bober, 2015).

The significant difference between ISO 9001 certification standard and the other accreditation standards, such as ISO 17025 and ISO 15189, is the lack of technical

requirements in the ISO 9001. Developers of ISO 17025 and ISO 15189 recognized that ISO 9001 is inadequate to guarantee the validity of analytical results in laboratories (Nasser, M'hamed, Badrane, Bencheikh, & Omaima, 2018). Therefore, the technical clauses of ISO 17025 and ISO 15189 are more field-specific than the requirements of ISO 9001 standard, which only apply to a management system (Wilson, Smye, & Wallace, 2016). The ISO 15189 standard consists of two major assessable sections, which are management and technical requirements (International Organization for Standardization, 2012). The management requirements in ISO 9001 are the same as in ISO 15189, although written specifically for medical laboratory personnel.

Accreditation and certification have different meanings when it comes to ISO standards, although people often use them interchangeably. Accreditation is a procedure where an authoritative body issues a formal recognition that a particular organization is competent to conduct specific tasks (Barradas & Sampaio, 2017). The critical word is *competence*, while certification refers to compliance. Accreditation is an inspection system checking for adherence with ISO standard requirements in a laboratory's manuals, processes, standard operating procedures (SOPs), and records (Wilson, Smye, & Wallace, 2016). Attainment of accreditation status by a laboratory demonstrates the existence of a documented QMS that satisfies ISO 15189 standard requirements and staff that can perform the tasks consistently, fulfilling the technical requirements of the field (Tzankov & Tornillo, 2017). Since accreditation is a thorough process, covering both the documentation of the ISO 15189 QMS and the competence aspects, mentorship strategies should, therefore, reflect both aspects of the system. Mentors can divide the mentorship

into different phases like the documentation and the implementation of the ISO 15189 QMS to ensure smooth system implementation. The process for designing and implementing a laboratory's ISO 15189 QMS should start with the documentation process. The laboratory management must first develop a team tasked with designing, documenting, and implementing a QMS that covers all the aspects of the standard (Vavoulidis et al., 2016). Using a team approach when designing the ISO 15189 QMS for the first time helps to cement the team approach mentality that all the members of staff should contribute towards the ISO 15189 system implementation. Healthcare managers can always consider teamwork to ensure sustainable, balanced, and effective ISO 15189 QMS.

Once the laboratory's ISO 15189 QMS documentation and implementation is complete, an assessment team comes on-site. The assessment team consists of the team leader and one or more technical assessors depending on the scope and size of the laboratory (Zima, 2017). The team leader assesses the laboratory's management system requirements and their interface with the technical aspects (Tzankov & Tornillo, 2017). The technical assessors evaluate the technical requirements using the vertical checklists or witness the laboratory personnel performing their activities (Zima, 2017). The accreditation assessment covers both the management and technical requirements of ISO 15189 and the competencies of staff in examining the samples through all stages of the process (pre-analytic, analytical, and post-analytical process) (Quintana, 2015). Likewise, the strategy for the ISO 15189 QMS implementation should also mirror the structure of the accreditation assessment plan, where the management and

technical requirements have different mentorship sessions for an in-depth fulfillment of the ISO 15189 standard requirements.

Upon completion of the on-site assessment, the assessors either recommend for the accreditation or deny the recommendation. Assessors recommend for ISO 15189 accreditation when a laboratory's QMS satisfies the standard requirements, demonstrated by the availability of adequate complete records (Tzankov & Tornillo, 2017). The assessors may raise nonconformities during the assessment and expect laboratory management to conduct root cause analysis and corrective actions before an agreed target date (Zima, 2017). After the laboratory submits all the evidence of the corrective actions, the accreditation approvals committee within the accreditation body reviews all the evidence of competence collected by the assessment team and the corrective actions provided by the laboratory (Tzankov & Tornillo, 2017). Accreditation is not a once and for all activity as the accreditation body arranges annual or biennial surveillance visits to check for continued implementation and continuous improvement of the laboratory (Wilson, Smye, & Wallace, 2016).

The process for ISO 15189 accreditation demonstrates two major fundamental skills, the regular assessments and the ability of the laboratory management to conduct effective root cause analysis and corrective actions. ISO 15189 mentorship should, therefore, aim at capacitating the laboratory management in performing root cause analysis and effective corrective actions (Zima, 2017). While mentors may do some work on behalf of the laboratory management, the strategy should be to empower the

management to perform corrective actions on their own as they will not always depend on the availability of the mentor.

Although most laboratory managers now understand the value of international accreditation, few laboratories in Africa attained ISO 15189 accreditation. Albert et al. (2017) reviewed the accreditation statuses of National Tuberculosis (NTB) laboratories in African countries and noted that only four had attained ISO 15189 accreditation by 2016, which is 10% of all NTB laboratories in Africa. Among the contributing factors preventing accreditation, Albert et al. (2017) noted that the significant factors were insufficient training in quality systems, poor staff motivation, lack of regular supervision, lack of an in-country accreditation program, insufficient advocacy, inadequate staff knowledge, and lack of funds. Healthcare managers, therefore, need to counter the effects of the factors identified by Albert et al. by providing training in the ISO 15189 QMS, motivating their staff, engaging in advocacy, and appealing for more funding for the implementation process. The success of the ISO 15189 QMS implementation is a result of regular supervision, and therefore, mentors may need to design systems and methods for the supervision of the ISO 15189 QMS from the initial stage.

Strengthening Laboratory Management Towards Accreditation (SLMTA) and Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA). The CDC, in collaboration with developing countries, introduced the SLMTA program to help laboratories implement the ISO 15189 QMS. SLMTA is a competency-based program that utilizes a series of three, short training workshops and work-based learning projects to effect measurable laboratory improvement and empower laboratory

management to implement the ISO 15189 QMS (Alemnji et al., 2017). The complete SLMTA program lasts between 12 to 18 months, and after each training workshop, the participants return to their workplaces to implement improvement projects (Guevara et al., 2014). The trainers conduct three supervisory visits and on-site mentoring in-between the training sessions and evaluate the project after the completion of the three alternative training workshops (Yao et al., 2014). The initial launch of SLMTA was in 2009, and since its introduction, there was a comprehensive implementation, especially throughout the developing countries (Ndihokubwayo et al., 2016).

An objective means of assessing the progress of laboratories in the SLMTA program is through the use of the WHO's Regional Office for Africa's (WHO-AFRO) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) program (Ndihokubwayo et al., 2016). In the SLIPTA program, assessors visit participating laboratories to evaluate the implementation of ISO 15189 standard requirements using a SLIPTA checklist (Albert et al., 2017). When the laboratory reaches five Stars level, it can consider applying for ISO 15189 international accreditation with accreditation bodies.

The SLMTA and SLIPTA ISO 15189 implementation processes have had many challenges. While evidence exists, that medical laboratories improve their performance in quality through SMLTA and SLIPTA, the implementation up to the attainment of a five-star rating took longer than the planned 12-18 months. Gachuki et al. (2014) reported 36 months for the Kenyan National HIV laboratory. Mbah et al. (2014) attributed the delays in the implementation process to the few numbers of SLIPTA auditors responsible for

audits and technical support of the ISO 15189 implementing laboratories. The longer the implementation time, the higher the cost of quality (Bespalov, Michel, & Steckler, 2019). Therefore, mentors and healthcare managers should design and use processes of the ISO 15189 QMS with a short implementation timeframe to reduce the total cost of quality.

An inherent weakness of the SLMTA and SLIPTA ISO 15189 implementation process is the focus on training a select few members of staff (Yao & Lumen, 2014). In a review of the SLMTA and SLIPTA program, Yao et al. (2014) noted the lack of teamwork and involvement of all members of staff, especially those who did not attend the SLMTA training. Lack of teamwork in the implementation of the QMS demonstrates an inherent weakness in the SLMTA process. Teamwork is a strategy that healthcare managers and mentors can use and may need to focus on at the initial stages of the design and implementation of the ISO 15189 QMS. ISO systems are usually a huge task, which requires cooperation and involvement of all members of staff to implement the different components of the system.

The implementation of the SLMTA and SLIPTA in the medical laboratories has had several positive impacts. More than 47 countries around the world implemented SLMTA and SLIPTA by the end of 2014 (Alemnji et al., 2017), and Ndihokubwayo et al. (2016) noted the raised awareness of quality systems and accreditation. Since the SLMTA and SLIPTA program incorporated training as part of the strategy of implementation, most medical laboratory personnel now have an understanding and appreciation of the ISO 15189 QMS. Healthcare leaders and mentors may consider the incorporation of an effective training program on the laboratory's ISO 15189 QMS to

ensure effective implementation and understanding of systems. Healthcare managers can design training programs on ISO 15189 for all members of staff instead of focusing on a single member of staff, as currently is the approach of the SLMTA program.

While the SLMTA program developers acknowledge the value of mentoring of ISO 15189 quality system, however, the program lacks detailed elaboration on how laboratory management can use it to implement the ISO 15189 QMS up to accreditation. Most studies about ISO 15189 discussed the experiences that medical laboratory personnel obtained from implementing the system directly and only a few on the ISO 15189 mentoring approach (Solis-Rouzant, 2015). Although Perrone et al. (2016) and Maruta, Rotz, and Trevor (2013) discussed a structured mentoring program for ISO 15189, they did not focus nor elaborate on the strategies a mentor uses to implement the QMS. Therefore, the use of a mentoring program requires a documented process and stages with different activities that healthcare managers and mentors require to implement during each phase.

Adequate evidence exists, demonstrating that mentors help improve the performance of medical laboratories. Sisay, Mindaye, Tesfaye, Abera, and Desale (2015) discovered that medical laboratories, which had the support of mentors either onsite or offsite, implementing the ISO 15189 QMS scored better than the laboratories without a mentor. Albert, Trollip, Erni, and Kao (2017) customized the SMLTA program to create Tuberculosis (TB) SLMTA. Albert et al. added a mentoring program in-between the SLMTA training sessions, and their findings were that mentoring contributed positively to the successful implementation of the TB SLMTA program. ISO 15189 mentors can

increase the effect of mentorship and help in transferring knowledge from the mentor to the mentees if they combine training workshops and mentorships.

Workplace Mentoring

The concept of workplace mentoring is now a common phenomenon. A mentor is a more experienced person who provides coaching or guidance to a less-experienced employee, the mentee or protégé (Wen, Chen, Dong, & Shu, 2017). A mentor may serve as another employee within the same organization or someone outside; however, the critical aspect is that he or she acts as a role model and shares advice, knowledge, and experience to help the mentee grow professionally (Wen, Chen, Dong, & Shu, 2017). Mentoring generally occurs in a workplace setting to provide guided learning and to transition theoretical or textbook knowledge to its practical application in a formal environment (Salter & Gannon, 2015). Therefore, effective mentoring can contribute to worker effectiveness, self-efficacy, increased skills, and competencies that support individual advancement both in career and educational domains (Montgomery, 2017). In the medical laboratories, mentors can serve as people who have experience in the implementation of the ISO 15189 QMS and have attained the requisite expertise in maintaining such a system.

No clear-cut difference exists between mentoring and coaching, as people often use these words interchangeably. Coaching focuses on improving performance in a specific role or skill of an individual or a team while mentoring focuses on enhancing an individual's potential in a broader, holistic development focusing on their career progress (Salter & Gannon, 2015). However, other authors like Serrat (2017) do not differentiate

between the two terms but instead use them interchangeably, arguing that a good mentor does both coaching and mentoring depending on the situation between the mentor and mentee. After a review of the historical writings about mentoring and coaching, Garvey, Stokes, and Megginson (2018) concluded that in both mentoring and coaching, knowledge, and skills transfer from one person to another. The focus of ISO 15189 mentorship should include both coaching and mentorship as the two activities result in skills transfer aimed at attaining international accreditation.

Mentoring is an art that evolved into a practice. In Greek mythology, a story exists where a mentor was a loyal friend and a close adviser to King Odysseus of Ithaca (Gisbert, 2017). When king Odysseus went off to fight the Trajan War, he entrusted the care of his household and son, Telemachus, to the mentor (Gisbert, 2017). The mentor became the teacher, coach, protector, and counselor to Telemachus through a relationship based on affection and trust (West, 2016). In addition to coaching, the ISO 15189 mentor can add techniques such as counseling and teaching. Counseling of mentees takes place in difficult scenarios, such as when the laboratory management receives discouraging assessment results. Teaching is important for difficult topics that require practical demonstration to understand.

Short (2014) noted a surge in the interest in mentoring, as reflected by a rapid increase in publications of more than 400 articles per year since the 1980s. One reason for the surge included the fact that mentoring has become a crucial part of the learning and training toolkit (Gisbert, 2017). Mains and McLean (2017) attributed the increasing interest in mentoring to the fact that it is a core requirement when it comes to dealing

with contemporary issues. Makatleho, Venteer, and Rootman (2016) attributed the increasing interest in mentoring to the positive impact and the critical roles that the concept plays in different areas, like teaching, medical, and management professions. On the contrary, mentorship demand has increased within the healthcare industry because of the client's need for quality healthcare services. Mentorship in ISO 15189 is a method for a quicker implementation of the QMS within the organization.

Although the literature review reveals a rich history of the use of mentoring in the medical field, most of the literature is from the nursing field and physician training programs (McBurney, 2015). Masters (2015) acknowledged the limitation of the on the job training programs for improving quality in healthcare institutions and recommended the use of the mentoring approach for driving real improvement. Masters (2015) noted that medical staff are not experts in the ISO 15189 QMS but can improve their organization's quality when they implement improvement projects with the support of a mentor. In the medical laboratory fraternity, the use of mentoring is mainly for developing the capacity for the medical laboratory management to develop and implement an ISO 15189 QMS and in the establishment of the business models when transforming laboratories towards adopting a business approach (Perrone et al., 2016).

Characteristics of mentors. Mentees have certain expectations of the attributes of the best mentor, and usually, these expectations are a powerful driver for the success of the mentoring relationship (Bailey, Voyles, Finkelstein, & Matarazo, 2016). Bailey et al. (2016) noted that mentees preferred mentors with a professional appearance as they considered these to have the requisite knowledge for guidance in the mentorship. Bailey

et al. also stated that mentees preferred valuable friendship and interpersonal qualities like a good sense of humor, friendliness, and approachability. The process for selecting the ISO 15189 QMS mentors should not be a random method but should focus on selecting people who are enthusiastic, understanding, provide easy access, and a meaningful connection with the mentee.

Mentorship approaches and models. Several methods exist through which mentoring can take place. Mangan (2013) identified nine strategies. One on one mentoring approach is by far the most common mentoring model, which involves one mentor with one mentee (Schwartz & Rhodes, 2016). Most people prefer this model as it allows the two parties to develop a personal relationship and thus ensures individual support for the mentee. Schwartz and Rhodes (2016) noted that the common challenge with this method is the limitation on the availability of the mentors as a single person spends more time with one mentee. While the one to one mentoring approach may have weaknesses, ISO 15189 mentors can use the approach when training of personnel on difficult topics like method validation, which require an in-depth contact time with a mentee.

The group mentoring model occurs when one mentor is working with several mentees at the same time (Harris, Cheng, & Gorley, 2015). The focus of group mentoring is to share insights and experiences between the mentees while the mentor acts as a group facilitator. A significant challenge of group mentoring is the difficulty in scheduling meetings for all groups of mentees and the lack of personal relations, which are preferable in ISO 15189 mentorship. Healthcare managers and mentors can adopt group

mentoring in areas where a single mentor is available, while several groups of people from different sections or departments require mentorship.

Team mentoring involves two or more mentors working with a single mentee or a group of mentees and works well when mentors complement each other (Behar-Horenstein & Prikhidko, 2017). Guise, Geller, Regensteiner, Raymond, and Nagel (2017) explored the advantages and disadvantages of team mentoring models. Among the benefits, Guise et al. reported that team mentoring provides a diversity of ideas and increased networking. The significant challenges Guise et al. discovered included difficulties in scheduling and managing conflicting opinions from the different mentors. The practical use of the team mentorship in the ISO 15189 QMS is when mentors have particular areas of specialty. Mentors specialized in the clinical chemistry department may have difficulties in mentoring the microbiology department as the two departments have different principles of application.

Virtual or e-mentoring is a type of mentorship that connects the mentor and the mentee electronically, for example, through email, Skype, or Whatsapp (Gregg, Galyardt, Wolfe, Moon, & Todd, 2016). Mangan (2013) recommended that at least one face-to-face meeting is necessary for building trust and noted that this approach is suitable in situations where long distances separate mentors and mentees. Considering the cost implications of keeping a mentor onsite for extended periods, ISO 15189 mentor can use the e-mentorship in-between the onsite mentorship sessions to ensure continued QMS implementation. Challenges of e-mentoring are that it requires asynchronous communication, which may prove difficult because of busy schedules or different time

zones, may lack privacy with the potential of recording communications, and it is difficult to establish trust (Gregg, Galyardt, Wolfe, Moon, & Todd, 2016).

Sanfey, Hollands, and Gantt (2013) discussed the different challenges faced during the mentorship of surgeons, which apply to the entire medical laboratory fraternity. A potential area for misunderstandings Sanfey et al. (2013) noticed was in cross-race or cross-gender relationships where mentors had difficulties understanding their mentee or vice versa. Sanfey et al. discovered that generational differences might significantly change the mentoring relations, especially between generation X (born between the 1960s to early 1980s) and the millennials (born early 1980s to early 2000). Careful selection and matching of ISO 15189 mentors are necessary to ensure that mentors and mentees do not have difficulty understanding each other.

Transition

In this section, I summarized Section 1 and provided an overview of the next two sections. In this qualitative case study, I explored the strategies of how healthcare managers structured and implemented the ISO 15189 QMS through a mentoring approach to improve organizational performance. In section 1, I presented an overview of the study and included the background, problem, and purpose of statements, nature of the study, the overarching research question, and the specific interview questions. Other parts presented in Section 1 included the theoretical framework, operational definitions of the main terms, assumptions, limitations, and delimitations of the study. The final part of Section 1 was an exhaustive review of the professional and academic literature, which included the following topics, healthcare quality, total quality management, mentoring,

characteristics of mentees and mentors, laboratory QMS and Strengthening Laboratory Management Towards Accreditation (SLMTA)

The next section is Section 2, in which I present a restatement of the purpose statement and include the role and the ethical obligations of the researcher. Other aspects included in Section 2 are discussions of the participants, research method, and research design. In Section 2, I also present a detailed explanation of the procedures selected to conduct the study, including data collection, organization, and analysis and I offer the best practices to support the reliability and validity of the study. In the final section, Section 3, I provide the findings of the study and the potential implications for social change. In the last part of Section 3, I provide recommendations for action and further research, along with a summary of this study.

Section 2: The Project

In Section 2, I start with a restatement of the purpose of this study, which is to explore the strategies that healthcare managers used to design, develop, and implement the ISO 15189 QMS. In general, my focus in Section 2 is to elaborate on the methods that I used in data collection and analysis. The specific topics covered in Section 2 include the role of the researcher, research participants, research methodology and design, and the justification for their selection. Other topics covered in Section 2 include the selected population, sampling technics, data collection instruments, ethical requirements of the study, study reliability, and validity.

Purpose Statement

The purpose of this qualitative multiple case study was to explore strategies used by managers in the healthcare industry in developing countries to design, develop and implement the ISO 15189 QMSs through a mentoring approach to improve organizational performance. The target population comprised healthcare managers located in East Africa (United Republic of Tanzania) who implemented and attained international accreditation in ISO 15189 through a mentoring approach. The selected population was appropriate because the participants had experienced the phenomenon of implementing an ISO15189 QMS through the assistance of a mentor and had attained the highest level of international recognition. The significant contribution this study may provide to social change includes improving the economic and health conditions of the populations of people served by the medical laboratories. Furthermore, the study has the

potential of improving people's perceptions about healthcare services and thereby may result in increased usage of healthcare services.

Role of the Researcher

My role as the researcher in this study was to explore strategies that medical laboratory managers used to design, develop, and implement an ISO 15189 QMS. In qualitative research, the researcher has a critical role in generating and interpreting data and thus serves as the instrument in data collection (Rosenthal, 2016). Qualitative work includes a reflection by the researchers to articulate their roles, positions, and subjectivities so that the readers can better understand the context of the study, that is, data gathering, analysis, and reporting of findings (Sutton & Austin, 2015). The qualitative researcher must maintain impartiality and use active listening skills to ensure accurate interpretation of data shared by participants during the interview process (Roulston & Shelton, 2015).

My role in this study as a researcher was to design and ask interview questions that are relevant to the central research question, record interview sessions, demonstrate engaged listening skills to ensure follow-up questions, and avoid subjectivity and bias. The critical factors that influence data collection in qualitative research include the ability to communicate, the experience and skills of the researcher, and the ability to ask the right questions (Rosenthal, 2016). Another essential aspect that the researcher must master during the data collection process is to encourage the participants to share their experiences and perspectives concerning the phenomenon under study (Sutton & Austin, 2015). Therefore, my role in this study was to help the participants to share their

knowledge and views as well as to record all the interview sessions in a nonsubjective nature.

My profession is in medical laboratory sciences with a specialization in implementing ISO 15189 QMSs. My experience is mainly working as an ISO 17043 quality manager for a medical laboratory proficiency testing program, as well as a team leader for the ISO 15189 QMS assessment with Southern African Development Community Accreditation Services (SADCAS). I have experience working with private and government-owned medical laboratories implementing the ISO 15189 QMS to improve the quality of the medical laboratory services. My work in private consultancy included establishing and helping to implement ISO 15189 QMSs in three African countries, namely Kenya, the United Republic of Tanzania, and Zambia (CLSI, 2014).

I worked in Eastern African countries, Kenya, the United Republic of Tanzania, and Zambia for 8 years and had extensive contacts with medical laboratory scientists from both the private and public health facilities. My role was to provide training workshops on various topics about ISO 15189 QMSs in the three countries and made several contacts with the study participants. In the 8 years of working in different countries, I created working relationships with some of the participants. Råheim et al. (2016) noted that some researcher and participant relationships create a power imbalance. However, in this study, no power imbalance existed because of the absence of supervisorial roles between myself and the participants. However, because of the mentor and mentee relationship, some power imbalance could have existed.

During the study, I completed a course on protecting human research participants

offered by the National Institute of Health (NIH). The NIH course content included the ethical requirements for dealing with human subjects in research. My exploratory review involved using human subjects and thus required strict adherence to all the ethical requirements. The Belmont report, published in 1979, is a seminal effort, which summarized ethical principles and guidelines when dealing with human subjects in research. The three main principles elaborated in the Belmont report are respect for persons, beneficence, and justice (US Department of Health and Human Services, 1979). Therefore, strict adherence to all the principles of the Belmont report ensured that my study fully satisfied all ethical requirements.

Eliminating bias entirely is unrealistic; however, researchers can limit the impact of bias on the study findings. Both qualitative and quantitative research methods are open to human subjectivity because people are fallible and can make mistakes (Sutton & Austin, 2015). In a case study research, the researcher's subjective feelings may influence the results of a study. Roulston and Shelton (2015) noted the researcher’s challenge is to eliminate bias and proposed that the researcher should recognize his or her preference developed along the course of their career. The researcher's prior knowledge, understanding, and experience of the study topic provide an advantage. However, the researcher may have to exercise special care to reduce selective perception during data collection and analysis (Sutton & Austin, 2015). Therefore, identification and maintenance of awareness of my biases from my previous knowledge and experience in the topic under study through self-introspection may have helped to reduce bias. Yin (2014) reported that researchers could mitigate the effects of bias in a case study research

by avoiding preconceived concepts about the study area and remaining open to alternative evidence that may be contrary to an initial premise.

In this study, I prepared and used an interview protocol. An interview protocol is a plan for conducting interviews, which provides a procedural guide in directing a qualitative researcher through the interview process (Castillo-Montoya, 2016). Developing and using an interview protocol means that the researcher has made a thorough review of the literature about the phenomenon under study and knows what other scholars say about the topic (Castillo-Montoya, 2016). The use of the protocols ensures that the researcher respects the privacy of the participants and helps to ensure the researcher does not forget something during the interview process (Peter, 2015).

Participants

In a broader sense, participant selection depends on their personal experience and knowledge of the topic under study. Cleary, as Horsfal, and Hayter (2014) noted, participant selection in qualitative research should have an obvious rationale and satisfy a particular purpose related to the research question. The study participants consisted of healthcare managers whose medical laboratories attained the ISO 15189 accreditation in the United Republic of Tanzania. The selection of the medical laboratory manager or the quality manager from the accredited laboratories was purposeful because the sample consisted of people with detailed information about mentorship strategies used by the laboratory mentors as they experienced the mentoring process.

I gained access to the participants by requesting a database of healthcare managers whose laboratories attained ISO 15189 accreditation from the Ministry of

Health officials in the United Republic of Tanzania and accessing the publicly available accreditation body database. Joseph, Keller, and Ainsworth (2016) recommended five strategies for accessing research participants, which include requesting a database, fostering collaborations, and building respectful and trustful relationships. The Ministry of Health, Medical Laboratory Directorate had the contact details of all the medical laboratory managers of the ISO 15189 accredited laboratories. Therefore, written approval to conduct the study from the Ministry of Health in the United Republic of Tanzania was a requirement, which I obtained before recruitment.

Establishing a working relationship with participants positively impacted the success of this study. Raheim et al. (2016) indicated that the relationship between the researcher and the participants chiefly is subject to the power imbalance between the two parties and the associated ethical concerns. Therefore, developing and maintaining relationships between the participants ensures that the researcher achieves the aims and objectives of a study. Investing time and adequate resources in the maintenance of the relationship between the participant's results in high response rates, more representative sample, and lower attrition rates (Enticott et al., 2017). Strategies to establish a working relationship in this study, therefore, included encouraging the participants to respond openly with more detail on the research questions. Another approach was to convince the participants of the value of their contributions and time. Sutton and Austin (2015) noted that the strength and success of any research study depend on the participant's belief that their time and contributions are valuable and worthwhile.

In this study, the participant's characteristics aligned with the primary research

question. My focus in this study was to explore the strategies that medical laboratory management used in structuring the mentorship process for ISO 15189 QMSs. Therefore, the essential characteristic of the study participants was their ability to understand the concepts of implementing the ISO 15189 QMS using a mentorship approach. Guetterman (2015) noted that the quality and completeness of research depends on the selection of the participants whose characteristics tie with the research question. Aligning the study participants with the primary research question ensures that the researcher collects complete and relevant information (Castillo-Montoya, 2016).

Research Method and Design

In this study, I used a qualitative multiple case study design involving five healthcare managers to explore the strategies they used to design, develop, and implement the ISO 15189 QMS. The qualitative research method is appropriate when the researcher wants to gain an understanding of complex phenomena under study (Lindlof & Taylor, 2017). I used a multiple case study design because it is useful when a researcher wants to study beyond a single and isolated variable.

Research Method

I used the qualitative research method in this study. The qualitative research methodology is a way of social inquiry, which includes how people interpret their experiences and make sense out of them in the world in which they live (Jindal, Singh, & Pandya, 2015). The qualitative research method is most suitable when the researcher wants to explore and understand the *why* and *how* behind certain behaviors or actions; therefore, it provides an in-depth understanding of the phenomenon (Rosenthal, 2016). In

contrast to quantitative research methodology, the qualitative research methodology does not involve statistical generalizations (Boddy, 2016). Therefore, a qualitative research methodology was more appropriate for understanding strategies healthcare managers used in implementing the ISO 15189 QMS. My study purpose was explorative, thereby making the qualitative research methodology the most suitable for use in answering the research question.

Research Design

The research design for this study was a multiple case study design. A research design is a plan or a framework for data collection, analysis, and interpretation of study observations that comprises several designs such as ethnography, phenomenological, and the case study design (Dasgupta, 2015). In this study, I used the case study research design because the results may provide insights not achievable by the other research designs. These insights are essential in understanding complex social phenomena (Dresch, Lacerda, & Miguel, 2015). Yin (2014) defined a case study research as an in-depth empirical inquiry investigating a contemporary phenomenon within its real-world context, mainly when no apparent boundaries exist between the phenomenon and the context.

Case studies are valuable during the preliminary, exploratory stage of a research project and thus act as a basis for the development of more structured tools required in surveys and experiments (Dasgupta, 2015). Case studies allow researchers to concentrate on an individual case but retain a holistic and real-world perspective, such as studying life cycles, organizational, and managerial processes (Sutton & Austin, 2015). Yin (2014)

differentiated the research designs depending on the type of question asked. Pacho (2015) noted that case studies are particularly advantageous when answering or explaining question terms like how and why and are particularly important when a need exists for in-depth explanations and descriptions. The case study research design was, therefore, the best approach to answer the research question posed in this study.

The ethnographic study design includes cultural groups in their natural setting for a prolonged time to understand how their culture and beliefs affect the behaviors and thoughts of the individuals (Bamkin, Maynard, & Goulding, 2016). The researchers collect data by spending all the time in the field collecting notes, observing, conducting interviews, and reviewing records that provide an understanding of the culture of a particular community (Bamkin, Maynard, & Goulding, 2016). In this study, I was not studying the culture of any specific group of people or community. However, I planned to understand the strategies that healthcare managers used to design, develop, and implement the ISO 15189 QMS. Therefore, the ethnography research design did not apply in this circumstance.

Padilla-Diaz (2015) noted three types of phenomenological studies. The first type of phenomenological study is descriptive, which is the study of personal experience and requires interpretation of the meanings of phenomena by the participants. The second type of phenomenological study is transcendental, where the researcher examines the essence perceived by consciousness concerning individual experiences. The third type of phenomenological is constitutional phenomenology, which refers to the analysis of the

self as a conscious entity. Considering the purpose of this study, a phenomenological research design could not have answered the research question: therefore, was not useful.

I reached the data saturation point when I had interviewed enough participants to identify all emerging themes. Data saturation is a situation that occurs when additional information collected produces no new themes (Fusch & Ness, 2015). Data saturation ensures the validity of a qualitative study. Researchers who use a qualitative research methodology sometimes experience a challenge of when and how to achieve data saturation (Morse, Lowery, & Steury, 2014). However, when the researcher notices that there is no new information gained from further data collection, that becomes the point of data saturation.

Population and Sampling

In this study, I used a purposive sampling method so that I could use only information-rich participants who participated and experienced the central phenomenon of a mentoring program of a medical laboratory in the ISO 15189 QMS accreditation. In a purposive sampling method, the researcher starts with a specific intention that he or she wants to study and then identifies the research participants who cover the full range of the perspective (Palinkas et al., 2015). Bristowe, Selman, and Murtagh (2015) reported that purposive sampling is beneficial as it includes the selection of participants who have unique characteristics such as knowledge and experience, which is relevant, and in alignment with the overarching research question. Patton (2015) indicated that in purposive sampling, the researcher selects participants based on their knowledge and experience, and therefore, they yield data that addresses the research question under

investigation.

The sample of participants for this study consisted of five medical laboratory managers drawn from the population of all medical laboratories, who implemented ISO 15189 QMSs through a mentoring program in the United Republic of Tanzania and attained international accreditation. The sample size in case study research is relative; that is, it depends on the attainment of a point of saturation, a point at which further interviews produce no new information (Malterud, Siersma, & Guassora, 2015). Therefore, I used a sample size of five as the sample consisted of homogeneous participants, that is, medical laboratory management. The study sample consisted of laboratory managers from the five ISO 15189 accredited laboratories in the United Republic of Tanzania, a country located in the East African region. I interviewed one participant from each of the five medical laboratories, which attained ISO 15189 accreditation.

Data saturation refers to the process of data gathering and analysis up to the point when no new insights exist and are important because it addresses whether a study has an adequate sample to demonstrate content validity (Boddy, 2016). Data saturation happens when the researcher has all the relevant information required for gaining complete insights into a research topic (Rijnsoever, 2017). Fusch and Ness (2015) noted three aspects needed to reach data saturation, which is: the presence of enough information to replicate the study, lack of additional new information, and that further coding is no longer feasible. Therefore, I determined data saturation by the lack of new code or themes during data analysis.

The participants for the study were primarily medical laboratory scientists, with experience working as medical laboratory managers. The second criterion for selecting the participants for this study was they should have had the experience of participation in a mentorship program to prepare their medical laboratory towards ISO 15189 accreditation in the United Republic of Tanzania. Considering that the sample represents a portion of the target population, the researcher must carefully examine whether the selected sample satisfies the study objectives (Mesa, González-Chica, Duquia, Bonamigo, & Bastos, 2016). Therefore, the selection criteria used in this study included the appropriate population that satisfied the research question.

Ethical Research

An essential step before data collection is addressing the informed consent of the study participants. Informed consent involves making the research participant to knowingly, voluntarily, and intelligently give their agreement to participate in the study (Sil & Das, 2017). Regarding the informed consent in this study, I sought first permission from Walden University Institutional Review Board (IRB) before data collection, followed by the recruitment of research participants. I advised the recruited participants of their rights and obligations as explained in the informed consent form, including their roles in the study, and informed them that their participation in the study was voluntary and could withdraw at any time. I sent the informed consent form to participants by email and asked the participants to respond to the email with the words “I consent” as a means for consenting to participate in the study. The use of informed consent forms provides objective evidence that research participants willingly participated in the interview

(Adams et al., 2017). The researcher has the responsibility to ensure research participants understand the consent form and that they engage voluntarily (Kadam, 2017).

I informed the research participants that their participation was voluntary and could withdraw without penalty or further obligation at any time in the process by either emailing or calling. In this study, I did not provide any form of compensation or incentives for participation. Sil and Das (2017) indicated that the consent form should include a statement that describes anticipated payment, which they recommended that it should not be excessive but only meant to reimburse for inconvenience and time spent. Kadam (2017) noted that informed consent should include the right to withdrawal from any study without penalization, at any time, and for any or no reason at all. Melham et al. (2014) supported the right to withdraw from research by participants at any time, as that is the core of the post-Nuremberg code of ethics.

I used a combination of letters and numbers to identify each participant (i.e., LM01-LM05) and used a pseudonym to identify hospitals instead of using the name of the hospital. The pseudonym and the alphanumerical identity of the participant concealed any information that might disclose the identity of the participants. Leyva-Moral and Feijoo-Cid (2017) emphasized the importance of confidentiality of research participant information to protect them from the aftereffects of participation in a study. Ayers, Caputi, Nebeker, and Dredze (2018) recommended using an alphanumerical coding of participants to prevent the reverse use of reverse identification. In addition to coding methods, Roets (2017) advocated for proper regulation, legislation, and strong institutional governance to protect the confidentiality of participants.

In this study, I provided ethical protection for the participants, as described in the 1979 Belmont Report, which protects participants under three main principles: beneficence, justice, and respect. The Walden University IRB approval number is 11-25-19-0640165**.** Participant and hospital names remain confidential to protect participants from harm. I have stored the participant's data in an external hard drive in a locked cupboard at home, safe from unauthorized access for 5 years. After 5 years, I will destroy all raw data by deleting the files from the flash drive and shredding all paperwork involved to ensure the anonymity of participant names. Laperrière, Messing, and Bourbonnais (2017) noted that ethical obligations regarding securing and protecting data for 5 years ensure the possibility of reviewing data and maintains the anonymity of the participants.

Data Collection Instruments

In this study, I generated the interview questions, interviewed the study participants, made telephone audio recordings, kept the interview notes, transcribed the responses, and reviewed reports and documents. I was, therefore, the data collection instrument for this qualitative study exploring the strategies used by management in mentoring medical laboratories seeking international accreditation in the ISO 15189. Singh (2015) noted that in a qualitative case study, the data collection tool is the researcher who personally conducts interviews and reviews documents. Sutton and Austin (2015) also posited that in a qualitative case study, data collection revolves around the researcher. Amrollahi and Rowlands (2017) further confirmed the central role of the researcher, in that the researcher must participate in the data collection physically.

I collected data for the study by using two methods, through the use of telephone semistructured interviews and a review of program documents and reports. I used semistructured telephone interviews and asked the participants open-ended questions to allow them to provide more information in their responses. Farooq and de Villiers (2017) argued that telephone interviews encourage participants to speak freely and give them greater control to direct the conversation towards areas they perceive essential. McIntosh and Morse (2015) noted that an advantage of semistructured interviews is that they elicit detailed contextual responses, which are relevant to the study topic (McIntosh & Morse, 2015). Jentoft and Olsen (2017) argued that semistructured interviews are easy to repeat and make comparative studies after data collection. Van and Struwig (2017) also noted that documents could provide supplementary research data, thereby making them useful in data triangulation.

I used an interview protocol (Appendix A) that consisted of opening remarks, research questions, and follow-up questions. Thi (2015) noted that the use of an interview protocol helps in establishing consistency in the interview process across participants and acts as a guide for the interviewer. Singh (2015) supported the use of an interview protocol by noting that it guides researchers during data collection and reduces threats to the trustworthiness of data. Castillo-Montoya (2016) argued that the use of interview protocols is crucial in establishing data collection consistency and helps to draw out accurate descriptions by the research participants. I kept a copy of the interview protocol in Appendix A, and it also appears in the table of contents.

I used the member checking method in enhancing the reliability and the validity of

the data collection instruments by sending the results of the interpretation of the collected data to the participants. Member checking involves the researcher reviewing the interpretation of the results of the study to the participants to check for accuracy according to their perception and resonance with their experiences (Birt, Scott, Cavers, Campbell, & Walter, 2016). Member checking is a method used for substantiating the interpretation of the results and adjusting the interpretations to ensure that they are accurate (Sutton & Austin, 2015). In member checking, the researcher collects the data, analyses, interprets, and validates the findings with the participants to confirm reliability (Thomas, 2017).

Data Collection Technique

I used semistructured telephone interviews made up of open-ended questions to collect data from the participants. I also used the review of the program documents and reports as a data collection tool for triangulation. The most common data collection techniques for qualitative case study researches are interviews, focus groups, observations, and the review of available documents and records (Yazan, 2015). Using two or more data collection methods in a single study is triangulation (Anney, 2015) and is the method that I applied in this study. To obtain consistent and reliable findings, I used an interview protocol to guide in adherence to the proposed data collection guidelines. The interview protocol is available in Appendix A.

Researchers can conduct interviews in different settings, such as face-to-face, focus groups, and telephone interviews. I used the telephone interviews in this study because of the inherent vast benefits. Farooq and de Villiers (2017) noted that telephone

interviews are useful when dealing with participants who are difficult to reach due to a broad geographical location. Weller (2017) also indicated that because of asynchronous communication, telephone interviews save costs and time as the interviewer does not need to travel to reach the participants. Carduff, Murray, and Kendall (2015) further noted that telephone interviews are more convenient and quicker to arrange as compared to arranging a face to face interview. Oltmann (2016) recommended the use of telephone interviews because it makes the interviewee comfortable as an interviewer is not in physical contact with the interviewer, especially when the questions are sensitive. Oltmann also added the fact that the interviewer can access the interviewees from anywhere as long as they have access to a telephone. The anonymity in telephone interviews reduces the interviewer bias by making the interviewing setting more calming leading to accurate and truthful responses (Farooq & de Villiers, 2017).

Data collection using telephone interviews has several limitations. The first disadvantage of a telephone interview is that the interviewer and interviewee cannot see each other as they are at different locations, and the interviewer cannot use body language as a source of extra information (Oltmann, 2016). Weller (2017) noted that telephone interviews depend on a technology that may potentially fail during the interview and thus disrupt the interview process or lack of telephone services for some participants. Carduff, Murray, and Kendall (2015) reported that since the interviewer cannot determine the environment of the interviewee, a potential for the distraction of the participants exists by activities that may take place within their environment.

In this study, I used member checking to verify the interpretation of the research

data, whereby I submitted the interpretations of the data to participants for their verification. Member checking, also known as participant validation, is a technique used by the researchers to explore the credibility of results and involves sending data interpretation to the participants to check for its accuracy (Birt, Scott, Cavers, Campbell, & Walter, 2016). Member checking improves the trustworthiness of the data collection process in qualitative research (Fusch & Ness, 2015). During the process of member checking, the researcher conducts interviews with participants, and then analyses the data, submits the interpretation of the data to the participant for verification. (Simpson & Quigley, 2016). Fusch and Ness (2015) further noted that the member checking process ensures that the participants intended expressed views are the ones included in the findings and that it leads to early correction of the discovered data.

Data Organization Technique

In this study, I used a reflective journal to record my thoughts about data collection and learning experiences. A reflective journal is a written narrative that one makes from the reflective and critical thinking about the learning experiences or learning events (Starr-Glass, 2014). Researchers can use the reflective journal as a tool that helps them to think carefully and evaluate the information shared by the participants (Denton, 2018). Lindroth (2015) noted that reflective journals are tools that provide researchers with important data on a participant's views and belief systems, which promotes growing awareness and new knowledge creation.

I named the folder of the data as *mentorship research* and contained five subfolders, each representing the laboratory manager who participated in the study with

the codes LM01 up to LM05. The use of codes in the identification of the interview participants was to protect each participant's identity and to maintain confidentiality (Patel, 2016). Sounders, Kitzinger, and Kitzinger (2015) recommended the letter and number anonymizing system in studies with few participants as naming them can easily result in their identification. Ummel and Achille (2016) favored using the anonymizing data system but noted that it was complicated when it comes to identifying dyads. Each folder contained the interview audio recording, interview transcript, and member checking data related to each participant. I transcribed the interviews word for word using Microsoft Word and converted the file into a portable document format (PDF) to prevent the corruption of the word file.

I will keep all the data collected in this study on a flash drive stored in a lockable file cabinet in my office and the second copy on cloud storage for at least 5 years. Patel (2016) identified several ways of storing research data, which include saving the data on the local computer, backing-up on external hard drives, using flash drives, and other servers, storing the data on cloud systems, and the use of data archives and repositories. Tripathi, Chand, Sonkar, and Jeevan (2017), in a study reviewing data storage methods by researchers, noted that researchers were storing research data in external portable hard discs, flash drives, and compact discs. Tightening physical access to data such as a lockable file cabinet ensures unauthorized access to data and protects against hacking and tempering (Koltay, 2017).

Data Analysis

One of the significant challenges of case study research is the management of data analysis as the data comes from multiple sources like interviews, documents, focus group discussions, and others (Carter, Bryant-Lukosius, DiCenso, Blythe, & Neville, 2014). Kern (2018) indicated that triangulation is a strategy in research for increasing the validity of inference achieved by combining either different data, investigators, theories, or methodologies in a single study. In this study, I used methodological triangulation from telephone interviews and the programmatic reports of mentorship conducted in the participating laboratories. Methodological triangulation is combining different sources of information to answer the research question (Renz, Carrington, & Badger, 2018). Gibson (2016) posited that methodological triangulation is the most popular form among the four types of triangulation as it is the easiest to implement. Kern (2018) noted the advantages of triangulation in that it increases confidence in the research data, reveals unique findings, and provides a clear understanding of a phenomenon.

Manolov and Moeyaert (2017) described the data analysis process of a qualitative case study as a systematic approach to resolving data into its constituent components to provide its real meaning and structure. Houghton, Murphy, Shaw, and Casey (2015) described a four-step process for case study data analysis that starts with a transcription of the data, coding of data, analysis of the codes, and making out the final propositions. The first step in qualitative case data analysis is the transcription of the interview data in paragraph form sentences (Houghton, Murphy, Shaw, & Casey, 2015). The second stage involved the creation of the codes which I used for the analysis of the case study and then

the efficient coding of the data. Codes in the case study data analysis are labels that assign units for identification of segments relating to the research questions or any potential themes (Manolov & Moeyaert, 2017). The third stage was the analysis of the coded data, in which I used the Nvivo analysis software to gain an understanding of the data. The fourth and final stage for data analysis was the search for the meaning of the data and the triangulation of the critical concepts and ideas from both the interviews and the programmatic reports for mentorship of the participant laboratories (Houghton, Murphy, Shaw, & Casey, 2015).

NVivo 12® qualitative data analysis software (QDAS) was the software I used to analyze the data from the interviews and the mentorship reports. Woods, Paulus, Atkins, and Macklin (2016) reviewed the usage of ATLAS.ti and Nvivo QDAS and noted a surge in the use of Nvivo software from the year 2001 up to date. Robins and Eisen (2017) used Nvivo in an extensive study they conducted and articulated the following advantages: the ability to handle voluminous data allows a team approach to data analysis and the software's ability to manage complex questions regarding the data. Oswald (2017) supported the use of QDAS, such as Nvivo, by noting that qualitative data is complex, and the software helps in streamlining the research process. Kaefer, Roper, and Sinha (2015) concluded that while the Nvivo software does not analyze the data, it, however, makes the analytical process more flexible, transparent, and trustworthy.

I focused on key themes by assessing alternative theories from the documents and interviews collected during the interview process. I compared data from the member checking follow-up interviews, and document reviews to confirm the credibility of the

collected data to identify key themes. Maher, Hadfield, Hutchings, and Eyto (2018) demonstrated how a researcher could categorize themes generated from data entered into the software and use the queries to identify words and phrases. I coded all the key themes from both the analysis of documents and interview transcripts into the Nvivo software for quick identification.

Reliability and Validity

I ensured the reliability of this study by applying consistency and carefulness in the application of research practices. Reliability in qualitative research refers to the replicability, repeatability, consistency, and the stability of the results or observations obtained in a study (Cypress, 2017). Morse (2015) equated a study's reliability to dependability, which he defined as the ability to obtain similar results should the researcher repeat the study. Dependability is the ability of the researcher to replicate the study processes and get consistent findings (Leung, 2015). Noble and Smith (2015) noted that the reliability of a study is synonymous with consistency and confirmability; aspects achievable when a researcher creates a decision trail that is transparent and clear.

Member checking involves giving the participants the results of the analysis to obtain additional information and provide them an opportunity to rectify the data (Morse, 2015). Birt, Scott, Cavers, Campbell, and Walter (2016) reported the different types of member checking, which include returning the interview transcript, a member checking interview, member check focus group, or returning of the analyzed synthesized data to the participants. Harvey (2015) noted that member checking is an important method for ensuring the dependability and credibility of a qualitative study. Netta (2018)

acknowledged that a considerable role of member checking is enhancing the validity and credibility of a study. I conducted member checking by sharing the results of the study with the research participants and seeking their feedback.

The validity of qualitative research is synonymous with its trustworthiness (Noble & Smith, 2015). Leung (2015) defined the validity of qualitative research as the appropriateness of the tools, processes, and the data obtained in a study. Validity considers whether the research question is valid for the desired outcome, the chosen methodology appropriately answers the research question, and the design in use is valid for the methodology (Cypress, 2017). Other aspects considered for the validity of qualitative research include the appropriateness of sampling and data analysis and that results, and conclusions obtained are valid for the sample and context (Cypress, 2017). Leung (2015) indicated that validity contains four similar criteria for evaluation, such as credibility, transferability, dependability, and conformability. I demonstrated the validity of the study by reaching data saturation, implementing member checking, and assuring that research findings are credible, transferable, and confirmable.

Korstjens and Moser (2018) defined the transferability of qualitative research as the extent of applicability of research results to other contexts or settings with other respondents. Unlike the author, readers interpret the results based on their ability to make a judgment of transferability (Korstjens & Moser, 2018). I ensured the transferability of research results through a detailed description of the participants and the research process. When authors provide sufficient information regarding their research design and data interpretation, their action ensures the transferability of research results (Moon,

Brewer, Januchowski-Hartley, Adams, & Blackman, 2016). Smith (2018) noted that some of the strategies for the transferability of research results include a detailed description of the participants and the research process.

Confirmability is primarily about establishing that the findings of the study are not fabrications by the researcher but derived from the data (Korstjens & Moser, 2018). To ensure confirmability, I recorded and transcribed each interview, kept all the data analysis records from Nvivo 12, and conducted a member checking for the interpretation. Korstjens and Moser (2018) recommended a clear description of each research step from the start to the end of the research and safekeeping of the records as a means of ensuring confirmability. Despite criticism, Smith (2018) posited that qualitative research contains confirmability based on the availability of a clear audit trail of the activities completed by the researcher. Leung (2015) recommended the use of triangulation, a proper audit trail, and documentation as a means of ensuring confirmability.

I ensured the credibility of my study by using member checking by verifying with the research participants my interpretation of the research results. Credibility essentially requires the researcher to link the research study's findings with the truth to demonstrate the veracity of the findings (Cypress, 2017). Noble and Smith (2015) identified some strategies that researchers can use to ensure the credibility of their study, which includes the use of member checking and data triangulation, among others. Birt et al. (2016) noted that researchers use member checking to explore the credibility of the study findings. Camfield (2018) reported the use of both data triangulation and member checking in establishing credibility in a huge qualitative research study.

Data saturation in qualitative research is the criterion for discontinuing data collection or analysis, whereby further data collection or analysis is unnecessary as they do not bring in new information (Saunders et al., 2018). Fusch and Ness (2015) defined the criteria for data saturation as a point when no new data, themes, coding, and the ability to replicate the study exist. Therefore, I determined saturation when, during data analysis, no new code or themes existed. Fush and Ness (2015) highlighted the importance of data triangulation in reaching data saturation. The principal method of determining data saturation is the point when similar and old themes keep on appearing from data analysis (Saunders et al., 2018). Tran, Porcher, Tran, and Ravaud (2016) noted the importance of no new themes generated as a signal of data saturation.

Transition and Summary

In Section 2, I restated the purpose of the study from Section 1 and then discussed the following topics: research methodology and design, the role of the researcher, research participants, and several other topics. In Section 2, I provided a detailed description of how to conduct telephone semistructured interviews with medical laboratory managers to explore strategies that managers used to mentor their laboratories towards the ISO 15189 accreditation. My data collection technique also included a collection of programmatic reports and documents. I triangulated the programmatic reports and documents with the interview results.

In Section 3, I begin with an introduction and a restatement of the purpose of the research study, as indicated in Section 1, together with the central research question. The main topics addressed in Section 3 include the study findings, the study's business

relevance, and application to professional practice. I conclude Section 3 with implications for social change, recommendations for action, and future studies.

Section 3: Application to Professional Practice and Implications for Change

Introduction

The purpose of this qualitative multiple case study was to explore strategies used by managers in the healthcare industry in developing countries to design, develop and implement ISO 15189 QMSs through a mentoring approach to improve organizational performance. The targeted population comprised of five healthcare leaders located in East Africa (United Republic of Tanzania) who implemented and attained international accreditation in ISO 15189 through a mentoring approach. The selected population was appropriate because the participants experienced the phenomenon of implementing the ISO 15189 QMS through the assistance of a mentor and attained international recognition. The results of this study may help healthcare managers implement ISO 15189 QMSs efficiently, thereby improving the economic and health conditions of the populations of people served by the accredited medical laboratories.

Presentation of the Findings

During the data collection process, I collected data from five healthcare managers from five different medical laboratories in East Africa (United Republic of Tanzania), who implemented and achieved international accreditation in the ISO 15189. The participants I selected had experience in implementing the ISO 15189 QMS using a mentorship approach and could respond to this study's research question. The research question was, what strategies do managers in the healthcare industry in developing countries use to design, develop, and implement the ISO 15189 QMS through a

mentoring approach? During my interviews with the healthcare managers, I received insight on strategies of implementing ISO 15189 QMSs using a mentorship approach.

After completing the interviews, I transcribed the interview recordings, conducted member checking by summarizing each manager's interview responses. I further conducted data coding until no new themes emerged and then did data triangulation. I performed data analysis using Nvivo 12 computer software programs. From the data analyses, I developed themes that support this study's conceptual framework. My themes were (a) unfreezing phase-preparation for change, (b) changing phase-implementation of the QMS, (c) refreezing the new behaviors, and (d) maximizing forces for change.

Table 1

Participants' Responses that Support Themes

Participants	Unfreezing phase	Changing phase	Refreezing phase	Maximizing forces for change
LM01	Gap assessment of the QMS	Periodic structured mentorships	The continued availability of mentor through e-mentorship	Maximizing cooperation from mentees
LM02	Availability of adequate resources	Assignments for upcoming activities	Creating a learning environment	Use of change management skills
LM03	Document development linked to ISO 15189	Using an action plan	Continuous improvement activities	Teamwork
LM04	Selection of key personnel	Hands-on guidance, delegation, and follow-up	External training	Friendly mentorship approach
LM05	Sensitization and training of people	Training and focusing on critical aspects of the standard	Continuous improvement activities-Problem solving, Corrective action, and root cause analysis	Maximizing cooperation from the leadership

Theme 1: Unfreezing phase-preparation for change

In response to Question 1, regarding the structure of the mentorship, LM01, and LM02, in collaboration with the mentorship reports from triangulation, indicated the sensitization of the hospital and laboratory management on the ISO 15189 QMS as a critical aspect for success. LM02 said, "step one is the sensitization meeting whereby the

laboratory quality officers, laboratory managers, and implementing partners are called upon and explained the details of the course of the accreditation and its importance." LM03, LM04, and LM05 also added the concept of sensitization and training of staff on the ISO 15189 QMS when answering Question 3 regarding strategies of overcoming implementation barriers.

A second strategy was brought out by both LM04 and LM05 when they mentioned the concept of conducting a gap assessment during the unfreezing phase. As highlighted in the mentorship reports, gap assessments help the mentors to determine the level of implementation of the ISO 15189 QMS as well as the amount of work remaining at the baseline stage. Solving the identified gaps requires the use of an action plan to monitor the progress towards their clearance. The gap assessment served is an indicator of the status of implementation of the QMS before the mentorship process starts. Gap assessment results can help to highlight to the healthcare managers the level of effort needed to reach towards ISO 15189 accreditation.

The third strategy brought out in both the interviews and the mentorship reports used during the triangulation was the documentation of the QMS following the ISO 15189 standard. LM02 said, "next phase, this is whereby the laboratory documents are developed such as manuals and SOPs and forms." LM02, LM03, and LM04 indicated that the laboratory should develop documents for the QMS, which aligns with the ISO 15189 standard requirements. The development of the QMS documents helped to prepare the laboratory staff of the upcoming changes at their workplace. The quality documents

defined how the laboratory management and staff intended to meet the ISO 15189 standard requirements in their settings.

The development of the system documents happened at the same time as the training of personnel on the ISO 15189 standard for the smooth implementation of the ISO 15189 QMS. All participants brought out firmly the idea of internal training of staff on quality management as a strategy that helped in the successful implementation of the ISO 15189 QMS. Mentee training during the unfreezing stage provided knowledge and understanding to the staff on the requirements of the ISO 15189 standard. Training at the unfreezing phase of Lewin's change model provided the mentees with the scope of the change and prepared them psychologically for the impending organizational change.

In response to what strategies the laboratory managers and mentors used to overcome the implementation barriers, LM03 indicated the selection of competent personnel on the key positions was very important. The key positions responsible for the implementation of the ISO 15189 QMS included laboratory and quality managers, together with their deputies. LM03 said, “and he used to advise the management to select the proper persons who show commitment to quality management systems to be placed on key positions.” Personnel who demonstrated interest and commitment in the implementation of ISO 15189 were more likely to spearhead and influence others in the implementation of the system to achieve international accreditation. Therefore, the correct selection of personnel provided the foundation for a smooth and quick implementation of the ISO 15189 QMS.

Tie findings to the literature. Previous researchers have supported the unfreezing phase as part of the change process, which is observable in almost all organizational change models. Unfreezing is the first stage for organizational change management that helps individuals to relinquish the old behavior and prepare them to adopt a new behavior (Cummings, Bridgman, & Brown, 2016). Hussain et al. (2016) identified employee involvement, knowledge sharing, leadership involvement, and support as critical strategies during the unfreezing phase of change. Bakari, Hunjra, and Niazi (2017) noted that the unfreezing phase of organizational change creates a readiness for change by delivering the motivational messages for staff to implement the change required.

Therefore, the ideas identified by participants, that is, gap assessment, documentation, sensitization of management, and training, tied well with literature as all the five-strategies identified within the unfreezing phase helped to create readiness for change. Guevera (2014) indicated the need to start the process of mentorship by first documenting all the required documents, including the quality manual, procedures, and forms. Polansky et al. (2019) identified that the initial phase before conducting a mentorship is a gap assessment to understand the position of the laboratory and provide laboratory-specific recommendations. Therefore, all the strategies identified under the unfreezing phase have support from the literature.

Tie findings to the conceptual framework. Most authors identified the unfreezing phase of organizational change as the first part of Lewin's organizational change process. Cummings, Bridgman, and Brown (2016) provided a genealogical

formation of the change management models, which included the Lippit's change model, Schein, and Benis'change model, and Kotter's 8 Steps of change. Interestingly all the models of organizational change conceptualized after Lewin's change model included an unfreezing phase for the preparation of change. Rosenbaum, More, and Steane (2018) also summarized the different change management models and realized that the unfreezing phase was observable in all change models and prepared the organization for change implementation.

Theme 2: Changing Phase-Implementation of the QMS

In response to Question 1 regarding the structure of the mentorship, LM04, in agreement with data from the mentorship reports, indicated that onsite, hands-on mentorship by the mentors provided the stimulus for the implementation of the ISO 15189 QMS. Other aspects discussed by LM04 included delegation of responsibilities and close follow-up of the mentees, especially on the assigned activities to ensure effective implementation. LM04 said "one of the strategies the mentor used was the delegation of work for the effective implementation of the QMS" The hands-on demonstration, delegation, and close monitoring of activities ensured that mentees became engaged in the new processes and procedures and made them understand the implementation of the ISO 15189 QMS.

In response to Question 1, LM01 emphasized on the need for periodically structured onsite mentorships in which the mentor conducted different activities during each mentorship period. The periodic mentorships helped the mentees to grasp a few aspects at a time instead of trying to overload them at once with the implementation of

the ISO 15189 QMS activities. Other participants did not mention the periodically structured mentorships; however, the mentorship reports of the laboratories indicated that the mentors visited the laboratories for mentorship between three to seven times before the laboratory achieved accreditation. Per each visit, the mentors spent between 2 to 4 weeks working on different aspects of the ISO 15189 standard until the laboratory attained international accreditation.

Regarding the second aspect of the mentorship structure, LM02 indicated the need for unambiguous assignment of responsibilities for implementing the ISO 15189 QMS activities to mentees at the end of each onsite mentorship as critical to the success of the mentorship program. LM02 said, “What we did with the mentor was we would agree on an action plan, so when he was exiting, he would leave us with an action plan”. LM03 added the importance of using an action plan for helping follow-up with the assigned activities on staff in-between the onsite mentorship periods. Effective assignment and follow-up with the use of an action plan helped the laboratory management and mentors to continue with the implementation of the activities when the mentor was not physically available at the laboratory. In response to the Question 9 regarding the strategies used by mentors to continue influencing the mentees when they were not physically present at the laboratory, all the participants unanimously indicated the use of e-mentorship, that is the use of email, telephone, and WhatsApp groups provided an excellent platform for continued implementation. LM02 said, “The mentor would make a follow-up on staff that would have been assigned activities through the email or through the mobile phone”.

However, the tools used for follow-up were the action plan indicating the clear assignment of duties for the mentees and the target completion dates.

In response to Question 1, LM05 indicated the importance of in-house training of mentees during the implementation of the ISO 15189 QMS. LM05 stated that training of mentees during the changing phase should focus on critical aspects of the system such as method validation, root cause analysis and corrective actions, internal quality controls. LM05 said, “there were a lot of trainings (sic) and supervision until the people got the message and got used to the new way of doing things.” The training conducted during the changing phase was aimed at providing an in-depth understanding of important topics for mentees to enable practical implementation of the ISO 15189 QMS.

Tie findings to literature. Polansky et al. (2019) identified the use of an action plan when handling the identified gaps and during follow-ups, training of personnel at the initial phase of the mentorship, use of email as a follow-up tool, and periodic on-site mentorship as the success factors for each mentorship program. Beyanga et al. (2018) reported on a successful mentorship program that led to the accreditation of the Bugando Medical Centre laboratory and noted the importance of ongoing internal training of staff and the use of experienced mentors as key to the success of the mentorship. Findings from my study agreed with those from Beyanga et al. as the strategies used during the mentorship included the use of internal training sessions and various mentorship engagements with trained and experienced mentors. Gumba et al. (2019) noted that training of staff helped to provide knowledge, strengthen skills and abilities, and, most importantly, helped to change the attitudes of the mentees. Therefore, the key to the

successful implementation of the ISO 15189 is the in-house training of staff on ISO 15189 standard and the ISO 15189 QMS development and implementation. Maruta (2013) emphasized the use of embedded mentorship, which involves hands-on guidance of mentees by the mentor within their work environment as part of the mentorship strategy.

Tie findings to the conceptual framework. The changing phase-implementation equates with the changing phase of the Lewin's change model. The changing phase is one of the three phases of Lewin's organizational change model. Cummings, Bridgman, and Brown (2016) noted that during the changing phase, the change agent takes time to physically implement the changes, such as moving from the old to the new behaviors. Rosenbaum, More, and Steane (2018) noted that during the changing phase, change does happen when staff takes up new tasks and responsibilities, which require learning of new skills, attitudes, and knowledge. Therefore, the findings from my study correlate well with the Lewin conceptual framework as the training, structured mentorship, and guidance of staff during the ISO 15189 implementation mentorships are the activities for successful change.

Theme 3: Refreezing the New Behaviors

In response to Question 1 regarding the structure of the mentorships, LM03 and LM05 identified one activity under the refreezing phase of the Lewin's model as continuous improvement. LM05 described the continuous improvement activities as a combination of problem identification, solving through on-going root-cause analysis, and corrective action. The idea of on-going problem identification and solving helped the

laboratory management to improve on the implementation of the ISO 15189 QMS. The continuous improvement activities fell under the refreezing phase as the activity helped to cement the new knowledge gained through the implementation of the ISO 15189 QMS.

LM02 identified the creation of a learning environment as another stage of implementation of the QMS. LM04 mentioned the importance of attending some external training workshops outside the facility as a strategy that helped in solidifying the implementation of the ISO 15189 QMS. LM04 said, "the other things and strategies that the mentor can use is being able to provide external trainings (sic) and workshops on QMS." Internal training was mentioned as well: LM05 said, "we would make sure that training was done every day, but we tried to make these training short in the morning so that people don't get bored." Both forms of learning mentioned here helped to create a new work culture where training on the ISO 15189 becomes part of the system, and thus, the knowledge becomes widely available.

LM02 indicated that the continued presence of the mentor through e-mentorship methods helped to solidify the implementation of the agreed the ISO 15189 QMS activities within the laboratory. The use of e-mentorships involved the mentor communicating with the mentees through emails, WhatsApp, telephone calls, and video conferencing facilities. Although the mentor may not have been physically available at the laboratory, the continued follow-up on the implementation of activities helped the mentees to become conscious of his or her presence.

Tie findings to literature. The strategies identified under the refreezing phase of Lewin's change model tied well with the existing literature. The three strategies

identified under refreezing new behaviors in my study included e-mentorship, continuous improvement opportunities, problem-solving, and training. Polansky et al. (2019) reported the use of e-mentorship where the mentor used e-mail to remain in contact with the laboratory management and staff while following-up on the agreed action plans. Continuous improvement activities involve a cycle of conducting several gap assessments, and implementation of the gaps helps in the early attainment of ISO 15189 accreditation (Beyanga et al., 2018). Ongoing training, internal and external, helps with the building and maintaining of new workplace culture for the ISO 15189 QMS implementation and compliance (Cummings, Bridgman, & Brown, 2016). Ogochi (2018) noted the benefits of ongoing training to keep every staff informed on the new organizational policies and practices.

Tie findings to the conceptual framework. The refreezing part of the ISO 15189 QMS implementation tied well with the existing literature. Lewin's refreezing phase indicated that the organization must stabilize in a new learning culture, ensuring that new behaviors take root (Rosenbaum, More, & Steane, 2018). Both the continuous improvement activities and the training sessions served to stabilize the newly learned skills and culture to support the laboratory staff in maintaining accreditation in the ISO 15189. Hussain et al. (2016) noted that the refreezing phase of the change process ensured that the implemented changes take root and that the staff continuously perform the new activities. Hossan (2015) indicated that the refreezing phase introduces new policies, procedures, and practices and causes the organization to reach a new quasi-stationary equilibrium. As mentioned in the findings, the three strategies identified under

the refreezing phase of Lewin's change model bring the organization to a new level of performance and equilibrium.

Theme 4: Maximizing Forces for Change

In response to Question 7, which directly addressed the strategies for dealing with resistance to change, LM01, LM02, and LM05 emphasized the importance of excellent communication within the organization. LM02 indicated that communication by the mentor involved explaining to the staff on the benefits and advantages of accreditation in the ISO 15189. For LM05, he said, “I think the first thing the mentor shared the bigger vision, he made staff aware of where we were going and how the whole process was going to be tackled.” LM05 also indicated that staff needed to understand that the whole process was about improving the quality of laboratory services and not about dealing with the different personalities.

LM02 was the only participant who indicated the need for the mentors and the laboratory management to apply the change management principles when implementing the ISO 15189 QMS. LM05 stated the need for a structured change program so that the mentees could easily follow and understand the changes happening within their laboratory. The reason other participants may not have discussed the structured change management was probably that the staff did not understand the concept of change management when implementing the ISO 15189 QMS.

LM03 discussed the need for teamwork within the organization as the most important strategy for resisting change. In response to Question 6 regarding strategies used by the mentor to influence and inspire the staff and laboratory management to adopt

and implement the ISO 15189 QMS, LM03 also indicated the need for teamwork. LM03 valued the importance of team collaboration when it came to the implementation of the ISO 15189 QMS, as that resulted in the quicker achievement of international accreditation. LM03 indicated that staff demonstrated a greater level of commitment because of the teamwork.

LM01 stated the importance of maximizing the cooperation of staff within the implementation of the ISO 15189 QMS. LM01 and LM02 both stated that it was good to have the staff develop their quality documents like the quality manual and the supporting procedures. The development of quality documents by staff enabled a sense of ownership of the ISO 15189 implementation program by the mentees. The active involvement of staff helped to ensure they understood the system and made it easy for them to implement the documented procedures, as they felt ownership of the documents.

In contrast to LM01, LM05 indicated the importance of maximizing the involvement of management. LM01 referred to the participation of hospital management and partners outside the hospital facility. LM05 referred to the participation of the implementing partners to support the provision of resources, which could be both human and financial for the implementation of the ISO 15189 QMS. LM05 said, “implementing partners came in with resources that the hospital could not afford.” The involvement of the Ministry of Health officials in terms of policy formulation and supervision was also an important aspect highlighted by LM05.

Question 6 was about how the mentor influenced and inspired the laboratory management to adopt and implement the ISO 15189 QMS. LM05 indicated the

importance of sharing the success stories of laboratory accreditation with the mentees. LM05 said, “they would share some success stories, including some benefits of accreditation, and also the key message that he pushed forward is that all the laboratories in the world are pushing for accreditation.” LM04 agreed with LM05 and indicated the need for the mentor to motivate the mentees to implement the ISO 15189 QMS using the stories and sharing the benefits of accreditation.

All the interview participants agreed that the relationship between the mentor and mentee had a positive effect on the success of the ISO 15189 mentorship program. On Question 11, LM01 indicated that the most crucial aspect was the constant availability of the mentor to guide the mentees even when the mentor was not physically present at the laboratory. LM02 indicated that the relationship between the mentor and mentee provided the smooth exchange of ideas between the two parties. LM04 stated that an excellent relationship offered the freedom and comfortability of the mentees to approach and discuss the quality management issues with the mentor. LM05 said,

> So the mentor really tried to engage us on a personal level, to understand us on a personal level. He would even go for lunch with us. He would even join our groups when we are chatting just to make sure that he bonded with us first.

Tie findings to literature. The different strategies outlined under this theme have substantial backing in the various existing literature. Ogochi (2018) indicated that without the requisite inspiration or motivation, management might not get the buy-in from the staff to participate in the implementation of change. Equally important, Ogochi (2018) also indicated that management should continuously communicate the change process by

defining the vision of the transition to the employees. Training and excellent communication, therefore, play a significant role in reducing the resistance to change, and personnel understands what they do.

The involvement of laboratory management, the use of a teamwork approach, and the friendly relationship between mentor and mentee towards implementing the ISO 15189 QMS have several references to literature. Aquilani, Silvestri, Ruggieri, and Gatti (2017) discovered that top management involvement, inter-departmental communication, coordination, teamwork, hospital-wide participation, continuous internal auditing were the critical factors for the successful implementation of a quality management program. The quality of the relationship between the mentor and the mentee was essential for realizing positive outcomes, and the nature of the relationship was the primary driver of change (Williamson, Lawrence, Lyons, & Deutsch, 2019). Therefore, the laboratory management can enhance the enabling factors by ensuring that they engage the hospital management as well as using a teamwork approach in implementing the ISO 15189 QMS.

Tie findings to the conceptual framework. Lewin noted that the *field* is the summation of several interrelated factors within the environment maintained by varying internal and external forces (Batras, Duff, & Smith, 2016) The force field analysis by Lewin helps to identify the positive forces for change (driving forces) as well as the forces opposing change (forces resisting change) (Burnes, 2020). The theme *maximizing the forces for change* is part of Lewin's change model and therefore aligned perfectly with the conceptual framework in use in this study. Lewin posited that by increasing the

driving forces, while reducing resisting forces, the organization could make change happen.

Applications to Professional Practice

The purpose of the qualitative multiple case study was to explore strategies some managers in the healthcare industry in developing countries design, develop, and implement the ISO 15189 QMS through a mentoring approach to improve organizational performance. The adoption and implementation of the strategies provided by the five study participants may accelerate the implementation of the ISO 15189 QMS in medical laboratories. Implementation of QMSs in the medical laboratories will help in the improvement of the internal processes, thereby aiding in the reduction of laboratory errors and risks to the patients (Tzankov & Tornillo, 2017). Reduced errors and complaints translate to reduced costs to the medical facility because of poor service quality and result in more savings by the hospital management.

The critical aspect of the ISO 15189 mentorship in medical laboratories is using a structured mentorship model. The use of periodically structured mentorships, that is, starting with a gap assessment, documentation, implementation, and continuous improvement of the ISO 15189 QMS, ensured the logical flow and easy attainment of international accreditation. As highlighted by Maruta, Rotz, and Trevor (2013), a structured mentorship approach helped the management in planning and budgeting, while for staff, the structured mentorship helped in understanding and managing expectations.

The involvement of hospital management in implementing the ISO 15189 QMS contributed positively to the success of the program. Sensitization of the upper

management in the ISO 15189 standard and the resources required to achieve accreditation was crucial in the success of the mentorship program. Polansky et al. (2019) observed that upper management awareness and support helped in unlocking the critical resources which are beyond the control of both the mentors and mentees such as laboratory space and procurement issues. Therefore, a strategy of engaging the upper management either through training or sharing of the gap assessment and program reports will make them aware of the needs required to unlock the mentorship.

Training of personnel on the ISO 15189 QMS was crucial from unfreezing, moving, and refreezing phases of the Lewin's organizational change model. The training served different purposes during each stage of the Lewin's organizational change model. In the unfreezing phase, training served to provide knowledge on the ISO 15189 standard requirements to the staff. During the changing or moving phase, the training helped the staff with the implementation of the standard requirements, and within the refreezing phase, training served to stabilize the new culture and kept the personnel aware of their ISO 15189 QMS. Therefore, investing in on-going training sessions for staff facilitated the achievement of the ISO 15189 accreditation within a short period.

The use of teamwork strategies in the ISO 15189 implementation was crucial in the quick attainment of accreditation. Teamwork in the ISO 15189 QMS implementation allowed the sharing of the workload while reducing pressure on the quality managers (Sanyal & Hisam, 2018). Teamwork helped to empower and develop the employees and provided an opportunity for employees to learn proper strategies to achieve tasks efficiently (Hanaysha, 2016). The performance of a team is usually higher when the job

requires a broader scope of knowledge, opinion, and judgment, which is typically the case in the ISO 15189 QMS (Sanyal & Hisam, 2018). Therefore, using a teamwork approach ensured that the tasks got completed within a shorter period as compared to when using individual effort.

Mentoring is an activity that depends much on the relationship between the mentor and the mentee. Bailey et al. (2016) noted that mentees preferred valuable friendship and interpersonal qualities like a good sense of humor, friendliness, and approachability. The friendly approach by mentors during the mentorship provided the mentees with the freedom to approach the mentors to ask for advice whenever the need arose. Chien et al. (2016) noted that a friendly mentorship approach was one of the essential characteristics that prevented barriers to effective mentorship. Failure to provide a friendly approach may have resulted in mentees not performing the tasks as expected, thereby failing the ISO 15189 QMS implementation.

A requirement within the ISO 15189 standard is that laboratory management should use competent personnel to perform both management and technical duties (International Organization for Standardization, 2012). Therefore, the selection of competent personnel to lead the implementation of the ISO 15189 QMS activities ensured the consistent, correct performance of activities. Alemnji et al. (2017) reported that in addition to the selection of competent personnel, healthcare managers should define the function, authority, and responsibility of personnel in the ISO 15189 QMS implementation.

The use of e-mentoring resulted in continued contact between the mentor and the mentee. E-mentorship helps the mentees to acquire knowledge and skills, just like with traditional face-to-face mentorships (Gregg, Galyardt, Wolfe, Moon, & Todd, 2016). Polansky et al. (2019) indicated that e-mentorship breaks down the accessibility barriers and ensures on-going participation by the mentor and mentee. The use of the e-mentorship model combined with the action plan provided a way for the healthcare managers to maintain contact with the mentor and track the implementation of the action items. The results of continued communication between mentor and mentee ensured quicker achievement of ISO 15189 accreditation.

Implications for Social Change

Implications for positive social change for this study are potentially at two levels, that is, individuals and communities. Medical laboratories not accredited to the ISO 15189 QMS may produce poor quality results, which may harm healthcare systems (Schroeder & Amukele, 2014). ISO 15189 accreditation has the potential to improve the quality of healthcare for patients with reduced misdiagnosis and a decrease in inappropriate treatment (Sisay, Mindaye, Tesfaye, Abera, & Desale, 2015). Therefore, for individuals and patients, accreditation in the ISO 15189 standard by medical laboratories gives them confidence that the medical laboratory services they receive are safe and conducted by competent personnel. The more confidence people have in medical laboratory results can lead to more reliance on the services and contribute to positive health-seeking behavior.

For hospitals, communities, and the nation, the implications for positive social change are biased towards health outcomes. Through successful implementation of the ISO 15189 QMS, more people may access quality health care services, thus promoting their health, worth, and dignity. Some potential long-term benefits of implementing the ISO 15189 QMS include improvement of patient care experience, improvement of the populations' health, and reduction of healthcare costs (Zima, 2017). Implementation of the ISO 15189 QMS results in better analytical performance and, as a result, fewer laboratory errors, which translates to healthier communities (Butcha et al., 2018).

Recommendations for Action

Based on the findings that emanated from this study, I recommend that healthcare managers, especially medical laboratory managers and hospital managers, learn from this study's findings and re-examine the methods they are using to implement the ISO 15189 QMS. Ministry of Health officials in developing countries, including developmental agencies, and implementing partners' management, should review the findings from this study and consider adopting the strategies into the national ISO 15189 technical capacity building programs for medical laboratories.

CDC and WHO have the SLMTA program for capacity building of medical laboratories in the ISO 15189 accreditation can adopt the strategies discussed in this study and include them in reviewing the program. The strategies include a structured mentorship program that involves a gap assessment, documentation of the QMS, implementation, and continuous improvement activities. Healthcare managers should also adopt and use teamwork, friendly mentorship approaches, selection of the interested and

competent personnel for critical positions, e-mentorship, and on-going internal training on the ISO 15189 QMS.

The results of this study will be of interest to a broad spectrum of healthcare managers and actors within the healthcare fraternity. The goal of conducting research is to advance knowledge frontiers and solve problems, and thus, findings from research should be disseminated to respective audiences (Fussy, 2018). I intend to publish this research study and share the copies with open access journals so that healthcare managers from developing countries can have access to the findings. Considering that I conducted this research in the United Republic of Tanzania, I intend to share with the Ministry of Health authorities and the implementation partners in the United Republic of Tanzania on the study results. The goal is to integrate the study results into the current program for capacity building of laboratories towards accreditation. Training of the medical laboratory managers in the United Republic of Tanzania on the conclusions of this study will help in quicker adoption and implementation of the strategies to implement ISO 15189 QMSs. Finally, I intend to find opportunities to present this study to a broader audience at medical laboratory conferences in Africa.

Recommendations for Further Research

Considering the limitations of this study, I have several recommendations for future research. First, I would recommend face-to-face interviews instead of telephone interviews because the interviewer can interpret the body language of the interviewees together with the actual message said. Another recommendation is that of expanding the research to cover a wider geographical area or countries within Africa. Since my research

was limited to the United Republic of Tanzania, it will be interesting to know how participants from different geographical regions and countries respond to the interview questions based on their perspectives and experiences. To reduce researcher bias, I recommend using a quantitative or semi-quantitative study to understand the strategies that healthcare managers use to implement the ISO 15189 QMS using a mentorship approach. To reduce the study participants responding to questions using their perspectives, I recommend using participants from recently ISO 15189 accredited laboratories as they will have more current experiences of the strategies employed during the mentorship, therefore reducing the recall bias.

Reflections

I can state with confidence that the DBA Doctoral study process has been a rewarding process for me on several dimensions. I gained extensive knowledge through this Doctoral study, which I do not think I would have learned if I had done it with another institution. Before this study, I did not know how to conduct research and used to confuse between qualitative and quantitative research methodologies; however, I have the confidence in even training other people on the difference between the two. Since my first degree was in Medical Laboratory Sciences, I had a bias towards quantitative research studies; however, the learning process which I used here in conducting qualitative research has opened my horizon, and I have more confidence in conducting qualitative research.

I thought that on-line education was not as good a classroom type of education; however, the experience that I have acquired has been rewarding as I now understand

what it takes to do an online study. In comparison with colleagues doing their doctoral studies with other universities, I now feel the Walden University study process was the most organized, fair, and has objective evidence. The most rewarding part of my Doctoral Study was completing the whole capstone study. I now appreciate the effort a student puts into the entire process. I can now use the Nvivo data analysis software, be able to generate study protocol, proposal, seeking ethical approval, conduct semi-quantitative interviews, and analyze the results.

Conclusion

Implementing the ISO 15189 QMS in medical laboratories is a business problem that has captivated the interest of scholars and healthcare leaders recently. Implementing the ISO 15189 QMS in medical laboratories improves patient safety and reduces errors by approximately 80 % (Schneider, Maurer, & Friedberg, 2017). The healthcare industry in America alone spends more than $29 billion because of medical errors attributed to inadequate QMSs (Zahar, Barkany, & Biyaali, 2016; Zineldin, Zineldin, & Vasicheva, 2014). Not implementing the ISO 15189 QMS in some healthcare organizations results in poor organizational performance and has negative consequences for business sustainability. The problem is not all healthcare leaders, or managers know strategies that they can use to implement the ISO 15189 QMS using a mentorship approach.

The purpose of this qualitative multiple case study was to explore strategies that healthcare managers use to design, develop, and implement the ISO 15189 QMS using a mentorship approach. Information obtained from data collection and analysis of qualitative data indicated that healthcare managers may use Lewin’s approach in

implementing ISO 15189 QMS, that is, (a) unfreezing, (b) changing (c) refreezing, and (d) maximizing forces for change. As healthcare managers implement the four phases of ISO 15189 using a mentorship approach, they can achieve ISO 15189 accreditation in a relatively shorter period.

Healthcare managers can use a structured mentorship model that starts with conducting a gap assessment, documentation, implementation, and doing continuous improvement activities to implement the ISO 15189 QMS. Healthcare managers can use teamwork to involve all staff to implement the ISO 15189 standard as each member can contribute their part to the overall system. The involvement and sensitization of the upper management in the ISO 15189 QMS implementation was crucial as that helped in securing the essential human and financial resources. Training of staff on the ISO 15189 standard and the laboratory's QMS was imperative as that ensured that staff understood what to do and helped to create a new work culture that maintained an on-going ISO 15189 QMS implementation. Maintaining a friendly mentorship approach to mentees by the mentor during the mentorship impacted positively on the adoption and implementation of the ISO 15189 QMS.

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Appendix A: Interview Protocol

Date_____

Interviewer_____

Interviewee_____

Orientation

Opening introduction and exchange of pleasantries

General Reminders to Participants

Purpose of the study

Reaffirm information shared will be confidential and used solely for the study's purpose.

Conversations will be recorded, and handwritten notes taken during the interactions.

On completion of the transcription and analyses, process participants will complete a member checking exercise

Participants

The targeted population consist of five healthcare managers, whose laboratories successfully implemented ISO 15189 quality management system. I chose five healthcare managers from the sample population of 5 accredited laboratories.

Length of Interviews

Each interview lasted approximately one hour. I will reserve the right to request follow-up interviews for further clarification of participants' responses, if necessary, to achieve complete data saturation.

Research Question

What strategies do healthcare managers use to design, develop, and implement ISO 15189 quality management systems through a mentoring approach?

Interview Questions

1. How does your organization 's mentor structure a mentorship program from the initial engagement phase up to the time the laboratory attains ISO 15189 accreditation?
2. Based upon your experience, what key issues positively affects the success of the mentorship program for implementing ISO 15189 quality management system?
3. What strategies do the laboratory mentors and management use to overcome ISO 15189 implementation barriers?
4. How does your organization's mentor effectively transfer the ISO 15189 knowledge to their protégés during the mentorship program?
5. How do your organization 's mentors prioritize activities to conduct during each ISO 15189 mentorship engagement?

6. How do your organization’s mentors inspire or influence the laboratory management and staff to adopt and implement the ISO 15189 quality management system?
7. What strategies does your mentor apply to manage resistance to change within your organization when implementing ISO 15189 QMS?
8. How did your mentor catalyze a new organizational culture that supports the implementation of your ISO 15189 QMS?
9. How do your mentors influence their mentees to implement ISO 15189 QMS in situations when the mentor was not physically at the site?
10. Based on your experience, how did the mentor-mentee relationship affect the success of the mentoring program?
11. What else can you share with me about the strategies and processes your organization's mentor use to achieve ISO 15189 accreditation?

Closing

Interviewer reviews manuscripts with the interviewee and allows time for reflection, feedback, and confirmation of the accuracy of interpretation of key terms.

Thanks the interviewee for their time and request permission to ask for a follow-up question.