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A Review of Continuous Improvement of Environmental Quality Management Standards in sub-Saharan Africa: The Nigeria Medical Laboratories perspective

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Abstract
Continuous improvement (CI) is a coordinated upgrade of quality of production activities, products and services, necessitated by the ever-changing competition globally. CI of International Organisation for Standards (ISO) enhances Quality Management (QM) practices in production activities, products and services. However, limited scholarship on CI of ISO in Sub-Saharan Africa constrains the effectiveness of compliance with Environmental Quality Management (EQM) requirements and practices. Here, we examined the quality management practices in the Nigerian medical laboratories to contextualize the implications of CI of ISO in sub-Saharan Africa, and evaluate the state of compliance with EQM requirements and practices, which are prerequisites for accreditation and certification in line with applicable ISO systems. The evaluation was enabled by descriptive literature review to enhance understanding of the subject of study, and to enable insight into the existing studies connected to this research topic. The study reveals limited CI activities among medical laboratories due to poorly regulated operational environment, poor awareness and limited capabilities. We recommend the mainstreaming of World Health Organisation's Regional Office for Africa Strengthening Laboratory Management towards Accreditation/Stepwise Laboratory Quality Improvement Process towards Accreditation (WHO-AFRO SLMTA/SLIPTA) programme in medical laboratory industry accreditation and certification requirements to enhance CI of ISO and optimize sustainable EQM practices among medical laboratories in Nigeria, and other sub-Saharan Africa countries.

Keywords
Continuous improvement, ISO, Accreditation, Certification, Environmental Quality Management System, WHO/AFRO SLMTA/SLIPTA Programme

1. Introduction
A world without changing, competing, comparative and improved approaches, methods, processes, technology, manufacturing practices, procedures, clients' production and products, as well as customers' demands and satisfaction can be unimaginable. Innovations, growth, transformation and development would have remained unattained in the present day world. Humans, organizations and societies would have remained unchanged or without improvement in quality of production activities, products and services. Juran (1989) postulated that "inconsistently, new technologies, new markets, social insurgencies, international conflicts create new client needs or alter the existing data".

Continuous improvement (CI) is a coordinated upgrade of quality of production activities, products and services, necessitated by the ever-changing competition globally (Singh & Singh, 2013). Roy and Ghose (2016) argue that the 20th Century marked a regime of expensive labour inputs in industrial/advanced countries, which resulted in a shift of focus to group collaboration and dynamics, especially the need to understand early warning signs of problems based on CI sequence. This was corroborated by Jung and Yung (2006), who considered CI as a proactive response mechanism that, demonstrates the ability to identify or detect changing elements in any environment, which signifies a key ingredient of managerial success. Many authors share diverse definitive perspectives of the concept of CI. Singh and Singh (2013) reported that CI originated from Japanese word, "Kaizen" meaning (Kai – do, change and Zen – well) representing a kind

of innovative thinking and management philosophy applicable to everyday life and multidisciplinary domains. In the west, it is known as "ongoing, continuous improvement (Malik et al., 2007). Karkoszka and Szewieczet (2007) defined CI as a "continuous progress, increase in value, intensification, and improvement", while Juran (1989) contends that the emergence and development of CI concept follows the same pattern as quality needs and demands in view of ever-changing client's needs, suggesting the non-existence of anything like permanent client's list. According to Imai (1986), "kaizen or continuous improvement implies a shift from the Taylorist paradigm of labor division", which requires conceptualizing a dual functional work system involving a shared responsibility between routine and improvement. The Taylorist paradigm implies that every organization's employee has a responsibility to function in two ways by offering solutions to problems and creating occasions for improvement.

CI is relatively simple to understand but its applicability to daily organization's activities is not so easy due to complex processes of achieving it in any industry and diversity of views (Singh and Singh, 2013). For instance, some studies confirming the diverse feedbacks from CI application in the US firms indicated that whereas 70% had implemented "lean manufacturing" techniques in their manufacturing plants, 74% were not convinced with the result obtained (Pay, quoted in Anand et al., 2009). On the other hand, further study revealed that only 11% of companies were convinced with the success of their CI activities (Mendelbaum, quoted in Anand et al., 2009). CI is therefore, linked to a diversity of managerial advancement such as implementation of "lean manufacturing" practices, total quality management (TQM), worker participation programmes, customer service initiatives, and waste minimization advocacy campaigns. Bhuyan and Baghel (2005) considered it as "a company–wide process of focused and continuous incremental innovation", while Garcia et al. (2008) emphasized "small incremental changes in productive processes or in working practices that permit an improvement in some indicator of performance". Garcia et al. (2008) definition aligns with Bessant et al. (1994) who also defined CI as "an incremental innovation process, focused and continuous, involving the entire organization". In this way, the cumulative outcomes of little strides, high rate of recurrence and little cycles of change occurring in isolated patterns can generate some organizational impacts that can contribute to the organization's performance indicators. Gonzalez et al. (2007) extended the scope of the Garcia et al. (2008) definition to innovation-based enhancement practices not restricted only to control of processes but aims at developing beneficial transformations in a systematic pattern resulting in achieving near-perfect and unimaginable performance status that was non-existent from the beginning.

ISO is an international, independent and non-governmental organization with a membership of 165 national standard organizations saddled with the responsibility to assemble experts to share knowledge and develop voluntary, consensus-based, market-relevant international standards that support innovations and provide solutions to global challenges. ISO standards aid companies or organizations in accomplishing their set objectives and goals, as well as guide or support the management to achieve effective monitoring and evaluation of in-house activities and operations (IISD, 2010). In other words, for example, any two organizations with completely different procedures and standards of environmental performance, can comply with ISO 14001 requirements (Federal Facilities Council Report, 1999). Most companies or organizations focus on qualifying for certification of the ISO 9000 and ISO 14000 families, which are considered as the most appropriate Quality Management Systems (QMS) for promoting CI and improved organizational QMS.

In Sub-Saharan African countries, including Nigeria, limited studies have considered the application of CI using ISO systems, especially in relation to the four components of good quality relevant to QMS Standards, namely, quality planning, quality control, quality assurance and quality improvement towards a sustainable Quality Management System (QMS) (Rose, 2005). In few cases where QMS exists in the internal processes of an organization, the QMS may not be functioning effectively in line with the required ISO standard, implying the non-existence of ISO certification in the organization. As a result of this scenario, CI programme cannot be anticipated in such organization due to lack of ISO standards certification, which provides the requisite guide or system for evaluating the effectiveness of any QMS and implementation of CI activities, thereby makes CI impossible. In a nutshell, the culture of QMS is generally rare, which creates challenges for effective implementation of CI through compliance with ISO standards in Nigeria (Nwaokorie & Ojo, 2019).

The main purpose of the paper is to examine the quality management practices in the Nigerian medical laboratories to contextualize the implications of CI of ISO in sub-Saharan Africa, and evaluate the state of compliance with EQM requirements and practices, which are prerequisites for accreditation and certification in line with applicable ISO systems. It also describes the current state of implementation of QMS, particularly EQMS towards achieving CI in different areas of practice and services in Nigeria, e.g. construction industry, medical laboratory services, etc. The study also evaluates the implications of SLMTA (Strengthening Laboratory Management towards Accreditation) and SLIPTA (Stepwise Laboratory Quality Improvement Process towards Accreditation) Programmes for the Nigeria Medical Laboratory Services Industry.

2. Conceptual Framework

The current rapidly changing and active business environment or marketplace have generated competitive interaction among organizations, exacerbating the demands on manufacturers, who in the last three decades have experienced an unimaginable magnitude of modifications, incorporating radical alterations in organization procedures, product and

process techniques, as well as customer expectations, supplier behaviours, and competitive attitudes. As a result of this changing and highly demanding business scenario, Shingo (1988) suggests that CI of operational processes and systems has become necessary if they must remain competitive and relevant; maintain their market stake in the world economy, meet the quality demands or expectations of the domestic and international economy and customers. Furthermore, due to the ever-increasing pressure from the customers/consumers and competitors in the manufacturing industries, as well as service industries on the global business environment, businesses are operationally challenged with the constant need to sustain minimum quality cost, cut down waste, cut down production lines, and speed up manufacturing to achieve and maintain competition. CI has been found to be the smart solution to these challenges. In the light of this, it has been described as "a culture of sustained improvement aimed at eliminating waste in all organizational systems and processes, and involving all organizational participants". This description or definition forms the general opinion of many authors and researchers (Singh & Singh, 2013). To that extent, CI can be revolutionary or evolutionary, implying that for the former, key transformations occur as a consequence of innovation or new technology. Put simply, it is the result of accumulated progressive advancements. Conversely, the latter involves advancements that occur as a result of usual incremental changes (Singh & Singh, 2013). In the light of these views, Singh and Singh (2013) highlighted that CI is also participatory, involving everyone functioning collectively to achieve improvements without essentially making enormous capital investments.

Globally, CI has been accepted as the stepping stone to realizing quality excellence towards attaining an advanced level in the vastly demanding world, but the prevalence of diverse views on the processes/procedures for achieving it has resulted to different approaches by different authors and industry players (Singh & Singh, 2013). In summary, the definition and application of CI techniques differ across diverse processes, procedures, and practices involved in achieving total quality improvements in manufacturing industries, medical laboratories, corporate bodies and other related organizations using the ISO-certified QMS.

Anderson and Chris (2013) describe QMS as a collection of business processes which concentrates on achieving quality processes and objectives. Among all QMS, the most broadly implemented family of standards worldwide is ISO 9000. ISO 9000 family developed in 1996 (Clements, 1996; Brorson & Larsson, 1999), relates to achieving customer's terms and conditions, customer fulfillment and compliance to regulations, as well as stringent effort to achieve continuous improvement (Valadão et al., 2013; Roy & Ghose, 2016). According to ABNT (2005), ISO 9000 provides regulatory prerequisites relevant to QMS where the organization has the responsibility to show its capability to meet the customers/clients quality of products and increase customers approval by applying the system innovatively, incorporating practices for continuous improvement with guaranteed adherence to the customers' and regulatory requirements. Among the ISO 9000 family, ISO 9004:2018 provides for Quality Management-Quality of an organization-Guidance to achieve sustained success (Continuous Improvement).

ISO 14000, on the other hand, concerns itself with impacts of companies' activities on the surrounding environment and evidence of companies' commitment to achieve improvement in this direction (Roy & Ghose, 2016). The previous environmental regulations were characterized by strict command and control mechanisms, but the ISO standards have evolved over time to establish quality requirements anchored on market measures, while ISO 14000 was designed to create voluntary approach to environmental regulations. The primary objective of ISO 14000 series is to support effective and efficient promotion of environmental management in an organization, as well as to facilitate useful and usable tools which are cost effective, system-based, flexible and reflect best organizational practices available for gathering, interpreting and communicating environmentally relevant information (Roy & Ghose, 2016). Specifically, ISO 14000 series assist in (i) reducing the negative environmental impact resulting from company's operational shortcomings, (ii) providing facilities for compliance with extant laws and regulatory requirements, as well as other environment-based provisions, and (iii) transmitting continuous improvement in the above facilities. ISO 14000 series contain 11 certification standards (Roy and Ghose, 2016), among which ISO 14062 discusses making improvements to environmental impact goals.

Essentially, among the ISO 14000 series, the Federal Facilities Council Report (1999) indicated that generally the main objective and primary principles for developing the ISO 14001 was for CI and its foundational basis like ISO 9000 series, include a four-phase methodology known as Plan-Do-Check-Act (PDCA) model (Standards Australia/Standards New Zealand, 2004). ISO 14001 comprises 17 elements and grouped into five phases relating to the Plan-Do-Check-Act model, namely, Environmental Policy, Planning, Implementation & Operation, Checking & Corrective Action and Management Review (Martin, 1998). ISO 14001 Environmental Management System (EMS) was established in 1996 by the ISO to provide a set of standard practices pertaining to the company's external environment (Larsen & Häversjö, 1999). Furthermore, subsequent revision and improvement have resulted in the updated version of ISO 14001 known as ISO 14001:2004 with clear and improved specification standards and descriptive document. ISO 14001 provides a structured management system that assists organizations to improve their environmental performance by controlling or minimizing the impact of their activities, services and products on the environment, as well as supports the culture of complying consistently with prescribed environmental laws and policies. There are three dimensions of CI in ISO 14001 as follows:

i) Expansion: Implementing ISO 14001 EMS enhances the inclusion of a vast number of diverse businesses.

ii) Enrichment: Implementation of ISO 14001 EMS enhances the sustainable management of many activities, products, processes, emissions, resources etc.
iii) Upgrading: This involves the improvement of the structural and organizational frameworks of the EMS and accumulation of competencies in dealing with business-related environmental issues.

In general, CI process (CIP), as a concept, supports the gradual migration of companies from ordinary operational environmental measures towards a strategic approach that effectively deals with environmental challenges. According to Roy and Ghose (2016), the CI of ISO models has evolved over time and involves other widely known quality management systems, such as ISO 3166 for standardized Country codes, ISO 26000 for maintaining quality Social responsibility, ISO 50001 for quality Energy management practices, ISO 31000 for quality Risk Management system, ISO 22000 for quality Food Safety Management system, ISO 27001 for standardized Information Security Management, and ISO 20121 for achieving quality Sustainable events.

3. Theoretical Framework

Many authors have examined the CI processes of many organizations and industries resulting in the categorization of the following seven implementation techniques or tools, namely, consideration of organizational core competencies, obstacles and facilitators (Mesquita & Alliprandini, 2003; Garcia, Val & Martin, 2008), models (Bessant, Caffyn, & Gallager, 2001; Wu & Chen, 2006), knowledge and learning process (Buckler, 1996; Murray & Chapman, 2003; Davison, Gordon, & Robinson, 2005; Savolainen & Haikonen, 2007; Jabrouni et al., 2011), quantitative studies of programmes in diverse sectors and countries (Tersiovski & Sohal, 2000; Scott, Wilcock & Kanetkar, 2009). Other implementation tools include the relationship of CI with change management and total quality management (TQM) (Choi, 1995; Jung & Wang, 2006), as well as the history and development of CI (Bhuiyan & Baghel, 2005; Suárez-Barraza & Dávila, 2009). Literatures and available resources reveal the key components or factors that elaborate successful CI initiatives or processes (table 1).

Table 1 Key Components of a CI Process

Key Components Assessed	Literature Sources
i) Formalization & Structure	(Wruck & Jensen, 1998; Terziovski et al., 2000; Grutter et al., 2002; Choo et al., 2007; Formento et al., 2007; Anand et al., 2009)
ii) Continuity / Duration	(Sillince et al., 1996; Terziovski et al., 2000; Rapp & Eklund, 2002)
iii) Deployment / Scope of Program	(Wruck et al., 1998; Choo et al., 2007)
iv) Training	(Terziovski et al., 2000; Bacdayan, 2001; Rapp et al., 2002; Wood, 2003)
v) Management Commitment	(Bashein et al., 1994; Attaran, 2003; Bateman & Rich, 2003; Jorgensen et al., 2003; Terziovski et al., 2003)
vi) Program Coordination	(Terziovski et al., 2000; Schuring & Luijten, 2001) Grutter et al., 2002; Rap et al., 2002;
vii) Methodology & Tools	(Garvin, 1993; Pil & Macduffie, 1996; Spear; Bowen, 1999; Terziovski et al., 2000; Handel & Gittleman, 2004; Bateman, 2005; Formento et al., 2007; Forrester, 2000)
viii) Performance Measurement	(Bessant and Francis, 1999; Hammer & Stanton, 1999; Das et al., 2000; Dennis et al., 2003; Foster, 2004; Evans & Lindsay, 2008)
ix) Communication of Results, Recognition & Incentives	(Buch & Spangler, 1990; Lawler III, 1991; Sillince et al., 1996; Fairbank & Williams, 2001; Kerrin & Oliver, 2002; Rapp et al., 2002)

Source: *Formento et al. 2013*

3.1 Formalization and Structure

Formalization generates the necessary field for the creation of support structure and establishment of the routines reported by Bessant et al. (2001) as the five developmental stages of process improvement, namely Environmental Policy, Planning, Implementation & Operation, Checking & Corrective Action and Management Review (Martin, 1998). Without a formalized structure, CI efforts will be irregular or discontinuous and influenced by and/or subjected to personalization and conditional stressors. In essence, formalization and structure create the enabling environment to advance beyond the initial developmental stage of CI.

3.2 Continuity / Duration

CI process, as the name implies, has no end point. Essentially, the integration of improvement cultures into the daily activities of any organization generates results that align with the company's strategic objectives. One of the most prominent examples is the Toyota Production System which has a stable and well organised spread of CI practices throughout the company operational processes (García-Sabater et al., 2009). Inability to maintain the continuity of improvement creates very limited and significant negative impact on the time (between one and four years), after going through three phases including introduction, dissemination and decline. The reasons for this limited and significant negative impact are various, but they generally occur in a system or organisation without the opportunity for steady development program (Lawler III, 1991; Sillince et al., 1996). Sometimes there is an improvement in the fourth phase as effort is repeated (Rapp et al., 2002). This idea, according to Wu et al. (2006), follows that all activities (including

revisions) follow a life cycle through which the introduction, growth, maturity and decline occur. If there is no continuous effort to effect regenerative bond with the times, the program fails and no CI is achieved.

3.3 Deployment / Scope of Program

Choo et al. (2007) and Wruck and Jensen (1998) argue that inadequate deployment of resources, processes and poor coordination of CI result in a less effective process, though some preliminary results may have been achieved. Whereas CI is important, another challenge often encountered in the process is the manner of deployment of processes to transmit improvement formalities that can affect all hierarchies of any organization. The universal approach propounded by Deming (1993) requires the consideration and handling of different processes as part of an inclusive system where quality of interaction determines the final outcome. In a nutshell, it is unthinkable for CI to succeed without the effective incorporation of all sectors and processes.

3.4 Training

Modification and transition from the traditional approach to problem-solving, characterized by trial and error, based on individualized knowledge to the team-based or inclusive systematic technique requires specialized and relevant capacity building in methodologies and tools for analysis. Spear et al. (1999) and Spear (2004) reported that in addition to the need for intensive human and organizational capacity building, it is logical to begin with topmost hierarchy of management to focus more on the agents of transformation, which will generate immense impact on the process. Several studies highlight the significance of implementing capacity building at the basic tools and moving towards the application of new tools as soon as more complex challenges necessitate their implementation (Terziovski & Sohal, 2000; Bacdayan, 2001; Rapp et al., 2002; Wood, 2003).

3.5 Management Commitment

There is a need for management commitment to initiate, activate and drive the culture of participation and teamwork in the organization (Bashein, Markus, & Riley, 1994; Attaran, 2003; Jorgensen, Boer, & Gertsen, 2003; Terziovski, Fitzpatrick & O'neill, 2003). According to García-Sabater et al. (2009), it is usually impossible to develop and implement a CI programme without a firm commitment of the topmost hierarchy of management. Executives and managers are required to commit the necessary resources, support or tailor activities to meet strategic goals, establish systems, procedures, policies and most importantly, create a culture of CI.

3.6 Program Coordination

Sustainability of CI within the managerial culture requires stakeholders and personnel who contribute actively to its realization in the context of daily processes and operations. García-Sabater et al. (2009) suggest that this role should not be restricted to few specific team leaders, but the involvement of one or more designated internal programme coordinators, who enhance organizational operations and responsibilities, facilitate access to resources and provide technical advice to team members.

3.7 Methodology & Tools

The need to establish a uniform systematic technique is fundamental, and should integrate a predetermined schedule of steps for the development of improvement projects (Garvin, 1993; Spear et al., 1999; Forrester, 2000). Bateman (2005) argues that a formalized technique facilitates a harmonized operational foundation on which changes are developed. This systematic analysis process replaces the traditional trial and error approach to problem-solving. A previous study of Australian firms by Terziovski et al. (2000) shows that "these companies still prefer the seven basic tools for the implementation of CI programme over more advanced ones such as Failure Mode and Effect Analysis (FMEA) and Quality Function Deployment (QFD)". Another study conducted in Argentina demonstrates that the ongoing use of the Plan-Do-Check-Act or Plan–Do–Check–Adjust (PDCA) cycle and its methods contributes to high proportion of improvement projects (figure 1). The Six Sigma methodology has been considered an alternative to PDCA, using "Define, Measure, Analyze, Improve, Control" (DMAIC) cycle, which is currently applied in few cases. In Six Sigma methodology, the PDCA cycle is called DMAIC. It is necessary to be conscious of the fact that the iterative nature of the PDCA cycle must be added to DMAIC procedure. According to Formento (2008), both methods apply the seven basic tools, which remain the most widely used.

3.8 Performance Measurement

The sustenance of CI capacities necessitates the process of monitoring, evaluation and measurement of outputs and results/outcomes to determine how they align with organization's strategic objectives (Bessant & Francis, 1999). Continuous assessment techniques applied to systems, processes, and key outcomes is fundamental to the realization of CI programme (Hammer et al., 1999; Das et al., 2000; Dennis, Carte & Kelly, 2003; Foster, 2004; Evans et al., 2008).

3.9 Communication of Results, Recognition and Incentives

Jabrouni et al. (2011) observed that the feedback from a CI programme enhances the initiation, analysis and facilitation of the knowledge exchange programme among professionals in problem-solving initiatives. The results or outcomes of such internal knowledge exchange programme is deployed beyond the specific team members and extended to the entire

organizational management structure. Additionally, in cases of external programmes, the success results of CI generate significant motivation to team members. Significant contributions measured on the strength of their impact or results are usually rewarded. These recognition programmes can be diverse in nature but always attempt to underline and influence positive attitudes (Buch et al., 1990; Lawler III, 1991; Sillince et al., 1996; Kerrin & Oliver, 2002; Rapp et al., 2002).

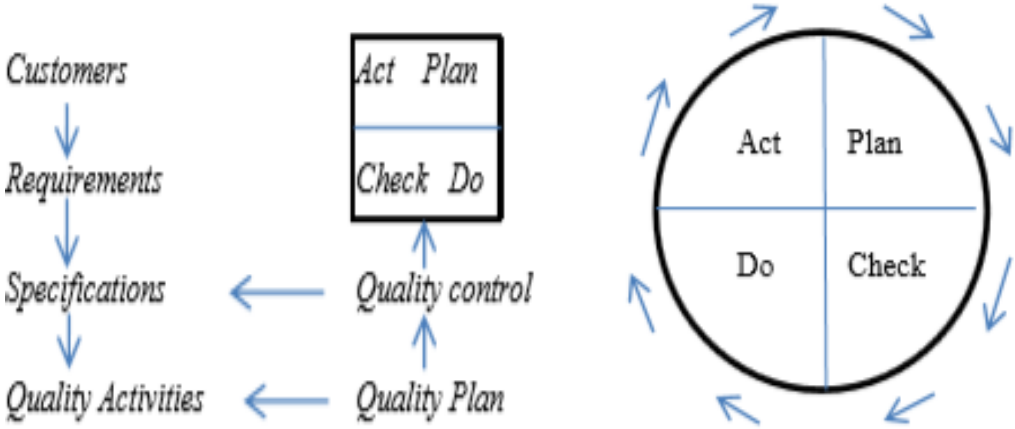

Fig. 1 The Plan-Do-Check-Act (PDCA) cycle **(***Quality journey: Quality improvement,* ***Source:*** *Rose, 2005)*

4. The State of CI of International Organization of Standards (ISO) and Environmental Quality Management System (EQMS) Practices in Sub-Saharan Africa: Example from Nigeria Medical Laboratory Services Industry

Indications from the importance of CI processes or strategies of ISO for achieving QMS generally and specifically, EQMS in Nigeria places a responsibility on organizations or companies to anticipate the future of their businesses, the impact of their business on the immediate environment, the production patterns, the quality of processes, production, products and services. In evaluating the ISO models and CI processes in Nigeria, findings have shown that monitoring and measuring CI of ISO models in achieving EQMS can be viewed in the context of the state of compliance and implementation of ISO models in the country's production, consumption and service sectors. This is expected to serve as a starting point of determining the effectiveness and impacts of CI of ISO on achieving EQMS in Nigeria.

Examining CI of ISO from industry perspective, for instance, in the medical laboratory industry in Nigeria, Nwaokorie & Ojo (2019) found that QMS is relatively new in the industry, as a considerable percentage of medical laboratories in the country are not accredited in conformity to internationally acceptable standards as recommended by ISO 15189:2012 (Yao et al., 2014). In fact, it has been reported that until 2010, most medical laboratories in Nigeria were either ignorant or yet to implement QMS (Nwaokorie & Ojo, 2019). Like in many laboratories in Sub-Saharan Africa, implementation or integration of QMS into local business processes in Nigeria remains uncertain. This has been associated to "limitations in physical infrastructure, climate extremes, equipment, consumables, financial constraints associated with inability to define cost and mobilize resources, as well as lack of staff training and education" (Bouchet, 2015). Earlier before 2015, none of the private and public laboratory services providers in Nigeria could fulfill the certification requirements for international accreditation for ISO certification. This, according to Nwaokorie and Ojo (2019) can be attributed to the rigorous requirements prescribed by International accreditation organizations, which seem unsuitable to the peculiarities of the Nigeria quality management environment. Independent report indicated that Nigeria had a total of about 18,516 accredited and unaccredited laboratories, out of which 12,717 (68.68%) are designated as private and 5,449 (29.4%) as public laboratories (Mboup et al., 2013). Interestingly, report from the Medical Laboratory Science Council of Nigeria (MLSCN) showed that most of these laboratories were not registered, as only 3,211 were officially listed with MLSCN as at March 2018 (AIDS Preventive Initiation of Nigeria, 2017). However, relying on the available record from this review, only eleven (0.34%) of Medical Laboratories in Nigeria were accredited according to ISO 15189: 2012. The number is considerably low, suggesting that a greater percentage of the laboratories in Nigeria operate at a low level of capability, which may not achieve quality laboratory services, let alone CI of ISO models, as defined by international standards for medical laboratories. Surprisingly, the MLSCN, which is responsible for medical laboratory accreditation in Nigeria, was yet to take membership of the International Laboratory Accreditation Cooperation (ILAC) or International Accreditation Forum (IAF). In corroborating the above findings, Nwaokorie (2014) also reported that stiff conditions and unaffordable costs of international accreditation schemes, is responsible for the poor level of accreditation in Nigeria and other developing countries. For example, the study by Nwaokorie (2014) highlighted that as at 2014, out of the forty nine (75.5%) countries in Sub-Saharan Africa, 37 have no laboratories accredited to international standards.

Furthermore, out of 380 accredited laboratories in Sub-Saharan Africa, 91% are in South Africa (Schroeder and Amukele, 2014). Comparatively, there are currently over 6000 indigenous medical diagnostic laboratories operating in

Nigeria, but only 2 (0.03%) have the ISO certification (Schroeder & Amukele, 2014), namely, Human Virology Laboratory (ISO 9001:2008), Nigerian Institute of Medical Research (NIMR Lagos) (now known as the Centre for Human Virology and Genomics) and the Pathcare Nigeria (ISO 15189), a South African-based company operating laboratory services in Nigeria (Nwaokorie et al., 2014). These evidences clearly indicate the poor state of certification and standardization of laboratory practices in Nigeria, which negatively impacts on the implementation of CI in Nigeria. Even where there is adequate level of awareness, inadequacies of competent or qualified manpower constrain the efforts to mentor and support laboratories to achieve quality improvement. Another constraint is the poor state of compliance and commitment of laboratory services practitioners in Nigeria to meeting the required certifications and standardizations. For instance, Nigeria has 7352 medical laboratory scientists and thousands of diagnostic medical laboratories rendering different forms of laboratory services across the federation. One major limitation includes inadequacy of laboratory infrastructures, obsolete and inconsistent test quality, which remains a growing challenge (Punch Newspaper, July 28, 2014). Interestingly, some exceptions are seen in laboratories that are supported by international organization. However, majority of these facilities are reference laboratories designed to perform specific services for HIV/AIDS and TB patients (Alemnji et al., 2014), which is a fraction of the huge demands for quality laboratory services in other diseases of public health interest. The implication is that accessibility of laboratory testing and the quality of available services still remain a great challenge.

5. Implications of SLMTA (Strengthening Laboratory Management towards Accreditation) and SLIPTA (Stepwise Laboratory Quality Improvement Process towards Accreditation) Programmes for the Nigeria Medical Laboratory Services Industry

The SLMTA programme is an initiative supported by the World Health Organisation (WHO) (also known as WHO/AFROSLMTA) launched in Rwanda in 2009 by twelve (12) African countries as a foundation for the enhancement of national health laboratory infrastructure, capacity development and guideline to overall improvement in quality management system (Gershy-Damet et al., 2010; Yao et al., 2010). Practically, the WHO/AFRO SLMTA programme is designed to ensure the achievability of conditions needed for laboratory accreditation in Africa (Nwaokorie et al., 2014), implemented as a joint programme in partnership with the US Centers for Disease Control and Prevention (CDCP), the American Society for Clinical Pathology (ASCP), and the Clinton Foundation. The WHO/AFRO SLMTA programme was first embraced in African country in Lesotho in 2012 (Mothabeng et al., 2012). Since then, it is implemented in many other African countries at different levels creating a clear roadmap to achieving international accreditation (Mothabeng et al., 2010; Mosha et al., 2011; Masanza et al., 2012). Participating in this programme provides laboratories the opportunity to know the level of their quality management systems compliance at any given time and how to make room for improvement. In between the workshops, laboratories are assessed and scored using the Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) checklist and ranked on a graded scheme from zero to 5 Star in the ascending order of 0 Star (<55%), 1 Star (55-64%), 2 Star (65-74%), 3 Star (75-84%), 4 Star (85-94%) and 5 Star (>95%). On attainment of the 3-star ranking, laboratories are advised to apply for ISO accreditation. Comparatively, SLIPTA is a framework for auditing developed in line with the ISO 15189:2012 Standards and in compliance with the 12 Quality System essentials of the CLSI Laboratory Quality Management System Guidelines. It is used to measure and evaluate the progress of laboratory quality system, and award a certificate of recognition for laboratories that attained the five star levels (12). Essentially, SLMTA Programme has served as a good foundation for enhancement of laboratory infrastructure, capacity development and overall quality system in Africa (Gershy-Damet et al., 2010; Yao et al., 2010; Mosha et al., 2011; Masanza et al., 2012; Alemnji et al., 2014). For instance, as at April 2014, out of the 30 medical laboratories in Nigeria involved in SLMTA programme, 8 have received Accredited Stepwise Laboratory Management (ASLM) recognition points which qualified them to seek for international accreditation according to ISO 15189 standards (Nwaokorie et al., 2014). The Human Virology Laboratory-NIMR and the National TB Reference laboratory, NIMR with recorded improvements (Audu et al. 2014) were among this number. Stepwise training through WHO/AFRO SLIPTA has been quite rewarding and is available to support facilities. Most interesting is the fact that with a strong zeal for quality, an aspiring laboratory has the opportunity to work through the WHO/ AFRO SLIPTA checklist and be part of QMS with or without the aim of accreditation. Based on reviews and experiences, Audu et al. (2014) highlighted the challenges faced by these two reference laboratories in SLMTA implementation. Of much concern is the inability to understand some of the requirements of the SLIPTA checklist, difficulties in interpreting ISO 15189:2012 standard requirements and auditor recommendations, as well as the inability to sustain quality improvement projects and maintain records.

In Nigeria, SLMTA programme implementation originated from Centre for Disease Control (CDC) through 23 Presidential Emergency Plan for AIDS Relief (PEPFAR)-supported health facilities (Mba et al., 2014). This programme has been implemented successfully in Nigeria. The two laboratories that attained international accreditation in 2017 were enrolled in the PEPFAR programme. With the successful implementation of this process; it is believed that there would be measurable quality improvement in medical laboratory service delivery and consequently on the entire healthcare system across the nation. In line with the objective of the programme, reports have shown remarkable improvement within one year after baseline assessments (Mbah et al., 2014). Marked improvements are seen with the assistance of an on-site assessor (Audu et al., 2014). Nigeria has progressive record on SLMTA cohort rollouts in-country. The country can boast of having 26 trainers, 60 Advocates/Implementers (SLMTAns), 11 mentors and 20 potential master trainers. In

addition, there are about 15 in-country Nigerian SLMTAns that are ASLM certified Auditors. This category of members are mostly used as Mentors for laboratories that have obtained 4 stars but are still awaiting exit audit by ASLM External Auditors. The success of QMS depends to a larger extent on the services rendered by auditors and assessors that ensure that standards are maintained and sustained. In 2017, The CDC Nigeria laboratory programme in collaboration with ASLM team, organized ISO15189 training and trained 24 auditors and SLMTAns in-country to better equip them to support laboratories for improved quality of services and compliance to international standards (Nwaokorie et al., 2014). It is important therefore to develop an all-encompassing in-country auditing guideline for Medical laboratories in Nigeria. Furthermore, there are 47 laboratories in Nigeria that have enrolled in the SLMTA training and mentorship program (Nwaokorie & Ojo, 2021). Six of the 23 facilities involved in the pilot program in Nigeria are supported by Family Health International 360 (FHI 360) (Mbah et al., 2014). Others were 6 laboratories supported by IANPH (Nwaokorie et al., 2014) and the NIMR TB Reference laboratory, supported by ASM since 2009. Similarly, 13 hospital Laboratories in FCT were enrolled with support from the Federal Capital Territory Administration. Through this stepwise training approach, it is believed that laboratories will be able to gradually receive credit for improvement and more would eventually attain accreditation.

In 2016, the Medical Laboratory Science Council of Nigeria (MLSCN) presented the national certificate of accreditation (ISO 15189:2012) to three deserving Medical Laboratories namely 661 Nigerian Air Force Hospital Laboratory, Clina Lancet Laboratories, and El-lab Laboratories all located in Lagos. In 2017, history was made when two Nigerian indigenous public laboratories received international accreditation according to ISO 15189 by South African National Accreditation System (SANAS). The first was Center for Human Virology and Genomics, Nigerian Institute of Medical Research and the second, APIN Laboratory, Jos University Teaching Hospital (JUTH), Jos (AIDS Preventive Initiation of Nigeria, 2017). The same year, Clina Lancet Laboratory with prior National (MLSCN) accreditation was also granted international accreditation by SANAS (SANAS, 2018). In early 2018, additional two laboratories were added. This brings the total number of internationally accredited laboratories to eight, namely, 3 PathCare Labs (located in Victoria Island Lagos, LUTH Lagos, and Abuja), CHVG, NIMR, APIN Lab JUTH, CLINA Lancet Laboratory, Virology Laboratory, University of Ibadan Teaching Hospital and IHVN PLASVERIC Laboratory.

In summary, the introduction of WHO-AFRO SLMTA Programme is believed to have brought awareness to Nigerians medical laboratories on the need for QMS. Participating in WHO/AFRO SLMTA is facilitated by CDC in Nigeria. As it is, many laboratories may be interested in participating in this program. The possibility of being part of this depends on interest and the availability of resources to support implementation. The State and Federal Ministries of Health, as well as international and national implementing partners support enrolment and implementation with technical assistance from CDC.

6. Conclusion

Implementation of QMS in Nigeria is at a low level, especially among medical laboratory service providers. Training and mentorship programmes provided by QMS implementing partners are in place to prepare and ensure quality services. Others are ISO 15189: 2012 adapted checklists mapped out to assess and re-assess, audit, recommend and monitor implementers on quality standards. For instance, the SLMTA programme has improved implementation of QMS in Nigeria. There is also slight, but non-formal progress through on-the-job training via Laboratory Quality Audit. Awareness has been created but more needs to be done for laboratory personnel to understand the processes involved, ways to handle challenges and best ways to implement Quality Management System.

7. Recommendation

Although structures are in place to support the improvement of laboratory quality management system in Nigeria, through the instrumentality of NIMR, from experience, this process is tasking but can be achieved. There is a need for adequate funding and a mechanism to support laboratories to enroll and be accredited in line with international regulations. It is important for laboratory facilities to recognize and prioritise the necessary requirements for effective and quality service delivery. There is also a need to increase the level of awareness and enforcement of laboratories that implement EQMS, and maintaining the culture of quality management should be of high priority. Laboratories should be encouraged to enroll into the WHO/AFRO SLMTA/SLIPTA programme, request for experienced mentors and get accredited. This will promote orderly and constant flow of activities; ensure safety standards, quality and competent services, as well as customer satisfaction and continuous improvement (CI) practices ultimately.

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