Overview of the Implementation of Quality Management System in Nigerian Medical Laboratories

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ABSTRACT

Background: Quality Management System (QMS) is implemented in laboratory medicine to ensure that accurate, precise and timely results are achieved with the overall goal being to accomplish patients’ satisfaction. Through QMS, laboratories achieve competence in technical ability and ensure that active quality management of professional services and those of personnel are maintained with or without the ultimate aim of obtaining accreditation.

Objective: To provide information on status, in-country structures, challenges and prospect of quality management system, and its implementation in Nigerian Medical Laboratories.

Materials and Methods: Published literature, online reports and websites related to the implementation of laboratory QMS, accreditation and WHO/AFRO Strengthening Laboratory Management towards Accreditation and Stepwise Laboratory Quality Improvement Process towards Accreditation SLMTA/SLIPTA programme.

Results: Quality Management System is relatively new in Nigerian medical laboratories as only a few are accredited. Majority of the facilities implementing QMS are those involved in diagnosis, management and surveillance of Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) and tuberculosis. QMS is mostly implemented in Nigeria through WHO AFRO SLMTA/SLIPTA programme. This has brought about improved and sustained quality management. Factors such as poor infrastructure, climate extremes, financial constraints, gaps in capacity building, lack of equipment and consumables, and dedicated and motivated personnel have been challenges. Major strength is in implementing the twelve quality essential elements and International Organization for Standardization (ISO) 15189 clauses are facility and safety, while documents and record, internal audits, as well as occurrence management is quite challenging. Aspiring laboratories need to start gradually and strongly advocating for management support, connect to national regulations and also participate in External Quality Assurance (EQA) programmes. Others are to observe and understand the local scene, find support and allies, keep documents and communication simple and straightforward and learn from previous mistakes. Laboratory personnel should imbibe positive behavioural change to promote quality in practice, be creative, with the ability to identify and adapt to local solutions, stimulate ownership and create a positive climate.

Conclusion: Awareness has been created but more needs to be done for laboratory personnel to understand the processes involved, as well as ways to handle challenges and implement Quality Management System. Intensified efforts are needed to enrol private and public facilities involved in hospital based patient care.

Keywords: Quality management, Laboratory accreditation, International Organization for Standardization, ISO 15189, Accreditation, Medical laboratory.

INTRODUCTION

The term “Quality Management System” and the acronym “QMS” was first introduced as far back as 1991 by Ken Croucher, a British management consultant (1). Since then, it has been recognized and implemented widely as a business requirement and compliance parameter to ensure quality. According to International Organization for Standardization (ISO), Quality Management System is a formalized system that documents processes, procedures and responsibilities for achieving quality policies and objectives (2). The system defines not only the goals and aspirations of an organization but also their policies, processes, documented information and resources needed to implement and maintain the organization. It involves implementation of dedicated activities in a project to obtain continuous improvement, and enhance the organization efficiency. Thus, helping to coordinate and direct an organization’s activity to meet client and regulatory requirements. In doing so, the organization has ample room to
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SLMTA/SLIPTA programme is designed to monitor improve Laboratory Management towards Accreditation and Stepwise following the introduction of WHO-AFRO Strengthening QMS. Since then, progress has been made to implement QMS laboratories in Nigeria were neither aware of nor implementing in laboratory practice in Nigeria. Until 2010, majority of unfortunately, the concept of quality management is not a norm managing the costs associated with these diseases.

Medical laboratories are essential elements in health care systems. They play a very important role in disease control and prevention programmes. Medical laboratories provide timely and accurate information about people’s health through screening, risk assessment, diagnosis, treatment selection, and monitoring of treatment response (3–5). The results of test obtained helps in guiding decisions regarding patient management (4). Ngo et al. (6) revealed that 35% of patients encountered in which diagnostic tests (laboratory, radiography, vital signs, respiratory, cardiology, and others) were performed had one or more laboratory tests ordered. An average of one or more laboratory tests is ordered in 98% of inpatient, 56% at emergency department, and 29% for outpatient respectively (6). For the laboratory test to be useful, it is important to ensure that human error are reduced to the barest minimum. The framework that would promote this, must ensure quality in all aspects of the laboratory operation, be it organizational structure, processes or procedures.

In laboratory practice, Quality Management System is a priority as recommended by ISO and by the Clinical and Laboratory Standards Institute (CLSI) (7). Implementing a QMS prevents mistakes from occurring, or at most, limits the risk of errors occurring. This system provides the tools to increase consistency in laboratory services. It also enhances the possibility of successful regulatory inspections, improve the use of time, resources and morale, and also boost opportunities for funding and research. In addition, it increases recognition by national and international partners, generates data for informed decisions, and most importantly increase client’s satisfaction (8).

Sub-Saharan Africa carries 24% of the global disease burden of tuberculosis, malaria and HIV/AIDS, coupled with incessant report of non-communicable diseases such as coronary heart disease, hypertension, cancer and diabetes (9, 10). Nigeria accounts for substantial fraction of these indexes (10), yet a high percentage of laboratories in the country are not accredited in conformity to internationally acceptable standards as recommended by ISO 15189:2012 (11). Current health care reform is focused on diagnosis and early intervention; it is imperative that timely and accurate laboratory results should be in place for quality patient care and for managing the costs associated with these diseases. Unfortunately, the concept of quality management is not a norm in laboratory practice in Nigeria. Until 2010, majority of laboratories in Nigeria were neither aware of nor implementing QMS. Since then, progress has been made to implement QMS following the introduction of WHO-AFRO Strengthening Laboratory Management towards Accreditation and Stepwise Laboratory Quality Improvement Process towards Accreditation (SLMTA/SLIPTA) programme (12–14). The WHO/AFRO SLMTA/SLIPTA programme is designed to monitor improvement, create awareness of QMS and promote the need for accreditation. It also kick started the success story of implementation of QMS and subsequent accreditation in collaboration with other stakeholders (12).

Like in other African countries, adapting QMS to local realities in Nigeria seems difficult. This has generally been attributed 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 (15). Despite such challenges, they provide haematology, clinical chemistry, microbiology, parasitology and sometimes blood transfusion services on a regular basis (16, 17). Over the years, this has called for the need to increase support to strengthen and improve the quality of the medical laboratory services.

Nigeria is the most populated African country with a population of 182,202,000 million people (18) distributed across 36 states and the Federal Capital territory. An independent study shows the total number of both registered and unregistered laboratories in Nigeria to be about 18,516 (19). Of this total, 12,717 (68.68%) are designated as private and 5,449 (29.4%) as public laboratories (19). Similarly, the Centre for Disease Control reported that 5,349 laboratories exist in the public healthcare facilities (20). Interestingly, not all these laboratories are registered with Medical Laboratory Science Council of Nigeria (MLSCN), as only 3,211 are officially listed with this National regulatory body as at March 2018. On the other hand, the laboratories may have registered with other regulatory bodies locally or internationally. However, going by the information available during this review, only eleven (0.34%) of Medical Laboratories are accredited according to ISO 15189: 2012 in Nigeria. This number is very low and tends to suggest that in a greater percentage of the laboratories in Nigeria, the level of laboratory capability may not translate to quality laboratory services as defined by international standards for medical laboratories. Thus, this poor infrastructure would have adverse effect on the vis-à-vis poor QMS and negate confidence clinicians and patients have in test results. Implementation of QMS is an uncommon culture in Nigeria (21). This paper gives an overview of the status and implementation of quality management system in Nigerian Medical Laboratories.

MEDICAL LABORATORIES

The American Society For Clinical Laboratory Science described Medical Laboratory Science professionals as “vital healthcare detectives, uncovering and providing laboratory information from laboratory analyses that assist physicians in patient diagnosis and treatment, as well as in disease monitoring or prevention” (22). They perform their duties in a laboratory using sophisticated biomedical instrumentation and technology, computers, and methods requiring manual skills to perform laboratory testing on blood and body fluids (22, 23). Most laboratories provide haematology, clinical chemistry, parasitology and sometimes blood transfusion services on a regular basis. Thus, the services involved are composed of the various activities that produce laboratory results for patient care and management. The entire set of operations that occur
in testing is represented as “PATH OF WORKFLOW” (24). This path begins with the patient and ends in reporting and results interpretation. At whatever level of operation, quality is of high priority in laboratory medicine. The capability and set up of QMS requires that many factors must be addressed to assure quality in the laboratory. It involves in all ramifications the physical, environmental and information resources, personnel, skills and expertise available for the examinations in question. Each of this entity have specific, as well as varying procedures that are performed to fulfill the goal of medical laboratory services. It is important that they are carried out correctly in order to assure accuracy and reliability of testing.

The organogram of medical laboratories allows administration to coordinate personnel, equipment, laboratory processes and information in such a way that quality is sustained. This sounds like what is obtainable in any business venture of which quality management system is a priority. Hence, this justifies the need for ISO to establish ISO 15189:2012 standards designed to ensure Medical laboratories meet particular requirements for quality and competence (11) and ISO/IEC 17025:2017 which ensures general requirements for the competence of testing and calibration laboratories, but provides specific requirements for implementation in medical laboratories (25). If every condition stipulated by ISO 15189:2012 and ISO/IEC 17025:2017 is maintained, it is expected that services rendered by medical laboratories would assist doctors to get correct diagnoses of communicable, non-communicable and genetic diseases. The laboratory will in addition provide hints on the appropriate time and how to commence treatment. It will also contribute in detecting drug failure and resistance to medications.

Laboratory services in Nigeria are primarily unified within the 3-tier public health system made up of primary, secondary and tertiary levels. In addition to this, there are various Reference and Research Laboratories involved in providing services for complex and special tests. It is expected that prior to the establishment of a laboratory, the management of both local and internationally owned facilities is given assess to review the conditions stipulated by the council (23, 26, 27, 28). This is aligned with subsequent inspection of the environment and facilities. Laboratories that meet these conditions are registered and certified to practice under periodic assessment and reassessment of QMS. Like in global practices, huge emphasis is laid on standard quality of laboratory services. This may not be the case as very few laboratories conform to these standards apparently due to inadequate knowledge of implementation (23). To ensure this, it is really important to use national guideline and policies to support and encourage implementation.

**QUALITY MANAGEMENT SYSTEM**

A quality management system (QMS) works on eight fundamental principles: customer focus, strong leadership, involvement of people, process approach, system approach, continuous improvement, decision making based on facts and creating value for the company, its clients and its suppliers (29). Quality management system involves policies formulated in line with specific objectives of several areas of business enterprise and are regularly reviewed to ensure continuous improvement of a system (30). In laboratory practice, quality management system can be defined as “coordinated activities to direct and control an organization with regard to quality”. This definition is used by the International Organization for Standardization (ISO) and by the CLSI (7, 12). The policy of ISO 15189:2012 recommends the assessment and monitoring of quality management systems in medical laboratories as a quality improvement effort towards quality laboratory services (23). Laboratory quality is maintained when accurate, reliable and timely test results are obtained (24) This is then made useful in clinical or public health setting to achieve proper patients’ management and satisfaction. In line with this, formal frame work has been designed to coordinate personnel, equipment, laboratory processes and information in such a way that quality is sustained.

In a more specific term, QMS in Medical Laboratories is not different from the overall importance in other fields. Quality management system helps laboratory management to achieve the goal and objectives of setting up a laboratory, be it in a public or private setting. It helps to drive impressive gains in quality and customer satisfaction. It is also known to ensure financial performance, cost effectiveness, increase in production, as well as process improvement. In addition to this, the system ensures that time is utilized effectively and with minimal waste of human and material resources. Moreover, the implementing facility will have the potential to successfully go through governmental and accreditation assessments. At whatever operational level that quality is maintained in a Medical Laboratory, there is a need to also have substantial improvement in the appropriate use of laboratory tests generated. Thus, laboratory specialists need to collaborate with clinical providers to optimize the value of testing. To achieve accreditation, successful implementation of the laboratory quality management system (LQMS) is very important.

**THE QUALITY MANAGEMENT SYSTEM MODEL**

Arrangement of all laboratory procedures and processes into an understandable and workable structure is vital in achieving organisational goals. The QMS model was developed by CLSI as contained in document QMS01-A4 (24) and this is fully compatible with ISO standards. It organizes all laboratory activities into 12 Quality Management Essentials (QMEs) (7, 24). These quality system essentials are a set of coordinated activities that serve as building blocks for quality management. In order to achieve overall laboratory quality improvement, each element must be addressed. Such has been mapped out as path of workflow from sample collection to release of results and is highly dependent on good management of all of the quality essentials. These elements are generic and can be implemented in the order that best suits the laboratory setting. This has been used to design the WHO/AFRO compactable MLSCN checklist (24) currently used in Nigeria for laboratory accreditation.
The 12 essentials are:

1. **Document and Records:** The nature of laboratory services is evidenced based. QMS ensures that laboratory documents are in place at all times to capture information on all activities. This varies from information on how things are done, who will do them to who did them and when it was done. Others include consistent information on Standard Operating Procedures (SOP), non-conformities, corrective actions and documented improvements. These documents are prepared, approved, controlled and made available for use to all staff involved and at the point where they are needed. The element ensures that records produced in the laboratory over time are meticulously maintained, accurate and easily accessible. Previously, documentation and records were maintained manually. However, advancement in technology has brought about electronic computer systems such as files and folders. Among other QSEs, achieving quality improvement relating to documents and record may be challenging (27). This is not unexpected because greater number of laboratory personnel appears to have poor attitude towards documentation. This however may vary with facilities because some laboratories implementing SLMTA (27) demonstrated commendable attitude towards documentation.

2. **Management Reviews:** The success of achieving accreditation depends on the support from the highest levels of management. This requires the documentation and review of all quality and technical records and communicating the right information effectively to management. According to ISO 15189 requirements, Management Review Meetings (MRMs) are conducted by quality manager in the presence of Technical Manager, Chairman and the Medical Laboratory Scientists of various specialties. The minutes of the meetings have to be documented (27) and actions regularly reviewed. This requires the service of a skilled Quality Manager that would drive this process. Moreover, inter professional relationship within institutions should be encouraged. This will encourage facilities to initiate strong advocacy and subsequently obtain the management support needed to drive QMS.

3. **Organisation and Management:** Organization in Medical Laboratory indicates the management and strong supporting organizational structures. An accurate and complete organizational chart is necessary to clearly define the role of each member of the organization and this is coordinated by the Laboratory and Quality Manager. Unfortunately, there are no data to show if this hierarchy potentiates effective work flow and improved productivity. Education and the zeal to update ones knowledge and skills are vital to personnel competency. These elements ensure that laboratory workers update their knowledge and skill regularly. Particular attention is given to quality assurance, good laboratory practice, and QMS. In addition, QMS specifies the importance and duties of a Laboratory Director and the Quality Manager. These managerial personnel should not only be skilled in QMS, but they should also have adequate knowledge and technical competence in medical laboratory techniques.

4. **Client Management and Customer Service:** It is important to have a process for managing customer communications. This element assists the laboratory to understand who the customers are. It makes provision on how to assess their needs and use customer feedback to make improvements. Users of laboratory services have opportunity to gather information regarding the pre-analytical issues surrounding patient testing and how to improve on them.

5. **Equipment:** Varieties of equipment are used and maintained in day to day running of medical laboratory. Technically, QMS requires that equipment should be maintained, serviced and repaired as at when due and by the right person. This is based on the concept that relevant equipment and a good equipment maintenance programme results in a high level of performance and greater confidence in the reliability of results. It is a requirement of ISO 15189 that the laboratory should maintain a service contract for analysers, as well as ancillary equipment (11). The culture of equipment maintenance is not a common practice. Moreover, almost all equipment used in Nigerian Laboratories are imported. Same as the running consumables, reagents and chemicals. Such burden would exert pressure on the cost of maintaining the minimum ISO 15189:2012 standard requirement for equipment.

6. **Evaluation and Audits:** It is a systematic examination carried out in a laboratory to ensure that all works meets with regulatory, accreditation and customer requirements. The assessment could be internal (involving staff working in a laboratory) or external (involving various staff from different laboratories). It is important that auditors engaged in SLIPTA audit exercise be trained on internal audits. Maina et al. (31) is of the opinion that internal audits and subsequent corrective actions play major roles in stimulating improvements in other areas of QMS. This element seems to be the commonest attempt in implementing QMS, especially if the facility has the opportunity to obtain and adapt the WHO AFRO or MLSCN checklist. Internal audits need to be conducted frequently to maintain the laboratory management system in such a way that it meets the minimum acceptable laboratory quality standards. In terms of QMS, laboratory rating is dependent on audit scores. Formal laboratory evaluation component is designed to identify weaknesses and areas that require improvement. Jegede et al. (32) assessed and highlighted the benefits of internal audits, reviews and follow-ups in improving quality essentials in 25 Anti-Retroviral Therapy Facilities in North West of Nigeria. Internal audit exercises have also assisted stakeholders in selecting facilities towards WHO/AFRO accreditation roll-out (32). The challenge is on how to create a standardized form of laboratory audit to accurately measure the level of improvement across every Medical Laboratory involved in QMS in Nigeria. Presently, Nigerian laboratories seeking for exit audit and subsequent external audit by African Society for Laboratory Medicine (ASLM) prior to International accreditation use SLIPTA checklist. Similarly, South African National
7. **Purchasing and Inventory:** Successful purchasing and careful management of inventory helps to prevent waste, which can occur if reagents and supplies are stored improperly or if reagents become out-dated before they are used. The standard practice clearly state that it is very important to check regularly the expiration date and shelf-life of strips, reagents and chemicals used to run tests in order to prevent generation of false negative/positive results. This element however is faced with inadequate logistic, unpredictable lead time and poor storage due to incessant electricity supply.

8. **Process Control:** The primary goal in a quality management system is continuous improvement of medical laboratory processes. This interestingly must be done in a systematic manner. The process for continual improvement includes identification of the problem, analysis of the data and the processes, determination of the root cause of the problem and generation of ideas for solutions. This refers to control of the activities employed in the handling of samples and processing from the pre-analytical, analytical and post-analytical testing processes. Clinical samples received in the laboratory such as blood, urine, stool etc. should be properly collected, stored and processed in due time. The system ensures that quality is controlled in each step and documented to detect, evaluate and correct errors before patient results are released. Most QMS implementing laboratories do not see this as a major challenge (28). Internal quality control (IQC) panels are commonly used to monitor the analytical phase of testing. These are mostly supplied by equipment manufacturers or vendors or prepared as in-house control by the laboratory.

9. **Information Management:** This ensures that the accessibility, accuracy, timeliness and security of all data (information) are well managed and that the confidentiality and privacy of patient information is put in check. Some hospitals in Nigeria have instituted, and others have shown interest in, the use of Electronic Medical Record (EMR) system in order to maintain quality (33, 34). It is expected that this initiative would be extended to a greater number of facilities in Nigeria with special emphasis on the Laboratory Information Management System (LMIS).

10. **Identification of Non-Conformities, Corrective and Preventive Action:** Corrective actions may be requested when a condition, which is adverse to quality or which has the potential for process improvement is identified. Preventive action should be seen as an on-going process involving analysis of laboratory data, including trend and risk analyses and external quality assessment (proficiency testing). It is also important that the Laboratory Director or the Quality Manager ensures implementation of corrective action. This requires managerial skill and discipline. Thus, it would be really important to continuously conduct training that would facilitate the skill to identify Non-Conformities, design and enforce Corrective and Preventive Action.

11. **Occurrence/Incident Management and Process Improvement:** Quality management makes provision for detection of human and technical errors. Irrespective of the nature of work flow, it is required that error should be minimized to the barest minimum and be detectable if they eventually occur. Consequently, this element ensures that errors are detected and corrected properly to prevent reoccurrence. Major factor to achieve quality improvement in occurrence management is the ability to document, review and effect corrective actions. This also require to a large extent managerial skills and commitment.

12. **Facilities and Biosafety:** This involves policies and procedures to prevent harm to medical personnel, visitors and the environment. Emphasis is placed on issues like floor plan, even prior to registration of a Medical Laboratory in Nigeria (26). In addition, both public and private diagnostic laboratories exhibit obvious deficiencies in the area of administrative control responsible for implementing biosafety. Studies have shown the absence of a biosafety officer who is the major focal person to drive and maintain safety in the laboratory (27, 35). More so, there are concerns over very poor compliance towards issues concerning facility design, presence of personal protective barriers, equipment, and administrative control of biosafety (35). However, in laboratories implementing QMS, facility and safety is seen as the strongest QSE element (27).

**REGULATORY STANDARDS ORGANIZATION**

The International Organization for Standardization (ISO) is the world’s largest standard-setting body established in 1946 (36). It is an independent, non-governmental international organization and has membership of 162 national standards bodies. This regulatory body develop and publish ISO guidelines. The ISO standards are peculiar and over 19,500 international standards covering almost all aspects of technology and manufacturing exist (36). In a broader sense, it gives world-class specifications for products, services and systems, to ensure quality, safety and efficiency. The standard particular to Medical Laboratories is based upon ISO/IEC 17025 and ISO 9001, from which the two ISO standards – ISO 15189:2012 (11) and ISO-IEC:17025:2017 (25), that are specific to laboratories in line with the medical services rendered, were developed. ISO 15189:2012 is intended for use by medical laboratories in developing their quality management systems and assessing their own competence (7, 11). Ultimately, it is made to be used by accreditation bodies in confirming or recognizing the competence of medical laboratories.

ISO 15189 was prepared by ISO/TC212 and was first published in 2003 followed by the revised versions of 2007 and 2012 respectively (11, 37). It is recognized officially by the International Laboratory Accreditation Cooperation (ILAC) and is used as the international standard for the accreditation of medical laboratories across the globe (37). The ISO/IEC 17025:2017 ensures general requirements for the competence
of testing and calibration laboratories but provides specific requirements for implementation in medical laboratories. The involvement of Clinical and Laboratory Standards Institute (CLSI), formerly known as the National Committee for Clinical Laboratory Standards (NCCLS), and World Health Organization (WHO) in providing guidelines is well recognized. The provision of CLSI on quality management is contained in document QMS01-A4 (24). Similarly, WHO provided a guide for the Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA) in the African Region (38).

Regulation according to ISO permits each country to establish their own specific guidelines or requirements applicable to some or all its professional personnel and their activities and responsibilities in this locality. This gave room for individual countries to develop in-country capacity and promulgate national regulatory bodies. In countries like South Africa where the highest number of accredited laboratories in Africa is located, accreditation of Medical Laboratories is regulated by South African National Accreditation System (SANAS)(39). Japan operates through the Japanese Committee for Clinical Laboratory Standards (JCCLS) and the Japan Accreditation Board for Conformity Assessment (JAB) (37). These bodies co-jointly started the accreditation program in Japan in 2005, and by 2010 over 46 medical laboratories had been accredited (38). Some other international accrediting bodies include CAP – College of American Pathologists, KENAS – Kenya Accreditation Service, SADCAS – Southern African Development Community Accreditation Service, IPAC – Instituto Portugues de Acreditacao, ENAO – Ethiopian National Accreditation Office, JANAAC – Jamaican National Agency for Accreditation, OGA – Organismo Guatemalteco de Acreditacion. Similarly in Nigeria, the Medical Laboratory Science Council of Nigeria is one of the accreditation bodies for Medical Laboratories (40). Organizations like the Nigeria National Accreditation Service (NiNAS) also exist. Besides, laboratories in Nigeria that have so far obtained international accreditation, registered with SANAS. Like in other countries, it would be necessary to have a broader in-country accreditation body. It is important to mention that Medical laboratories can implement QMS to maintain quality and improvement without being accredited by a regulatory body. In such circumstance, certification and licensure could be ideal.

**LICENSE, CERTIFICATION AND ACCREDITATION**

When standards are specified, it is expected that there should be a system to indicate that the laboratory complies. A laboratory can obtain licensure, certification, and accreditation from a body with the mandate to do so. It is well known that the quality of medical laboratory services is judged by accreditation. Achieving accreditation in laboratories is a challenge in Nigeria. While this is attainable at high rate in developed world with stronger medical framework, policies and regulations, the case is different here. Adapting QMS to local realities proves difficult due to limitations of infrastructure, equipment, consumables and staff. Studies has shown that factors like the problem of defining cost and mobilization of resources, difficulties in defining roles and responsibilities in the laboratory challenges associated with the uncertainty about starting point, perception of lack of time, lack of management commitment and political support, as well as personal bridge due to resistance to change and managing change in an evidence-based system affect implementation of QMS (16). Even with that, laboratories still get accredited especially when proper channel, training, implementation and application are followed, coupled with adequate managerial and financial support/sponsorships from relevant stakeholders. In as much laboratory accreditation is a necessity, review of what is obtainable has shown that not all sections of the laboratories can be accredited at once. This has given some facilities the opportunity to start implementation of QMS at a smaller scale.

**SLMTA (STRENGTHENING LABORATORY MANAGEMENT TOWARDS ACCREDITATION) AND SLIPTA (STEPWISE LABORATORY QUALITY IMPROVEMENT PROCESS TOWARDS ACCREDITATION) PROGRAMMES**

Quality Management System (QMS) is uncommon in clinical laboratories in Nigeria. Prior to 2015, none of the public and private laboratories in Nigeria was able to achieve the certifications required to initiate the process of getting an international accreditation. This can be traced to the stringent conditions stipulated by the International regulatory body that seems unfavourable to African countries. In order to trigger and coordinate efforts to improve on laboratory service quality, the US Centers for Disease Control and Prevention (CDC), in collaboration with the American Society for Clinical Pathology, the Clinton Health Access Initiative and the World Health Organization’s Regional Office for Africa (WHO AFRO), launched the Strengthening Laboratory Management Toward Accreditation (SLMTA) training programme, in Kigali, Rwanda in 2009 (13). African nations adopted the World Health Organization Regional Office for Africa Stepwise Laboratory (Quality) Improvement Process towards Accreditation (WHO/AFRO/SLIPTA) in 2010 (13, 41). This effort led to the Strengthening of Laboratory Management towards Accreditation (SLMTA) training program and Stepwise Laboratory (Quality) Improvement Process towards Accreditation (SLIPTA) (41, 42). The mission is to transform the laboratory system by strengthening quality management systems aligned to international standards using a continuous quality improvement approach, and by fostering a quality culture based on excellence of services (12, 43).

SLMTA is a task-based training and mentoring toolkit provided to the laboratory personnel in a multi-workshop implementation model. It empowers laboratory management to initiate immediate laboratory improvement measures, even without additional resources or external assistance (12). Comparatively, SLIPTA is a framework of 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). The SLMTA/SLIPTA program was

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intended to provide an interim pathway for measuring, monitoring and recognizing improvement toward the realization of international laboratory standards and subsequent application to a national or internationally recognized accreditation body (42). Member states are encouraged to implement this approach to ensure quality improvement in laboratory services. As at 2017, SLMTA is implemented in 1103 laboratories in 49 countries in Africa, the Caribbean, Latin America and Southeast Asia and fifty nine of them have obtained accreditation (43). From inception it was envisaged that the program could be challenged by higher cost of training a participant, because it involved multi-workshop format and required supervisory visits (12, 41). Such has been evidenced by reports from implementation countries across African Nations and the Caribbean (12, 44). Even with that, progressive achievements are well documented (12, 44).

SLMTA-Nigeria

SLMTA-Nigeria program implementation originated from CDC through 23 PEPFAR (President’s Emergency Plan for AIDS Relief) supported health facilities (27). This programme has been implemented successfully in Nigeria. The two laboratories that attained international accreditation in 2017 were enrolled in this 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 (27). Marked improvements are seen with the assistance of an on-site mentor (28).

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. 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 (45). Six of these 23 facilities in the pilot program in Nigeria are supported by Family Health International 360 (FHI 360) (46). Others were 6 laboratories supported by IANPH (47) and The NIMR TB Reference laboratory, supported by ASM since 2009. Similarly, 13 hospital Laboratories in FCT are enrolled with support from the Federal Capital Territory. 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. Apart from the SLMTA programme, most Anti-Retroviral Therapy Facilities in North West Nigeria have been involved in an on-the-job training through Laboratory Quality Audit (32).

QUALITY MANAGEMENT SYSTEM IN MEDICAL LABORATORIES IN NIGERIA

The culture of QMS is rare in medical laboratories in Nigeria. It was introduced in 2006 at Human Virology, Nigerian Institute of Medical Research (21) now Centre for Human Virology and Genomics. In the same year, PathCare Care Nigeria, a private medical Laboratory affiliated to PathCare South Africa, became the first internationally ISO 15189 accredited laboratory in the entire West Africa region (47). By 2009, the Human Virology Laboratory (HVL) had ISO certification but not ISO 15189. In 2016, the Medical Laboratory Science Council of Nigeria (MLSCN) presented a 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 (20). The same year, Clina Lancet Laboratory with prior National (MLSCN) accreditation was also granted international accreditation by SANAS (39). In early 2018, additional two more laboratories were added. This brings the total number of internationally accredited laboratories to eight; 3 PathCare Labs (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.

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 are supporting enrolment and implementation with technical assistance from CDC.

Most laboratories currently implementing QMS and/or seeking accreditation are supported by foreign implementing agencies and few are supported by government agencies and private partners (47). They sustain the facilities by providing the resources required to facilitate the needs of the laboratory, service of engaging mentors, application for accreditation and logistics associated with implementation. It is worrisome that much focus is placed on medical laboratories involved in diagnosis, treatment, prevention and surveillance of HIV/AIDS and Tuberculosis. Little or no attention has been given in a broader sense, to the entirety of all aspect of laboratory services associated with patient care.
Although the Medical Laboratory Science Council of Nigeria has taken the mantle of regulating accreditation in Nigeria, they are yet to be a member of International Laboratory Accreditation Cooperation (ILAC) or International Accreditation Forum (IAF). There is a need to have Nigerian regulatory body with full membership with ILAC. Such body should encompass all relevant professional and regulatory bodies involved in providing medical/clinical laboratory services in Nigeria. Moreover, it will be cheaper to have a Nigerian based regulatory body provide such service. The current situation warrants that relevant Associations, Ministries, Industries, Marketers and regulatory bodies involved in medical laboratory services in Nigeria come together and harmonize in-country policies and guidelines for accreditation of Medical Laboratories in Nigeria. In line with an earlier suggestion in 2014 (28), there is an urgent need to have a National Laboratory Strategic Plans to provide roadmaps for the implementation of quality laboratory services and develop a National Laboratory Quality Standards to guide the provision of quality clinical laboratory services and accreditation in Nigeria. Following the recorded progress and the fact that more laboratories might likely be accredited exponentially in the nearest future, this may eventually be achieved.

Modalities for preparation and implementation of QMS are easily available through the regulatory bodies and can freely be accessible online (17). Training and mentorship programmes are conducted by some organizations, especially PEPFAR implementing partners, CDC and Medical Laboratory Science Council of Nigeria on Quality Assurance, Quality Management System, safety, among others to assist laboratories in Nigeria to educate, prepare, implementation and ensure quality while providing services. Similarly, AIDS Prevention Initiative in Nigeria organizes training on accreditation preparedness, with emphasis on quality management systems for laboratories that the organisation supports (28). The Regional SLMTA workshop, Regional SLMTA TOT workshop, WHO AFRO stepwise training and MLSCSN trainings and workshops have been quite encouraging.

Step wise training through WHO/AFRO SLIPTA is 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. (28) highlighted the challenges faced by 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. On the other hand, the best practices for implementing QMS in low-resource settings have fully been emphasized (17, 27, 28, 31, 46, 47). Much emphasis is laid on the need for aspiring laboratories to connect to national regulations and public health laboratories and also participate in EQA programmes. In addition, it is necessary to observe and understand the local scene, find support and allies. Furthermore, the laboratories are advised to start gradually, and augment trainings received at SLMTA workshops with mentorship support (28, 32). Other ways include the need for laboratories to keep documents and communication simple and straightforward. Learning from previous mistakes should not be overlooked. Most importantly laboratory personal should imbibe positive behavioural changes to promote quality in practice (17, 28, 32). Other suggestions were the need for medical laboratory personnel to exhibit creative ability to identify and adapt to local solutions, stimulate ownership and create a positive climate (17).

RECOMMENDATIONS
1. There is a need to harmonize in-country policies and guidelines for the implementation and auditing of QMS in Nigeria.
2. Develop and promulgate a National Laboratory Strategic Plans to provide roadmaps for the implementation of quality laboratory services.
3. Develop and encourage the use of National Laboratory Quality Standards.
4. Inter-professional relationship, within institutions should be maintained. This will encourage facilities to initiate strong advocacy and subsequently obtain the management support needed to drive QMS.
5. Aspiring laboratories should start gradually and connect to national and international regulations and also participate in EQA programmes.
6. More laboratories in private and public sectors should be encouraged to implement QMS.
7. There is a need to integrate SLMTA into pre-service curriculum and in-service trainings and workshops.

CONCLUSION
Implementation of QMS in medical laboratories in Nigeria is at a low level. Training and mentorship programmes provided by QMS implementing partners are in place to prepare and ensure quality while providing services. Others are ISO 15189:2012 adapted checklists mapped out to assess and re-assess, audit, recommend and monitor implementers on quality standards. The SLMTA programme has improved implementation of QMS in Nigeria. There are also slight but non formal progresses 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. In addition, efforts should be intensified to enrol private and public facilities involved in hospital based patient care.

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CONFLICT OF INTEREST
None declared.
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