



SJMLS-3 (3)-001

Provision of a Quality, Customer-Focussed and Continually Improving Laboratory Service in NigeriaErhabor, O.¹, Erhabor, T.², Okara, G.C.³, Adias, T.C.⁴, Dangana, A.⁵

Department of Haematology, School of Medical Laboratory Science, College of Health Sciences, Usmanu Danfodiyo University Sokoto Nigeria¹, Medical Laboratory Science Council of Nigeria², Dr. Hassan's Clinic and Diagnostic Centre Maitama, Abuja³, Federal University Otuoke, Bayelsa State, Nigeria⁴, Department of Haematology, University of Abuja Teaching Hospital Gwagwalada, Abuja⁵.
Author for Correspondence: n_osaro@yahoo.com/+234-813-962-5990

Summary

It is no longer news that a healthier hospital begins with a healthier diagnostic laboratory. The aim of this editorial is to highlight objective steps and evidenced- based best practices that Medical Laboratory Scientist as custodian of laboratory service delivery in Nigeria can implement to ensure the delivery of a quality, customer-focussed and continually improving service to their customers. Provision of a quality, customer-focussed and continually improving diagnostic service is a possibility in Nigeria. However, it can only be achieved by the implementation of evidenced-based best practice. There is need for a paradigm shift in the mind-set of Medical Laboratory Scientist and the implementation of evidenced-based best practices; quality management system oriented service, implementation of quality audits, IQC and EQA, document control, carrying out customer satisfaction surveys and risk analysis, having a robust training and competency testing programme, prompt reporting and objective investigation of all incidents, accidents and near misses, implementing a process-oriented diagnostic service concentrating on the continual identification and removal of waste and all non-value adding activities from the process, implementing the principle of GLP, GMP, infection control, occupational health and housekeeping, pre-acceptance testing (reagent certification) and equipment validation prior to use, implementing governance by having periodic management review meeting and running the service as a business (geared towards meeting the changing requirements of the customer and making profit) and having a long-term strategic planning mind-set.

Keywords: *Quality, Customer-Focussed, Continually Improving, Laboratory, Service, Nigeria*

Who is a Medical Laboratory Scientist?

Medical Laboratory Scientist (MLS) or Biomedical Scientist (BMS) work in healthcare and conduct a range of complex laboratory test to diagnose, monitor, manage disease, evaluate the effectiveness of treatment and carry our scientific researches through the analysis of body fluids and tissue samples from patients. Medical Laboratory Science is the science in the heart of healthcare. Laboratory Scientist provides the “engine room” of modern medicine with 70% of medical diagnosis and by extension treatment based on the laboratory results provided by these extremely important professionals. They work as part of a multi-disciplinary health team that includes nurses pharmacist, doctors, physiotherapist and others. Building structural relationships, collaboratives, partnerships and knowledge sharing within and between these health professionals that make up the health team is key to the provision of quality healthcare services and can potentially contribute to improvement in the quality and safety of care offered to patients and customers (Cunningham *et al.*, 2013). While Nigeria has one of the largest numbers of human resources for health in Africa, the relative numbers are still inadequate to meet the country's needs. An inventory of health care personnel for the year 2006 indicated 12,860 medical laboratory scientists (0.09 medical laboratory scientists /1,000 population), 39,210 doctors (0.3 doctors /1,000 population), 124,629 nurses (1.03 nurses/1000 population), 88,796 midwives (0.67

midwives/1000 population), 2,482 Dentists (0.02 dentists/1000 population), and 12,072 Pharmacists (0.05 pharmacists/1000 population) Nigeria with a population currently estimated as 198 million, is the most populous country in sub-Saharan Africa and the seventh globally. A current inventory indicates that there are 35,000 registered Medical Laboratory Scientist which translates into about 0.18 medical laboratory scientist/1000 population (Erhabor, 2018). This number is grossly inadequate to meet the laboratory service needs of Nigerians. There is need for the Nigerian government to invest in human capacity development with the hope of meeting the WHO recommended 4.45 skilled health workforce per 1000 population worldwide to facilitate the attainment of the health-related SDGs in 2030 (WHO, 2016).

Nigeria can no longer afford to maintain the status quo in Medical Laboratory Scientist and other health worker production and employment as this will slow the progress and worsen the continuing global imbalances in the number of healthcare workers needed to provide essential services (need) and the availability of health professionals (supply). Significant efforts are required in the recruitment, development, training, remuneration and retention of Medical Laboratory Scientist and other healthcare workers in Nigeria. There is also the need to ensure that these healthcare workers are equitably distributed to both urban and rural healthcare settings to enhance their accessibility. The morale of healthcare workers will need to be optimized (valued, respected and proud) to ensure their performance and productivity.

Table 1: Number of some Categories of Health Workers per 100,000 Population in Nigeria in 2006.

Health Care Profession	Number of Staff	Number of Staff/100,000 Population
Medical Laboratory Scientist	12,860	12
Doctors	39,210	30
Nurses	124,629	100
Midwives	88,796	68
Dentists	2,773	2
Pharmacist	12,072	11
Community Health Practitioners	117,568	19
Physiotherapists	769	0.62
Radiographers	519	0.42
Health Record Officers	820	0.66
Environmental Health Officers	3441	3
Dental Therapist	872	0.69

(Federal Republic of Nigeria. National Human Resources for Health Strategic Plan, 2007)

Medical Laboratory Scientist are at the heart of the medical team providing other professionals with vital scientific information allowing them to make informed medical judgements needed for the effective management of the patients (Ferraro et al., 2016). When a major incident occurs, it is the MLS that ensure the right amount of blood reaches the right patient in the right quantity, condition, in the right place and at the right time. They measure vital blood chemicals to monitor patient conditions and detect signs of

internal bleeding, determine coagulation analysis to determine patients prone to thrombosis and require anticoagulation, screen blood and blood products intended for transfusion to patients to ensure they are free from transfusion-transmissible infections, carry out blood cultures to determine patients with septicaemia that require antibiotics treatment, determine the specific antibiotics that is required to treat infective processes in patients and study biopsies to determine if patients have cancers or are predisposed to cancers.

Without the important life- saving services provided by Medical Laboratory Scientists, accident and emergency wards would shut down, blood transfusion services will be unavailable, there will be inadequate management of hospital- associated infections (MRSA), coagulation clinics to provide thrombosis-prone patients with anticoagulation would shut and premature babies would struggle to survive. Whenever a sample taken from a patient by a doctor or nurse, it is usually analysed by a MLS. Quite simply, without the services and support of these oracles of modern medicine, doctors would frequently be unable to diagnose diseases properly or treat their patients effectively. Registration by the regulatory Medical Laboratory Science Council of Nigeria to practice as a Medical Laboratory Scientist requires the completion of a Bachelor of Medical Laboratory Science academic degree (BMLS) plus a period of training (Internship) in an approved laboratory to develop their practical skills and ensure competence to allow for the protection of the vulnerable public and for patient safety (Brass, 2009; Ogrinc *et al.*, 2003).

Specialising in the field of medical laboratory science

Training of Medical Laboratory Scientist is generic in the first 4 years of training and often covers a broad spectrum of courses in; haematology, blood transfusion, chemical pathology, immunology, histology, cytology medical microbiology, virology, parasitology and cytogenetics. However, in the final year of study the student is expected to specialize in any of the medical laboratory science speciality (Bosch and Casadevall, 2017). MLS in microbiology study micro-organisms such as bacteria, fungi and parasites which cause disease. They identify these organisms and establish the antibiotic treatment required to effectively eliminate them therefore stopping the disease. Diseases diagnosed in the microbiology laboratory include meningitis, tuberculosis, gonorrhoea and other sexually transmitted diseases (STD's) and food poisoning. In clinical chemistry also known as chemical pathology, MLS analyse blood, body fluids and other biological materials to help the diagnosis of diseases (such as renal failure, chronic liver

disease and diabetes). They also carry out toxicological studies (kidney and liver function test) and monitor the effect of therapies.

In blood transfusion, MLS identify donor blood groups for blood donation, screen transfusion recipients for atypical antibodies, ensure the correctly grouped and crossmatched blood are available for patients in whom transfusion is indicated, ensures that enough blood is available in case of emergency such as road traffic accidents, operations and cancer treatments, screen blood donors for transfusion-transmissible infections, select antigen negative units and specialized products for patients with alloantibodies and in patients in whom these products are indicated, carry out investigation for foeto-maternal haemorrhage (FMH) in Rhesus negative women delivered of Rhesus positive babies to enable the effective dosing of prophylactic anti-D to prevent incidence of haemolytic disease of the foetus and newborn (HDFN) in subsequent Rhesus positive pregnancies, investigate transfusion reactions and other unexpected negative outcome associated with transfusion of blood and blood products, manage stock levels of blood and blood products, prepare blood components (packed red cells, fresh frozen plasma, platelets concentrate and cryoprecipitate) from whole blood to ensure the optimum utilization of the limited allogenic donor stock and manage the stock and usage of pharmacologic agents such as anti D (for prophylactic use in Rhesus negative pregnant women to prevent anti-D haemolytic disease of the foetus and newborn), antifibrinolytics such as aprotinin and tranexamic acid, novo 7, prothrombin complex concentrate and fibrinogen concentrate (to manage haemorrhage).

MLS in Haematology is involved in the study of the formation, composition, functions and diseases of the blood. Some of the diseases diagnosed in haematology include leukaemia, lymphoma, multiple myeloma, myelodysplastic syndrome, anaemia, haemoglobinopathies, coagulopathies and malaria. They study the etiology, diagnosis, treatment, prognosis, and prevention of haematological disorders that affect the production blood cells (red cells, white

cells and platelets), haemoglobin and blood proteins.

In histology also called anatomical pathology, tissue samples are studied microscopically to establish the cause of illness. Tissue may be taken during surgery or at post mortem. Diseases such as cancer are diagnosed by looking for abnormal features in tissue cells. Anatomical pathology is a medical laboratory science specialty that is concerned with the diagnosis of disease based on the gross, microscopic, chemical, immunologic and molecular examination of organs, tissues, and whole bodies (autopsy). In cytology, MLS screen cervical smears and also provides non-gynaecological service. Specialised techniques are used to prepare and study samples of cellular materials. Cytology involves carrying out cervical screening which involves cervical smears investigations to test women for the presence of cytological abnormalities in the cervix (neck of the womb) that can potentially develop into cancer. This test is performed regularly and routinely as a preventive measure to reduce mortality from cervical cancers.

MLS in virology study viruses and the disease caused by them such as German measles, HIV, Hepatitis B, Hepatitis C, Ebola, Monkeypox, Ebola, Herpes Simplex virus and chickenpox. They are also involved in production and monitoring of the effects of vaccines. The virology laboratory also performs viral studies, experimentation, testing, analysis and research. Virology is becoming increasingly complex, rapidly developing in areas such as nucleic acid technology, antiviral chemotherapy, new viral vaccines, identification of new human viruses, and management of infection control problems in both the hospital and local community. MLS in immunology deals with the body's immune system and its role in infectious diseases, parasitic infestations, allergies, tumour growth, tissue grafts and organ transplants. Medical laboratory science is an evolving science moving into new areas such as cytogenetics and molecular biology.

MLS in cytogenetics are involved in the

processing and analysis of the chromosomes of different types of sample with the purpose of detecting and interpreting chromosomal abnormalities. They analyze blood from individuals from a variety of chromosomal syndromes such as congenital abnormalities, learning difficulties, reproductive difficulties and sexual development-related problems, prenatal diagnosis of chromosomal abnormalities such as Down's syndrome from the amniotic fluid or chorionic villus samples and analyze bone marrow and blood samples from patients with haematological malignancies such as leukaemia to aid diagnosis and management. MLS in molecular biology deals with the molecular basis of biological activity. This field overlaps with other areas of medical laboratory science.

Medical Laboratory Science is one of the most dynamic medical professions. MLS are expected to actively participate in continuous professional development (CPD) by carrying out a mixture of learning activities (attendance of seminars, workshops, paper presentation, reflective practice, book review, publication of articles and books, top up training, training of subordinate staff and other relevant training activities that is relevant to their work). This ensures that they are up-to-date in their practice to enable them practice safely and effectively in the interest of the vulnerable public.

Nigerian patients (customers) require and deserve the best quality of laboratory service. From a customer point, there is a general expectation that the service should produce a precise, accurate, reproducible, timely and cost-effective laboratory results that clinicians need to be able to make an informed decision and judgement in the management of the patient. Quality diagnostic service is not just wished but often produced by the implementation of evidenced-based best practices. The aim of this current editorial is to discuss these evidenced-based best-practices that need to be implemented by MLS in Nigeria to ensure the provision of a quality, customer-focussed and continually improving laboratory service.

Quality Management System -oriented laboratory service delivery

Laboratory quality management system (QMS) is the sum total of all the processes that allow for the effective control of the whole diagnostic process. It includes the use of a documented set of policies and procedures that define how you achieve a defined quality of product or service. In the laboratory, a quality product or service is a service that meets the customer's requirements. It is providing the right result on the right specimen from the right patient in a way that is cost effective (value for money), reliable, accurate, reproducible (best possible care), timely (improving health), communicated effectively

and appropriately by a highly motivated MLS (joy and pride at work) to the users of the service. Quality management system enhances the quality of care offered to the customer. Indicators that can be used to monitor the quality of laboratory delivery include variables such as; turnaround times monitoring, implementation of a robust internal quality control programme and participation in external quality assessment programme. Internal quality control is a way a laboratory can monitor precision and identify possible bias and need for calibration of their equipment. Figure 1 shows the elements of Quality Management.



Figure 1: Element of Quality Management (Lab Test Certification)

Quality Assurance includes all arrangements put in place by a laboratory organization to ensure that products and services meet the quality required by the customer. Other elements of quality assurance include; staff training, proactive maintenance of equipment, use of internal quality control (IQC), enrolment in external quality assessment programmes (EQA), use of standard operating procedures (SOPs), regular performance of quality audits (vertical, horizontal, and examination), submission to accreditation by accreditation agencies (MLSCN) and carrying out of regular user (patients and other users of services) satisfaction surveys. The advantages of having a Quality System is enormous; helps a laboratory achieve accreditation, allows for a better control of processes, drives continuing quality improvement (documented quality system is a mechanism for improvement), it is a proof (particularly in case of litigation) that adequate procedures are in place to allow for the provision of a safe, effective, and high-quality diagnostic service, facilitates an improved service delivery to customers, ensures increased efficiency through reduction of mistakes and waste and it can potentially improve the profitability of the diagnostic laboratory as a business.

Laboratory accreditation is a formal recognition by third-party organizations such as the MLSCN of a laboratory's capability to carry out accurate high-quality diagnostic testing. Individual laboratories themselves must ensure that there are processes in place to ensure that the quality standards of accrediting agencies are being met. The regulatory Medical Laboratory Science Council of Nigeria is expected by law to accredit all diagnostic laboratories in Nigeria based on ISO 15189 as a way of building the confidence of service users and the laboratory that the quality requirements are being maintained and to reduce quackery (Kawai, 2014). During the accreditation process, areas that require attention (non-conformances) are often identified allowing laboratories to focus their improvement efforts in a systematic, action planned and strategic manner. This creates a positive feedback mechanism that helps to accelerate improvements within the laboratory (Peter *et al.*, 2010).

Audits are part of the continuous quality improvement process and one of the key elements of effective clinical governance (Waise, 1999). The implementation of audits in laboratories in Nigeria is poor. There is the urgent need to instil and build a culture of objective and proactive quality auditing of the process in laboratories in Nigeria. A quality audit is a systematic, independent, and documented process of evaluating selected elements of a quality system. It is a systematic examination of a quality system. It is carried out either by an internal or external quality auditor or an audit team. It is an important part of an organization's quality management system and a key element in the ISO quality system standard, ISO 9001 and 15189. It is a requirement of most accreditation bodies (CPA, MHRA, and MLSCN). Audits are an essential management tool used for verifying that standard operating procedures are being followed, that materials required to get work done are in place, and that statutory requirements for carrying out a process are in place. Audits can either be horizontal audit (assessment of one element of the quality system), examination (process whereby the assessor watches a test being performed to ascertain if staff performing task is trained, competent and following the standard operating procedure) or vertical (audit of the entire process and involves a system whereby a named sample is tracked from receipt to the issue or result to enable the identification of all the quality impacting non-conformances in the process) (Erasmus and Zemlin, 2009). Quality audits re-emphasize the following; the importance of proper record-keeping and documentation, the need to work to defined standards and procedures, the importance of effective and appropriate storage and monitoring of temperature-dependent reagents, the need for proactive maintenance of equipment, the need to develop a culture of continuous improvement, the need for an enabling and safe laboratory environment, the need for high morale among staff, the need to investigate all incidents, accidents and near misses, the need for competencies and appraisals of staff, the need for good laboratory practice and effective housekeeping in the laboratory.

There is need to build a culture of internal quality

control in the daily routines in laboratories in Nigeria. Equipment should ideally be maintained daily and quality controlled before patients' samples are tested. Reagents should also be quality controlled daily before use in the testing of patient's sample. All IQC failures must be investigated and patients' samples must not be tested using equipment and reagents unless the equipment have been maintained, the reagent quality controlled quality controlled and found to be fit for purpose (Eden, 2015; Khatri *et al.*, 2013, Westgard, 2001).

There is need for regulatory Medical Laboratory Science Council of Nigeria to implement a robust external quality assessment (EQA) scheme in Nigeria to enable laboratories monitor the accuracy of the result they generate (Prijavudhi *et al.*, 2002; Libeer, 2001). It is not sufficient for diagnostic laboratories in Nigeria to sit back and assume that they are doing fine in terms of quality. In fact, since no system is perfect, there is every likelihood that laboratories do make mistakes. If we do, then it is extremely important to keep data (how many mistakes do we make on a monthly basis and why, are there trends in the number of mistakes we make as a laboratory, how often do we exceed our turnaround times and how often do we produce an incorrect result or send the correct result but for the wrong patient) to enable us monitor trend and implement root cause analysis, solve the problems by implementing corrective action and by extension build a culture of continuous quality improvement. It is vital for every laboratory organization to measure their performance. Measuring our performance is the only way to monitor and measure improvements. Most laboratories in Nigeria don't carry out user satisfaction surveys. One of the cardinal reasons why laboratories exist is to meet the requirement of the user of the service they provide. Customer satisfaction survey is a measure of the extent to which a product or service satisfies customer requirements. Most Laboratory accrediting agencies requires laboratories to assess user satisfaction to allow a laboratory work around meeting the need and requirements of their customers. Quality is defined as the degree to which a set of inherent characteristics fulfils customer requirements. In terms of a laboratory,

quality means the right result on the right specimen from the right patient that is accurate, timely, cost effective and properly interpreted. Customer satisfaction is the customer's perception of the degree to which their requirements have been fulfilled. The two key phrases in these definitions are; fulfils requirements and customer perception. Monitoring of customer satisfaction in the laboratory is one of the most important quality indicators in laboratory service delivery. Measuring and implementing corrective actions and suggestion from the customer are essential aspects in laboratory service delivery. It is vital that laboratories in Nigeria periodically find out what their customers think of the service they provide. It is only by so doing that they can confirm whether their customers are satisfied or not. Also, laboratories can use the information obtained to drive quality improvements within their own process. The advantages of carrying out a customer satisfaction surveys include; enable laboratories to learn the requirements and the level of satisfaction of customers and improve liaison with customers to enable the laboratory put in place strategies to raise the level of customer satisfaction. Customer satisfaction surveys are great ways of getting feedback from your customers that can be used to drive quality improvement of the service rendered (Koh *et al.*, 2014). Carrying out customer satisfaction surveys and implementing quality improvement suggestions made by customers goes a long way to prove to customers that their opinions and suggestions are appreciated and that the service provider listens to the concerns of their customers. Data, comments and suggestions from customers should be objectively and impartially analyzed and corrective actions implemented to increase customer satisfaction (Oja *et al.*, 2006). Ways of carrying out such surveys include the use of printed questionnaires (short, relevant and straight to the point). It should include open ended questions on what customers like about your product or service, what their definition of a good product or service is, ways they think the present product or service can be improved. It can either be; face to face or one on one customer interviews, electronically via e-mails, online, telephone interviews or via post.

Risk analysis -oriented service

Laboratory testing and use of equipment are prone to errors that can potentially occur at pre-analytical, analytical and post-analytical phases of testing. Evaluating these factors and conditions that could lead to errors and outlining the necessary steps to detect and prevent errors before they cause patient harm is critical to effective laboratory service delivery (Njoroge and Nichols, 2014). The accuracy (quality) of laboratory result can be affected by a range of factors, particularly those that occur in the pre-analytical, analytical and post analytical phases of sample analytic process. The process involved in the sample analysis cycle from test ordering to sample collection to transportation to the laboratory up to result transmittance and availability to the requesting clinician. Risk analysis is an attempt to capture all the steps and risk involved in the process of getting a result on a patient sample. It also shows some of the critical control measures put in place in the laboratory/hospital at each step of the analysis cycle to manage this risk. The process of risk analysis can also potentially detect risk for which the laboratory may need to develop critical control. Laboratories should periodically do a risk analysis of their process to identify critical areas in the process where things can potentially go wrong to enable the implementation of corrective measures to be put in place to mitigate the risk.

Training and Competency of Medical Laboratory Scientists

Certification of analyst is a required part of quality assurance. Some acceptable proof of satisfactory training and/or competence with specific laboratory procedures must be established by laboratory managers for each analyst. Execution of these basic procedures will be repeated, if necessary, until satisfactory results are obtained (evaluated based on analytical accuracy and precision). Apart from being certified and licensed to legally practice the profession of Medical Laboratory Science, it is vital that MLS work towards achieving a level of competence equivalent to the training level required for registration by the MLSCN. It is critical for laboratory managers in Nigeria to develop a competency-based training system. It

is evidenced –based best practice for laboratory managers to post only staffs that have been adequately trained and competency tested to carry out assigned task. It is unethical to ask laboratory staff to carry out laboratory testing using equipment that they have not been appropriately trained and certified competent to use. Similarly, laboratory staff should only be rostered to carry out a task within their scope of practice. It is bad practice to ask a laboratory technician for example to carry out a task that is within the scope of practice of a qualified MLS. Having a dedicated training and competency programme is vital and enables the documentation of all staff to ensure that they are fully trained and are keeping up- to- date their knowledge and skills to enable them continue to render a quality service and to prevent inter-analyst variation in testing (Woods *et al.*, 2000). Pre-acceptance testing (reagent certification) and equipment validation

Good Laboratory Practice guidelines emphasize that all reagents intended for use in the analysis of patient sample must be tested and quality controlled and certified fit for it intended use. Such certification must follow accepted procedures, and must be adequately documented. Each container of laboratory reagent must be labelled with information related to its certification value, date, and expiration time. Time expired reagents must never be used for diagnostic purposes on patients' samples. It is best practice that reagents must have pre-acceptance testing done on them when supplied to the laboratory and they must be quality controlled daily before use. Equipment must be proactively maintained and quality controlled with reagents including after every major maintenance work is done on it. Reagents including temperature dependent reagents must be appropriately stored. Most temperature dependent reagents are stored optimally between 2-8^oC. Evidence of temperature monitoring of fridges used for storage of reagents must be kept to show remedial actions taken when temperature is not maintained within the optimum temperature range.

Instrument validation is a process that is very important for any analytical laboratory.

Instrument validation ensures that an instrument is fit for its intended use (fit for purpose). Data produced by faulty instruments may give the appearance of valid data. These events are particularly difficult to detect with modern computer-controlled systems which remove the analyst from the data collection and instrument control functions. Important points on instrument validation include; it is essential that some objective procedures are implemented for continuously assessing the validity of laboratory instrument and the data they provide, these procedures must be executed on a regular basis to establish the continuing acceptable operation of laboratory instruments within manufacturers prescribed specifications, time-related graphical records of the results of these instrument validation procedures (control charts) must be documented either electronically or as a soft copy.

Document Control

A central feature of GLP guidelines is the maintenance of records in a clear, accurate and auditable form. Documentation is important for several reasons; specimen origins, chain-of-custody, raw analytical data, processed analytical data, SOP's, instrument validation results, reagent certification results, analyst certification documents and other relevant records must be available and kept safe for a specified period of time. Maintenance of instrument and reagent certification records provides for post-evaluation of results, even after the passage of several years. Maintenance of all records specified provide documentation which may be required in the event of legal challenges due to repercussions of decisions based on the original analytical results. Many equipment manufacturers now provide many of these capabilities as part of computer packages for operating modern instruments. For example, most modern computer-based instruments will provide for the indefinite storage of raw analytical data for specific samples in a protected (tamper-proof) environment as well as maintenance of historical records of control chart data establishing the operational quality of instruments during any period during which analytical data have been acquired by that instrument. The length of time over which

laboratory records should be maintained will vary with the situation and from one country to the other. The general guidelines followed in regulated laboratories are to maintain records for at least five years. In some countries like the United Kingdom these records are being maintained for as long as 30 years. The development of higher density storage devices for digitized data is making this kind of record-keeping possible.

Management review meeting

Laboratory management must have regular annual management review to identify changes required to the process to ensure that the laboratory continues to meet the changing requirements of users (Theodorou and Giannelos, 2015). It is a way of ensuring governance and management commitment to laboratory service delivery. Laboratory should conduct an annual review of quality policy and objectives of all services. Such review should include; reports from management and supervisors, report of user satisfaction surveys and complaints, internal audit of quality management system, report of external quality assessments, report of any assessment from external organization, report of errors, near misses, unfavourable outcomes, status of preventive and corrective actions and improvements required, evaluation of quality indicators required to monitor the laboratory's contribution to patient care, recent changes to organizational structure, management, resources (human and material) and report on follow up on previous review. Findings from management reviews as well as all agreed actions must be recorded. Management is to ensure that agreed actions are dispatched within set times scales. Management reviews should contain an executive summary that must be sent to accreditation and regulatory agencies.

Implementing the principle of GLP, GMP, Infection Control, Occupational Health and housekeeping.

Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which studies are planned, performed, monitored, recorded, reported and archived. Laboratory testing carried out by MLS are

generally recognized as affecting decisions literally concerned with life and death issues. There is therefore the need to adopt sound laboratory practices directed at assuring the quality of service delivered (Bornstein-Forst, 2017). The primary product of a laboratory is results of analysis carried out on a specimen. The various elements of good laboratory practice that laboratory managers in Nigeria must strive to implement include; use of Standard Operating Procedures (SOP's), availability of statistical procedures for data evaluation, availability and

use of personal protective equipment (PPE), availability and use of infection control equipment, effective management of waste including sharps, availability of post exposure prophylaxis for exposed staff, ensure that staff are up-to-date for the protective vaccination, instrumentation validation, reagent/materials certification, analyst certification, laboratory facilities certification, sample tracking, staff appraisal compliance and continuous professional development (Kuwahara, 2002). Figure 2 shows the elements of GLP.

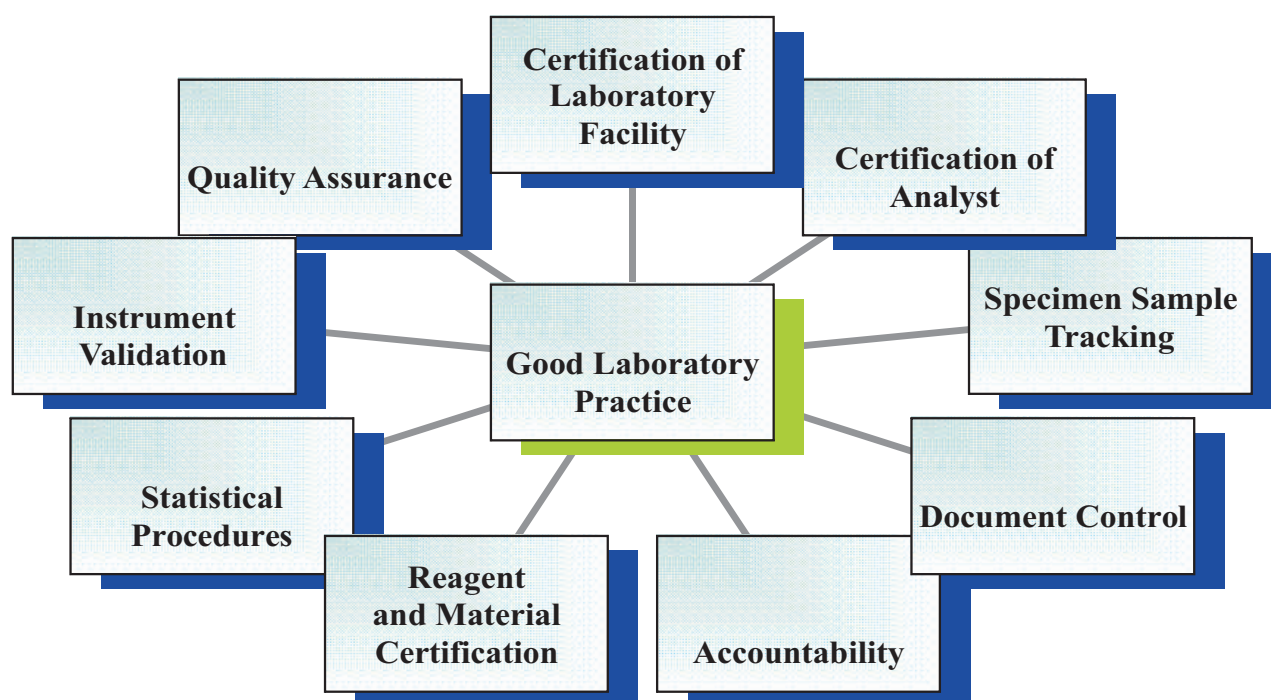


Figure 2: Elements of GLP

Good Manufacturing Practice (GMP) is that part of quality assurance that ensures that products are consistently produced and controlled to the quality standards appropriate for their intended use. It is designed to minimize the risks involved in production. It ensures the safety and efficacy of reagents and services. All activities in the process in the laboratory must follow SOP. All staff involved must be trained and competency assessed regularly. QC must be tested before testing workload. There must be a process for recall of products or result not fit for use. All process must be audited regularly and corrective actions implemented. Cleanliness is essential to prevent contamination (product, equipment and staff). Cleanliness is linked to safety. Workplace

must be kept cleaned and tidy (with documentary evidence that cleaning is being carried out). Equipment must be proactively maintained and cleaned (documented). Personal hygiene is important to prevent contamination (hand washing and removal of laboratory coats before leaving the laboratory). Managers must ensure that laboratory processing and testing areas are not used as a right of way as well as ensure that unauthorized persons are not allowed entry into restricted area. This minimises damage/contamination by those who do not understand the risk associated with working in the laboratory). Use of clearly written documentation prevents errors. Document used must be reviewed regularly and up-to-date (Patel

and Chotai, 2011). Anyone involved in the process can suggest a change to a document (using the continuous improvement form and SOP change form) (Howard, 1979). Document should not be hand written except for entry of

data (must be legible). All entry must be written in permanent ink (use of pencil or correction fluid is not allowed). Table 2 shows the 10 Commandments of Good Manufacturing Practice.

Table 2: 10 Commandments of Good Manufacturing Practice

10 Commandments of Good Manufacturing Practice

- Ensures that all activities in the process in the laboratory must be based on SOP.
- Ensure that all staff involved in process are qualified, trained and competency assessed regularly.
- Quality Control must be tested before testing workload.
- There must be a process for recall of products or result not fit for use.
- All process must be audited regularly and corrective actions implemented.
- Cleanliness and Personal hygiene is vital to prevent contamination (product, equipment and staff).
- Equipment must be proactively maintained
- Ensure prompt and accurate documentation of all work
- Certify all reagents and validate equipment before use
- Ensure traceability (process must be in place for batch or testing to be traced and information retained in a comprehensible and accessible format.

Lab are categorized (type of biohazard handled into pathogen or protection level) P1 to P4. Labs are high- risk environment for exposure to hazardous chemical and bio- hazardous materials. Good lab housekeeping is essential to ensure a clean, safe and pleasant environment. Good housekeeping in the laboratory is essential to prevent accidents and harm to staff and visitors (*Giménez-Marín et al., 2015; Robb and Seddon, 2010; Singer et al., 2009*). Work in the lab is associated with three categories of hazards; chemical (have potential to cause harm or injury if appropriate precaution is not taken), biological (microbes, toxins, organisms, and viral vectors) and physical (electrical, ergonomic hazards, manual handling and handling of sharps). Fire, property loss, injury and loss of life are often associated with poor laboratory housekeeping (*Gauld. and Horsburgh, 2014*). There are several housekeeping dos and don'ts that laboratory managers will need to continue to emphasize and implement. Such housekeeping don'ts include; no mouth pipetting is allowed, no eating, chewing of gum and smoking is allowed in the laboratory, floors, aisles, exits, fire-extinguishing equipment, eyewashes, showers,

electrical and other emergency equipment shall remain unobstructed, storage of food and drink is prohibited in the laboratory, never lick labels of chew pens in the laboratory, never handle the phone, computer mouse or keyboard with hand gloves on, wash your hands before leaving the laboratory, never block emergency exit, never resheath needles, never use the lab as right of way, never smell or taste any chemicals, long hairs, loose clothing and high heeled shoes are not indicated in the laboratory particularly when working with moving equipment and machine, never use electrical equipment in a damp environment, never add water to a concentrated acid but rather always add acid to water slowly, no horseplay is allowed in the laboratory, never temper with equipment provided for health and safety, correction fluid is not allowed in the laboratory (when mistakes are made put a single line through, sign and date it) (*Sewunet et al., 2015*). Housekeeping Do's that should be implemented include; observe universal precaution all the time when working in the laboratory, reduce the risk of slips, trips and falls by cleaning up liquid or solid spills immediately, ensure you protect your own Health and Safety

(H&S) as well as those of your co-workers and visitors, label all containers appropriately (content and date of reconstitution), wear appropriate PPE when required (hand gloves, goggles, apron, lab coats, ear and nose protector), ensure staff are up-to-date with all appropriate protective vaccinations (HBV, TB, etc), segregate appropriately all lab waste and dispose of them safely, keep work benches clean and uncluttered, store heavy items on the lower and lighter items on the upper shelves, use appropriate manual handling tool for all manual handling task, wash your hands before leaving the lab, store flammable and combustible chemicals in flammable cabinet, ensure the lab is sign posted with necessary hazard warnings, ensure that rooms where chemicals are handled are properly ventilated, reduce cosmetic use in the lab, store inflammable chemicals in flammable box or cabinet, report and investigate all accidents, incidents and near misses to appropriate staff, use fume hood when dealing with chemicals (harmful vapours), know the location of all safety and emergency equipment, be up-to-date with mandatory training (fire, infection control, H&S and manual handling), know fire drill procedures, locations of fire exits, know the location and how to use fire extinguishers, dispose chemicals, broken glass and other laboratory materials appropriately, wear shoes that adequately cover the whole foot (low-heeled shoes with non-slip soles), remove any protective equipment (before leaving the lab) and check the label to verify it is the correct substance before using it.

The need for implementation of strategic business principles in Laboratory service delivery

The term strategic planning is used to describe the making long-term decisions and allocating resources to pursue the strategy. It is a crucial management function. It is concerned with the aim and direction of a business. It provides staff with a sense of direction of the business. How well a business is doing is dependent on what extent they have met their strategic and business plan objectives. Regulatory and changing customer requirements are affecting the way

diagnostic service is carried out. Funds for laboratory diagnosis and patient management are on the decline. Population in most countries is gradually aging (increasing need for diagnostic services). This is a growing shift from treating disease to predisposition to diseases (genomics). Laboratory particularly in developing countries may need to work smartly (having a cost saving mentality) without compromising quality. Partnership, consolidation and networking among laboratories seem the way forward (*Plebani, 2002*). Diagnostic services will need to be run with a business mentality. Laboratories will need to implement cost effectiveness plans such as deciding to lease equipment rather than outright purchase and bulk buying of reagents and consumables. Laboratories that must remain afloat in these challenging times must be competitive and develop a competitive strategy by the careful and objective analysis of the 4 key elements of competitive strategy; strengths, weaknesses, opportunities and threats (SWOT) (*Barthel, 2017*). The era of sub optimally endowed laboratories is over forever in Nigeria. Partnership, networking and consolidation are the way forward. Only MLS who think partnership, networking and consolidation are likely to remain in business in future (*Erhabor et al., 2016*). MLS will need to pull their resources together to set up state of the art and fit for the future laboratories. Financial institutions are more disposed to offering loan facility to fit for purpose laboratories. MLS from the various specialities can form a partnership. Resources can be pooled together to ensure an enabling environment, the best equipment and best qualified, motivated and remunerated staff. Diagnostic service must become business oriented and tailored towards meeting the changing needs of the customer. Equipment leasing rather than outright purchase, bulk buying of reagents and consumables (via 3rd party agent) and partnership in the ownership of fit for purpose private laboratories seems future strategic decisions that laboratories in Nigeria will need to make. Networking and consolidation among laboratories, cross disciplinary working (multi-disciplinary

laboratories), use of high throughput analyzers with track system, remote access and validation of laboratory results and outsourcing of low volume expensive low stability reagents associated diagnostic testing.

Process Oriented Diagnostic Service (Identifying and removing waste and non-value adding activity from our process)

Lean is based on Toyota's philosophy that when you make lead time short and focus on keeping production line flexible, you get better quality, responsiveness, productivity, maximize utilization of staff, equipment's and space (Poksinska, 2010). Lean is about speed and continuous removal of waste (*muda*). It is about sorting out, setting apart, shinning, standardizing, sustaining level of quality improvement and being safety conscious. It is the relationship between step and process. It is about eliminating non-value-added elements from the process (Joosten *et al.*, 2009). It is not batching but shrinking sizes down to *create a one-piece flow*. The ideal batch size in a leaned process is one. It also includes a decreased distance that staff needs to travel to complete task. Lean can potentially improve turnaround times for laboratory results. About 70% of patient management decision is dependent on laboratory results. Improvements in the process in the laboratory can have a significant effect on patient waiting time in critical departments (accident and emergency, intensive care unit and high dependency unit) and patient discharge. Lean principle implementation can potentially detect the bottlenecks and waste in the system enabling the process to run more efficiently. The following constitutes waste from lean perspective; injuries (untapped employee creativity, including damage to people like stress), inventory (stuff waiting to be worked, waiting list, and samples waiting to be analyzed), defects (stuff that need fixing, samples that needs repeating), overproduction (unnecessary request and excess inventory), waiting (waiting for materials to arrive), motion (unnecessary human movement, having to walk up and down to obtain appropriate supplies and materials to achieve a given task). Transportation (moving stuff) and processing waste (task that does not add value to process e.g. continuing to care for patient in

hospital when they could be discharged home). Key principles of lean include; value (what the customer perceives as value), value stream (how we deliver value -centred service to our customers from start to finish). Three categories exist in our work; value added (activity that contribute directly to satisfying the needs of customers e.g. having an operation; non-value added (activity that uses time or resources but does not contribute directly to satisfying customer need e.g. waiting for the operation; essential but non-value added (activity that does not add value but required in service delivery e.g. cleaning the theatre. Lean can improve productivity, cost efficiency, quality and service delivery in laboratories. Successful lean improvement has been shown to improve patients care, reduced errors, decreased cost, reduced waiting time, improved networking and interaction among departments and increased employee satisfaction (Naidoo and Mahomed, 2016).

Reducing Incidents and Accidents

GLP and GMP principles require that all errors, near misses, incidents, accidents and complaints should be reported and investigated. The prompt reporting and management of incidents, accidents and near-misses is a key element in the governance of a laboratory organisation. Having a system that enables the capture and analysis of incident information in a timely fashion is the cornerstone to effective risk management and can assist in the learning of lessons, prevention of harm, improvement of performance and building of a culture of continuous quality improvement. Reducing mishaps, accidents and incident in patient management is central to efforts to improve quality and lower costs. Effective feedback from incident reporting is essential for organizational learning (Rooksby *et al.*, 2007). Risk rating of laboratory incident (severity) can either be; none, minor, moderate, major or catastrophic. Likelihood of incident occurring can either be; rarely, unlikely, possible, likely or almost certain. The MLSCN requires that all incidents in the laboratory is investigated and reported in a timely fashion. The laboratory and hospital environment are risky environment where accidents can potentially occur. As a

patient, you are a hundred times more likely to die from a critical incident or error in the hospital environment than you are in a transport accident (Fetherston, 2015). Human error, unsafe procedures and equipment, underlie many of the accidents and incidents which occur in a hospitals environment (Kohn *et al.*, 2000). The aim of reporting and investigating incidents include; to obtain accurate data (collected immediately after incident), ensure optimum learning outcome (build a culture of CQI) and implementation of corrective actions to avoid subsequent occurrence of the incident (Mahajan, 2010). Objectives of incident reporting and management include; to ensure that all incidents relating to quality and safety are recorded promptly and appropriately investigated in accordance GLP & GMP principles, to instil the culture of corrective and preventive action to prevent the re-occurrence of incident, it ensures that accurate record of incident is available in case of audit and investigation and it facilitate the reporting of incidents to statutory authority like the MLSCN. There is need for the implementation of incident reporting scheme in Nigeria. MLS need to be enlightened on types of incidents to be reported, the process needs to be simplified with feedback given to reporters and it should not be punitive (Travaglia *et al.*, 2009). Examples of incidents, accidents and near misses in the lab that should be reported and investigated include; laboratory testing error, needle stick injury, blood transfusion reaction and other transfusion-related adverse events, blood administration errors, transfusion of bacterial contamination of blood products.

Conclusion

Provision of a quality, customer-focussed and continually improving diagnostic service is a possibility in Nigeria. It will not come by wishful thinking but rather from the implementation of evidenced –based best practices; provision of a quality management system oriented service, implementing quality audits, IQC and EQA, document control, carrying out customer satisfaction surveys and risk analysis, having a robust training and competency testing programme, investigation of all incidents,

accidents and near misses, implementing a process-oriented diagnostic service concentrating on the continual identification and removal of waste and all non-value adding activities from the process, implementing the principle of GLP, GMP, infection control, occupational health and housekeeping, pre-acceptance testing (reagent certification) and equipment validation prior to use, implementing governance by having periodic management review meeting and running the service as a business with a strategic mind-set.

References

- Barthel, M. (2017). Achieving success in the clinical laboratory through strategic planning. *Medical Laboratory Observer*. December 21, 2017.
- Bornstein-Forst, S.M. (2017). Establishing Good Laboratory Practice at Small Colleges and Universities. *Journal of Microbiology and Biology Education*; 18(1):18.1.10.
- Bosch, G. and Casadevall A. (2017). Graduate Biomedical Science Education Needs a New Philosophy. Pirofski L-A, ed. *MBio*; 8(6): e01539-17.
- Brass, E.P. (2009). Basic Biomedical Sciences and the Future of Medical Education: Implications for Internal Medicine. *Journal of General Internal Medicine*; 24(11):1251-1254.
- Cunningham, F.C., Ranmuthugala, G., Plumb, J., Georgiou, A., Westbrook, J.I. and Braithwaite, J. (2013). Health professional networks as a vector for improving healthcare quality and safety: a systematic review. *British Medical Journal of Quality and Safety*; 21(3):239-249.
- Eden, P.R. (2015). Quality control in clinical laboratory samples. *Medical Laboratory Observer*. January 18, 2015.
- Erasmus, R.T. and Zemlin, A.E. (2009). Clinical audit in the laboratory. *Journal of Clinical Pathology*; 62(7):593-597.
- Erhabor, T. (2018). Ag. Registrar/CEO Medical Laboratory Science Council of Nigeria Plot 1166 Mohammed N. Umar Lane, Durumi Phase 2, Abuja – FCT.
- Erhabor, O., Abdulrahman, Y., Egenti, B.N., Buhari, H., Fredricks, C., et al. (2016) Strategic Business Planning in Key to



- Effective Diagnosis and Management of Blood Disorders in Developing Countries. *Journal of Blood Disorders and Transfusion*; 7: 350.
- Federal Republic of Nigeria (2007). National Human Resources for Health Strategic Plan 2008 to 2012:12-14.
- Ferraro, S., Braga, F. and Panteghini, M. (2016). Laboratory medicine in the new healthcare environment. *Clinical Chemistry and Laboratory Medicine*;54(4):523-533.
- Fetherston, T. (2015). The importance of critical incident reporting – and how to do it. *Community Eye Health*; 28(90):26-27.
- Gauld, R. and Horsburgh, S. (2014). Healthcare professional perspectives on quality and safety in New Zealand public hospitals: findings from a national survey. *Australian Health Review*; 38(1):109-114.
- Giménez-Marín, A., Rivas-Ruiz, F., García-Raja, A.M., Venta-Obaya, R., Fusté-Ventosa, M., Caballé-Martín, I., Benítez-Estevéz, A., Quinteiro-García, A.I., Bedini, J.L., León-Justel, A. et al. (2015). Assessment of patient safety culture in clinical laboratories in the Spanish National Health System. *Biochemistry Medicine (Zagreb)*; 25(3):363-376.
- Howard, T. (1979). Personnel Elements of Good Laboratory Practices. *Clinical Toxicology*; 15:527-538
- Joosten, T., Bongers, I. and Janssen, R. (2009). Applications of lean thinking in Health care: Issues and observations. *International Journal for Quality in Health Care*; 21(5): 341-347.
- Kawai, T. (2014). Significance of clinical laboratory accreditation based on ISO 15189, and recent trend of international clinical laboratory accreditation program. *Rinsho Byori*; 62(6):615-619.
- Khatri, R., Shrestha, P. and Sinha, J.N. (2013). Implementing self-sustained quality control procedures in a clinical laboratory. *Journal of Nepal Medical Association*; 52(189):233-237.
- Koh, Y.R., Kim, S.Y., Kim, I.S., Chang, C.L., Lee, E.Y., Son, H.C., & Kim, H.H. (2014). Customer Satisfaction Survey with Clinical Laboratory and Phlebotomy Services at a Tertiary Care Unit Level. *Annals of Laboratory Medicine*; 34(5): 380–385.
- John, L.T., Corrigan, J.M. and Donaldson, M.S. (2000). To err is human: building a safer health system. Washington, DC: National Academy Press: 1–16.
- Kuwahara, S.S. (2002). Good laboratory practice to good manufacturing practice transitions during the product development process. *Journal of Good Practice Complement*; 7(1):13–19.
- Liberer, J.C. (2001). Role of external quality assurance schemes in assessing and improving quality in medical laboratories. *Clinical Chemistry Acta*; 309(2):173-177.
- Mahajan, R.P. (2010). Critical incident reporting and learning, *BJA: British Journal of Anaesthesia*; 105 (1): 69–75.
- Naidoo, L., Mahomed, O.H. (2016). Impact of Lean on patient cycle and waiting times at a rural district hospital in KwaZulu-Natal. *African Journal of Primary Health Care & Family Medicine*: 1-9.
- Njoroge, S.W., Nichols, J.H. (2014). Risk Management in the Clinical Laboratory. *Annals of Laboratory Medicine*; 34(4):274-278.
- Ogrinc, G., Headrick, L.A., Mutha, S., Coleman, M.T., O'Donnell, J. and Miles, P.V. (2003). A framework for teaching medical students and residents about practice-based learning and improvement, synthesized from a literature review. *Academic Medicine*; 78(7):748-756.
- Oja, P.I., Kouri, T.T. and Pakarinen, A.J. (2006). From customer satisfaction survey to corrective actions in laboratory services in a university hospital. *International Journal of Quality Health Care*; 18:422–428.
- Patel, K. and Chotai, N. (2011). Documentation and Records: Harmonized GMP Requirements. *Journal of Young Pharmacists*; 3(2):138-150.
- Peter, T.F., Rotz, P.D., Blair, D.H., Khine, A.A., Freeman, R.R. and Murtagh, M.M. (2010). Impact of Laboratory Accreditation on Patient Care and the Health System. *American Journal of Clinical Pathology*; 134 (4):550–555.
- Plebani, M. (2002). Charting the course of medical laboratories in a changing environment. *Clinical Chemistry Acta*; 319:87-100.

- Poksinska, B. (2010). The current state of lean implementation in health care: Literature review. *Quality Management in Health Care*; 20(2):319-329.
- Prijavudhi, A., Kotivongsa, K., Cotivongsa, P. and Pavaro U. (2002). Thailand intensive external quality assessment schemes as dynamic tools for improving laboratory quality and standard. *Southeast Asian Journal of Tropical Medicine and Public Health*; 33(2):14-17.
- Robb, G. and Seddon, M. (2010). Measuring the safety culture in a hospital setting: a concept whose time has come? *New Zealand Medical Journal*; 123(1314):68-78.
- Rooksby, J., Gerry, B. and Smith, A.F. (2007). Incident reporting schemes and the need for a good story. *International Journal of Medical Information*; 76: 205-211.
- Sewunet, T., Kebede, W., Wondafrash, B., Workalemaw, B. and Abebe, G. (2014). Survey of Safety Practices among Hospital Laboratories in Oromia Regional State, Ethiopia. *Ethiopian Journal of Health Sciences*; 24(4):307-310.
- Singer, S.J., Gaba, D.M., Falwell, A., Lin, S., Hayes, J. and Baker, L. (2009). Patient safety climate in 92 US hospitals: differences by work area and discipline. *Medical Care*; 47(1):23-31.
- Theodorou, D. and Giannelos, P. (2015). Medical laboratory quality systems - a management review. *International Journal of Health Care Quality Assurance*; 28(3):267-273.
- Travaglia, J.F., Westbrook, M.T. and Braithwaite, J. (2009). Implementation of a patient safety incident management system as viewed by doctors, nurses and allied health professionals. *Health (London)*; 13(3):277-296.
- Waise, A. (1999). Clinical audit and the contribution of the laboratory to clinical outcome. *Clinical Chemistry Acta*; 280(1-2):47-57.
- Westgard, J.O. (2001). Electronic QC, the total testing process and the total quality control system. *Clinical Chemistry Acta*; 307: 45-48.
- World Health Organization (2016). Health Workforce Requirements for Universal Health Coverage and the Sustainable Development Goals. Background Paper No. 1 to the Global Strategy on Human Resources for Health.
- Woods, R.S., Longmire, W., Galloway, M.J., et al. (2000). Development of a competency-based training programme to support multidisciplinary working in a combined biochemistry/haematology laboratory. *Journal of Clinical Pathology*; 53:401-404.

Citation: Erhabor, O., Erhabor, T., Okara, G.C., Adias, T.C., Dangana, A. Provision of a Quality, Customer-Focussed and Continually Improving Laboratory Service in Nigeria. *Sokoto Journal of Medical Laboratory Science*; 3(3): 5 - 20

Copyright. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.