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RESEARCH ARTICLE

Medical Laboratories in Nigeria (Part 1): Assessment of Quality Management Practices and Accreditation Status

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ABSTRACT

Background: ***Given*** **observed challenges with the quality of results, this study was aimed at assessing the current level of the use of aspects of quality management practices by medical laboratories in the south-south region of Nigeria.**

Methods: **This was a cross-sectional survey of 80 randomly selected medical laboratories from the 6 states of south-south Nigeria. Self-administered questionnaires on aspects of quality management practices were given to selected staff of each laboratory.**

Results: **Out of the 80 questionnaires, only 42 were completed. None (0%) of the laboratories were accredited for quality service delivery. Only 88% of the laboratories were licensed by relevant authorities. 90% of the laboratories used quality control (QC) sera for their operations. 30% used commercial QC. 70 % used unreliable locally-produced QC. 90% reported that their equipment was regularly maintained (66% by Biomedical Engineers and 24% by Medical Laboratory Scientists). 90% of the laboratories claimed to calibrate their equipment regularly by Biomedical Engineers (66%) and Laboratory Scientists (24%). 74% of the laboratories were headed by Laboratory Scientists; 26% by Pathologists. 62% of the laboratories used de-ionized water; 13% distilled water; 7% used both interchangeably. 60% bought their water commercially; 40% produced their water locally. Only 10% of the laboratories had means of monitoring the water quality. Only 21% were enrolled on EQA schemes. 80% bought their reagents in the open market. 90% used the poor-quality national grid as their main source of electricity supply. Only 40% had training/re-training programs for their staff. Only 45% of the laboratories used SOPs in their operations.**

Conclusion: **The results of this study indicate that currently, the majority of the medical laboratories in south-south Nigeria have not sufficiently embraced the use of several aspects of the quality management essentials in their routine operations. This state of affairs is a recipe for unreliable and poor-quality results that may lead to wrong diagnoses and mismanagement of patients.**

Keywords: Accreditation, Laboratories, Quality management.

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1. Introduction

Medical laboratories produce results which are used by clinicians in making critical diagnostic and therapeutic decisions. These results are expected to be reliable, accurate and timely. The consequences of inaccurate laboratory results are huge and grave and may lead to wrong diagnoses, wrong clinical management, prolonged periods of treatment, unnecessary wastage of scarce resources or inadvertent loss of lives.

Biochemical laboratory assays are largely procedures involving the measurement of the concentration of biochemical parameters in clinical specimens [1]. Thus, as applicable to any measurement process, some inherent random and/or systematic errors may be encountered during the analytical process. Varying degrees of these errors in

different laboratories may lead to differences in the numerical value of analytical results for the same parameter in the same clinical specimen from different medical laboratories.

However, despite these inherent errors of measurement, it is still expected that results for the same parameter from the same sample produced by different medical laboratories should be in agreement within an allowable margin of error, regardless of the method of analysis used. It is also vitally important and desirable that results from different laboratories for the same parameter should be similar and comparable, and should lead to the same clinical diagnostic and therapeutic decisions. It is only when these conditions are fulfilled and satisfied that there could be reasonable interdependency of results from different medical laboratories globally.

The introduction of the quality management essentials in medical laboratory practice by the International Standard Organization (ISO) was aimed at standardizing laboratory practice and promoting interdependency of results from different laboratories [2]. This would only be possible if the inherent errors in the measurement processes of laboratories are reduced to the barest minimum. This could be achieved by standardizing every step of the analytical process from the stage of specimen acquisition through to the stage of reporting and interpretation in all medical laboratories.

Practically, however, it is known that the numerical value of results from different medical laboratories may be significantly different from each other, leading to different diagnostic and therapeutic decisions. These differences and discrepancies in the numerical values of such medical laboratory test results usually arise from errors occurring at different stages of the total testing process. Testing processes and procedures like patient preparation, sample collection, transferring the right sample into the right sample container, mode of transportation, nature of sample storage and so on, are all prone to errors (pre-analytical errors), which constitute about 70% of errors affecting the accuracy of laboratory results [3].

Analytical errors could be reduced through processes such as the right application of Standard Operating Procedures (SOPs), the use of the proper quality of reagents, the use of appropriate quality control materials, the functional state and efficiency of analytical equipment used, proper and regular calibration and recalibration of equipment, etc. Other sources of analytical errors may include non-conducive working environments such as; poor air-conditioning, lack of regular and good quality electricity supply, and poor laboratory ergonomics. Lastly, in the post-analytical phase, the verification, transcription, interpretation and reporting of laboratory results could also constitute common sources of error.

All processes involved in the laboratory analytical value chain need to be standardized globally to reduce these inherent errors across laboratories. This standardization has been articulated by the International Standard Organization through the introduction and implementation of the 12 quality management essentials in medical laboratory practice (ISO 15189) [4].

To monitor the conformance and compliance of medical laboratories to these set standards, these laboratories are usually periodically audited and accredited by certified and registered accreditation agencies in different countries and regions of the world [4]. This process of accreditation and certification is necessary and mandatory for the licensing of medical laboratories to perform laboratory analysis on clinical specimens and has been adopted as a standard practice in most developed countries and many developing regions of the world. This certification is a quality assurance process that ensures that such certified laboratories can produce good quality and reliable results, thus ensuring the interdependency of results from different medical laboratories.

Unfortunately, in many developing countries, including Nigeria, it has been difficult to introduce and implement the twelve quality management essentials in medical laboratory practice [5]. This has largely resulted from a lack of adequate resources (infrastructure, equipment, equipment maintenance, manpower, financial, regulatory oversight, and so on) for modern standard medical laboratory practice. The result has been a lack of adequate legal and regulatory framework for the delivery of good quality medical laboratory services in these developing countries.

Consequently, in most of these developing countries, especially in sub-Saharan Africa, medical laboratories are not mandatorily audited or accredited for quality service delivery, hence the results from these laboratories may be largely inaccurate and unreliable. This will therefore mean that results from different laboratories in these regions may not be readily comparable and interdependent.

Given these prevailing circumstances, this study (Part 1) was therefore aimed at assessing the current level of adoption of quality management practices, including quality assurance and quality control practices and accreditation status of medical laboratories in the south-south geo-political (Niger Delta) region of Nigeria, as a reflection of the current state of medical laboratory practice in the entire country.

2. Methods

This was a cross-sectional study where 80 medical laboratories, public and private, including some in tertiary hospitals (Teaching Hospitals, Federal Medical Centers), General hospitals, private clinics/hospitals and private medical laboratories/diagnostic centers, were randomly selected from across all the 6 states of the South-South (Niger delta) geo-political region of Nigeria (Edo, Delta, Bayelsa, Rivers, Akwa Ibom and Cross Rivers states). This was made up of 9 tertiary hospital laboratories, 23 Public General Hospital laboratories and 48 Private laboratories (see distribution in Table I). Self-administered questionnaires were given to selected key staff of each laboratory by a local collaborator. The questions related to several aspects of the quality management system as practised in the laboratories. Other relevant information about the laboratories' operations was elicited to assess their level of compliance with internationally accepted standard quality management practices and procedures. Observations of some basic facts and processes were carried out by local study collaborators to authenticate some of the answers

given. Responses from the questionnaires were analysed with Microsoft Excel software.

TABLE I: Total Quality Management Practices

Number of questionnaires sent out	80 (100%)
Number of questionnaires completed	42 (52.5%)
Type of laboratory	
Private	56 (70%)
(Corporate)	35 (44%)
(Sole proprietor)	21 (26%)
Tertiary/Teaching hospital	8 (10%)
General hospitals	16 (20%)
Use of quality control materials	
Yes	37 (88%)
No response	05 (12%)
Locally repaired control materials	29 (78%)
Commercial control materials	8 (22%)
Laboratories accredited for training	6 (14%)
Laboratories accredited for quality service	0 (0%)
Laboratories with foreign affiliation	6 (14%)
Licensed laboratories by:	
State ministry of health	37 (88%)
MLSCN	8 (19%)
Both	08 (19%)
Not licensed	**05 (12%)**
Regular maintenance of equipment	**38 (90%)**
Maintenance of equipment done by:	
Biomedical engineers	25 (66%)
Lab. scientists	9 (24%)
Manufacturer's rep	4 (10%)
Regular calibration of equipment	
Yes	38 (90%)
No	4 (10%)
Calibration done by:	
Biomedical engineers	25 (66%)
Lab. scientists	9 (24%)
Manufacturer's representatives	4 (10%)
Headship of laboratories:	
Pathologist	11 (26%)
Laboratory scientist	31 (74%)
Others	0 (0%)
Quality of water used	
Deionized water	26 (62%)
Distilled water	13 (31%)
Both	3 (7%)
Source of water	
Commercial	25 (60%)
Locally produced	17 (40%)
Monitoring of water quality	
Yes	4 (10%)
No	38 (90%)
Source of reagent	
Open market	34 (80%)
Licensed dealer	8 (20%)
Training and retraining programs	
Yes	17 (40%)
No	25 (60%)
Source of power supply	
National grid	38 (90%)
Generators	4 (10%)
Use of standard operating procedures (SOP)	
Yes	19 (45%)
No	23 (65%)
Participation in external quality assurance scheme	
Yes	9 (21%)
(Tertiary hospitals)	5 (11%)
(Cooperate/private labs)	4 (10%)
No	33 (79%)

3. Results

A total of 80 laboratories selected from the 6 states of the south-south geo-political zone of Nigeria were enrolled on this study, of which 8 (10%) were serving public (Government) Teaching/Tertiary Hospitals, 16 (20%) were serving public (Government) General hospitals while 56 (70%) were privately owned. The 21 (26%) of the privately owned laboratories were owned by individuals (sole proprietors) while the rest of 35 (44%) were corporate (limited liability company) laboratories. The 6 (14%) of the corporately owned private laboratories had foreign affiliations.

Questionnaires were sent to all the enrolled laboratories but only 42 (52.5%) out of the 80 questionnaires were completed and voluntarily returned. The remaining 38 (47.5%) laboratories did not return the questionnaires. The reasons for not completing/returning the questionnaires were not stated.

3.1. Quality Management Practices

i) *Accreditation Status*: None (0%) of the laboratories were accredited for quality service delivery. 6 (14%) of the laboratories were accredited for manpower training by their respective regulatory bodies and they were mostly laboratories serving Teaching/tertiary hospitals which were accredited for the training of medical students, resident doctors (Pathologists) and/or medical laboratory scientists. 6 (14%) of the private corporately-owned laboratories had foreign affiliations.

ii) *Licensing Status*: Most of the laboratories 37 (88%) claimed to be licensed either by their respective State Ministries of Health or regulatory bodies Medical Laboratory Science Council of Nigeria (MLSCN) 8 (19%) or both 8 (19%).

iii) *Use of Quality Control Sera*: 37 (88%) of the laboratories claimed to use quality control materials in their routine operations while 5 (12%) laboratories gave no response to this question. 29 (70%) laboratories used locally prepared control sera while only 8 (30%) used commercially prepared control materials. Those that used commercially prepared quality control materials were mostly the tertiary hospitals, some corporate laboratories and a few general hospital laboratories.

iv) *Equipment Maintenance*: 38 (90%) of the laboratories reported that their laboratory equipment was regularly maintained at different periods, depending on the schedule of the laboratory. The maintenance activity was reported to be carried out by Biomedical Engineers in 25 (66%) and by Laboratory Scientists in the remaining 9 (24%) laboratories.

v) *Equipment Calibration*: 38 (90%) laboratories reported that they undertake regular calibration of their equipment, while 4 (10%) laboratories did not calibrate their equipment regularly. 25 (66%) of the laboratories reported that their equipment calibration was routinely done by Biomedical Engineers, while it was done by Laboratory Scientists in the remaining 9 (24%) laboratories.

vi) *Headship of Laboratories*: 31 (74%) of the laboratories were headed by Laboratory Scientists while 11 (26%) laboratories were headed by Pathologists. The 11 laboratories headed by Pathologists were made up of 8 tertiary hospital laboratories and 3 private corporate-owned ones. All (100%) the sole-proprietor-owned laboratories were headed by Laboratory Scientists.

vii) *Type and Quality of Water*: 26 (62 %) of the laboratories used de-ionized water while 13 (31%) used distilled water. The 3 (7%) of the laboratories claimed to use both de-ionized water and distilled water interchangeably, depending on which was available at any given time.

viii) *Source of Water*: 25 (60%) of the laboratories purchased their water from commercial sources, while 17 (40%) generated their water internally.

ix) *Monitoring of Water Quality*: Only 4 (10%) of the laboratories claimed to routinely monitor the quality of the water used in their routine operations. These comprised 1 public tertiary hospital laboratory and 3 corporate-owned private ones. The remaining 38 (90%) laboratories did not monitor the quality of water used in their routine operations.

x) *Participation in External Quality Assessment (EQA) Schemes*: 9 (21%) of the laboratories claimed to participate in external quality assurance (EQA) schemes. These were made up of 5 (56%) public tertiary hospital laboratories and 4 (44%) private corporately-owned laboratories. The other 33 (79%) did not participate in any EQA scheme.

xi) *Source of Reagents*: 8 (20%) of the laboratories purchased their reagents from accredited/licensed dealers, while 34 (80%) purchased their reagents from the open market.

xii) *Main Source of Power Supply*: 38 (90%) laboratories depended on the national grid as the main source of their electricity supply, while only 4 (10%) laboratories used Electricity Generators as their main source.

xiii) *Regular Use of Training/Re-Training Programs*: 17 (40%) of the laboratories had regular training/re-training programs for their staff, while 25 (60%) did not have any training/re-training programs.

xiv) *Availability and Use of Standard Operating Procedures (SOPs)*: 19 (45%) laboratories reported availability and regular use of SOPs in their routine operations, while in twenty-three laboratories, SOPs were not available nor regularly used.

4. Discussion

This study was essentially designed to evaluate the current accreditation status, quality management and quality assurance practices of medical laboratories in the south-south geo-political region of Nigeria. The research questionnaire given to the participating laboratories was designed to evaluate these parameters, but regrettably, about half 38 (47.5%) of the participating laboratories failed to complete the questionnaires and no reasons were given for this inaction. It may thus be reasonably postulated that this could have been due to some reluctance to expose their poor-quality management practices. This definitely constitutes a significant red flag concerning quality management practices, as laboratories with standard quality management practices would gladly identify with such policies and practices with the aim of further improvement if the need arises.

42 (52.5%) laboratories that completed the questionnaire for this study, none were locally accredited for quality service delivery, as there is presently no such quality conformance assessment service or agency available in the country [6]. The 6 out of the 35 (17%) Corporate private laboratories with international affiliations claimed to have been accredited for quality service delivery by foreign accreditation agencies. What was observed, though, was an affiliation certificate, which was questionable and not verified.

This is a sad state of affairs for our medical laboratories in this 21st century. Worse still, there are presently no legislations or regulatory policies for quality audit and accreditation of medical laboratories in Nigeria before they can be licensed for clinical service delivery. The need to urgently reverse this state of affairs in Nigeria cannot be over-emphasized as it will serve as the first step in the right direction in terms of quality service delivery.

In place of quality management accreditation, (37) (90%) of these surveyed laboratories reportedly were licensed by their respective State Ministries of Health. 8 (19%) laboratories were also concomitantly licensed by the Medical Laboratory Science Council of Nigeria (MLSCN). Such licensing legalized their operations. The licensing procedures usually involve inspection and verification of available infrastructure, equipment and manpower after payment of some stipulated licensing fees. The emphasis here is usually on the payment of some stipulated or statutory fees and taxes, without an assessment of their quality management practices. This means the licensing process as now practiced will not necessarily guarantee quality results.

Interestingly, the results of this study still indicate that about 5 (12%) of our medical laboratories are not even licensed. The chances of having instituted quality management practices in these types of unlicensed laboratories would be more remote as compared to those that are licensed.

However, the results of this study show that 6 (14%) of the participating laboratories were accredited for the training of undergraduate medical students, medical laboratory scientists and postgraduate residency training programs for Pathologists. These training accreditations are usually performed by the Nigerian Medical and Dental Council for undergraduate medical training, the West African College of Physicians, the West African College of Surgeons and/or the Nigerian Postgraduate Medical College

for postgraduate residency training in various specialities of medicine, including Pathology and the Medical Laboratory Science Council of Nigeria for the training of undergraduate medical laboratory scientists, respectively. These training accreditations usually only involve resource verification for infrastructure, equipment and manpower for the respective training programs and are usually minimally concerned with quality management assessment which affects the quality of results.

A similar scenario was seen with regard to participation in External Quality Assessment (EQA) schemes. Only 9 (21%) of the laboratories that completed the study questionnaire claimed to have participated in any EQA scheme. This consisted of 4 private corporate laboratories and 5 tertiary/teaching hospital laboratories. Surprisingly not all the tertiary/teaching hospital laboratories accredited for training participated in the EQA schemes. The rest of the laboratories (79%) did not participate in any such EQA scheme. This state of affairs is not consistent with international quality management best practices and is certainly undesirable for medical laboratory practice in a country that is as endowed as Nigeria in terms of human and material resources in this 21st century.

Though 37 (88%) of the laboratories that completed the questionnaires claimed to use quality control materials while performing laboratory analyses, the majority could not show their quality control charts, citing management directives/decisions. This was rather unexpected and unusual as medical laboratories that had instituted such quality management practices as part of their standard operating procedures would have willingly shown off these charts. It could therefore be reasonably inferred that these medical laboratories without records of serial quality control charts for the different parameters that they assay are unlikely to have been using "acceptable" quality control materials and practices. This casts some doubt on the quality of their results. Good record-keeping constitutes an important part of quality management practice. Therefore, the lack of such important records as serial quality control charts constitutes another significant red flag in our medical laboratory practice [7].

Even among those that claimed to use quality control sera for their assays, only 8 (30%) were using the reliable and traceable commercial quality control sera, while 29 (70%) were using unreliable "locally prepared" quality control sera with doubtful and probably inaccurate assigned values. This is an unhealthy quality management practice which may lead to "in-breeding" and replication of errors in a literal scenario of "the blind leading the blind".

All the participating laboratories (100%) claimed to use either distilled water or de-ionized water, which was either commercially purchased or locally produced. The importance of using either quality of water was however defeated since most of the laboratories had no means of testing and confirming the quality of the water used for their routine analyses. Since the day-to-day quality of both types of water is based on the functional status of the distilling or de-ionizing equipment, malfunctioning equipment may produce water of poor quality, which may adversely affect the numerical results of the analytical process. This applies both to analytical water produced in-house or bought from different commercial sources. Worse still is the fact that in some of the laboratories 3 (7%) reported using de-ionized and distilled water interchangeably. This is not good quality management practice as the electro-physical properties of these different water varieties may affect the eventual numerical results produced [8].

From the results of this study, 34 (80%) of the participating laboratories purchased their laboratory reagents from the open market and only 8 (20%) made their purchases from approved/licensed/authorized agents or dealers. This practice is a big challenge that should not be encouraged as the quality of reagents from such open markets may not be optimal. This is because traders in the open market are likely to be untrained and may be ethically deficient, especially concerning storage conditions. Furthermore, open market business is known to be largely profit-driven rather than quality considerations [9]. Though the open market promotes competitive pricing among dealers and may be more easily accessible to laboratories, regulating the quality of reagents sold may be difficult [9].

It is recommended that there should be instituted regulations and legislation that encourage the practice of assessing and guaranteeing the quality of medical laboratory reagents and supplies before purchase, including a ban on the sale of laboratory reagents in the open market. This would put a check on the sale of low-quality reagents in the country and contribute to the production of better-quality results from our medical laboratories.

To further improve on the quality of diagnostic equipment, kits and reagents, it may be necessary to enforce pre-shipment inspection of these largely imported items by the relevant government-appointed pre-shipment inspection agents. This can be done through appropriate legislation. The National Agency for Food and Drug Administration and Control (NAFDAC) and, to an extent, the Standards Organization of Nigeria (SON), may already be playing some role in this regard, but there is an urgent need for improved efficiency and effectiveness [10]. Improved collaboration with relevant professional bodies and other stakeholders in this area will further enhance the fight against low-quality imported laboratory equipment, reagents and kits. One of these collaborating institutions should have the sole responsibility of licensing dealers. The effect of poor-quality equipment, reagents and kits on the quality of generated laboratory results is obvious and often associated with systematic errors as seen in other previous studies [11], [12].

Apart from the corporate private laboratories and those attached to tertiary institutions, all the other laboratories were headed by Laboratory Scientists and in most cases, they were also the sole proprietors. These Laboratory Scientists in most of the privately owned laboratories were the only professionally qualified staff, as other members of staff were called Laboratory Assistants with little or no training and certification. It was observed that most times, the processes of sample collection, sample preparation and storage were done by these staff (laboratory assistants), forgetting that about 70% of laboratory errors occur at these pre-analytical stages [2]. This also suggests that one person (the sole proprietor) may be responsible

for performing every investigation, regardless of his area of specialization, thereby calling his expertise into question.

Depending on the number of tests performed per day, these sole proprietor Laboratory Scientists may be overworked, with the consequence of increasing various analytical errors occasioned by fatigue. Again, this could mean that he or she may be supervising himself, which is a practice that is deemed non-optimal for good-quality results.

All the laboratories (42/100%) claimed to have regular maintenance of their equipment. Maintenance was claimed to be done by Biomedical Engineers in 29 (69%) laboratories; by Medical Laboratory Scientists in 9 (21%) laboratories and by Manufacturer's Representatives in 4 (10%) laboratories. For those laboratories where routine equipment servicing and maintenance was being done by manufacturer's representatives, it would have been largely due to the terms of the equipment purchase, most probably from an authorized vendor. Though this is a good and recommended practice, regrettably, however, the percentage of laboratories with such service contracts was relatively poor (10%). This could be due to the relatively higher cost of purchasing laboratory equipment from established and licensed vendors or manufacturers' representatives. Laboratories would rather buy from the open markets, without any service agreement, since they are usually relatively cheaper. Sadly, the long-term effect of this mode of purchase is the use of equipment that may not be performing optimally, which may affect the quality of the laboratory results adversely, with subsequent deleterious effects on patient management.

However, it should be noted that it is a known fact that there is a dearth of properly trained and certified Biomedical Engineers in most developing countries, Nigeria inclusive. It is thus most likely that those who were referred to as Biomedical Engineers may not have been properly trained and certified by any statutory regulatory agency. For now, Nigeria has no such statutory regulatory agency for the certification and registration of Biomedical Engineers, to the best of our knowledge. It is thus most probable that those involved in the routine maintenance of equipment in the majority of our medical laboratories may be improperly trained "quacks". This state of affairs may adversely affect the functional status of equipment in most of our laboratories, with dire consequences on the quality of our laboratory results.

Similarly, most (38/90%) of the laboratories claimed that they undertook regular calibration/re-calibration of their equipment. Calibration was claimed to be done by Biomedical Engineers in 25 (66%) laboratories and by Laboratory Scientists in 9 (24%) laboratories. The frequency of maintenance, calibration and recalibration varied from daily to weekly, monthly or quarterly and this was found to be largely based on equipment malfunction and troubleshooting, rather than the manufacturer's recommendations.

Again, the same scenario applies with regards to the training and certification of these "so-called" Biomedical Engineers, as it is likely the same "Biomedical Engineers" that carry out the equipment maintenance that would also calibrate them. This is definitely another red flag with regard to the quality of our laboratory results.

The results of this study indicate that 80% of the laboratories used the unreliable and poor-quality national grid as their main source of electricity supply, with generators as backup. Only 20% of the laboratories used generators (with better quality current) as their main source of supply of electricity. The decision to use generators as the main source of power supply was said to be aimed at regulating and stabilizing the voltage supply, which is very important for the proper functioning of laboratory equipment. Though those who had the national grid as their main source of electricity supply claimed to use stabilizers to maintain the voltage, this still remains a major challenge, as the voltage supply affects equipment performance. A constant fluctuation of voltage supply will adversely affect the performance of laboratory equipment.

The cost of power is usually factored into the cost of laboratory tests, especially for privately owned laboratories. To cut costs, some laboratories may elect to cut power for a while. This may affect the timely separation of specimens, storage of samples and a conducive working environment (lack of air conditioning and adequate lighting). The cost of generating power and the importance of a stable voltage on the efficiency of equipment and storage of samples are important factors for the provision of quality results and this cannot be overemphasized, especially in this current era of hikes in the cost of gasoline and diesel occasioned by the sudden removal of fuel subsidy in Nigeria.

Only about 17 (40%) of the participating laboratories had some form of periodic training and retraining programs for their staff while the remaining 60% had no such continuous retraining programs. This finding is also another red flag, as training and retraining of staff is necessary for continuous quality improvement and production of good quality results [13]. This is an important part of the quality management process, as laboratory equipment is always changing, with new equipment being procured regularly.

Again, the resource persons and methods of training are as important as the training program itself. From our findings during this study, it is obvious that the majority of the participating laboratories had their training and retraining programs carried out by in-house staff. The need to engage external resource persons with relevant expertise in these training and retraining programs cannot be overemphasized.

From the results of this study, over half 23 (55%) of the participating laboratories did not have written-out standard operating procedures (SOPs) for most of the analytical methods used in their laboratories. This implied that the staff relied mainly on the initial verbal training/instructions for their routine analytical work and would seek clarification from any more experienced staff available when the need arose. This practice is a system set for failure as errors are bound to arise due to a lack of standardization. The encouraging thing is that those who had SOPs 19 (45%) claimed that they were made available to all staff. The training/retraining of staff and the ready availability of SOPs is a combination that ensures good quality results, as errors are reduced as much as possible [14].

Only about 9 (21%) of the participating laboratories (mainly those attached to tertiary institutions and private corporate laboratories) participated in some form of external quality assurance (EQA) scheme. External quality assessment schemes serve as a form of laboratory peer review mechanism using results produced by these participating laboratories in some ways to evaluate the quality of practice by these laboratories, as results produced by the different laboratories are compared within allowable error limits. Enrolment in external quality assurance (EQA) schemes by medical laboratories is a globally accepted standard practice designed to help improve and standardize laboratory practice amongst participating laboratories and should therefore be encouraged [15]. It also improves inter-laboratory cooperation, comparability of results and the confidence of the participating laboratories about the accuracy and quality of their results.

Laboratories that participate in external quality assessment (EQA) schemes and obtain unacceptable results are expected to do a root cause analysis of possible errors in their laboratories. This, in a way, puts such participating laboratories on their toes concerning adopting and reviewing their quality management practices. Though this is believed to mainly address the errors in the analytical phase, a proper root cause analysis would also improve the total laboratory testing process and encourage educational support amongst participating laboratories [15], [16]. The importance of all the above facts to producing good quality results is obvious since EQA encourages continuous improvement that is necessary for quality [16], [17].

Most of the laboratories 37 (88%) that participated in this study claimed to have been registered and/or licensed by the relevant regulatory authorities such as the State Ministries of Health and the Medical Laboratory Science Council of Nigeria. However, this practice is noted to be driven largely by financial considerations rather than quality of practice as those who pay their license fees are usually licensed or have their licenses renewed, with little or no recourse to evaluation of the quality of equipment, staffing, laboratory processes and procedures. There is currently no existing legislation prescribing the minimum standards for licensing and registration.

Most of those responsible for licensing in the states, though doctors, are usually not Pathologists or Laboratory Scientists and so have inadequate knowledge about the processes and requirements of a standard laboratory and the 'must haves' when licensing a laboratory. This invariably means that different medical laboratories may be operating under different quality standards and guidelines. This is not good for good quality laboratory practice and patient care, which depends largely on these laboratory results for the diagnosis, management and monitoring of the progress of patients. Regrettably, about ten per cent 5 (10%) of the laboratories that participated in this study were not even licensed or registered, implying that their operations are not even known to the government!

The need for developing countries, including Nigeria, to comply with international standards in various sectors of the economy, in a globally competitive and free market economy of this 21st century, as stipulated by the International Standards Organization (ISO), cannot be over-emphasized. The health industry, including medical laboratory service, is not excluded from this global standardization scheme. To satisfy this need and fill existing gaps in this regard, the Federal government established the Nigeria National Accreditation Service (NiNAS) in 2015. NiNAS was established within the framework of the European Union (EU)-funded National Quality Infrastructure Project for Nigeria (NQIP), implemented by the United Nations Industrial Development Organization (UNIDO). The project was aimed at supporting the improvement of missing standards and quality control bodies in Nigeria, with the overall objective of improving the competitiveness of Nigerian goods and services domestically and internationally.

NiNAS was designed to serve as the Nigerian national accreditation body that should provide a variety of accreditation services to Conformity Assessment Bodies (CABs) following standards published by the International Organization for Standardization (ISO) [18]. The objective of NiNAS was to attest to the competence and impartiality of CABs according to international standards, to monitor and improve the quality and reliability of their outputs, thus promoting competitiveness, trade, health, safety and protection of the environment [17]. In the first implementation phase, NiNAS was to offer accreditation services to testing and calibration laboratories and assess whether they are technically competent, impartial and capable of performing their tasks by ISO/IEC 17025. It was hoped that later, the services would be extended to medical laboratories, product certification bodies, inspection bodies, as well as management systems and personal certification bodies.

Unfortunately, since it was established, NiNAS appears to have had more focus on the certification of the quality of goods and services for export, rather than medical laboratory services. However, available information indicates that they may have the capacity for clinical laboratory accreditation services, though they are yet to establish any significant functional relationship with the Federal or State ministries of Health or any of the relevant regulatory agencies under the Federal Ministry of Health [18].

The need to establish the necessary medical laboratory accreditation agencies and institute adequate legislation for mandatory accreditation and licensing of medical laboratories before being allowed to render services to the public, as practised in developed countries, cannot be overemphasized. This is essential to guarantee reliable and good-quality results from our medical laboratories [19].

Upon the realization of these deficiencies in medical laboratory practice in developing countries, the World Health Organization (AFRO Region) in collaboration with the African Society for Laboratory Medicine (ASLM), U.S. Centers for Disease Control and Prevention (CDC) and some host countries established the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) program in 2009 to strengthen the laboratory systems of its Member States [20], [21]. This quality improvement process towards accreditation of medical laboratories in developing countries was to further provide learning opportunities and pathways for continuous improvement, mechanisms for identifying resources and

training needs, and measuring of progress and a link to the WHO/AFRO National Health Laboratory Service Networks [15].

Simultaneously, another complementary laboratory quality service improvement program, "Strengthening Laboratory Management Towards Accreditation" (SLIPTA), was launched by PEPFAR (President's Emergency Plan for AIDS Relief) in 2009. While SLIPTA was to measure laboratory quality by conducting periodic audits and measuring improvements in quality, SLMPTA provided the needed training and mentoring for running of medical laboratories following the 12-quality management essentials [21]–[23]. These two programs were designed to complement each other by providing the tools and processes needed to turn the aspirations for laboratory quality accreditation into reality in developing and low-income countries [19].

Regrettably, while these "donor" programs are considered laudable and desirable, their uptake and implementation in many developing countries, including Nigeria, has been poor, as they are reported to have been implemented in only 1,368 laboratories in 56 developing countries in Africa, Asia, Latin America and Oceania [16]. They have been able to help only 341 laboratories attain accreditation to international standards in these developing regions of the world. Unfortunately, here in Nigeria, there is hardly any credible evidence of any substantial buy-in into these programs by the relevant health authorities of the Federal or sub-national governments over the years. This poor attitude towards the prioritization and improvement of the quality of medical laboratory services in the health system would most likely be responsible for the present state of affairs in our medical laboratories, as seen from the results of this study.

The Federal Ministry of Health, the Medical and Dental Council of Nigeria, the Medical Laboratory Science Council of Nigeria, the States Ministries of Health, the National Council on Health, the National Assembly (Parliament) of Nigeria and the various professional bodies in the medical laboratory sub-sector of the Nigerian Health System, including the Conference of Nigerian Pathologists (CNP) and the Association of Medical Laboratory Scientists of Nigeria (AMLSN) must wake up to their responsibilities in this regard and take a lead in this effort to improve the quality of results from our medical laboratories.

5. Conclusion

The results of this study clearly indicate that, by extension, the majority of the medical laboratories in Nigeria are not accredited for quality service delivery; do not participate in external quality assessment (EQA) schemes and do not incorporate the use of most of the 12 quality management essentials in their routine practice. This state of affairs is a recipe for unreliable and poor-quality laboratory results that may lead to wrong diagnoses, ultimately leading to clinical mismanagement of patients. This would invariably lead to higher costs of medical treatment through wrong diagnosis and wasteful treatments, longer stays of patients in hospitals and unnecessary loss of manpower. These disadvantages are undesirable for developing and struggling economies in sub-Saharan African countries, including Nigeria.

Conflict of Interest

Authors declare that they do not have any conflict of interest.

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