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Original Article

Quality of Medical Laboratory Services in a Tertiary Health Institution in Sokoto, Nigeria

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A B S T R A C T

Background and Aims: The issue of the quality in healthcare cannot be ignored anymore. Laboratories play vital roles in control and prevention of diseases by providing timely and accurate result for patient management including disease surveillance. The aim of the study is to assess the quality of laboratory services in a Tertiary Health Institution in Sokoto.

Materials and Methods: A descriptive cross sectional study was used and a two-stage sampling technique applied to select the 96 laboratory respondents and 60 clinicians from a tertiary hospital in Sokoto Nigeria. Close-ended, self-administered questionnaires and a checklist were used to collect data, which were analyzed using SPSS.

Results: More than two-thirds of laboratory respondents have not received in-service trainings and among the few that received trainings, only three had training on laboratory quality management. Nearly all the laboratories have the basic infrastructure to ensure quality services. More than two-thirds of laboratory respondents had committed errors on the bench while 83% reported observing other laboratory staff commit errors. Three-quarters of the errors committed were at the pre-analytical and analytical phases, the most prevalent being mislabeling or failing to label the sample and complete loss of results, respectively. Length of time to obtain results and opportunity to discuss the findings with the laboratory personnel were laboratory services rated poor by clinicians.

Conclusions: Few laboratory respondents received in-service training on laboratory quality assurance and most prevalent errors committed were at pre-analytical and analytical phases. Staff trainings and enforcement of quality standards in medical laboratories is recommended.

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Introduction

International Organization for Standardization (ISO) 9000 defines the quality as the degree to which a set of inherent characteristics fulfills requirements [1]. Laboratory quality is defined as accuracy, reliability, and timeliness of the reported test results [2]. Though laboratory is the key element of health systems, nevertheless in Sub Saharan Africa, with characteristically huge disease burden, laboratories are among the world's poorly equipped and resourced limited facilities with consequent paucity of laboratory supplies [3]. Quality is an essential component of any service and production process, yet quality management systems (QMS) are uncommon in clinical laboratories in Nigeria. By 2006, only human virology laboratory began implementation of QMS; by 2008, it conformed to the ISO requirements making it the first laboratory to be certified in Nigeria out of 5349 laboratories. The outcome of the process had improvement in the pre-analytical and analytical indicators whileanalyzed and data entry errors decreased in the post-analytical process even though there was significant increase in the delay of returning laboratory results [3].

In 2002, ISO 15189 was introduced as an international standard for quality management systems specifically for medical laboratories. Its emphasis is on laboratory personnel safety, patients and all others involved in testing services, including service suppliers, continued competency and improvement of personnel skills with regard to training and the emphasis on the pre-analytical, analytical and post analytical stages of testing and the result reporting [4].

Availability and access to the quality of laboratory services are among the major challenges contributing to delay or inappropriate responses to outbreaks disease control and patient management [5]. The most important laboratory resource is competent, trained, and motivated personnel. Laboratory personnel should be fully aware of their roles and responsibilities with respect to the analysis or evaluation they are performing [6].

The results of laboratories must be as accurate as possible, all the operational process must be reliable and timely released to those who need it to make clinical decision; however, all these relies on adequate trained personnel and infrastructure of the health laboratories. On this background, this study was conducted to answer the following research questions: Are there adequate infrastructures to support provision of quality laboratory services in the study centre? What category of errors in their different form is/are frequently encountered in the laboratory? What is the clinicians' perception of the laboratory results? Are the clinicians satisfied with the results generated from these laboratories?

Materials and Methods

The study was carried out in a Tertiary Hospital in Sokoto, Nigeria among all the four laboratories namely; Medical Microbiology and Parasitology, Histopathology and

Morbid Anatomy, Chemical Pathology and Immunology and Hematology and Blood transfusion. The study population comprised of all the laboratory personnel (scientists and technicians) and clinicians who are the key consumers of the laboratory test results. The scientists are laboratory personnel with university degree in laboratory science while the technicians have diploma qualifications on laboratory science. Those that voluntarily consented to participate in the study were included however, the laboratory interns, house officers, students who are on training/ attachments in the laboratories, including laboratory assistants and resident doctors less than six months of working in the hospital were excluded from the study.

A descriptive cross-sectional study was used and the minimum sample size required to validate the study was calculated using the appropriate formula [7]. Attrition rate formula, [8] allowing for 90% response rate, was applied on the sample size obtained from Fisher et al. formula and finally sample size of ninety-six laboratory personnel and sixty clinicians was obtained and exact numbers were enrolled into the study. A two stage sampling technique (systematic and simple random sampling technique) was used to select the study respondents among laboratory personnel and the clinicians.

Data were collected using questionnaires and a checklist through self-interview and observation, respectively. The laboratory personnel questionnaire assessed questions on the process of quality assurance management system in the laboratories; clinicians questionnaire focused on their satisfaction with laboratory services while the observation checklist were used to assess the infrastructural availability to support quality laboratory services. Both the questionnaires for laboratory respondents and clinicians, including the checklist were pretested from another tertiary health facility that were not part of main study site in order to ensure validity of the study. Data collected were checked for completeness, cleaned, coded, and analyzed using Statistical Package for Social Sciences (SPSS version 20) software. Continuous data, e.g. respondents' ages were summarized using mean and standard deviation and categorical data expressed in frequency and percentage. Chi-square test of association was carried out to determine the association between Physicians' characteristics and the level of satisfaction with laboratory services.

Results

Table 1 shows the mean age of the laboratory respondents that it was 33.3±7.2 years. There were more males (74%) compared to females (26%) and laboratory scientist accounted for 53% of the respondents while the technicians constituted 43%.

Table 1. Socio-demographic characteristics of laboratory respondents

Variables	No. (%)
Age (Year)	
22-24	8 (8.3)
25-39	68 (70.8)
40-55	20 (20.8)
Sex	
Male	71 (74)
Female	25 (26)
Marital status	
Married	75 (78.1)
Single	21 (21.9)
Tribe	
Hausa	64 (66.7)
Yoruba	11 (11.5)
Igbo	7 (7.3)
Others	12 (14.5)
Religion	
Islam	86 (89.6)
Christianity	10 (10.4)
Categories of laboratory personnel	
Scientist	53 (55.2)
Technician	43 (44.8)

Table 2 shows that more than two-thirds has not received further trainings since working in their current laboratory. However, among the few that received trainings, only five had training on laboratory quality management and almost half (48%) do not participate in the continuous medical education and professional development.

Result in table 3 reveals that three of the laboratories have standard operating procedures and sample rejection criteria appropriately placed. Concerning the main working area, only two laboratories assessed have required personal protective equipment such as hand gloves, safety boot, facemask, lab coat (disposable) and also fire buckets and accident record books. In addition, only two laboratories had fire buckets, accident record books, disinfection logbook. None has quality control team or quality manager designated in the laboratory.

Table 2. Work related characteristics of laboratory personnel

Variables	No. (%)
Laboratory of work place	
Microbiology	29 (30.2)
Chemical pathology	20 (20.8)
Histopathology	18 (18.8)
Haematology	29 (30.2)
Time since working in the laboratory (years)	
Less than 5	56 (58.9)
5-10	29 (30.5)
Greater than 10	10 (10.5)
Previous laboratory working experience	
Yes	54 (56.3)
No	42 (43.8)
Job in this laboratory	
Performing test	64 (66.7)
Collecting specimens	34 (35.4)
Making reagents	17 (17.7)
Managing the laboratory	21 (21.9)
On-the-job training received since working in this lab	
Yes	12 (12.6)
No	83 (87.4)
Type of training received	
Assisted reproductive technology	2 (16.7)
Safety on fire outbreak	1(8.3)
Genotype film reading	1(8.3)
Malaria microscopy training	1(8.3)
Nigerian field epidemiology and laboratory training program	1(8.3)
Quality control of laboratory	5 (41.8)
TB/ HIV co- infection	1 (8.3)

The results of table 4 reveal that 69% of the laboratory respondents have committed errors while working in the laboratory and 83% reported observing other laboratory personnel commit errors. Three-quarters of the errors committed were observed in the pre-analytical and analytical phase while one-quarter occurred in the post-analytical phase. Most prevalent pre-analytical error was mislabeling or failing to label the sample and during analytical phase, failure to follow an established guideline while post analytical phase most common error was complete loss of result.

Table 3. Infrastructural level at the four medical laboratories in the health facility

Characteristics	Specifications	Yes	No
Reception area			
	Standard operating procedure rejection criteria	3	1
	Handling of different samples Protocol	4	0
Main working area			
Security and safety	Fire extinguishers	4	0
	Required personal protective equipment: gloves, safety boot, face mask, lab coat (disposable)	2	2
	Safety symbols	2	2
	Sample analysis room/section restricted to laboratory technical staff	4	0
	Accidents record book	2	2
	Laboratory walls and ceilings painted with washable, glossy paint	4	0
	Floor made of material easy to clean and disinfect	4	0
Work bench	Laboratory work bench top made up of ceramic tiles/wood/steel/formaker	4	0
	Work benches organized according to type of analysis/samples/pathogen	4	0
	Work benches have adequate space for bench top equipment, standard operating procedure while in use, display job aids	4	0
Cleaning of facility	How often is the laboratory floors cleaned	Daily	
	How often ceilings and walls are cleaned	Weekly	
	How often refrigerators and storage areas cleaned	Monthly	
	Number of laboratories with disinfection log book	2	2
Essential facilities			
Patient waiting area	Laboratories with patient waiting area	1	3
Water	Running tap water	4	0
Power	Electric power	4	0
Waste disposal	Appropriate sharp objects container	3	1
	Color coded waste containers with coded bin liners	0	4
Toilet	For all staff	4	0
	For patient/client	0	4
Administration	List of members of quality control team	0	4

Table 4. Process of the quality assurance management system in the Health Institution

Variables	No. (%)
Did you ever commit error in the laboratory	
Yes	66 (68.8)
No	30 (31.2)
Did you observed another laboratory staff commit error	
Yes	80 (83.3)
No	16 (16.7)
Type of examination phase the error was committed	
Pre- examination phase	56 (38.4)
Examination phase	54 (37.0)
Post- examination phase	36 (24.6)
Pre–examination phase errors observed	
Collecting wrong sample	19 (24.1)
Mislabeling the sample	23 (29.1)
Stored sample incorrectly prior to testing	12 (15.2)
Handling samples under conditions that will damage it	17 (21.5)
Improper storage of reagents	8 (10.1)
Examination phase error observed	
Failure to follow established guideline	26 (40.0)
Reporting results when quality control materials are out of range	12 (18.5)
Incorrect measuring/ dilution of sample	13 (20)
Using expired or improperly stored reagents	14 (21.5)
Post- examination phase error observed	
Exchanging patient information	7 (14)
Hand written report that is illegible	7 (14)
Sending report to wrong location	5 (10)
Complete loss of report	21 (42)
Not sending the result to patient	10 (20)

Results of table 5 show that 63% of the respondents perceived laboratory request forms were not appropriately filled by clinicians and the part frequently neglected were patient medical history (29.2%), time and date of specimen collection (27.2%). Almost three-quarters (74%) of the laboratory personnel reported ever rejecting samples because of poor labeling. Table 6 shows that the mean age of the clinicians was 34.4±6.0 years. Respondents were selected from all the clinical departments of the hospital and 87% were the resident doctors while consultants accounted for 13%.

Table 5. Perception laboratory personnel on laboratory request from clinicians

Variables	No. (%)
Appropriate filling of laboratory request form by clinicians	
Yes	35 (36.8)
No	60 (63.2)
Part of laboratory form frequently neglected by clinicians	
Patient name	5 (5.2)
Identification number	15 (15.6)
Type of test to be performed	25 (26)
Patient medical history	28 (29.2)
Time and date of specimen collection	26 (27.2)
Name and address of requesting clinician	19 (19.8)
Primary type of specimen	8 (8.3)
Have you rejected sample because of poor labeling	
Yes	73 (76.8)
No	22 (23.2)
Communicated to clinician the reason for rejection	
Yes	41 (44.1)
No	52 (65.9)
Number of specimen rejected within the last three months	
1-14	66 (97.1)
15-30	2 (2.9)
Reasons for specimen rejection	
Specimen form not appropriately filled	27 (28.1)
Inadequate sample collected	44 (45.8)
Wrong sample collected	28 (29.2)
Inappropriate specimen container used	26 (27.1)

Results in table 7 show that 93% of the clinicians have received wrong results from the laboratories and nearly all of them had received between one and ten wrong results within the period under review. Most prevalent action taken by clinician was to send another sample for repeat analysis and 16.7% reported to the head of the laboratory. Three-quarters of the clinicians thought the results obtained were helpful in patient diagnosis and management; and 80% ever changed patient management in view of culture and sensitivity results obtained.

The results of table 8 show that, of the six different aspects of laboratory services assessed with respect to clinicians' satisfaction, 58% rated length of time to get laboratory results poor. The opportunity to discuss findings with the laboratory personnel was also rated poor by 70% of the clinicians.

Table 6. Clinicians' socio-demographic characteristics

Variables	No. (%)
Age (Years)	
≤ 40 years	46 (76.1)
> 40 years	14 (23.3)
Sex	
Male	41 (68.3)
Female	19 (31.7)
Department	
Medicine	12 (20)
Paediatrics	11(18.3)
Obstetrics and Gynaecology	13 (21.7)
Family medicine	6 (10)
Surgery	11(18.3)
Community medicine	7 (11.7)
Designation of clinicians	
Consultant	8 (13.3)
Senior Resident	17 (28.3)
Junior Resident	35 (58.3)

Table 7. Clinicians' experience with laboratory services at the health facility

Variables	No. (%)
Do you receive wrong results from the laboratory	
Yes	56 (93.3)
No	4 (6.7)
Number of wrong result received in the last one year	
≤ 5	43 (93.5)
6-10	2 (4.3)
≥ 11	1 (2.2)
Action taken on wrong result received	
Reported to head of the laboratory	10 (16.7)
Send another sample for analysis	50 (83.3)
How helpful laboratory results are in patient diagnosis and treatment	
Very helpful	12 (20.3)
Helpful	33 (55.9)
Somewhat helpful	14 (23.7)
Do you change patient management in view of culture and sensitivity results obtained from the laboratory	
Yes	48 (80)
No	12 (20)
How often do laboratory diagnosis tally with clinical diagnosis	
Most times	19 (31.7)
Sometimes	41 (68.3)
Do you send a repeat sample to laboratory outside this health facility	
Yes	48 (80)
No	12 (20)
How often do you send samples to laboratories outside this health facility	
Most times	2 (4.2)
Some times	44 (91.7)
Rarely	2 (4.2)

Table 8. Clinicians' level of satisfaction with different aspects of laboratory services

Characteristics	Excellent No. (%)	Very Good No. (%)	Good No. (%)	Poor No. (%)
Adequacy of information on laboratory form	4 (6.7)	27 (45.0)	26 (43.3)	3 (5.0)
General conduct of laboratory staff in relation to service	0	9 (15.0)	37 (61.7)	14 (23.3)
Length of time to get laboratory result	2 (3.3)	2 (3.3)	23 (38.3)	35 (58.4)
Reliability of laboratory result	1 (1.7)	10(16.7)	34 (56.7)	15 (25.0)
Opportunity to discuss the result finding with lab	0	4 (6.7)	14 (23.3)	42 (70.0)
Perception of the quality of laboratory service	0	5 (8.3)	38 (63.3)	17 (28.4)

In table 9, except for microbiology laboratory where large proportion (60%) of respondents had poor perception, majority had excellent to good perception of haematology, chemical and histopathology laboratories. Majority of the clinicians had excellent to good satisfaction rating for results from histopathology and haematology while 53% had poor satisfaction rating for results from microbiology laboratory.

Table 9. Clinicians' perception and satisfaction level with results from each laboratory

Variables	Excellent No. (%)	Good No. (%)	Poor No. (%)
Perception about laboratory results			
Microbiology	0	24 (40)	36 (60)
Haematology	2 (3.3)	39 (65)	19 (31.7)
Chemical pathology	1(1.7)	36 (60)	23 (38.3)
Histopathology	22 (36.7)	34 (56.7)	4 (6.7)
Clinicians' level of satisfaction with results	**Very satisfied No. (%)**	**Satisfied No. (%)**	**Dissatisfied No. (%)**
Microbiology	0	28 (46.7)	32 (53.4)
Haematology	2 (3.3)	41(68.3)	17(28.3)
Chemical pathology	0	40 (66.7)	20 (33.3)
Histopathology	27 (45)	29 (48.3)	4 (6.7)

Results in table 10 show that 63% of the clinician respondents expressed satisfaction with the overall laboratory services at the study centre. Chi-square test of association revealed that only respondents' department showed a statistically significant association with satisfaction with laboratory services, (λ^2= 12.12, df= 5, p< 0.03).

Table 10. Relationship between clinicians' socio-demographic characteristics and their levels of satisfaction with laboratory services

Variables	Level of satisfaction		p-value
	Satisfied No. (%)	Dissatisfied No. (%)	
Sex			
Male	12 (54.5)	29 (76.3)	0.08
Female	10 (45.5)	9 (23.7)	
Department			
Medicine	3 (13.6)	9 (23.7)	
Paediatrics	3 (13.6)	8 (21.1)	
Obstetrics and gynaecology	7 (31.8)	6 (15.8)	0.03*
Family medicine	5 (22.7)	1 (2.6)	
Surgery	1 (4.5)	10 (26.3)	
Community medicine	3 (13.6)	4 (10.5)	
Respondents' Designation			
Consultant	3 (13.6)	5 (13.2)	0.76
Senior resident	5 (22.7)	12 (31.6)	
Junior resident	14 (16.3)	21 (55.3)	

*Significant at $p<0.05$

Discussion

Quality in clinical laboratory can be defined as the comprehensive and coordinated efforts to meet quality objectives [9]. However, a quality management system is defined as "coordinated activities to direct and control an organization with regard to quality." [10] It was against this background that this study was conducted in one of the tertiary hospital in Sokoto to assess the quality of laboratory services among all the four medical laboratories of the hospital. The findings from this study revealed that the majority of the laboratory personnel are laboratory scientists, followed by laboratory technicians and medical doctors while the laboratory assistants were the least. The large number of laboratory scientist is due to the fact that there is a school of medical laboratory science at the institution, which ensures large numbers are produced every year and also in line with regulations that the cadre is required in tertiary health facilities in order to provide quality services. This is in agreement with the findings of a study at South Africa by Cohen and Rampal on the need for a quality standard for assurance in medical research laboratories [11]. The implication for the finding of a mixture of medical doctors, medical laboratory scientists and technicians working in the laboratory suggests a good composition of laboratory staff necessary for the running of a quality laboratory [12].

Our study findings show that more than two-thirds of the laboratory personnel have not received further professional training after employment with only three receiving training in laboratory quality management. The findings of the current study are in contrast with a study done by Audu et al on the experience of quality management system in clinical laboratory in Nigeria; two personnel were sent to a laboratory in Dakar, Senegal to study the implementation of quality management system and they subsequently trained thirty- three staff via regular and quality focused staff

meetings [3]. The implication of this finding is that laboratory quality management is neglected to the backyard and more effort needs to be put on staff re-training especially in the issues of quality. The availability of standard operating procedures, sample rejection criteria, biosafety gadgets, fire safety equipment's and quality managers in three-quarters of the clinical laboratories accessed from this study is heartwarming because this implies that at least there is the will to implement biosafety and some standard practices in the laboratories we accessed even though other aspects of quality management were lacking. The possession of fire safety gadgets in all the clinical laboratories accessed is in contrast with an earlier study done in Edo where only 11.3% of the laboratories had a fire extinguisher [13]. We advocate that special emphasis should be paid to biosafety requirements in the clinical laboratories in line with international guidelines.

This study shows that more than half of the respondents have committed a laboratory error themselves or have observed other laboratory staff commit errors majorly in pre- examination phase and examination phase. Concerning the results of the present study, there is failure to follow established guidelines by the personnel possibly due to sub-optimal administrative control. In contrast to our study, Audu et al[3] reported that following re-training the staff of their laboratory showed improvement in pre- analytical and post- analytical examination and less improvement in analytical phase. This might be due to the continuous laboratory education on stakeholders involved in laboratory testing.

Our study findings showed that more than half of the laboratory personnel complained of inappropriately filled request forms by clinicians; with patient's medical history being the most frequently neglected, followed by time/date of specimen collection. This is in contrast with a study done at Stellenbosch University by Zemlin et al[14], which showed that medical details with a patient were most frequently neglected (74.5%), followed by clinicians contact details (65.2%), and 20.8% had no diagnosis. They reported that patient history was filled in from their study site, which they attributed to the fact that most of their laboratory request forms being pre-stamped with clinic details and the use of patient identity stickers.

The study findings show that almost all the clinicians have received wrong results from the laboratories, although greater than two thirds of them feel that laboratory results are necessary for patient management. This is a worrisome finding in a Tertiary Health Center of Excellence. All effort must be directed toward ensuring that the quality results are generated from the clinical laboratories in the view of their value in patient management. Tuijn et al in Northern Tanzania reported that only 33.3% clinicians use the test results that are provided with as against our study findings [15]. They attributed their unreliable results to lack of a highly-educated laboratory technician to perform tests, paucity of equipment's and expired/lack of reagents.

Our study findings show that all the six aspects in client satisfaction for the four laboratories were rated excellent to good. This is in contrast with a study in Western Ethiopia where 62% were satisfied, 8% dissatisfied and 30% were neutral. The observable differences might be due to fewer number of health professionals approached in this study [16]. The study also shows that there is good perception for three laboratories; except for the medical microbiology laboratory, which was rated with poor perception. Finally, in the overall satisfaction for all aspect of laboratory services, more than half of the clients were dissatisfied. This may be attributable to poor communication and feedback between the clinicians and the laboratorians. This was similar to the study by Tuijn et al. in Tanzania where they showed that the lack of communication between the laboratory staff and clinicians lead to poor satisfaction and the clinicians' doubts about laboratory test results [15].

Conclusions

The study demonstrated that only few laboratory personnel in the tertiary health institution received in-service training on laboratory quality management. Laboratory errors occured and most prevalent errors committed were at pre-analytical and analytical phases. The most of the results churned out from these laboratories may not be accurate and thus may mislead the clinicians in patient diagnosis and management. All of the four laboratories neither have quality control team nor a person designated as quality manager. In line with these findings, it is recommended that laboratories should be strengthened in line with the WHO/AFRO initiative. This is in addition to regular training/re-training of laboratory staff and enhanced communication between the clinicians and the laboratory personnel.

Conflict of Interest

The authors hereby declare that there is neither competing interest in the outcome of the study nor conflict of interest in the conduct and publication of this research work.

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