

Quality Management of the Pre-Analytical Phase Errors: Monitoring and Way Forward

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Abstract

Inadequate quality management during laboratory analysis can increase errors, specimen rejection, and economic resources wastages. A laboratory quality management system (QMS) helps to streamline and coordinate all the processes and operations within the lab, ensuring that each step is well planned, controlled, and correctly performed. Quality management ensures that results are accurate, reliable, and obtained under a traceable process that can easily detect errors. The study aimed to investigate quality practice among laboratory workers during pre-analytical phase activities. Unexpected deviation from quality procedures consequently compromise laboratory test results, leading to patient mismanagement and patient safety risks. Analysis of results showed that 97.1% (340 respondents) were knowledgeable on quality management of pre-analytical phase, and 2.9% (10 respondents) were not. 99.1% (347 respondents) agreed to availability of quality management materials and 0.9% (3 respondents) had no resources. 4.6% (16 respondents) do not practice quality management system at pre-analytical phase and 94.5% (334 respondents) practiced quality improvements. 3.4% (12 respondents) agreed that quality improvement is the responsibility of phlebotomist and field staff. 96.6% (338 respondents) agreed that quality management is the responsibility of everyone at the facility. There was maximum knowledge of quality management at the facility. Availability of quality management resources at the facility was standard. The practice of quality management was below standard. Facility requires training in quality management. It is recommended that quality management system be integrated into the curriculum of school of health technology to guide graduates at work.

Keywords: *Quality, Improvement, Patient, Management, System.*

Introduction

Inadequate quality management practices and non-conformity to laboratory quality management system, guidelines and procedures during pre-analytical stage has contributed to frequent specimen rejections at the facilities, increase of pre-analytical errors and wastage of economic resources. Consequently, a targeted effort is required to resolve error causations in the pre-analytical phase [1-3]. For any laboratory to be successful there must be

quality. Quality Management System is a formalized system that documents processes, procedures, and responsibilities for achieving quality. The four main components of every Quality Management System (QMS) are quality planning, quality control, quality assurance, and quality improvement. A quality plan could be a document, alternatively several documents, which collectively specify quality standards, practices, resources, and specifications. However, the sequence of Quality Control

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planning is simply to identify the quality goals, standards, and procedures relevant for the execution of the project. Furthermore, Quality Control is the process of physically inspecting and testing laid out plans to ensure success. It guarantees the services or products to be adequately measured and analyzed to achieve uniformity that meet standard. Quality Assurance (QA) in the laboratory involves a range of activities that enable laboratories to achieve and maintain high levels of accuracy and proficiency irrespective of changes in volume of specimens tested and methods. Quality Improvement enhances thorough review of the findings from the last three components and recommends methods for future improvements.

Laboratory quality assurance has operating principles that enable laboratories to produce defensible data of known accuracy and precision while Laboratory quality control is all the measures put in place to eliminate the risk of non-conforming outcomes. Laboratory quality control systems safeguard the accuracy of test performance, reliability, and quick turnaround time of laboratory results. It is capable of early detection of erroneous results or measurement with errors and has procedures to rectify them. Nevertheless, laboratory quality control should be regularly and consistently performed, and materials should be the same as samples all through the test run. In addition, the QC measures developed within the laboratory are the building blocks for the process of certification and accreditation. There should be continuous quality improvements; as failure to integrate quality control in a laboratory system led to several negative consequences, time wastage, resources wastage, experiments, and tests repeats. The budget implications are increased reagents requirements to repeat tests and experiments. The integrity of a laboratory can be compromised with unreliable results, any funding options, certification and accreditation process, loss of customer loyalty and satisfaction. This also has an impact on

safety concerns due to non-compliance in the absence of quality control mechanisms resulting in delayed diagnosis and unnecessary treatments for patients.

The process of setting up laboratory quality management system begins with identifying all the laboratory total testing processes, and practices that are sensitive to inadequacies, errors, and safety concerns. To build systems that secure all the above, it is necessary to identify and minimize the readily known laboratory errors that are likely to occur during the three analytical phases in the laboratory.

In the pre-analytical stage, test samples and materials should not be mishandled prior to analysis to avoid resultant errors. However, in the analytical stage, these errors must be resolved through appropriate remedial actions.

QMS also involve the managerial and technical aspects of laboratory to have one in place. In laboratory quality improvement programs, there is the need to extend quality and consistency throughout laboratory set-up by measuring and monitoring instrument performance, staff competency, and key quality metrics. Negligence in any of these steps can lead to erroneous results attributed to total testing processes of all analytical phases. Pre-analytical phase is the time interval in which the physician makes a laboratory request and the time in which the sample is ready for analysis. But if the sample is collected from outpatients, transportation and storage is important. Variations and unexpected condition changes during these dynamic processes adversely affect laboratory test results, leading to patient mismanagement and compromised patient safety [4, 5].

However, there are several clinical laboratories that encounter challenges in meeting up with the quality management system to improve and monitor pre-analytical processes and quality of tests due to lack of standard process and procedures [6]. In this era of modern technology, there are highly developed and designed control system in place

now to ensure the quality of the analytical phase, nevertheless, the quality improvement system targeting the reduction in pre-analytical errors as part of total quality management is what is being emphasized. Availability of SOPs, establishment of criteria for effective error detection methods, and preventive strategies, monitoring and implementation of continuous quality improvement programs and quality management system (QMS) can increase efficiency [7, 8].

A laboratory information system based on integrated quality management system can facilitate error detection, identification, and error tracking to ensure timely and accurate test results [9-11]. Common interferences, such as hemolysis, icterus, and lipemia, are critical for detection and prevention. However, implementation and estimation of the hemolysis, icterus, lipemia indices and other rejection criteria by front-end automation, analytical instruments, middleware, or laboratory information system programs can increase efficiency and accuracy of error detection, quality control and quality assurance [12-14].

Specimens should be rejected and the whole process repeated if an error is detected. In readiness for quality testing, quality control and quality assurance of laboratory tests, laboratories need to establish specimen quality markers to enable the quality system execute error detection and specimen rejection [15, 16, 17]. Quality management system practice at the pre-analytical phase can be increased through compliance with standards and acquisition of skills.

The objectives of this research are:

1. To investigate laboratory quality management of specimens at St Mary's Hospital, Okpoga, Okpokwu LGA of Benue State, North Central of Nigeria.
2. To highlight quality management system and quality improvement measures for laboratory implementation.

3. To provide steps that can minimize pre-analytical errors through continuous quality management or improvement techniques.

Design

The design of this research is a descriptive cross-sectional study of randomly selected 350 specimens from out-patients only.

Setting

This study was carried out at St. Mary's Hospital Okpoga. St. Mary's hospital is one of the oldest serving health facility in Idoma west, which serves three LGAs of the Idoma west region and act as a referral facility for other private hospitals in that region. This place provides opportunities for experimentation, observation, or practice in the field of study with a lot of health workers to provide relevant information. Study Population: Study population was from the out-patients whose specimen were to be analyzed at St. Mary Hospital Okpoga. A random sample technique was employed in the selection of 350 specimens out of 1000 specimens collected for analysis.

Materials and Methods

Materials

A total of 350 respondents were surveyed for the analysis. The respondents were randomly sampled from the study population of Nurses, Medical laboratory scientists, medical laboratory technologist, medical laboratory technicians, Phlebotomists, and out-patients. Study tools were Questionnaires/ Checklist and oral interview. Physical screening, oral interview and questionnaires /checklist as reflected on Table 1.

Methodology

This is a cross-sectional study on quality management, continuous improvement and monitoring of pre-analytical errors at the laboratory. The sampling was randomly conducted among facility workers at St. Mary's

Hospital Okpoga in Okpokwu LGA of Benue state, Nigeria. Qualitative data analysis sections began with respondent answering yes or no to ascertain the level of understanding and performance on quality improvement activity at the study facility. Random sampling technique method was adopted in choosing the population for the study. Random sampling is a technique in which research participants are picked and selected arbitrary for screening and to answer questions. 350 respondents were randomly sampled, and questions were asked, and

respondents provided the answer [3]. There was an arbitrary sample of 350 respondents randomly sampled from study population of Nurses, Medical laboratory scientists, medical laboratory technologist, medical laboratory technicians, Phlebotomists, and out-patients.

Result of Findings for the Research

The study tool was administered to respondents within the facility and the following results were obtained.

Table 1. Results of Quality Management Checks in the Laboratory Pre-analytical Phase at Study Health Facilities

SN	Questions	Respondents Reply		Remarks
1	Pre-analytical variables: Does the Clinicians assess dieting, body mass, age, gender, pregnancy, smoking exercise etc. before recommending patients for laboratory test?	Yes	No	-
		300	50	
		85.7%	14.3%	
2.	Specimen collection variables Was there Variation in diurnal, posture, time of collection, fasting status, tourniquet, and presence of IVS, order of draw, anticoagulants, and insufficient volume?	Yes	No	-
		335	15	-
		95.7%	4.3%	-
3	Specimen handling variables Were variables like haemolysis or clotting, lipemia, centrifugation, processing time, temperature, Sunlight, evaporation, labelling aliquoting and condition of transport considered in specimen handling?	Yes	No	This is the point where quality can be compromised for several reasons like negligence, lack of experiences etc.
		350	-	
		100%	0%	
4	Pre-analytical errors- Types of pre-analytical errors Do you have existing SOPs, guidelines, bench aids in the facility to guide test request, patient identification, patient preparation and condition, time of specimen collection, wrong or missing identification, mislabelled/unlabelled specimens, haemolysis, incorrect order of draw, wrong tube type/sample/anti-coagulant processes during pre-analytical stage activities?	Yes	No	-
		347	3	
		99.1%	0.9%	
5	Do you practice quality management system?	334	16	-
		95.4%	4.6%	
6	Whose responsibility is quality	12	338	-

	improvements? Phlebotomist or every lab worker?	3.4%	96.6%	
7	Criteria for rejection of specimen	Yes	No	-
8	Do you check for Clotted Specimens, under filled and overfilled specimen, Incorrect labelling or unlabelled specimens, incorrect specimens, specimen too old to process, Haemolysed specimen, incorrect and insufficient quantity of specimen, broken and leaking tubes before rejecting specimens?	342	13	-
		97.7%	3.7%	
9	Pre-analytical errors process improvement	Yes	No	-
10	Do you have a pre-analytical quality improvement approaches in place?	340(2.9%)	10(2.9%)	-
11	Do you plan and develop strategy focusing measurable error detection?	320(91.4%)	30(8.6%)	-
12	Do you develop a plan to trouble shoot and attack the most common errors and important problems?	344(98.28%)	6(1.7%)	-
13	Do you have standards for procedures and processes?	350(100%)	0(0%)	-
14	Do you have effective communication system, education and training in place?	350(100%)	0(0%)	-
15	What about system based practice for quality improvement?	340(97.1%)	10(2.9%)	-
Quality indicators (QI) of the pre-analytical phase checklist.				
Tests	Numbers of respondents	YES	NO	-
What is the appropriateness of test request	How many numbers of requests have clinical questions?	350(100%)	0(0%)	-
	How many numbers of tests were appropriate in respect to the clinical question?	350(100%)	0(0%)	-
Examination requisition	How many numbers of requests are without physician's identification?	0(0%)	350(0%)	-
	How many numbers of unintelligible requests are found?	0(0%)	350(100%)	-
Identification	How many are the numbers of requests with errors in patient identification?	0(0%)	350(100%)	-
	How many are the numbers of requests with errors in identification of physician?	0(0%)	350(100%)	-
Test Request	How many numbers of	10(2.9%)	340(99.1%)	-

	requests had test input			
Samples	How many numbers of samples were lost/not received	0(0%)	350(100%)	-
	How many numbers of samples were collected in inappropriate containers?	4 (1.1%)	349(99.7%)	-
	How many numbers of samples were haemolysed	4(9.7%)	349(99.7%)	-
	How many numbers of samples were clotted	0(0%)	350(100%)	-
	How many numbers of samples are with insufficient volumes	10(2.9%)	340(97.1%)	-
	How many numbers of samples have inadequate sample-anticoagulant ratio?	0(0%)	350(100%)	-
	How many numbers of samples were damaged in transport	4(9.7%)	349(99.7%)	-
	How many numbers are improperly labelled samples?	10(2.9%)	340(97.1%)	-
	How many numbers are of improperly stored samples?	0(0%)	350(100%)	-
	How many numbers of samples were rejected due to mishandling	42(12%)	308(88%)	-

A total of 350 respondents were screened for quality management system and continuous quality improvement measures at the study facility within the period of July to September 2022 and the following results were obtained. Findings on pre-analytical variable revealed that 345 respondents representing 98.6% of total samples agreed that clinicians assessed patients on dieting, body mass, age, gender, pregnancy, smoking exercise etc. before recommending for laboratory tests while 5 respondents representing 1.4% of total samples disagreed on patients' variable assessments. On sample collection variables 335 respondents representing 95.7% of total samples analyzed agreed that there was variation in diurnal, posture, time of collection, fasting status, tourniquet, and presence of intravenous (IVS),

order of draw, anticoagulants, and insufficient volume while 15 respondents representing 4.3% of total samples disagreed. 350 respondents representing 100% of sampled respondents agreed that variables like hemolysis or clotting, lipemia, centrifugation, processing time, temperature, sunlight, evaporation, labeling aliquoting and condition of transport were considered in specimen handling. From the findings, it is believed that this could be the point where quality in pre-analytical phase is mostly compromised if mishandled for several reasons like negligence, lack of experience, non-conformity to procedures etc. Analysis of results showed that 340 respondents representing 97.1% of sampled numbers were knowledgeable on quality management of pre-analytical phase, and 10 respondents

representing 2.9% of total sampled respondents were not. 334 respondents representing 95.4% of total number sampled practiced quality management system at pre-analytical phase and 16 respondents representing 4.6% of respondents disagreed on practice of quality improvements. 12 respondents representing 3.4% of total sampled number agreed that quality improvements are restricted to phlebotomist and field staff only at the pre-analytical phase. 338 respondents representing 96.6% of the total sample number agreed that quality management is the responsibility of everyone at the facility. Findings on pre-analytical errors types revealed that 347 respondents representing 99.1% of total samples agreed to have existing SOPs, guidelines, bench aids in the facility to guide test request, patient identification, patient preparation and condition, time of specimen collection, wrong or missing identification, mislabeled or un-labeled specimens, haemolysis, incorrect order of draw, wrong tube type, wrong sample, and anti-coagulant processes during pre-analytical stage activities, while 3 respondents representing 0.9% of total numbers disagreed not to have existing document. Screening on criteria for rejection of specimen revealed that 342 respondents representing 97.7% of total samples analyzed agreed to check for clotted specimens, under filled and overfilled specimen, incorrect labeling or unlabeled specimens, incorrect specimens, specimen too old to process, haemolysed specimen, incorrect and insufficient quantity of specimen, broken and leaking tubes before rejecting specimens while 13 respondents representing 3.7% of total samples disagreed.

Findings on pre-analytical errors process improvement revealed that 340 respondents representing 97.1% of total sampled population agreed that there is pre-analytical quality improvement approaches in place, while 10 respondents representing 2.9% of total sampled respondents disagreed. 320 respondents

representing 91.4% of total sampled respondents agreed that they plan and develop strategy focusing measurable error detection, while 30 respondents representing 8.6% of total sampled respondents disagreed. 344 respondents representing 98.3% of total sampled respondents agreed to develop a plan to trouble shoot and attack the most common errors and important problems, while 16 respondents representing 1.7% of total sampled population disagreed. All the 350 respondents representing 100% of the total sampled population agreed to have standards for procedures and processes. 350 respondents representing 100% of the total sampled population agreed to have an effective communication system, education, and training in place. 340 respondents representing 97.1% of sampled population agreed that there is system based practice for quality improvement at the facility, 10 respondents representing 2.9% of sampled respondents disagreed. Findings on quality indicators (QI) of the pre-analytical phase checklist revealed that; on the appropriateness of test request 350 request representing 100% of total sampled numbers of requests have clinical questions. 350 requests representing 100% of tests were appropriate in respect to the clinical question. Findings on examination requisition, physician's identification, intelligible requests, showed that all the 350 requests had 100% correctness. Findings on patient identification revealed that 350 numbers of requests representing 100% of request had correct patient identification and physician's identification. It was discovered that some test requests had input or feedback on the form, and this accounted for 10 test input representing 2.9% of test requests that had errors, while 340 test request representing 97.1% requests had no test input.

Findings revealed on sample management that 350 representing 100% of total samples were not lost/ but received. 4 samples representing 1.1% of total samples were collected in inappropriate containers, while 349 samples representing 99.7% of total samples

were collected in appropriate containers. Four (4) samples representing 1.1% of total samples were haemolysed, while three hundred and 349 representing 99.7% of total samples were not haemolysed. 10 samples representing 2.9% of samples were insufficient in volumes, while 340 samples representing 97.1% of total samples had sufficient volumes. 350 samples representing 100% of total samples had adequate sample-anticoagulant ratio. 4 samples representing 1.1% of total samples were damaged in transport, while 349 samples representing 99.7% of total samples were not damaged. 10 samples representing 2.9% of total samples were improperly labeled, while three hundred 340 samples representing 97.1% of total sample had proper labels. 350 samples representing 100% of the total numbers of samples were properly stored. 42 samples representing 12% of total samples were rejected because of mishandling and non-conformance to procedures and had to undergo repeat test. Great efforts should be made to eliminate and further reduce the rates of rejected samples in order to increase the quality of patient care.

Discussion

Laboratory analytical testing process requires a complete quality management system in achieving quality results, most especially at the preparatory stage. All stages of laboratory analysis must undergo quality processes in readiness for testing; and it starts from the time a laboratory request is ordered by a physician until the time sample is ready for analysis and covers other laboratory processes [18, 19,20]. Any variation or unexpected change in conditions results in inaccurate results. Monitoring of laboratory testing process with Quality Indicators is a common practice and continuous process in the laboratory. Performance indicators are measures of project impacts, and outcomes, hence, laboratories must monitor testing with quality indicators, record, and document results [5, 28]. Laboratories should monitor patient and

specimen identification, test order accuracy and specimen acceptability and know the percentage of specimens accepted for testing.

A total of 350 respondents and specimens were screened for quality management system and continuous quality improvement measures and monitoring at the study facility. Findings on pre-analytical variable carried out revealed that 345 respondents representing 98.6% of total samples agreed that clinicians assessed patients on dieting, body mass, age, gender, pregnancy, smoking exercise etc before recommending for laboratory tests while 5 respondents representing 1.4% of total samples disagreed on patients' variable assessments. On sample collection variables 335 respondents representing 95.7% of total samples analyzed agreed that there was variation in diurnal, posture, time of collection, fasting status, tourniquet, and presence of intravenous (IVS), order of draw, anticoagulants and insufficient volume while 15 respondents representing 4.3% of total samples disagreed. 350 respondents representing 100% of sampled respondents agreed that variables like hemolysis or clotting, lipemia, centrifugation, processing time, temperature, sunlight, evaporation, labeling aliquoting and condition of transport were considered in specimen handling. From the findings, it is believed that this could be the point where quality in pre-analytical phase is mostly compromised if mishandled for several reasons like negligence, lack of experience, non-conformity to procedures etc. Analysis of results showed that 340 respondents representing 97.1% of sampled numbers were knowledgeable on quality management of pre-analytical phase, and 10 respondents representing 2.9% of total sampled respondents were not. 334 respondents representing 95.4% of total number sampled practiced quality management system at pre-analytical phase and 16 respondents representing 4.6% of respondents disagreed on practice of quality improvements. 12 respondents representing 3.4% of total sampled number agreed that

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It was discovered that some test requests had input or feedback on the form, and this accounted for 10 test input representing 2.9% of test requests that had errors, while 340 test request representing 97.1% requests had no test input.

Findings revealed on sample management that 350 representing 100% of total samples were not lost/ but received. 4 samples representing 1.1% of total samples were collected in inappropriate containers, while 349 samples representing 99.7% of total samples were collected in appropriate containers. 4 samples representing 1.1% of total samples were haemolysed, while 349 representing 99.7% of total samples were not haemolysed. 10 samples representing 2.9% of samples were

insufficient in volumes, while 340 samples representing 97.1% of total samples had sufficient volumes. 350 samples representing 100% of total samples had adequate sample-anticoagulant ratio. 4 samples representing 1.1% of total samples were damaged in transport, while 349 samples representing 99.7% of total samples were not damaged. 10 samples representing 2.9% of total samples were improperly labeled, while 340 samples representing 97.1% of total sample had proper labels. 350 samples representing 100% of the total numbers of samples were properly stored. 42 samples representing 12% of total samples were rejected because of mishandling and non-conformance to procedures and had to undergo repeat test. Great efforts should be made to eliminate and further reduce the rates of rejected samples to increase the quality of patient care.

Conclusion

This study specifically provided information on quality management processes at the pre-analytical phase of the total testing processes for monitoring and control. It was discovered that in Nigeria particularly in St Mary's hospital, Okpoga, the most quality management practice was on variables like haemolysis or clotting, lipemia, centrifugation, processing time, temperature, labeling aliquoting and condition of transport considered in specimen handling. This was buttressed by the availability of standards of procedures and processes for best practices, effective communication system, education and training in place for personnel. Though discrepancies may arise in other quality management processes due to differences related to wide availability of varieties of indicators and area of application/practices, nevertheless, laboratory scientists and Technologists can use the result of this study to choose the appropriate quality management indicators to combat a particular error in pre-analytical process. Administering QMS indicators that specifically target the error

that are causing the test failure and repeats can reduce challenges, which target many variables responsible for rejection of samples and for failure of test run. Thus, laboratory Scientist/Technologist's application of outcome of this study can decrease the frequency with which errors evolve at the pre-analytical stage.

This study has provided baseline data for more extensive research to be conducted in quality management processes of the laboratory pre-analytical phase. Further research is recommended to determine quality measures and indicators by reviewing and harmonization to have streamlined standard quality management processes in place to guide laboratory operations. The importance of quality in the laboratory cannot be overemphasized, as poor quality work leads to economic wastage of limited resources, efforts, and time. Quality management of the laboratory can potentially be used to increase laboratory efficiency, effectiveness, accurate test results, and rapid public health response.

Way Forward

The way forward is to have qualified personnel on the grounds to effectively carry out their work. Their capacity should be built by training and re-training in relevant areas of their work. The availability of SOPs, policy, and guideline documents for use at the laboratory will help to increase the quality of work. There should be proper documentation of every activity conducted and an update of the laboratory information system for reference and follow up. Conduct regular and supportive visits to personnel at workstations. Provide on the job mentoring and guide them at their jobs. Monitoring can be enhanced by introduction and implementation of quality improvement tools like Q/A, Q/C, QMS, DMAIC (Define measure, analyse, improve and control for process improvement). 5S support, simplify (set in order), sweep (shine), standardize and sustain in a highly visual workplace. Do root cause analysis, use Lean (Waste removal) method, six

sigma (Reduction of variability) and FMEA (Failure modes ethics analysis) to monitor quality of work. There has to be vigilance and active continuous monitoring of all processes and procedures at every stage to guide against error occurrence. When each step is audited and validated at the end of the work, it will greatly assist in reduction of errors, thereby leading to good quality test results.

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