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Assessment of Extra-analytical Phase: Improving Laboratory Service and Patient Safety

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Author's contribution

The sole author designed, analyzed and interpreted and prepared the manuscript.

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ABSTRACT

Background: Laboratory quality management plans with pre-analytic, analytic and post-analytic components are key elements in ensuring patient safety. The greatest impact for overall improvement would be to focus on pre-and post-analytic services where most errors occur.
Objectives: To develop and maintain high quality practice standards for laboratory testing, to ensure patient safety by minimizing medical errors associated with laboratory service.
Methods: A review of quality management of the extra-analytic phase of the test system for improving patient safety
Results: The proportion of errors associated with the two extra-analytical phases is 4-5 times that seen in the analytical phase with the pre-analytical phase consistently representing over half of the all errors in published studies.
Conclusion: The current focus on analytical quality of the total process alone has to be expanded to include the extra-analytical phases. Laboratories need to take greater responsibility for activities, outside their immediate control for an effective laboratory service.

Keywords: Quality management; laboratories; patient safety; extra-analytical phases.

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1. INTRODUCTION

Laboratory testing process can be divided into pre-analytical, analytical and post-analytical phases. Traditionally, only the analytical phase was of concern to the laboratory professional. However, modern advances in laboratory practice that include an increase in the number of tests and complexity as well as their effect on patient care demand that quality assurance activities extend outside the laboratory.

The pre-analytical and post analytical phases are considered the extra-laboratory areas which involves individuals and departments outside the laboratory. Medical diagnosis is highly dependent on laboratory test results and erroneous test results can have a significant impact on patient care [1].

The analytical phase of laboratory service is arguably the best performing sector in health care with close to 5 sigma performances [2,3]. This is more than 3000 times lower than the rates of infection and medication errors and reflects the standardized quantitative nature of much of laboratory testing, which is suited to statistical quality control measures [4]. However, the accomplishments of laboratory service drop when errors in all phases of the total testing process are considered [5,6]. The proportion of errors associated with the two extra-analytical phases is 4-5 times that seen in the analytical phase with the pre-analytical phase consistently representing over half of all errors in published studies [7,8,9]. Accreditation agencies are increasingly requiring laboratories to go beyond analytical quality to take responsibility for the extra-analytical phase where most errors arise. These new challenges are a change from the traditional laboratory-based activities with which many laboratory staff are comfortable [10].

This review outlines the different phases of the laboratory testing process, discussed accreditation requirements and quality management systems for extra-analytical phase.

2. POTENTIAL ERRORS IN THE LABORATORY TESTING PROCESS

The operation of the medical laboratory can be viewed as a series of processes, each of which has potential sources of error. The procedure begins with the clinician making a test request either on paper or electronically. The process leading to a medical laboratory result is composed of the following steps: pre-analytical phase, analytical, and post-analytical phase. Each stage of the laboratory testing process has potential sources of error. Table 1 shows the processes that take place from the time of the physician's initial request for a test to the time of the final interpretations of the test result.

The pre-analytical phase involving collection and transport of specimen and reporting (post-analytical phase) have been identified as error-prone [11,12,13]. The proportion of errors associated with the two extra-analytical phases is 4-5 times that seen in the analytical phase, with pre-analytical phase consistently representing over half of all errors in published studies [14,15,16].

Although some laboratories have developed mechanisms to detect errors and improve pre- and post-analytical quality, there remains significant room for improvement in the quality of the extra-analytical testing phase [17,18,19].

The term "laboratory error" is defined in International Organization for Standardization (ISO) 22367 as "failure of planned action to be completed as intended or use a wrong plan to achieve an aim occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them and is the preferred term [20]. Recent changes to accreditation requirements are forcing laboratories to pay attention to this area.

3. ACCREDITATION REQUIREMENTS FOR THE EXTRA-ANALYTICAL PHASE

A series of publications in the US and UK between 1999 and 2004 subsequently led to greater requirements for active management of the extra-analytical phase of the total testing process [21,22,23,24].

The institute of medicine reports "To err is human: building a safer Health system" (1999) and "crossing the Quality chasm: a new health system for 21st century (2001) described the high rates of medical error in hospital in the United States and outlined strategies to reduce their incidence. While the first report highlighted the many American patients, who die each year from medical errors, the second described six aims for patient care, specifically safeness, effectiveness, efficiency, equitability,

Table 1. Laboratory testing processes and their potential errors

Process	Potential errors
Test ordering	• Inappropriate test • Handwriting not legible • Wrong patient identification • Special requirements not specified • Cost or delayed order
Specimen Acquisition	• Incorrect tube or container • Inadequate volume • Incorrect patient identification • Invalid specimen (e.g. haemolyzed or too dilute) • Collected at wrong time • Improper transport conditions
Analytical Measurement	• Instrument not calibrated correctly • Specimen mix-up • Incorrect volume of specimen • Interfering substance present • Instrument precision problem
Test reporting	• Wrong patient identification • Report not posted in chart • Report not legible • Report delayed • Transcription error
Test Interpretation	• Interfering substances not recognized • Specificity of test not understood • Precision limitations not recognized • Analytical sensitivity not appropriate • Previous values not available for comparison

Adapted from [15]

patient-centeredness timeliness and rules for care delivery redesign the majority of medical errors was not the result of individual recklessness or the actions of a particular group but was caused by faulty systems processes, and conditions that led people to make mistakes or fail to prevent them. Amongst the strategies proposed were the raising of performance standards and expectations for improvements in safety through the actions of oversight organizations and professional groups and the implementing of safety systems in healthcare organizations to ensure safe practices at the delivery level. These recommendations are yet to be translated into specific requirements to enhance patient safety by Nigerian accreditation bodies. The ISO 15189:2007 standard is designed for use by medical laboratories in developing their quality management systems and assessing their own competence and for use by accreditation bodies in conforming or recognising the competence of medical laboratories [25].

4. LEGISLATIVE AND REGULATORY INITIATIVES TO PROTECT PATIENT SAFETY

Published data suggest that 24-30% of laboratory errors have an effect on patient care while actual or potential patient harm occurs in 3-12% Errors in health care are of concern when they lead to actual or potential adverse outcomes for patients [26,27,28].

Laboratory professional bodies and Federal/State governments should take steps to block unethical practices that can distort rational medical decisions, and adversely affect patient safety and care. There is need for passage of legislative bills to back support the noble advocacy.

To ensure the highest quality of patient health and safety, it is recommended as follows: -

1. Laboratory professionals should recognize and identify all potential problem and vulnerabilities in laboratory.
2. Patient safety initiatives be designed to reduce errors in all clinical environments including the laboratory.
3. The laboratory/hospital accreditation process as well as standard operating procedures be utilized to help minimize patient safety goal.
4. Continuing medical education for health professionals to promote patient health and safety.
5. Certification and licensure of laboratory personnel as a means to ensure laboratory safety
6. Laboratory industry should hold meetings between laboratory and non-laboratory health professionals to discuss patient safety strategies.
7. Collaboration within the laboratory community to optimize the value of laboratory.

5. QUALITY INITIATIVES

The management of quality in medical laboratories today is generally subject to national or international guideline for good laboratory practice. For example, many countries adapt some version of the international Organization for standard (ISO) guidelines for quality and competency as described in ISO 15189.

Quality in the laboratory has a huge impact on diagnosis and patient management as about 80% of all diagnosis is made on the basis of laboratory tests [29]. The international standard ISO 15189:2012 require the use of quality indicators QIs for assessing and monitoring the quality of all steps of the total Testing process (TPP) [30].

In recent years, the concepts and practices of quality assessment programs such as the implementation of ISO 15189:2012 standard in laboratory tests are important strategy workshops to prevent or reduce errors [31]. Errors in the pre-analytical phase of the testing process have a great impact on patient outcomes. They can come from injury to patients or even result to their death. The health care system is increasingly dependent on reliable clinical laboratory services which as part of the overall health care system are prone to errors.

6. CONCLUSION

The concern of the laboratory professionals only to the analytical quality over the years has given rise to huge error rate which is greater than most areas of health care delivery service. However, the realization of the prevalence of errors in the extra-analytical phase of the testing process has led to the increasing demand for laboratories to take more responsibility in the extra-laboratory areas which involve individuals and departments. Quality management of the extra-analytical phase of the laboratory testing process seems to be a pre-requisite for an effective laboratory service. Laboratory professionals must be leaders in ensuring patient safety both within and outside of the walls of the laboratory.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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