



REVIEW ARTICLE

Assessment of laboratory errors and best laboratory practices in human healthcare.

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Received: June 11, 2016; Revised: June 17, 2016; Accepted: June 22, 2016

Available online: 1st July 2016

Abstract: Laboratory error is defined by ISO 22367 as "Failure of planned actions to be completed as intended or use a wrong plan to achieve an aim". Lundberg in 1981 outlined the concept of Total Testing Process (TTP) and Plebani elaborated it further and classified the whole testing process into five phases of Pre-Pre Analytic, Pre Analytic, Analytic, Post Analytic and Post - Post Analytic. The errors have to be identified and resolved in each phase of the process. The medical laboratories have to run Internal and External Quality Control programs and abide by the guidelines of ISO 15189 in order to be accredited by bodies like JCI, CAP or NABL. Active communication and regular interaction between the clinicians and the laboratory is recommended during Pre Analytic and Post Analytic phases of TTP in order to achieve the target of Best Laboratory Practices.

Key words: Laboratory Errors; Error Analysis; Total Testing Process; Accreditation

Introduction

The error anywhere leads to chaos and especially laboratory errors may affect the patient care. The laboratory error has been defined by different bodies in different terms. 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 them" [1, 2] Another author has described error as any defect from ordering tests to reporting results and appropriately interpreting and reacting on these errors in laboratory medicine are intrinsically obscure as they are difficult to identify and, when found, are less easily understood than other types of medical error.

Types of errors in a Medical laboratory

The error in laboratory may be an actual error which may have occurred at any phase of processing or it may be simply a perception of the clinician in whose views any laboratory result not corresponding to his clinical diagnosis is an error on the part of the laboratory. The later may be the case most often encountered by laboratory personnel.

Laboratory medicine, as a specialty that had prioritized quality control, has always been at the forefront of error reduction. In terms of quality control and error rates, laboratory medicine has a far better record than most other fields in health care. Some studies indicate that, in the analytic phase, the average error rate is as low as 0.002%; this is functioning at the five sigma level. As a comparison, the rates of infections and medication errors are closer to the sigma three. (3)

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Total Testing Process and Phases of Laboratory Work

Lundberg (4) is the man who emphasized and classified the Total Testing Process (TTP) in laboratory in three main phases keeping in mind the Clinician's initial impression of the case, choice of tests advised, collection of samples and their transportation to the laboratory, actual analysis and the testing in the lab, reporting of results and their interpretation by the clinicians. These activities have been categorized in three following phases. The TTP is the unique framework for identification of laboratory errors in a traditional laboratory or at a Point of Care Testing (POCT). (5)

1. Pre Analytical Phase
2. Analytical Phase
3. Post Analytical phase

Plebani (6,7) has further extended this to five phases by adding Pre Pre and Post Post phases: -

The Pre Analytical Phase:

The pre-analytical phase of TTP deals with all the steps before the actual phase of Analytical Testing, starting with physician's order of choice of relevant investigations, proper collection of samples with proper technique of phlebotomy and choice of anticoagulant, prescribed blood anticoagulant ratio and finally the proper procedure of transportation. In order to ensure proper collection of samples we have introduced training workshops for the nursing staff conducted by our Laboratory specialists.

The Analytical Phase:

From the moment the test samples are received in the laboratory, the proper segregation of sample for each investigation, its time of receiving, entry



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of patient's particulars along with its unique hospital Id and lab number, centrifugation, incubation and running of sample on a semi or fully automated equipment or staining of smears in Hematology or Cytology, entry of results in computer, validation by the technicians and laboratory experts till the dispatch of reports to the respective departments within the accepted turnaround time come under Analytical phase. This is the phase which is totally managed by the laboratory itself. The laboratory's Internal and external quality programs are run to monitor this phase, however an error in the pre analytical phase shall definitely affect the quality of results in spite of best analytical phase.

Post Analytical Phase:

All steps in the overall laboratory process between completion of analytical phase in the laboratory and the results receipt by the requesting physician. The process includes the dispatch of reports either manually to the respective wards or electronically to the concerned physician's computer system. The laboratory has to ensure the specified turnaround time. The responsibility of interpretation of laboratory results lies with the physicians.

In recent years, there has been increasing interest in quality improvement and patient safety activities in healthcare. The clinical laboratory has a leader in the field of healthcare quality management with a focus on analytical quality born of its scientific background. Accreditation agencies are increasingly requiring laboratories to go beyond analytical quality and take responsibility for the pre- and post-analytical phases where most errors arise.

Errors in the Total Testing Process

Laboratory has always stuck to Quality Management Procedures by strictly complying to Internal and External Quality Control procedures which are properly documented in any standard laboratory, unlike lack of proper quality management of Physicians clinical approach which is guided by individual perceptions.

Error rates are often described using the sigma concept, which refers to the number of standard deviations that lie between the process mean and the specification limit. The analytical phase of laboratory medicine is arguably the best performing sector in healthcare with close to 5 sigma performance (0.002%) (8,9). This is more than 3,000 times lower than the rates of infection and medication errors and reflects the standardized quantitative nature of much of laboratory medicine testing.

In a representative study, an Italian stat laboratory used the same methodology to assess error rates in 1996 and 2006 and found that, despite a 34% reduction in error rate, the pattern of 62% pre-analytical, 15% analytical and 23% post-analytical phase errors remained basically unchanged. (10).

The commonest causes of errors in the total testing process as compiled by Plebani are shown below (11-15).

1. Pre-pre-analytical (46-68%)
Inappropriate test request, order entry, patient/specimen misidentification, sample collected from infusion route, sample collection (hemolysis, clotting, insufficient volume, etc.), inappropriate container, handling, storage and transportation.
2. Pre-analytical (3-5%)
Sorting and routing, pour-off, aliquoting, pipetting and labeling, centrifugation (time and/or speed).
3. Analytical (7-13%)
Equipment malfunction, sample mix-ups, interference (endogenous or exogenous), undetected failure in quality control.
4. Post-analytical (13-20%)
Erroneous validation of analytical data, failure in reporting/addressing the report, excessive turn-around-time, improper data entry and manual transcription error, failure/delay in reporting critical values.
5. Post-post-analytical (25-46%)
Errors in healthcare are of concern when they lead to actual or potential adverse outcomes for patients

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%. (12)

The areas of patient safety improvement in laboratory medicine can be prioritized in the following order. (12, 15)

1. Accuracy of patient/specimen identification
2. Effectiveness of laboratory data communication
3. Communication of critical test results
4. Sample acceptability and rejection criteria
5. Appropriateness of test request
6. Avoiding manual transcription of data

In study by Carraro, Errors were classified as pre-analytical (88.9%), analytical (9.6%) and post-analytical (1.5%). Classification and grading of quality failures in the clinical biochemistry laboratory showed that 72.7% of errors had an actual adverse impact score of 1 labeled as least severe grade while 65.9% of errors had a potential adverse impact score of 5 labeled most severe grade. (13)

In a study conducted in the hematology section of Subharti Medical College, Meerut, India in 2011,

Pre-analytical errors were detected in 1% of all samples. Most of the samples were rejected due to misidentification.

Significance of Communication between Physician and laboratory: It has been observed that most of the discrepancies and disputes between the physicians and laboratory occur due to lack of communication between the physician and the Laboratory during the pre-analytic and post-analytic phase. It is advisable that before ordering the investigations the physicians should discuss the clinical presentation of the patient with the Laboratory specialist regarding the relevant investigations. The nursing staff if not properly trained must ask about the procedure of proper sample collection and transportation from the laboratory. In the post-analytic phase if the interpretation of laboratory tests is discussed between the physician and the Lab specialist it helps in order to clinch the diagnosis and start an early management.

Accreditation Requirements:

Accreditation bodies such as Joint Commission International (JCI) and College of American Pathologists (CAP) specifically require healthcare organizations to have clear and effective procedures for patient/sample identification and communication of critical results and to monitor their performance in these areas. (16)

The most acceptable and applicable model of code is ISO 15189: brought in 2007 under the heading of Medical laboratories - Particular requirements for quality and competence (16). In Indian context now "National Accreditation Board for Testing and Calibration Laboratories" (NABL) is the most reliable and standard agency for accreditation of Laboratories. The body imparts courses of ISO/IEC 17025 and ISO 15189 for Assessor's Training Course. The medical laboratories are issued accreditation certificate separately for each section of Clinical Pathology & Hematology, cytology, Histopathology, Biochemistry and Microbiology if the section complies by all the standards of NABL. (17)

Summary

It is almost mandatory for laboratories to run Internal and External Quality Control Programs, identify and minimize the errors occurring in TTP. The best laboratory practice is achieved by regular interaction between the clinicians and Laboratory during the Pre-Analytical and Post-Analytical phases of TTP.

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Cite this article as:

Syed Riaz Mehdi, Sharique Ahmad, Noorin Zaidi. Assessment of laboratory errors and best laboratory practices. *International Journal of Bioassays* 5.7 (2016): 4704-4706.
<http://dx.doi.org/10.21746/ijbio.2016.07.008>

Source of support: Nil
 Conflict of interest: None Declared