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An Analysis of Iceberg of Errors in Clinical Laboratory

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Abstract

Background: The current increasing awareness about quality system in clinical laboratories and increasing attention on patient safety and the need to reduce lab errors, it is important to know the prevalence of error rates in the whole testing process, including pre examination, examination and post examination phases, so that the preventive actions can be taken for good lab results. The goal of this study to was to analyse the prevalence and type of errors contributing to the errors in the clinical laboratory during 1 year period.

Materials and Methods: This study was done for a period of one year 2014-2015, taking the retrospective data in the clinical laboratory.

Results and Discussion: Out of 97295 samples received in this period, 70-90% problems occurred during the pre and post examination phase.

Conclusion: Based on these finding, the proper collection and transportation are prime steps involved in the testing process. If this area is compromised, it will significantly affect the patient result and patient safety. So continuing medical education programmes are needed to improve the quality of lab reports.

Key words: Pre-examination, Hemolysis

Introduction:

Quality in lab medicine should be defined as the “guarantee that each and every step in the total testing process is correctly performed”, thus assuring the appropriate medical decision making and prompt patient care.1 Following the development and successful implementation of high-quality analytical standards, analytical errors are no longer the main factor influencing the reliability and clinical utilization of laboratory diagnostics. Errors occurring within the extra-analytical phases are still the prevailing source of concern.2 Accordingly, lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, account for up to 93% of the errors currently encountered within the entire diagnostic process. The more recent surveys on errors in laboratory medicine conclude that in the delivery of laboratory testing, mistakes occur more frequently before (pre-examination) and after (post-examination) the test has been performed. Most errors are due to pre-examination (analytical) factors (46–68.2% of total errors), while a high error rate (18.5–47% of total errors) has also been found in the post-analytical phase.3 The lack of attention to these phases pose increased risk of errors in reporting the results.

Materials and Methods:

Study design

After obtaining the ethical clearance from the institution, we performed this study in the time period 2014-2015. The six types of laboratory test groups were included: clinical chemistry (three analysers: Abbott Architect, BA400, Roche analyser; tests such as metabolites, enzymes, electrolytes, lipids, etc, immunoassays such as thyroid function tests, fertility hormones, tumor
markers etc.; haematology (sysmex analyser: 12 parameters); glycated haemoglobin (HbA1c, one analyser: Bio-Rad D10); coagulation (one analyser: Destiny Plus, prothrombine time, PTT.) and erythrocyte sedimentation rate (ESR) (one analyzer: Excyte 40).

The samples are collected using evacuated tubes (vacationers’ evacuated tubes from BD (Franklin Lakes, NJ). The lab provides routine and reference testing in biochemistry, haematology and microbiology sections. Upon receiving the samples, the lab supervisor visually detects any problems. When an error occurs, entries are made in the problem notification log book. The data generated is reviewed on a weekly basis. The data collection procedure involved review of blood samples received from the inpatient as well as outpatient departments. Venous blood samples are considered unsuitable according to the following accepted criteria: inappropriate volume, wrong or missing patient identification, inappropriate container, visible haemolysis after centrifugation. The pre-examination variables evaluated included all the criteria mentioned above for sample rejection as well as incomplete/incorrect patient details and illegible handwriting. The number of tests re run were entered in the log book as soon as it is done. The typographical errors were identified.

**Results:**
A total of 97295 samples were received during this study period. The total error rate was 1.90%. The distribution of the different types of errors was then calculated for each phase of testing (Fig.1). The pre analytical/examination phase contributed the major 72.47%, analytical/examination phase 9.9% and post analytical/examination phase about 17.53%.

In the pre analytical/examination phase the major source for rejection was haemolysed samples, which accounted for 40.2%, followed by insufficient (inadequate), clotted and wrong test request forms 23.9%, 21.4% and 14.5% respectively (Fig 2). The causes for different sources of errors are given in the table 1.

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**Table 1: Causes for different sources of error.**

<table>
<thead>
<tr>
<th>Phase of testing process</th>
<th>Type of error</th>
<th>%</th>
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<tbody>
<tr>
<td>Pre examination</td>
<td>Inappropriate test request</td>
<td>72.47%</td>
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<tr>
<td></td>
<td>Order entry errors</td>
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<tr>
<td></td>
<td>Misidentification of patient</td>
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<td></td>
<td>Container inappropriate</td>
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<tr>
<td></td>
<td>Sample collection and transport inadequate</td>
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<tr>
<td></td>
<td>Inadequate sample/anticoagulant volume ratio</td>
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<tr>
<td></td>
<td>Insufficient sample volume</td>
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<tr>
<td></td>
<td>Sorting and routing errors</td>
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</tr>
<tr>
<td></td>
<td>Labelling errors</td>
<td></td>
</tr>
<tr>
<td>Examination</td>
<td>Equipment malfunction</td>
<td>9.9%</td>
</tr>
<tr>
<td></td>
<td>Sample mix-ups/interference</td>
<td></td>
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<tr>
<td></td>
<td>Undetected failure in quality control</td>
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<tr>
<td></td>
<td>Procedure not followed</td>
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<tr>
<td>Post examination</td>
<td>Failure in reporting</td>
<td>17.53%</td>
</tr>
<tr>
<td></td>
<td>Errorneous validation of analytical data</td>
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<tr>
<td></td>
<td>Improper data entry</td>
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</tbody>
</table>
Discussion:
In our study, test requests and blood samples of clinical chemistry, immunoassay, haematology, and coagulation test were evaluated. Types of inappropriateness were evaluated as follows: haemolysed, clotted, insufficient volume of samples, misidentification, inappropriately labelled samples and test request form errors, number of re-testing and typographical errors.

Based on the findings in this study, haemolysed and insufficient samples accounted for the majority of rejection for the analysis. The percentage of (%) haemolysed samples received was 40%. Haemolysis of samples occurs when blood is forced through a fine needle, shaking the tubes vigorously and centrifuging the sample specimens before clotting is completed. Freezing and thawing of blood specimens may cause massive hemolysis. In a study by Jay and colleagues, the majority of haemolysed samples could be attributed to in vitro process resulting from incorrect sampling procedure or transportation.

Haemolysis leads to extravasation of intravascular contents into the plasma, leading to high values of potassium and intracellular enzymes such as Aspartate Transaminase (AST), and Lactate Dehydrogenase (LDH). It also leads to a prolonged turnaround time due to the need for fresh samples for processing the test.

Another factor which was responsible for rejection of analysis in our study was insufficient sample. Every examination process requires a fixed volume of serum or plasma for analysis. The main reason behind this error is ignorance of the phlebotomist, difficult sampling as in paediatric patients, patients with chronic, debilitating diseases and patients on chemotherapy whose veins are difficult to localize.

Pre and post examination phase is the most vulnerable part of the total testing process and is one of the greatest challenges to the lab professionals. However, the pre examination activities like unsuitable specimens and reporting policies are not harmonized worldwide. A correct pre examination phase procedure is critical to get an adequate and appropriate samples and consequently get the reliable lab results, thus promoting patient safety.

Pre-examination phase is defined as “steps starting in chronological order from the clinicians request and including the examining the requisition forms, patient preparation for sample collection, transportation to and within the laboratory and ending when the analytical procedure begins”. This clearly identifies the need to evaluate, monitor and improve all the procedures and processes in the initial phase of the brain-to-brain loop.

As stated by Lundberg several years ago on introducing the concept of the ‘brain-to-brain loop’ for describing the Total Testing Process(TTP), the generation of any laboratory test result involves nine steps: ordering, collection, identification, transportation, separation or preparation, analysis, reporting, and action. Interestingly, although the ‘brain-to-brain’ concept was defined as long as 40 years ago, it is still considered the working paradigm in assuring quality and safety for requesting physicians and patients.

Most of human dependent and preventable pre-analytical errors have occurred during sample drawing. Plasma–citrated samples were especially exhibited the highest percentage of rejection rate of blood drawing errors. Coagulation tubes were used in first order of blood draw and more vulnerable to inappropriate mixing and fulfilling of tubes causing to clotted and insufficient volume of specimen errors. These non-conformities could be prevented by phlebotomists’ training.

The percentage of error in the examination phase was 9.9%, which was may be due to sample mix up and interferences mainly, followed by undetected...
failure in quality control and equipment malfunction. In the post examination errors, there were typographical errors while entering values in the Laboratory Information System (LIS), which accounted for about 17.5% error, where again ignorance plays a major role. The introduction of a hospital computerized order entry system has eliminated some errors, such as a wrong patient name or care unit and the performance of unrequested laboratory tests, but it has not eliminated the risk of mismatching patients. These errors derive from poor compliance with written procedures, emphasizing some unsatisfactory aspects of information technology. There are certain measures which can prevent these errors if followed. A comprehensive plan to prevent pre-examination errors has 5 interrelated steps:

1. Developing clear written procedures.
2. Enhancing health care professional training.
3. Automating functions, both for support operations and for executive operations.
5. Improving communication among health care professionals and fostering interdepartmental cooperation.

Development and widespread implementation of a Total Quality Management (TQM) system is the most effective strategy to minimize uncertainty in laboratory diagnostics. Pragmatically, this can be achieved using 3 complementary actions: preventing adverse events (error prevention), making them visible (error detection), and mitigating their adverse consequences when they occur (error management).

**Conclusion:**

In a modern approach to total quality, centered on patients' needs and satisfaction, the risk of errors and mistakes in pre- and post-examination steps must be minimized to guarantee the total quality of laboratory services. The profound awareness that complete elimination of laboratory testing errors is unrealistic, especially those relating to extra-analytical phases that are harder to control, highlights the importance of good laboratory practice and compliance with the new accreditation standards, which encompass the adoption of suitable strategies for error prevention, tracking and reduction, including process redesign, the use of extra-analytical specifications and improved communication among caregivers. Alongside the challenging and long road of patient safety, pre and post examination phase’s offers room for improvement.

**References:***


