Study of Pre-analytical Errors in a hospital based clinical Biochemistry laboratory.

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Background: Accurate laboratory results are vital for patient safety and laboratory errors can occur at any of the lab testing phases viz, Pre-analytical, Analytical or Post-analytical phase. The aim of this study is to identify and estimate the pre-analytical errors, so that appropriate preventive and corrective measures can be taken.

Methods: A total number of 73,173 OPD and IPD samples were analysed for the pre-analytical errors over a period of 6 months. Each sample was followed from the time of blood withdrawal to the testing equipment. The different types of pre-analytical errors obtained were recorded and categorized, and their percentages calculated.

Results: Pre-analytical errors were detected in 477 out of 73173 samples with an error rate of 0.7%. Haemolysis and Samples not being received were the most commonly observed error.

Conclusion: Although it is impossible to eliminate all pre-analytical errors, compliance with best practices can reduce their incidence.
INTRODUCTION:
Laboratory services are vital for the modern health care sector. To obtain accurate results is the first and foremost requirement for patient safety and to improve the medical diagnosis of patients. Laboratory testing is a sum total of highly complex and standardized process. Effective laboratory service is the sum total of accuracy, precision, and turn-around time. Even after a number of advances in laboratory science, these services are still susceptible to various types of systemic and manual errors (1). In modern clinical diagnostic laboratories, the total testing process includes each and every step right from the ordering of a test to the receipt of results by the concerned clinician.

The laboratory testing process comprises three phases: First is the Pre-analytical phase, which according to the standard for Laboratory accreditation (International Organization for Standardization (ISO) 15189:2012) encompasses all the steps from the ordering of a test, sample collection, proper transport and registration of the sample till the start of specimen analysis according to test requested. Second is the Analytical phase, which accounts for the correct analysis of the analytes and technical validation of results obtained. Third is the Post-analytical phase, which involves the correct interpretation of the test results, approval from the Laboratory manager and then reporting to the concerned clinician. Laboratory errors can occur at any of these three phases. The errors in the reporting lead to an increased demand of resources, incorrect clinical decisions, delayed diagnosis and longer duration of hospital stays (2).

Clinical laboratories have focussed their attention on proper quality control methods and proper quality assessment programs, dealing with every analytical aspects of testing. However, recent studies had demonstrated that quality in clinical laboratories cannot be assured by only focusing on purely analytical aspects (3). Both pre and post analytical phases have been recognized as a large source of the laboratory errors, mostly pre-analytical phase. Approximately, 70% of the total errors in any clinical laboratory test results occurs in the pre-analytical phase (4). Main reasons for such a large number of errors in pre-analytical phases being that it is the most crucial and hardest to regulate and monitor because of the involvement of too many professionals (such as physicians, specialists of laboratory medicines, nurses, laboratory technicians and phlebotomists), difficulty in achieving standardized procedures for sample collection, unlike the analytical phase, this phase seldom subject to quality control schemes. The International Federation of Clinical Chemistry and Laboratory Medicine Working Group for Laboratory Errors and Patient Safety (IFCC-WG-LFPS) has organized a number of quality markers in the pre-analytical phase to improve pre-analytical phase errors (2).Among the commonest pre-analytical errors are: Inappropriate test order, identification error of patient, sampling timing errors and preparation, lipemic and haemolytic blood samples, missing test requests and/or samples, insufficient quantity, improper sample collection due to faulty venipuncture technique, improper vacutainer mixing, inappropriate order of draw. The aim of the present study was to identify and estimate the errors that occur during the pre-analytical phase of laboratory testing, so that appropriate corrective and preventive measures can be taken, in order to achieve reliable and accurate laboratory results for proper patient care.

MATERIALS AND METHODS
A retrospective observational study was done in the Department of Laboratory Medicine at a tertiary care cancer hospital in India for a period of 6 months. All out-patient and in-patient samples received during this period were included in the study. All the samples were followed from the time of blood withdrawal till the testing equipment. The blood sample collection was done at our collection centre. The samples are transported to the lab immediately without any delay. The blood specimens were allowed to clot, then centrifuged at a speed of 4000 rpm for 10 minutes and delivered to the analyser machine. The laboratory works 24x7 and is equipped with highly sophisticated, fully automated analysers from Roche. The laboratory conducts a wide range of routine and specialized tests such as tumour markers. Internal QC was monitored daily and performed twice a day for both the levels (as per NABL guidelines). Any analytes observed to be out of range were subsequently calibrated. Calibration
was performed according to each analyte requirements and after each lot change of reagents. In case of drift in calibration, re-calibration of the affected parameter was performed. The preventive maintenance of all the laboratory equipment was carried out by the authorized agency at regular intervals. The laboratory also participates in an external quality assurance (EQAS) program regularly. The EQAS samples were run on a monthly basis, and the results obtained are submitted to the concerned authority for verification. For pre-analytical errors all samples and their accompanying requisition slips were screened. All types of errors obtained were recorded in a separate problem notification register. The errors obtained were further categorized into 1). samples not received 2). wrong sample identification 3). lipemic samples 4). haemolysed samples 5). insufficient quantity 6). samples received in inappropriate containers 7). wrong timing of sample collection and 8). miscellaneous.

RESULTS & DISCUSSION
The total number of samples received during the study period was 73,173. The pre-analytical errors were detected in 477 samples with an error rate of 0.7% (see Table 1). Haemolysis and samples not being received were the most commonly observed error.

<table>
<thead>
<tr>
<th>Errors observed</th>
<th>No. of samples</th>
<th>Percentage</th>
<th>Causes of error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preanalytical Errors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemolysis</td>
<td>199</td>
<td>40.9</td>
<td>Wrong phlebotomy technique, incorrect transport, centrifugation before sample is clotted</td>
</tr>
<tr>
<td>Sample Not Received/requisition slip not received</td>
<td>201</td>
<td>41.4</td>
<td>Carelessness at the level of laboratory staff</td>
</tr>
<tr>
<td>Sample Identification Error</td>
<td>02</td>
<td>0.4</td>
<td>Lax attitude of phlebotomists / other laboratory staff involved in sample collection and filling up of requisition slips</td>
</tr>
<tr>
<td>Sample in inappropriate containers</td>
<td>10</td>
<td>2.1</td>
<td>Lack of knowledge of phlebotomists</td>
</tr>
<tr>
<td>Wrong timing of sample</td>
<td>04</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Quantity Not Sufficient</td>
<td>32</td>
<td>6.6</td>
<td>Lack of knowledge regarding sample volume required, difficult sampling as in old / pediatric patients</td>
</tr>
<tr>
<td>Lipemic</td>
<td>29</td>
<td>6.0</td>
<td>Collection under non-fasting state, hyperlipidemia</td>
</tr>
<tr>
<td>Total</td>
<td>477</td>
<td>97.8</td>
<td></td>
</tr>
</tbody>
</table>

In general, the magnitude of the effect of laboratory errors on patient care is very high, as it affects around 60 – 70 % of clinical decisions. Therefore, it is essential for any laboratory to generate accurate and reliable patient test reports. The processes that comprise the errors in pre-analytical phase of clinical laboratory are manually done. Compared to the errors in analytical and post-analytical phases, these errors are largely due to human mistakes; and hence largely preventable (4,5). In recent times analytical phase errors have now been controlled due of the automation and adoption of various Quality control programmes, but it is pre-analytical and post-analytical errors that still remains neglected. A study conducted by American Pathologist program after enrolling 660 laboratories showed 4.8% order error rate from outpatient centres. Similarly, the College of American Pathologists, concluded misidentification as a common laboratory error which included 120 centres. Further, a Danish study conducted on laboratory errors showed 81% of laboratory errors were pre-analytical, as compared to only 10% of laboratory errors were
found to be analytical. Moreover, in that study 82.6% human errors and 4.3% technical errors were noted (2).

In this study, haemolysis was observed to be main reason for majority of sample rejections. A total of 199 haemolysed samples were received during the 6-months study period, amounting to 41% of the errors. The main reason for haemolysis is due to mechanical trauma to the specimen such as use of small gauge needles, inappropriate syringe size, shaking of tubes vigorously, improper transfer of specimen from syringe to vacutainers or due to centrifugation of samples before complete clotting) (6). Further, haemolysis leads to extravasation of intracellular contents into the plasma, which leads to false high values of various laboratory parameters like potassium, creatinine, AST, ALT; while some analytes like sodium, chloride, Albumin and ALP show relatively false low values. Hence, it also leads to Turn Around Time (TAT) that is prolonged than usual, due to the requirement of repeat samples for processing the requested test.

Not received samples in the laboratory contributed to 41% of the total rejections. Moreover, lipemic samples contributed to 6% of total rejected samples, as these samples interfered in the proper analytical measurement of parameters such as cholesterol, creatinine and glucose. Another important factor leading to sample rejection is ‘Quantity not sufficient’, as for proper analytical process fixed quantity of serum/plasma is required. In our study, this was observed to be 6.6%. The reason behind this error may be ignorance of the phlebotomists, patients with chronic and debilitating diseases, difficult sampling as in paediatric patients, non-compliance of patients and patients on chemotherapy (leading to thin veins that would be difficult to localize).

For the proper analysis of samples especially in case of Fasting and Post Prandial Glucose estimation, one of the most crucial details required is the timing of sample collection. However, in approximately 0.8% cases this information has been observed to be missing. Illegible handwriting on requisition slips and sample identification error were found to be the least observed (0.4%) (Figure 1).

**Figure 1: Distribution of errors**

![Distribution of errors](image)

- Wrong identification: 0.4%
- Sample not received: 41%
- Hemolysis: 6%
- Lipemic: 7%
- Insufficient sample volume: 2.1%
- Sample not received: 41%

Hence, in order to assure the proper quality of laboratory services, all the risk of pre-analytical phase errors needs to be minimized by taking the appropriate corrective and preventive measures, to maintain a good quality of laboratory reports. Although, it is practically impossible to eliminate all pre-analytical phase errors, but compliance with best possible practice can significantly reduce its incidence. For proper prevention of pre-analytical errors, excellent communication and co-operation among the
significant proportion of health care team is required, as most sources of these errors are not part of clinical laboratory territory. Laboratory professionals need to survey the pre-analytical procedures from time to time and take all the necessary corrective measures in order to improve testing process, to ensure better health outcomes.

**Funding:** The author(s) received no financial support for the research, authorship, and/or publication of this article.

**Ethical Approval:** Not applicable.

**Conflict of Interest:** No potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

**REFERENCES**


