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Pre-analytical errors in clinical chemistry laboratory of a tertiary care hospital in western Uttar Pradesh, India

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ABSTRACT

Background: Diagnosis of various diseases in the present medical scenario is largely dependent on the tests performed in Clinical Chemistry Laboratory. TQM (Total quantity Management) in a laboratory ensures that the results obtained be free from errors. **Objectives:** To identify the nature and frequency of pre-analytical causes of sample rejection and to take corrective steps. **Methodology:** This study was conducted on 46,404 (OPD &IPD) samples and pre-analytical causes for sample rejection were noted and the data was analysed. **Results and Conclusion:** Pre-analytical errors were responsible for 2.32% (1077) of samples to be rejected over a period of one year. Thus, substantial number of samples undergo repeated testing because of rejection owing to pre-analytical errors.

Keywords: Total quality management (TQM), Pre-analytical errors, Clinical Chemistry Laboratory.

Clinical chemistry laboratory plays a vital role in the diagnosis, treatment and prognosis of patients in today's medical scenario.TQM (total quality management) is essential for generating accurate and reliable reports from the laboratory (Bonini P *et al*, 2002). The process of sample testing in a clinical chemistry laboratory is done in three phases: Pre-analytical, analytical and post-analytical. With increasing automation in Clinical Chemistry Laboratory errors in the analytical phase and post–analytical phase have been reduced to a great extent. Accuracy in the analytical phase and post- analytical phase has largely been considered for reporting from laboratory. On the contrary, importance of determining errors in the pre-analytical phase has not largely been stressed upon. Errors during collection and transport of biological specimens, errors in processing of the samples and in patient's data entry may occur. It has been reported that the errors in the pre-analytical phase may occur to the extent of 60% (Bonini P *et al*, 2008). Pre-analytical errors influence the total error thus hindering TQM in laboratory, consequently decreasing the accuracy and reliability of the results generated.

This study has been conducted with the aim to determine nature and frequency of the occurrence of pre-analytical errors. These errors have been identified and corrective measures suggested minimising them.

The objectives formulated for present study were: 1. to perform categorization of pre-analytical errors; 2. to determine the frequency of occurrence of these errors; 3. to determine the percentage occurrence of these errors; 4. to strive to make entire process of sample collection, transport and labelling of samples error free and 5. to take corrective measures to prevent the occurrence of such errors in future.

Materials and Methods

Present study was conducted in a Tertiary care hospital setting with the capacity of 900 beds comprising of various super speciality departments like Nephrology, Urology, Neurosurgery, Endocrinology and Paediatric surgery. The entire study was conducted in the Central Clinical Chemistry Laboratory of Teerthanker Mahaveer Hospital, Moradabad which is equipped to perform various routine biochemical tests, specialized profiles such as renal, liver, cardiac, iron profiles etc. and also hormonal analysis is possible. The present study was conducted over a period of one year (January 2012 to December 2012) on 46,404 samples which included both OPD (24,404) &IPD (22,000) collection.

Internal and external quality assurance has been maintained in the laboratory thus, ruling out any error in the analytical phase and assuming that any error that was there was due to pre-analytical variables.

Pre-analytical variables considered were-

- Haemolysis (identified on observation and confirmed by potassium determination).
- Clotted blood (observed on naked eye and confirmed by inverting the collection tubes).
- Improper blood collection tubes (identified by colour coded caps of vacutainers).
- Wrong preservative (by confirming the colour coding of test tubes).
- Wrong timing (timing of collection of fasting and post-prandial samples was determined).
- Wrong volume (volume of the sample checked in relation to the number and the type of tests ordered).
- Mislabelled samples (by matching the patient's details on requisition slips and vacutainer labels).

- Lipemia (milky appearance of serum sample was looked for).

All the samples along with the requisition forms were analyzed. Sample rejection data with the pre-analytical variable responsible was noted down in a log book. The data was collected and summarized on monthly basis. 46,404 samples were analysed after which the study was closed.

Results

46,404 samples (24,404 OPD and 22,000 IPD) were analysed, it was seen that 1077 samples (2.32%) were rejected due to some unfavourable pre analytical variable. However, repeat samples were demanded to complete reporting for these samples.

Out of total 1077 samples being rejected, the cause of abandoning tests in 323 samples was hemolysis, followed by clotted blood as being the second most frequent cause of rejection of samples as seen in 194 samples. Blood collection in wrong tube and due to addition of wrong preservative was seen as the cause of rejection in 247 samples. Due to insufficient sample volume total of 87 samples were redemanded for investigations to be performed. Inappropriate timing of collection of samples resulted in the rejection of 97 samples. Mislabelling or misidentification was seen as a preanalytical error in 76 samples. Lipemia was considered as the preanalytical variable responsible for rejection of 53 samples (Table 1 and Figure 1).

Table 1. Frequency and nature of occurrence of preanalytical errors in 1077 rejected samples

Pre-analytical Variable	No. of Rejected Samples	% of Rejected Samples
Hemolysis	323	29.99
Clotted Blood	194	18.01
Wrong Tube	129	11.98
Wrong Preservative	118	10.96
Wrong Volume	87	8.08
Mislabelled Samples	76	7.06
Wrong Timing	97	9 .0
Lipemia	53	4.92

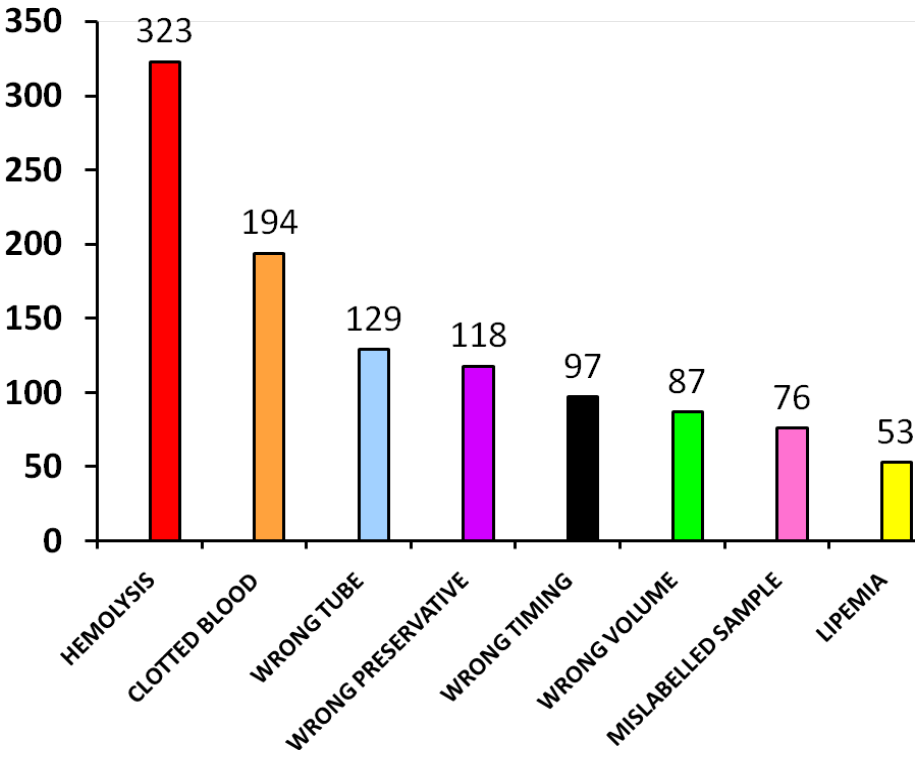

Figure 1. Frequency of occurrence of pre-analytical errors

The percentage occurrence of the preanalytical variables was also determined which indicated that hemolysis was seen in 29.99% samples, clotted blood in 18.01% of the samples. Collection of blood samples in wrong tube, wrong preservative and obtaining wrong volume collectively accounted for faulty results in 31.02% of the samples due to which they were rejected. Incorrect timing of collection of samples was seen in 9% of the total samples. Mislabelling of the samples by the laboratory personnel was seen as a cause of rejection of 7.06% of the samples. 4.92% lipemic (milky) samples were rejected being a interfering factor in analysis (Figure 2).

- Overall prevalence of pre analytical errors in our laboratory was found to be 2.32%
- By far the most prevalent pre analytical variable seen responsible for sample rejection was found to be hemolysis seen in 29.99% of samples.
- Closely followed by the addition of clotted blood as the second most common factor responsible for sample rejection was seen in 18.01% of the samples.

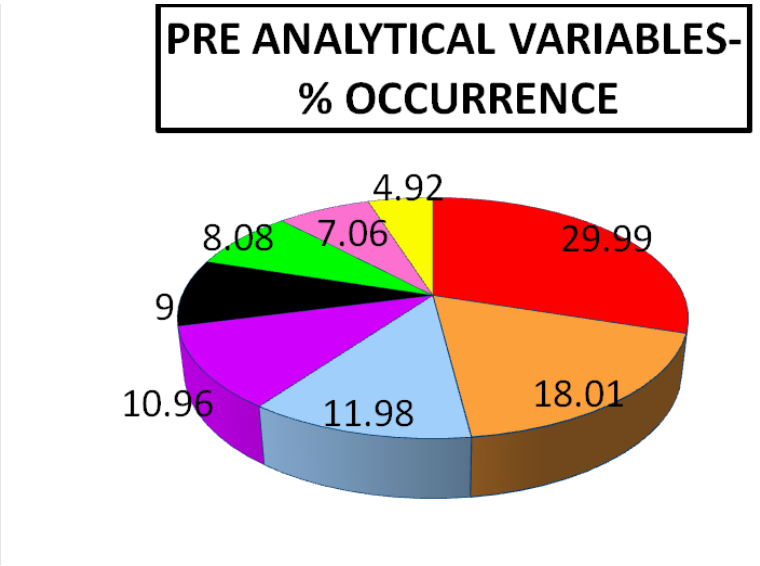

Figure 2. Hemolysis (29.99%) Clotted blood (18.01%) Wrong tube (11.98%) Wrong preservative (10.96 %) Wrong timing (9%) Wrong volume (8.08%) Mislabelled sample (7.06%) Lipemia (4.92%)

Discussion

With the advent of automation, errors have decreased considerably since past few years in Clinical Chemistry Laboratory. This decrease in errors has largely been seen in the analytical phase and consequently pre-analytical phase is the one in which most of the errors are expected to occur now (Lippi G *et al*, 2011) Pre-analytical phase being mainly manually operated is subjected to many errors. These errors may yield erroneous results, which may even be life threatening for the patients and hence, the need to identify them and minimise them exists (Lippi G *et al*, 2006) . Therefore, it becomes imperative for the laboratory personnel to minimise these errors in order to ensure accurate and precise report generation from the Clinical Chemistry Laboratory. So, in this study after the collection of data the pre-analytical variables responsible were identified and were categorized. Each variable was then considered separately and analysed for causes leading to these errors after which measures were suggested to the laboratory personnel to avoid them (Prabhat kumar Nigam, 2011). Thus, individual consideration of these factors was done and proactive steps to avoid them were suggested.

In our study haemolysis was found to be the commonest cause of sample rejection. These findings were similar to the study done (Ashakumari S *et al*, 2011). The possible factors which were identified for in vitro haemolysis in the samples

were found to be improper phlebotomy techniques, blood collected in insufficient amount of additive in the tube, traumatic venipuncture , abrupt freezing and thawing ,vigorous shaking of tubes after collection and transfusing of the blood directly from a small diameter needle. Technical staff was made aware about all these factors leading to haemolysed samples and to take measures to avoid them. It was found that the clotted blood sample reaching the laboratory could be done away with blood collection in proper anticoagulant tubes and proper vacutainers. Collecting the blood in proper vacutainers which are easily identifiable by colour coding would also ensure avoidance of wrong results due to incorrect volume of the sample reaching the laboratory (Shashi Upreti *et al*, 2013). It was seen that prompt transfer of the sample from the blood collection unit to the laboratory was good enough for avoiding wrong timing of the sample. Moreover, it was emphasized that giving proper instructions to patients regarding collection of timed samples will also go a long way in avoiding such type of errors. Insufficient volume also accounted for false results in substantial number of patients for which the technical staff were directed to practice proper phlebotomy techniques and the use of vacutainers for the collection of blood samples. Mislabelling or misidentification of the samples was seen in 7.06% of the patients which were similar to the finding obtained by (Bonini P *et al*, 2008). Misidentification in terms of errors in recording name, sex, sample number, tests recommended and even double entry was recorded for the blood samples. Lipemic samples were identified for 4.92% patients which was the least common factor responsible in our study. Technical staff was guided to use lipemia clearing agent and dilution techniques in such samples to avoid errors due to lipemia.

Conclusion

Pre-analytical phase is a lesser identified area for the occurrence of errors in a Clinical Chemistry Laboratory which can account to a large extent for the generation of faculty reports from the laboratory (Chawala R *et al*, 2010). Frequency, type and percentage occurrence of these errors must be identified in each laboratory so that corrective measures may be taken to overcome these errors.

Inferences

- Mere accuracy in analytical phase is not sufficient for reliable reporting (Firdushi Begum, 2014).
- Advances in automation be used for proper sample collection and transport (Szecsi P B *et al*, 2009).
- Vacuum tubes / vacutainers with proper colour coding be used for proper collection.

- Incorrect transportation technique and abrupt freezing and thawing be avoided to prevent hemolysis.
- Laboratory personnel should be trained to minimise errors due to preanalytical errors Young D S *et al*, ed).

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