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Clinical pre analytical phase of samples: Important criteria phase study

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Abstract
Introduction: Among the three phases of clinical chemistry laboratory i.e. pre-analytical, analytical and post-analytical, it is the pre-analytical phase which contributes to most of the errors. Pre-analytical phase includes completion of laboratory requisition form, phlebotomy, specimen identification, sample handling and transportation to the laboratory. From various pre-analytical errors, the errors related to sample collection are very high. This study was undertaken to completely assess the sampling errors in a tertiary care teaching hospital.
Material and Methods: The study was undertaken to access the sampling errors in a biochemistry laboratory of a tertiary care hospital. It was a prospective study. Following quality indicators were assessed in the study i.e. inappropriate container, hemolysed sample, insufficient sample volume, damage to the container, improperly labeled sample and mismatch sample.
Results: Out of total 972 samples the maximum percentage of error was seen due to improperly labeled sample accounting to 1.23%, this is followed by hemolysed sample accounting to 1.03%.
Conclusion: Our study shows that there is need to understand the importance of pre-analytical phase with special emphasis on the sample collection related errors. Sensitizing the healthcare professionals about the errors related to sample collection reduces the overall percentage of errors which has a positive impact on the health outcome of the patients.

Keywords: preanalytical phase, sampling error, hemolysed sample

Introduction
One factor which is important source of medical error affecting patient's safety is laboratory testing [1-3] among the three phases of clinical chemistry laboratory i.e. Pre-analytical, analytical and post-analytical [4], it is the pre-analytical phase which contributes to most of the errors accounting to 68.2 % [5] and this preanalytical phase is not under the control of clinical laboratory and the laboratory physician. Pre-analytical phase includes completion of laboratory requisition form, phlebotomy, specimen identification, sample handling and transportation to the laboratory [5-7] From various pre-analytical errors the errors related to sample collection are very high, which includes errors related to inappropriate container, hemolysis sample, sample with insufficient volume, damaged sample, improperly labeled sample and mismatch sample. As these errors exerts a powerful influence on healthcare expenditures, a proper control of these errors results in fruitful outcome not only on expenditure front but also for the patients. Hence this study was undertaken to completely assess the sampling errors in a tertiary care teaching hospital.

Material and methods
The study was undertaken to access the sampling errors in a biochemistry laboratory of a tertiary care hospital. Quality indicators developed by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Laboratory Errors and Patient Safety (WG-LEPS) were used [8-10] It was a prospective study. The study was conducted in Biochemistry laboratory of RAJEEV GANDHI COLLEGE AND HOSPITAL BHOPAL M.P. Duration of the study was between 15/01/2017 to 15/12/2017 and all the OPD forms coming to the biochemistry laboratory between 09:00 AM to 04:00PM were included. Institutional ethical committee clearance was accorded to the study. Following quality indicators were assessed in the study i.e. inappropriate container, hemolysed sample, insufficient Sample volume, damage to the container, improperly labeled sample and mismatch sample.

Statistical analysis
The information provided on laboratory requisition form was recorded on day to day basis in Microsoft Excel spread sheet windows 7 and evaluated using software package used for statistical analysis (SPSS) version 21. The results were interpreted as percentages; Defects per million (DPM), Sigma value and Sigma based performance level. Calculation of performance as per sigma metrics -

DPM = (number of errors × 10, 00,000)/total number of specimens

The DPM rate was converted to a sigma value based on calculators available online (http://www. westgard.com/six sigma- calculators-2.htm.)
Performance levels based on the sigma metrics evaluation were used to compare our laboratory results
1. Very good: ≥ 5.0 sigma
2. Good: 4.0-<5.0 sigma
3. Minimum: 3.0-<4.0sigma

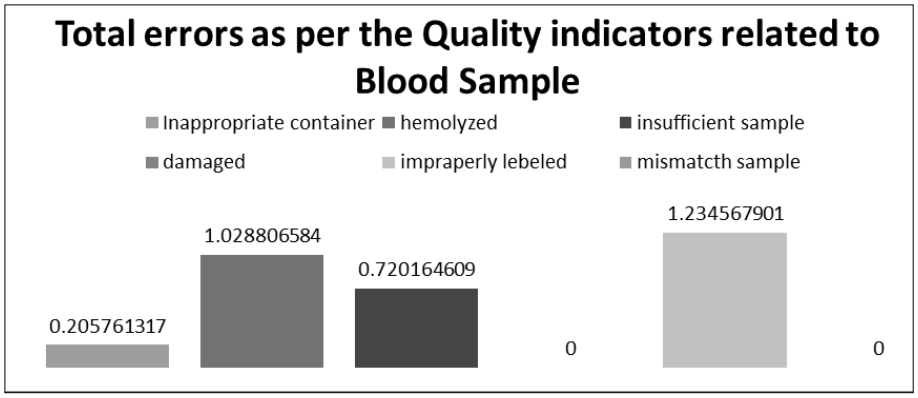
4. Unacceptable: <3.0 sigma

Results

Total 972 samples were assessed during the duration of the study. The maximum percentage of error was seen due to improperly labeled sample accounting to 1.23%, this is followed by hemolysis sample accounting to 1.03%. DPM value and sigma value for improperly labeled sample was 12346 and 3.8 respectively. DPM value and sigma value for hemolysed sample was 10288 and 3.9 respectively as shown in Table 1 and Figure 1. Besides the percentage error, DPM value, Sigma value and Sigma based performance were calculated as shown in the table.

Table 1: Total errors as per the Quality indicators related to Blood Sample

No.	Quality indicator	Total no of samples	Total no of errors	Error in percentage	Dpm value	Sigma value	Sigma based performance level
1	Inappropriate Container	972	2	0.21	2058	4.4	Good
2	Hemolyzed	972	10	1.03	10288	3.9	Minimum
3	Insufficient Sample	972	7	0.72	7202	4.0	Good
4	Damaged	972	0	0.00	0	≥5.0	Very good
5	Impraperly Lebeled	972	12	1.23	12346	3.8	Minimum
6	Mismatcth Sample	972	0	0.00	0	≥5.0	Very good



Discussion

There is ever increasing demand for reliability and accuracy of the laboratory tests. The various factors contributing to the accurate test results can be divided into three phases: pre-analytical, analytical and post analytical. Among the three phases the major contributor to the errors in the result is the pre-analytical phase and to reduce the number of errors in the pre-analytical phase, particular attention must be provided to this phase.

The present study is an attempt to find out the frequency of various sample related errors in the biochemistry laboratory. The maximum percentage of error in our study was seen due to improperly labeled sample accounting to 1.23%, this is followed by hemolysed sample accounting to 1.03%. The DPM value and sigma value of improperly labeled sample is 12346 and 3.8 respectively. Improperly labeled sample results in repetition in sample collection which delays the generation of the report which can be critical in medical emergencies. This is in contrast to the study conducted by Makubi *et al* [11] which showed improperly labeled samples to be as high as 82.2%. Haslina *et al* [12] showed inappropriately labeled specimen in 66.3 % and study done by Raji *et al* [13] showed 31.5 % cases to be improperly labeled. In our hospital OPD phlebotomy is done by highly trained phlebotomists who are continuously educated to reduce the errors related to sampling and this can be the reason for very low frequency of improperly labeled specimen.

Hemolysed sample accounted to second most common cause of error in our study, which can occur when blood is collected with excessive aspiration force, is rapidly forced through a large bore needle, is collected before the disinfectant has evaporated from the skin, when the blood containing tube is shaken vigorously and when the specimen is centrifuged before clotting process is complete. Hemolysis has always plagued clinical laboratories with prevalence as high as 3.3 % [14]. Hemolysis could cause chemical, biological, immunological interference with reaction mechanism of several assays [15]. Hemolysed samples if processed then results do not correlate with patient's condition. This will lead to rerun of the test thus not only increasing the burden of the laboratory but also increases the finances involved. This further leads to delayed dispatch of the laboratory reports which is important especially in emergency medical conditions. The total error due to hemolysis in our study was 1.16 %. The DPM value and sigma value for hemolysed sample is 10288 and 3.9 respectively. This is in agreement with the study conducted by Sampath *et al* [16] which showed hemolysis in 0.34 % samples in NABL accredited laboratory and with Sujitha *et al* [17] which showed hemolysis in 0.825 % cases.

The errors related to inappropriate container in our study was 0.21 % as compared to study by Sujitha *et al* [17] which showed that none of the sample was collected in inappropriate container.

Insufficient volume of blood also leads to recollection of blood which is a problem in neonates and very old age group individuals. This further delays the dispatch of the laboratory reports. Errors related to insufficient volume in our study is

0.72 % which is in comparison to Sujitha *et al* study 17 showing insufficient volume error to be 0.152 %.

Conclusion

The results of laboratory testing add to the clinical decision making which finally predicts the patient's outcome. As with more stringent steps in analytical phase, the pre-analytical phase should equally be given the due importance. Our study shows that there is need to understand the importance of pre-analytical phase with special emphasis on the sample collection related errors. Sensitizing the healthcare professionals about the errors related to sample collection reduces the overall percentage of errors which has a positive impact on the health outcome of the patients.

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