EVALUATION OF PREANALYTICAL ERRORS IN CLINICAL BIOCHEMISTRY LABORATORY IN A TERTIARY CARE HOSPITAL IN KOLKATA

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ABSTRACT

BACKGROUND

Accurate laboratory results are vital for patients' safety. Errors in laboratory may occur in the pre-analytical, analytical and post analytical phase. In the present study, we tried to identify the types of the pre-analytical errors in clinical biochemistry laboratory in a tertiary care hospital in Kolkata by retrospective analysis.

MATERIALS AND METHODS

This study is a retrospective descriptive study. 164, 946 test requests were received, different types of errors were registered by the laboratory personnel. Percentage of occurrence of errors, defects per million (DPM) and Sigma value of each error were calculated.

RESULTS

99.97 % of the requisitions missed clinical information. 7.7%, 7% and 6.2% (sigma metric 3, 3 and 3.1) samples were without proper mention of sample collection dates, sex and age of the patient respectively. Among errors in the sample, percentage of haemolysed samples were the highest (5.2% with sigma metric 3.2) followed by insufficient sample quantity (1.6% with sigma metric 3.7) and clotted sample (1.5% with sigma metric 3.7).

CONCLUSION

Proper awareness in preanalytical procedure is need of the hour. Training of personnel responsible for preparation of patient, collection of biological sample and transportation of samples should be done with utmost care, so that pre-analytical error can be minimized.

KEYWORDS

Pre-Analytical Error, Error Percentage, Sigma Value.

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BACKGROUND

Laboratory investigations have a great impact in diagnosis and treatment of patients in present time. So, accurate laboratory results are vital for patient safety. Clinical laboratory errors directly lead to inappropriate clinical decisions as well as sample rejection and hence increased turnaround time culminating in delayed diagnosis and longer hospital stays which ultimately end up in added cost to laboratory and increased healthcare costs, decreased patient and physician satisfaction.

In the year 1981, Lundberg introduced the concept of the 'brain-to-brain loop' for describing the total testing process (TTP), which includes nine steps starting from ordering, collection, identification, transportation, separation or preparation, analysis, reporting, and upto action.¹ The total testing process generally comprises three phases- 1) Events before the sample test/analysis (Pre-analytical

phase), 2) Analysis of sample (analytical phase) and 3) Events after the analysis (post analytical phase). Quality in laboratory medicine should be defined as the guarantee that each and every step in the total testing process (TTP) is correctly performed.² A quality indicator is thus 'an objective measure that potentially evaluates all critical care domains as defined by the Institute of Medicine (IOM) (patient safety, effectiveness, equity, patient-centredness, timeliness and efficiency), that is based on evidence associated with those domains, and can be implemented in a consistent and comparable manner across settings and over time.'³

Laboratory errors may be defined as "any defect from ordering tests to reporting results and appropriately interpreting and reacting on these."⁴ Despite advanced automation in diagnostic labs, there are still considerable error rates at clinical diagnostic labs.⁵ Previous studies have focused on the analytical phase of diagnostic tests, and many quality control programs were initiated at diagnostic labs to monitor analytical phase errors. However, pre- and post-analytical errors were neglected worldwide. Interestingly, a majority of diagnostic lab errors are either pre-analytical (46-68%) or post-analytical (18-47%). Indeed, only 7-13% of errors actually occur during the analytical phase.⁶ In this background, we tried to identify the types of the pre-analytical errors in clinical biochemistry laboratory in a tertiary care hospital in Kolkata with a goal to minimize the pre-analytical error by improving the knowledge, attitude

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and skill of persons involved in preparation of patient and collection and transport of biological samples to laboratory.

MATERIALS AND METHODS

This study, a retrospective descriptive study was done after approval of the study proposal by the institutional ethics committee. A retrospective analysis for errors in the pre-analytical phase in the clinical chemistry laboratory in a tertiary care hospital in Kolkata has been carried out. Upon sample receiving, any defect in the specimen was visually detected by the investigator. Different types of errors, rejections and its causes were then registered by the laboratory personnel following the quality indicators developed by the International Federation of Clinical Chemistry and Laboratory Medicine Working Group for Laboratory Errors and Patient Safety (IFCC-WG-LEPS) for the pre-analytic phase.⁷ Percentage of occurrence of defects was calculated as-

$(\text{Number of defects} \div \text{Total number of tests}) \times 100$

Defects per million (DPM) and Sigma value of each error were calculated, using the Westgard calculator⁸. According to the table of equivalence between the Sigma level and defects per million (DPM), an error rate of 6.68% corresponds to a Sigma value 3, equivalent to borderline unacceptable, while an error rate of 0.62% corresponds to a Sigma value 4, which reflects a good level of control.^{8,9}

RESULTS

164, 946 test requests were received during the data collection period. Errors were documented owing the following reasons: 99.97 % of the requisitions missed clinical information (Sigma values were < 0.1), in 7.7% of samples collection dates were missing. 7% and 6.2% samples were without proper mention of sex and age of the patient respectively. Sigma values were 3 in case of missed collection date and 3 and 3.1 in cases of absent or wrong information about patient's age and sex. While considering errors in sample, 5.2% samples (sigma value 3.2) were haemolysed and 1.6% (sigma value 3.7) had insufficient sample quantity and in 1.5% (sigma value 3.7) samples were clotted. No parameters could reach six sigma value.

Erroneous Patient ID	Avg.% of Error in One Year Period	D P M	Sigma
Name (absent / wrongly written)	0.3	3092	4.3
Age (absent / wrongly written)	6.2	622202	3.1
Sex (absent / wrongly written)	7	70265	3
Reg. no. (absent / wrongly written)	0.4	3880	4.2
Ward/unit/physician (absent / wrongly written)	0.3	2546	4.4
Date (absent / wrongly written)	7.7	76995	3
Clinical information (absent)	99.9	999679	Below the lower limit of calculation

Table 1

Errors in Sample	Avg.% of Error in One Year	D P M	Sigma
Inappropriately labelled	0.4	4486	4.2
Inappropriate container	0.2	2486	4.4
Insufficient quantity	1.6	15740	3.7
Improperly stored	1.1	10939	3.8
Haemolysed sample	5.2	52630	3.2
Clotted sample	1.5	15193	3.7
Lipemic sample	0.1	1398	4.5
Contaminated sample	0.3	2674	4.3
Sample lost/not received	0.1	1033	4.6
Inadequate blood anticoagulant ratio	0.2	1945	4.4

Table 2

Figure 1

Figure 2

DISCUSSION

In 2007, Carraro and Plebani reported 61.9% of the laboratories errors were pre-analytical, 15% were analytical, and 23.1% were post-analytical.¹⁰

Similarly, Goswami et al. found that the pre-analytical errors were the most commonly encountered, with a frequency of 77.1% followed by post analytical accounting for 15% and analytical contributing upto 7.9%¹¹ In a survey on outpatient phlebotomy procedure, most unsuitable samples resulted from haemolysis (18.1%), insufficient quantity (16.0%), and clotting (13.4%)¹² These data are comparable to

those provided by additional investigations, which confirm that problems directly related to specimen collection are the main causes of preanalytic errors, especially haemolysed, clotted, insufficient, and incorrect samples.¹³⁻¹⁶

In our study, there was a high percentage of errors in the requisition slips. 99.97% (sigma metric <0.1) of the requisition slips missed clinical information, in 7.7% (sigma metric 3) of samples, sample collection dates were missing. 7% and 6.2% samples (sigma metric 3 and 3.1) were without proper mention of sex and age of the patient respectively compared to 22.5% phlebotomy orders with missing information in study by Dale JC.¹² This could be due to excessive patient load or lack of awareness regarding importance of patient information.

While considering errors in sample, 5.2% samples were haemolysed (Sigma metric 3.2) while Dale JC et al found 18.1%.¹² Jones BA et al also found the most frequent reason for rejection was haemolysis, which occurred five times more frequently than the second most cited reason.¹⁴ Haemolysis of samples can be prevented by proper technique during blood collection, storage and sample preparation like avoiding forcing the blood through a fine needle, shaking the tubes vigorously, prolonged tourniquet application or repeated freezing and thawing of blood specimens and centrifuging after proper standing time and clot retraction.

Another factor leading to rejection of blood samples in our study was insufficient volume of blood sample and 1.6% samples had insufficient sample quantity. The main reasons behind this may be ignorance of the phlebotomists, difficult sampling as in paediatric and geriatric patients, patients with anasarca or debilitating diseases.

In 1.5% samples, blood was clotted in spite of presence of anticoagulants. This may be due to errors in mixing the blood with anticoagulant or using vials with expiry dates.

Limitations of the Study

Further studies are necessary to bring out the differences in types of errors that may occur in samples received in our laboratory from both indoor and outdoor of COMSDH.

CONCLUSION

Effective improvements in the initial and final steps of the TTP can be achieved only if proper endeavour is taken to arrive at consensus on the preparation, adoption and monitoring of effective standard operating procedures in the initial steps of laboratory testing. Medical interns and house staffs, in spite of their theoretical knowledge, often fail to fill up requisition form properly and follow correct phlebotomy procedure. So, continuing medical education program incorporating practical skill training is extremely important. Pre-analytical errors are not inevitable. These types of errors should be monitored, documented and analysed regularly and can be avoided with a continuing education inculcating awareness, adequate laboratory personnel capable of handling a huge patient load and effective collection systems to ensure total quality patient care.

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