ORIGINAL ARTICLE

A Comparative Study of Pre-analytical Errors in Central Clinical Laboratory in a Tertiary Care Hospital in Maharashtra

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Abstract:

Background: Diagnosis of various diseases in the present medical scenario is largely dependent on the tests performed in Central Clinical Laboratory. Sample testing in laboratory requires skills where errors can occur at any phase, i.e., pre-analytical, analytical and post-analytical phase. This leads to a misdiagnosis and can have serious patient hazards. *Aim and Objectives*: Present study focuses on the pre-analytical phase, with the aim to evaluate different types of pre-analytical errors in the clinical biochemistry laboratory and to compare the frequency of pre-analytical errors before and after training the phlebotomists. *Material and Methods:* The present study was conducted in Central Clinical Laboratory of Ashwini Rural Medical College, Hospital and Research Centre, Kumbhari, Solapur, Maharashtra for the period of 12 months in two phases, each phase of six months. During this period, different types of pre-analytical errors were monitored and compared in the first phase and the second phase of study after giving training to the phlebotomists. *Results:* A total of 980 pre-analytical errors were noted in the year 2019 of which 740 (75.51%) errors were from the first phase of study and 240 (24.48%) errors were from the second phase of study. It was observed in the present study that there was a significant decrease in pre-analytical errors in second phase ($p<0.0001$) when they are compared with first phase after training period. *Conclusion:* Proper training to the phlebotomists played a very important role in significant reduction of pre-analytical errors in second phase of study which is of great importance.

Keywords: Central Clinical Laboratory, Training, Pre-Analytical Errors, Rejection of Sample

Introduction:

Central Clinical Laboratory is the backbone to the hospital set up, as it contributes considerably in making the right diagnosis to the right patient at right time and hence the right treatment, which affects the duration of hospital stay, early treatment response and the well-being of the patient [1].

Accurate laboratory outcomes are essential for the medical diagnosis and patient care because errors occurring at any of the phases may lead to wrong diagnosis and thereby causing serious impact on overall health of the patient [2-4].

In clinical diagnostic laboratories, the total testing process includes every step from the test request to the receipt of results. The laboratory testing process generally comprises three phases. First is the pre-analytical phase, which, according to the International Organization for Standardization (ISO) 15189:2012 standard for laboratory accreditation, encompasses all the steps from test request, sample collection, transport and registration of the sample up to the start of specimen analysis. Second is the analytical phase, which involves the analysis of the analytes and technical validation of the results. Third is the post-analytical phase, which includes the interpretation

of the results, approval from the lab manager and reporting to the clinician. Laboratory errors might occur at any of these three phases and errors are not exclusive to the analytical phase. Errors lead to an increased demand of resources, inappropriate clinical decisions, delayed diagnoses and longer hospital stays [5]. Accurate laboratory results are vital for patient safety and improving the medical diagnosis of patients, and many studies have shown that 70% of medical diagnostic decisions depend on the accuracy of laboratory tests [1-6].

Modern day medicine practice is purely evidence based which focuses on the valid laboratory reports for the effective and timely management of patients. Advancement in the automation along with point of care testing, in the laboratory testing has occupied utmost position in the modern health care. With increasing automation in Central Clinical Laboratory errors in the analytical phase have been reduced to a great extent but there is less focus on efficiency of pre-analytical phase. According to a study done by Plebani *et al*. [6], most of the errors were seen outside of the analytical phase. Several studies have reported that the errors in the pre-analytical phase may occur to the extent of 60% [7-8]. So, keeping this in mind, this study has been conducted with the aim to determine nature and frequency of the occurrence of pre-analytical errors and also to see the impact of training on the phlebotomists.

Material and Methods:

The present study was conducted in Clinical Biochemistry section of Central Clinical Laboratory in a tertiary care hospital of Ashwini Rural Medical College, Hospital and Research Centre, Kumbhari, Solapur, Maharashtra. Institutional Ethics Committee Clearance was obtained for the present study. The Central Clinical Laboratory is equipped to perform various routine biochemical tests, specialized profiles for instance renal, liver, cardiac, iron and hormonal analysis. Internal and external quality assurance has been maintained in the laboratory. During the study period, there was a training conducted by expert pathologists for fifteen phlebotomists who used to collect blood samples from outdoor as well as indoor departments of the hospital. The topics covered included selection of veins, common sites for phlebotomy, inappropriate sites for vein puncture, tourniquet application, cleaning the site, performing the draw of blood, rejection criteria for samples, the choice of appropriate colour coding of vacutainer tubes and transport of the specimen from collection site to laboratory. At the end of the training a test was conducted to evaluate the effectiveness of the training. The comparison of the pre-analytical errors was done using data from laboratory records for 12 months in two separate phases, each of six months. First phase was from January 2019 to June 2019 (six months) and second phase was from July 2019 to December 2019 (six months). Descriptive statistics such as frequency and percentage were used to present the data. Comparison between first phase and second phase was assessed by using chi-square test. *P* value of less than 0.05 was considered as significant. Data analysis was performed by using software SPSS Version 16.0. Upon receiving the samples in the laboratory, the lab supervisor visually tries to detect any error. Rejection of sample was done according to standard operating procedures of laboratory by laboratory staff were duly noted in the rejected sample log book. The data for the specific durations, before as well as

after the training was obtained retrospectively from the recorded log books in the biochemistry laboratory and analyzed for this study.

Results:

A total of 980 pre-analytical errors were observed in first phase and second phase of study. The most common rejection criteria's that were observed in this study are:

1. Inadequate sample quantity
2. Hemolyzed sample
3. Lipemic sample
4. Sample transportation delay
5. Sample collection in wrong tube

Out of 980 pre-analytical errors a total of 740 pre-analytical errors occurred during the first phase (January 2019 to June 2019) with a fairly uniform distribution in each month, ranging in-between 16% to 17%. A total of 240 pre-analytical errors occurred during the second phase (July 2019 to December 2019) with a fairly uniform distribution in each month, ranging in-between 16% to 18%.Table 1 depicts the types and percentage of pre-analytical errors under various categories in first phase of study. We found that hemolysis was the most common pre-analytical error amongst all other errors. Table 2 depicts the types and percentage of pre-analytical errors under various categories in second phase of study. Table 3 shows the comparison of number and types of pre-analytical errors between first phase and second phase of study. It was that there was no significant difference in the proportions of different types of errors between the two phases.

Table 1: Types and Percentage of Pre-analytical Errors under Various Categories in First Phase of Study

Month	Hemolyzed sample	Lipemic sample	Inadequate sample quantity	Sample transportation delay	Sample collection in wrong tube	Total
January	45 (36.8%)	27 (22.1%)	23 (18.8%)	13 (10.6%)	14 (11.4%)	122
February	43 (35.5%)	24 (19.8%)	24 (19.8%)	16 (13.22%)	14 (11.5%)	121
March	47 (37.9%)	23 (18.5%)	23 (18.5%)	18 (14.5%)	13 (10.4%)	124
April	43 (36.4%)	21 (17.8%)	22 (18.6%)	17 (14.4%)	15 (12.7%)	118
May	45 (57%)	28 (21.8%)	24 (18.7%)	17 (13.2%)	14 (10.9%)	128
June	48 (37.8%)	24 (18.9%)	23 (18.1%)	18 (14.1%)	14 (11%)	127
Total	271	147	139	99	84	740

Table 2: Types and Percentage of Pre-analytical Errors under Various Categories in Second Phase of Study

Month	Hemolyzed sample	Lipemic sample	Inadequate sample quantity	Sample transportation delay	Sample collection in wrong tube	Total
July	15 (34.8%)	8 (18.6%)	7 (16.2%)	8 (18.6%)	5 (11.6%)	43
August	15 (37.5%)	7 (17.5%)	8 (20%)	5 (12.5%)	5 (12.5%)	40
September	14 (35%)	8 (20%)	8 (20%)	6 (15%)	4 (10%)	40
October	14 (35.9%)	8 (20.5%)	8 (20.5%)	4 (10.2%)	5 (12.8%)	39
November	15 (37.5%)	8 (20%)	8 (20%)	5 (12.5%)	4 (10%)	40
December	15 (39.4%)	8 (21%)	7 (18.4%)	4 (10.5%)	4 (10.5%)	38
Total	88	47	46	32	27	240

Table 3: Comparison of Types of Pre-Analytical Errors between First Phase and Second Phase of Study

Parameters	Number and % of pre-analytical errors in first phase of study	Number and % of pre-analytical errors in second phase of study	X^2	*P*
Hemolyzed samples	271(36.6%)	88 (36.7%)	0.00001	0.99
Lipemic samples	147 (19.9%)	47 (19.6%)	0.00001	0.99
Inadequate sample quantity	139 (18.8%)	46 (19.2%)	0.001	0.97
Sample transportation delay	99 (13.4%)	32 (13.3%)	0.0003	0.98
Sample collection in wrong tube	84 (11.4%)	27 (11.3%)	0.002	0.96

Discussion:

The first step for patient safety is to develop knowledge and understanding of errors in health care by developing a standard agenda, to note down the problems, evaluate methods for identifying and preventing errors and communication of activities to improve patient safety. Laboratory medicine has been recognized as a very complex process and its proper management is required to minimize the risk of occurrence of pre-analytical, analytical and post-analytical errors [9-11]. The present study showed a total of 980 pre-analytical errors including first phase and second phase of study, out of which 740 were from first phase and 240 were from second phase of study. There was a significant decrease ($p < 0.0001$) in pre-analytical errors in second phase as compared to the first phase. Further it was also found that hemolysis was the commonest pre-analytical error in the study. These findings were similar to the study done by Kapoor *et al.* [10]. The possible reasons for *in-vitro* hemolysis in the samples could be improper phlebotomy techniques, blood collected in insufficient amount of additive in the tube, abrupt freezing and thawing and vigorous shaking of tubes after collection. Technical staff was made aware about all these factors causing haemolysis in training period and in second phase of study there was a reduction in the errors. Hemolysis was followed by pre-analytical errors like lipemic samples, inadequate sample quantity, sample transportation delay and collection of samples in wrong tube in first phase of study. But the second phase showed significant reduction in all types of pre-analytical errors. This was due to the training session which was structured during the study period. Training had great impact on them. After training their analytical skills were improved and they improved in their sample collection techniques. They were strictly following instructions briefed to them which reduced the errors of hemolysis, lipemia, etc. Samples were collected in appropriate tubes with adequate quantity and delay in transportation of sample was also found to be minimized.

Pre-analytical errors lead to increased turn-around time for laboratory diagnostics, inconvenience to patients for repeat collection of blood sample and increased cost to hospital. Hence quality check at each and every step of pre-analytical phase in laboratory testing and proper training would definitely minimize not only the errors but also reduce the turn-around time in making clinical decisions as well as cost to hospital. After the training though the errors reduced, a significant number (240) of errors still occurred. Therefore, the laboratory management held interviews and counseling sessions with phlebotomists and tried to analyze the cause and motivated them to reduce these errors to attain zero occurrence of errors in the future.

Conclusion:

In conclusion, our study elucidates that the pre-analytical errors in the Central Clinical Laboratory can be minimized by proper training of the laboratory personnel's i.e. phlebotomists, analytical technicians and lab attainders etc. In our study, we found a significant improvement in the pre-analytical errors after training period in second phase which is of great importance.

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