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Characterization of Pre-Analytical Errors Using Six Sigma Metrics and Process Capability Index in a Clinical Biochemistry Laboratory

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ABSTRACT

Objective: Pre-analytical errors have been the commonest source of error in the total testing process. Errors of this nature prove to be a burden for the laboratory, misleading for clinicians, disturbing for management of patient, and a serious issue for the hospital administration as sample rejection leads to loss of critical time and adds to the cost of patient care. The aim of the study is to determine the incidence and types of pre-analytical errors leading to sample rejection.
Materials & Method: A prospective observational study was conducted over a period of two months in the Dept. of Laboratory Medicine in a teaching hospital for biochemistry investigations with an aim to determine the incidence and types of pre-analytical errors leading to sample rejection using six sigma metrics and to generate preventive and corrective actions to achieve higher quality laboratory reports. Sigma value for each error was identified and the defects per million (DPM) yield of the process were calculated.
Results: Of the total 19,002 samples received, 401 (2.11%) were rejected due to pre-analytical problems. Level of sample rejection was unsatisfactory with a sigma metric of 3.6. A larger proportion of errors (73.3%) occurred at the time of sample collection as opposed to errors related to patient identification factors (26.6%). The commonest pre-analytical error was detected to be hemolysis (64.0%).
Conclusion: Pre-analytical errors, although preventable, still remains a major cause of poor quality test results and wastage of resources. By standardization and monitoring the steps involved in obtaining a sample, the pre-analytical errors will greatly reduce. Competent administrative bodies teaming up with laboratory physicians can bring a positive change in patient care. Awareness amongst health care providers cannot be overemphasized.

Key words: Pre-analytical error, Process Capability Index, Six Sigma Metrics

INTRODUCTION

Clinical laboratory is responsible for accurate and timely reports of the patients. The current emphasis on reducing cost and providing quality reports by the laboratories can be achieved by analyzing the procedural systems. In order to achieve good quality reports, laboratories need to focus holistically on all processes involved i.e. pre-analytical, analytical and post-analytical phases of testing. However, pre-analytical errors have been shown to be the commonest source of error in the total testing process (TTP) [(1–3)] and constitutes about 70% of the total errors encountered in investigations [(4)]. The pre-analytical phase as described by ISO 15189 includes the steps starting from the clinician's request, preparation of the patient, collection of the primary specimen its transportation to

laboratory and delay in processing as well as error during sampling from specimen within the laboratory and ends when the analytical procedure begins [5]. Pre-analytical errors greatly interfere with the test analysis thus affects patient management protocols. Errors of this nature prove to be a burden for the laboratory and a serious issue for the hospital administration as sample rejection leads to loss of critical time and adds to the cost of patient care [6,7]

Following the introduction of automation in the clinical laboratories, quantum of analytical errors has tremendously reduced due to limited human intervention. However, pre-analytical errors continue to be the major source of poor laboratory test results, although reduced considerably by bar coding, pre-phlebotomy automation with correct use of evacuated tubes having proper anticoagulants and, post-phlebotomy automated conveying of specimens to the laboratory space. The error rates, however, continue to be bothering due to the multiple steps involved in the acquisition of a quality sample, mostly occurring outside the laboratory which remains unsupervised by the laboratory. Of several initiatives for quality management which have been implemented in the laboratories, the important one is the six sigma process [8,9]. As it helps to evaluate the performance of the process quantitatively, we incorporated the five-stage six sigma goal that includes defining, measuring, analysing, improving, and controlling (DMAIC)and calculated the process capability index (Cpk) to identify the commonly occurring errors that require rigorous attention in our set up and thus brought objectivity in evaluation of the pre-analytical phase. The objective was to determine the incidence and types of pre-analytical errors leading to sample rejection by using six sigma metrics and process capability index and to generate preventive and corrective actions to achieve higher quality laboratory reports.

MATERIALS AND METHODS

The prospective observational study was conducted over a period of two months in a tertiary care teaching hospital. All samples received from the hospitalized patients in the clinical biochemistry laboratory were included in the study. Outpatient samples were excluded.

Definition

At the time of receiving samples, screening for (i) barcoding related errors like a wrong barcode and improper pasting of barcodes (ii) insufficient specimen volume (iii) wrong evacuated tube (vial with anticoagulant) was done. Following centrifugation, serum was visually inspected for (iv) in-vitro haemolysis and (v) lipemia. (vi) EDTA contamination was identified after analysis by examining the test reports for calcium, alkaline phosphatase and potassium values.

All errors observed were further categorized into two groups: 1. Errors related to the patient identification and patient preparation and 2. Errors occurring at the time of sample collection.

An unsatisfactory level was defined at a sigma metric <4 and Cpk value <1.33.

Measurement

An error rate was calculated by the following formula:

Error rate = number of errors observed x 100/ total number of specimens

Defects per million (DPM) for each error identified was calculated using the formula given below:

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

The yield of the process, defect and sigma values were calculated using an online calculator [10]. Sigma values (short term sigma) were also calculated using the Westgard six sigma calculator available online [11]. Long-term sigma was calculated to account for the process shift that is known to occur over time. The table available online was used to obtain the process capability index (Cpk) [12].

RESULTS

During two months of study, of the total 19,002 specimens received and *analysed*, 401 (2.1%) were rejected due to different pre-analytical issues. Level of sample rejection was unsatisfactory with a sigma metric of 3.6 and Cpk of 1.20. Characterizations of all errors observed are shown in Table 1. A larger proportion of errors (73.3%) occurred at the time of sample collection as opposed to errors related to patient identification factors (26.6%) as illustrated in Table 2. The commonest pre-analytical error was hemolysis (64.0%) as shown in Figure 1.

Improvement strategies and Controlling measures

The following strategies and control measures were taken up in the department, following documentation of unsatisfactory level of pre-analytical errors:

- installation of automated tube labelers in the centralized collection center and barcoding system
- incorporation of information system for hospital and laboratory (HIS & LIS)
- periodic in-house training program on good phlebotomy practices for staff
- six monthly sessions on 'Know your laboratory' elaborating on the potential sources of errors for the newly joined resident doctors and faculty members.

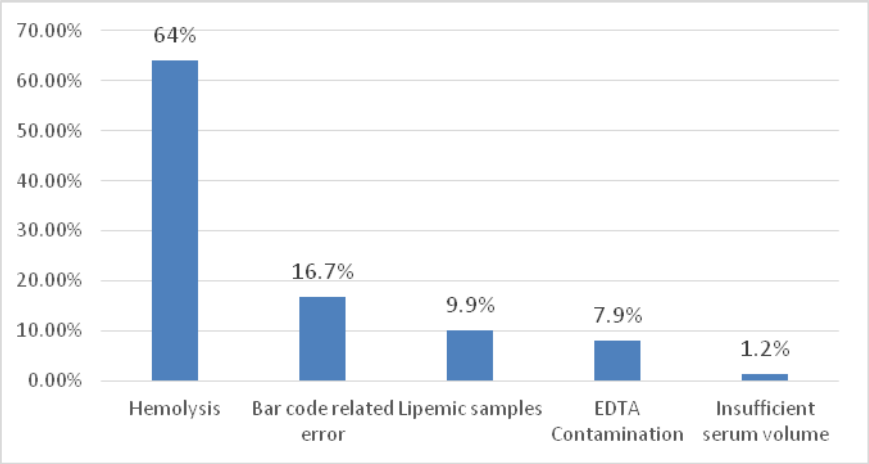

Figure 1: Pre analytical errors in clinical biochemistry laboratory

Table 1: Characterization of various observed pre-analytical errors :

S. No	Type of pre-analytical error	Frequency (N)	Proportion of the assessed errors	Defects per million (DPM)	Defect (%)	Yield (%)	Process Sigma	By Westgard sigma calculator		
								Sigma short term	Sigma Long term	Cpk
1	Hemolysis	257	64.0%	13,525	1.35	98.65	3.71	3.8	2.3	1.27
2	Bar code related error	67	16.7%	3,526	0.35	99.65	4.19	4.2	2.7	1.40
3	Lipemic samples	40	9.9%	2,105	0.21	99.79	4.36	4.4	2.9	1.47
4	EDTA contamination	32	7.9%	1,684	0.17	99.83	4.43	4.5	3	1.50
5	Insufficient serum volume	5	1.2%	263	0.03	99.97	4.97	5	3.5	1.67
Total no of Samples = 19,002		**401**	**100%**	**21,103**	**2.1**	**97.89**	**3.53**	**3.6**	**2.1**	**1.20**

DISCUSSION

Studies on quality control of laboratory results show the impact of the high rate of pre-analytical errors on patient care[6,13]. The goal of the serving clinical laboratory is to reduce errors with a priority in the pre-analytical phase and to achieve the standards of high quality by incorporating good laboratory practices during analysis.

The major findings of the present study are (i) Unsatisfactory level of sample

rejection as shown by sigma metric and cpk value, (ii) Errors during sample collection accounts for majority of pre- analytical error and (iii) Hemolysis is the most common pre-analytical error.

Table 2: Categorization of pre-analytical errors in clinical biochemistry laboratory

S. No	Category	Indicators	Error rate	Contribution to errors in each phase	Defects per million (DPM)	By Westgard sigma calculator	
						Sigma short term	Sigma Long term
1	Error related to patient factor	Patient identification	0.5%	26.6%	5631	4.1	2.6
		Patient preparation					
2	Error in sample collection	Wrong vacutainer	1.5%	73.3%	15472	3.7	2.2
		Insufficient sample					
		In vitro Hemolysis					
		EDTA contamination					

Pre-analytical variables result in vulnerabilities of test-results. The erroneous results thus generated can negatively impact patient care [(11)]. In the present study, a total of 2.1% of the total samples received were rejected, higher than most studies reported, although in different clinical settings [(12,14-16)]. To identify and solve problems in this study, it was found that our pre-analytical phase in the TTP is unsatisfactory with a process sigma value 3.6. Average products, regardless of their complexity, have a quality performance value of about 4 sigma. The best, or "world class" products have a level of performance of 6 sigma [(17)]. This showed us where and how to take care of the lapses in the pre-analytical phase and ultimately improving the quality and performance of clinical laboratories as shown in other studies [(18,19)].

This study also shows that about two-thirds of the pre-analytical errors occur at the time of sample collection which is consistent with several other studies [(16,20)]. However, Bhatia P *et al*. showing patient identification error due to improper labeling as the major one [(21)]. Errors occurring at the time of sample collection included insufficient specimen volume, wrong evacuated tube, in-vitro hemolysis, lipemia and EDTA contamination of tubes while patient identification error included barcoding related errors like a wrong barcode and improper pasting of barcodes. Hemolysis is the commonest cause of sample rejection in this study. In concurrence with our study, several other studies have also reported hemolysis as the commonest cause of sample rejection. [(16,17,22)]

Such results call for repeat sampling, cause pain to patients, add up to the cost of patient care and mismanagement of time and available resources. Pin pointing the sources of error lead us to take appropriate corrective steps. We understand that the measurement of performance of the TTP by quality assessment does not improve the performance of the laboratory immediately. Identification and documentation help in implementing quality planning which eventually eliminates errors. Patient identification and test tube labeling are very important steps in TTP and can be addressed by bringing automation in the pre-analytical phase [(21,23)]. Training laboratory personnel on best phlebotomy practices or having dedicated phlebotomists for sample collection can standardize the process. Using standard operating procedures for sample collection can significantly reduce number of errors. Alertness at the time of selection of correct evacuated tube, quality and quantity of specimen drawn, and regularizing the duration of application of tourniquet will reduce the incidence of errors. Use of correct size needle, optimizing tourniquet

duration and correct collection techniques can greatly reduce hemolysis in patient's blood specimen. Also, by following the recommended order of draw while drawing blood in multiple tubes will reduce the chances of error further [14].

One-third of errors that are found related to patient factors could be easily addressed in the clinic, where the clinician may emphasize the importance of timing of specimen collection while ordering the tests by counseling the patient about the importance of overnight fasting, and the interferences in test results due to drug and diet. The onus is on the laboratory physicians to identify the errors promptly and educate the fellow clinicians on the importance of correct blood collection practices that greatly contribute to accurate and quality reports [24].

Currently, there is a lack of acceptable definition of either error or allowable error rate in clinical laboratory practice, which if formulated properly could help in evaluating the impact of laboratory error on patient outcomes [11]. Generating strict guidelines on sample collection and transport procedure and defining the criteria of rejection will definitely improve laboratory performance.

Limitation of the study:

The effect of laboratory error on patients' outcome could not be ascertained.

Strength of the study:

Study done on large number of samples during a duration of two month points out the important problem area to be looked upon.

To conclude, pre-analytical errors, although preventable, are still a major cause of poor-quality test results and wastage of resources. By standardization and regular monitoring of steps involved in obtaining a quality sample for testing will greatly reduce the pre-analytical variables thereby reducing the incidence of pre-analytical errors. Awareness generated amongst health care providers regarding the same cannot be overemphasized. Competent administrative bodies teaming up with laboratory physicians can bring in a positive change in patient care by policies and guidelines to reduce and overcome these errors.

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