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Impact of intervention on preanalytical errors assessed by six sigma and Pareto's principle

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Abstract: *Introduction:* Preanalytical steps are the major sources of error in the clinical laboratory. The analytical errors can be corrected by quality control procedures but there is a need for stringent quality checks in the preanalytical area as these processes are done outside the laboratory. Sigma value depicts the performance of the laboratory and its quality measures. Hence in the present study, six sigma and Pareto principle were applied to preanalytical quality indicators to evaluate the impact of the intervention. *Materials and Methods:* The present analytical interventional study was conducted in a tertiary care hospital after obtaining Institute's ethical waiver. A total of 31,003 samples before intervention and 31,114 samples after intervention were screened for preanalytical errors in sample collection like Hemolysed, clotted, inadequate sample, Lipemic from clinical biochemistry section over a period of one year**.** Six sigma values were calculated using the Westgard online formula. *Results:* The clotted and inadequate samples were the major preanalytical errors with a sigma value of 3.5 and after intervention sigma value was 4.6 and 4.7 respectively. The Pareto`s chart (80/20 rule) also depicted the same results. *Conclusion:* The interventions like training and providing standard operating procedures to laboratory technicians and nursing staff reduces the frequency of preanalytical errors and improves the sigma value.

Keywords: Six sigma, Preanalytical, Quality indicators, Pareto's chart, Intervention.

Introduction

Clinical laboratory errors continue to be an important issue for laboratory professionals. Frequent, preventable medical errors can have an adverse effect on patient safety and quality as well as leading to wasted resources [1].

The laboratory errors can be classified into pre-analytical, analytical, and post-analytical errors. However most of the laboratory errors occur during the pre-analytical stage due to various reasons like patient factors, such as the fact that specimen collection is an almost entirely manual process, frequent turnover of technical staff, shortage of skilled technicians and overburdened system making these preventable preanalytical errors up to 60% of total laboratory errors compromising on patient safety and increase in health expenses [2].

In contrast, analytical and post analytical processes in the modern clinical laboratory are often automated and managed by laboratory professionals, and reliable computer-based safeguards can be implemented. Some of the more common preanalytical errors, such as incorrect test orders, incorrect sample handling, collection, and specimen mislabeling in the inpatient wards are out of laboratory activities and are currently difficult to control with computerized or robotic solutions.

The laboratory professionals should not only monitor or develop a quality indicator but also develop corrective strategies to overcome these errors. In this regard, our study emphasizes monitoring of preanalytical quality indicators, implementation of interventions to reduce errors and assessment

of the impact of the intervention by six sigma and Pareto`s principle. "Six Sigma focuses on reducing defects, intending to improve precision so that six SDs can fit within tolerance limits, which corresponds to only 3.4 defects per million opportunities (DPMO)" [3].

The Methodology of six sigma improves quality by analyzing data with statistics to find out the root cause of quality problems and to implement controls. A Pareto's chart [4] is a statistical tool that can be utilized to identify the variables that are the most significant. A Pareto chart is a vertical bar graph in which the relative frequency of each of the events is plotted in decreasing order from left to right. A line, representing the cumulative total, is then plotted on top of the bars. Pareto`s charts are used to determine the most significant aspects of a body of information.

Material and Methods

The present analytical interventional study was conducted over a period of one year from March 2017 to May 2018 including intervention for a period of two months for laboratory technicians and nursing staff of a tertiary care hospital after obtaining Institute's ethical waiver for the project. Test requisition forms from all the clinical departments were included for screening and requisition from other institutes was excluded. The blood samples collected from outpatient and inpatient patients were included in the study.

All the samples from OPD and IPD were barcoded and transported within an hour to the central laboratory through laboratory attendants. Preanalytical quality indicators in sample collection namely Hemolysis, Lipemic, insufficient samples, clotted samples, samples in inappropriate containers, patient misidentification errors were included in the study. Inside the laboratory, the samples were screened for preanalytical errors and recorded in registers. The study data was recorded from the registers. As all the samples were barcoded properly none of the samples were misidentified. All the samples were transported with an hour to the laboratory without any delay because of the sufficient number of laboratory and ward attendants.

Statistical analysis: Descriptive and inferential statistical analysis was carried out in the present study. Results on continuous measurements were presented as mean ± standard deviation (minimum − maximum), and results on categorical measurements were presented in number (%). Statistical significance was assessed at a 5% level of significance. $P \leq 0.05$ was considered as statistically significant. Unpaired t-test (two-tailed, independent) was used to find the significance of study parameters on a continuous scale between two groups (intergroup analysis) on metric parameters. Six sigma values were calculated using Westgard online formula and also reference was taken from textbook [5].

The number of defects observed and sample size for that particular month was fed into Westgard online formula and six sigma value was obtained. Pareto`s chart was plotted using an excel sheet. In this chart, both bars and lines are represented in same graph and individual errors are represented in descending order by bars and cumulative total by the line. The statistical software SPSS 17, Med Calc 9.0.1 version was used for data analysis.

Results

The present analytical interventional study was conducted over a period of one year from March 2017 to May 2018. A total of 31,003 samples before the intervention and 31,114 samples after intervention were screened for preanalytical errors from clinical biochemistry section.

Table-1: Depicts the frequency of each preanalytical errors and corresponding six sigma values. In the month of March, April, June, July, August sigma value for hemolysis is 3.7. In the month of May sigma value is 3.8 highest compared to other months. For Lipemic samples, sigma value ranged from 4.1 to 4.3. In April and May month, sigma value for insufficient samples is 3.4 lowest when compared to other months. In the month of April and May the lowest six sigma value is 3.4 for clotted samples. A sigma value of six implies fewer defects i.e. 3.4 defects per million. Sigma value of 3 implies 66,800 defects per million and the process needs corrective and preventive measures.

Table-1: Six Sigma for preanalytical quality indicators before the intervention												
	Hemolysis			Lipemic			Insufficient sample			Clotted		
Month	No	DPM	Six sigma	No	DPM	Six sigma	No	DPM	Six sigma	No	DPM	Six sigma
March (N=5997)	85	14174	3.7	29	4836	4.1	120	20010	3.6	98	20010	3.6
April (N=5680	87	15317	3.7	15	2641	4.3	180	31690	3.4	120	31690	3.4
May (N=4421)	58	13119	3.8	20	4524	4.2	130	29405	3.4	94	29405	3.4
June (N=4147)	65	15674	3.7	25	6058	4.1	85	20596	3.6	85	20596	3.6
July (N=5131)	83	16176	3.7	18	3508	4.2	129	25141	3.5	120	25141	3.5
August (N=5627)	89	15817	3.7	20	3554	4.2	93	16527	3.7	82	16527	3.7
Total (N=31,003)	467	15063	3.7	127	4096	4.2	737	23772	3.5	599	23772	3.5

Table-2: Depicts the six sigma values for preanalytical quality indicators after the intervention. The laboratory technicians and nursing staff were given hands-on training on Best practices in Phlebotomy, Standard operating procedures, biomedical waste management. Six sigma values were calculated after intervention from December to May.

Table-2: Six Sigma calculation for preanalytical errors after the intervention												
	Hemolysis			Lipemic			Insufficient sample			Clotted sample		
Month	No.	DPM	Six sigma	No.	DPM	Six sigma	No.	DPM	Six sigma	No.	DPM	Six sigma
December (N=6210)	33	2168	4.4	13	2168	4.4	12	2133	4.5	31	5169	4.7
January (N=5562)	30	2289	4.4	11	1937	4.4	13	2289	4.4	23	4049	4.4
February (N=5621)	20	2262	4.2	10	2262	4.4	14	3167	4.6	21	4750	4.8
March (N=4246)	28	2653	4.3	12	2894	4.3	17	4099	4.8	26	6270	4.6
April (N=4231)	18	1559	4.2	10	1949	4.4	20	3898	4.6	18	3508	4.8
May (N=5244)	16	1066	4.5	12	2133	4.4	12	2133	4.8	18	3199	4.8
Total (N=31,114)	145	4677	4.1	68	2194	4.4	88	2839	4.3	137	4419	4.2

Table 3: The preanalytical quality indicators like hemolysis, Lipemic, insufficient samples, and clotted samples were significantly reduced after intervention as indicated by sigma values and p <0.05.

Table-3: Comparison of preanalytical quality indicators before and after the intervention				
Type of Preanalytical error	**Quality Indicator**	**Before Intervention**	**After Intervention**	**P -Value**
Hemolysed sample	Mean ± SD	77.8 ±13	24 ± 7.1	0.001*
	DPM	15046 ± 1167.3	1999.5 ± 578.6	
	Six sigma	3.7 ± 0.04	4.3 ± 0.12	
Lipemic	Mean ± SD	21.2 ± 5	11.3 ± 1.21	0.004*
	DPM	4186.8 ± 1207	2223.8 ± 352.1	
	Six sigma	4.2 ± 0.1	4.38 ± 0.04	
Insufficient	Mean ± SD	122.8 ± 33.7	14.7 ± 3.2	0.001*
	DPM	23894.8 ± 588.1	2953.2 ± 898.7	
	Six sigma	3.5 ± 0.1	4.6 ± 2.0	
Clotted sample	Mean ± SD	99.8 ± 16.7	22.8 ± 5.0	0.001*
	DPM	23894.8 ± 5881.1	4490.8 ± 1142.2	
	Six sigma	3.5 ± 0.1	4.7 ± 0.2	
**Strongly significant (P≤0.05)				

Figure 1: Depicts that out of 80% of preanalytical errors in our laboratory, clotted sample and sample insufficient for processing constitutes the major cause of the preanalytical error as stated by Pareto`s 80/20 rule.

Fig-1: Pareto`s chart before intervention for preanalytical errors

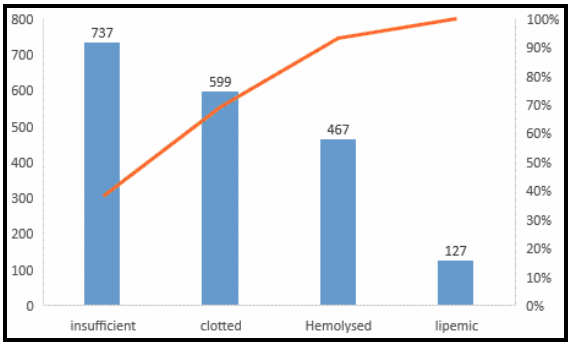
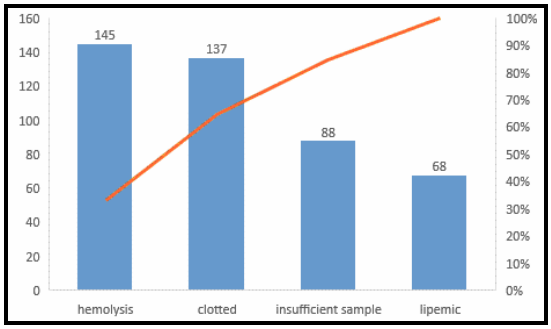


Figure 2: Depicts that after the intervention the frequency of insufficient sample and clotted samples the major causes of preanalytical errors were reduced. TheHemolysed and Lipemic samples werealso reduced when compared to before the intervention.

Fig-2: Pareto`s chart after intervention for preanalytical errors



Discussion

The International Organization for Standardization (ISO) 15189:2022 defines the preanalytical phase as the process which starts with clinician requesting or ordering for a test and ends at centrifugation of samples [6].

The total testing process in a clinical laboratory is divided into three main stages describing sample processing before, during and after laboratory analysis. Maximum number of laboratory errors occur in a preanalytical stage before the sample reaches

to the laboratory. Plebani and Carraro [7] found that 26% of laboratory errors have a negative impact on patient care. Any error during total testing process from sample collection, transport, analysis of the sample to the reporting of test results invalidates the quality of report. A correct preanalytical phase procedure is critical to get an adequate sample and consequently to achieve the most reliable laboratory results, promoting patient safety. Continuous laboratory staff changes create the need to establish improvement strategies to reduce error risk. To ensure up to date performance and service, the process of identification and correction of error risk should be integrated into the quality system of the laboratory. The implementation of quality indicators in the laboratory is essential not only to detect the errors but also to formulate quality improvement strategies [8].

The efficiency of the use of quality indicators is demonstrated by the improvement found in performance. Three approaches to reducing preanalytical errors include improving training and education for operators; identifying weaknesses and system redesign; and increasing automation to reduce human input [9]. In the present study, we have monitored preanalytical errors namely hemolysis, clotted samples, insufficient samples, Lipemic samples as quality indicators of sample collection. As part of the quality assurance and accreditation process, the central laboratory and all inpatient wards maintain a register for these quality indicators and data was obtained from these registers. Hemolysed, clotted, Lipemic and insufficient samples were rejected before analysis. This lead to wasting of manpower, reagents, time and difficult to get repeat sample for these indicators.

Hemolysis is the most common preanalytical source of error in the clinical laboratories and responsible for nearly 60% of rejected samples. In vitro hemolysis caused by improper sample drawing, handling, mixing, an improper ratio of blood to anticoagulant, storage of blood sample without separation or improper centrifugation. Hemolysis can be prevented by proper sampling in vacutainer tubes, mixing of samples by inversion and properly balancing centrifugation. Chawla R [10] in their study reported 0.7% Hemolysed samples, 0.34% improper sample for coagulation profile. Ricos [11] and colleagues reported 0.2% Hemolysed samples. Dale JC [12] reported 18.1% of Hemolysed samples in their study.

In our study before intervention, hemolysis frequency was 1.5% and after intervention, it has reduced to 0.5%. All the technicians and nursing staff were given training on sample collection in vacutainers by using mannequins and training on proper centrifugation, mixing of samples, storage was given by laboratory in-charge over a period of two months in batches. In a study done by Yazar H [13] on preanalytical variables showed that intensive training to technicians and nursing staff working in emergency wards reduced the number of preanalytical errors.

Clotted samples for coagulation studies are one of the major preanalytical errors for which samples were rejected. Improper collection and choice of collection tube or insufficient blood volume in the collection tube, delayed transportation to laboratory leads to clotting of the blood sample. Coagulation samples should preferably be collected before other test samples are drawn, if these contain stronger anticoagulant agents such as ethylene ediaminetetraacetic acid (EDTA) (for a complete blood count), lithium-heparin (for clinical chemistry testing), as well as clot activators (thrombin), since these materials may contaminate a subsequent coagulation test sample. A specific order of draw is provided by the CLSI [14]. Kaur et al [15] in their study reported about 0.28% clotted samples. Sample insufficient for analysis was due to the inadequate collection and newborn babies sample from NICU.

Lipemic samples will block the sample probe and due to light scattering effect interfere with the analysis of bilirubin, calcium, phosphorus, and enzymes like AST, ALT, gamma-glutamyl transferase (GGT) levels [16]. Patients and phlebotomists were given proper instructions to collect samples between eight to ten hours of overnight fasting. Laboratory technicians were instructed to ultracentrifuge highly Lipemic samples.

Six sigma is a system of statistical tools and techniques focused on eliminating defects and

reducing process variability. The Six Sigma process includes measurement, improvement and validation activities. Six sigma relates to the connection between the number of defects per million opportunities and the number of standard deviations found within a process specification. Six sigma indicates a good process with only 3.4 defects per million and a sigma value of 3 or less indicates the process needs corrective and preventive action. In our study, there is a significant improvement in sigma values after the intervention and was statistically significant P< 0.05 (Table3).

The Pareto Principle (also known as the 80-20 rule) states that for many phenomena, about 80% of the consequences are produced by 20% of the causes. In our study out of 80% of preanalytical errors recorded in sample collection, clotted and Hemolysed samples constitute 20% of causes for preanalytical errors and are depicted in figure1. After intervention Pareto`s chart depicts there is a decrease in the number of Hemolysed samples and clotted samples which were major causes for rejection of samples.

Hence as an interventional strategy, we conducted training sessions on Best practices in phlebotomy for laboratory technicians and nursing staff. Standard operating procedures for sample collection and training on the Hospital Information Management system were given to all technicians and nursing staffas a corrective and preventive action. The Impact of intervention was assessed by six sigma and Pareto`s principle. Six sigma values and Pareto`s chart was plotted before and after intervention.

Conclusion

The educational program for nursing staff and laboratory technicians is relevant and important as it was observed in the decrease in the number of sample errors and the resulting quality improvement. The barcode label system minimizes the potential labeling errors by printing the labels according to the requested tests. The detection, identification, and monitoring of the errors and implementation strategies to improve preanalytical quality, reduces error numbers and thereby improves patient safety and health system outcomes.

Limited studies have assessed the impact of the intervention on preanalytical errors by both six sigma and Pareto`s principle. Hence our analytical interventional study emphasizes the role of interventions like frequent training, standard operating procedures in reducing the number of preanalytical errors as assessed by Six Sigma and Pareto`s principle.

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