Evaluation of Preanalytical Quality Indicators by Six Sigma and Pareto's Principle

Sweta Kulkarni¹ · R. Ramesh¹ · A. R. Srinivasan¹ · C. R. Wilma Delphine Silvia²

Received: 14 January 2017 / Accepted: 11 April 2017 / Published online: 21 April 2017
© Association of Clinical Biochemists of India 2017

Abstract Preanalytical steps are the major sources of error in clinical laboratory. The analytical errors can be corrected by quality control procedures but there is a need for stringent quality checks in preanalytical area as these processes are done outside the laboratory. Sigma value depicts the performance of laboratory and its quality measures. Hence in the present study six sigma and Pareto principle was applied to preanalytical quality indicators to evaluate the clinical biochemistry laboratory performance. This observational study was carried out for a period of 1 year from November 2015–2016. A total of 1,44,208 samples and 54,265 test requisition forms were screened for preanalytical errors like missing patient information, sample collection details in forms and hemolysed, lipemic, inappropriate, insufficient samples and total number of errors were calculated and converted into defects per million and sigma scale. Pareto's chart was drawn using total number of errors and cumulative percentage. In 75% test requisition forms diagnosis was not mentioned and sigma value of 0.9 was obtained and for other errors like sample receiving time, stat and type of sample sigma values were 2.9, 2.6, and 2.8 respectively. For insufficient sample and improper ratio of blood to anticoagulant sigma value was 4.3. Pareto's chart depicts out of 80% of errors in requisition forms, 20% is contributed by missing information like diagnosis. The development of quality indicators,

application of six sigma and Pareto's principle are quality measures by which not only preanalytical, the total testing process can be improved.

Keywords Preanalytical error · Six sigma · Pareto chart · Test requisition form · Blood samples

Introduction

Recent advances in the field of laboratory medicine have virtually replaced manual testing of parameters into automated processing. Despite the decrease in analytical errors, preanalytical errors continue to pose problems and constitute approximately 60% of total laboratory errors [1]. This is because of dependence of laboratory on clinical departments for proper filling of test requisition forms, sample collection from wards, instructions to the patients for sample preparation, proper labelling and transportation. The critical decisions in patient management depend on laboratory reports. It is the inherent responsibility of the laboratory to provide quality reports. Quality is the main issue of all testing laboratories and there is an immediate need for enforcing stringent quality management in preanalytical laboratory processes. The total testing process involves nine steps: ordering, collection, identification, transportation, separation or preparation, analysis, reporting and action. The total quality management starts from proper test ordering to dispatch of laboratory reports to correct person [2].

Quality indicators constitute objective measures that can be used to evaluate critical health care dimensions. These indicators denote the extent up to which a certain system meets the needs and expectations of the customers [3].

Six sigma was initially used by industries such as Motorola to detect errors in their quality system and to

✉ Sweta Kulkarni
Shwetakulkarni82@gmail.com

¹ Department of Biochemistry, Mahatma Gandhi Medical College and Research Institute, Puducherry 607403, India

² Department of Biochemistry, Akash Institute of Medical Sciences and Research Centre, Devanahalli, Bangalore, Karnataka, India

enhance the total quality management. In laboratories six sigma can be applied to pre analytical, analytical and post analytical processes. A sigma value of six implies 3.4 defects per million and a sigma value of three indicates 66,807 defects per million opportunities and there is a need for corrective and preventive action. The sigma value indicates the efficiency of laboratory in managing the quality processes [4].

Hence in the present study preanalytical errors during sample collection and in test requisition forms were studied and sigma value was calculated for each preanalytical error. Pareto's principle was applied by taking into consideration cumulative percentage and preanalytical errors.

Methodology

This observational study was conducted at Mahatma Gandhi Medical College and Research Institute which is a tertiary care hospital in Pondicherry. This study was conducted for a period of 1 year during November 2015–2016 following institute ethics committee permission. The hospital has broad specialty and superspecialty departments. The central laboratory is comprised of three departments' biochemistry, pathology and microbiology. The clinical chemistry laboratory receives monthly approximately 5000 test requisition forms and 9500 blood samples from out and inpatient departments. The clinical chemistry lab is equipped with autoanalyzers Hitachi 902 for routine blood investigations and Roche e411 for hormones, tumour markers and Biorad D10 for Glycated hemoglobin estimation. The clinical chemistry department has separate test requisition form which includes patient details, sample information and investigations. All blood samples were collected in vacutainer and transported in an icepack to central lab. Upon receiving the sample in lab, technicians and section incharge observed for any preanalytical errors in requisition form and in the sample. When an error is observed, entries were made in the register and in excel sheet earmarked for preanalytical errors.

The preanalytical errors included in the study were- in the test requisition form, patient details like name, age, sex, date, OPD/IPD number, clinical history or provisional diagnosis, sample routine/urgent, time of receiving sample in lab and signature of doctor. During collection of sample any double pricks and untoward incidents that had occurred were recorded. Each inpatient ward is having register for recording double pricks and untoward incidents and data was collected from the registers. Blood samples were observed for hemolysis, lipemia, improper blood to anticoagulant ratio, wrong vacutainer, missing samples, improper transportation, storage and insufficient sample for processing. All the data was entered in an excel sheet. The

Statistical software SPSS 15 was used for the analysis of the data.

Results

The present study was conducted over a period of 1 year. A total of 1, 44, 208 samples and 54, 268 test requisition forms were screened for preanalytical errors from clinical biochemistry section. Of these 1.5% samples and 74% of test requisition forms had errors. A total of 77,854 in patient samples, 32,342 inpatient requisition forms and 66,354 outpatient samples, 21,926 outpatient requisition forms were screened for preanalytical errors. A total of 1354 samples from inpatient wards and 795 samples from out patient department were having preanalytical errors and were rejected. The distribution of errors in preanalytical phase in sample collection is depicted in Table 1 and distribution of preanalytical errors in test requisition forms is shown in Table 2. A total of 451 samples (0.31%) were found insufficient for further investigations and 337 (0.23%) samples were found unacceptable, since they were hemolysed and the departments concerned were duly informed about this. 75% of test requisition forms had not mentioned diagnosis/provisional diagnosis. 13.8% forms were without stat label and 10% forms were observed without the type of sample being mentioned on them. The incidence of double pricks and untoward incidents was 0.17 and 0.005% respectively. A sigma value of 4.5 for double pricks and 5.4 for untoward incidents was obtained which indicates good performance.

Following computation of percentage of preanalytical errors, cumulative percentage was calculated and Pareto's chart was plotted as shown in Fig. 1. 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. In the present study a total of 19 preanalytical errors were observed. According to Pareto's principle, the chart depicts (Fig. 1), out of total 19 preanalytical errors studied, 80% of preanalytical errors are due to missing information in forms like diagnosis, routine or stat sample, type of sample and sample received time and in these 80% of errors, 20% of errors are attributed to diagnosis which was not mentioned in test requisition forms.

Number of defects observed, size of the sample were fed into the Westgard online formula to calculate defects per million and six sigma for each preanalytical error (www.westgard.com/six-sigma-calculators). Insufficient sample for testing and improper ratio of blood to anticoagulant were having sigma value of 4.3 indicating a need for improvement in sample collection. Missing information in test requisition forms like diagnosis, type of sample, routine or stat were having sigma values of 0.9, 2.9, and 2.6 respectively.

Table 1 Distribution of preanalytical errors in sample collection

S. no	Preanalytical error	Number of defects	Frequency (%)
1	Sample insufficient	451	0.31
2	Sample transportation	213	0.15
3	Sample storage	200	0.13
4	Missing samples	55	0.03
5	Collection in wrong vacutainer	287	0.20
6	Improper ratio of blood to anticoagulant	433	0.30
7	Hemolysed	337	0.23
8	Lipemic	173	0.12
9	Double pricks during collection	253	0.17
10	Untoward incidents during collection	8	0.005
	Total	2410 Defects	

Table 2 Distribution of preanalytical errors in test requisition form

S. no	Preanalytical errors	Number of defects (out of 54,268 forms)	Frequency (%)
1	OPD/IPD number	1580	2.9
2	Date	1350	2.5
3	Age	169	0.31
4	Gender	156	0.28
5	Diagnosis	40,900	75
6	Receiving time	4886	9
7	Routine/stat sample	7480	13.8
8	Type of sample	5590	10.3
9	Signature of doctor	110	0.20
	Total	62,221 Defects

Fig. 1 Pareto chart depicting preanalytical errors

Discussion

In recent years there is increasing concern over quality improvement in clinical laboratory. Although quality controls are available for monitoring analytical errors still there is a need to improve preanalytical process which contributes 60% of total laboratory errors. There is a wide

variation in the total number of laboratory errors ranging from 0.1 to 9.3% [5]. A sigma value of ≤ 3 was considered as poor performance with 66,807 defects per million opportunities and a sigma value of four implies 6210 defects per million opportunities. A preanalytical quality indicator with a sigma value of ≥ 4 was considered as well controlled process which was also reported by the author Alsina et al. The preanalytical quality indicator with a sigma value below the set sigma benchmark was considered as poor performance and needs corrective and preventive action.

Insufficient blood sample collected was the most common error in our laboratory. 0.31% samples were insufficient in quantity. In a similar study done by Begum, [6] 1.74% samples were insufficient for processing. Lippi and his fellow members reported insufficient specimen quantity and quality accounting for over 60% of pre-analytical errors [7]. Insufficient sample might be due to lack of knowledge of phlebotomists to collect adequate sample, neonate sample from NICU and paediatric ward or too many investigations ordered for one sample and also due to lax attitude towards blood collection by the phlebotomists, nurses and interns. A sigma value of 4.3 was obtained for insufficient sample and Pareto's chart also showed out of

19 preanalytical errors studied, 20% of errors are due to sample collection and 80% of errors are due to missing information in forms. A study done by Alsina et al. reported a sigma value of 4.3–5 as specification for insufficient sample. In our study, although a sigma value of 4.3 for insufficient sample indicates well controlled process but the technicians and nurses should be aware that each analytical process needs a specific quantity of sample for processing. The technicians, nursing staff should undergo frequent training in sample collection and also they should read standard operating procedure (SOP) before collecting blood sample. The technicians, nurses and interns might not have noticed the mark on vacutainer tube while collecting the blood samples leading to overfilling or under filling of vacutainer causing improper ratio of blood to anticoagulant leading to hemolysis of the sample. For hemolysed samples the recommended provisional specification is 0.6% which is equivalent to sigma value of 4.1 as reported by Gomez et al. In our study a sigma value of 4.4 was obtained for hemolysis. Hemolysis can be prevented by using appropriate vacutainer tubes, proper mixing of blood and anticoagulant by inversion and proper centrifugation technique. The training classes and standard operating procedures will help the health care staff in reducing the number of preanalytical errors. The hemolysed samples should be rejected as serum enzyme levels get elevated like alanine amino transferase (ALT), aspartate amino transferase (AST) and lactate dehydrogenase (LDH) and also potassium levels [8]. The concerned departments and wards were informed about the hemolysed sample and

requested for fresh sample. This leads to delay in reporting and increased turnaround time. In our laboratory 0.23% samples were hemolysed. In a study done by Chawla et al. [9] for a period of 1 year, 0.74% samples were hemolysed. In a similar study done by Jay and colleagues [10] hemolysis (>95%) was due to incorrect sampling, mixing and transportation.

Lipemic samples will block the sample probe and interfere with analysis of bilirubin, calcium, phosphorus and enzymes AST, ALT, gamma glutamyl transferase (GGT) levels [11]. 0.12% of samples were lipemic and a sigma value of 4.6 was obtained and indicates well controlled process but improper information regarding patient preparation by the clinicians and phlebotomists can lead to lipemic samples. The clinicians and phlebotomists should give proper instructions for sample collection and each laboratory should display the list of tests requiring fasting samples. The concerned departments were informed about lipemic samples.

The sample collected in the wards or in phlebotomy room should be transported within an hour of collection. In our laboratory for sample transportation we got a sigma value of 4.5 which indicates well controlled process and there was no delay in transport of sample s from wards and phlebotomy room. The arterial blood gas samples, cerebro spinal fluid and samples for blood glucose estimation should be transported as early as possible. The sample for ACTH should be transported in an icepack. The SOP for sample transport should be available in each ward. If there is any delay in analysis, the samples should be stored at

Table 3 Six sigma values for preanalytical quality indicators

S. no	Preanalytical error	DPM (defects per million)	Sigma value
1	Sample insufficient	3137	4.3
2	Sample transport	1477	4.5
3	Sample storage	1387	4.5
4	Missing sample	381	4.9
5	Wrong vacutainer	1990	4.4
6	Improper ratio of blood to anticoagulant	3003	4.3
7	Hemolysis	2337	4.4
8	Lipemic	1200	4.6
9	OPD/IPD number	29,115	3.4
10	Double pricks	1754	4.5
11	Untoward incidents	55	5.4
12	Date	24,877	3.5
13	Age	3114	4.3
14	Sex	2875	4.3
15	Diagnosis	753,667	0.9
16	Receiving time	90,035	2.9
17	Routine/stat	137,834	2.6
18	Type of sample	103,007	2.8
19	Signature of doctor	2027	4.4

appropriate temperature. In our laboratory a sigma value of 4.5 for storage of sample was obtained. A sigma value of 4.9, 4.4, and 4.3 was obtained for missing sample, collection in wrong vacutainer and improper ratio of blood to anticoagulant respectively. The preanalytical errors with a sigma value ≥ 4 indicate a well controlled process. The preanalytical errors in sample collection can be controlled by frequent training to phlebotomists and nursing staff and by making them aware of availability of standard operating procedures for each preanalytical process in each inpatient ward.

Test requisition forms continue to serve as one of the crucial tools for interpretation of reports and also for sample collection and dispatch of reports. They have information of patient identity, sample details and tests to be done. Samples without duly filled test requisition forms were rejected and informed to concerned wards. In our laboratory 75% of test requisition forms were without diagnosis or brief on clinical symptoms of the patient. Chillar et al. [12] reported in their study that 61% forms did not have diagnosis. Nutt et al. [13] reported that the details of diagnosis were not indicated in 19.1% whereas in 80.9% where diagnosis was mentioned, 37.3% were in abbreviated forms. A sigma value of 0.9 was obtained as shown in Table 3 for diagnosis which was not mentioned in forms which indicate very poor performance and need for correction. Without mentioning diagnosis in forms it is difficult to interpret the reports especially for hormones like thyroid profile and the clinical biochemist needs information on hypothyroid or hyperthyroid symptoms and about the treatment.

In 13.8% of test requisition forms, whether the samples have to be processed as a routine or stat sample was not mentioned which led to delay in reporting of stat samples. A sigma value of 2.6 for this preanalytical error indicates poor performance. The turnaround time for routine and stat samples is different. It may lead to delay in treatment plan for the patients in casualty and intensive care units. The other information in requisition forms like sample received time in lab is also important as to verify whether reports are dispatched within turnaround time for that particular parameter. A sigma value of 2.9 indicates poor performance and laboratory technicians should make entry of sample received time in forms to know whether report is dispatched within turnaround time and to identify whether there was any delay in transportation. The type of sample whether it is blood, urine, CSF or any other body fluid sample should be mentioned in requisition forms. 10.3% of forms were without this information which led to delay in processing the sample and reporting and sigma value of 2.8 was obtained. The CSF samples should be processed within an hour of collection.

The WHO criteria states that minimum of two identifiers should be present on vacutainer for identification of sample. The OPD and IPD number of a patient should be present on the vacutainer and in requisition forms for tracing the origin of sample and for proper dispatch to patients. 2.9% of requisition forms were without OPD/IPD number and we got a sigma value of 3.4. The age and gender of the patient is also important when reporting because the reference range for parameters differs by gender and age. A sigma value of 4.3 was obtained for age and sex. A sigma value of 3 indicates there are 66,807 defects per million opportunities and the process needs corrective and preventive action [14]. The laboratory technicians, nursing staff, interns should be given frequent training on sample collection, transport and proper filling of requisition forms. For resident doctors and interns during orientation programme a topic on sample collection should be included before they start to work in the inpatient wards. To Err is a human being nature those who correct it are good human beings.

Conclusion

The cardinal concept portrayed in the present study was to find out the most common preanalytical error in our laboratory. Although the test requisition forms are filled by interns and doctors there is lack of awareness on importance of filling the information in forms. The diagnosis or brief note on patient's symptoms helps the clinical biochemist to interpret the report and this information was lacking in most of the forms. The Pareto chart and sigma value when interpreted together may give information regarding most common type of preanalytical error and the corrective measures to be taken to prevent recurrence and also there is a need for frequent training on Best practices in phlebotomy for technicians, interns and doctors to reduce the number of errors and to improve the total quality management in the laboratory.

Acknowledgement Authors would like to thank the faculty of Department of Biochemistry and laboratory technicians of Mahatma Gandhi Medical College and Research Institute.

References

1. Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. *Clin Chem*. 2002;48:691–8.
2. Plebani M. The detection and prevention of errors in laboratory medicine. *Ann Clin Biochem*. 2010;47:101–10.
3. Barth JH. Clinical quality indicators in laboratory medicine. *Ann Clin Biochem*. 2012;49:9–16.
4. Giménez-Marín A, Rivas-Ruiz F, Mdel Pérez-Hidalgo M, Molina-Mendoza P. Pre-analytical errors management in the

- clinical laboratory: a five-year study. *Biochem Med.* 2014;24(2):248–57.
5. Plebani M. Appropriateness in programs for continuous quality improvement in clinical laboratories. *Clin Chim Acta.* 2003;333:131–9.
 6. Begum F. A study of pre-analytical errors in a hospital based clinical biochemistry laboratory and formulation of measures for correction. *Int J Bioassays.* 2014;3(9):3270–5.
 7. Lippi G, Blanckaert N, Bonini P, Sol G, Kitchen S, Palicka V, et al. Causes, consequences, detection and prevention of identification errors in laboratory diagnostics. *Clin Chem Lab Med.* 2009;47:143–53.
 8. Carraro P. Hemolyzed specimens: a reason for rejection or a clinical challenge? *Clin Chem.* 2000;46:306–30.
 9. Chawla R, Goswami B. Identification of the types of Preanalytical Errors in the clinical Chemistry Laboratory: 1 Year study at GB Pant Hospital. *Lab Med.* 2010;41:89–92.
 10. Jay DW, Provasek D. Characterization and mathematical correction of hemolysis interference in selected Hitachi 717 assays. *Clin Chem.* 1993;39:1804–10.
 11. Nikolac N. Lipemia: causes, interference mechanisms, detection and management. *Biochemia Medica.* 2014;24(1):57–67.
 12. Chillar N, Khurana S, Agarwal R, Singh NK. Effect of pre-analytical errors on quality of laboratory medicine at a neuropsychiatry institute in North India. *Indian J Clin Biochem.* 2011;26:46–9.
 13. Nutt L, Annalise EZ, Rajiv TE. Incomplete lab request forms: the extent and impact on critical results at a tertiary hospital in South Africa. *Ann Clin Biochem.* 2008;45:463–6.
 14. Gajjar M, Patel A, Jain S. Monitoring of quality indicators in pre analytical phase of testing in the clinical biochemistry laboratory of a tertiary care hospital attached with government medical college. *IOSR-JDMS.* 2016;15(7):62–8.