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Original Research Article

Evaluation of quality indicators in pre-analytical phase of testing in clinical biochemistry laboratory of a tertiary care hospital in India

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ABSTRACT

Introduction: Preanalytical errors account for nearly 70% of the total number of laboratory errors. Hence, controlling them is a big challenge. Quality Indicators expressed as sigma metrics provide a convenient way to objectively quantify errors.
Aim: To quantify performance in the preanalytical phase of the testing process in Clinical Biochemistry laboratory of a tertiary care hospital in India using quality indicators.
Materials and Methods: Study period: January to September 2016. Quality Indicators (QIs) used: samples lost–not received (QI-8); samples collected in an inappropriate blood collection tube (QI-9); haemolyzed samples (QI-10); clotted samples (QI-11); samples with insufficient sample volume (QI-12); improperly labelled (QI-15); damaged in transport (QI-14). Sigma metric was calculated for the above mentioned QIs.
Results: The total number of samples received during the study period was 5,73,694 and the total number of preanalytical errors was 1,782. Among the preanalytical errors, 43.9% were samples with insufficient volume (sigma: 4.5), 33.2 % were haemolyzed samples (sigma: 4.6), 11.3% were samples collected in an inappropriate blood collection tube (sigma: 4.9), 6.7% were samples not received in the laboratory (sigma: 5.1), 4.2% were clotted samples (sigma: 5.2), 0.7% were improperly labelled (sigma: 5.6), only one sample (0.06%) was lost over 9 months period due to spill in pneumatic chute.
Conclusion: QIs serve as a tool to monitor process performance in the laboratory. In this study, insufficient sample volume and haemolysis were the major causes of preanalytical errors. All QIs had acceptable sigma value. Regular training of phlebotomists regarding the preanalytical errors needs to be conducted to achieve six sigma performance.

1. Introduction

Testing processes in laboratory are divided into pre-analytical, analytical and post-analytical phases. Preanalytical errors account for nearly 70% of the total number of laboratory errors.[1–3] This increases turnaround times and healthcare costs and negatively affect patient safety.[1,4,5] Hence, controlling them is a big challenge. In order to evaluate testing process and reduce laboratory errors, IFCC has developed several Quality indicators (QIs).[5,6] Quality indicators are tools that quantify quality in various dimensions of health care and compares it with selected criteria.[7] Sigma metrics helps in the detection of processes that need improvement.[8] A convenient method of quantifying performance of the QIs is calculation of errors or defects per million (DPM) and conversion to sigma metric. Sigma scale also helps to judge the process quality with 3σ being minimum allowable performance and 6σ being world class quality. Hence, the objective of this study was to quantify performance in the preanalytical phase of the testing process in Clinical Biochemistry laboratory of a tertiary care hospital in India using quality indicators.

2. Materials and Methods

This study was conducted during January to September 2016 in the clinical biochemistry laboratory of a tertiary

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care hospital in India. The source of data were the laboratory specimen rejection records, Table 1 shows the QIs that were evaluated.

2.1. Data analysis

All the data was entered and analysed on Microsoft Excel 2016. Percentage of each error was calculated. DPM were calculated using the formula:

DPM = (number of errors × 1,000,000)/total number of specimens.

The DPM was converted to a sigma value based on tables available online as shown in Table 2.[9]

Table 1: Quality Indicators evaluated

Quality Indicators (QI)	Description
QI-8	Samples lost–not received
QI-9	Samples collected in an inappropriate blood collection tube
QI-10	Hemolyzed samples
QI-11	Clotted samples
QI-12	Samples with insufficient sample volume
QI-15	Improperly labelled
QI-14	Damaged in transport

Table 2: Conversion of DPM to sigma metric

Sigma Metric	Defects per million
1.0	698,000
2.0	308,000
2.5	159,000
3.0	66,800
3.5	22,750
4.0	6,210
4.5	1,350
5.0	233
5.5	32
6.5	3.4

3. Results

Of the 5,73,694 clinical chemistry specimens received in the laboratory during the study period, 1,782 specimens were rejected according to our rejection criteria. Figure 1 shows the percentage of errors observed. Insufficient sample volume (783 samples) turned out to be the most common cause of preanalytical errors followed by haemolysis (591 samples). Wrong tube (n=201), samples lost-not received (n=119), clotted samples (n=75) were also important causes of rejection. 12 samples were rejected due to improper labelling. There was only one sample loss due to spill in pneumatic chute.

Table 3 depicts the sigma metric for each QI. All QIs showed well controlled performance.

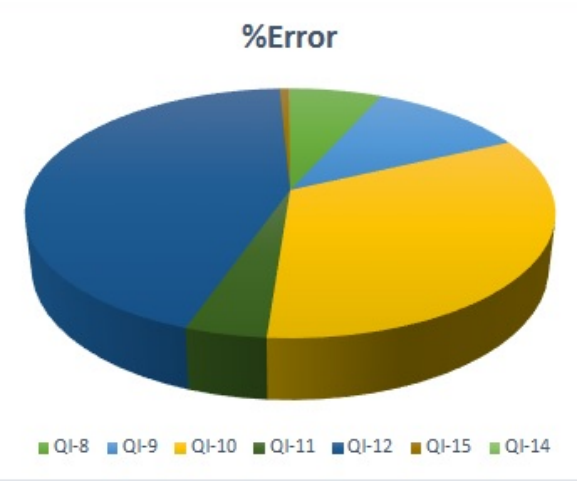

Fig. 1:

4. Discussion

Pre analytical errors are the main cause of specimen rejection in the clinical laboratory. Specimen rejection leads to inconvenience and discomfort of repeat collection and leads to delayed reporting of test results. Hence, monitoring of acceptability of specimens is an important quality assurance measure for clinical laboratories.[10]

Quality Indicators help to objectively quantify laboratory performance and evaluate critical dimensions.[11]

In this study all QIs had acceptable sigma value. Insufficient sample volume and haemolysis were found to be the major causes of preanalytical errors in our study.

These observations were similar to the study conducted by Agarwal et al. in which they found insufficient sample volume to be the most common cause of specimen rejection followed by haemolysis.[12]

Chawla et al. also found haemolysis to be a major cause of sample loss in their study conducted in 2009, but unlike our study, insufficient sample volume was seen as a minor cause.[13]

In contrast to this study, the study conducted by Liyun Cao et. al found contamination to be most common cause of specimen rejection.[14]

In our review of recent literature we found insufficient sample volume to be a less common cause of sample loss in international studies (<20%).[1,10,15]

This indicates that there is a high percentage of recoverable sample loss due to insufficient sample volume in our hospital. If a tube contains insufficient sample volume, the excess anticoagulant will interfere with a variety of clinical chemistry tests. To minimize this error, all blood collection tubes should be filled to the correct volume.[4]

In this study, rejections were more common for specimens collected on the inpatient basis. Being high-

Table 3: Sigmametrics for the QIs evaluated

QI	Error	% Error	Sigma	Performance
QI-8	Samples lost-not received in the laboratory	6.7%	5.1	Well controlled
QI-9	Samples collected in an inappropriate blood collection tube	11.3%	4.9	Well controlled
QI-10	Haemolyzed samples	33.2%	4.6	Well controlled
QI-11	Clotted samples	4.2%	5.2	Well controlled
QI-12	Samples with insufficient volume	43.9%	4.5	Well controlled
QI-15	Improperly labelled	0.7%	5.6	Well controlled
QI-14	Sample lost due to spill in pneumatic chute	0.06%	-	-

pressure work environments, the inpatient services like ICUs and ED are more prone to errors. This was also reported by Dikmen et al. [16]

It is essential that correct phlebotomy procedures be taken to reduce pre-analytical errors. Phlebotomists and in patient staff need to be made aware of these errors, standard operating procedures need to be implemented and regular trainings need to be conducted to reduce these errors. These approaches will lead to improvement in the quality of laboratory services.

A limitation of this study was that the data for specimen rejection is recorded by the laboratory personnel hence, can be influenced by laboratory vigilance in detecting and recording preanalytical errors.

5. Conclusions

Six Sigma metrics is an efficient way of monitoring quality in a clinical laboratory. [17]

All QIs studied were found to be well controlled (>4σ). Specimen rejections for various reasons are a continuous challenge for laboratories. Any error, no matter how frequent, should be treated seriously as they adversely affect patient safety. Follow-up studies regarding awareness of phlebotomists need to be conducted and necessary interventions need to be taken to reduce these errors.

6. Source of Funding

None.

7. Conflict of Interest

None.

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