Evaluation of performance in the pre-analytical phase of a clinical biochemistry laboratory in a Tertiary Medical College Hospital

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ABSTRACT

Background: Pre-analytical phase is the major source of errors in a clinical biochemistry laboratory. **Aims and Objectives:** The study aims to determine the quality of laboratory performance in the pre-analytical phase using quality indicators (QI) specified by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Laboratory Errors and Patient Safety and sigma metric scale for both the inpatient and outpatient samples received in the clinical biochemistry laboratory. **Materials and Methods:** All samples and requisition forms received in the laboratory were examined before analysis. The percentages of the seven QI were calculated. The frequency, percentage, and defects per million rates of each pre-analytical error were calculated. Sigma value was obtained using an online sigma calculator. The laboratory performance was then categorized by the IFCC-based performance levels and sigma-based values. **Results:** Out of 30,546 samples received during a period of 6 months, pre-analytical errors occurred in 2.8% of them. The highest number of pre-analytical errors was due to hemolysis (29.9%). The outpatient samples showed a desirable to optimum performance with a good sigma value. There were more errors and lower quality-based performance, in the case of inpatient samples. Errors were highest in September at the start of the study followed by a gradual decrease over the next 5 months. **Conclusion:** The laboratory performance in the pre-analytical phase was found to be favorable and consistent with the international specifications.

Key words: Quality indicators; Pre-analytical errors; Six sigma; Quality control

INTRODUCTION

Patient laboratory reports form the backbone of the health-care system in the modern age of evidence-based medicine. More than 60% of medical decisions are based on diagnostic test results.[1] According to ISO 15189:2012 standard for "Medical laboratories – Requirements for quality and competence," the total testing process in a laboratory is divided into pre-examination, examination, and post-examination processes.[2] The pre-examination or the pre-analytical phase in a laboratory comprises all the procedures that begin with the physician's test requests, patient identification and preparation, sample collection, transport, storage and processing, and end with the initiation of sample analysis in the analytical phase.[1-4] With

the introduction of laboratory automation, internal and external quality assurance system, the analytical errors in the diagnostic process have drastically reduced.

Out of all the laboratory errors, nearly 70% of them occur during the pre-analytical phase.[4-7] The commonly encountered pre-analytical errors in a clinical laboratory include missing patient identification data, inadequate samples, samples in wrong containers, hemolyzed or clotted samples, improper labeling, missing clinical history, improper storage and transport, and lost samples.[3,8,9] The pre-analytical processes involve the participation of clinicians, patients, nurses, laboratory technicians, sample transporters, and other logistic personnel. All these variables can become a potential source of human error

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and result in the non-conformity of test results. Hence, it becomes a challenging task to implement quality control measures in the pre-analytical phase.

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Laboratory Errors and Patient Safety (WG-LEPS) has defined 16 quality indicators (QI) for the pre-analytical phase, as shown in Table 1.[6,10,11] QI can be implemented as a tool for systematic monitoring and evaluation of the laboratory performance during the pre-analytical phase of the total testing process. The performance levels for each QI are defined as unacceptable, minimum, desirable, and optimum.

Another management tool that can be used to evaluate the quality of the pre-analytical phase of the testing process is the six sigma methodology. Six sigma is defined as a defect rate of 3.4 defects per million (DPM) opportunities and detects the frequency of errors in the process. The number of errors in the process is expressed as DPM which is then converted into sigma metrics using the sigma calculator

available online. Performance at three sigma indicates minimum acceptable quality and six sigma implies best in class quality.[4,11,12]

This study aims to evaluate the quality of laboratory performance during the pre-analytical phase by application of some of the QI and sigma metrics to both the inpatient and outpatient samples, received in the clinical biochemistry laboratory of a tertiary medical college and hospital, for a period of 6 months. The ultimate goal of this study is to identify and rectify the pre-analytical errors and implement corrective measures, where required, to improve the reliability of patient reports.

Aims and objectives

The study aims to determine the quality of laboratory performance in the pre-analytical phase using quality indicators (QI) specified by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Laboratory Errors and Patient Safety and sigma metric scale for both the inpatient and outpatient samples received in the clinical biochemistry laboratory.

Table 1: Performance levels of quality indicators for the pre-analytical phase of testing developed by the International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety

Key activity in the laboratory	Quality indicator	Performance level			
		Optimum	Desirable	Minimum	Unacceptable
Test ordering	QI-1 – Number of requests with clinical question/total number of requests from physicians (in percentage)	>87	58–87	29–57	< 29
	QI-2 – Number of appropriate requests, with respect of clinical question from general practitioners/number of requests that reports clinical question from general practitioners' (in percentage)	>97	65–97	32–64	<32
Formulation and input of requests	QI-3 – Number of requests without physician identification/total number of requests (in percentage)	<5.0	5.0–6.0	6.1–8.0	>8.0
	QI-4 – Number of unintelligible requests/total number of requests (in percentage)	<0.20	0.20–25	0.26–0.30	>0.30
	QI-5 – Number of requests with errors concerning patient identification/total number of requests (in percentage)	<0.40	0.40–0.50	0.51–0.60	> 0.60
	QI-6 – Percentage of "Number of requests with errors concerning physician identification/total number of requests"			<0.1	
	QI-7 – Number of requests with errors concerning input of tests (missing)/total number of requests (in percentage)	<0.30	0.20–0.25	0.41–0.50	>0.50
Sample identification, collection, handling, and transport	QI-8 – Number of samples lost-not received/total number of samples (in percentage)	<0.20	0.20–0.40	0.41–0.60	>0.60
	QI-9 – Number of samples collected in inappropriate container/total number of samples (in percentage)	<0.07	0.07–1.13	1.14–0.20	>0.20
	QI-10 – Number of samples hemolyzed (chemistry)/total number of samples (in percentage)	<1.0	1.0–1.5	1.6–2.0	>2.0
	QI-12 – Number of samples with insufficient sample volume/total number of samples (in percentage)	<0.40	0.40–0.80	0.81–1.20	>1.20
	QI-13 – Percentage of "Number of samples with inadequate sample-anticoagulant/total number of samples with anticoagulant"	<0.20	0.20–0.30	0.31–0.40	>0.40
	QI-15 – Number of samples improperly labeled/total number of samples (in percentage)	<0.07	0.07–0.15	0.16–0.20	>0.20
	QI-16 – Number of samples improperly stored/total number of samples (in percentage)			<0.01	

MATERIALS AND METHODS

The present study is a prospective observational study conducted in the Department of Biochemistry of College of Medicine and JNM Hospital Kalyani, West Bengal, for a period of 6 months from September 1, 2019, to February 29, 2020. The clinical biochemistry laboratory is equipped with two fully automated clinical chemistry analyzers (EM 360), one electrolyte analyzer (EASYLYTE), two centrifuge machines, and other instruments for sample storage, processing, and testing. The inpatient samples were collected in respective wards by on duty doctors and nurses and sent to the laboratory by hospital staff. The outpatient samples were collected in the blood collection room in the central laboratory by phlebotomists. The clinical biochemistry test requisition forms have patient details such as name, age, sex, registration number, OPD and ward name, clinical history, and list of investigations printed on it. The labeling of all the sample tubes along with the requisition forms, received in the central laboratory, are checked and noted down in the "Sample Entry" registers made separately for the inpatients and outpatients, and then forwarded to the biochemistry, pathology, and microbiology laboratories. On receipt into the biochemistry laboratory, all samples are visually inspected for any problems and accepted samples are processed further before loading them on to the autoanalyzer.

This study aims at evaluating the laboratory performance level in the pre-analytical phase based on the QIs specified by IFCC WG-LEPS and by application of sigma metric scale. The performance in the pre-analytical phase was calculated in this study, using, 2 QIs from formulation and input of request – QI-5 and QI-7, 5 QIs from sample identification, collection, handling, and transport – QI-8, QI-9, QI-10, QI-12, and QI-15. Data were recorded on a daily basis.

The detailed procedure for evaluating QI is as follows-
1. QI-5: Percentage of "Number of requests with errors concerning patient identification/Total number of requests" – the samples with any mismatch regarding patient data between the requisition form and the data on sample collection tube
2. QI-7: Percentage of "Number of requests with errors concerning input of tests/Total number of requests" – the requisition forms with the required tests not mentioned
3. QI-8: Percentage of "Number of samples lost-not received/Total number of samples" – the requisition forms present for uncollected samples
4. QI-9: Percentage of "Number of samples collected in inappropriate container/Total number of samples"

– the samples collected in the wrong collection tube (clot/fluoride/EDTA)
5. QI-10: Percentage of "Number of samples hemolyzed (chemistry)/Total number of samples" – samples with hemolysis detected on visual examination during sample receipt or after centrifugation
6. QI-12: Percentage of "Number of samples with insufficient sample volume/Total number of samples" – samples with volume <2 ml in case of adults and <1 ml in pediatric patients
7. QI-15: Percentage of "Number of samples improperly labeled/Total number of samples" – samples which had incomplete or wrong labeling of patient details.

The frequency and percentage of pre-analytical errors were noted. The DPM rates of each pre-analytical error were calculated using the following formula –

DPM = (number of errors × 1,000,000)/sample size

The second performance parameter, sigma value was obtained from DPM rates using sigma score calculators available online at http://www.westgard.com/calculators/calculators.

The laboratory performance level was categorized based on their sigma value –
1. Very good: ≥5.0 sigma
2. Good: 4.0–<5.0 sigma
3. Minimum: 3.0–<4.0 sigma
4. Unacceptable: <3.0 sigma.

Ethical clearance and approval
This research study has been approved by the Institutional Ethics Committee vide reference no. F-24/PR/COMJNMH/IEC/21/216.

RESULTS

A total of 30,546 samples were received in the clinical biochemistry laboratory during the period of 6 months from September 2019 to February 2020. Out of these, 26,842 samples were received from the outpatient departments and 3704 specimens were received from the inpatient departments.

The total pre-analytical errors observed were 857, which accounted for 2.8% of the total number of samples received in 6 months.

The performance levels in the pre-analytical phase for the QI are expressed as percentages and sigma metric values, for the outpatient and inpatient samples, as shown in Tables 2 and 3, respectively.

Table 2: Performance levels in the pre-analytical phase for outpatient samples received in the laboratory

Quality indicator code	Descriptor	No. of errors	Obtained value (%)	IFCC-based performance level	DPM	Sigma value	Sigma-based performance level
QI-5	Patient identification errors	63	0.23	Optimum	2347	4.4	Good
QI-7	Missing input of tests	107	0.39	Desirable	3986	4.2	Good
QI-8	Samples lost	105	0.39	Desirable	3912	4.2	Good
QI-9	Samples in inappropriate container	19	0.07	Desirable	708	4.7	Good
QI-10	Hemolyzed samples	186	0.69	Optimum	6929	4	Good
QI-12	Insufficient samples	162	0.6	Desirable	6035	4.1	Good
QI-15	Improperly labeled samples	39	0.14	Desirable	1453	4.5	Good

Table 3: Performance levels in the pre-analytical phase for the inpatient samples received in the laboratory

Quality indicator code	Descriptor	No. of errors	Obtained value (%)	IFCC-based performance level	DPM	Sigma value	Sigma-based performance level
QI-5	Patient identification errors	14	0.37	Optimum	3780	4.2	Good
QI-7	Missing input of tests	9	0.24	Desirable	2430	4.4	Good
QI-8	Samples lost	15	0.4	Desirable	4050	4.2	Good
QI-9	Samples in inappropriate container	19	0.51	Unacceptable	5130	4.1	Good
QI-10	Hemolyzed samples	71	1.9	Minimum	19168	3.6	Minimum
QI-12	Insufficient samples	42	1.13	Minimum	11339	3.8	Minimum
QI-15	Improperly labeled samples	6	0.16	Minimum	1620	4.5	Good

The total number of pre-analytical errors during the period of 6 months is shown in Figure 1.

The month-wise distribution of pre-analytical errors for the outpatient and inpatient samples is shown in Figure 2.

The results of this study were compared with the previous studies on pre-analytical errors with respect to the error percentages and sigma values on Tables 4 and 5, respectively.

DISCUSSION

The application of QI and sigma metrics in the laboratory helps to keep the total testing process under control, by systematic monitoring and identification of errors based on which suitable action should be taken.[10]

Since majority of pre-analytical errors occur during the collection process, so performance level was separately noted for the inpatient and outpatient samples. Our laboratory showed an optimum performance for QI-5 and QI-10 and desirable for the rest of QIs, for the outpatient samples. It was found that errors due to sample collection and handling indicating by QI-9, QI-10, QI-12, and QI-15 were more for inpatient than outpatient samples, as indicated by the IFCC-based performance levels and sigma values.

The highest number of pre-analytical errors that occurred in the laboratory during the 6 months was due to

hemolyzed samples. Sample hemolysis was detected visually and all hemolyzed samples rejected, were recollected by phlebotomists. Since we do not have an automated hemolysis detection system in the autoanalyzer in our laboratory, this is a major limitation of this study. The laboratory staff are regularly intimated and prompted about the common causes of sample hemolysis during blood collection such as forcefully evacuating the sample through the small gauge needle, application of excessive pressure during sample collection, vigorously shaking the sample during mixing and transport, and centrifuging the sample before it has clotted.[8,13,14]

The next common cause of pre-analytical errors was due to inadequate sample volume and was more prevalent in inpatient samples. For the inpatient samples rejected due to insufficient volume, the requisition forms are sent back to the ward with a note on minimum sample volume required for testing. For the outpatient samples, the phlebotomists are regularly notified about it. Although we are aware of the difficulty of obtaining adequate specimen by venipuncture in neonates, pediatric, geriatric, cancer, and ICU patients, we have to keep in mind that an inadequate volume can lead to underestimation of test parameters, improper mixing with anticoagulants, and finally affect the accuracy of the reports.

Missing samples included all such requisition forms that were received without the sample. The major causes of lost

Table 4: Comparison of QI performance level (%) with the previous studies

Quality indicators	Grecu et al.	Gajjar et al.	Bir et al.	Present study	
				Outpatient	Inpatient
QI-5 – Requests with errors concerning patient identification	0.01	-	0.04	0.23	0.37
QI-7 – Requests with errors concerning test input	0.002	-	0.016	0.39	0.24
QI-8 – Samples lost-not received	0.05	0.02	0.025	0.39	0.4
QI-9 – Samples collected in inappropriate container	0.002	0.01	0.01	0.07	0.51
QI-10 – Hemolyzed samples	0.4	0.18	0.12	0.69	1.9
QI-12 – Samples with insufficient sample volume	-	1.23	0.03	0.6	1.13
QI-15 – Improperly labeled samples	-	-	0.02	0.14	0.16

Table 5: Comparison of sigma metrics with the previous studies

| Quality indicators	Grecu et al.	Gajjar et al.	Bir et al.	Present study	
				Outpatient	Inpatient
QI-5 – Requests with errors concerning patient identification	5.3	-	4.9	4.4	4.2
QI-7 – Requests with errors concerning test input	5.6	-	5.2	4.2	4.4
QI-8 – Samples lost-not received	4.8	5	5	4.2	4.2
QI-9 – Samples collected in inappropriate container	5.6	5.2	5.2	4.7	4.1
QI-10 – Hemolyzed samples	4.2	4.5	4.6	4	3.6
QI-12 – Samples with insufficient sample volume	-	3.8	5	4.1	3.8
QI-15 – Improperly labeled samples	-	-	5.1	4.5	4.5
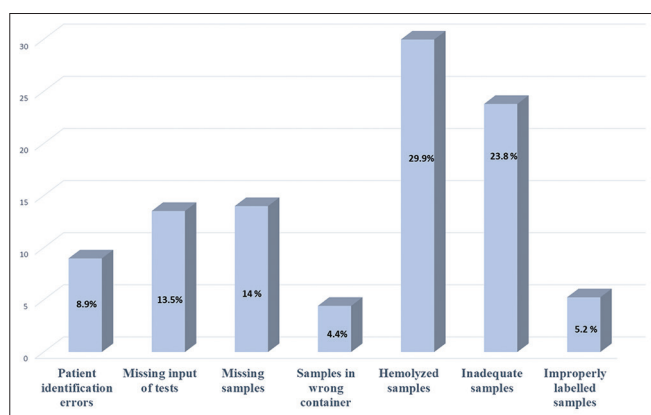
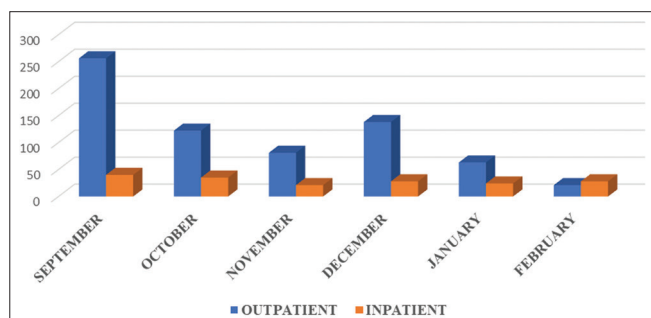**Figure 1:** Pre-analytical errors in the clinical biochemistry laboratory for a period of 6 months

Figure 2: Month-wise distribution of pre-analytical errors for the outpatient and inpatient samples

samples included mishandling during transportation and failure of some patients to return for postprandial sample collection. All such patients are informed, and samples are redrawn on the next available date.

The highest number of errors occurred in the month of September at the start of the study. The error rates decreased in following months, with a surge again in December, probably due to higher patient load.

In this study, we could not achieve a very good sigma value of more than 5 for any of QI applied to both the inpatient and outpatient samples. The higher rate of hemolysis and inadequate samples was mainly due to monthly change of contractual phlebotomists involved in sample collection and involvement of interns during sample processing. Over the period of 6 months during the study, we could achieve a decrease in the pre-analytical error frequency in the laboratory, with daily continuous on-the-job training of all laboratory staff. Hands-on practical experience on sample collection, receipt, and processing techniques are provided to all the phlebotomists, interns, and laboratory technologists on daily basis. All laboratory staff are regularly imparted knowledge about the significance of identifying and correcting pre-analytical errors in the testing process and how they impact the quality of patient reports.

Limitations of the study
The major limitation of this study is that all the QIs could not be studied. The study could not be conducted for a longer duration. The training of staff could not be documented and hence the effect of training on the pre-analytical phase could not be studied and compared over a period of time. The pre-analytical errors for the inpatient samples could not be traced to the various clinical departments.

CONCLUSION

The information provided by laboratory reports directly affects patient treatment. To minimize errors and maximize quality, there should be proper coordination, cooperation, and regular training of all hospital and laboratory staff dealing with patient samples. The implementation and systematic evaluation of QI in the pre-analytical phase will go a long way to achieve accurate and precise reports. A good performance in the pre-analytical phase will help to avoid unnecessary investigations, diagnostic delays, incorrect therapeutic interventions, longer hospital stays, additional costs on workforce, and resources.

We conclude in our study that the performance of our laboratory in the pre-analytical phase meets the standard international specifications. This study emphasizes the need for monitoring and periodic auditing of all pre-analytical operations for targeted continuous quality improvement in health-care services.

ACKNOWLEDGMENTS

We are thankful to the entire laboratory staff for their sincere cooperation throughout the study.

REFERENCES

1. Cornes MP, Atherton J, Pourmahram G, Borthwick H, Kyle B, West J, et al. Monitoring and reporting of preanalytical errors in laboratory medicine: The UK situation. Ann Clin Biochem. 2016;53(2):279-284.

   https://doi.org/10.1177/0004563215599561

2. Sonmez C, Yıldız U, Akkaya N and Taneli F. Preanalytical phase errors: Experience of a central laboratory. Cureus. 2020;12(3):e7335.

   https://doi.org/10.7759/cureus.7335

3. Cakirca G. The evaluation of error types and turnaround time of preanalytical phase in biochemistry and hematology laboratories. Iran J Pathol. 2018;13(2):173-178.

4. Mukhopadhyay T, Shekhar S, Dagar VK and Mukhopadhyay AK. Characterization of pre-analytical errors using six sigma metrics and process capability index in a clinical biochemistry laboratory. 2021;11(2):171-176.

5. Wadhwa N. Evaluation of quality indicators in pre-analytical phase of testing in clinical biochemistry laboratory of a tertiary care hospital in India. Int J Clin Biochem Res. 2020;7(3):354-356.

   https://doi.org/10.18231/j.ijcbr.2020.076

6. Grecu DS, Vlad DC and Dumitrascu V. Quality indicators in the preanalytical phase of testing in a stat laboratory. Lab Med. 2014;45(1):74-81.

   https://doi.org/10.1309/lm9zy92ybzrfpfqy

7. Sushma BJ and Shrikant C. Study on "pre-analytical errors in a clinical biochemistry laboratory": The hidden flaws in total testing. Biochem Anal Biochem. 2019;8:374.

   https://doi.org/10.35248/2161-1009.19.8.374

8. Najat D. Prevalence of pre-analytical errors in clinical chemistry diagnostic labs in Sulaimani city of Iraqi Kurdistan. PLoS One. 2017;12(1):e0170211.

   https://doi.org/10.1371/journal.pone.0170211

9. Alavi N, Khan SH, Saadia A and Naeem T. Challenges in preanalytical phase of laboratory medicine: Rate of blood sample nonconformity in a tertiary care hospital. EJIFCC. 2020;31(1):21-27.

10. Sciacovelli L and Plebani M. The IFCC Working Group on laboratory errors and patient safety. Clin Chim Acta. 2009;404(1):79-85.

    https://doi.org/10.1016/j.cca.2009.03.025

11. Bir A, Ghosh A, Sinha S and Banerjee A. Quality indicators are effective to monitor the performance level of preanalytical phase-a study in a clinical laboratory of eastern indiaquality indicators are effective to monitor the performance level of preanalytical phase a study in a clinical laboratory of eastern india. J Evid Based Med Healthc. 2018;5:236.

    https://doi.org/10.18410/jebmh/2018/236

12. Kulkarni S, Ramesh R, Srinivasan AR and Silvia CR. Evaluation of preanalytical quality indicators by six sigma and pareto's principle. Indian J Clin Biochem. 2018;33(1):102-107.

    https://doi.org/10.1007/s12291-017-0654-5

13. Chawla R, Goswami B, Tayal D and Mallika V. Identification of the types of preanalytical errors in the clinical chemistry laboratory: 1-Year study at G.B. pant hospital. Lab Med. 2010;41(2):89-92.

    https://doi.org/10.1309/LM9JXZBMLSVJT9RK

14. Lippi G, Plebani M, Di Somma S and Cervellin G. Hemolyzed specimens: A major challenge for emergency departments and clinical laboratories. Crit Rev Clin Lab Sci. 2011;48(3):143-153.

    https://doi.org/10.3109/10408363.2011.600228