QUALITY INDICATORS ARE EFFECTIVE TO MONITOR THE PERFORMANCE LEVEL OF PREANALYTICAL PHASE- A STUDY IN A CLINICAL LABORATORY OF EASTERN INDIA

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ABSTRACT

BACKGROUND

In clinical laboratories, establishment and monitoring of multiple Quality Indicators in preanalytical phase to cut down the error rate has a promising role in Quality Assurance.

MATERIALS AND METHODS

The total pathway of preanalytical phase was traced to evaluate various Quality Indicators already established by International Federation of Clinical Chemistry (IFCC) and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety (WG-LEPS), among them, we monitored QI-5 (Requests with errors concerning patient identification), QI-7 (Requests with errors concerning test input), QI-8 (Samples lost-not received), QI-9 (Samples collected in inappropriate container), QI-10 (Haemolysed samples), QI-12 (Samples with insufficient sample volume) and QI-15 (Improperly labelled samples).

RESULTS

During 1 year of study period, a total no of 108000 samples were received in the Clinical Biochemistry laboratory. Total preanalytical errors recorded was 277 (0.25% of the total number of samples). Among them, patient identification error was 11.1%, missing test inputs was 4.3%, 49% were haemolysed, 10.1% were not received in the laboratory, 5% were collected in wrong container, 11.9% samples showed inadequate sample to anticoagulant ratio and 8.3% of samples were improperly labelled. The results were compared with specifications of IFCC (WG-LEPS). All the evaluated QIs were found to be within optimal level. Sigma values also were within acceptable range.

CONCLUSION

The performance in preanalytical phase of our laboratory was found favourable and complies with international quality specifications.

KEYWORDS

Preanalytical Errors, Quality Indicators, Sigma Metrics, Clinical Biochemistry, Laboratory.

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BACKGROUND

Quality assurance in laboratory medicine is now considered as one of the key to patient safety in modern day healthcare system. The Total Testing Process (TTP) in a Clinical laboratory is complex "brain to brain loop" and comprises of 3 phases - Pre- analytical, Analytical and Post analytical.[1,2] Technological upgradation in the form of automation and implementation of multiple quality indicators in the form of internal and external quality control have cut down the rate of analytical errors in laboratory diagnostics.

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But the pre and post analytical phases are still in neglect. It is reported that 70% of total errors within the entire diagnostic process occurs in pre-analytical phase.[3] Moreover, few of the steps in pre-analytical phase like test requesting, patient and sample identification, blood collection, sample handling and transportation (identified as Pre-pre analytical errors) usually are not performed in the clinical laboratory; therefore, monitored unsatisfactorily.[4]

Recently, a number of Quality Indicators (QIs) have been introduced by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Laboratory Errors and Patient Safety (WG-LEPS) to monitor the clinical laboratory performance.[5,6] The project (February 2008 through December 2009) reviewed data from the 39 laboratories and the following parameters were calculated for each QI with their Quality Specification (QSs). Of these, 16 QIs were defined to analysis and evaluate performance of preanalytical phase.[5,6]

From the collected data, the mean, median and the interval between the highest and lowest value were

calculated for each QIs. Three performance levels - minimum, desirable and optimum, and their specific ranges are defined depending on the distribution of results. When the range between the highest and lowest value was very wide, the median value was defined as the desirable level of performance.

For those QIs where a higher score represented better performance (QI-1 and QI-2), a value of greater than or equal to 25% above the median was defined as the optimum target, and a value less than or equal to 25% below the median was defined as the minimum target;

For those QIs where a lower score represented better performance (QI-3 to QI- 16), a value less than or equal to 25% below the median was defined as the optimum target, and a value greater than or equal to 25% above the median was defined as the minimum target. The performance levels reported by the IFCC WG-LEPS for some QIs for the preanalytical phase are shown in Table 1.

Key Activity in the Laboratory	Quality Indicators	Performance Level			
		Optimum	Desirable	Minimum	Unacceptable
A) Test Ordering	QI-1 Percentage of 'Number of requests with clinical question from general practitioners/Total number of requests from general practitioners'	>87	58-87	29-57	<29
	QI-2 Percentage of 'Number of appropriate requests, with respect of clinical question from general practitioners/Number of requests that reports clinical question from general practitioners'	>97	65-97	32-64	<32
B) Formulation and Input of Request	QI-3 Percentage of 'Number of requests without physician identification/Total number of requests'	<5.0	5.0-6.0	6.1-8.0	>8.0
	QI-4 Percentage of 'Number of unintelligible requests/Total number of requests'	<0.20	0.20-25	0.26-0.30	>0.30
	QI-5 Percentage of 'Number of requests with errors concerning patient identification/Total number of requests'	<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-7a Percentage of 'Number of requests with errors concerning input of tests (missing)/Total number of requests'	<0.30	0.20-0.25	0.41-0.50	>0.50
	QI-7b Percentage of 'Number of requests with errors concerning input of tests (added)/Total number of requests'		0.20-0.40		
	QI-7c Percentage of 'Number of requests with errors concerning input of tests (misinterpreted)/Total number of requests'	<0.20		0.26-0.30	>0.30
C) Identification, Collection, Handling and Transport of Samples	QI-8 Percentage of 'Number of samples lost-not received/Total number of samples'	<0.20	0.20-0.40	0.41-0.60	>0.60
	QI-9 Percentage of 'Number of samples collected in inappropriate container/Total number of samples'	<0.07	0.07-1.13	1.14-0.20	>0.20
	QI-10a Percentage of 'Number of samples haemolysed (hematology)/Total number of samples'	N/A			
	QI-10b Percentage of 'Number of samples haemolysed (chemistry)/Total number of samples'	<1.0	1.0-1.5	1.6-2.0	>2.0
	QI-11a Percentage of 'Number of samples clotted (haematology) /Total number of samples with anticoagulant'	<0.50	0.50-1.0	1.1-2.0	>2.1
	QI-11b Percentage of 'Number of samples clotted (chemistry)/Total number of samples with anticoagulant'	N/A			
	QI-12 Percentage of 'Number of samples with insufficient sample volume/Total number of samples'	<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-14 Percentage of 'Number of samples damaged in transport /Total number of samples'		<0.1		
	QI-15 Percentage of Number of samples improperly labelled/Total number of samples	<0.07	0.07-0.15	0.16-0.20	>0.20
	QI-16 Percentage of Number of samples improperly stored/Total number of samples		<0.01		

Table 1. Performance Levels of Quality Indicators for the Preanalytical Phase of Testing Developed by the International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety

Another method to assess Preanalytical performance quality is the Six Sigma methodology developed by Motorola, Inc.[7] Using six sigma metrics, number of errors can be expressed by counting defects per million (DPM). Then, using statistical tables, DPM can be converted to sigma metrics.[8] The sigma value indicates the frequency of errors in a process. The higher sigma value points towards less likely incorrect results.[9] Quality is assessed on a sigma scale where 3 sigma indicates the minimum allowed value for routine performance and 6 sigma, best-in-class quality. World-class quality means around 3.4 errors per million in Six sigma level and the average products, regardless of their complexity, shows a quality performance value of approximately 4 sigma.[10]

In this study, we have evaluated the performance of a Clinical Biochemistry Laboratory in a hospital of Eastern India in term of few of the QIs for preanalytical phase. We also have categorised the quality according to sigma values. The purpose of the study was to initiate corrective measure, where applied, for improvement of accuracy in laboratory results.

MATERIALS AND METHODS

The study was conducted in the Clinical Biochemistry section of Central Laboratory in IQ City Medical College, West Bengal from 1st December, 2016 to 30th November, 2017. IQ City Medical College is a 700-bedded tertiary care hospital and medical college offering specialized healthcare system to the eastern zone of the state. The clinical biochemistry wing is equipped with three fully automated analyser (SIEMENS), electrolyte analyser (Easylyte), HPLC (HbVario, ERBA) and necessary support of sample processing.

Specimens from inpatient departments were collected by clinical departmental staff including nurses and doctors, whereas specimens from outpatients are collected on site at a centralized collection centre by phlebotomists. The samples were delivered to the lab manually by paramedical staff from the wards and laboratory support staffs from the OPD.

Upon receiving the samples, the lab supervisor visually detected if any problems were present. Samples within the acceptability criteria were entered in 'SAMPLE ENTRY' register with sample identity, receiving time, name of both receiver and transporter. The rejected sample is also entered in 'SAMPLE REJECTION' logbook with sample identity, entry time, observer's and transporter's names and the reason of rejection. Both the logbooks were reviewed on weekly basis. The data collection procedure involved review of blood samples received from the inpatient as well as outpatient departments. The accepted samples were then either processed for analysis or stored.

To calculate the performance level of the lab, two Quality Indicators regarding formulation and input of request i.e. QI-5 and QI-7 and five indicators regarding identification, collection, handling and transport of samples (QI-8, QI-9, QI-10, QI-12, QI-15) were selected. Data were collected on monthly basis for one year. The percentage and the sigma-scale metrices were calculated for respective quality indicators for evaluation.

The Detailed Procedure to Identify the Errors as Follows

QI-5 Percentage of 'Number of requests with errors concerning patient identification/Total number of requests'- if mismatch regarding the identification data (The first name and surname of the patient and unique identification code) on the test request form and the data on the sample collection tube were present.

QI-7 Percentage of 'Number of requests with errors concerning input of tests /Total number of requests' – if missing tests, samples collected for unrequested tests.

QI-8 Percentage of 'Number of samples lost-not received/Total number of samples' – if requests/requisition present for uncollected samples.

QI-9 Percentage of 'Number of samples collected in inappropriate container/Total number of samples' – if samples collected in a blood collection tube with inappropriate anticoagulant

QI-10 Percentage of 'Number of samples haemolysed (chemistry)/Total number of samples' – haemolysis detected by visual examination on receiving or after centrifugation

QI-12 Percentage of 'Number of samples with insufficient sample volume/Total number of samples' – if sample volume was less than 2 ml in case of adults and less than 1 ml in paediatric patients.

QI-15 Percentage of 'Number of samples improperly labelled/Total number of samples' - if bar code number/patient identity were absent.

The percentage of errors and sigma metrics for these QIs were calculated.

To obtain Sigma metric values, DPM rates were first calculated using the following formula:

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

The DPM rates were then converted to a sigma value using Sigma score calculators available online at http://www.westgard.com/calculators/calculators.

Laboratory performance level were categorised depending on the sigma values as given below (similar to the WG-LEPS levels).[11]

1. Very good: ≥ 5 sigma
2. Good: 4- < 5 sigma
3. Minimum: 3 -< 4 sigma
4. Unacceptable: < 3 sigma

The calculated performance level, both percentages and Sigma metrics, were compared to a few already performed projects for performance assessment.

RESULTS

A total no of 108000 samples from both IPD and OPD were received in the Clinical Biochemistry laboratory during the course of the study.

The total number of preanalytical errors was 277, which accounted for 0.25% of the total number of samples received that year. Related to Formulation and input of

requests, 11.1% were erroneous in-patient identification and 4.3% errors were due to missing test inputs.
Related to errors over samples identification and its quality, 49% of total samples were haemolysed, 10.1% were not received in the laboratory, 5% were collected in wrong container, 11.9% samples showed inadequate sample to anticoagulant ratio and 8.3% of samples were improperly labelled. In Table 2, details of the preanalytical errors in terms of types and quantity are given. The table also contains the performance levels obtained for the quality indicators expressed as percentages and on a sigma scale.

QI Code and Meaning	Descriptor	No. of Errors	Obtained Value (%)	IFCC-Based Performance Level	DPM	Sigma Value	Sigma-Based Performance Level
QI-5 Requests with errors concerning patient identification	Request forms with errors concerning patient identification /total no. of request forms	31	0.04	Optimal	400	4.9	Good
QI-7 Requests with errors concerning test input	Requests with errors concerning input of tests (missing tests) /total no. of request forms	12	0.016	Optimal	155	5.2	Very Good
QI-8 Samples lost-not received	Samples lost–not received /total no. of samples	28	0.025	Optimal	259	5	Very Good
QI-9 Samples collected in inappropriate container	Samples collected in a blood-collection tube with inappropriate anticoagulant/total no. of samples	14	0.01	Optimal	130	5.2	Very Good
QI-10 Haemolysed samples	Haemolysed samples (in biochemistry)/ total no. of samples	136	0.12	Optimal	1259	4.6	Good
QI-12 Samples with insufficient sample volume	Samples with inadequate Quantity/ Total no. of samples	33	0.03	Optimal	306	5	Very Good
QI-15 Improperly labelled samples	Percentage of 'Number of samples improperly labelled /Total number of samples'	23	0.02	Optimal	213	5.1	Very Good

Table 2. Types and Number of Errors found in Preanalytical Phase and Performance Levels Obtained for Quality Indicators.

DISCUSSION

Quality indicators have been proved to be very efficient in clinical laboratory performance evaluation.[12] Out of the 16 QIs, 7 were selected in this study based on the type and frequency of preanalytical errors occurred in our laboratory.

Based on 'Sample acceptance' and 'Sample rejection' criteria' which are set in our lab, the errors were recorded in daily basis and analysed. In our study, all the evaluated QIs were found to be at an optimum level of performance according to the specifications of the WG-LEPS.[5,6]

The results of our study were compared with others with respect to the preanalytical errors reported in percentage as well as in sigma metrics. (Table 3 and Table 4).

Quality Indicators	Daniella et al.	Lippi et al.	Chawla et al.	Gajjar et al.	Present Study
QI-5 Requests with errors concerning patient identification	0.01%				0.04%
QI-7 Requests with errors concerning test input	0.002%				0.016%
QI-8 Samples lost-not received	0.05%			0.02%	0.025%
QI-9 Samples collected in inappropriate container	0.002%			0.01%	0.01%
QI-10 Haemolysed samples	0.40%	0.77%	0.7%	0.18%	0.12%
QI-12 Samples with insufficient sample volume				1.23%	0.03%
QI-15 Improperly labelled samples					0.02%

Table 3. Comparison of QI Performance level (%) with Different Studies

Quality Indicators	Daniela et al.	Sciacovelli et al.	Gajjar et al.	Present Study
QI-5 Requests with errors concerning patient identification	5.3	5.3		4.9
QI-7 Requests with errors concerning test input	5.6	4.1		5.2
QI-8 Samples lost-not received	4.8	5.5	5.0	5
QI-9 Samples collected in inappropriate container	5.6	5.0		5.2
QI-10 Haemolysed samples	4.2	3.6	4.5	4.6
QI-12 Samples with insufficient sample volume		5.0	3.8	5

Table 4. Comparison of Sigma Metrics with Different Studies

Samples were considered lost where requisition is received without samples. Among the reasons of missing samples, difficulty in sample collection, improper patient preparation and failure of patients to reappear for post prandial samples were noted. Quantity of missed samples were minor (0.18%); for which few corrective methods were implemented. Prior and detailed instruction to the patients before giving samples and tracking them till all the test samples drawn were important of them.

Sample haemolysis was detected visually and on rejection phlebotomists were asked to collect new samples. Collection by small gauge needles, application of excess pressure during sample collection, over-shaking of sample collection tube or improper mixing, early, high speed or prolonged centrifugation of samples were accounted to that. The visual examination for haemolysis is a limitation to the study; but no widely accepted criteria yet set for sample rejection on this basis.[13]

Sample inadequacy were mostly seen in electrolyte samples where more serum was required and in paediatric patients where sample collection is tedious.

To elimination of preanalytical errors and to improve the performance level, certain proactive steps were formulated. Adequate staffing in phlebotomy section as well as in laboratory technicians were recommended. Awareness program and hands-on training on correct procedure of blood collection, correct sample volume, proper mixing with anticoagulants were arranged. Prompt and adequacy of transport system were supervised. Continuous on-the-job training and regular competency assessments were introduced.[14]

There are a few limitations in our study. All the Quality Indicators were not monitored. The rate of errors was higher due to lesser staffs present in night shift. The involvement of junior residents and trainee nurses in sample collection also contributed to the errors in various pre-analytical levels.[15]

CONCLUSION

The performance of preanalytical phase can be assessed using any indicator irrespective of their expression means i.e. percentage or sigma scale. As long as the same parameter (e.g.-number of haemolysed sample or number of inadequate sample) is used as reference, these indicators provide means to compare the performance of individual laboratories with each other.[16,17]

We conclude that in our study, the results are at par with the worldwide scenario, and the performance of preanalytical phase meets the standard international specifications. The purpose of such total quality management is to ensure patient safety. As the clinical diagnosis is hugely dependent on accurate laboratory results, it is mandatory for labs to emphasize on prevention of medical errors to avoid adverse outcome. Hence the performance of all the phases of testing requires regular supervision, continuous evaluation and auditing of errors as per ISO specifications, in order to implement corrective strategies to maximise the error-free healthcare delivery.

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