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Original Article

Sigma metric analysis of quality indicators across the testing process as an effective tool for the evaluation of laboratory performance

N.K. Swetha [a,*], K.S. Kusuma [a], K.R. Sahana [a], C.R. Shobha [a], D. Abhijith [a], P. Akila [b], M.N. Suma [c]

[a] Assistant Professor (Biochemistry), JSS Medical College, JSSAHER, Shivarathreeshwaranagar, Mysore, India
[b] Professor (Biochemistry), JSS Medical College, JSSAHER, Shivarathreeshwaranagar, Mysore, India
[c] Professor & Head, (Biochemistry), JSS Medical College, JSSAHER, Shivarathreeshwaranagar, Mysore, India

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ABSTRACT

Background: Laboratories across the world are successfully using quality indicators (QIs) to monitor their performance. We aimed to analyze the effectiveness of using the peer group comparison and statistical tools such as sigma metrics for periodic evaluation of QIs and identify potential errors in the preanalytical, analytical, and postanalytical phases.

Methods: We evaluated the monthly QIs for 1 year. A total of 11 QIs were evaluated across the three phases of the total testing process, using percentage variance, and sigma metric analysis.

Results: Our study observed that based on sigma metric analysis, the performance was good for all the QIs except for the number of samples with the inappropriate specimen hemolyzed samples, clotted samples, and turnaround time (Sigma value < 3). The percentage variance of QIs in all the phases was plotted in a Pareto chart, which helped us in identifying turnaround time and internal quality control performance are the key areas that contribute to almost 80% of the errors among all the QIs.

Conclusion: Laboratory performance evaluation using QIs and sigma metric analysis helped us in identifying and prioritizing the corrective actions in the key areas of the total testing process.

Introduction

Clinical laboratories across the world are under the constant pressure of delivering accurate laboratory results. Patient safety is one of the important aspects of the healthcare delivery system. The impact of laboratory errors on patient safety is a serious matter of concern. Laboratories need to develop an effective quality management system, which aims at maintaining quality in the key areas of the testing process.[1] In the past, laboratories concentrated mainly on analytical errors, but later, it was realized that most errors occur in the

* *Corresponding author.*
E-mail address: swethank@jssuni.edu.in (N.K. Swetha).
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preanalytical and postanalytical phases. Laboratories are now focusing on suitable procedures to recognize these errors and measures to minimize the errors.[2]

Quality indicators (QIs) have been identified as the key performance markers of various phases of the total testing process. QIs are effective tools that measure how well an organization meets the needs of the end users.[3,4] However, monitoring the QIs itself will not lead to quality improvement. The laboratories need to analyze the trend of these QIs and assess the effect of these errors on patient care through periodic performance evaluation.

Around 27 QIs were introduced in the IFCC-WG leps project to encourage laboratories to use these indicators to improve their efficiency.[5,6] Quality specifications (limits of acceptability) for various QIs were proposed in this project, which is expressed as a percentage relative to the total volume of the activity for each process. Analysis of the QIs by using the quality specifications as a benchmark gives a better evaluation of the quality process. In addition, it also helps to verify the effectiveness of the corrective and preventive measures.[6–8]

In addition to percentage variance, sigma metric analysis is also a useful quality management tool and an alternative approach to assess these QIs and improve the quality in various laboratory processes. Sigma metric quantifies the performance of processes as a rate of Defects Per Million Opportunities and is expressed on the Six Sigma scale (0–6). Six Sigma scale 6 represents 3.4 defects in a million events. A Sigma value of 3 and above is considered good performance, whereas the healthcare industry and laboratories are still operating between 2 and 3 sigma levels. Sigma metric analysis helps evaluate the laboratory's performance and provides an opportunity to minimize the defects through appropriate corrective and preventive actions.[9,10]

Earlier studies have tried to assess the laboratory performance primarily focusing on the QIs in the preanalytical phase.[11] However, a comprehensive evaluation of the laboratory performance is the need of the hour to minimize the errors and improve the efficiency of any laboratory. Hence in this study, we intend to assess the laboratory performance by using percentage variance of QIs in all the phases (preanalytical, analytical, and postanalytical) of the testing process by comparing them with the standard specifications and also by sigma metric analysis. In addition, we have tried to analyze the possible reasons for these defects and their corrective actions.

Materials and Methods

The study was conducted in the Clinical Biochemistry Laboratory of a tertiary care hospital. Institutional Ethical Committee approval was obtained for the study. The Clinical Biochemistry Laboratory provides diagnostic services for routine biochemistry tests, special tests such as hormones, fertility profile, cardiac markers, vitamins, tumor markers, newborn screening, and maternal serum screening. Informed consent was given by all participants.

As a part of the quality assurance program, QIs are being monitored in the Clinical Biochemistry Laboratory. The QI-related data were obtained from the Rejection register, Critical alert register, Amended Reports log, Laboratory information system (LIS), Internal Quality Control (IQC) data from Infinity software, and External Quality assurance (EQAS) data from Bio-Rad EQAS reports. The QIs that were most suitable and feasible for implementation in our laboratory setup were selected based on the "IFCC model of QIs."[5]

Preanalytical QIs: Samples with the wrong request, incorrect vacutainer, insufficient sample, hemolyzed samples, clotted samples, inappropriate specimen (e.g., specimen diluted, specimen contaminated with anticoagulants, etc.)

Analytical QIs: The percentage of the number of IQC parameters falling outside the acceptable CV%, percentage of the number of unacceptable performances of EQAS.

Postanalytical QIs: Percentage of reports delivered beyond turnaround time (TAT), number of critical results informed, and number of reporting errors/amended reports.

The monthly QIs monitored for 1 year, from January 2020 to December 2020, were evaluated to assess the laboratory performance. The QIs were assessed based on the percentage variance and were compared with standard specifications proposed by Plebani et al. and Ricos et al. under the IFCC-WG leps project. The performance specifications for medium quality were considered for comparison.[8,9,12,13] Sigma metrics for the previously mentioned QIs were calculated, taking into consideration the number of observations vs the total number of samples received or the total number of tests performed, over 1 year. Sigma value above 3 was considered as good performance, and a value <3 was considered as poor performance.

Sigma values for analytical QIs were calculated with 1.5 SD shift, whereas the sigma value for extra-analytical QIs was calculated without including 1.5 SD shift.[14] Sigma value for critical alerts was not calculated, as it is not an error but an indicator of the laboratories effort to inform the reports to clinicians.

Calculations

Percentage variance = (number of defects × 100)/total number of specimens or requests.

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

The defects per million rate and sigma value were calculated using the sigma metrics online calculator, available online.[15,16]

Although we have assessed the performance of each of these QIs using both the tools, the performance of sigma metrics was given greater emphasis in comparison to percentage variance, as Sigma metrics provide a more stringent assessment of the performance.

A Pareto chart was plotted to identify the areas that contribute to maximum errors (80/20 rule) so that these areas can be prioritized first for suitable corrective actions.

Results

The total number of samples received in the year 2020 was 156,446. The total number of tests performed in the year 2020 was 800,910. In our study, the total sample rejection rate was

2.50%. The percentage variance and sigma value for each QI in the preanalytical, analytical, and postanalytical phases are shown in Tables 1 and 2. We observed that based on sigma metric analysis, the performance was good for QIs such as tests with the wrong request (percentage variance: 0.03%, Sigma value of 3.58), number of samples with incorrect vacutainers (percentage variance: 0.02%, Sigma value of 3.66), number of samples with insufficient volume (percentage variance: 0.16%, Sigma value of 3.14), QC performance: number of tests with CV% higher than the selected target (percentage variance: 6.15%, Sigma value of 3.1), unacceptable performances in EQAS (percentage variance: 1.88%, Sigma value of 3.6), number of critical values reported (1.82%), and number of amended reports (percentage variance: 0.02%, Sigma value of 3.77). However, QIs such as the number of samples with the inappropriate specimen (percentage variance: 0.33%, Sigma value of 2.94), hemolyzed (percentage variance: 1.20%, Sigma value of 2.51), clotted samples (percentage variance: 0.77%, Sigma value of 2.67), and TAT (percentage variance: 9.63%, Sigma value of 1.66) needs improvement.

The percentage variance of QIs in all the phases was plotted in a Pareto chart (Fig. 1) with QIs across all phases shown in the X-axis, Percentage variance of each of these QIs is shown in the Y-axis. Based on the Pareto chart, we could identify that TAT and IQC performance are the key areas that contribute to almost 80% of the errors among all the QIs.

Discussion

Monitoring of QIs using various self-assessment tools helps in the improvement of laboratory processes. Although we have used both percentage variance and sigma metrics, the final evaluation was based on sigma metrics. Sigma metric analysis measures process performance quantitatively and provides opportunities for improvement in the process.[11] Our study observed that the laboratory performance was good for most of the QIs except for the number of samples with the inappropriate specimen hemolyzed samples, clotted samples, and TAT.

Among the QIs in the preanalytical phase, the percentage variance of inappropriate test requests was 0.03%, and the number of samples with incorrect vacutainer was 0.02%, with a sigma value around 3.58 and 3.66, respectively, indicating good performance. However, these errors can be further reduced by creating awareness among the hospital staff regarding accurate data entry and sample collection, through appropriate staff training, especially the recruits, and improving the LIS.[3,8]

In our study, the total sample rejection rate was 2.51%, with a Sigma value of 3.5. Zeliha et al. have also reported a specimen rejection rate of 2.5%.[17] The reasons for rejection include hemolysis, clotted samples, improper specimen, insufficient sample, and lipemic samples. Sample rejection involves redoing the entire process of sample collection, which leads to unnecessary delay in the report generation, with wastage of time and money. Hence, there is a need for each hospital to audit its specimen rejection rate, identify the reasons, and take appropriate efforts to minimize the rejection rate.[10,17]

Among the analytical QIs, we have evaluated IQC and EQAS performance. IQC helps in evaluating the precision of the tests, identifying the outliers, and improving with suitable corrective actions. The percentage of IQC outside the acceptable CV% was 6.15% (Sigma value: 3.1), which is higher compared with the acceptable specifications. One possible reason could be that we have considered the monthly IQC summary and compared it with peer group monthly CV%. The parameters that were commonly affected were sodium, chloride, total protein, albumin, and lipase magnesium. However, the CV% of these parameters except electrolytes

Table 1 – Performance of quality indicators in the three phases of the testing process.

Phases of testing process (QI code)	Percentage variance (%) (Number of defects × 100)/total number of specimens or requests	Quality specifications (%)
Pre analytical phase reference: Sciacovelli L **et al 2019**[8]		
Test ordering: Number of test orders with the wrong request **(Pre Mis R)**	0.03 (53/156,466)	0.007–0.083
Number of samples with incorrect vacutainer **(Pre WroCo)**	0.02 (39/156,466)	0–0.03
Number of samples hemolyzed **(Pre HemR)**	1.20 (1870/156,466)	0.060–0.670
Number of samples clotted **(Pre Clot)**	0.77 (1200/156,466)	0.117–0.517
Number of samples with insufficient volume **(Pre Ins V)**	0.16 (246/156,466)	0.02–0.14
Number of samples with inappropriate specimen **(Pre wrong Type)**	0.33 (519/156,466)	0–0.022
Analytical phase		
Number of unacceptable performances in EQAS monthly report/total number of parameters **(Intra-Unac)**	1.88 (19/1008)	2.4–3.8 Ricos C et al., 2004[13]
Number of IQC parameters outside the acceptable CV%/total number of parameters chemistry **(Intra-UnIQC)**	6.15 (62/1008)	0.07 Plebani **et al, 2006**[7]
Postanalytical phase		
Percentage of reports delivered outside the defined turnaround time (Post Out time)	9.63 (77,185/800,910)	0.060 Sciacovelli L **et al, 2016**[9]
Number of critical values reported (Post In Cr)	1.82 (14,553/800,910)	2.43 Sciacovelli L **et al, 2016**[9]
Number of amended reports issued (Post Rect rep)	0.02 (133/800,910)	0.008 Sciacovelli L **et al, 2017**[12]

Table 2 – Sigma metrics of quality indicators in various phases of the total testing process.

Sl No	Quality indicators captured for one year	Defects per million (DPM)	Sigma metrics
1	**Test ordering**: Number of test orders with the wrong request	339	3.58
2	Number of samples with incorrect vacutainer	249	3.66
3	Number of samples hemolyzed	11,953	2.51
4	Number of samples clotted	7670	2.67
5	Number of samples with insufficient volume	1572	3.14
6	Number of samples with inappropriate specimen	3317	2.94
7	Number of unacceptable performances in EQAS monthly report/total number of parameters	18,849	3.6
8	IQC out of acceptable CV%/total number of parameters	61,508	3.1
9	Number of reports delivered outside the defined turnaround time	96,372	1.66
10	Number of amended reports issued	166	3.77

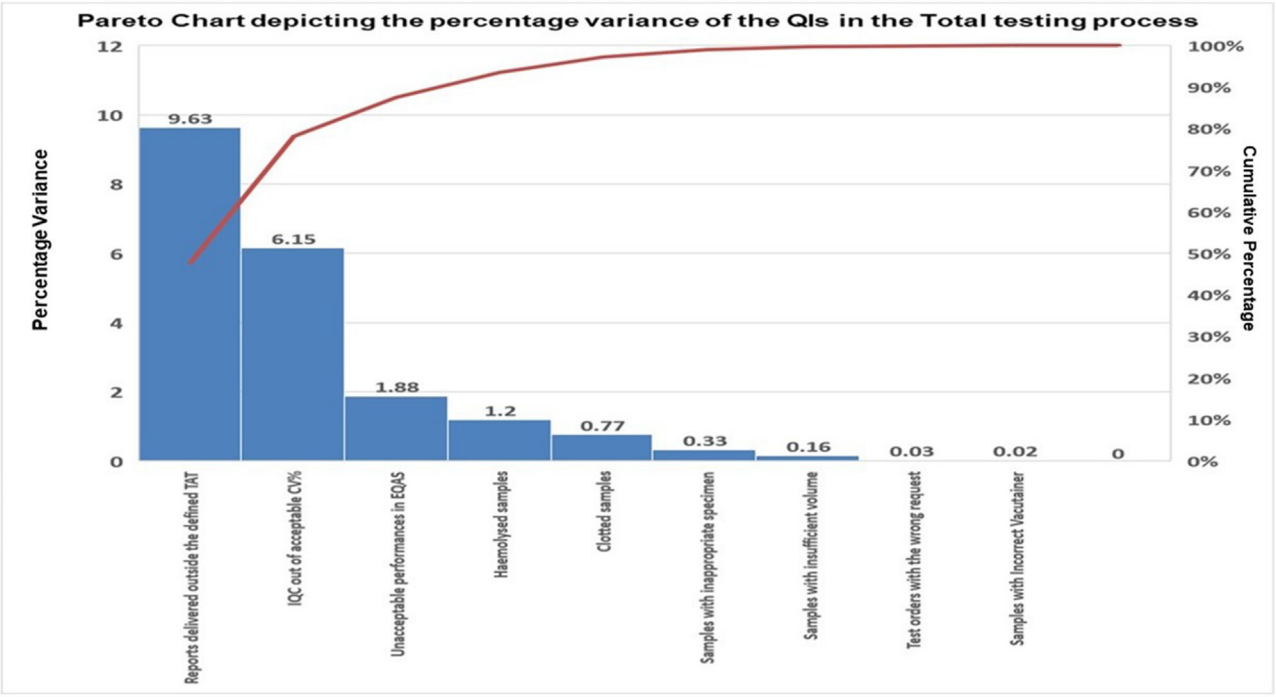

Fig. 1 – Pareto chart depicting the percentage variance of the QIs in the total testing process.

was within the acceptable CV% specified under the Westgard and EFLM database. Nevertheless, Sigma value for IQC performance was >3, indicating good performance. Achieving the narrow biological variation target for electrolytes is very challenging. Probably, sigma metric analysis of the individual parameters using total allowable error, CV%, Bias%, and a more stringent IQC monitoring would improve the performance.[13,18]

EQAS performance helps evaluation of the accuracy of our results in comparison with the peer group and identifying the deviation and improving with suitable corrective actions. The percentage of unacceptable performances of EQAS in our study was 1.88%, which is comparable to other studies, which showed the percentage of unacceptable performances of 2.1%.[19]

Ensuring quality by any laboratory is to deliver the right report at the right time. TAT is often used as a criterion for assessing laboratory performance by clinicians as well as patients. The percentage of reports delivered beyond the specified TAT was 9.63%, which is within the acceptable specifications of 11%. But the sigma value of 1.66 for TAT depicts that we need to prioritize this area for suitable corrective action.[20,21] The parameters that contributed to the increase in the TAT were biochemical parameters in urine, electrophoresis, newborn screening, fluid analysis, etc. The possible reason was that some of these tests involved manual procedures, and a limited number of technicians were trained in carrying out these procedures. Suitable skill enhancement and continual improvement training were initiated for the other technicians.

Using critical value reporting as a QI helps the laboratories to evaluate its effort to inform the reports to clinicians and can prove lifesaving in critical cases. Our critical value reporting

was 18.2 per 1000 samples (1.82%), and our results are comparable with other studies that showed the critical alert frequency of 14 per 1000 samples.[22,23]

Another important postanalytical indicator is amended reports, monitoring of which helps to identify the causes of erroneous results so that suitable corrective and preventive actions are initiated to prevent their recurrence. The percentage of amended reports was 0.02%, with a sigma value of 3.77, which indicates good performance. The majority of these errors were due to transcriptional errors, sample mismatch, IQC errors, and LIS interface issues. These issues were identified, and measures were initiated to minimize these errors.[24,25]

Pareto chart helped us in prioritizing the key contributors to the errors among the QIs, and appropriate corrective actions were initiated.

Limitations of the study

QIs such as technician competency evaluation, feedback from clinicians/patients, and percentage of reports with interpretative comments were not monitored. A thorough evaluation of IQC performance of individual test parameters using sigma metric analysis was not done in our study.

Future directions

a. Monitoring of these QIs distinctly in outpatient and inpatient groups to assess the variation.
b. Sigma metric analysis of IQC for all the parameters based on CV%, bias%, and total allowable error.

Conclusion

Evaluating the performance of the laboratory based on the QIs and comparing with the acceptable specifications and sigma metric analysis, helped us in identifying and prioritizing critical areas in the total testing process. Our study has opened new avenues for further multicentric studies to reach a consensus on the key QIs, which can be implemented to improve the efficiency of the laboratories.

Disclosure of competing interest

The authors have none to declare.

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