Research Article

The Analytical Performance Evaluation of Routine Clinical Chemistry Parameters by Six Sigma Approach: An Effective Tool for Laboratory Quality Management

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Abstract

Background: Clinical laboratories errors can impose serious adverse effects on patient management. Clinical laboratories can evaluate their analytical performance by effective quality management tool i.e. Six Sigma metrics.

Objectives: To evaluate the analytical performance of routine chemistry parameters by Six Sigma approach.

Methods: Cross sectional, study carried out from July 2022 till February 2024 in the Chemical Pathology section of University of Lahore Diagnostic Lab and Research Center, Lahore. Analytical performance of nineteen routine chemistry parameters were evaluated by using the external and internal quality control material. Only those parameters were selected who enrolled in External Quality Assurance Scheme. Inclusion criteria for IQC following West gard rule +/- 2 SD while for EQAS results follow +/- 2 Z score. Sample size for 19 parameters analyzed in EQAS from July 2022 till December 2023 was 342. 2700 IQC samples were analyzed from August 2023 till February 2024. All control values were entered in Microsoft Excel 2013 calculated manually by conventional equations.

Results: Most of our laboratory parameters showed satisfactory analytical performance in between 3-6 when evaluated by six sigma metrics.

Conclusion: Control frequency for parameters showed score > 6 can be reduce for saving laboratory resources whereas parameters with sigma score around 3 needs more vigilant monitoring. Health care and laboratory outcome need high quality results to improve patient health. Six sigma tool allows laboratory to identify the right method, right rule, run controls at right frequency to enable the right patient outcome.

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Introduction

Around 80% of medical diagnosis and treatments, depend on results from clinical laboratories. Clinical laboratory errors can impose serious adverse effects on diagnosis and patient management. Since clinical labs are dealing with hundreds, thousands and millions of test results per year decreasing the percentage of erroneous results is crucial for clinical laboratories so that health care professionals can do their job more efficiently. A single inaccurate laboratory test result undeniably lead to misdiagnosis, mismanagement or death of a patient.[1]

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analytical testing process, internal and external quality assurance procedures are routinely carried out. The analytical performance of a system should be evaluated by additional approaches which is Six Sigma (6σ) and Quality goal index (QGI).[2]

Six Sigma as a global management strategy was first introduced in the manufacturing industries in the 1980s, with remarkable success in terms of profitability and client satisfaction. To achieve similar benefits in the healthcare system, Six Sigma approach was first introduced into lab medicine in 2001. Hence, the entire arena of Six Sigma applications within the clinical laboratories is just about two decades old. Now Six Sigma is globally deployed in several clinical laboratories as an essential component of total quality management system to cope up with the pressure to reduce the cost per test without compromising the quality of lab results.[3,4]

A Six Sigma level or value shows how often errors are likely to occur in an analytical process. More precisely, it represents the number of errors per million opportunities. The higher the Sigma, the fewer the number of errors. Six Sigma is the highest level on the Sigma scale, representing just 3.4 defects or errors per million opportunities whereas one Sigma is the lowest level. The "Sigma" in Six Sigma refers back to the benchmarking scale upon which all technical defects are judged. The "Six" in Six Sigma refers to the ideal ultimate goal of all processes that six standard deviations can fit within the defined tolerance limits of a process, and that anything beyond those tolerance specifications is considered a defect. Defects can be counted and then converted to a defects-per-million (DPM) ratio. This DPM ratio then transforms into a Sigma metrics. The Sigma methodology has various levels of evaluation about the quality of medical laboratories. In this system, sigma at the 3rd level reflected that this parameter has minimum quality standard, while sigma at 6th level is considered to have the excellent performance and meet quality standards.[5-7]

Quality Goal Index (QGI) further elaborates the parameter who scored <6 on sigma metrics, the problem is due to imprecision or inaccuracy with respect to their quality goals.

The current study was conducted to evaluate the analytical performance of the laboratory parameters by sigma value, which will subsequently be cost effective by doing modification in internal quality control rules, by reducing the frequency of control measurements required per run without compromising the quality of test results. Moreover six sigma metric is a component of ISO standard 15189:2012 clause 5.6 i-e., ensuring the quality of examination results of internal quality control, if followed by laboratory this will further allow to investigate and rectify the laboratory error underscored by sigma value and QGI. We evaluate the analytical performance of routine chemistry parameters by Six Sigma approach.

Methods

The cross sectional study carried out from July 2022 to February 2024 in the Chemical Pathology section of University of Lahore Diagnostic Lab and Research Center. Lahore. Pakistan, after getting approval from the Ethical Review Board of University College of Medicine and Dentistry, University of Lahore, Reg. No. ERC/08/24/02. Total nineteen routine chemistry parameters were included in this study, in which five parameters High Density Lipoprotein (HDL-C), Total Cholesterol, Triglycerides and Glucose were analyzed on cobas c111 based on photometry. Thirteen routine chemistry parameters namely total protein, albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, total bilirubin, direct bilirubin, total calcium, uric acid, creatinine and urea were analyzed on cobas c311 also based on photometric principle. Potassium were analyzed by ion selective electrodes (ISE) while three parameters Total T3, Total T4 and TSH were analyzed on cobas e411 based on electrochemiluminescence immunoassay methodology. External Quality Control (EQC) material of EQAS (External Quality Assurance Scheme) cycle 21 was received from Bio-Rad in the lyophilized form which was reconstituted by adding 5 ml of deionized water and analyzed for twelve consecutive months from July 2022 till June 2023 and for cycle 22 six control samples were included from July 2023 till December 2023. Internal Quality Control (IQC) material of Roche diagnostics were used for daily runs whereas all reagent kits from Roche Diagnostics were used as per manufacturer guidelines. IQC of two levels (Physiological PCC1 and Pathological PCC2) were analyzed before processing of patients samples. Only those parameters were included

in this study who were enrolled in External Quality Assurance Scheme (EQAS). IQC value following West gard rule +/- 2 SD while for EQC parameters results follow +/- 2 Z score values were included. EQAS results were observed for one and half year for analysis of bias%. The total sample size for 19 parameters analyzed in EQAS for eighteen consecutive months was 342. For IQC data was available for last seven months from August 2023 till February 2024. Total sample size for IQC was 2700. All control values were entered in Microsoft Excel 2013 for calculation of mean ($\bar{x}$) and standard deviation (SD) whereas Bias%, Average Bias%, coefficient of variation% (CV %), Sigma value and QGI were calculated manually by conventional equations. For EQC results peer mean was observed and manufacturer mean was observed for IQC to calculate Bias %. For total allowable error (TEa) the Clinical Laboratory Improvement Amendment 88(CLIA 88) guidelines were followed.[8,9] Bias% were calculated by formula: Bias%= Lab mean – peer mean/Peer mean x100. CV% was calculated by: SD/Mean x 100. Sigma values were calculated by using equation: Ó= TEa% - Bias% divided by CV%.[10] QGI was calculated by formula Bias/1.5XCV% to inspect low sigma value is due to imprecision or inaccuracy.[11,12]

Results

Sigma value of 6 indicates world class quality, 5 indicates high quality results, 4 good quality results while 3 was considered an average but satisfactory performance. Sigma values for EQAS was calculated by TEa, Average bias % and CV % showed in Table 1 and Table 2 along with QGI. Sigma values for IQC was calculated by manufacturer mean, laboratory mean, bias %, CV%, and TEa showed in Table 3 along with QGI. QGI value <0.8 indicates impression, QGI 0.8 to 1.2 indicates accuracy and precision together is the matter of attention and QGI value of >1.2 indicates accuracy warrants to be scrutinized whereas comparison of sigma values of EQAS and IQC mentioned in figure1.

Discussion

Six sigma methodology can act as an obtainable tool to evaluate and improve the quality process of clinical laboratories, as an overall measure to quantify defects per million and process outcomes. Six Sigma methodology incorporates five stages that is described by DAMIC model which is used for the existing system i.e. Define, Analyze, Measure, Improve and Control. Clinical Laboratories needs to meet and maintain quality

Table 1: *Sigma values and QGI for EQAS (July2022 – December 2022).*

EQAS: Cycle 21						
Parameter	**Method**	**TEa%**	**Ave Bias %**	**CV%**	**Sigma value**	**QGI**
Albumin(g/dL)	BCG Gen.2	10	2.1	2.5	3.2	0.56
Total Protein(g/dL)	Biuret Gen.2 monchromoatic	10	0.7	2.9	3.2	0.16
ALP (U/L)	IFCC acc. to Schumann Gen 2	30	7.5	3.5	6.4	NA
ALT (U/L)	IFCC without pyridoxal phosphate	20	1.36	2.9	6.4	NA
AST (U/L)	IFCC without pyridoxal phosphate	20	2.0	3.3	5.5	0.40
T.Bilirubin(mg/dL)	Gen.3 Diazonium	20	2.9	3.7	4.6	0.52
D. Bilirubin(mg/dL)	Diazo Gen2 Jandrassik -Grof	20	1.9	4.1	4.4	0.32
Calcium(mg/dL)	5-nitro-5'-methyl- BAPTA	11.9	1.0	2.4	4.5	0.27
HDL-C(mg/dL)	Enzymatic colorimetric Gen 4	10	0.96	3.0	3.0	0.21
Total Cholesterol(mg/dL)	CHOD-PAP Gen.2 stand ID/MS	10	1.5	2.6	3.3	0.39
Triglycerides(mg/dL)	GPO-PAP	25	3.3	3.1	7	NA
Urea(mg/dL)	Urease/GLDH	9	1.6	2.5	3.0	0.42
Creatinine(mg/dL)	Jaffe Gen.2, Kinetic Alkaline Picrate	15	2.5	3.7	3.3	0.45
Uric Acid(mg/dL)	Enzymatic colorimetric	17	1.2	2.9	5.4	0.27
Glucose(mg/dL)	Hexokinase	10	1.9	2.6	3.1	0.48
Potassium(mmol/L)	ISE indirect potentiometry	17.4	2.1	1.48	10.3	NA
TSH (mIU/L)	Elecsys TSH	12.78	1.28	3.8	3.02	0.22
Total T3(ng/mL)	Elecsys T3	23.15	1.28	2.76	7.9	NA
Total T4(ug/dL)	Elecsys T4	20	10.3	3.2	3.2	2.14

Table 2: *Sigma values and QGI for EQAS (January2023 – December 2023).*

EQAS	Cycle 21 Jan2023 till June 2023					Cycle 22 July2023 till Dec 2023			
Parameter	**TAE%**	**Ave Bias %**	**CV%**	**Sigma value**	**QGI**	**Ave Bias%**	**CV%**	**Sigma value**	**QGI**
Albumin(g/dL)	10	2.7	2.3	3.2	0.78	2.1	2.3	3.4	0.66
Total Protein(g/dL)	10	1.4	2.7	3.2	0.34	2.0	2.0	4.0	0.66
ALP (U/L)	30	5.0	3.6	6.9	NA	2.8	2.51	10.8	NA
ALT (U/L)	20	1.25	3.3	5.7	0.25	2.8	2.3	7.4	NA
AST (U/L)	20	3.28	3.5	4.8	0.62	1.8	2.6	7.0	NA
T.Bilirubin(mg/dL)	20	3.28	3.1	5.4	0.70	1.89	2.8	6.5	NA
D. Bilirubin(mg/dL)	20	3.5	3.3	5.0	0.70	3.25	3.0	5.6	0.72
Calcium(mg/dL)	11.9	2.0	1.78	5.7	0.74	2.1	1.92	5.1	0.72
HDL-C(mg/dL)	10	1.96	2.5	3.3	0.52	1.8	2.1	4.0	0.57
Total Cholesterol(mg/dL)	10	0.8	2.5	3.7	0.21	1.7	2.5	3.3	0.45
Triglycerides(mg/dL)	25	2.9	2.6	8.5	NA	5.9	2.6	7.3	NA
Urea(mg/dL)	9	2.4	2.1	3.1	0.76	1.4	2.6	3.0	0.35
Creatinine(mg/dL)	15	3.7	3.6	3.1	0.68	2.1	3.4	3.8	0.41
Uric Acid(mg/dL)	17	3.8	2.9	4.5	0.87	3.0	2.7	5.2	0.72
Glucose(mg/dL)	10	1.78	2.5	3.3	0.47	1.92	2.3	3.5	0.55
Potassium(mmol/L)	17.4	1.86	1.26	12.3	NA	1.59	1.4	11.2	NA
TSH (mIU/L)	12.78	1.9	3.5	3.1	0.36	1.9	3.9	3.2	0.32
Total T3(ng/mL)	23.15	2.9	5.9	3.4	0.32	7.14	5.3	3.0	0.89
Total T4(ug/dL)	20	5.6	4.8	3.0	0.77	5.45	3.0	4.8	1.21

Table 3: *Sigma values and QGI for IQC two levels (August 2023 till February 2023)*

IQC	PCC1							PCC2					
Parameters	**TEa %**	**Manufacturer Mean**	**Lab Mean**	**Bias %**	**CV %**	**Sigma value**	**QGI**	**Manufacturer Mean**	**Lab Mean**	**Bias %**	**CV %**	**Sigma value**	**QGI**
Albumin (g/dL)	10	3.3	3.3	0	3.0	3.3	0	5.41	5.45	0.7	1.85	5.02	0.25
Total Protein (g/dL)	10	5.04	5.0	1.3	2.4	3.6	0.36	8.48	8.36	1.4	2.7	3.2	0.34
ALP (U/L)	30	113	104.3	7.69	4.4	5.1	1.16	239	225.5	5.6	3.1	7.8	NA
ALT (U/L)	20	48.1	47	2.2	4.0	4.5	0.36	124	123.2	0.6	3.8	5.1	0.10
AST (U/L)	20	44.2	46	4.0	3.9	4.1	0.68	141	147	4.2	2.3	6.8	NA
T.Bilirubin (mg/dL)	20	0.97	0.95	2.0	5.2	3.5	0.25	3.5	3.5	0	5.4	3.7	0
D. Bilirubin (mg/dL)	20	0.96	0.96	0	6.25	3.2	0	2.6	2.7	3.8	3.7	4.4	0.68
Calcium (mg/dL)	11.9	8.9	9.0	1.1	2.2	4.9	0.33	13.5	13.4	0.74	2.08	5.4	0.23
HDL-C (mg/dL)	10	29.0	29.2	0.6	3.0	3.1	0.01	49.5	49.7	0.4	2.4	4.0	0.11
Total Cholesterol(mg/dL)	10	101	102	0.9	2.7	3.4	0.22	163	162.7	0.18	2.5	3.9	0.04
Triglycerides (mg/dL)	25	117	119	1.7	3.1	7.5	NA	215	218.7	1.7	3.0	7.8	NA
Urea (mg/dL)	9	39.8	40.0	0.5	2.9	3.0	0.11	122	122	0	2.7	3.3	0
Creatinine (mg/dL)	15	1.07	1.05	1.8	3.8	3.5	0.31	3.56	3.60	1.1	3.0	4.6	0.24
Uric Acid (mg/dL)	17	4.84	4.73	2.2	3.1	4.7	0.47	10.1	9.88	2.1	3.4	4.4	0.41
Glucose (mg/dL)	10	102	104	1.9	2.7	3.0	0.46	243	246	1.2	2.6	3.3	0.30
Potassium (mmol/L)	17.4	3.55	3.58	0.84	2.8	6.0	NA	7.13	7.14	0.14	1.8	9.5	NA
TSH (mIU/L)	12.78	1.50	1.50	0	2.6	4.9	0	8.60	8.50	1.1	3.5	3.3	0.20
Total T3(ng/mL)	23.15	1.40	1.40	0	7.1	3.2	0	3.31	3.40	2.6	5.8	3.5	0.29
Total T4(ug/dL)	20	7.3	7.7	6.0	3.8	3.7	1.05	10.1	10.6	4.9	4.7	3.2	0.69

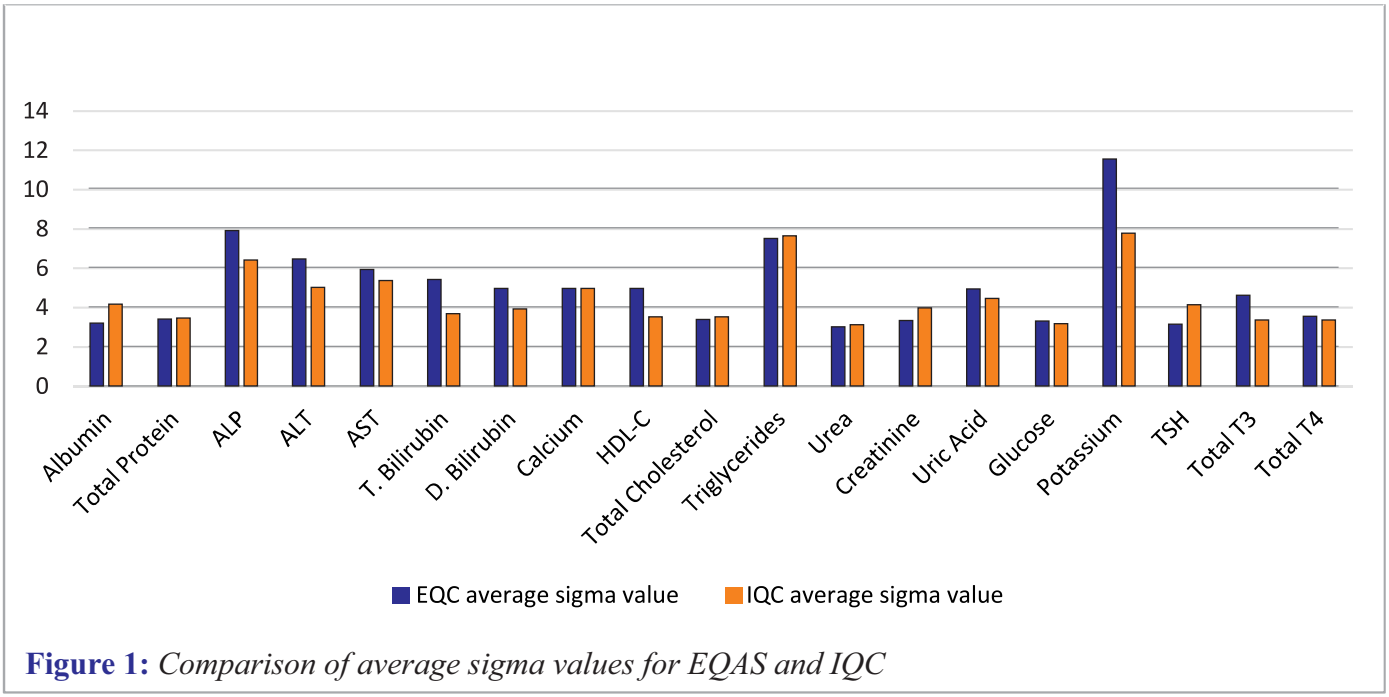

Figure 1: *Comparison of average sigma values for EQAS and IQC*

standards for reliable outcome by adopting the best Quality Assurance Program. As analytical errors typically have a low frequency 8-10% of overall errors, and in order to further lessen such errors and to monitor analytical errors IQC and proficiency testing programs are usually adopted by different laboratories. Individual laboratory can customize their QC programs according to national and international accreditation bodies' guiding principles.[13] Current study involved determination of Sigma metrics level and QGI for individual parameters of IQC and EQAS in the central Diagnostic Laboratory of University of Lahore teaching hospital.

Current study concept of performance evaluation of laboratory parameters by using six sigma metrics and QGI approach as a quality assessment tool correlate with the study conducted at Armed Forces Institute of Pathology, Pakistan by Qurat ul Ain et al.[14] They determined the sigma value of ten immunoassay parameters by using the same equations for bias%, CV%, Sigma value, QGI and followed the CLIA 88 TEa% as in present study. Most of their parameters showed good performance sigma value 4-5 in both IQC and EQAS similar to current study findings most of laboratory parameters also showed satisfactory performance.

Another retrospective cross sectional study was conducted by Parul Goel, et al in which they estimated the performance of fourteen routine clinical chemistry parameters using IQC data of two levels for six months for CV% and EQAS reports for Bias%. Sigma values was calculated by using same equation by using total allowable error targets as per CLIA guidelines as in current study. Their reported sigma values for level 2 IQC; Triglycerides, Total Cholesterol, Alkaline phosphatase showed excellent performance with sigma value of > 6 while sigma value < 3 was reported for AST, Total Protein, Glucose, BUN and ALT whereas in IQC level 3 poor performers were only ALT, BUN and Calcium. Triglycerides and Cholesterol showed sigma> 6.[15]

In present study the parameters which falls on 6 sigma or >6 sigma exhibit world class quality and showed excellent performance. According to Westgard Sigma Rules for 2 levels of control materials 6-sigma quality requires only a single control rule, 13s, with 2 control measurements in each run one on each level of control. Parameters fall on 5 sigma also exhibit high quality results which requires 3 rules, 13s, 22s, R4s, with 2 control measurements in each run. Parameters fall on 4 sigma also exhibit good quality performance and requires addition of a 4th rule and implementation of a 13s, 22s, R4s, 41s multi-rule, preferably with 4 control measurements in each run. Parameters with <4-sigma quality showed average but acceptable performance and requires a multi-rule procedure that includes the 6x rule, which can be implemented with 6 control measurements in each runs to keep that analyte under control.[16-18]

Concerning QGI most of the parameters with <6 sigma

score showed QGI value <0.8, which revealed that precision desires to be improve for these analytes on priority and for IQC QGI 1.05 suggested that both precision and accuracy was the matter of concern for total T4.[19,20]

It was conducted at clinical chemistry section of diagnostic laboratory and include only those parameters enrolled in EQAS to evaluate the analytical performance only. It should be expanded to all sub-specialties for good analytical performance bench mark and should be applied to other phases like pre-analytical and post-analytical and to all analytes of clinical laboratories in order to improve quality management after the sigma metrics evaluation. Sigma metrics assessment should be correlated with clinician's and patient's feedback.

Conclusion

Control frequency for parameters showed score > 6 can be reduce for saving laboratory resources whereas parameters with sigma score around 3 needs more vigilant monitoring. Health care and laboratory outcome need high quality, high sigma analytical results in order to improve patient health. Six sigma tool allows laboratory to identify the right method, right rule, run controls at right frequency to enable the right patient outcome.

Ethical Approval: The Ethical Review Board of University College of Medicine & Dentistry, The University of Lahore approved the study vide No. ERC/08/24/02.

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Authors' Contribution:

AR: Conception & design, analysis & interpretation of data, drafting of article, critical revision for important intellectual content, final approval

SS: Conception & design, critical revision for important intellectual content, final approval

LH: Conception & design, drafting of article, final approval

FJ: Analysis & interpretation of data, drafting of article,

MAA: Analysis & interpretation of data, drafting of article

AI: Conception & design, drafting of article, final approval

TN: Critical revision for important intellectual content, final approval

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