From Data to Quality: Using Six Sigma to Assess Lab Performance

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Abstract. Since doctors' decisions are primarily based on laboratory results, accurate test results are essential to the healthcare system. Maintaining accurate laboratory results requires regular performance evaluations. The most recent iteration of total quality management is called Six Sigma. The study's main goal was to comprehend the benefits of Six Sigma as a performance metric and use it to measure the caliber of outcomes in a clinical biochemistry lab. We examined IQC data from the clinical biochemistry lab. For over 15 years, our lab has been accredited by the NABL. For Siemens Dimension EXL 200 fully automated chemistry analyzers for both levels of IQC control (BR1 & BR2), data of 23 parameters were retrospectively examined over a 6-month January 2025 to June 2025.The results were plotted on a Levey-Jennings chart, were analyzed statistically. Alkaline Phosphatase, CRP, Iron, Magnesium, HDL & Triglycerides, satisfactory sigma values (>6), indicating less strict QC guidelines and low false rejection. The sigma values for parameters were found to be between 3 &6: albumin, total bilirubin, direct bilirubin, calcium, creatinine, glucose, phosphorus, protein, AST, ALT, uric acid, sodium, potassium, chloride, and glycosylated hemoglobin. It`s acceptable, but it indicates that additional QC guidelines need to be put in place. Parameters urea and cholesterol had poor sigma scores (<3), indicating that these procedures need to be improved. The IQC process would be greatly improved by the application of six sigma principles, which also offer the justification for the precise amount of QC that is required. The Six Sigma methodology is the best option for resolving managerial and analytical issues in laboratory and reducing errors.

Keywords: Six sigma, Bias, Total allowable error, Standard deviation, Lab performance

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1 Introduction

Laboratory test results are essential for modern healthcare - they form the basis for diagnosis, treatment decisions and the tracking of patient progress (1). Doctors rely on the accuracy of those results to choose the correct care. If the numbers are wrong, the patient may receive an incorrect diagnosis, the wrong treatment or both, which harms the patient (2). On that account high quality laboratory work is not only a technical task - it is a core part of patient safety. Clinical laboratories have built many quality systems to stop analytical mistakes plus to give trustworthy results. One of those systems is Six Sigma, a method that uses data to improve quality. Six Sigma started in manufacturing, where its purpose was to lower process variation and raise quality through statistical tools.(3). The Greek letter sigma (σ) stands for standard deviation (4). Motorola set up the six sigma method in the early 1980s as a way to measure but also improve quality. Since that time many businesses and service areas have adopted it. The steps are - define, measure, analyze, improve as well as control (DMAIC).(5-7) Any field including healthcare laboratories, may apply those steps. The sigma scale counts defects per million opportunities (DPM) and shows how often an error is expected. When a laboratory applies Six Sigma, it counts its own mistakes in the same way. In clinical laboratories, Six Sigma quantifies how well an analytical method performs - counting defects per million opportunities - the target is a result almost free of error. The method uses three main numbers - total allowable error (TEa), bias or precision (CV). Those numbers help the laboratory find weak points and change quality control rules when necessary (8). Rigid rule based quality control follows fixed rules. Six Sigma changes control rules so that they match current test performance. Test results stay accurate and fewer wrong results pass Six Sigma is rarely used in clinical chemistry because staff know little about it plus claim that it is hard. We studied 23 routine biochemical tests in one NABL-accredited laboratory, calculated the sigma metric for each test and showed how Six Sigma works in daily practice. The aim is to show that Six Sigma improves laboratory quality but also protects patients.

Sigma metrics and defects have the following relationship.

Six sigma level	Percentage accuracy	Defects per million
6	99.9997	3.4
5	99.98	233
4	99.4	6210
3	93.3	66,807
2	69.1	308,537
1	31	698,000

Fig. 1. Six sigma chart (9)

2 Aims and Objectives

The study's main goal was to comprehend the benefits of Six Sigma as a performance metric and use it to measure the caliber of outcomes in a clinical biochemistry lab.

3 Materials and Methods

3.1 Study Setting and Duration

The study used records kept in the clinical biochemistry unit of a main diagnostic laboratory. The unit holds National Accreditation Board for Testing and Calibration Laboratories (NABL) approval for more than 17 years. Laboratory has a protocol of processing 2 levels of control every day before processing patient samples. Internal quality control values of all 23 parameters were retrospectively studied for the period of 6 months from January 2025 to June 2025, for fully automated analyser Siemens Dimension EXL 200 for 2 levels of control Biorad 1& Biorad 2. Two levels of internal QC materials were assayed daily for all 23 parameters, results were plotted on Leavy-jennings chart and westgard rules were followed to monitor quality of test results before processing and releasing report of patient samples. Lab participate with Bio-rad company for Proficiency testing programme i.e. EQAS (External Quality Assessment Scheme) .Every month EQAS sample is processed for the 23 parameters.

3.2 Instrumentation and Quality Control Procedures

Tests processed on Siemens Dimension EXL 200 analyzers. Each working day staff processed two control sera, BR1 and BR2, for every test. Levey-Jennings charts were drawn and Westgard rules were applied before patient results left the laboratory. The unit also joined the monthly Bio-Rad External Quality Assessment Scheme(EQAS).

The parameters assessed were : Albumin, Alkaline phosphatase (ALP),Total Bilirubin (TBI), Direct bilirubin (DBI), Calcium, Cholesterol, Creatinine, High Density Lipoprotein (HDL), Glucose, Magnesium, Phosphorus, Total Protein (TP), Aspartate Aminotransferase (AST), Alanine Aminotransferase (ALT), Triglyceride (Tg), Urea, Uric acid (UA),Sodium (Na), Potassium (K),Chloride (Cl), C-Reactive Protein (RCRP), Iron, Glycosylated hemoglobin(HbA1c).

3.3 Statistical Analysis

1. Total allowable error (TEa): Total allowable error (TEa) is the largest permitted deviation of a single result from its reference value. TEa limits came from the Clinical Laboratories Improvement Act (10,11)

2. Bias: Bias is the steady difference between the laboratory result and the value obtained by an accepted reference method. The bias figure came from the Bio-Rad EQAS proficiency survey.(11,12)

Bias (%) = (Mean of all laboratories using same instrument and method – Our mean) X 100 / Mean of all laboratories using same instrument (1)

3. Method Coefficient of Variance (CV %) is the analytical coefficient of variation of the test method. Coefficient of variance (CV) was calculated from Biorad internal QC material data for all the parameters. (11)

$$CV\ (\%) = (\text{Standard deviation X } 100) / \text{our laboratory mean} \quad (2)$$

4. Sigma metrics were calculated from CV, percentage bias and total allowable error for all the parameters by the following formula: (11)

$$\text{Process Sigma } \Sigma\ (\sigma) = (TEa - \text{bias}) / CV\% \quad (3)$$

[TEa = total allowable error, CV% = Coefficient of variance]

4 Results

- The table evaluates 23 biochemical parameters based on their Total Allowable Error (TEa %), Bias %, and Sigma metrics, which measure the strength of the testing process.
- **High performance parameter- (sigma > 6)**. - Parameters having sigma value more than 6 are recognized as `World Class` in quality performance. This means that these parameters are highly stable and are less likely to go outside acceptable error limits. These included parameters as Alkaline Phosphatase, C-reactive protein (CRP), Iron, Magnesium, High-Density Lipoprotein (HDL), and Triglycerides.
- **Medium Or Good performance parameter (sigma value 3 to 6)** - Parameters having sigma value between 3 & 6 are recognized as `Good ` in quality performance. This means that these parameters which fall in this category are acceptable and Ok but require to follow more quality control rules to maintain accuracy These include parameters as Albumin, TBI, DBI, Calcium, Creatinine, Glucose, Phosphorus, Protein, AST, ALT, UA, Chloride, and Glycosylated Hemoglobin (HbA1c).
- **Low Performance Parameter (sigma <3)**- Parameters having sigma value less than 3 are recognized as `Poor or Marginal`. This means that these parameters often need strict quality control rules or improvements in analytical methods. These include parameters as Urea and Cholesterol.

Table 1. SIGMA MATRIX OF 23 PARAMETERS FOR BOTH LEVELS (LEVEL-1 AND LEVEL-2)

Sr.No.	Parameter	Total allowable error %	bias %	L1 Quality control		L2 Quality control	
				CV1 (%)	**Sigma**1**	CV2 (%)	**Sigma**2**
1	Albumin	10	2.80	2.27	**3.18**	2.13	**3.38**
2	Alkaline phosphatase	30	1.34	3.68	**7.78**	3.53	**8.11**

3	Total Bilirubin	20	3.19	4.22	**3.99**	4.27	**3.94**
4	Direct bilirubin	20	4.97	3.5	**4.3**	3.55	**4.23**
5	Calcium	10	1.73	2.52	**3.28**	2.58	**3.2**
6	Cholesterol	7.69	2.73	2.47	**2.14**	2.28	**2.32**
7	Creatinine	16	4.00	3.63	**3.3**	3.47	**3.46**
8	HDL	30	7.39	3.52	**6.43**	3.08	**7.33**
9	Glucose	10	2.28	2	**3.86**	2.37	**3.26**
10	Magnesium	25	3.78	3.48	**6.09**	3.5	**6.06**
11	Phosphorus	12	1.85	2.62	**3.88**	2.43	**4.17**
12	Protein	10	2.07	2.12	**3.75**	2.18	**3.63**
13	AST	20	2.90	4.75	**3.6**	4.5	**3.8**
14	ALT	20	1.13	5.73	**3.29**	5.58	**3.38**
15	Triglyceride	25	2.93	3.63	**6.09**	3.58	**6.16**
16	Urea	12	1.51	4.38	**2.39**	3.85	**2.72**
17	Uric acid	17	3.47	2.95	**4.59**	3.18	**4.25**
18	Sodium	6	0.10	1.6	**3.69**	1.75	**3.37**
19	Potassium	5	0.34	1.25	**3.73**	1.37	**3.41**
20	Chloride	5	0.43	1.43	**3.19**	1.37	**3.35**
21	RCRP	20	4.89	2.45	**6.17**	2.52	**6**
22	IRON	20	4.18	2.37	**6.69**	2.62	**6.05**
23	Glycosylated haemoglobin(hba1c)	6	0.23	1.8	**3.21**	1.63	**3.53**

5 Discussion

Physician and surgeons depend upon the laboratory for making their crucial decisions. As a laboratory person, it is our responsibility to provide the physician or surgeons with quality test results and it may be possible only if we maintain the quality of the test

results because a single defect in the test results may affect the treatment plan. Hence, we should maintain the quality of the test results. Quality may be described as a range of activities and processes that influence the features of a product or service. Six Sigma,which emphasizes data collection, analysis, and quality improvement, is what we are using in the clinical biochemistry lab for the same purpose. The statistical concept upon which the sigma metrics is based is that the errors in the lab may be reduced by maintaining 6 standard deviations. (14)

Table 2. Comparison of our sigma values with various other studies (14*)*

Studies→	**Bhavna Sing et al**	**Sunil Nanda et al.**	**Nitinkumar et al.**	**Chauhan K P, et al**	**Present study**
Total parameters	15	13	10	12	23
Period of Study	6 months	6 months	4 months	12 months	6 months
Instrument used for analysis	Olympus	Cobas integrated	ILAB-650	Cobas integrated	Siemens Dimension EXL 200
Internal Quality Control company	Randox	Bio-Rad	Bio -Rad	Randox	Bio -Rad
No of QC level processed	2	2	2	2	2
EQAS company	Randox	CMC	Bio-rad	Bio-Rad	Bio-Rad
TEa Guidelines	CLIA	CLIA	CLIA	CLIA	CLIA
sigma value > 6	Creatinine, HDL, ALP, Bilirubin	Bilirubin, UA, ALT, AST, ALP		ALP, AST, ALT (L2), TG, UA, Glucose (L2	ALP, HDL, Magnesium, TG, CRP, Iron
sigma value between 3 to 6	Glucose, Urea, ALT, AST, CK, Amylase	Creatinine, TG, Urea	Glucose, ALP, total protein, TG, HDL, UA, Amylase	Albumin, ALT (L1), Total Cholesterol, Total bilirubin, Glucose	Albumin. TBI, DBI, Calcium, Creatinine, Glucose, Phosphorus, TP,AST,

				(L1), Total protein	ALT,UA, HbA1C, Na, K, Cl.
sigma value < 3	Cholesterol, TG, Protein, Na, K	Protein, Albumin, Cholesterol, Cl-	ALT, AST, Cholesterol	Urea, creatinine	Urea, Cholesterol

The table is a comparison of the top practices and results of various studies, including the present study, which is aimed at clinical biochemistry studies.The study analyzes 23 parameters, which is more than other previous studies by Bhavna Sing et al. (15 parameters), Sunil Nanda et al. (13 parameters), Nitinkumar et al. (10 parameters) and Chauhan K P et al. (12 parameters). This study performs a superior assessment of biochemical parameters by involving additional parameters. This has the potential to enhance the clinical utility and validity of the results.

The duration of the current study is six months like the study by Bhavna Sing et al and Sunil Nanda et al. Chauhan K P et al. took 12 months to conduct the study and Nitinkumar et al. took a shorter period of four months duration. The six month period is sufficient to allow the collection of data and at the same time for practical constraints. It allows the relioable quality assessment and avoid unnecessary delays.

Various instruments are applied in different studies. This paper utilizes the Siemens Dimension EXL 200 auto-analyzer as opposed to the Olympus, Cobas integra and ILAB models suggested in other studies. These instrumentation differences could influence the quality of analysis and the result comparability as a result of the differences in technology, sensitivity, and the calibration procedures.

In all studies the quality control practices are good. All studies applied two levels of internal quality control (IQC) from a recognized company such as- Bio-Rad and Randox. The quality of presnt study is not compromised, as it is based on Bio-Rad IQC material, which is similar to the practices of Nitinkumar et al. and Chauhan K P et al. The external quality assessment schemes (EQAS) are also employed in most of the studies but mainly by Bio-Rad, with some variations in the source of validation with Sunil Nanda et al. using CMC (only).

The guidelines of total allowable error (TEa) are in line with CLIA standards for all studies. This provides a valid structure of evaluating the analytical accuracy and precision.

The Six Sigma performance indicators indicate significant variations in the quality of the parameters. The present study determines six parameters whose values are above Six Sigma of 6. This shows that ALP, HDL, magnesium, TG, CRP and iron have a `World Class` process capability. This observation is consistent, yet not identical to

those of Bhavna Sing et al. and Sunil Nanda et al. who suggested other parameters that were up to this criterion. The 3-6 Sigma range of parameters in this experiment, such as Albumin. TBI, DBI, Calcium, Creatinine, Glucose, Phosphorus, TP, AST, ALT, UA, HbA1C, Na, K, Cl., show moderate performance but yet satisfactory, and it is important to note that these parameters have to be constantly monitored to enhance their reliability and performance. Parameters such as Urea and Cholesterol (Sigma values less than 3) shows `Poor `performance, where cholesterol performance matches with 3 studies Bhavna Sing et al, Sunil Nanda et al., & Nitinkumar et al. It is suggested that to achieve a higher value of reliability, it is necessary to work on improving them to make them `World Class ` performance.

To conclude, the work expands the existing body of knowledge, not only by covering additional parameters but also demonstrating good performance on a widely used auto-analyzer. Standardized IQC materials and EQAS involvement will support the continuity of the current research besides providing quality improvement opportunities upon a Six Sigma measure.

A low sigma value means large random error or a systematic shift error - whose cause can be with the reagent lot, the calibration set up or the operator, which requires further studies by doing Root Cause Analysis which may help to improve the poorly performing parameters (15) Bringing Six Sigma into a routine clinical laboratory is demanding. The laboratory must gather enough valid data, train staff as well as fit the new tool into the quality system that is already in place, and we will achieve markedly decrease in analytical error rates and improves patient safety (16).

6 Conclusion

The Six Sigma methodology is the best option for resolving managerial and analytical issues in laboratory medicine, minimizing errors, and cutting costs (17). We assessed 23 parameters of clinical chemistry of two levels by sigma scale. Sigma value of more than six was found for 6 parameters which does not require stringent quality control. Sigma value of 3-6 was found for 15 parameters, which are acceptable but requires continuing monitoring and whereas sigma value below 3 for 2 parameters, which requires adoption of more stringent QC runs and rules application. Six Sigma measures offer a practical and scientific foundation for the assessment and enhancement of laboratory test processes. Their application facilitates a move from reactive to proactive quality management, and it allows laboratories to uphold internationally accepted standards and provide reliable results upon which physicians and patients can rely.

Lastly the ultimate objective of six sigma approach in clinical lab is to market our medical lab service quality, attain good economical result and offer the finest patient care. It will also be useful in helping to reduce the occurrence of false rejection (Pfr) and raise the occurrence of error detection (Ped) (14).

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