Research Article

Enhancing Laboratory Quality: A Comprehensive Sigma Metric Analysis for Diverse Biochemical Parameters

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Article Info

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Abstract

Background: Ensuring quality in the analytical phase of clinical chemistry is paramount for accurate diagnosis and treatment. Sigma metrics offer a quantitative framework to assess and enhance laboratory performance. In this study, we intend to comprehensively assess diverse biochemical parameters using three different QC databases to determine their suitability and design a tailor-made QC plan based on this assessment.

Methods: This is a retrospective study, from an NABL-accredited laboratory. The coefficient of variation (CV) % was obtained from the IQC results and the Bias % from Proficiency Testing (PT) results. The Sigma value was calculated using the TEa from three different biological variation databases (EFLM database, Westgard database, CLIA database). QGI was calculated for parameters with a Sigma value <3.

Results: Around 28-33 parameters in different instruments showed a Sigma value <3 (poor performance). However, several parameters lack TEa values in the CLIA database, preventing their inclusion in assessments of acceptability.

Conclusion: By integrating Sigma calculations with established TEa standards, this study helped in identifying areas needing improvement. This comprehensive assessment ensured the evaluation of the performance of diverse analytes, thereby ensuring higher accuracy and reliability in patient test results.

Introduction

In the current era of evidence-based medicine, healthcare providers increasingly rely on laboratory investigations to guide patient management. Consequently, the demand on laboratories has intensified, necessitating the delivery of high-quality reports. Ensuring quality in laboratory processes has now become more crucial than ever, aiming to enhance the accuracy and timeliness of reports for better patient care. Laboratories must meticulously uphold the quality standards across the various phases of the testing process to ensure the accuracy of the test results [1].

Quality Control (QC) constitutes an integral component of the Total Quality Management system, encompassing all processes dedicated to upholding the quality of test results. Notably, this includes internal quality control (IQC) procedures executed prior to the analysis of patient samples. Regularly assessing the performance of QC is paramount for the success of any quality management system. Sigma metrics have emerged as a particularly effective tool in this regard, providing a simple and efficient means of evaluating IQC performance. Serving as a valuable guide, sigma metrics aid in planning corrective and preventive actions to enhance overall quality [2].

Sigma metrics serve as a quality management tool that delineates the defects per million opportunities (DPMO). The application of Six Sigma proves valuable in pinpointing error occurrences and shaping an effective strategy for enhancing quality. The scale of six sigma DPMO values spans from 0 to 6, where a sigma value surpassing 6 denotes excellent performance, while a sigma value less than 3 signifies below-par performance. Computation of sigma values involves factors like TEa, bias % and CV%. Numerous studies have leveraged the sigma metrics tool to evaluate their IQC performance for specific parameters, successfully identifying areas of poor performance and implementing corrective measures. However, the unavailability of total allowable error (TEa) values for all parameters poses a challenge. Studies have used either the The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) database or Biological variation from Westgard and Clinical Laboratory Improvement Amendment (CLIA) TEa for sigma values calculations [3,4].

Despite this, there is a scarcity of studies that assess the application of this tool in evaluating a majority of biochemical parameters such as immunoassays, blood gas parameters, and urine parameters. Hence, the current study intends to conduct a comprehensive sigma metric analysis across a diverse array of biochemical parameters to quantify performance errors accurately. Furthermore, a meticulous comparative analysis was undertaken using TEa values from all three QC databases to select the most suitable one for our laboratory setup. This analysis is intended to design a tailored quality control plan using the Sigma metric approach and thorough root cause analysis (RCA), ensuring the delivery of accurate results to the patient.

Methodology

This is a retrospective study, and data for the study were extracted between Jan 2023 to June 2023 from an NABL-accredited laboratory. The coefficient of variation(CV) % was obtained from the IQC results and the Bias % from Proficiency Testing (PT) results.

This study was done to assess the IQC performance of 90 biochemical parameters analysed on COBAS 6000 (c501, e601), COBAS 311(c 311), COBAS 411 (e411) fully automated Biochemistry analyzers, Radiometer Basic 800 series blood gas analyser, Gonotec OSMOMAT 3000 Osmometer and Bio-Rad D10 Haemoglobin system on a Sigma Scale by calculating the sigma metrics for each parameter.

The total TEa was obtained from three different biological variation databases:

1. CLIA Requirements for Analytical Quality-88 Proficiency Testing Criteria in terms of total allowable error “TEa” for acceptable performance for each analyte,
2. Desirable Biological Variation Database specifications, and
3. EFLM (desirable total error was taken into consideration) [5–7].

- CV% was calculated from BIORAD Internal QC for the parameters.

  $CV\% = (SD/mean) \times (100)$
- Bias percentage for each parameter was calculated from the PT results

  $Bias\% = (\text{Our EQAS result} - \text{peer group mean using the same instrument and method}) \times 100$

  Peer group mean using the same instrument and method
- Sigma metrics was calculated with the following formula:

  $Sigma = (TEa - Bias\%)/CV\%$ where Bias and CV% are the indicators of systematic and random errors respectively.

Sigma value was calculated for all the parameters using all three biological variation databases. However, TEa was not available for all the parameters in CLIA requirements for analytical quality and Desirable Biological Variation Database specifications, hence quality goal index (QGI) and QC plan was designed based on the EFLM database.

QGI was calculated for those parameters with Sigma value <3 (based on EFLM Sigma)

The QGI ratio was calculated using the following formula,

$QGI = Bias/1.5 \times CV\%$

The criteria used for interpreting QGI when test parameters fall short of Six Sigma is

<0.8 Imprecision, 0.8-1.2 Imprecision and inaccuracy, >1.2 Inaccuracy

Statistical analysis

Data collected were entered in MS Excel 2010. Descriptive analysis measures like Mean, SD and CV% were obtained from the IQC data. Bias%, Sigma and QGI values was calculated using the formulas as described in the methodology section. The TEa values were as per the guidelines described above.

Results

A total of 90 parameters analysed in the NABL-accredited clinical biochemistry lab were selected.

Table 1 depicts the performance of the parameters based on Sigma metrics. EFLM TEa, EFLM Sigma, and QGI calculated are depicted in Table 2. Table 3 depicts the Sigma Metric tools for QC design and frequency.

Table 4 depicts the QC plan (Control rules to be applied and QC frequency) was designed based on Sigma value calculated using the EFLM TEa%.

Table 1: Performance of the parameters based on Sigma metric analysis using three different TEa sources.

TEa Sources	Instrument	≥ 3Sigma	< 3 Sigma
EFLM- sigma	**Clinical Chemistry:** COBAS c501	Urea, triglyceride, LDL, Total Bilirubin, GGT, Creatine kinase, LDH, iron, amylase, CRP,	sodium, potassium, chloride, total protein, albumin, ALP (level 1), calcium, magnesium, cholinesterase.
		Glucose, creatinine, uric acid, total cholesterol, HDL, ALP (Level 2) AST, ALT, phosphorus, lipase, free kappa, free lambda	
	Clinical Chemistry: COBAS c311	Creatinine, uric acid, urea, total cholesterol, triglyceride, LDL, Total Bilirubin, AST, ALT, IgM,	Sodium, chloride, direct bilirubin, albumin, Calcium, beta 2 microglobulin
		Glucose, potassium, HDL, Total protein, Albumin, ALP, Phosphorus, D-dimer, IgA, IgG	
	Immunoassay: COBAS e601 & COBAS e411	Insulin, PSA, Testosterone	Ferritin, free T3, free T4, T3, PTH, T4, Vitamin D, Vitamin B12, beta HCG, C-peptide,
		Cortisol, folic acid, FSH, LH, prolactin, T3 (e411), TSH, Trop T, AFP, CA 19-9, CA 125, CEA	
	Others: Radiometer / BIORAD -D10 / Osmometer	PCO2, PO2	pH, HbA1c
BV-sigma	**Clinical Chemistry**: COBAS c501	Total Bilirubin, direct bilirubin, ALT, Creatine kinase, LDH, amylase, lipase, lactate, cholinesterase, iron	Uric acid, sodium, potassium, chloride, triglyceride, calcium, UIBC, total protein, albumin, Magnesium (level 1), urine creatinine, urine chloride.
		Glucose, creatinine, urea, total cholesterol, HDL, LDL,AST, , ALP, GGT, phosphorus, magnesium (level 2),CRP, free kappa, free lambda, G6PD, homocysteine, Urine albumin, potassium, sodium, protein & antiTPO	
	Clinical Chemistry: COBAS c311	Creatinine, urea, total cholesterol, LDL, Total Bilirubin, direct bilirubin, AST, ALT, IgA, IgM,	Uric acid, sodium, chloride, triglyceride, albumin (level 2), ALP, Calcium, ammonia, ADA, Beta2 microglobulin.
		Glucose, potassium , HDL, total protein, albumin (level1), phosphorus, D-dimer, IgG	

	Immunoassay: COBAS e601 & COBAS e411	C-peptide, Cortisol, Folic acid, FSH, insulin, prolactin, PTH, T3 (e411), TSH, testosterone, CKMB, Trop T, BNP, AFP, CA 19-9, CA-125, CEA, Vitamin B12, Anti TPO	Free T3, Free T4, T3 (Cobas 6000), T4
	Others: Radiometer / BIORAD -D10 / Osmometer	pH, PCO2, PO2 (level1, 2) Urine osmolality,	PO2 (level 3)
CLIA- sigma	**Clinical Chemistry**: COBAS c501	Creatinine, uric acid, triglyceride, total bilirubin, AST, ALT, ALP, Creatine kinase, LDH, Magnesium, iron	Potassium, chloride, HDL, LDL, Direct bilirubin, GGT, calcium, phosphorus, lipase, lactate, UIBC, cholinesterase
		Glucose, urea, sodium, total cholesterol, total protein, albumin, amylase	
	Clinical Chemistry: COBAS c311	Glucose, creatinine, uric acid, total cholesterol, triglyceride, Total Bilirubin, Total protein, AST, ALP, IgG	Potassium, HDL, LDL, Direct bilirubin, calcium, phosphorus, D-dimer, IgA, IgM
		Urea, sodium, chloride, Albumin, ALT	
	Immunoassay: COBAS e601 & COBAS e411	Cortisol, folic acid	FT3, FT4, beta HCG(level1,2), T3 (Cobas 6000), T3 (e411- level1), TSH, AFP (e411- level 1)
		Insulin, Beta HCG (level 3), T3 (e411), T4, AFP (e411- level 3)	
	Others: Radiometer / BIORAD -D10 / Osmometer	PCO2, PO2	pH

> 6 sigma > 3 < 6 sigma < 3 sigma

Table 2: Quality Goal Index based on European Federation for Laboratory Medicine TEa and Sigma.

Analyte	CV%	Bias %	EFLM-TEa	EFLM-Sigma	QGI	Imprecision/ Inaccuracy
HbA1c	2.62	-2.05	3.1	1.96	-0.52	Imprecision
	2.54	-2.05	3.1	2.02	-0.53	Imprecision
Beta 2 Microglobulin	2.394	5.69	6.4	0.29	1.58	Inaccuracy
	3.342	5.69	6.4	0.21	1.13	Inaccuracy
	3.212	5.69	6.4	0.22	1.18	Imprecision & Inaccuracy
Ferritin e601	4.544	11.4	13.8	0.53	1.67	Inaccuracy
	3.862	11.4	13.8	0.62	1.97	Inaccuracy
	3.954	11.4	13.8	0.61	1.92	Inaccuracy
Free T3 e411	5.286	13.19	6.5	-1.27	1.66	Inaccuracy
	4.576	13.19	6.5	-1.46	1.92	Inaccuracy
	4.122	13.19	6.5	-1.62	2.13	Inaccuracy
Free T4 e411	3.614	-1.775	6.3	2.23	-0.33	Imprecision
	3.942	-1.775	6.3	2.05	-0.3	Imprecision
	5.102	-1.775	6.3	1.58	-0.23	Imprecision

Intact Parathormone 601	5.932	5.75	20	2.4	0.65	Imprecision
	5.946	5.75	20	2.4	0.64	Imprecision
	6.968	5.75	20	2.05	0.55	Imprecision
Total T3 e601	4.33	-0.43	11.6	2.78	-0.07	Imprecision
Total T4 e601	4.394	-0.43	8.6	2.06	-0.07	Imprecision
	4.212	-0.43	8.6	2.14	-0.07	Imprecision
	4.088	-0.43	8.6	2.21	-0.07	Imprecision
Total T4 e411	4.96	1.53	8.6	1.43	0.21	Imprecision
	5.534	1.53	8.6	1.28	0.18	Imprecision
	4.726	1.53	8.6	1.5	0.22	Imprecision
25-OH Vitamin D-total e601	39.95	-1.59	12.4	0.35	-0.03	Imprecision
	9.53	-1.59	12.4	1.47	-0.11	Imprecision
	6.718	-1.59	12.4	2.08	-0.16	Imprecision
Sodiumc501	1.268	-0.41	0.7	0.88	-0.22	Imprecision
	1.356	-0.41	0.7	0.82	-0.2	Imprecision
Potassiumc501	1.752	0.97	4.8	2.19	0.37	Imprecision
	1.564	0.97	4.8	2.45	0.41	Imprecision
Chloridec501	1.84	1.33	1.3	-0.02	0.48	Imprecision
	1.694	1.33	1.3	-0.02	0.52	Imprecision
Total Proteinc501	1.674	-0.72	3.5	2.52	-0.29	Imprecision
	2.008	-0.72	3.5	2.1	-0.24	Imprecision
Albuminc501	1.706	0.37	3.4	1.78	0.14	Imprecision
	2.608	0.37	3.4	1.16	0.09	Imprecision
Alkaline Phosphatase c501	3.196	2.25	10.4	2.55	0.46	Imprecision
Calcium (Gen 2) c501	1.34	1.04	2.3	0.94	0.52	Imprecision
	1.192	1.04	2.3	1.06	0.58	Imprecision
Magnesium c501	2.772	-0.95	4	1.79	-0.23	Imprecision
	1.772	-0.95	4	2.79	-0.36	Imprecision
Cholinesterase c501	1.386	-0.71		0.51	-0.34	Imprecision
	1.016	-0.71		0.7	-0.47	Imprecision
Sodium c311	1.106	-0.84746	0.7	1.39	-0.51	Imprecision
	1.124	-0.84746	0.7	1.38	-0.5	Imprecision
Chloride c311	1.138	-1.1	1.3	2.11	-0.64	Imprecision
	1.184	-1.1	1.3	2.03	-0.62	Imprecision
Albumin c311	1.548	-1.08	3.4	2.89	-0.47	Imprecision
	1.866	-1.08	3.4	2.4	-0.39	Imprecision
Calcium (Gen 2) c311	1.486	1.33	2.3	0.65	0.6	Imprecision
	1.18	1.33	2.3	0.82	0.75	Imprecision

QGI <0.8: Imprecision, 0.8-1.2 Imprecision and inaccuracy, >1.2 Inaccuracy

Note: QGI could not be calculated for these parameters as EFLM value was not available: Osmolality serum and urine, Ammonia, Anti-TPO, AMH, G6PD, HCYS, ADA, CSF, and urine parameters, pH, pO2, Connecting-Peptide, ß- HCG, Vitamin B12, 25-OH Vitamin D-total, CKMB Mass, NT-Pro Brain Natriuretic Peptide

Table 3: Sigma Metric tools for QC design and frequency.

Sl. No	Sigma Metric	Control Rule	QC Frequency
1	Sigma ≥6	13s, N=2	1 per 1000 patient sample
2	Sigma 5 <6	1 3s/2 2s/R 4s, N = 2	1 per 450 patient samples
3	Sigma 4 < 5	1 3s/2 2s/R 4s /4 1s, N= 4	1 per 200 patient samples
4	Sigma 3 < 4	All Westgard rules as above including 10X, N = 6	1 per 45 patient samples
5	Sigma < 3	Maximum Westgard rules, N = 6	1 per 10 patient samples

Table 4: QC plan (Control Rule and QC frequency) based on Sigma metrics.

Sl. No	Sigma Metric	Control Rule	QC Frequency	Parameters
1	Sigma ≥6	$1_{3s,}$ N=2	1 per 1000 patient samples	**Roche Cobas 6000**: - Urea, Triglycerides, LDL Cholesterol, Total Bilirubin, Gamma-Glutamyl transferase, creatine kinase, LDH, Amylase, Iron, CRP, Insulin, Total Testosterone, Total PSA **Roche c311**- Creatinine, Urea, Uric acid, Total Cholesterol, Triglycerides, LDL Cholesterol, Total Bilirubin, Aspartate Transaminase, Alanine Transaminase, IgM **Roche e411**: Cortisol, FSH, Luteinizing Hormone, Prolactin, TSH, Total T3
2	Sigma 5 <6	$1_{3s}/2_{2}s/R_{4s}$, N = 2	1 per 450 patient samples	**Roche Cobas 6000**- Uric acid, HDL Cholesterol **Roche c311**- potassium, HDL Cholesterol, Phosphorus, D-Dimer, IgA
3	Sigma 4 < 5	$1_{3s}/2_{2s}/R_{4s}/4_{1s,}$ N= 4	1 per 200 patient samples	**Roche Cobas 6000**- Total Cholesterol, Aspartate Transaminase, Phosphorus, Lipase **Roche c311**- glucose, Potassium, Total Protein, Alanine Transaminase, IgG, ALP **Roche e411**: CA 19-9, CA 125, CEA **Radiometer**: pCO2
4	Sigma 3 < 4	All Westgard rules as above including 10X, N = 6	1 per 45 patient samples	**Roche Cobas 6000**- Glucose, hs Troponin T, Folic acid **Roche c311**- Free Kappa, Free Lambda **Roche e411**: Troponin T, AFP
5	Sigma < 3	Maximum Westgard rules, N = 6	1 per 10 patient samples	**Roche Cobas 6000**- Creatinine, Sodium, potassium, chloride, Total Protein, Albumin, ALP, Calcium, Magnesium, Cholinesterase, Ferritin, Total T3, Total T4 **Roche c311**- Sodium, Chloride, Direct Bilirubin, Albumin, Calcium, Beta 2 Microglobulin **Roche e411**: Free T3 and T4, Intact Parathormone, C peptide, Total T4, **Biorad D10**: HbA1c

Discussion

Quality Management (QM) in clinical laboratories encompasses the supervision of all tasks and activities necessary to maintain high standards of excellence. It involves establishing a quality policy, implementing quality assurance and planning, and continuously improving quality in the testing process. These components collectively form the foundation of Total Quality Management (TQM). Dr. James O. Westgard emphasized this by stating, "Quality is everyone's job"[8].

Six Sigma Metrics

The Greek letter Sigma in Six Sigma represents "Standard Deviation". "Six Sigma aims to maintain an error rate that is more than six standard deviations from the mean, indicating a process with minimal defects. The Six Sigma approach incorporates robust techniques such as Define-Measure-Analyze-Improve-Control (DMAIC) and RCA to identify and eliminate defects and variations within a process. Additionally, it offers an objective assessment of analytical techniques and equipment, alongside the strategic framework needed for practical implementation [9].

Globally, many laboratories design their IQC protocols based on their national standards. The frequency of QC runs per day is often determined by the daily sample load in the laboratory [10,11]. According to the National Accreditation Board for Testing and Calibration Laboratories (NABL 112) guidelines in India, it is recommended to run two levels of IQC before analyzing patient samples, followed by one level of IQC every eight hours to maintain laboratory quality. However, each laboratory should develop a unique, customized Individualized Quality Control Plan (IQCP) based on Six Sigma values. This approach, which ensures six standard deviations between the parameter mean and its control limits, is crucial in minimizing laboratory errors [2,12].

Principal Findings

Sigma Metrics: In this study, 27 parameters demonstrated a Sigma value less than 3 based on the EFLM database TEa values.

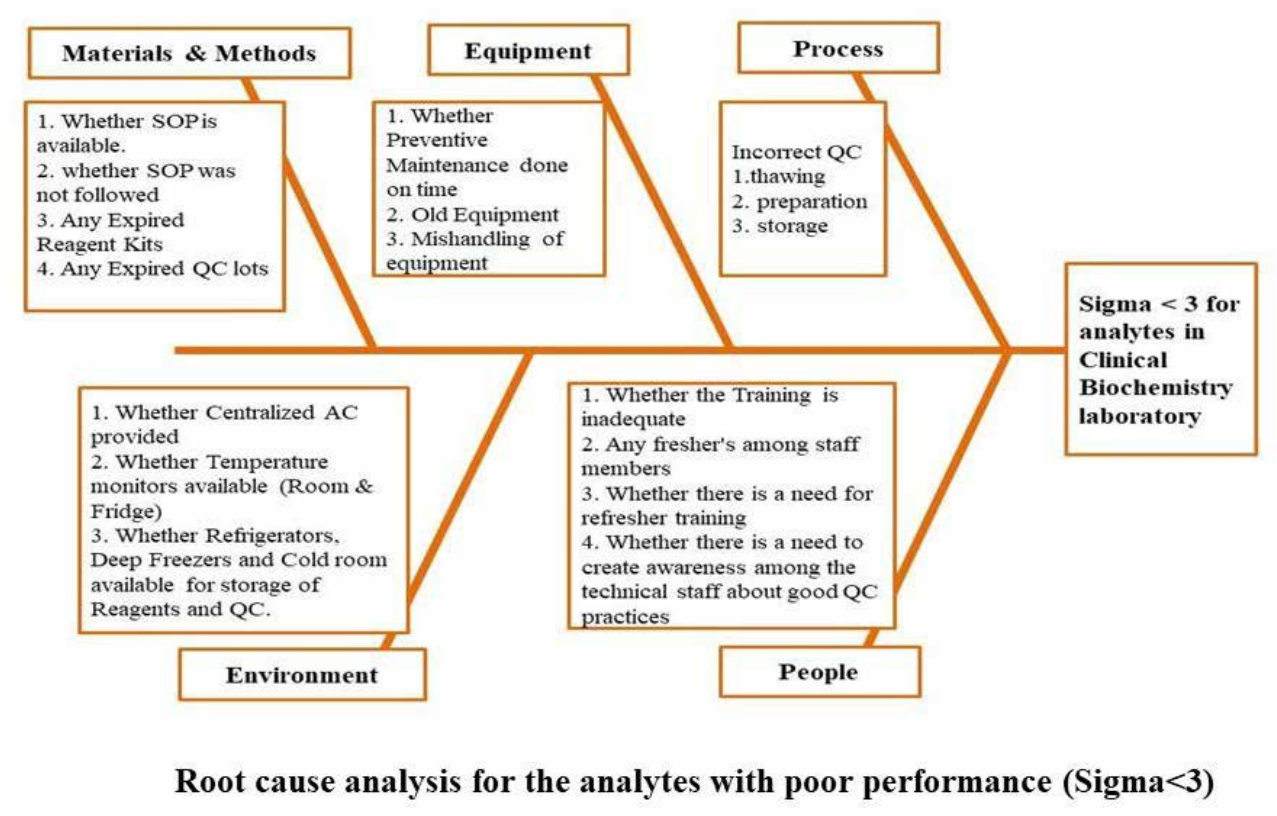
1. Using Desirable Biological Variation database specifications published on the Westgard website, 27 parameters showed a Sigma value less than 3.
2. Nearly 29 parameters demonstrated a Sigma value less than 3 from TEa values obtained from the CLIA database.

These findings suggest that several parameters lack TEa values in the CLIA database, preventing their inclusion in assessments of acceptability. Several studies[9–12] conducted earlier have evaluated the clinical chemistry and immunoassay analytes, while the analytes of Blood Gas analysis, HbA1c, Osmolality, Urine parameters and Tumour markers were not analysed in them. However, the present study is unique in that it has included all these analytes for Sigma Metric analysis along with the routine clinical chemistry and immunoassay analytes. A study conducted by Chinese Researchers [13] has made use of the TEa values derived from the EQA standard of China for all the urinary analytes as no other database has the TEa values for the Urinary Analytes.

Table 1 presents the aforementioned findings, while Table 2 details the QGI analysis based on TEa values from the EFLM database. QGI values help assess QC performance, identifying whether the issues are due to imprecision or inaccuracy or both. Most analytes exhibited either inaccuracy or imprecision, except Beta2-Microglobulin in c311 and Alkaline Phosphatase Level 2 in c501, which showed both. Addressing these issues will significantly enhance the quality of reports, thereby minimizing errors.

RCA was conducted for parameters with a Sigma value less than 3, highlighting imprecision or inaccuracy. Figure 1 illustrates the Fishbone diagram, which identifies potential issues in the laboratory that could lead to a lowered Sigma value. These issues may stem from materials, methods, equipment, processes, the environment, or personnel. Any deficiencies in these areas can affect Sigma metrics and result in errors in patient results. Therefore, it is critical to monitor Sigma metrics more frequently, rather than on a semi-annual or annual basis.

Figure 1: Root cause analysis for the analytes with poor performance (Sigma<3).



The practical application of Sigma Metrics in clinical biochemistry has direct implications for designing a QC program. Our study demonstrates that the Sigma metrics vary depending on the TEa guidelines used, with no universally accepted TEa guidelines currently available [4]. Various TEa guidelines/databases are utilized worldwide, including those from the College of American Pathologists (CAP), The Royal College of Pathologists of Australasia and the Australasian Clinical Biochemist Association Quality Assurance Program (RCPA), American Association of Bioanalysts (AAB), Desirable Quality Specifications based on Biological Variation (BV) on Westgard Website, Wadsworth Center of the New York State Department of Health (NYS), Wisconsin State Laboratory of Hygiene (WSLH), CLIA Amendments (CLIA), Canadian Fixed limits from the College of Physicians and Surgeons of Saskatchewan (CFX) and EFLM database

In the present study, TEa values from the CLIA, BV, and EFLM databases were used. It was observed that CLIA does not provide TEa for several Immunoassay and Chemistry parameters, while the BV and EFLM databases cover most analytes, except for ammonia, G-6PD, ADA, Homocysteine, CK-MB, NT-proBNP, C-peptide, Anti-TPO, Vit B12, Beta HCG, urine and CSF parameters. Among the three, EFLM database was the most stringent with narrower TEa values. The differences in Sigma values observed with different TEa guidelines showed that CLIA generally resulted in higher Sigma values compared to the BV and EFLM database for most of the analytes, though some analytes like Potassium, HDL, and Bilirubin, showed the opposite trend. Additionally, variations in Sigma values were noted between different instruments (e.g., c501 vs c311 and e601 vs e411) for different analytes. However, a previous study indicated that the Sigma variations across different TEa guidelines were more significant than the variations across different instruments using the same TEa guidelines [14].

A previous study conducted in North India [15] evaluated the Sigma metric values of HbA1c using the BIORAD-D10 instrument and reported Sigma values greater than 5 for both Level 1 and Level 2 Randox IQC, indicating excellent performance. In contrast, the present study, which used BIORAD QC for HbA1c, found Sigma values below 3. The Quality Goal Index (QGI) further indicated the presence of imprecision. This discrepancy underscores the potential impact on diabetic patient care if laboratory quality were assessed solely based on IQC or EQAS, without incorporating Sigma metric analysis.

The findings highlight the critical role of Sigma metrics, QGI, and RCA in ensuring accurate laboratory results. The RCA in this case suggested that the lower Sigma value (<3) for HbA1c may have resulted from improper handling of QC material, such as thawing or usage beyond the recommended 7-day period post-preparation. This issue was promptly communicated to laboratory technicians, emphasizing the need for strict adherence to QC handling protocols to avoid compromising

patient outcomes.
Additionally, a recent study from Libya published in Cureus [16] conducted Sigma metric analysis for blood gas analytes - pH, pO2, and pCO2 - across three different ABG analyzers. The study reported an unacceptable Sigma value (< 3) for pH, consistent with findings from the present study. However, both pO2 and pCO2 demonstrated marginal to excellent performance, with Sigma values ranging from 3 to 6, similar to the observations in our study. The RCA for the pH Sigma value being <3 indicated that samples analyzed on the Radiometer occasionally contained invisible clots. This was traced to a pre-analytical error - specifically, improper mixing of the blood sample at the time of collection. These tiny clots became lodged in the tubing near the electrode, compromising the accuracy of IQC, EQAS, and patient sample results. This finding reinforces the value of Sigma metric analysis in the early detection of such errors. In response, company personnel provided training to the nursing staff on proper techniques for blood sample collection, mixing, and transport to prevent recurrence.

QC frequency

The calculation of QC frequency, as shown in Table 3, [12,17] helps determine the number of QC runs required for different sample loads. QC frequency was planned based on the sigma metrics [17] and is summarized in Table 4. Planning and executing a QC plan based on the sigma metrics ensures the delivery of high-quality results to patients in a timely manner, consistent with the hospital's vision and mission.

The uniqueness of our study lies in its extensive analysis of a wide range of biochemical parameters using three different biological variation databases. This comprehensive analysis provides valuable insights into IQC performance across various parameters and has facilitated the implementation of appropriate corrective actions. However, the lack of TEa values for certain parameters across various biological variation databases was a limitation of our study. Our study emphasizes the need for standardization and harmonization of TEa models that are suitable for specific regions. However, achieving harmonization of TEa across laboratories remains a significant challenge, particularly in LMIC settings. Key barriers include the absence of standardized guidelines, weak regulatory frameworks for implementing TEa models, limited resources, economic constraints, inadequate training, variability in test methods, use of diverse testing platforms, and a general lack of prioritization for quality assurance protocols. Future large-scale, multi-centric collaborative approaches will be crucial in establishing uniform and standardized TEa models and quality control strategies.

Conclusion

Analytes with suboptimal performance require continuous monitoring by laboratory supervisors to ensure accurate and reliable reports. Laboratories are encouraged to explore the practical application and feasibility of integrating Sigma metrics into routine QC practices, particularly for analytes with a Sigma value below 3. Moreover, selecting appropriate TEa guidelines is critical when applying Sigma metrics to ensure accurate assessment of analyte performance.

Any conflict of interest

Authors declare no conflict of interest.

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