e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com doi: 10.25258/ijpqa.16.8.19

International Journal of Pharmaceutical Quality Assurance 2025; 16(8); 112-117

Original Research Article

Analysis of Hematology Quality Control using Six Sigma Metrics

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Received: 10-06-2025 / Revised: 09-07-2025 / Accepted: 10-08-2025

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Conflict of interest: Nil

Abstract:

Background: Quality control (QC) in clinical haematology laboratories is crucial for ensuring accurate and reliable test results, which directly impact patient care. Traditional QC programs, relying mainly on Westgard rules, often lead to unnecessary reruns and inefficiencies. Six Sigma metrics offer an advanced statistical approach to assess and enhance analytical performance by quantifying process variation and defects.

Aim & Objective: This study was aimed to analyse haematology quality control using Six Sigma metrics, and determine appropriate frequencies of quality checks based on Sigma values.

Methods: This was a cross-sectional observational study. Quality control (QC) samples were analysed twice daily at three levels for ten consecutive days, yielding 360 observations per control level. Sigma metrics were calculated for certain complete blood count (CBC) parameters like RBC, WBC, haemoglobin (Hb), Hematocrit (HCT), and platelet count in Sysmex XN 330 analyzer using standard formulas.

Results: The Sigma metric analysis enabled categorization of analytes based on performance, supporting tailored QC strategies. Majority of the parameters like RBC, WBC, Hb, HCT and platelets had good to excellent performance (sigma >6) and hence one level QC can be run per day under the 1_{3s} rule. Platelet showed poor performance (sigma <3) in L1 (low QC) suggesting maximum quality control runs for that particular level.

Conclusion: Six Sigma metrics provide an effective framework for optimizing haematology QC programs, minimizing unnecessary reruns, and improving laboratory efficiency. This method supports evidence-based QC planning and continuous quality improvement in resource-limited settings.

Keywords: Haematology, Six Sigma, Quality Control, Sigma Metrics, Laboratory Performance, Westgard Rules.

Introduction

Quality is characterized by its adherence to the expectations of the end users.[1] Quality Control focuses on the prompt identification of errors through the monitoring of the accuracy and precision of analytical processes. The implementation of quality control (QC) is an ongoing dynamic process aimed at ensuring the reliability of test results generated by the laboratory. In statistics, Sigma denotes the Standard Deviation (SD), which serves as an indicator of the extent of variation within a set of processes. Sigma quantifies how much a specific process diverges from perfection and is widely recognized as a valuable tool in quality management systems for enhancing processes. Assessing errors in quality control levels using sigma metrics helps in pinpointing and correcting the errors based on the results.[2] Clinical laboratories play a vital role in enhancing the efficiency of inpatient care and preserving patient lives. Choosing the appropriate test, obtaining reliable results, and ensuring correct interpretation are crucial for improving the well-being of patients. Consequently, it is essential to implement quality management strategies in routine patient care, as laboratory errors significantly affect the quality of patient care.[3] Quality control (QC) is fundamental to guaranteeing the accuracy

and precision of laboratory tests and identifying errors.[4] There are two primary types of QC-External quality control (EQC) and internal quality control (IQC). EQC involves control samples provided by an external agency for analysis, whereas IQC is performed internally at regular intervals, continuously monitoring the analytical system.[5] Traditionally, the quality control program in a haematology laboratory encompasses the implementation of internal quality controls (IQC) and an external quality assurance scheme (EQAS). The IQC employs commercial controls with known values, against which daily runs are charted on Levey-Jennings (L.J.) Charts and assessed using the Westgard rules, which have been recognized for decades. Westgard has consistently promoted the 'Westgard Rules', for the customization of internal quality control procedures to maintain the quality of the test. Nevertheless, this approach has led to what many refer to as 'one set of rules governing all'. The Westgard rules have been applied by the laboratory across various parameters, resulting in an increased number of unnecessary reruns whenever a single parameter is identified as an outlier. This not only prolongs the process but also places additional pressure on the already trained personnel, equipment, and resources, particularly in settings with limited resources. The term "Sigma" in Six Sigma denotes the standard scale used to evaluate all the quality control process defects which can be further converted into a defects-per-million (DPM) ratio. Sigma metrics are routinely employed by numerous clinical biochemistry laboratories, and various studies and literature exist on this topic. However, in the realm of clinical haematology laboratories, while the concept is not unfamiliar in terms of quality and utility, its application remains in the early stages of development. In the book "Basic Quality Management Systems"[6] authored by James Westgard in 2014, a new tool was introduced that is more efficient and user-friendly compared to previous tools. This tool is referred to as "Westgard Sigma Rules TM" to differentiate this method from the original Westgard Rules. In this context, Sigma metrics offer a unique perspective as they encompass both Internal Quality Control (IQC) and External Quality Assessment Schemes (EQAS) for individual parameters. Based on the sigma metrics value, it may be possible to reduce the number of re-runs by selecting the appropriate set of sigma rules, as outlined below. The sigma rules that are applicable for the three levels of controls are described below.

- 6-sigma value necessitates only a 1_{3s} rule and one quality control measurement at each of the three levels of controls.
- 5-sigma value necessitates the addition of two 3_{2s} and R_{4s} rules for application suggesting one quality control measurement at each of the three levels of controls.
- 4-sigma value mandates the inclusion of a 3_{1s} rule for application with one quality control measurement at each of the three control levels.
- 3-For values which are below 4-sigma, a multi-rule procedure is required. This includes the 6x rule and a doubling of quality control measurements to a total of six. This sigma rule suggests that the three levels of controls should be analyzed in duplicate within a single run (N=6, R=1) or divided into two runs with three control measurements per run (N=3, R=2) in a day. If a 9x rule is applied instead of the 6x rule, then the quality control measurement could be segmented into three runs with three controls per run (N=3, R=3) in a day.

Sysmex XN 330 is an automated haematology analyser that facilitates the quantitative identification and analysis of the existence ratio of tangible components found in blood and body fluids (including red blood cells and their indices, white blood cells, and platelets) through the use of electrical impedance, laser light scattering, and fluorescent labeling.

In our study we had analyzed the internal quality control of the hematology parameters using the sigma metrics method and devised the frequency of quality checks based on the results obtained after the six sigma metric analyses.

Materials and Methods

This cross-sectional observational study was conducted at the Department of Pathology at Trichy SRM Medical College Hospital and Research Center for duration of six months. After getting approval from the institutional ethical committee (Ref. No.- 1170/TSRMMCH&RC/ME-1/2024-IEC No:151 on 18.10.2024). In this study, quality control (QC) samples at three concentration levels (low, normal, and high) were analyzed twice daily. Each lot of QC material was used for a period of 10 consecutive days, after which a fresh lot was introduced. This protocol was systematically repeated for six months. Over the course of the study, a total of 360 observations were generated for each QC level, ensuring adequate data points for performance evaluation.

Inclusion Criteria: Sigma metrics will be calculated for selected parameters in the CBC such as RBC, WBC, Hematocrit, Hemoglobin and Platelet count.

Exclusion Criteria: Rest of the parameters in the CBC will be excluded from the calculation of sigma metrics.

Brief Methodology: For the calculation of sigma metrics, the following parameters are required such

as Total allowable error, coefficient of variation in percentage and bias.

- The internal quality control will be run on 12th hourly basis for Low (L1), Normal (L2) and High (L3) quality control levels.
- The internal quality control data that is the laboratory mean and standard deviation will be collected from the Levey Jennings chart following Westgard rules.
- Targeted mean will be obtained from the control kit insert
- Total allowable error (TEa) values will be obtained from Clinical Laboratories Improvement Act (CLIA) guidelines for RBC, WBC, Hematocrit, Hemoglobin and Platelet count are 6, 15, 6, 7 and 25 respectively.[7]
- Bias was calculated using the formula,
  - Formula 1: Bias= [(our laboratory mean-target mean)/ target mean] x 100
- The Coefficient of variation (CV %) was calculated using the formula,
  - Formula 2: (Standard deviation/ Mean) x 100
- Sigma was calculated using the formula,
  - Formula 3: [(Total allowable error- Bias %) / CV%] x 100

Results

Table 1: Sigma values for three level quality controls in the month of October & November 2024

Levels		Oct-24					Nov-24				
	Parameters	**RBC**	**WBC**	**HCT**	**Hb**	**Platelet**	**RBC**	**WBC**	**HCT**	**Hb**	**Platelet**
L1	**Mean**	2.28	2.5	16.1	5.4	60	2.28	2.46	16.3	5.6	62
	SD	0.021	0.064	0.25	0.05	7.3	0.028	0.062	0.26	0.04	7.6
	CV%	0.9	2.6	1.5	1	12.1	1.2	2.6	1.6	0.7	12.4
	Bias%	-0.8	1.6	-0.6	1.8	11.1	-1.7	-0.8	-2.9	-1.7	6.8
	Sigma	**7.5**	**5**	**4.4**	**8.8**	**1.1**	**6.4**	**6**	**5.5**	**12.4**	**1.4**
L2	**Mean**	2.28	6.72	34.5	12	225	2.28	7.17	36.1	12.9	210
	SD	0.034	0.102	0.42	0.08	9	0.038	0.109	0.46	0.07	9
	CV%	0.8	1.5	1.2	0.7	4	0.9	1.5	1.3	0.5	4.3
	Bias%	-0.8	0.9	0	-0.8	2.2	-0.4	0.2	-1	-0.7	0
	Sigma	**8.5**	**10.6**	**5**	**11.1**	**5.7**	**7.1**	**9.8**	**5.3**	**15.4**	**5.8**
L3	**Mean**	2.28	17.61	46.8	16.7	546	2.28	16.54	45.2	16.3	508
	SD	0.039	0.192	0.68	0.08	12.1	0.046	0.2	0.54	0.08	11.2
	CV%	0.7	1.1	1.4	0.5	2.2	0.9	1.1	1.3	0.5	2.2
	Bias%	-0.5	0.1	1.2	0	2.8	-0.5	-0.3	0.8	0	-0.5
	Sigma	**9.2**	**13.7**	**5.1**	**14**	**10.1**	**7.2**	**13.9**	**4**	**14**	**11.5**

Table 1, shows the three level quality control values for the month of October and November 2024. In level 1, the sigma value for platelets is <3, the sigma values for WBC & HCT is between 4 to 6 and the sigma values for RBC and Hb is >6. In level 2, the sigma values for platelets and HCT falls between 4 and 6 and the sigma values for RBC, WBC & Hemoglobin is more than 6. In level 3, the sigma values for HCT lies between 4 and 6 and the sigma values for rest of the parameters are above 6.

Table 2: Sigma values for three level quality controls in the month of December 2024 and January 2025

Levels		Dec-24					Jan-25				
	Parameter	**RBC**	**WBC**	**HCT**	**Hb**	**Platelet**	**RBC**	**WBC**	**HCT**	**Hb**	**Platelet**
L1	**Mean**	2.32	2.49	16.4	5.6	65	2.3	2.46	16.5	5.6	60
	SD	0.025	0.067	0.19	0.06	10.7	0.031	0.065	0.23	0.08	8.2
	CV%	1.1	2.7	1.2	1.1	16.4	1.3	2.7	1.4	1.4	13.7
	Bias%	0	0.4	-2.3	-1.7	12	-0.8	-0.8	-1.7	-1.7	-3.3
	Sigma	**5.4**	**5.4**	**6.9**	**7.9**	**0.7**	**5.2**	**5.8**	**5.5**	**6.2**	**2**
L2	**Mean**	4.39	7.21	36.4	12.9	216	4.38	7.17	36.5	12.9	215
	SD	0.032	0.105	0.31	0.07	14.2	0.027	0.129	0.28	0.07	11.3
	CV%	0.7	1.5	0.9	0.6	6.5	0.6	1.8	0.8	0.5	5.2
	Bias%	0.4	0.8	-0.2	-0.7	2.8	0.2	0.2	0	-0.7	2.3
	Sigma	**8**	**9.4**	**6.8**	**12.8**	**3.4**	**9.6**	**8.2**	**7.5**	**13.4**	**4.3**
L3	**Mean**	5.35	16.57	45.6	16.3	512	5.33	16.53	45.7	16.3	511
	SD	0.04	0.236	0.44	0.09	13.3	0.045	0.242	0.44	0.11	9.3
	CV%	0.8	1.4	1	0.5	2.6	0.8	1.5	1	0.7	1.8
	Bias%	1.5	-0.1	1.7	0	0.1	1.1	-0.3	2	0	0
	Sigma	**5.6**	**10.7**	**4.3**	**14**	**9.5**	**6.1**	**10.2**	**4**	**10**	**13.8**

Table 2, shows the three level quality control values for the month of December 2024 and January 2025. In level 1, the sigma value for platelets is <3, the sigma values for WBC, RBC & Hematocrit (January 2025) is between 4 to 6 and the sigma values for HCT (December 2024) and Hemoglobin is >6. In level 2, the sigma values for platelets is <4 and the sigma values for RBC, WBC, HCT & Hemoglobin is >6. In level 3 quality control, the sigma values for RBC & HCT is between 4 to 6 and the sigma values for WBC, Hemoglobin and Platelet count are >6.

Table 3: Sigma values for three level quality controls for the month of February & March 2025

Levels		Feb-25					Mar-25				
	Parameters	**RBC**	**WBC**	**HCT**	**Hb**	**Platelet**	**RBC**	**WBC**	**HCT**	**Hb**	**Platelet**
L1	**Mean**	2.29	2.48	16.8	5.9	57	2.31	2.5	17.1	5.9	59
	SD	0.024	0.069	0.2	0.07	4.8	0.026	0.081	0.23	0.07	6.1
	CV%	1	2.8	1.2	1.1	8.4	1.1	3.2	1.3	1.2	10.4
	Bias%	2.1	-0.8	-4.5	-1.6	-1.7	-1.2	0	-2.8	-1.6	1.7
	Sigma	**3.9**	**5.6**	**8.7**	**7.8**	**3.2**	**6.5**	**4.6**	**6.7**	**7.1**	**2.2**
L2	**Mean**	4.37	6.52	36.2	13	202	4.4	6.61	36.9	13	209
	SD	0.048	0.121	0.5	0.1	7.5	0.041	0.166	0.39	0.1	12.2
	CV%	1.1	1.9	1.4	0.8	3.7	0.9	2.5	1	0.7	5.9
	Bias%	-1.1	-0.9	-2.9	-0.7	-1.9	-0.4	0.4	-1	-0.7	1.4
	Sigma	**6.4**	**8.3**	**6.3**	**9.6**	**7.2**	**7.1**	**5.8**	**7**	**11**	**4**
L3	**Mean**	5.32	15.66	46	16.7	497	5.36	15.83	46.9	16.8	510
	SD	0.051	0.226	0.56	0.09	9	0.049	0.307	0.55	0.16	15.2
	CV%	1	1.4	1.2	0.5	1.8	0.9	1.9	1.2	0.9	3
	Bias%	-0.1	-0.1	-1.7	-0.5	-1.5	0.5	0.8	0.2	0	0.9
	Sigma	**6.1**	**10.7**	**6.4**	**15**	**14.7**	**6.1**	**7.4**	**4.8**	**6.6**	**8**

Table 3, shows the three level quality control values for the month of February & March 2025. In level 1, the sigma value for platelets is <3 in March 2025, the sigma value for platelets and RBC is >3 in February 2025, the sigma values for WBC & RBC is between 4 to 6 and the sigma values for HCT and Hemoglobin is >6. In level 2, the sigma values for platelets and WBC is between 4 to 6 (March 2025) and the sigma values for RBC, WBC (except March 2025), HCT, Hemoglobin and platelets (except March 2025) is >6. In level 3 quality control, the sigma values for HCT (March 2025) are between 4 to 6 and the sigma values for RBC, WBC, HCT (except March 2025), Hemoglobin and Platelet count are >6.

Table 4: Overall sigma metrics for all three quality controls from October 2024 to March 2025

Sigma metrics	L1	L2	L3
<3	Platelet	-	-
3 – 4	RBC, Platelet	Platelet	HCT
4 - 6	WBC, HCT	HCT	HCT
>6	Hb, RBC, HCT	RBC, WBC, HCT, Hb	RBC, WBC, Hb, Platelet

Table 4, shows the overall sigma metric values for all the three quality controls from October 2024 to March 2025. Majority of the parameters in various quality control levels showed good to excellent performance (sigma >6) and a single parameter mainly platelets in level 1 except for the month of February 2025 showed poor performance (sigma <3).

Discussion

The Six Sigma methodology, first developed by Motorola in the 1980s, aims to reduce process variation and defects. In clinical laboratories, Six Sigma has been widely adopted as a quantitative tool to assess analytical performance. Westgard and colleagues were pioneers in applying Six Sigma metrics to laboratory quality control, integrating sigma values with Quality Control (QC) planning. Haematology analyzers generate large volumes of routine patient data; thus, ensuring precision and accuracy is critical. QC in haematology includes the daily analysis of control materials with known target values. Analytical performance is affected by factors such as instrument calibration, reagent quality, operator proficiency, and maintenance schedules. Various studies have evaluated Six Sigma metrics for common hematology parameters like Hb, WBC, RBC, HCT, MCV, MCH, PLT, e.g., Shah et al. (2016) evaluated Six Sigma metrics for automated haematology analyzers and found that Hb, WBC, and RBC often met higher sigma levels, while platelet counts may show lower sigma performance due to inherent analytical and biological variability. Similar research by Coskun (2011) [8] emphasized the use of Total Allowable Error (TEa), Coefficient of Variation (CV), and Bias for

calculating sigma metrics. Studies suggest that Six Sigma provides a robust framework for selecting appropriate QC rules and run size. The fundamental design of total quality management (TQM) consists of five essential steps. These steps include establishing goals (Quality Planning), formulating laboratory policies (Quality Process), executing the plan through specific procedures (Quality Control), evaluating the plan's effectiveness (Quality Assurance), and ultimately taking necessary actions to achieve the desired results (Quality Improvement).[9] The five stages of the six sigma model is defined, measured, analyzed, improved, and controlled (DMAIC). Unlike the TQM model, the six sigma approach incorporates an additional step of 'Control,' which is vital. [10,11] Quality indicators serve as a valuable tool for assessing laboratory performance, particularly during the pre-analytical phase. Another quality assessment tool used in clinical laboratory other than internal quality control is calculation of six sigma metrics, which is applicable in the pre-analytical phase.[12] The six sigma concept was developed by Mikel J Harry and Bill Smith in 1986 while they were employed at Motorola Company.[13] It aims to reduce variation within the system, enhancing compliance.[14] This six sigma scale was initially assessed by Nevalainen D et al[15] in 2000 and Westgard JO in 2001 to assess the overall laboratory performance. Its goal is to enhance the QC process by creating an effective strategy that minimizes variability and errors in a process.[16,17] Six sigma analysis significantly lowers the current error rate, thereby improving the process quality.[18] In the Hematology laboratory, sigma metrics function as a comprehensive quality control tool, complementing existing external quality control and internal quality assurance schemes.[19] The precise number of errors can be quantified by integrating bias, precision, and TEa. The primary challenge in six sigma is to determine TEa, which is influenced by analytical performance limits derived from research on biological variation or constraints imposed by regulatory bodies.[20] TEa effectively represents the tolerance threshold within the laboratory.[19] Based on the six sigma values obtained, Cooper et al., outlined the IQC frequency and QC run criteria for each category as mentioned below:[21]

- >6σ (excellent performance) – One QC run per day with alternating levels between days and a 13s rule.
- 4σ–6σ (good performance) – Two levels of QC run per day and 12.5s rule.
- 3σ–4σ (poor performers) – A combination of rules with two levels of QC conducted twice daily.
- <3σ (problems) – Maximum QC. Three level runs in a frequency of three times daily and preferably testing specimens in duplicate.

In the results obtained from our study, majority of the parameters like RBC, WBC, Hb, HCT and platelets had good to excellent performance and hence one level QC can be run per day under the 13s rule. Platelet showed marginal performance in certain levels only (L1 & L2) suggesting a combination of rules with two level QCs per day which is similar to the study done by Nagaraj et al. [3]

Conclusion

Six Sigma metrics provide an effective framework for optimizing haematology QC programs, minimizing unnecessary reruns, and improving laboratory efficiency. This method supports evidence-based QC planning and continuous quality improvement in resource-limited settings.

Abbreviations

QC- Quality Control

CBC- Complete Blood Count

RBC- Red Blood Cells

WBC- White Blood Cells

HCT-Hematocrit

Hb- Hemoglobin

IQC- Internal Quality Control

EQAS- External Quality Assurance Scheme

MCV- Mean Corpuscular Volume

MCH- Mean Corpuscular Hemoglobin

Ethics: This study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Research Board of Trichy SRM Medical College Hospital & Research Centre (IRB Project ID- LXX- IRB-05 conducted on 27.09.2024). Formal informed written consent was not required with a waiver from the Institutional Research Board of Trichy SRM Medical College Hospital & Research Centre.

Acknowledgement: I sincerely thank the laboratory technicians of the Department of Pathology, Trichy SRM Medical College Hospital & Research Centre, for their constant support. I also extend my heartfelt thanks to our statistician (VANNAMAYIL) for his assistance in data analysis.

Authors' Contribution: The concept and methodology were designed by Dr. K. Shiyamala and Dr. G. Vinoth Kumar. Dr. Fathima Jackia Banu and Dr. K. Shiyamala were involved in data curation, formal analysis, resource collection, statistical analysis and writing the original draft under the supervision of Dr. R. Suganya and Dr. S. Priya Banthavi. The validation, review and editing of the manuscript and final approval was done by all the authors.

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