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APPLICATION OF SIX SIGMA METHOD EVALUATING THE QUALITY OF PERIPHERAL BLOOD CELL TESTING AT PHUONG CHAU INTERNATIONAL HOSPITAL

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ABSTRACT: The Six Sigma approach provides laboratories with a structured framework to assess analytical performance, optimize IQC protocols, and determine appropriate IQC frequencies. This study aimed to evaluate the quality and optimize the IQC procedure for selected hematology tests on the Advia 2120i automated hematology analyzer. A cross-sectional descriptive study was conducted using internal quality control and external quality assessment data from April 2024 to December 2024 at Phuong Chau International Hospital. The results showed that the average sigma values were 5.2 for White Blood Cell (WBC), 3.0 for Red Blood Cell (RBC), 4.2 for Hemoglobin (HGB), and 7.1 for Platelet (PLT). WBC demonstrated good analytical performance, RBC was at the acceptable threshold requiring stricter IQC management, HGB achieved acceptable to good performance, and PLT reached world-class performance. These findings demonstrate that the Six Sigma approach is effective in monitoring and improving test quality by enabling the selection of appropriate IQC strategies for each parameter.

Keywords: sigma metrics, total allowable error, bias, coefficient of variation.

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1. INTRODUCTION

Hematology tests are among the most commonly ordered laboratory investigations and are critical for diagnosing diseases, assessing prognosis, and monitoring treatment. Reliable measurements of parameters such as white blood cell, red blood cell, hemoglobin, and platelet counts are essential for accurate clinical decisions. However, maintaining consistent analytical quality in hematology testing remains challenging due to factors like instrument variability, reagent instability, pre-analytical errors, and limitations in internal quality control. These issues highlight the need for laboratories to implement structured quality management systems, such as the Six Sigma method, to objectively evaluate analytical performance and enhance test reliability. The Six Sigma method defines evaluation levels as follows: 6-Sigma is considered world class, 5-Sigma is excellent, 4-Sigma is good, 3-Sigma is acceptable, 2-Sigma is poor, and 1-Sigma is unacceptable. The goal is to achieve a 6-Sigma level, with the minimum acceptable level being 3-Sigma. When evaluating the quality of a test on the Six Sigma scale, a higher sigma value indicates better test quality. Therefore, the sigma scale provides a quantitative framework for assessing method performance and offers objective evidence for the process of improving test quality [1].

The Laboratory Department at Phuong Chau International Hospital applies the set of criteria for assessing laboratory quality issued by the Ministry of Health, as per Decision No. 2429/QD-BYT dated June 12, 2017. It also integrates the ISO 15189:2022 and Joint Commission International (JCI) standards into its quality management system. Our laboratory conducts daily internal quality control and participates in external quality assessment programs with the Center for Standardization and Quality Control in Medical Laboratory of Ho Chi Minh City (CSQL of HCMC) to ensure test quality. Applying the Six Sigma scale in quality management can help the Laboratory Department assess test quality, identify limitations, and propose plans for quality improvement. For this reason, we conducted the study "Application of the Six Sigma method to evaluate the quality of peripheral blood cell testing at Phuong Chau International Hospital," with the objective of evaluating the quality and selecting the internal quality control statistics for several hematology tests on the automated hematology analyzer Advia 2120i.

2. MATERIALS AND METHODS

2.1. Materials

The subjects of this study were the internal quality control (IQC) and external quality assessment (EQA) results for White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (HGB), and Platelet count (PLT) tests performed on the Advia 2120i automated hematology analyzer at the Laboratory Department of Phuong Chau International Hospital from April to December 2024.

Inclusion criteria:

- Daily IQC results for WBC, RBC, HGB, and PLT performed on the Advia 2120i automated hematology analyzer and controlled by Westgard rules.

- Monthly EQA results for WBC, RBC, HGB, and PLT performed on the Advia 2120i and analyzed by the CSQL of HCMC.

Exclusion criteria:

- IQC results that violated or were not controlled by Westgard rules.

- EQA results that had not been analyzed by the CSQL of HCMC.

2.2. Methods

Study design: This was a descriptive cross-sectional study.

Sample size: During the study period, we collected 2196 IQC results and 24 EQA results that met the inclusion and exclusion criteria.

Research content:

- Assessing precision of the tests using the standard deviation (SD) and coefficient of variation (CV) obtained from six months of IQC results at two levels of quality control serum (QC). Precision was considered acceptable when the coefficient of variation (CV) was lower than the maximum allowable imprecision (I%) [2].

- Assessing accuracy of the tests through the bias from six months of EQA

results. To assess accuracy, the average bias over the months was calculated and compared with the maximum allowable bias (B%) for each test according to established standards [2]. A test method is considered accurate if its bias is less than the desirable bias (B%).

- The sigma value of the test method was calculated based on the total allowable error (TEa), CV, and Bias using the following formula:

+ Sigma value: SigmaQC = (TEa − Bias)/CV

+ Mean sigma value: SigmaAVE = (SigmaQC1 + SigmaQC2 + SigmaQC3)/3

- A method with a sigma value ≥ 6 is considered to have "World Class" performance, ≥ 5 is "Excellent," ≥ 4 is "Good," ≥ 3 is "Acceptable," ≥ 2 is "Poor," and a value < 2 is "Unacceptable" [3].

- The quality control (QC) strategy is selected based on the Westgard Sigma Rules chart, tailored to the sigma value of each specific test [4].

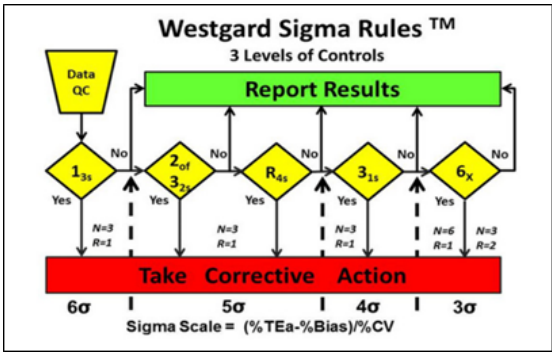

Figure 1. Westgard Sigma Rules Chart [4]

2.3. Data analysis

Data processing was performed using Microsoft Excel 2023, with statistical values including mean, standard deviation (SD), coefficient of variation (CV), and bias.

2.4. Research ethics

The study was approved by the Scientific Research Evaluation Committee of Phuong Chau International Hospital under Decision No. 70/QD-BVPC-2024 dated April 19, 2024. The study did not interfere with the medical examination and treatment process, incurred no additional costs, and ensured patient information confidentiality.

3. RESULTS

3.1. Precision of the tests

Hematology test precision was assessed by comparing the coefficient of variation (CV%) with the maximum allowable imprecision (I%) across three quality control (QC) levels. WBC and PLT showed consistent performance with CV% lower than I% at all IQC levels. HGB exceeded the allowable imprecision (I%) at QC1 and QC2, while RBC slightly exceeded I% at QC2. These findings (Table 1) indicate that most tests achieved acceptable precision, though HGB and RBC may require closer monitoring.

Table 1: Precision of the tests on the Advia 2120i analyzer

Parameters (Unit)	I%*	CVQC1 (%)	CVQC2 (%)	CVQC3 (%)
WBC (109/L)	5.7	2.8	2.3	2.8
RBC (1012/L)	1.6	1.3	1.7	1.6
HGB (g/L)	1.4	1.9	1.5	1.2
PLT (109/L)	4.6	4.4	2.7	2.5

*I%: the maximum allowable inaccuracy from the website: http://westgard.com/biodata-base1.htm

3.2. Accuracy of the test

The results of this study showed that all hematology tests demonstrated Bias% values lower than the allowable bias (B%), indicating good analytical accuracy. Among these, the platelet (PLT) test showed the highest Bias% at 3.5%, whereas the hemoglobin (HGB) test exhibited the lowest Bias% at 0.8%, as presented in Table 2.

Table 2. Bias of tests on the Advia 2120i analyzer

Parameters (Unit)	Analytical bias (Bias%*)	Allowable bias (B%‡)
WBC (109/L)	1.3	6.0
RBC (1012/L)	1.5	1.7

HGB (g/L)	0.8	1.8
PLT (109/L)	3.5	5.9

*B%: allowable bias at the desired level from the website: http://westgard.com/biodatabase1.htm

‡Bias% was calculated as the average from the results of six months of external quality assessment.

3.3. Sigma values of the tests

Based on the calculated sigma values, at QC1 level, two tests WBC and PLT achieved sigma >4, classified as "Good," while two tests RBC and HGB reached sigma >3, considered "Acceptable." At QC2 level, WBC and PLT both attained sigma >6, indicating "World Class" performance; HGB showed sigma >4 ("Good"); and RBC had sigma >2 ("Poor"). At QC3 level, PLT achieved sigma >6 ("World Class"); HGB reached sigma >5 ("Excellent"); WBC showed sigma >4 ("Good"); and RBC remained at sigma >2 ("Poor") as presented in Table 3.

3.4. Internal quality control statistics of laboratory tests based on sigma values

IQC frequency and Westgard rule selection were based on the lowest sigma value to ensure control at the weakest analytical level and maintain consistent test performance. For tests with the lowest sigma values between 4 and 5, such as WBC and PLT, the quality control strategy can be maintained at a standard level. These tests require the application of Westgard rules 13s, 2 of 32s, R4s, and 31s performed with three internal quality control (IQC) levels and one run per day, which is sufficient to

Table 4. Internal quality control statistics of hematology tests based on sigma values

Parameters (Unit)	Sig-maQC1	Sig-maQC2	Sig-maQC3	Recommended Westgard rules	IQC level (N)	Run (R)
WBC (109/L)	4.8	6.0	4.9	13s; 2 of 32s; R4s; 31s	3	1
RBC (1012/L)	3.5	2.6	2.9	13s; 2 of 32s; R4s; 31s; 6X	3	2
HGB (g/L)	3.3	4.1	5.1	13s; 2 of 32s; R4s; 31s; 6X	3	2
PLT (109/L)	4.9	7.8	8.7	13s; 2 of 32s; R4s; 31s	3	1

Table 3. Sigma values with TEa according to the Clinical Laboratory Improvement Amendments (CLIA)

Parameters (Unit)	TEa* (%)	Bias (%)	CVQC1 (%)	Sig-maQC1	CVQC2 (%)	Sig-maQC2	CVQC3 (%)	Sig-maQC3	Sig-maAVE
WBC (109/L)	15.0	1.3	2.8	4.8	2.3	6.0	2.8	4.9	5.2
RBC (1012/L)	6.0	1.5	1.3	3.5	1.7	2.6	1.6	2.9	3.0
HGB (g/L)	7.0	0.8	1.9	3.3	1.5	4.1	1.2	5.1	4.2
PLT (109/L)	25.0	3.5	4.4	4.9	2.7	7.8	2.5	8.7	7.1

*TEa%: Total allowable error according to CLIA from the website: https://www.westgard.com/clia.htm

ensure reliable performance. In contrast, tests with the lowest sigma values below 4, including RBC and HGB, demand more stringent IQC management due to their higher risk of analytical errors. For these parameters, additional rules such as 6X should be incorporated, with three IQC levels and two runs per day, in order to strengthen error detection and maintain acceptable test quality.

4. DISCUSSIONS

Evaluation of the precision of the tests was conducted through the coefficient of variation (CV) obtained from the internal quality control results of the Advia 2120i automated hematology analyzer. The smaller the coefficient of variation or dispersion among test results, the higher the precision, and vice versa. The allowable imprecision index was used to evaluate the precision of the method. A CV lower than the maximum allowable imprecision (I%) indicates that the test has high precision. Based on the results in Table 1, most tests had CV% < I%, indicating high precision. However, RBC and HGB tests showed CV% > I% at QC1 and QC2 levels. In this study, the allowable imprecision for each test was selected at the desirable level according to CLIA standards. For some tests such as RBC and HGB, which have low TEa values, the criteria applied here may be relatively strict and stringent. The PLT test demonstrated high precision, although its performance was close to the maximum allowable imprecision. Therefore, the laboratory should pay attention to this issue and implement more rigorous quality control measures to improve the precision of these tests. The findings of this study are consistent with those of Bui Minh Hang (2022), Berta DM (2023), and Goel S (2024) [5], [6], [7].

The accuracy of the tests was evaluated through bias, obtained by participating in the external quality assessment program of the Ho Chi Minh City Quality Control Center. Bias, defined as the difference between the measured value and the true value, is used to describe the inaccuracy of a method. The smaller the bias and the lower it is compared to the allowable bias, the closer the measured value is to the true value, and the higher the accuracy. Results presented in Table 2 showed that all tests in this study had bias values lower than the allowable limits. Tests such as HGB and WBC demonstrated low bias, indicating high accuracy. However, tests with larger bias, such as PLT, indicate lower accuracy. Laboratories should pay attention when performing external quality assessments to monitor and improve the quality of tests, even though the analytical results met the permissible standards. The findings of this study are consistent with those reported by Bui Minh Hang at the National Hospital of Endocrinology [5].

The results from Table 3 show the sigma values of the tests performed on the Advia 2120i analyzer with TEa according to CLIA. Most of the tests in this study had sigma values >3 at all three IQC levels. Some tests, including WBC and PLT, achieved sigma values >4 across all IQC levels. HGB showed values between 3 < sigma < 6, while RBC had values between 2 < sigma < 4 at all three IQC levels. The sigma results in this study were comparable to those reported by Berta DM [7] but lower than those reported by Bui Minh Hang and Goel S [5], [6]. Applying the sigma scale evaluates test performance and supports effective quality management by guiding the selection of appropriate internal quality control strategies. Tests with sigma values ≥3 are considered acceptable for routine use. In contrast, tests with sigma values <3 indicate that test quality cannot be ensured, even with multiple QC runs, and therefore require root cause analysis, method performance improvement, and stricter QC procedures to ensure reliable results. As method performance differs across laboratories, each laboratory should design QC procedures corresponding to the sigma values of individual tests to ensure test quality.

Before conducting the study, we performed and monitored internal quality control using Westgard rules such as 12s, 22s, 13s, R4s, 41s, and 9X. Similarly, Berta DM also reported that laboratories in their study commonly used only a subset of rules, such as 12s, 22s, 13s, R4s, 41s, and 9X for quality control. External quality assessment results at our laboratory were accepted when the SDI criteria were within ±2, which is consistent with the findings described by Berta DM [7]. After calculating the sigma values, we analyzed the results to develop appropriate internal quality control (IQC) strategies. The selection of QC rules was made according to the Westgard Sigma Rules [5], corresponding

to the analytical performance of each test. To ensure reliability across all concentration levels, the frequency of IQC runs and the specific Westgard rules were determined based on the lowest sigma value among the three control levels. This approach focuses on the concentration level with the weakest analytical stability, thereby enhancing error detection and maintaining consistent test quality throughout the measuring range. Tests WBC and PLT with the lowest sigma values between 4 and 5 required QC management using the rules 13s, 2 of 32s, R4s, and 31s with 3 QC levels and one run per day. Tests RBC and HGB with the lowest sigma values <4 required more stringent QC management using the rules 13s, 2 of 32s, R4s, 31s, and 6X with 3 QC levels and two runs per day.

The use of multiple QC levels or increasing the frequency of QC runs provides more information to evaluate the acceptability of analytical runs. In this study, we selected 3 QC levels with one run per day for tests with 4 < sigma < 5, and 3 QC levels with two runs per day for tests with sigma < 4. After selecting the appropriate QC strategies based on sigma values, we re-evaluated sigma values after 3 months of implementing improved internal QC procedures for the tests in this study.

5. CONCLUSIONS

WBC and PLT tests achieved sigma values >4 at all three IQC levels. HGB showed values between 3<sigma<6, while RBC showed values between 2<sigma<4 at all three IQC levels. RBC and HGB tests with sigma values <4 require stricter QC management using the rules 13s, 2 of 32s, R4s, 31s, and 6X with 3 IQC levels and two runs per day.

REFERENCES

[1] Westgard J.O. Six sigma quality design and control. Madison WI. 2006. 11-28.

[2] Ricos C, Alvarez V, Cava F, et al. Current databases on biologic variation: Pros, Cons and Progress. Scandinavian Journal of Clinical and Laboratory Investigation. 1999. 59, 491-500, http://dx.doi.org/10.1080/00365519950185229.

[3] Westgard JO, Sharon SE, Teresa D. CLIA Final Rules for Quality System. Madison WI. 1992. 186-187.

[4] Westgard JO, Westgard SA. Basic Quality Management Systems. Madison WI. 2014.171-189.

[5] Bui Minh Hang, Do Tien Dung, Nguyen Thu Ha. Application of Six Sigma in evaluating the performance of peripheral blood cell testing on the DXH800 hematology analyzer at the National Hospital of Endocrinology during 2019-2021. Vietnam Medical Journal. 2022; 520(1A), 276-281. https://doi.org/10.51298/vmj.v520i1A.3789.

[6] Goel S, Nisal AR, Raj A, Nimbargi RC. Analysis of hematology quality control using six sigma metrics. Indian J Pathol Microbiol. 2024. 67(2), 332-335, https://doi.org/10.4103/ijpm.ijpm_352_23.

[7] Berta DM, Melku M, Adane T, Girma M, Mulatie Z, Chane E, Birke Teketelew B. Analytical Performance Evaluation of Hematology Analyzer Using Various TEa Sources and Sigma Metrics. Pathology and Laboratory Medicine International. 2023.15, 65-75, https://doi.org/10.2147/PLMI.S414693.