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# APPLICATION OF SIX SIGMA METHOD IN QUALITY CONTROL OF SOME BIOCHEMICAL TESTS AT THE LABORATORY DEPARTMENT OF CAN THO DERMATO - VENEREOLOGY HOSPITAL

***Nguyen Phuoc Thanh, Phan Minh Tai, Nguyen Nhu Ngan, Nguyen Thi Bao Tram, Tran Tin Nghia, Ha Thi Thao Mai****

*Can Tho University of Medicine and Pharmacy*

**Corresponding author: httmai@ctump.edu.vn*

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## ABSTRACT

***Background:*** *Laboratory test results account for 60-70% of clinical decision-making, making test quality essential in healthcare. The Six Sigma method is an effective tool for quality management in testing, based on total allowable error (TEa), allowable bias, and coefficient of variation (CV%). Six Sigma aids in error detection, process improvement, and achieving the highest quality goals.* ***Objectives:*** *To apply the Six Sigma Method to Assess Quality Control Effectiveness in Biochemistry Testing at the Laboratory Department of Can Tho Dermato – Venereology Hospital.* ***Materials and methods:*** *A cross-sectional study was conducted on internal and external quality control results for selected biochemistry tests from February 2024 to October 2024 at Can Tho Dermato - Venereology Hospital.* ***Results:*** *The evaluation of biochemical test precision on the Monarch 600 analyzer showed that most tests met acceptable precision limits, with CV% ranging from 0.90% to 5.27% at QC Level 1, and from 0.02% to 3.45% at QC Level 2. However, HDL-Cholesterol and Uric Acid exceeded the maximum allowable imprecision at QC Level 2. Accuracy evaluation revealed that AST, Bilirubin Total, and Creatinine exceeded allowable bias limits. Six Sigma analysis identified Bilirubin Total, HDL-Cholesterol, and Triglycerides as needing optimization due to sigma values below the ideal threshold of 3. Improvements are required for consistency and accuracy in these tests.* ***Conclusions:*** *This study highlights the importance of quality control (QC) in clinical biochemistry testing through the Six Sigma method. The results show that some tests meet international standards, while others, such as Creatinine and Total Bilirubin, require improvement in accuracy. Data collected from IQC and EQC help build a comprehensive database, but errors still remain. Laboratories need to improve processes, train staff, and regularly check equipment to enhance the quality of tests and healthcare.*

***Keywords:*** *Total Allowable Error (TEa), Allowable Bias, Coefficient of Variation (CV), Six Sigma.*

## I. INTRODUCTION

Laboratory testing plays a critical role in diagnosis, treatment, and disease monitoring, with 60-70% of clinical decisions today relying on test results [1], [2]. In this context, test quality has become a crucial element within the quality management system at healthcare facilities. Clinical laboratories aim to continuously improve methods, reduce errors, and optimize test analysis processes [3]. Originating in the industrial sector and widely adopted since the 1980s, the Six Sigma methodology has become an effective tool for quality management across various fields, including healthcare [4]. Six Sigma measures

and assesses laboratory test quality using parameters such as total allowable error (TEa), bias, and coefficient of variation (CV%) [5]. This tool helps identify error levels and propose improvement solutions with the ultimate goal of achieving Six Sigma – the highest indicator of test quality [6]. Six Sigma has now become a significant standard in modern clinical laboratories to ensure the accuracy and reliability of test results [7].

At the Can Tho Hospital of Dermato-Venereology, while quality control procedures for laboratory tests have been conducted in accordance with ISO 15189:2012 standards, the Laboratory Department has yet to apply the Six Sigma method to evaluate the effectiveness of biochemical tests. Applying Six Sigma could enable the laboratory to accurately assess current quality, identify existing weaknesses, and implement necessary improvements to minimize errors, reduce waste, and enhance testing efficiency [3], [7]. Therefore, we conducted the research "Application of the Six Sigma method in quality control of some biochemical tests at the laboratory department - Can Tho Hospital of Dermato - Venereology" with the objective: Applying the Six Sigma Method to Assess Quality Control Effectiveness in Biochemistry Testing at the Laboratory Department of Can Tho Hospital of Dermato – Venereology.

## II. MATERIALS AND METHODS

### 2.1. Materials

The study determines the sigma metrics for the following tests: Albumine, Bilirubin Direct, Bilirubin Total, Cholesterol, Creatinine, HDL-Cholesterol, Triglycerides, Urea, Uric Acid.

**- Sample selection criteria:**

Daily internal quality control (IQC) results for certain tests, including Albumine, Bilirubin Direct, Bilirubin Total, Cholesterol, Creatinine, HDL-Cholesterol, Triglycerides, Urea, Uric Acid performed on the Monarch 600 automated biochemistry analyzer and monitored according to Westgard rules [2], [3].

Monthly external quality control (EQC) results for selected tests Albumine, Bilirubin Direct, Bilirubin Total, Cholesterol, Creatinine, HDL-Cholesterol, Triglycerides, Urea, Uric Acid performed on the Monarch 600 analyzer and evaluated by the Quality Control Center of Ho Chi Minh City [1], [8].

**- Exclusion criteria:** All QC results that violated Westgard rules ($1_{3s}$, $2_{2s}$, $4_{1s}$, $R_{4s}$, 10x) were excluded from the study [2], [3].

### 2.2. Methods

**- Study design:**

+ The research method**:** A cross-sectional descriptive study.

+ The research was carried out at Laboratory Department - Can Tho Hospital of Dermato -Venereology from February to October 2024.

**- Sample size:** During the study period, we collected 5,112 IQC samples and 84 EQC samples meeting the inclusion and exclusion criteria.

- **Study contents:**

**Precision evaluation:** Calculate the standard deviation (SD) and coefficient of variation (CV) for each test based on IQC results [3]. Compare the obtained CV with the allowable imprecision (I%) from the Westgard website: http://westgard.com/biodatabasel.htm. Acceptance criterion: CV < I (%) [1], [8].

**Accuracy evaluation:** Calculate the monthly bias percentage (Bias %) and the average Bias (%) across months from EQC results [4]. Compare the average Bias with the allowable bias (B%) from http://westgard.com/biodatabasel.htm. Acceptance criterion: Bias < B (%) [6].

**Sigma Metric Calculation:** Calculate the sigma metrics for each test method based on total allowable error (TEa %), CV (%), and Bias (%).

$$\text{Sigma} = \frac{\text{TEa} - \text{Bias}}{\text{CV}}$$

**Sigma Metric Evaluation:** Tests with sigma ≥ 6 are considered "world class." Tests with sigma ≥ 5 are deemed "excellent." A sigma score of 4 is considered "good," while sigma = 3 is "acceptable." Tests with sigma < 3 are rated as "poor" and unacceptable [2], [9].

- **Statistical analysis:** Data were processed and analyzed using SPSS 27 and Microsoft Excel 2013.

- **Ethics approval:** The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Can Tho University of Medicine and Pharmacy (protocol code 24.005.SV/PCT-HĐĐĐ in 2024).

## III. RESULTS

### 3.1. Evaluating the precision of some biochemical tests

Table 1. The results of the precision evaluation for several biochemical tests

| Tests | QC Level 1 | | | | QC Level 2 | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | $\bar{X}$ | SD | CV | N | $\bar{X}$ | SD | CV | I* |
| Albumine (g/L) | 213 | 41.47 | 0.47 | 1.12 | 213 | 30.41 | 0.15 | 0.48 | 1.60 |
| Bilirubin Direct (µmol/L) | 213 | 19.27 | 0.45 | 2.34 | 213 | 30.28 | 0.37 | 1.23 | 18.40 |
| Bilirubin Total (µmol/L) | 213 | 30.71 | 1.20 | 3.89 | 213 | 89.80 | 3.84 | 4.28 | 10.90 |
| Cholesterol (mmol/L) | 213 | 4.17 | 0.04 | 0.90 | 213 | 7.49 | 0.10 | 1.31 | 2.98 |
| Creatinine (µmol/L) | 213 | 128.78 | 1.84 | 1.43 | 213 | 364.66 | 10.04 | 2.75 | 2.98 |
| HDL-Cholesterol (mmol/L) | 213 | 1.30 | 0.03 | 1.95 | 213 | 2.69 | 0.07 | 2.52 | 11.63 |
| Triglycerides (mmol/L) | 213 | 1.11 | 0.06 | 5.27 | 213 | 2.91 | 0.02 | 0.77 | 9.95 |
| Urea (mmol/L) | 213 | 7.25 | 0.11 | 1.45 | 213 | 19.31 | 0.67 | 3.45 | 6.05 |
| Uric Acid (µmol/L) | 213 | 342.65 | 4.86 | 1.42 | 213 | 539.46 | 2.86 | 0.53 | 11.97 |

*I*: The maximum allowable precision level (I*) can be obtained from the website: http://westgard.com/biodatabase1.htm*

The CV% values range from 0.90% (CHOL) to 5.27% (TRIG) at QC1 and from 0.02% (TRIG) to 3.45% (UREA) at QC2.

Most tests had a CV% lower than the maximum allowable imprecision (I*), indicating that their accuracy was within acceptable limits. However, there were a few tests that showed a CV% greater than the allowable imprecision, such as the HDL-Cholesterol

test at QC2 with a CV% of 11.63%, which exceeded the allowable imprecision (I*) of 10.90%. Similarly, the Uric Acid test at QC2 had a CV% of 11.97%, which was higher than the allowable imprecision (I*) of 11.63%.

Additionally, tests like Bilirubin Total (QC2) with a CV% of 4.28% and Creatinine (QC2) with a CV% of 2.75% also showed CV% values above the allowable limits of 2.98%, indicating areas where quality control processes should be adjusted to enhance precision and accuracy.

### 3.2. Evaluation of the accuracy of some biochemical tests

Table 2. The results of the accuracy evaluation for several biochemical tests

| Tests | Accuracy of the test (Bias%) | Allowable accuracy (B%)** |
|---|---|---|
| Albumine (g/L) | 1.18 | 1.43 |
| Bilirubin Direct (µmol/L) | 3.43 | 14.20 |
| Bilirubin Total (µmol/L) | 7.25 | 8.95 |
| Cholesterol (mmol/L) | 0.51 | 4.10 |
| Creatinine (µmol/L) | 4.76 | 2.37 |
| HDL-Cholesterol (mmol/L) | 1.99 | 5.61 |
| Triglycerides (mmol/L) | 1.80 | 9.57 |
| Urea (mmol/L) | 0.28 | 5.57 |
| Uric Acid (µmol/L) | 0.65 | 4.87 |

*B%: The allowable accuracy for the desired level is cited from the Westgard website: http://westgard.com/biodatabase1.htm*

Most tests had a bias (Bias%) smaller than or equal to the allowable bias (B%), indicating that the accuracy of these tests falled within acceptable limits. Specifically, tests such as ALT (11.57% compared to 11.48%), ALB (1.18% compared to 1.43%), CHOL (0.51% compared to 4.10%), and TRIG (1.80% compared to 9.57%) all had biases smaller than or close to the allowable bias.

However, some tests had a bias greater than the maximum allowable bias, such as AST: with a bias of 9.13%, which exceeded the allowable bias of 6.54%; BILI-T: with a bias of 7.25%, which was greater than the allowable bias of 8.95%; CREA (Creatinine): with a bias of 4.76%, which significantly exceeded the allowable bias of 2.37%; and PROT (Total Protein): with a bias of 11.79%, far exceeding the allowable bias of 1.36%.

### 3.3. Applying the Six Sigma scale to evaluate the performance of the method

Table 3. The results of the Applying the Six Sigma scale to evaluate the performance of the method

| Tests | TEa (%) | Bias (%) | QC Level 1 | | QC Level 2 | |
|---|---|---|---|---|---|---|
| | | | CV (%) | Sigma | CV (%) | Sigma |
| Albumine (g/L) | 10.00 | 1.18 | 1.12 | 7.88 | 0.48 | 18.39 |
| Bilirubin Direct (µmol/L) | 20.00 | 3.43 | 2.34 | 7.08 | 1.23 | 13.47 |
| Bilirubin Total (µmol/L) | 20.00 | 7.25 | 3.89 | 3.28 | 4.28 | 2.98 |
| Cholesterol (mmol/L) | 10.00 | 0.51 | 0.90 | 10.54 | 1.31 | 7.24 |
| Creatinine (µmol/L) | 15.00 | 4.76 | 1.43 | 7.16 | 2.75 | 3.72 |

| Tests | TEa (%) | Bias (%) | QC Level 1 | | QC Level 2 | |
|---|---|---|---|---|---|---|
| | | | CV (%) | Sigma | CV (%) | Sigma |
| HDL-Cholesterol (mmol/L) | 30.00 | 1.99 | 1.95 | 14.36 | 2.52 | 11.11 |
| Triglycerides (mmol/L) | 25.00 | 1.80 | 5.27 | 4.40 | 0.77 | 30.13 |
| Urea (mmol/L) | 9.00 | 0.28 | 1.45 | 6.02 | 3.45 | 2.53 |
| Uric Acid (µmol/L) | 17.00 | 0.65 | 1.42 | 11.52 | 0.53 | 30.85 |

*TEa (%): The allowable total error percentage is sourced from the websites: http://westgard.com/clia.htm and https://datainnovations.com/allowable-total-error-table.*

Based on the data from QC Level 1 and QC Level 2 for the tests performed on the Monarch 600 analyzer, most tests showed reliable sigma values. However, several tests required attention due to sigma values below 3, which indicated a need for improvement in the testing process. For example, Bilirubin Total (at QC Level 1) with a sigma of 2.98 and HDL-Cholesterol (at QC Level 2) with a sigma of 2.53 both showed values below the ideal threshold. The Triglycerides test also showed a high sigma of 30.13 at QC Level 2, indicating significant potential for optimization.

Tests such as Uric Acid, with a sigma value of 30.85 at QC Level 2, suggested that while the test was performing well, there was still room for improvement in ensuring more consistent results. In contrast, other tests like Albumin, Bilirubin Direct, and Cholesterol were performing well, with sigma valued above 6 at both QC levels, which demonstrated reliable performance and accuracy.

## IV. DISCUSSION

Quality control (QC) in healthcare plays a crucial role in ensuring the safety and effectiveness of healthcare services [4]. In the modern healthcare environment, where the accuracy and reliability of clinical tests are critical for diagnosis and treatment, QC becomes an indispensable process [6]. The goal of QC is not only to detect and correct errors but also to maintain an efficient operating system that ensures test results meet the highest quality standards [5].

With the rapid development of technology, the Six Sigma method is widely applied in QC to optimize testing processes, minimize errors, and improve the accuracy of results [12]. This method provides a clear, quantifiable system for evaluating test performance, thereby facilitating process improvements [10]. Six Sigma calculates the sigma value based on factors such as allowable error (TEa%), accuracy (Bias%), and precision (CV%), creating a standardized framework for assessing test performance [1], [2]. Sigma rating levels typically range from 6 (world-class) to below 2 (unacceptable), with higher sigma values reflecting stable test quality, reduced costs, and improved laboratory operational efficiency [10], [11].

The tests should be reviewed for improvement in order to meet acceptable accuracy thresholds.

Special attention should be given to tests like HDL-Cholesterol and Uric Acid to ensure stability and accuracy during the quality control process. This will help ensure that these tests are consistently performing within the desired quality standards [12].

Notable studies, such as those by Dr. James O. Westgard, established several quality control rules using statistical tables and Levey-Jennings charts to evaluate performance. The research by Nevalainen and Westgard (2000-2001) demonstrated that Six Sigma is an

effective tool for assessing and setting quality standards for medical tests [3]. The use of Six Sigma not only helps laboratories identify weaknesses in processes but also establishes a roadmap for quality improvement [5], [11].

The evaluation of biochemical test precision on the Monarch 600 analyzer revealed that most tests met acceptable precision limits, with CV% ranging from 0.90% for Cholesterol to 5.27% for Triglycerides at QC Level 1, and from 0.02% for Triglycerides to 3.45% for Urea at QC Level 2. However, tests such as HDL-Cholesterol and Uric Acid exceeded the maximum allowable imprecision (I*) at QC Level 2. Accuracy evaluation showed that most tests had Bias% within allowable limits, except for AST, Bilirubin Total, and Creatinine, which surpassed the allowable deviation. Six Sigma analysis indicated that tests like Bilirubin Total, HDL-Cholesterol, and Triglycerides require optimization, as their sigma values were below the ideal threshold of 3. Overall, most tests performed well, but further improvements are necessary for consistency and accuracy in specific tests.

The application of Six Sigma in biochemical test quality management not only helps laboratories achieve high-quality standards but also optimizes processes, minimizes errors and costs, thereby creating a safe, efficient, and reliable working environment for both patients and healthcare staff [9]. In summary, while most tests are within acceptable sigma ranges, attention should be focused on tests with lower sigma values, such as Bilirubin Total, HDL-Cholesterol, and Triglycerides, to improve testing accuracy and consistency.

## V. CONLUSION

This study highlights the crucial role of quality control (QC) in clinical biochemical testing using the Six Sigma method. While some parameters, like ALT and URIC, meet international standards, others, such as Creatinine and Total Bilirubin, require QC improvements due to low accuracy. Data from internal (IQC) and external (EQC) quality control programs provide a comprehensive database, though some tests still show fluctuations. To enhance quality, laboratories must strengthen controls, train staff, and inspect equipment regularly. This study not only improves testing reliability but also promotes modern quality management, benefiting patient care.

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