SIX SIGMA FOR EVALUATION OF QUALITY CONTROL IN CLINICAL LABORATORY

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ABSTRACT

Background: Quality control in the haematology laboratory is intended to ensure reliable test results with the necessary degree of precision and accuracy. The purpose of the quality control system is to monitor analytic processes, detect analytic error during analysis, and prevent the reporting of incorrect patient value. Six Sigma is a widely-accepted quality management system with statistical method to find and eliminate defects and variation. The purpose of this research was to evaluate the analytical performance of our haematology parameters using sigma metric.

Materials and Methods: The study was conducted in Clinical Pathology Laboratory Airlangga Hospital. Internal quality control (IQC) data of 5 analytes were analyzed retrospectively over a period 2 month from December 2017 to January 2018 using Sysmex XT-1800i. The analytics assessed were red blood cell (RBC), haemoglobin (HGB), hematocrit (HCT), platelet (PLT) and white blood cell (WBC).

Result: The highest CV (%) value is 3.88 for PLT and the lowest value is 0.68 for HGB. The highest Bias % value is 2.67 for PLT and the lowest value is 0.70 for HGB and WBC. The highest sigma value is 9.30 for HGB, and the lowest sigma value is 5.52 for RBC. The criteria sigma value for haematology test is good to excellent to world class performance.

Conclusion: Sysmex XT 1800i assay for haematology is excellent ranging from 5 to > 6 sigma. Good sigma value, acceptable imprecision, the accuracy performance are suitable for routine examination.

Keywords: Six Sigma, imprecision, laboratory, quality control, haematology
1.0 Introduction

Clinical laboratories play an important role in helping to save lives. To achieve efficiency in patient care and improve patient wellbeing. One type of examination in laboratory is Haematology. Haematology is a purely laboratory endeavor concerned with quantitation of the formed elements of the blood and the study of their morphology and that of the bone marrow, spleen, and lymphoid tissues. Haematology is also seeking to understand the normal and pathologic physiology of the hematopoietic system, uses all the method of such diverse scientific disciplines as biochemistry, cell biology, genetics and nuclear medicine (Lee, Foerster, Lukens, Paraskevas, Greer, & Rodgers, 1999). Many laboratory now use automated technique. Automated techniques are more precise than manual or semi manual technique, but their accuracy depends on correct calibration and use of reagent the usually specific for the particular analyzer (Lewis, Bain, & Bates, 2006). However, All of the technique to examination should be done quality control.

Quality control in the haematology laboratory is intended to ensure reliable test results with the necessary degree of precission and accuracy (Lewis, Bain, & Bates, 2006). The purpose of the quality control system is to monitor analytic processes, detect analytic error during analysis, and prevent the reporting of incorrect patient value (Bishop, Fody, & Schoeff, 2005). The assumption is that any error should be evident in quality control sample analysis to the same extent as it is in patient sample (Kinns, Pitkin, Housley, & Freedman, 2013). The accuracy and thoroughness of the results of laboratory tests are very important for patients and doctors because ± 70% of medical measures to be performed are based on the results of laboratory tests Accurate laboratory result can prevent medical error incident. The errors can occur in any of step in a laboratory (Coskun, 2007). Study have estimated 7%-13% of error in the total testing process occur within the analytical phase (Elbireer A, Gable AR, & Jackson JB, 2010). Laboratory error is also an issue of patient safety; the joint commission have the identification of patient as their first international patient safety goal (IPSG) (Saleem & Surimi, 2016). For this reason quality management policy should be implemented not only as an analyitical requirement, but also as a standard part of patient care (Coskun, 2007).

Six Sigma is a widely-accepted quality management system, perhaps best known outside of healthcare as the product of innovation at General Electric and Motorola. Six Sigma is a metric that quantifies the performance of processes as a rate of Defects-Per-Million Opportunities, (DPM, or DPMO). Six Sigma programs also encompass robust techniques such as Define-Measure-Analyze- Improve-Control (DMAIC) and Root Cause analysis to find and eliminate defects and variation within a process. The goal of Six Sigma, in its simplest distillation, is to eliminate or reduce all variation in a process (Wesgard S., 2016).

The purpose of this research was to evaluate the analytical performance of our hematology parameters on sysmex XT 1800i using sigma metric.

2.0 Materials and Methods

The study was conducted in Clinical Pathology Laboratory Airlangga Hospital. Internal quality control (IQC) data of 5 analytes were analyzed retrospectively over a period 2 month from December 2018 to January 2018 using Sysmex XT-1800i. The analytes assessed were
red blood cell (RBC), haemoglobin (HGB), hematocrit (HCT), platelet (PLT) and white blood cell (WBC).

Quality control material normal was assayed before analysing of patient samples every day. Each quality control material were belong to saba diagnostic manufacture and QC value were based on the reference method. The instrument was calibrated and maintenance regularly. IQC data were obtained from internal quality control document laboratory. Faulty value arising from false control samples were excluded.

2.1 Imprecision

Imprecision (random error) is determined from a replication experiment during method validation studies or SQC data collected during routine operation. Labs perform replication experiments to verify precision and then monitor on going performance from SQC data collected under conditions of routine operation (Wesgard & Wesgard, 2006). Imprecision, expressed as coefficient of variation (%CV) was determined from the calculated mean and standard deviation evaluated from internal quality control (IQC) data. CV is the ratio of the SD which is obtained from a data set to the mean and it is expressed as a percentage of variance to the mean

\[ CV(\%) = \left( \frac{SD}{mean} \right) \times 100 \]

2.2 Bias

Bias was calculated as the percentage difference of the average of observed results for each analyte from the target values provided in the control package inserts. Percent bias values of each test were calculated separately between December 2017-January 2018. This can be summarised by the following formula:

\[ \%Bias = \left( \frac{our \ laboratory \ mean \ of \ IQC \ data - target \ mean \ of \ IQC \ data}{target \ mean \ of \ IQC \ data} \right) \times 100 \]

2.3 Total Allowable Error

Total allowable error: It is the total allowable difference from accepted reference value seen in the deviation of single measurement from the target value. TEa values of various parameters were taken from Clinical Laboratories Improvement Act (CLIA) guidelines.

2.4 Sigma

Sigma (s) value was used in order to determine the analytical performance characteristics of sigma value tests by using CV (obtained from IQC data), Bias% and TEa values. Sigma value calculated using the standard equation:

\[ \text{Sigma} (\sigma) = \left( \frac{TEa-Bias}{CV} \right) \]

High sigma values means low analytical errors and acceptable test results. Low sigma metric value is accepted as an error or a defect (Nar1 & Emekli, 2017). Sigma values were used to determine the analytical performance characteristics of the test. A sigma level <3 is an
indication of a poor performance procedure, sigma level 3 - 4 is an indication marginal performance, sigma level 4 – 6 is an indication good to excellent performance. Above six sigma level is a world class performance (Wesgard & Mirlohi, 2015).

3.0 Result

3.1 Mean, SD, CV and Sigma Value

Internal quality control (IQC) data of 5 analytes were analyzed retrospectively over a period of 2 months from December 2017 - January 2018 used 40 quality control data result with Sysmex 1800i. We have calculated the mean, SD, % CV, bias, and sigma values for all the 5 analytes. Results are given in the table 1

Table 1: Tea, Target, Mean, Bias and Sigma Value of Each Test

<table>
<thead>
<tr>
<th>NO</th>
<th>PARAMETER</th>
<th>PERFORMANCE QUALITY CONTROL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TARGET</td>
</tr>
<tr>
<td>1</td>
<td>HGB</td>
<td>12,5</td>
</tr>
<tr>
<td>2</td>
<td>WBC</td>
<td>7,07</td>
</tr>
<tr>
<td>3</td>
<td>RBC</td>
<td>4,39</td>
</tr>
<tr>
<td>4</td>
<td>HCT</td>
<td>36,7</td>
</tr>
<tr>
<td>5</td>
<td>PLT</td>
<td>227</td>
</tr>
</tbody>
</table>

Based on table 1 we can see the highest CV (%) value is 3,88 for PLT and the lowest value is 0,68 for HGB. The highest Bias % value is 2,67 for PLT and the lowest value is 0,70 for HGB and WBC. Desirables CV (%) and Bias (%) based on J.Y.Vis & A.Huisman (2016), the CV (%) value for PLT is higher than desirable CV (%) value from literature but the other test is lower than the desirable CV (%) value from literature. Bias (%) value is lower than the desirable bias (%) for all the test in this research.

3.2 Sigma Value Distribution of Internal Quality Control

Result of sigma value of each test can be seen in table 2

Table 2. Sigma Value Distribution of Internal Quality Control

<table>
<thead>
<tr>
<th>NO</th>
<th>PARAMETER</th>
<th>PERFORMANCE QUALITY CONTROL</th>
<th>NOTE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>% CV</td>
<td>% Bias</td>
</tr>
<tr>
<td>1</td>
<td>HGB</td>
<td>0,68</td>
<td>0,70</td>
</tr>
<tr>
<td>2</td>
<td>WBC</td>
<td>2,48</td>
<td>0,70</td>
</tr>
<tr>
<td>3</td>
<td>RBC</td>
<td>0,83</td>
<td>1,44</td>
</tr>
<tr>
<td>4</td>
<td>HCT</td>
<td>0,97</td>
<td>0,31</td>
</tr>
<tr>
<td>5</td>
<td>PLT</td>
<td>3,88</td>
<td>2,67</td>
</tr>
</tbody>
</table>
Based on table 1 we can see the highest sigma value is 9.30 for HGB, and the lowest sigma value is 5.52 for RBC. The criteria sigma value for haematology test is good to excellent to world class performance. The quality of laboratory performance is good and feasible to be used in routine inspections.

**4.0 Discussion**

Quality control in the clinical laboratory refers to the process of detecting analytical errors within the laboratory, evaluate and correct errors due to test system failure, environmental conditions, or operator performance, before patient results are reported to ensure both the reliability and accuracy of test results in order (WHO, 2011).

In order to evaluate the imprecision and accuracy of laboratory tests in clinical laboratories, internal and external quality controls were studied at different levels. Westgard rules are followed during the evaluation of internal quality. Quality control materials are used to follow the performance of analytical methods. The Six-Sigma Method is one of the important quality control analyses which are used in the evaluation of quality and performance and, it is based on statistical calculations.

Based on the result study the perform imprecision (CV%) value of hematology quality control in clinical laboratory, the imprecision value several test higher than the same research by wesgard (2009) for WBC, RBC, HCT and PLT. The high imprecision is a function of an unstable analytical process with wide fluctuations around the true concentration of the analytes (Afrifa, et al., 2015). Precision is closeness of agreement between independent, repeated results obtained from the same sample under specific conditions. Lesser the CV, better is the precision. This suggests that precision is low for above mentioned parameters (Adiga, A. Preethika, & K. Swathi, 2015). Imprecision (random error) is associated with the fact that when a measurement is repeated it will generally provide a measured quantity value that is different from the previous value. It is random in that the next measured quantity value cannot be predicted exactly from previous such value. If a prediction were possible, allowance for the effect could be made. In general there can be number of contributions to each type of error (JCGM, 2009).

Bias result for WBC is higher than the same research by wesgard (2009). Bias is the difference between the measured result and actual value. It is used to describe the inaccuracy of the method. Lower the bias more is the accuracy. Inaccuracy was considered to be the measure for systemic analytical error (Afrifa, et al., 2015). Systematic analytical error is associated with the fact that a measured quality value contain an offset (JCGM, 2009).

The Six-Sigma scale is generally evaluated between 0 and 6, and it may exceed the 6 Sigma value in case of low variability. 3 Sigma is acceptable for a process and it is evaluated as minimum performance. If the performance is below 3 Sigma, the process is evaluated as unstable and unacceptable. In this study, the sigma value > 3 for all test. The sigma value can be used as a guide for developing a QC strategy. If the result obtained high sigma value, the laboratory will be easier to make QC strategy. QC design and frequency of QC strategy is
Parameter with >6σ (world class performance) for HGB, evaluate with one QC per day (alternating levels between days) and a 1:3.5 s rule. Parameter RBC, PLT, HCT and WBC with 4σ–6σ (good to excellent performance), evaluate with two levels of QC per day and the 1:2.5 s rule. If there are obtained parameter with 3σ–4σ (marginal performance), use a combination of rules with two levels (“Westgard Rules”) of QC twice per day. If an upgrade analyzer is needed and better method selection may be considered to increase the sigma value. Using sigma metrics for QC design should be modulated with other considerations like: a) risk assessment, b) clinical utility, c) number of tests performed (volume), d) level of education of staff performing the test, and f) external minimal legal requirement (Cooper, et al., 2011)

5.0 Conclusion and recommendation

In conclusion, the sysmex XT 1800i assay for haematology is excellent ranging from 5 to > 6 sigma. Good sigma value, acceptable imprecision, the accuracy performance are suitable for routine examination.

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Declaration

Author(s) declare that there is no conflict of interest regarding publication of this article

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