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# Six Sigma for Performance Analysis of Quality Control in Laboratory

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**Abstract-**The accuracy and thoroughness of the results of laboratory tests is very important for patients and doctors because ± 70% of medical measures to be performed are based on the results of laboratory tests. Six sigma is one method that can be used to assess the quality of laboratory examination results. The purpose of this research is to analyze the clinical chemistry parameter performance by using sigma and to arrange control strategy plan at clinical chemicals cobas C 311 in Clinical Pathology Laboratory of Airlangga Hospital. This research is a retrospective observational study. Primary data were obtained from internal quality control documents in January and February 2018. The control materials used were precicontrol clin-chem multi 1 which was done using the Cobas C311 tool. The parameters were evaluated by SGOT, SGPT, ALB, BUN, CREAT, UA, GLU, CHOL, TRIG, HDL and LDL. The results of the examination were calculated of imprecise value (CV) inoculation (Bias) and sigma value. The highest Bias value is HDL and the lowest is CHOL. The highest CV value is UREUM and the lowest is LDL. The average sigma value of the parameter examined is 4-6 sigma (good to excellent performance). The highest sigma value is in the parameter SGOT, SGPT, HDL and LDL. They have sigma value > 6 (world class performance). The lowest sigma value is performing at UREUM obtained one sigma value (poor performance).The mean of sigma value at parameter which assessed is 4-6 sigma (good to excellent performance) ALB, CREAT, UA, GLU, CHOL and TRIG its meaning that the clinical chemistry is suitable for routine examination. Parameters that have poor performance should be fixed.

**Index Terms-**six sigma, clinical chemistry, laboratory

## 1. INTRODUCTION

Clinical laboratories are particularly important because physicians make their decision mostly in accordance with laboratory result[6]. The accuracy and thoroughness of the results of laboratory tests is very important for patients and doctors, because ± 70% of medical measures to be performed are based on the results of laboratory tests[4]. In this context, accurate test results are crucial for physicians and their patients. First, the laboratory must be able to produce an accurate result before any other dimension of quality becomes importance. From the point of view, the evaluation of laboratory performance is critical to maintaining accurate laboratory result[3]. Accurate laboratory result can be prevent medical error incident. The errors can occur in any of step in laboratory. To overcome the serious errors originating in clinical laboratories, a new perspective and approach seem to be essential. All laboratory procedures are prone to error because in many test, the rate human intervention in higher than expected. It appears that the best solution for analyzing problem in clinical laboratory is the application of Six Sigma[1]. Six Sigma is a disciplined quality improvement methodology that focuses on moving every process that touches the customers every product and service towards near perfect quality [10].

Clinical chemistry is a much demanded examination by clinician Clinical chemistry is a diagnostic method which tests for various components of blood and urine and enables healthcare professionals to overview significance of abnormal values. Typical clinical chemistry tests may include for blood glucose (testing for the risk for diabetes or hypoglycemia), electrolytes (e.g. indication of certain metabolic and kidney disorders), enzymes (assessment of specific organ function or damage), hormones (gland function check), lipids (evaluation of heart and liver disease), other metabolic substances, and proteins (e.g. assessment of metabolic or nutritional disorder). Aim of the study was to study sigma metrics of clinical chemistry parameters and plan the quality control strategy.

## 2. RESEARCH METHOD

The study was conducted in the clinical Pathology laboratory of Airlangga Hospital Indonesia. We analyzer sigma metrics of 11 parameters with automated chemistry analyzer, Cobas C 311 in Clinical Pathology Laboratory of Airlangga Hospital. Internal quality control (IQC) data of 11 parameter were analyzed retrospectively over a period of 2 months from January to February 2018used 40 quality control data result with Cobas C 311. Quality control material precicontrol clin-chem multi 1 were assayed before commencing reporting of patient samples every day. The instruments were calibrated regularly. The

parameter assessed were glucose, urea, creatinin, uric acid, albumin, SGOT, SGPT, ALP, Total cholesterol, triglycerides, LDL and HDL.

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 [11].

Bias: Bias is the systematic difference between the expected results obtained by the laboratory's test method and the results that would be obtained from an accepted reference method. Bias was derived as follows:

$$\text{Bias (\%)} = \frac{\text{Mean of all laboratories using- our mean}}{\text{Mean of all laboratory using same instrument and method}} \times 100$$

CV% is the analytical coefficient of variation of the test method. Coefficient of variance (CV) were calculated as follows. CV (%) = (SD x 100)/ mean Sigma metrics were calculated from CV, percentage bias and total allowable error for the parameters by the following formula: $\Sigma\,(\sigma) = (\text{TEa- bias})\,/\text{CV\%}$

## 3. RESULT AND DISCUSSION

Internal quality control (IQC) data of 11 parameters were analyzed retrospectively over a period of 2 months from January to February 2018 used 40 quality control data result with Cobas C 311. We have calculated mean, SD, CV%, bias, TEa and sigma values for all the 11 parameters. Results are given in the following tabulated columns.

**Table 1.** Result of mean, SD, CV%, bias, TEa and sigma values for 11 parameters

| Parameter | Bias | CV% | Sigma | TEa | Keterangan |
|---|---|---|---|---|---|
| SGOT | 3 | 2,2 | 7,53 | 20 | world class performance |
| SGPT | 2,95 | 2,26 | 7,55 | 20 | world class performance |
| ALB | 0,98 | 1,97 | 4,58 | 10 | good to excellent performance |
| UREUM | 3,25 | 4,58 | 1,26 | 9 | poor performance |
| CREAT | 2,43 | 2,2 | 5,72 | 15 | good to excellent performance |
| UA | 1,94 | 2,82 | 5,34 | 17 | good to excellent performance |
| GLU | 2,30 | 1,76 | 4,37 | 10 | good to excellent performance |
| CHOL | 0,77 | 2,06 | 4,47 | 10 | good to excellent performance |
| TRIG | 5,3 | 3,95 | 4,98 | 25 | good to excellent performance |
| HDL | 6,99 | 1,85 | 12,43 | 30 | world class performance |
| LDL | 2,52 | 1,53 | 6,18 | 12 | world class performance |

The result Table 1 showed that the highest bias value is HDL and the lowest is CHOL. 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. This suggests the chances of inaccuracy in the methods for measurement of above mentioned parameters which need evaluation.

The reasons for bias in clinical chemistry are numerous, varying in importance between measurement methods, for example: Instability of the sample during transport or storage, for example, during transport in extremes of heat and cold, and mechanical effects on cells and blood gases when transporting samples through pneumatic tubes in hospital transport systems, Uncorrected loss of measured at extraction, for example, when preparing samples for measurement using high-performance liquid chromatography or mass-spectrometry, errors when the calibrator is prepared, including errors in volume measurements or in weighing of calibrators in the laboratory, using sample matrix that differs from the matrix in the samples, for example, using de-fatted and lyophilized stable materials for internal quality control or proficiency testing programs, Interferences in the samples, for example, the color of hemoglobin and bilirubin in hemolytic and icteric samples, or the presence of high concentrations of proteins or lipids in the sample (myeloma or hyperlipidemia)[9].

Table 1 also showed that highest CV value is UREUM and the lowest is LDL. CV is correlated to precision. 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[1].

Measurement of laboratory analytical errors fall into two main categories, systematic error and random error. Systematic errors are predictable problems influencing observations consistently in one direction, while random errors are more unpredictable. Systematic errors are assessed by the bias, while random errors by the imprecision measured by the coefficient of variation (CV). Imprecision affects the reproducibility and repeatability of results. Reproducibility is the closeness of the results of successive measurements under changed conditions which require multi centre trials. Repeatability is the closeness of the results of at least twenty successive measurements under similar conditions. Bias is the average deviation from a true value with minimal contribution of imprecision while inaccuracy is the deviation of a single measurement from the true value with significant contribution by imprecision. Multiple measurements, at least twenty and preferably forty, are therefore required for calculating imprecision as well as bias [8].

The result Table 1 showed that the average sigma value of the parameter examined is 4-6 sigma (good to excellent performance). The highest sigma value is in the parameter SGOT, SGPT, HDL and LDL. They have sigma value > 6 (world class performance). The lowest sigma value is performing at UREUM obtained one sigma value (poor performance). This indicates that the quality of laboratory results is good and feasible to be used in routine inspections.

In this research, sigma value for SGOT (7,53), SGPT (7,55), ALB (4,53), CREAT (5,72), CHOL (4,47), HDL (12,43), LDL (6,18) is higher than higher the research conducted by Dewi (2015) SGOT (5,5), SGPT (2,2), ALB (2,3), CREAT (5,72), CHOL (2,5), HDL (5,1), LDL (4,8). But the other parameter in this research have lower sigma value TRIG (4,98)GLU (4,37), UA (5,34) than other research conducted by Dewi (2015) TRIG (7), GLU (4,6) UA (5,5). And sigma value for UREUM (1,2) similar with research conducted by Dewi (2015).

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) SGOT, SGPT, HDL and LDL, evaluate with one QC per day (alternating levels between days) and a 1:3.5 s rule. Parameter ALB, CREAT, UA, GLU, CHOL and TRIG 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. Parameter UREUM with <3σ (poor performance), maximum QC, three levels, three times a day. Consider testing specimens in duplicate[2]. Parameters with sigma values <3 should not be used for routine checks before their performance increases, since the sigma value <3 is not suitable for routine checking [5]. If an upgrade analyzer is needed and better method selection may be considered to increase the sigma value[7].

## CONCLUSSION

The mean of sigma value at parameter which assessed is 4-6 sigma (good to excellent performance) ALB, CREAT, UA, GLU, CHOL and TRIG its meaning that the clinical chemistry is suitable for routine examination. Parameters that have poor performance should be fixed.

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