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Evaluation of Quality Control in Clinical Hematology laboratory by using Six- Sigma

[1]Renuka Bangalore Nagaraj, [2]Md Khursid Alam Ansari, [3]Dr Shivanna [4]Basavarajaiah Doddagangavadi Mariyappa

[1]Pathologist, National Institute of Unani Medicine, Bangalore, India,[2]PG Scholar, Department of Pathology, National Institute of Unani Medicine, Bangalore, India, [3]Department of Paediatrics , Bowring and Lady Curzon Hospital, Bengaluru, [4] Department of Statistics, Computer Science, KVAFSU(B),Hebbal, Bengaluru
Corresponding Author: Renuka Bangalore Nagaraj**,** National Institute of Unani Medicine, Bangalore, India

Abstract

Background

Clinical laboratories' unreliable and false results have serious implications for patients. Sigma metrics is a standardized tool for assessing the quality of test results in a laboratory. The goal of quality control in the hematology laboratory is to ensure that reliable test findings are produced with the required precision and accuracy. The quality control system's aims to keep record and track the analytic processes, we discover the analytic errors during the process of analysis, and prevent inaccurate patient values are being reported. Six σ is a well-known quality management approach that employs statistical tool or methods to identify to remove flaws and variations of observations .In this proximity of the research gap, the present study was undertaken to evaluate the quality of the analytical performance of clinical hematology well on laboratories by calculating sigma metrics.

Material and Method

The study was conducted at Clinical Pathology Laboratory, National Institute of Unani Medicine Hospital, Bangalore. Internal quality control (IQC) datasets of 5 analytes were analyzed retrospectively in 2 months from January 2021 to February 2021 by using Councell V3 plus Auto HematologyAnalyzer. The analytics were assessed for red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), platelet (PLT) and white blood cell (WBC) etc.

Results

Thehighest co efficient of variation (CV %) percentage value was 8.7% for platelet and the lowest was 1.06% in HB. The highest Bias percentage value is 6.5% in HB and the lowest <1 % for WBC. In case of IQC, HB, WBC, RBC, HCT, PLT the criteria sigma value for world class performance was seen in HB &HCT, good to excellent performance on RBC &WBC ,poor performance for PLT.

Conclusion

The Councell V_3 plus Auto hematology assay would be excellent, with a expressive range of 5 to > 6 sigma values. The accuracy performance is more suitable for routine examination of research intervention, because its accuracy and reproducibility, the imprecision is acceptable level. However, the

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low sigma expression is an indication for Vigorous monitoring and CAPA will be implemented by advice.

Keywords: IQC, analytical errors, hematological parameters, Six sigma

Introduction

The clinical laboratories serve as critical role in helping and saving the lives of patients and also to increase patient well-being and efficiency of inpatient care. The right tests must be chosen, and the test results will be trustworthy and we can appropriately interpretedthe results to enhance efficiency in patient care and improve patient wellbeing. As a result, quality management policies should be applied as a routine aspect of patient care, not just as an analytical needs.[1] Hematology is one sort of laboratory investigations.Moreover,the study of morphology of the produced constituents of the blood, as well as the morphology of the bone marrow, spleen, and lymphoid organs is the only focus of hematology.[2]Laboratory errors have a major impact on patient care quality.[3]Previous Studies have found that there is a 2.7%–13% chance of an adverse event occurring as a result of a laboratory errors.[4]An automated techniques are being used in many laboratories ref., techniques are more exact than manual or semi-automated approaches, but their precision is dependent on the proper calibration and the use of reagents that are usually unique to the analyzer.[5] However, the quality control should be applied to all examination techniques.[2]Autovalidation and auto reporting are becoming increasingly important.[6] The laboratory's ultimate evaluation will be based on its quality. Advanced, beautiful software should be used to help with quality.[7] The selection of appropriate IQC material is critical to the success of a quality control method ref. First, to minimize matrix effects on analyte measurement, IQC material should strongly matched the makeup of patient samples.[4]3-Sigma performance is considered the minimum in any industrial process. The typical performance of a business or industry process is considered to be around 4-Sigma. The first goal of a Six Sigma project in business and industry is usually to improve from 4-Sigma to 5-Sigma. This is a very significant improvement: a 100-fold reduction in defects in the short term. Some processes never reach 6-Sigma. But reaching 5-Sigma may be good enough. A sigma score of six indicates that the assay performance is optimal and thus efforts to further improvement in the quality are unwarranted. In some cases, the process can be re-engineered to achieve 6-Sigma performance.[4,8]Six sigma provides an easy way to talk about different process by using a common mathematical framework.[9]In this propinquity of the research gap, the present study aims to correlate the sigma metrics of clinical chemistry analytes and plan the quality control strategy. Further , we determine the total permissible error in clinical laboratory and correlate the findings by the use of CLIA guidelines(thereby evaluate the functioning of the instrument as well as the adequacy of the methodology being followed).

Material and Methods:

The study was conducted in the Clinical Pathology Laboratory National Institute of Unani Medicine. Internal quality control (IQC) data of 5 analytes were analyzed retrospectively over a period of 2 months from January 2021 to February 2021 using Councell V_3 plus Haematologyanalyser. The analytes assessed were red blood cell (RBC), hemoglobin (HGB), hematocrit (HCT), platelet (PLT), and white blood cell (WBC). Quality control material normal was assayed before analyzing of patient samples every day. E-check quality control material was belonging to R&D systems (CBC-3D) and QC values were obtained based on the standard reference method. The instrument was calibrated and maintained regularly. IQC datasets were obtained from the internal quality control document laboratory. If falsible values arising from the sample of control , that values were eliminated.

Imprecision

Imprecision (random error) is determined from a replication experiment during method of validation studies or SQC data was collected during the process of routine operation. The Labs performed replication experiments verified, the precision was cross checked and then monitor ongoing performance from SQC data collected under the conditions of routine operation (Wesgard & Wesgard, 2006). An imprecision expressed values was modeled as coefficient of variation (%CV) , it was determined from the calculated mean and standard deviation evaluated from the internal quality control (IQC) data. The CV is the ratio was calculated from the ratio of numerator value SD to the actual mean obtained from the data set.

CV (%) = (SD/mean) x 100

Bias

Bias was calculated as the percentage difference of the average of observed results on each analytes from the target values which was provided from the control package inserts. Percent bias values in each tests were determined separately between January 2021-February 2021.This can be summarized by the following formula

% bias = [(our laboratory mean of IQC data-target mean of IQC data)/target mean of IQC data] ×100.

Total Allowable Error

In 1974, Westgard was the first to propose the concept of total error (TE). A single measure of the uncertainty of a test result was created by combining analytical imprecision and bias i.e., systematic error (SE).[10]Total allowable error is the total allowable difference from the accepted reference value seen in the deviation of a single measurement from the target value. TEa values of various parameters were taken from Clinical Laboratories Improvement Act (CLIA) guidelines.

TEa observed in this assay was calculated using the formula -

TEa observed = bias + % CV* 2. Thus, observed TEa was compared with CLIA guidelines.

Sigma

Sigma (s) value was used to determine the analytical performance characteristics of sigma value tested by using CV (obtained from IQC data), Bias%, and TEa values. Sigma value is calculated using the standard equation: Sigma (σ)= (TEa-Bias) / CV .A sigma score of 6 indicates that ,the assay's performance is ideal and made further efforts to improve quality Assays with a sigma value of 4–6 are considered adequate their intended purpose, while those with a sigma score of 3–4 are considered unsatisfactory. For an assay with a sigma metric of less than 3, no amount of IQC provided appropriate error detection rates, hence efforts should be focused on enhancing the test's quality. We should improve the precision of the assay, duplicate or triplicate analysis may be used.[4]

Results

Descriptive statistics like mean, SD, CV, and Sigma Value Internal quality control (IQC) data of 5 analytes were analyzed retrospectively in 2 months, January and February 2021 by using quality control data result with Councell V3plus hematology Analyser. The mean, SD, CV (%), bias, and sigma values for all 5 analytes were calculated. Results are presented in the table matrics

Table 1. Descriptive statistics of PQC –January 2021

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Performance Quality Control for month of January 2021							
Parameter	Target value	Mean	SD%	CV%	Bias%	TEa	Six sigma
HB	13.8	12.9	0.13	1.06	6.5	7.0	4.7
WBC	8.04	8.19	199	2.43	1.8	15.0	5.4
RBC	4.71	4.5	0.05	1.1	4.4	6	1.4
HCT	40.3	42.2	0.7	1.75	4.7	6	7.4
PLT	258	3.72	0.3	8.7	4.4	25.0	2.8

Table 2.Descriptive statistics of PQC –February 2021

Performance Quality Control for month of February 2021							
Parameter	Target	Mean	SD%	CV%	Bias%	TEa	Six sigma
HB	13.8	13.2	0.46	3.5	4.3	7.0	10
WBC	8.04	7.5	113	15.1	6.7	15.0	5.4
RBC	4.71	4.7	0.08	1.8	2.0	6	3.3
HCT	40.3	44.0	0.96	2.1	9.1	6	2.7
PLT	2.58	2.6	0.35	13.5	7.0	25	1.8

Table 3: Six sigma distribution and Internal Quality Control

Parameter	Performance quality control for month of January 2021				
	Cv%	%Bias	%TEa	Sigma	Note
HB	1.06	6.5	7.0	4.7	Good to Excellent performance
WBC	2.43	1.8	15.0	5.4	Good to Excellent performance
RBC	1.1	4.4	6	1.4	Poor performance
HCT	1.75	4.7	6	7.4	Good to Excellent Performance
PLT	8.7	4.4	25	2.8	Poor performance

Table 4 Performance quality control for month February 2021

Parameter	Performance quality control for month February 2021				
	Cv%	%Bias	%TEa	Sigma	Interpretation
HB	3.5	4.3	7.0	10	Good to Exellent performance
WBC	15.1	6.7	15.0	5.4	Good to Exellent performance
RBC	1.8	2.0	6	3.3	Good to Exellent performance
HCT	2.1	9.1	6	2.7	Poor Performance
PLT	13.5	7.0	25	1.8	Poor performance

A sigma level<3 is an indication of a poor performance procedure, sigma level 3- 4 is an indication of marginal performance, sigma level 4 – 6 is an indication good to excellent performance and above six sigma level is a world-class performance.[8]

Discussion

QC is used to evaluate the examination (analytic) phase of testing as part of the quality management system. Before patient results are presented, the purpose of QC is to detect, assess, and fix errors caused by test system malfunction, environmental circumstances, or operator performance etc.[11]Internal and external quality controls are investigated at various levels to determine the precision and accuracy of laboratory tests of clinical laboratories. When evaluating internal quality, Westgard standards are applied. Analytical procedures' performance is monitored using quality control materials.[2]The role of quality control in clinical laboratories is well-established.[12] IQC practice, on the other hand, differs greatly between laboratories. Standardization of procedures to IQC material selection, target and range assignment, statistical rule application, IQC review, and troubleshooting will improve the quality of results and ease pathology service standardization.[4]The analytical phase accounts for 7%–13% of all errors in the entire testing process. Internal quality control (IQC) procedures are critical for discovering errors in the analytical phase and thereby enhancing patient care quality.[13] Commutability, appropriateness of analyte concentration, stability, and vial-to-vial variability should all be considered when choosing an IQC material. Ideal QC material should have long stability and matrix same as patient sample.[14]Target values and ranges should be assigned locally. Material for IQC should come from a third-party source and not be the same as that utilized for calibration. IQC samples should be treated in the same way as patient samples are.[4]The sigma values <3 i.e. for PLT, HCT, Upgraded analyzers and better methodologies may help in achieving sigma values. This was in comparison with the other studies done by Usha Adiga et.al where the sigma score was very less for few parameters. For less than 3 sigma, method performance must be improved before the method can be used for routine production. For less than 3 sigma, method performance must be improved before the method can be used for routine production. A method with a sigma of less than 3 necessitates method modification as the test's quality improves even after multiple QC runs, assurance cannot be guaranteed. As a result, sigma metrics values can be useful in a variety of situations establishing internal quality control acceptance criteria.[15] The six sigma scale is evaluated between 0-6 and may exceed more than 6 in case of low variability. In the result obtained from the observation study the parameter HB, WBC, RBC are showing Good to excellent performance, hence two levels of QC per day has been run following 1;2.5s rule. HCT has marginal performance use of a combination of rules with two levels (Westgard rules)of QC twice per day has been run, however, PLT has poor performance as per six sigma, hence low six sigma calls for more vigorous monitoring and CAPA.[8] According to Cooper et al, 3s (problems) – should be corrected with maximum QC, which is run three levels, three times a day and consider testing specimens in duplicate. 3s–4s (poor performers) should use a combination of rules with two levels of QC twice per day. 4s–6s (suited for purpose) should be evaluated with two levels of QC per day and the 1:2.5 s rule. 6s (excellent tests) should be evaluated with one QC per day (alternating levels between days) and follow 1:3.5 s rule.[3]

Conclusion

Grading laboratory errors according to their severity should aid in identifying quality improvement priorities and encourage a focus on corrective/preventive efforts. It's crucial to examine, not only the actual patient injury but also the worst-case scenario if an error happens. Sigma metrics help us to assess analytical methodologies and augment laboratory performance. It acts as a guide for planning a quality control strategy. It can be a self-assessment tool regarding the functioning of a clinical laboratory. specialists

Limitations of the study

This is only a pilot project we can understand the significance of the six Sigma metrics application for total quality management of the laboratory. Further, this studies involving a wide range of parameters over an extended period which is being recommended for a significant conclusion.

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