Study of Quality Control in Clinical Hematology Laboratory by Using Six-Sigma in a Medical College &Tertiary Care Center

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ABSTRACT:

Background: Clinical laboratories' unpredictable and counterfeit results have grave 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 make sure that reliable test findings are created with the vital precision and accuracy. The quality control system aims to keep record and track the analytic processes, identify investigative errors during the process of analysis, and prevent inaccurate patient values. Six σ is a distinguished quality management approach that employs statistical tool or methods to identify removable flaws and variations of observations .In this immediacy of the research gap, the study was undertaken to evaluate the quality of the analytical performance of clinical hematology in laboratories by calculating sigma metrics.

Materials & Methods: The study was conducted at Central Clinical Laboratory, NKP SIMS RC & LMH Nagpur. Internal quality control (IQC) datasets of 5 analytes were analyzed retrospectively in 2 months from May 2023 to June 2023 by using Advia -2120 - 5 Part Cell Counter. The analytics were assessed for red blood cell (RBC), hemoglobin (Hb), hematocrit (HCT), platelet (PLT) and white blood cell (WBC) etc.

Results: The highest coefficient of variation percentage (CV %) value was 8.7% for platelet and the lowest was 0.93 % for Hb. The highest Bias percentage value was 6.5% in Hb and the lowest was 1.70 % 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 in RBC &WBC, poor performance for PLT.

Conclusion: The Advia -2120 - 5 Part Cell Counter would be excellent, with an expressive range of 5 to > 6 sigma values. The accuracy performance is more suitable for routine examination of research intervention, because of its accuracy and reproducibility, the imprecision is within acceptable levels. However, the low sigma expression is an indication for Vigorous monitoring and Corrective and Preventive Action (CAPA) will be implemented by advice.

KEY WORDS: IQC, analytical errors, hematological parameters, six sigma