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Determination and Evaluation of Quality Control Processes Using Six Sigma Metrics on Major Tests at Mzimba South District Medical Laboratory, Malawi

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Abstract: *This observational study on retrospective and prospective data for 35 months examined whether the laboratory department at Mzimba district hospital ensures a total quality management across all its processes is achieved using the sigma-metric. Bias and bias percentage were calculated using true values collected from external quality assurance results and package inserts. Total allowable errors for each parameter were extracted from the Clinical Laboratory Improvement Amendment (CLIA), with the Coefficient variations extracted from past statistical control values of the same lot numbers and external quality assurance results. Six sigma metrics formula was used for metrics calculation of all 23 parameters for this entire medical laboratory department. All 23 EQC parameters had less than 5 sigma metrics at p value of 0.0000. White blood count (WBC), Mean cell haemoglobin concentration (MCHC), and platelet (PLT) had sigma metrics between 4-5. Red blood cells (RBC), hematocrit (HCT), Mean cell volume (MCV), and haemoglobin (HGB) had sigma metrics < 3. Alkaline phosphatase (ALP), total protein (TP) had sigma between 1-3. Albumin (ALB), total bilirubin (BIL T), direct bilirubin (BIL D), alanine aminotransferase (ALT), aspartate transaminases (AST), Gamma Glutamyl Transaminase (GGT), creatinine (CR) and UREA had sigma metrics less than 3. Low and High parameters for both Viral load and SARS-Cov-2 scored less than 1 sigma metrics. On comparisons between years none of the parameters performed satisfactorily. There is a need to meet high class performance on quality control processes across all quality management system essentials.*

Keywords: *Bias, Total allowable error, Six sigma, Coefficient of variation, True value, Quality control*

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1. Introduction

Hospital based laboratories aim to release results that are timely, accurate, and reproducible as physicians use such evidence for diagnosis, monitoring and prognostic purposes (Shiferaw, Yimsaw & Magnitude (2019). To produce such results with minimal to no errors, hospital laboratories monitor and evaluate their analytical processes by employing several quality control processes at different levels of an analytical process (Hawkins, 2012, Yeste & Liboria, 2021 and Teshome, Worede & Asmelash, 2021).

According to Michel (2013), Quality Control (QC) is an overall system of activities whose rationale is to maintain the quality of reagents, analyzers and environmental conditions. To have value for clinical decision points, an individual laboratory test result must have total error small enough to reflect the biological condition being assessed. Quality control numbers and how often QCs are run differ from laboratory to laboratory. Two level controls should be run either at 8 or 24 hours interval depending on differences in workload (Shah, Saini & Singh 2014 and Van Heeden, George & Khoza, 2022)

An observation by Sharma, Datta and Sharma (2020) shows that sigma metrics is a measurement tool that seeks to upgrade the quality of process outcomes by pointing and removing the causes of defects and or error and reducing variability in health service care, manufacturing and business processes. It is recommended that six sigma metrics be applied in all segments of the laboratory process to gauge performance phases. Sigma metrics can be used to predict assay quality, allowing easy comparison of instrument quality and predicting which tests will require minimal QC rules to monitor the performance of the method. A Six Sigma QC program can result in fewer controls and fewer QC failures for methods with a sigma metric of 5 or better. The higher the number of methods with a sigma metric of 5 or better, the lower the costs for reagents, supplies (Westgard, Bayat & Westgard, 2018) and the lower the control of material required to monitor the performance of the methods (Pulakanam, 2012; Cian, et al, 2014 and Listen, 2017).

Sigma metrics help to evaluate laboratory performance in process control systems determined to be suitable if it performs according to international standards. Data obtained may act as guidelines for QC strategy and plan their QC frequency accordingly (Adiga, Preethika & Swathi, 2015). Using six sigma metrics may also allow comparison of different processes with each other using retrospective data and thus improving quality (Ciulla, et al, 2018; Kam et al, 2021 and Kashyap et al, 2021).

Almost 98 percent of review articles on six sigma metrics had results for individual departments such as chemistry or haematology (Vijatha & Desai, 2018). According to National Laboratory Policy 2017, Malawi Government introduced quality laboratory services by fully participating in Quality Management Systems through certification and accreditation since 2012. This policy was applied to each individual district laboratory testing all major tests such as full blood count, renal function, Liver function, Covid-19 and Viral load. These of course are different scopes, but in Malawi these tests are conducted under one roof. However. Since 2012, less than 1 percent (1%) of district laboratories have achieved international accreditation.

In this study, a high class six sigma metrics performance tool was used to calculate and evaluate external quality control (EQC) of the major tests if they were meeting international standards. It was also explored to determine if the tool could be applied to detect the degree of error at real time testing and correct it instantly rather than waiting for internal and external audits.

2. Literature Review

The Six sigma, an adopted strategy that originated from motor manufacturing industries, aims to provide an objective assessment of process performance, and quantifies the performance thus risk of an analytical test process. It improves operations and reduces organizational defects thereby increasing profitability and customer satisfaction (ref). In the successful measurement of success using Six Sigma, there is need to select and track right metrics that align with institutional goals, process and customer needs. Six Sigma projects follow the DMAIC method, thus define, measure, analyse, improve and control in which metrics are integral to measure and analyse phases of the methodology. Essentially Six Sigma metrics includes the Defects Per Million Opportunities (DPMO), that is used as a long term measure of process performance; The First Time Yield (FTY), a process oriented method that measures the effectiveness and efficiency of a process; the Rolled Throughput Yield (RTY), that quantifies a process of or products' overall quality; the Process Capability Indices (Cp and Cpk) that gauges whether customer specification are being met; The Sigma level, a statistical term of Standard Deviation (SD), an absolute measure of variation in data and the Cost of Poor Quality (COPQ), that measures the financial losses incurred in a process.

Healthcare as a service sector for the provision of medical aid needs rigorous upgrade of its efficiency and productivity. In its adoption to the health care, Rathi et al (2021) noted that if implemented it creates significant service improvements, creates a continuous improvement environment which sustains the improvements achieved.

Since the adoption of Six Sigma in healthcare sector, it has been applied in various sections of the hospital management systems including the outpatient section (Kam et al, 2021), Mobile clinics (Sunder et al., 2019), primary care centres (Basta et al., 2016), Operating theatre (Tagge et al., 2017), and the laboratory (ref). The adoption of Six Sigma in health care has registered several positive outcomes, in a study by Niemeijer et al., 2012) after a five year implementation of the tool at University Medical Center Rotterdam, significant impacts were observed in the quality of care. This was also observed by Ahmed et al., (2018) where he reported the positive impacts of Six Sigma implementation on Malaysian hospital performance.

Medical laboratories strive to produce accurate and precise results that physicians rely on for diagnosis, monitoring and prognosis of patients (ref). The laboratory monitors and evaluate analytical processes using different quality control (QC) processes including precision and accuracy. A high standard deviation indicates a poor precision and high random error (Van Heerden et al., 2022). There is an observed variation in the number of QC levels and frequency of QC runs (Shah et al., 2014). In the interpretation of QC data, laboratories use a combination of Westgard rules to identify both random and systematic errors.

In regard to the application of the tool in clinical laboratory department, The Six Sigma scale provides an objective way of assessing quality by incorporating imprecision and bias observed in laboratory performance. As indicated by Litten (year) the implementation of a Six Sigma designed QC programme may result in fewer controls per run, fewer rejections, simpler westward rules and significant savings on laboratory consumables.

Kumar (2019) however, recommended that six sigma metrics be applied to all segments of the laboratory process to gauge their performance on sigma scale. As agreed by Bhattacharjee et al., 2024), diagnostic laboratories should incorporate Six Sigma metrics to identify gaps in their performance and thus ensuring better quality control and patient safety.

This review supports the importance of the implementation of the tool in different areas of the healthcare system and in all departments of the medical laboratory. It highlights the importance of understanding the current state of quality aspects that would guide proper implementation strategies in enhancing the relevance of medical laboratory services to the healthcare system.

3. Methodology

3.1 Study setting

The study was conducted at Mzimba South District Hospital laboratory in the Northern Region of Malawi. This study was conducted from 5th July to 30th November, 2021.

3.2 Study design

This was an observational study on retrospective and prospective quality control data. Retrospective data on EQCs was collected from data sheets from April, August, December 2019 and February, June and November 2020. Prospective IQC data was collected from runs conducted in March, July and November 2021. A systematic random sampling was used to select 9 months from the 35 month period. At least 155 EQCs samples for each 23 parameters were used to collect data from. The EQC parameters on major tests were performed on Mindray BS 120 chemistry analyzer (Shenzhen, Guangdong, China) for chemistry parameters, KN21 sysmex hematology analyzer (1-5-1,Wakinohama-kaigandori, Chuo-ku, Kobe, Hyogo 651-0073, Japan) for hematology parameters and Abbott 2000m analysers (Abbott Park, Illinois, U.S.) for molecular parameters.

Tests that were included in this study were; Complete Blood Count EQCs parameters including; White Blood Count (WBC), Hemoglobin (HGB), Platelets, Red Blood Count, RBC, Hematocrit (HCT), Mean cell volume (MCV), Mean cell Hemoglobin (MCH), Mean cell Hemoglobin Concentration (MCHC) and Chemistry parameters including Urea and Creatinine, Albumin, Total protein, Bilirubin Total, Bilirubin Direct, Alanine aminotransferase (ALT), Aspartate Transaminase AST, Gamma Glutamyl Transaminase (GGT) and Alkaline Phosphatase (ALP), Glucose. Virology parameters including HIV RNA PCR EQCs Low and High, SARS-CoV-2 Abbott EQCs Positive and Negative.

3.3 Data collection and analysis

EQC data were collected. SD, Bias %, CV% and sigma metrics were calculated using Microsoft excel sheet formula. Sigma metrics = (% Tea –% Bias)/% CV.

4. Results and Discussion

In hematology, none of the EQC parameters achieved sigma >6. 2 parameters achieved sigma > 5, 2 parameters had sigma >3 and 4 parameters achieved sigma values < 3. Figure 1. All results are presented at *p* value of 0.00.

Comparison of FBC EQA parameters between 2019-20 and 2020-21, parameters achieved comparable sigma values as presented in Table 1.

Table 1: Sigma metrics FBC comparison between 2019-20 to 2020-21. (WBC: White Blood Cells, RBC: Red Blood Cells, HCT: Hematocrit, MCV: Mean Cell Volume, MCH: Mean Cell Hemoglobin, MCHC: Mean Corpuscular Hemoglobin concentration, HGB: Hemoglobin, PLT: Platelets)

EQC	Perfect Performance	WBC	RBC	HCT	MCV	MCH	MCHC	HGB	PLT
2019-20 Sigma	6	5.37	1.36	2.27	2.88	3.19	4.2	1.8	5.5
2020-21 Sigma	6	5.38	1.29	2.3	2.88	3.2	4.15	1.9	5.59

For chemistry analytes, none of the analytes achieved sigma >6. Only one analyte had a sigma value of >3. Eleven chemistry parameters had sigma value <3. Comparing metric scores for chemistry analytes for 2019-20 and 2020-21, analytes have very comparable scores. All analytes had sigma score <3 (see Table 2)

Table 2: Sigma metrics LFT and RF performance comparison between 2019-20 to 2020-2. (ALB: Albumin, TP: Total Protein, T Bil: Total Bilirubin, D. Bil: Direct Bilirubin, ALT: Alanine amino transferase, AST: Aspartate Amino transferase, GGT: Gamma glutamyltransferase, ALP: Alkaline phosphatase, GLUC: Glucose, UA: Uric Acid, URE: Urea)

EQC	ALB	TP	BIL T	BIL D	ALT	AST	GGT	ALP	GLUC	UA	CR	URE
2019-2020	0.12	2.16	0.31	0.07	0.05	0.06	0.15	1.6	0.17	0.06	0.13	0.07
2020-2021	0.1	2.20	0.15	0.05	0.06	0.10	0.16	1.58	0.18	0.08	0.14	0.09

For Virology analytes. All analytes had a sigma value of <3 as presented in Table 3. Comparing metric virology analytes for 2019-20 and 2020-21 very comparable matrix were obtained. All analytes had sigma score <3 (Table 4).

Table 3: Sigma metrics Viral load EQC and SARS Cov2. (EQC: External Quality Control)

Viral load EQC			Sigma metrics for SARS cov2		
Parameter	Low	High	Parameter	Pos	Neg
Sigma	0.01	0.41	Failed	14	14
			Total	61	61
			Sigma	2.3	2.3

Table 4: Sigma metric Viral load performance comparison between 2019-20 to 2020-21(EQC: External Quality Control)

Viral load performance comparison		
EQC year	Sigma	
	Low	High
2019-20	0.01	0.41
2020-21	0.02	0.45

Discussion

The results indicate that all 23 parameters on average had a sigma metrics score of less than 3. It signifies low standard testing which requires continuous improvement for quality control process (Kashyap, et al. 2021). A method performing with less than 3 is unreliable, needs immediate changing (Verma et al. 2018; Sayeed, Ganji & Mopuri, 2019 and Teshome, worede & Ashmelash, 2021). A laboratory with poor sigma metrics, less than 3, likely cost a lot of time, effort and money to maintain its quality of results (Kayshap, et al. 2021) and Schoenmakers, et al. (2011) suggest that there could be a possible inherent analyzer error which continued to pause significant inaccuracies and imprecision as indicated by QGI which was out of range as well.

In Haematology, 63% of parameters had less than 3 sigma level with CI (95%). They had a constant error accumulated over the past 35 months. This is indicated by the Quality Goal Index which was out of range as well. The comparison between two years had the same unsatisfactory performance with CI (95%). The implication of this performance is transferred from KN21 Sysmex haematology analyzer.

In Chemistry, 80% of parameters had sigma metrics of less than 3 with CI (95%). All 2 levels QC had issues, Normal and pathology IQC had average score of <2 sigma. They had a constant error accumulated over the past 33 months. This is indicated by the Quality Goal index which was out of range as well.The implication of this performance is transferred from BS 120 Mindray analyzers. In virology, 0% of the parameters scored greater than 1 sigma level. Low and High parameters for both Viral load and SARS cov2 scored less than 1 sigma metrics.

On comparisons between years, none of the parameters had performed satisfactorily. All 2 levels had performed poorly, Low and High EQC had average scores of <2 sigma. They had a constant error accumulated over the past 35 months. This is indicated by the Quality Goal index which was out of range as well. The implication of this performance is transferred from Abbott m2000 analyzer.

Results obtained in the current study are plain proof that the laboratory currently operates in an environment in which world class performance requires serious reconsideration to be achieved. This calls for a need to set proper quality goals, strictly follow them, and assess them periodically to maintain quality in the results issued. Comparably low sigma metrics were obtained (Kashyap et al. 2021; Adiga, Preethika & Swathi, 2015 and Nanda & Ray, 2013) augmenting the need to utilize sigma metrics to determine performance of current method and in the design of QC approaches.

When the method quality objectives are set at six sigma stringent internal controls are mandatory. The six sigma idea sustains an association between the numbers of products defects, wasted operations costs and levels of customers' satisfaction. Processes that were easily controlled, with a sigma value approaching or exceeding 6, a high probability of error detection, and a low probability of false rejection (Rajashekharaiah, 2016). Six Sigma (SS) needs no introduction, as it is now re-garded as an intensive approach to improve the process quality and be able to meet the global standards (Farr & Freeman, 2008).

In industry outside healthcare, 3 sigma is considered the minimal acceptable performance for a process. When performance falls below 3 sigma the process is considered to be essentially unstable and unacceptable. Sigma > 6 is an excellent test with higher class performance befitting the health care (Mahmood, et al. 2018). It is evident that six sigma metrics is the best tool to employ in any environment where quality services is the goal. In instances where set sigma metrics are not met, root cause analysis must be employed to find out why most parameters are at unsatisfying sigma level. Some experiments involved in equipment, calibrations, purchasing and inventory, validations and verifications must be strictly checked, performed and documented (Sha, et al. 2014).

No fewer than these experiments should be accepted. Equipment selection and purchasing must be done at the local council involving laboratory managers and district management teams. Service of equipment must be done every three months to tally with EQC expiry dates and lot to lot verifications. All EQC Westgard rules must be established by using Sigma metrics, this will prevent false positives and false rejection. Laboratory must strictly adhere to LJ charts standard operating procedures in EQC and sigma metrics attached to it electronically. The management of nonconformity is supposed to be strictly done along with the occurrence database being kept. This will help to detect small errors for the entire laboratory that may accumulate into affecting the sigma metric (Coskun, 2007 and Westgard & Westgard, 2016).

5. Conclusion and Recommendations

An average sigma metrics of <3 was very poor for all 23 EQC parameters that need improvement. Results released from the laboratory are critical in the diagnosis, patient monitoring and have crucial prognostic value, proper management of patients, and additional action mostly depends on such results. Laboratories should at all times aim to reduce avoidable errors that may have a serious effect on patient outcomes. Sigma metrics has the capability to be an important quality management tool for observing analytical performance in relation to largely recommended and accepted standards. In this laboratory, all aspects of equipment calibration, purchasing and inventory, validation must strictly be followed in order to reduce nonconformities. Sigma metric analysis provides a benchmark for the laboratory to design a protocol for IQC, addresses poor assay performance, and assesses the reliability as well as the efficiency of existing laboratory process. It warrants a root cause analysis from the past towards future improvement. The study recommends a comprehensive study of Six Sigma metrics on quality indicators of all QMS participating laboratories in Malawi. All district and central hospital laboratories should determine their overall performance using the Six Sigma Metrics tool. We recommend also a possible review of the quality manuals and quality assurance standard operating procedures in regard to Six Sigma metrics.

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