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Internal Quality control Monitoring & Evaluation of Creatinine, Urea, Alanine aminotransferase and Inter-Laboratory Assessment of Some Haematological Parameters In Two Hospitals in Central Nigeria.

Stephen I. Audu[1*],Isah Jibrin[1], Maryam JibrinS.[2],
J. Mohammed[1]andMartha E.Ogbole[3].
[1]Department of Chemistry, Nasarawa State University, Keffi, Nigeria,[2]Department of Science Laboratory Technology,Federal Polytechnic,Nasarawa[3]Department of Veterinary Microbiology,University of Abuja, Nigeria.
**Corresponding Author: Stephen I. Audu*

Abstract: *The integrity of quality control samples is important to both management of overall quality as well as to meeting requirements of proficiency testing.The study was done to assess the quality control monitoring and evaluation of creatinine,urea,alanine aminotransferaseand also for inter-laboratory studies of somehaematological parameters packed cell volume (PCV),Mean cell Volume (MCV)andmean corpuscular haemoglobin (MCH), in Nisa Premier Hospital Abuja and the Benue State University Teaching Hospital Makurdi,North central Nigeria.The quality control monitoring& evaluation were conducted for two consecutive months using the spectrophotometer(kenza240 TXbiolabo France),and the inter -laboratory studies was performed directly on blood samples at both locations using the Automated Haematology Analyzer (KX-21N Sysmex, USA).The results of quality control assessment showed that Trends (loss of reliability) and shifts (abrupt changes in the control mean) were noted in the results of this study. The results of inter-laboratory assessment of the haematological parameters shows that both imprecision and bias exist between both laboratories. Although imprecision values were generally in the range of "Acceptable to marginal performance", the overall bias between laboratories was in the range: SDI >1.5 or SDI < -1.5; In this study, Warning signs were recorded but there was no cause for rejection of the analytical run exception of alanine aminotransferase.*

Keywords: *Quality Control, Urea, Creatine, alanineaminotransferase, Inter-laboratory, Westgard Rule*

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I. Introduction

In internal and external statistical quality control(SQC), random and systematic errors must be detected at an early stage and then every step should be taken to minimize them[1].The Internal Quality Control (IQC) includes all SQC methods which are performed every day by the laboratory personnel with the laboratory's materials and equipment. It checks primarily the precision (repeatability or reproducibility) of the method.The External Quality Control (EQC) includes all SQC methods which are performed periodically (i.e. every month, every two months, twice a year) by the laboratory personnel with the contribution of an external center (referral laboratory, scientific associations, diagnostic industry among others). It checks primarily the accuracy of the laboratory's analytical methods. However, there are certain EQC schemes that check both the accuracy and the precision. Other terms for external quality control are: inter-laboratory comparisons, proficiency testing (PT) and external quality assessments schemes (EQAS). The metrics of internal and external quality control are based on statistical science (e.g. SDI, CV, Z-score) and they are graphically represented by statistical charts (control charts). Some of them are common in other industries while others are specific for internal or external quality control in clinical laboratories [2]. Quality control must be practical, achievable and affordable. The primary aim of quality control is to do the test reliably. The broad aim of quality control is that results from one laboratory should be comparable with that from any laboratory in the world provided the same method is followed[3]. Collaborative trials or method performance studies are used to test the performance (generally the precision) of a single analytical method. A standard method, which is routinely used in several laboratories, can also be examined collaboratively to test for a possible bias of either the method (method bias) or the laboratories (laboratory bias) that routinely use it [4].Westgard rules are used to define specific performance limits for a particular assay and can be used to detect both random and systematic errors. Westgard rules are programmed in

to automated analyzers to determine when an analytical run should be rejected. These rules need to be applied carefully so that true errors are detected while false rejections are minimized. The rules applied to high volume chemistry and hematology instruments should produce low false rejection rates[5,6,7].Amino acids from ingested food that are not used for the synthesis of proteins and other biological substances — or produced from catabolism of muscle protein — are oxidized by the body as an alternative source of energy, yielding urea and carbon dioxide [8]The oxidation pathway starts with the removal of the amino group by a transaminase, the amino group is then fed into the urea cycle. The first step in the conversion of amino acids from protein into metabolic waste in the liver is removal of the alpha-amino nitrogen, which results in ammonia. Because ammonia is toxic, it is excreted immediately by fish, converted into uric acid by birds, and converted into urea by mammals[9]Creatine is a derivative of the guanidiniumcation. A cyclic form of creatine, called creatinine, exists in equilibrium with its tautomer and with creatine. Creatine undergoes phosphorylation, by the action of creatine kinase to give phosphocreatine. The phosphate group is attached to an NH center of the creatine. The P-N bond is highly reactive[10]

II. Materials and Methods

2.1. Study Setting and Design

The study was carried out at theHaematology Laboratory of the Benue State University Teaching Hospital (BSUTH), Makurdi,and the biosciences laboratories of Nisa premier Hospital,Abuja,Nigeria. These laboratories provide services to inpatients, outpatients and patients on emergencies. The study was approved by the Health Research and Ethics Committee of the Hospitals.

2.2.QualityControl

Quality control monitoring and evaluationof urea,creatinine and alanine aminotransferasewere conducted using BiolaboExtrator-N (Normal) and BiolaboExtratol-P (Pathological) by gently mixing 5mL of Extrator-N buffer with lypholized Bovine Serum and inserting into the spectrophotometer Kenza240 TX and results collated for two consecutive months of July and August 2016.The quality control product which is a patient-like material ideally made from human serum, urine or spinal fluid [1].

2.3 Determination of haematological parameters:

The following haematological parameters[packed cell volumel (PCV),Mean cell Volume[MCV]Mean corspuscularHeamoglobin (MCH) were determined in blood samples collected randomly from 520 patients at both locations. At both locations determination was performed using the same instrumentation; Automated Haematology Analyzer ((KX-21N Sysmex, USA) .The blood samples of patients were collected into bottles containing EDTA anticoagulant and inserted directly into the Automated haematology Analyzer and concentrations of the haematological parameters were read.The Automated heamatologyAnalyzer used thecounlter principle,which blood is passed between two electrodes through an aperture so narrow that only one cell can pass through at a time. The change in impedence is proportional to cell volume resulting in a cell count and measure of volume[1].

2.4 Statistical analysis

Data collected were collated on Microsoft Excel spread sheet and analysis was done using Analyse-it ® Version 4.6,(Analyse-it Leeds,UK)[11]. The Two important metrics of an interlaboratory program are the coefficient of variation ratio (CVR) and standard deviation index (SDI), which are the metrics of imprecision and bias, respectively wereused,and the Levey-Jeneys chart was used for quality control.

III. Results

The results of quality control showed that Trends (loss of reliability) and shifts (abrupt changes in the control mean) were noted in the results of this study as presented in figure 1 to figure3.The result of interlaboratory study shows that imprecision and bias exist in both laboratories,but imprecision was within Acceptable to marginal performance as presented in table 1.

Table :1 Results of Haematologicalanalysis of inter-laboratory study

Haem. Parameter	Laboratory	Mean	SD	CV	CVR_ Nisa	CVR_ BSUTH	Average CRV	SDI_ Nisa	SDI_ BSUTH	Average SDI
PCV	Nisa	12.70	3.05	0.0024						
	BSUTH	42.79	11.03	0.0026	0.884	1.131	1.000	3.379	3.942	3.661
MCV	Nisa	38.26	9.09	0.024						
	BSUTH	82.86	5.99	0.0007	0.922	1.085	1.003	34.383	38.580	36.481
MCH	Nisa	27.76	3.10	0.0011						
	BSUTH	26.57	1.43	0.005	0.483	2.069	1.276	17.621	9.241	13.431

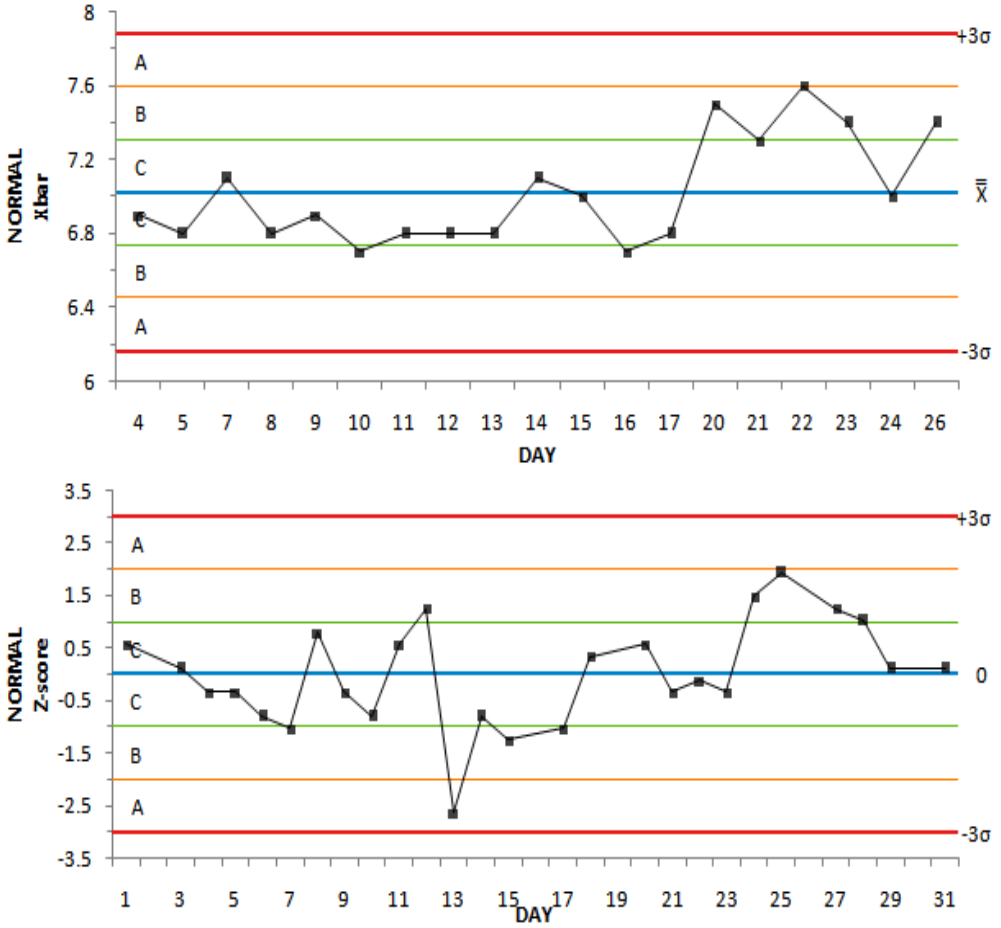

Figure: 1 QC charts for Bilirubin figure
Figure: 1 QC charts for Urea

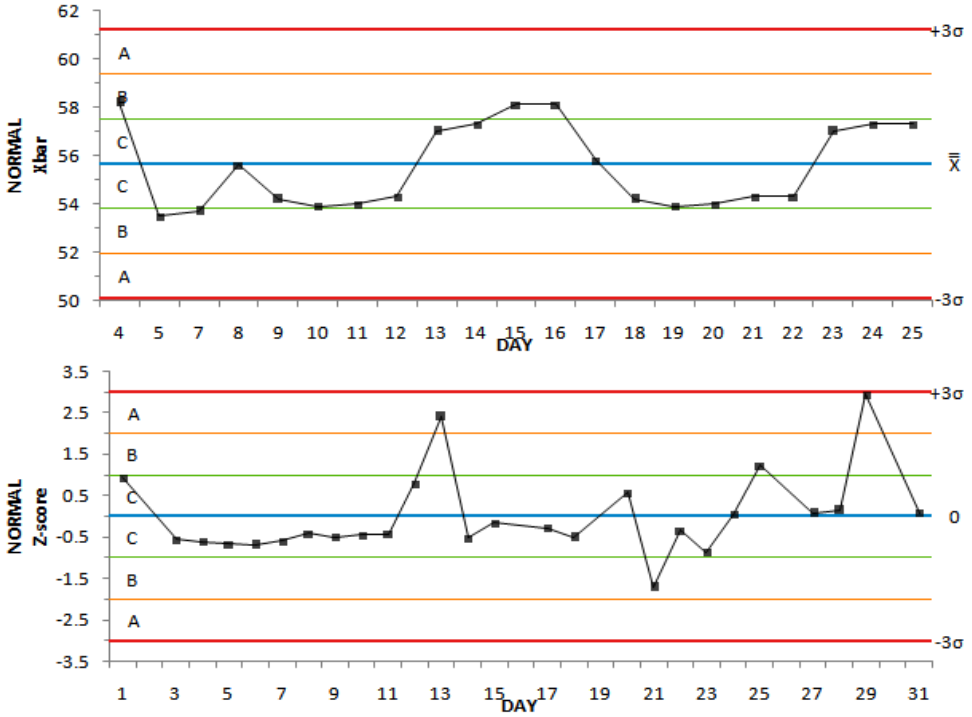

Figure: 2 QC charts for Alanine aminotransferase- July/August 2016

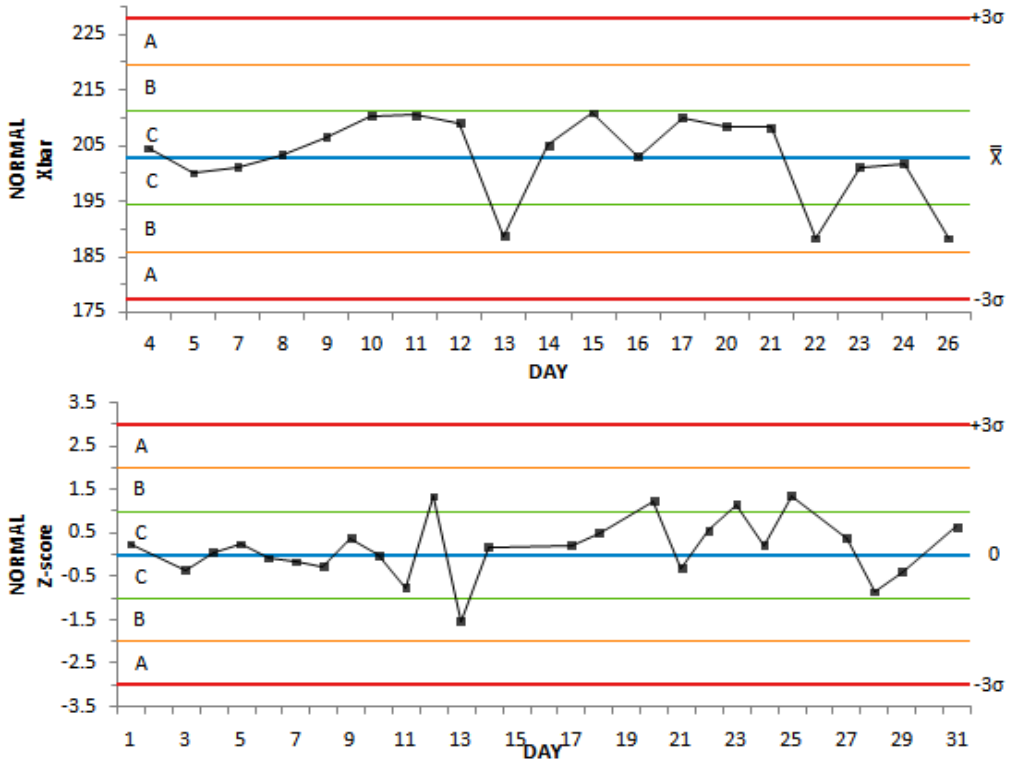

Figure 3 QCcharts for Creatinine July/Aug 2016

IV. Discussion

The results of quality control showed that Trends (loss of reliability) and shifts (abrupt changes in the control mean)[18]were noted in the results of this study as presented in figure 1 to 3,there were two major trends in July and more shifts in the month of August than in the month of July forcreatinine and a major trend and two violations of the Westgard Rule for urea.there was a major trend in the month of august for alanine

aminotransferase and control values were out of control and violated the 1_2s and 1_3sWestgard rule for in the month of July and August, this indicate a systematic error which requires a corrective action.The internal quality control is a key technical requirement through accreditation by the NF EN ISO 15189. This presents recommendations to assist the medical laboratory to design, implement and operate daily and retrospectively an efficient system of internal control quality[12].In this study some warning signs were recorded, which is not unusual,l but in the course of the study the laboratories had to introduce unusual attempts to bring their system in control.These violations typically identify smaller systematic error oranalytical bias that is not often clinically significant or relevant [11].The result of interlaboratory study for haematological parameters(Table 1) shows that both imprecision and bias exist between both laboratories.

Although imprecision values were generally in the range: 1< CVR <1.5, indicating "Acceptable to marginal performance; this implies that there is a need to investigate test system imprecision", the overall bias between laboratories were high;in the range: SDI > 1.5 or SDI < -1.5; this indicate Marginal performance; which require corrective action[13]. It has been reported that in many sub-Saharan African countries, medical laboratory systems are adversely affected by poor laboratory infrastructure and lack of well-trained personnel [14]. And quality in the laboratories can only be achieved in a systematic way through the implementation of a quality management system so findings from this study is very essential for both the patients and laboratory staffs in northcentral Nigeria as Laboratory quality control is designed to detect, and correct deficiencies in a laboratory's internal analytical process before reliable clinical decision is taken,and also to improve the quality of the results reported by the laboratories.

V. Conclusion

The results of the study shows that both imprecision and bias exist between both laboratories, which indicatescorrective action to be taken for both laboratories in terms of measurement imprecision.As quality control studiesare conducted in clinical laboratories to facilitate reliable clinical decision making through precise,,accurate and reliable laboratory results. Some warning signs were recorded, it is not completely unusual these violations typically identify smaller systematic error oranalytical bias that is not often clinically significant or relevant.

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References

[1]. Audu .I.,Stephen(2017): Analytical Validation Methodology for some Diagnostics methods Used In Clinical Laboratories.Unpublished PhD Thesis,Benue state University Makurdi,Nigeria
[2]. Karkalousos, P. (2011), Evangelopoulos A. Quality Control in Clinical Laboratories. Appl Exp Qual Control;331–60.
[3]. Kumar V, Abbas AK, Fausto N Robbins &Cotran pathologic Basis of Disease.ed. 7th 2004 Saunders USA.
[4]. Hund, E., Massart, D.L,andSmeyers-Verbeke, J. (2000). Inter-laboratory studies in analytical chemistry. AnalyticaChimicaActaVol 432. p. 145–657).
[5]. Westgard, J.O. (2010). Managing quality vs. measuring uncertainty in the medical laboratory. Clinical Chemistry and Laboratory Medicine.vol 28 p. 31–40
[6]. Westgard, J.O., P.L. Barry, and M.R. Hunt (1981). "A Multi-rule Shewhart Chart for Quality Control in Clinical Chemistry,"Clinical Chemistry, vol. 27, pp. 493-501.
[7]. Westgard, J.O., P.L. Barry (1986). "Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes"AACC Press.
[8]. International Chemical Safety Cards: cdc.gov
[9]. *Sakami W, Harrington H (1963). "Amino acid metabolism".Annual Review of Biochemistry.**32** (1): 355–98*
[10]. Cannan*RK, Shore A (1928). The creatine-Creatinineequilibrium.The apparent dissociation constants of creatine and creatinine.The Biochemical Journal.**22** (4): 920–9.*
[11]. Analyse-it. Analyse-it v.4.6 (2015). Clinical and Analytical Method Validation Statistical Software for Microsoft Excel. Analyse-it Software, Ltd. Leeds, United Kingdom.
[12]. Giroud, C., Arnaud, J., Adjidé, V. and Vassault. (2010). Internal quality control. Vol. 68, Annales de biologie clinique. p. 203–21.
[13]. Carstensen, B. (2010). Comparing clinical measurement methods : a practical guide. John Wiley & Sons.
[14]. Cobbina, E., Agbezudor J.Y, Amuzu P.S,and Gyampomah, T.K. (2012). The current status and future of medical laboratory quality regulation and accreditation in Ghana. *Accredit Quality Assurance*;17(6):613–9

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