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The Accuracy and Performance of Different Clinical Laboratory Classes in the Sudan

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Abstract

Currently we aimed to assess laboratory performance of current situation by implementation of quality assurance program. A total of 136 laboratories were randomly selected and classified based on instruments, personnel, reagents and distribution of population (class A, B and C). Two pathological lyophilized control sera were sent to each laboratory for estimation of Glucose and Creatinine levels blindly as routine test. Data regarding reagents, type of instruments and personnel were measured. Independent t-test analysis showed significant decrease of class C mean glucose level as end point mode *p*-value 0.017, while insignificant difference was observed in class B *p*-value 0.211 in comparison with highly quality and well equipped reference (Class A). Fixed timed mode which presented by mean creatinine level showed significant decreases of both classes B and C with *p*-value 0.038 and 0.014 respectively, versus class A laboratories. Z-score results found significant differences of unsatisfied results of blood glucose level obtained from class B and C when compared with Class A *p*-value 0.002, also creatinine revealed similar results with *p*-value 0.001 of both classes. The study concludes that, type of instruments, validity of reagents, lack of training and poor quality system have an adverse effect on accuracy and reliability of both mode of reactions.

Keywords: Quality Control, Quality Assurance, Accuracy, Performance, Clinical Laboratory, Sudan.

INTRODUCTION

Quality control (QC) is one component of the total quality management system which has been defined as all systematic actions necessary to provide adequate confidence to the laboratory services which satisfy given medical needs for patient care, which achieved by applying QC techniques to minimize errors (Samuel, 1995; Davies, 1999; Giedt, 2000). Quality assurance (QA) has been summarized as the right result, at the right time, on the right specimen from the right patient (Davies, 1999). Laboratory medicine has a strong impact in the prevention of risk to the patient and laboratories must

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implement procedures to minimize further risks of errors. Quality Assurance Programs (QAPs) represent an important tool that allows us to identify errors and pinpoint any need for further systematic investigations (Raab, 2006). The errors rose from personnel, instruments and reagents. The staff must be adequately trained and the laboratory must be constructed with high quality functioning equipment, high quality reagents and consumables, thus laboratory environment should have enough space to perform day-to-day operations safety and efficiently (Hwang et al., 2013; Jegede et al., 2015; Ayatollahi *et al.,* 2006). The laboratory was classified based on laboratory service to class-A which in high referral facilities, class-B in intermediate referral facilities and class-C in low referral facilities (Plebani, 2015).

MATERIALS AND METHOD

This was analytical comparative study which was conducted in eight States (Khartoum, Gazira, Red Sea, North Kurdofan, Gadarif, River Nile, White Nile and Kassala) in the Sudan, from April 2009 – May 2012. A total of 136 laboratories were randomly selected, then classified based on personnel qualification and training, instrument types (manual, semi-automated and fully automated analyzers) and quality of reagents into three laboratory classes (A, B and C), class A is well equipped and used as reference laboratory. Two pathological lyophilized control sera were blindly distributed for measuring of glucose (endpoint) and creatinine (fixed time reaction) level as routine assays. Approval was obtained from the ethical committee of Al Neelain University college of Medical Laboratory Sciences and acceptance from authorized general directors of Ministries of Health (MOH) into eight states which had selected and verbal inform consent was taken from each laboratory.

Statistical analyses

Data are presented as Mean±SD. ANOVA test was used to compare mean concentration of accuracy obtained from different laboratory classes, and Z-Score to evaluate the performance of laboratories. Significant difference considered as p-value ≤ 0.05. All statistical analyses were performed in SPSS version 21.0 (SPSS Inc., USA) software was used for statistical analysis.

RESULTS

Independent t-test analysis showed mean glucose level of class C laboratory (173.6±14.9 mg/dl) was significant decrease when compared with class A (207.2±4.6 mg/dl) p-value 0.002, while class B (195.8±4.6 mg/dl) showed insignificant difference with p-value 0.211, which presented in Fig 1. The mean creatinine level of class B (3.7±1.2 mg/dl) and class C laboratories (3.2±1.2 mg/dl) were significantly decreases in comparison with class A (4.2±1.9 mg/dl) with p-valve 0.038 and 0.014 respectively, which presented in Fig.2.

DISCUSSION

Laboratory personnel must receive training and continuing education to carry out their function. Maintenance and quality of laboratory equipments are necessarily for accurate and reliable results. In addition reagents must be performing under optimum and specific conditions, to enhance their quality thus customer satisfaction (Manickam et al., 2015). Accordingly we hypothesized that, lack of training; types of instruments and quality of reagents have an adverse effect on the laboratory performance. To assess the reaction mode (end point and fixed time reaction) on the accuracy and reliability of the results, both modes were employed by estimation of glucose and creatinine respectively.

The accuracy is most measure indicating parameter to laboratory performance (Ezzelle, 2008). In fact that, fixed time reaction preformed in optimal condition which required special instrument type (digital with thermal control) to achieve accurate and reliable result. Therefore, our results provide evidence that, the accuracy of class C laboratory showed significant decrease of mean glucose level, while insignificant difference was observed in class B, in comparison with highly equipped Class A laboratory. Also independent t-test analysis revealed significant decreases of mean creatinine level of both classes B and C laboratories when compared with class A laboratory. Poor performance of class B and C laboratories were attributed to the lack of training, quality of reagents and type of instruments, these elements are necessarily for high competency of laboratory and thus accuracy and reliability of the results (Hallak, 2005; Mbah, 2014; David et al., 2000). To assess the effect of different mode of reaction on the accuracy and reliability of test, glucose (end point) and creatinine (fixed time reaction) were measured. The present study found that, fixed time reaction mode fall to achieve accurate and reliable results than end point mode, which in turn attributed to the type of instruments used in class B and C laboratories, these classes are not adequately equipped and used analogue instruments rather than digital, therefore altimetry lack of temperature control on analogue readout device more probably affected by the angle of a person who record
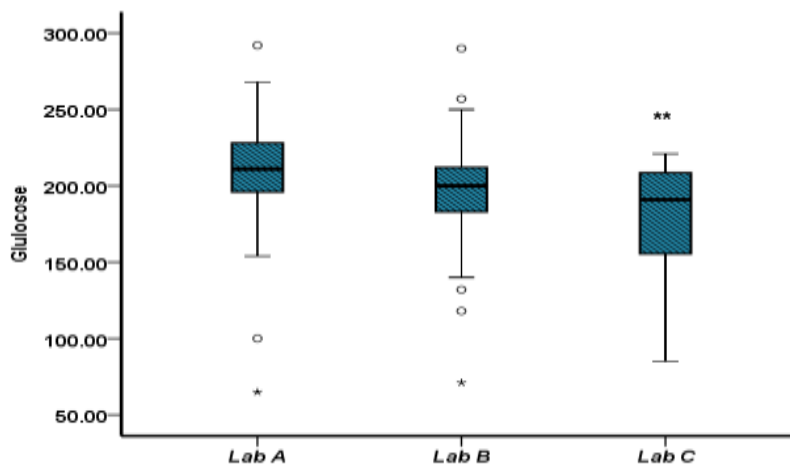
Fig 1. Showed mean glucose (end point) level from different laboratory classes
*Indicate   significant ** Indicate highly significant
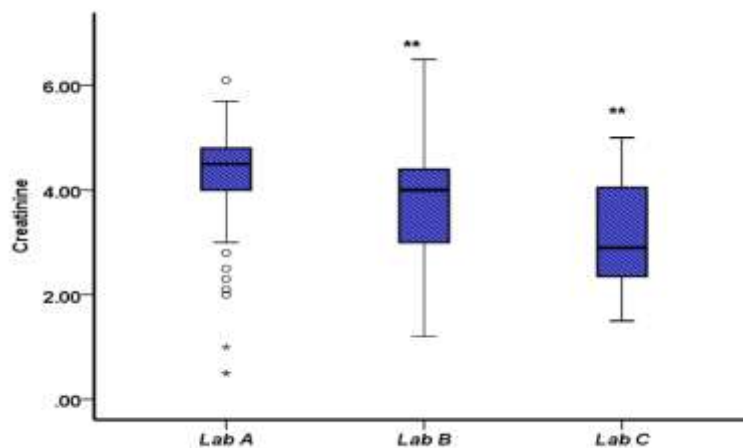
Fig 2. Showed mean creatinine (Fixed time reaction) level from different laboratory classes
*Indicate significant ** indicate highly significant.

Table 1. Z-Score analysis of glucose results classified as satisfactory, questionable and unsatisfactory which obtained from different laboratory classes

Type of laboratory	Z-Score Satisfactory	Questionable	Unsatisfactory	Chi-Square Sig
A % within lab-level	41.0%	11.5%	47.5%	
% within Z-score	75.8%	28.0%	40.3%	
B % within lab-level	13.8%	25.9%	48.6%	
% within Z-score	24.2%	60.0%	48.6%	
C % within lab-level	0.00%	27.3%	72.7%	0.002
% within Z-score	0.00%	12.0%	11.1%	

Table 2. Z-Score analysis of creatinine results classified as satisfactory, questionable and unsatisfactory which obtained from different laboratory classes

Type of laboratory		Z-Score Satisfactory	Questionable	Unsatisfactory	Chi-Square Sig
A	% within lab-level	68.9%	9.80%	21.3%	
	% within Z-score	63.6%	30.0%	29.5%	
B	% within lab-level	37.9%	20.7%	41.4%	
	% within Z-score	33.3%	60.0%	54.5%	
C	% within lab-level	18.2%	18.2%	63.6%	0.001
	% within Z-score	3.00%	10.0%	15.9%	

the results. Consequently fixed time more affected than end point reaction. There are several sources analytical errors these include lack of experience, mode of reaction, laboratory ambiance temperature, types of instruments and analytical quality control (Westgard, 2010; Abdulla, 2010).

CONCLUSION

Finally, the present study focused on accuracy and reliability of different Sudanese laboratory classes, most clinical laboratories in the Sudan are less equipped, lack of training and reagent quality testing especially in remote area, as consequently both Class B and C fall to achieve accurate and reliable results in two mode of reaction employed in the study. Thus we recommended implementing such elements to satisfy the customers, such as continuous training system, uses of high quality instruments and reagents and implementation of quality assurance program.

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CONFLICT OF INTEREST

The authors declare that no conflict of interest related to this manuscript.

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