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Evaluation of a Portable Blood Lead Analyzer as an Alternative to Graphite Furnace Atomic Absorption Spectrophotometer

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ABSTRACT

Objective: To evaluate LeadCare II analyzer, a portable electro-analytical instrument used to rapidly analyze blood lead levels (BLL) in children, and compare it to gold standard, graphite furnace atomic absorption spectrometry (GFAAS)

Methodology and results: Twenty two (22) duplicate fresh capillary blood samples were tested using both LeadCare II kits and GFAAS. There was a strong, positive correlation ($r = 0.787$, $r^2 = 0.62$) between the BLL determined by LeadCare II and GFAAS. In this study, LeadCare II analyzer scored 57% sensitivity, 80% specificity and positive predictive value (PPV) of 0.8. However, its predictive value depends on prevalence of disease and the number of individuals.

Conclusion and application of findings: LeadCare II offers an opportunity to cost effectively screen for childhood lead poisoning in Kenya. Deployment and use of this technology could improve patient care by providing instant results. During a visit to a health centre, lead levels can be determined and treatment initiated immediately where necessary.

Key words: Blood lead levels, Kenya, GFAAS, LeadCare II analyzer

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INTRODUCTION

Lead is a heavy metal that is introduced to the environment through human activities. Excessive lead exposure through air, water, soil and food is harmful to the health and intellectual development of millions of children (Markowitz *et al*., 2000). For instance, exposure to lead could cause neurotoxic (nerve poison) effects, particularly in children whose growing bodies are highly susceptible (Markowitz *et al*., 2000). Evidence has been obtained of lead levels above the allowed environmental limits within Nairobi area, Kenya (Mutuku, 2005). Olewe (2008) found 7% prevalence of elevated blood lead levels among children less than five years old living in Kibera slums in Nairobi.

High cost of blood lead testing using graphite furnace, atomic absorption spectrophotometer (GFAAS) has made routine pediatric blood lead screening in Kenya impractical. The cost of LeadCare II analyzer is $ 2,200 compared to $ 20,000 for GFAAS. The cost per blood lead test is cheaper by LeadCare II at $6 compared to $105 by GFAAS. LeadCare II analyzer has not been used widely in Kenya, where it could offer expeditious analytical results to health professionals in field settings and areas lacking laboratory infrastructure.

LeadCare II analyzer employs anodic stripping voltammetry (ASV) to measure lead in blood (Ashley, 1994; Wang, 1996). In this study, this tool was evaluated against the gold standard GFAAS, as a potential alternative for routine monitoring of exposure to lead in Kenya. LeadCare II blood analyzer received 510(k) market clearance from Food and Drug Administration (FDA) in the USA and is classified under the clinical laboratory improvement amendments (CLIA) of 1988 as a moderately complex medical device (Federal Register, 1997). It has been used elsewhere with success for pediatric screening (Shannon & Rafai, 1997).

MATERIALS AND METHODS

This was a descriptive, cross-sectional study of 387 children, who presented at Yes to Kids (Y2K) program, VIPS Health Services at Woodley, Nairobi between June and August 2007. Ethics and Research Committee approval was obtained and training of interviewers and laboratory technicians held in tandem with pre-testing of the questionnaires. Parents, guardians or care givers gave consent for children's participation in the study. Participating children were carefully screened by medical doctors based on well defined criteria. Trained laboratory technologists collected duplicate capillary blood samples for lead analysis. Capillary tubes, 50ul each, provided with LeadCare II blood lead analyzer kits were used to collect 22 blood samples, following instructor's protocols. Another 22 blood samples for lead analysis by GFAAS were collected following protocols described by Schonfeld *et al*. (1995) from the same group of children using 50ul Sarstedt microvette CB300 tubes with EDTA anticoagulant. The tubes were filled to ¾ and standardized analytical methods (Flajnik *et al*., 1994) followed at the Massachusetts Public State Laboratory in Boston, USA.

Data analysis: Statistical Package for Social Sciences (SPSS) software, version 10 was used for data management and analysis. Regression analysis was carried out to determine the measure of association between LeadCare II and GFAAS results. Validity, in terms of sensitivity and specificity, as well as predictive values of LeadCare II as a potential blood screening device were calculated. Validity is a measure of extent to which the LeadCare II was capable of correctly diagnosing the presence (BLL ≥ 10ug/dl) or absence (BLL < 10ug/dl) of lead poisoning. The cut off point for lead poisoning was set at BLL ≥ 10ug/dl.

RESULTS AND DISCUSSION

Graphite furnace atomic absorption spectrophotometer (GFAAS) is considered to be the gold standard for blood lead level (BLL) assay. LeadCare II blood analyzer was evaluated as an alternative method for BLL assay by comparing its readings with those from GFAAS on duplicate blood samples drawn from 22 children (Table 1).

Various models were applied to determine the one with a strong correlation between the variables of interest (Fig. 1). The Inverse model of regression generated a strongly positive (Pearson's correlation, $r = 0.787$, $r^2 = 0.62$), with statistically significant correlation ($F = 32.64$, $p<0.05$) between the blood lead level determined using LeadCare II and GFAAS. Inverse regression estimated 62% of the reading of BLL by LeadCare II for a given value by GFAAS.

The regression equation using the inverse model generated is: *LeadCare II = 12.427 – 26.04/GFAAS* ($r = 0.787$, $r^2 = 0.620$). This equation compares well with that of Kevin (2002), who using simple linear regression found $r^2 = 0.67$ (LeadCare = .91GFAAS + 3.0). The correlation coefficient in this study ($r^2 = 0.620$) was weaker than that reported by ESA Biosciences Inc. (2004) as $r^2 = 0.992$ (LeadCare II = 1.040 x GFAAS + 0.12, $S_{y,x} = 1.30$).

As indicated by the sensitivity level, LeadCare II correctly identified 57% (Table 3) of children with BLL ≥ 10ug/dl. LeadCare II also has high specificity as it correctly identified 80% of children with BLL < 10ug/dl (Table 3). These results indicate that LeadCare II analyzer has additional potential application as a confirmatory testing device for lead poisoning.

Table 1: Blood lead levels as determined by LeadCare II blood analyzer and Graphite furnace atomic absorption spectrophotometer (GFAAS) on duplicate blood samples (n = 22).

Sample number	Blood Lead Levels (ug/dl)	
	LeadCare II	GFAAS
1	10.6	9.0
2	11.1	15.0
3	12.1	9.0
4	9.5	9.0
5	13.2	8.0
6	4.7	3.0
7	8.5	6.0
8	3.4	3.0
9	3.3	3.0
10	8.1	11.0
11	9.7	7.0
12	10.5	11.0
13	11.3	13.0
14	8.9	8.0
15	8.9	11.0
16	7.8	12.0
17	6.0	8.0
18	12.0	18.0
19	9.1	9.0
20	4.8	5.0
21	9.0	5.0
22	6.9	7.0

Table 2: Comparison of lead poisoning outcomes as indicated by screening test results using LeadCare II blood analyzer and graphite furnace atomic absorption spectrophotometer (GFAAS).

LeadCare Vs GFAAS	BLL ≥ 10ug/dl	BLL < 10ug/dl
BLL ≥ 10ug/dl	4 (TP – true positive)	3 (FP – false positive)
BLL < 10ug/dl	3 (FN – false negative)	12 (TN – true negative)

Table 3: Validity and Predictive values using LeadCare II analyzer for blood lead levels.

	Measures	Formula	Value
Validity	Sensitivity	TP/(TP + FN) X 100	57.14%
Testing	Specificity	TN/(TN + FP) X 100	80%
Predictive Values	Positive PV	TP/(TP + FP)	0.57
(PV)	Negative PV	TN/(FN + TN)	0.80

Given the test results obtained using LeadCare II analyzer, the likelihood of lead poisoning actually being present or absent was tested by computing the predictive values. Positive predictive value (PPV) of 0.57 (Table 3) showed about 60% chance that children who tested BLL ≥ 10ug/dl were actually lead poisoned. Negative predictive value (NPV) of 0.8 (Table 3), showed about 80% chance that children who tested BLL < 10ug/dl were actually below the action level (BLL < 10ug/dl) for lead poisoning. It is important to note that PPV increases with higher prevalence while NPV decreases as prevalence increases. Hence, the use of LeadCare II as a screening device in the high prevalence settings would potentially be more cost effective.

The predictive value depends on the sensitivity and specificity of the test as well as the prevalence of the disease in the population being

tested. Even with a high sensitivity and high specificity, if the prevalence is low, the positive predictive value of a test may be low. Therefore, to improve on positive predictive value it would be beneficial to screen populations with high prevalence of the disease, using the targeted as opposed to universal screening strategy.

In conclusion, we observed a strong, positive correlation (Pearson's correlation, r = 0.787, r^2 = 0.62), between the BLL determined by LeadCare II and GFAAS. LeadCare II is portable; battery operated and costs less per test as compared to GFAAS. The cost per blood lead test by LeadCare II was $ 6 compared to $105 by GFAAS. In this study, LeadCare II analyzer scored 57% sensitivity, 80% specificity and PPV of 0.8. It offers the potential for medical office-based measurement of BLL in children as well as, for screening and routine use in high prevalence, resource limited settings such as Kenya.

The evaluation could however not comment of the performance of LeadCare II outside the reportable range of 3.3 to 65 ug/dl. The practitioners may need to consult user's guide for the list of drugs that may affect the result BLL using LeadCare II.

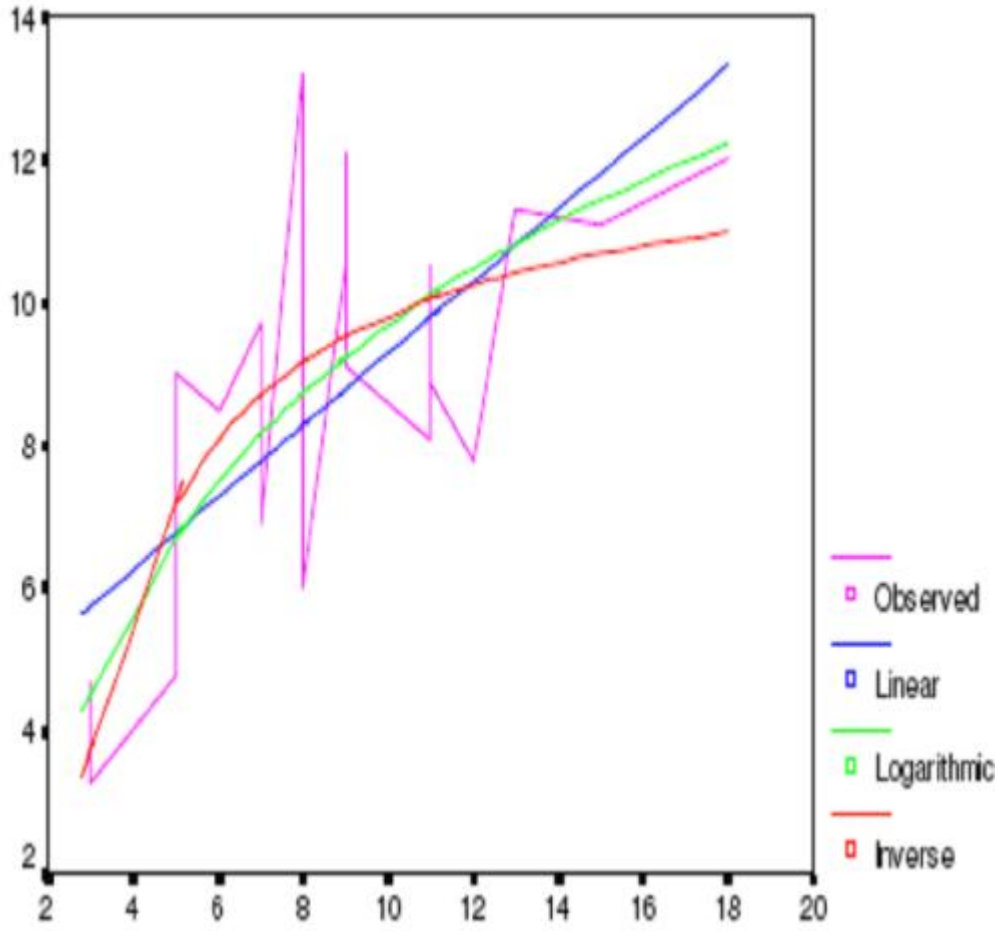

Figure 1: Correlation between blood lead levels (BLL) obtained using LeadCare II and GFAAS on duplicate samples (n=22).

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