ORIGINAL ARTICLE

QUALITY OF LIVER AND KIDNEY FUNCTION TESTS AMONG PUBLIC MEDICAL LABORATORIES IN WESTERN REGION OF AMHARA NATIONAL REGIONAL STATE OF ETHIOPIA

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ABSTRACT

BACKGROUND: ***Medical laboratories play essential roles in measurements of substances in body fluids for the purpose of diagnosis, treatment, prevention, and for greater understanding of the disease process. Thus, data generated from have to be reliable for which strict quality control, management and assurance are maintained. The aim of this study is to assess the accuracy and precision of clinical chemistry laboratories in western region of Amhara national regional state of Ethiopia in testing liver and kidney functions.***

METHODS: ***Eight laboratories in hospitals and a Regional Health Research Laboratory Center participated in this study from February to March, 2011. Each participant was requested to measure six specimens for six chemistry tests from two control samples. Three hundred twenty four test results to be reported from all participant laboratories, if all measurements can be made, were designed to be collected and statistically evaluated.***

RESULTS: ***None of the study subject laboratories could deliver all the six tests for estimation of both liver and renal functions simultaneously during the study period. Only 213 values from the expected 324 values were reported and about 65 % of the 213 values reported fell outside of the allowable limits of errors for the chemistry tests of the control specimen used.***

CONCLUSION: ***This study finding showed that there were lack of accuracy and precision in chemistry measurements. A regular survey on medical laboratories should be conducted questioning the accuracy and precision of their analyses in order to sustain improvements in the quality of services provided by participating laboratories for the benefit of patients. Laboratory Quality Management Systems appreciate the need for regular quality control and quality assessment schemes in medical laboratories.***

KEYWORDS: ***Laboratory Medicine, External Quality Assessment, Clinical Chemistry Tests***

INTRODUCTION

Laboratory service is an essential component of the health care system (1-5). The investigation of epidemics and surveillance of endemic diseases cannot be successful without adequate and organized laboratory facilities and trained human resources. Reliable clinical laboratory services are essential for diagnostic, control and treatment of diseases.

One area where the laboratory plays a great role in disease diagnostic, monitoring and control is in Antiretroviral Therapy (ART) programs for HIV/AIDS patients (6, 7). Laboratory data supplied by the clinical chemistry laboratory play an important role for HIV/AIDS Patients. Test results for kidney functions and liver functions in HIV diagnostic and monitoring laboratory are extremely important for decision making with patients under ART programs, and the consequences of erroneous results are huge (8, 9).

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According to a study made by the US Institute of Medicine a portion of medical errors in a health system may be attributed to errors in data provided by the clinical chemistry laboratories (10). Every day, the clinical chemistry laboratory is faced with many opportunities for errors that may be hazardous to patients. As such, it is essential to make sure that the data provided by the chemistry laboratories is reliable. Laboratories should be standardized, properly managed and regularly assessed for quality to provide their functions (11-15).

The government of Ethiopia has been undertaking different interventions to curb HIV/AIDS destruction on communities; among which the ART service program is one and of which the laboratory service is one strong arm for the health care providers and for the HIV patients in the ART program (16, 17). The quality of clinical chemistry results in such programs is frequently assessed in developed countries for different tests (18, 19). However, quality control schemes are not common in Ethiopia and in many developing countries due to a problem on trained man power, facilities and habit of quality management system on real needs and performance of the laboratories. The performance of public medical laboratories in west Amhara region has not been reported so far. The objective of this study is to assess the performance of medical laboratories in west Amhara region of Ethiopia in testing liver and kidney functions which are usually used in monitoring HIV/AIDS patients following antiretroviral drugs. It is known that the reliabilities of clinical laboratories are best assessed in terms of selected test results than other data that do not clearly show the quality of the services.

MATERIALS AND METHODS

External quality assessment was conducted among hospital based medical laboratories in west Amhara region of Ethiopia from February to March, 2011 by a research team in Bahir Dar University. The region studied covers an estimated 10,826,171 people. There are eight medical laboratories based in government hospitals and a Regional Health Research Center in this region which gives laboratory services for ART service users. The laboratories under study are shown in Table 1.

Table 1. Public Medical Laboratories in West Amhara Regions, 2011.

Laboratory Code	Hospital	Woreda
Laboratory A	Debark Hospital	North Gondar
Laboratory B	Debremarkos Hospital	Gozamin
Laboratory C	Debretabor Hospital	Farta
Laboratory D	Feleghiwot Hospital	Bahir Dar
Laboratory E	Funeteselam Hospital	Jabi Tehnan
Laboratory F	Gondar Hospital	Gondar
Laboratory G	Shedie Hospital	Metema
Laboratory H	Mota Hospital	Hulet Ej Enese
Laboratory I	BDHRC*	Bahir Dar

*BDHRC = Bahir Dar Health Research Centre

Pooled serum control samples Humatrol N (*Human GmbH, Max-Planck-Ring 21 – D-65205 Wiesbaden, CS-HNS-N/022, INF 1351102, 04-2008-1*) and Humatrol P *(Human GmbH, Max-Planck-Ring 21 – D-65205 Wiesbaden, CS-HPS-P020, INF 1351202, 09-2008-2)* were used. Initially 5 ml of distilled water were added to six bottles of the control samples, Humatrol N and Humatrol P (3 bottles each), then the solutions in the bottles were shacked manually for 10 minutes to increase the solubility. After that the three bottles of Humatrol N solutions were collected in one beaker (labeled A) and the three bottles of Humatrol P solutions were collected in another beaker (labeled B). Next, 54 necked bottles (27 for beaker A and 27 for beaker B) were prepared

to contain a specimen solution of 0.5 ml control solutions from each beaker. The necked bottles are labeled as: A_1, A_2, $A_{3...}$ and A_{27}; and B_1, B_2, B_3 … and B_{27}. Each participant laboratory was then requested to measure six specimens from two control samples for the chemistry tests ($3A_n$ and $3B_n$; 6 specimens x 9 Laboratories = 54; 54 specimens x 6 tests = 324 test results expected). The bottles had no other markings and were packed in an ice box for safe storage and transport.

The 324 test results to be reported from all participant laboratories, if all measurements can be made, were then designed to be collected and be statistically evaluated using SPSS 17. On-site observations and interviews with technicians and customers were performed. The allowable limits of error for each test were calculated by means of an empirical formula based on the premise that errors should not exceed one quarter of the normal range (20). This follows:

$$\text{Allowable limits of error (in \%)} = \pm\left(\frac{\frac{1}{4}\text{of the normal range}}{\text{Mean of the normal range}}\right)\times 100\%$$

The maximum limits for determinations were set at ± 10 % on the premise that errors should not exceed 10 % and for this study then the allowable limits of error calculated were ± 10 % for all except for total Cholesterol = ± 7 %. Both sample A and sample B had the same allowable limits of errors. Control values for Humatrol N and Humatrol P are shown in the Tables 2 and 3.

Table 2. Control values for Hematrol N in IU/L and mg/dL* (Control As), Bahir Dar, 2011.

Test Type	**Normal range**	**Stated value**	**Mean value**	**Acceptable range based on stated Value**	**Acceptable range based on mean Value**
SGOT/AST	27.5 - 43.9	35.7	35.5	31.9 - 38.9	32 - 39
SGPT/ALT	24.8 - 39.6	32.2	30.8	29 - 35.4	27.8 -33.8
ALP	164 - 273	218	220	196.2 -239.8	198 - 242
Creatinine*	1.31 - 2.05	1.68	1.6	1.5 -1.85	1.44 -1.76
BUN*	50.4 - 78.8	64.6	62	58.1 - 71	55.8 - 68.2
Total Cholesterol*	145 - 193	169	164	157.2 -180.8	147.6 - 180.4

Table 3. Control values for Hematrol P in IU/L and mg/dL* (Control Bs), 2011.

Test Type	**Normal range**	**Stated value**	**Mean value**	**Acceptable range based on stated Value**	**Acceptable range based on mean Value**
SGOT/AST	117 - 187	152	152.2	136.8 -167.2	137 - 167.4
SGPT/ALT	112 -180	146	143	131.4 - 160.6	128.7 - 157.3
ALP	395 - 658	526	510	473.4 - 578.6	459 -561
Creatinine*	3.55 - 5.55	4.55	4.8	4.1 - 5.0	4.3 -5. 3
BUN*	115 - 179	147	136.1	131.4 -160.6	122.5 - 149.7
Total Cholesterol*	217 - 287	252	244	234.4 - 259.6	227 – 261

After reconstitution, participant laboratories were then requested to test six specimens ($3A_n$ and $3B_n$; 6 specimens x 9 Laboratories = 54) for *Serum Glutamic Oxaloactetic Transaminase or Asparate Aminotransferase,* SGOT/AST; *Serum Glutamic Pyruvate Transaminase or Alanine Aminotransferase,* SGPT/ALT; *Alkaline Phosphate,* ALP; *Blood Urea Nitrogen,* BUN; *Creatinine* and *Total Cholesterol*. The test results were collected with a report sheet with information to be included on the methods and the type of instrument used. An evaluation of the accuracy of each component was determined by calculating the percentage of results which fell

outside of these allowable limits of errors. To evaluate precision, standard deviations were used.

RESULTS

All the eight medical laboratories and the Regional Health Research Laboratory Centre, which were invited to participate in this scheme, completed the study. However, not all laboratories in the west Amhara region can deliver all the chemistry measurements for estimation of liver and kidney functions. Only 213 values from the expected 324 values were reported. The laboratory in Metema (Shadie) was not able to perform the tests; Total cholesterol, ALP, Creatinine and BUN due to unconditioned laboratory facilities unstable with high temperature conditions during the season. Except the Regional Health Research Laboratory Center and Gondar hospital laboratory, total cholesterol was not tested in other Laboratories due to lack of reagents for the test.

The results of all the test values and statistical relations reported from different laboratories are summarized in Table IV. The scatter diagrams (Figures 1-3) for all the samples tested by the different clinical chemistry laboratories were done by plotting sample A, Humatrol N, values against their corresponding sample B, Humatrol P, values. These diagrams show not only the actual values obtained but also the correlation between the sets of values. The vertical and horizontal lines are drawn to outline the acceptable ranges (based on the stated value). Each point represents a different laboratory test result.

From the reported values for SGOT/AST (A), 18.5 % of the reported values fell below the acceptable range and 18.5 % fell above the acceptable range with a total error of 37 % fell out of the acceptable range of values and for SGOT/AST (B), 59 % of the test results fell below the acceptable range and 15 % of the test results fell above the acceptable range, totally 74 % of the results fell out of the acceptable range based on the stated value (Figure 1).

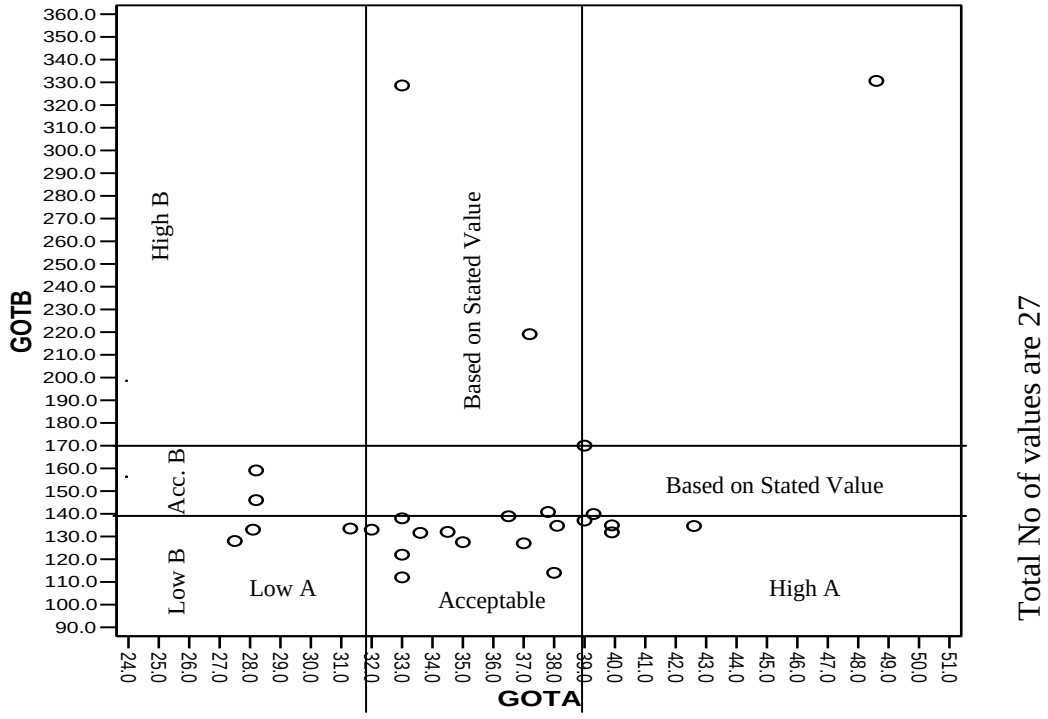

Figure 1. Plot of sample SGOT/AST (A) in Hematrol N values versus sample SGOT/AST (B) in Hematrol P values, Bahirdar, 2011.

From the reported values for the test SGPT/ALT (A), 33 % fell below the acceptable range and 15 % fell above the acceptable range with a total error of 48 % fell out of the acceptable range of values and for SGPT/ALT (B), 74 % of the test results fell below the acceptable range and 11 % of the test results fell above the acceptable range, totally 85 % of the results fell out of the acceptable range (Figure 2).

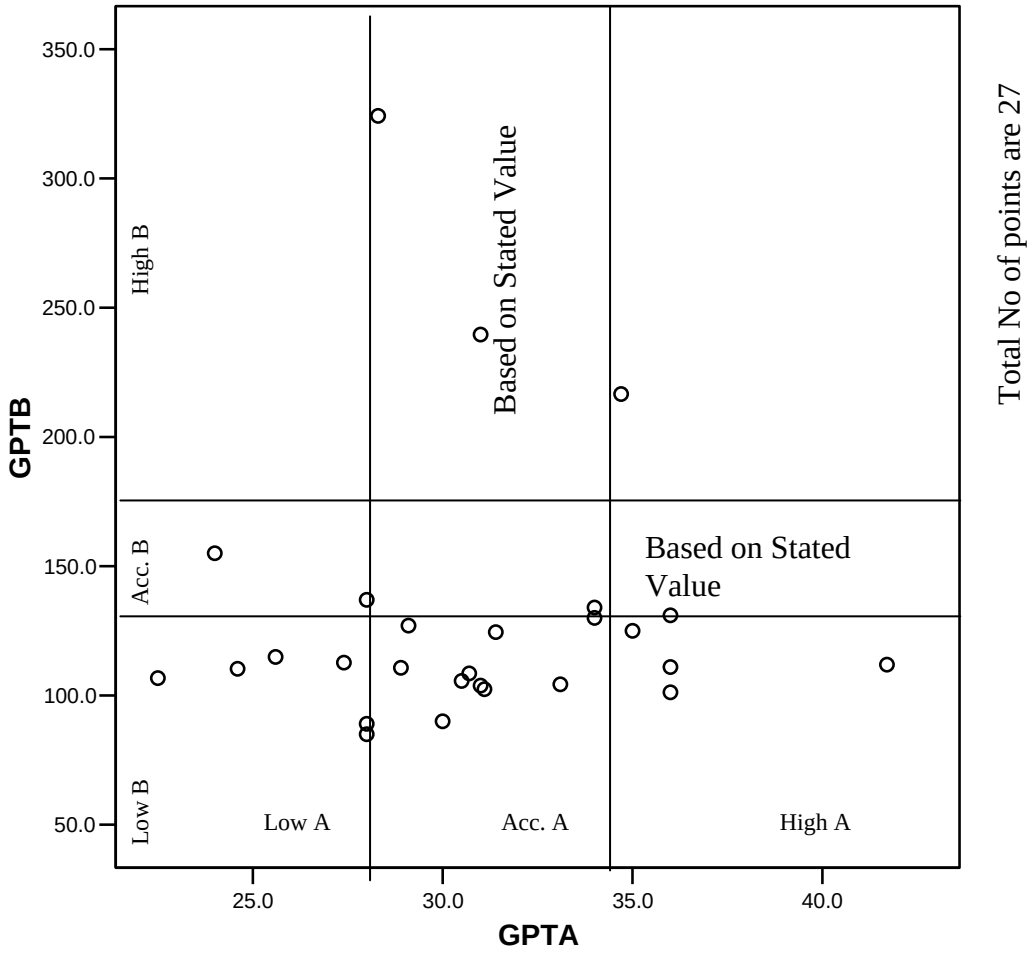

Figure 2. Plot of sample SGPT/ALT (A) in Hematrol N values versus sample SGPT/ALT (B) in Hematrol P values. Bahir Dar, 2011.

From the reported values for the test ALP (A), 50 % of the reported values fell below the acceptable range and also 25 % fell above the acceptable range with a total error of 75 % fell out of the acceptable range of values and for ALP (B), also 50 % of the test results fell below the acceptable range and 25 % of the test results fell above the acceptable range, totally 75 % of the results fell out of the acceptable range (Figure 3).

For Creatinine (A), 53 % of the reported values fell below the acceptable range and no values fell above the acceptable range and a total error of 53 % fell out of the acceptable range of values and for Creatinine (B), totally 80 % of the test results all fell below the acceptable range.

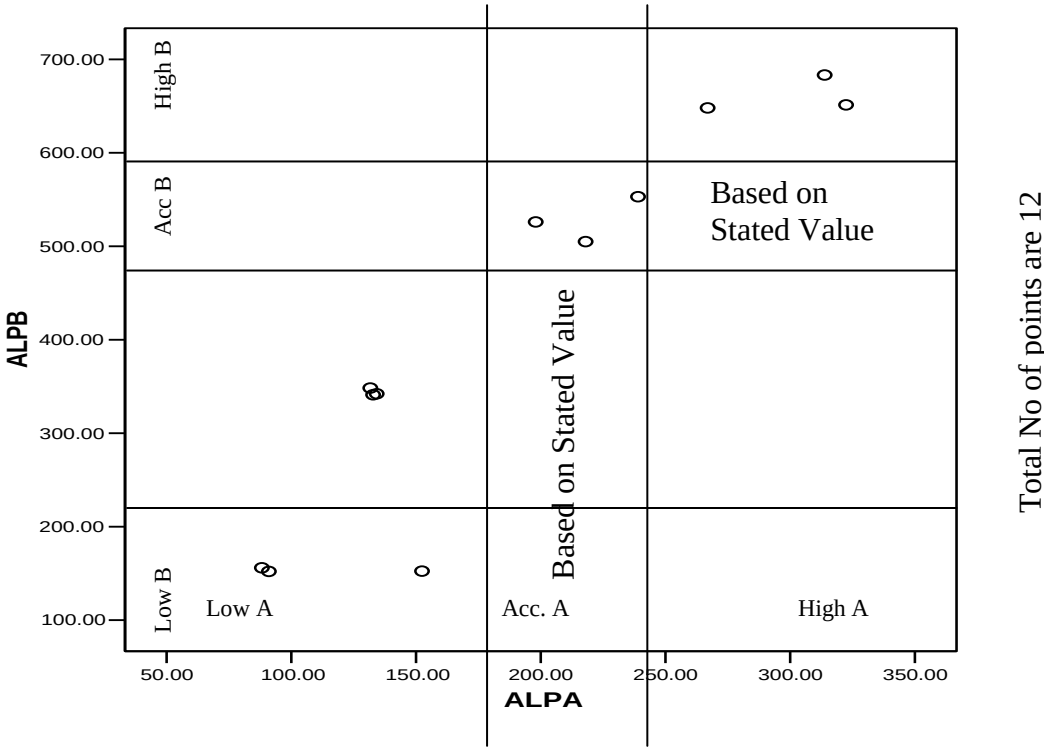

Figure 3. Plot of sample ALP (A) in Hematrol N values versus sample ALP (B) in Hematrol P values, Bahir Dar, 2011.

For BUN (A), 57 % of the reported values fell below the acceptable range and also 4.8 % fell above the acceptable range with a total error of 61.8 fell out of the acceptable range of values and for BUN (B) 23.8 % of the test results fell below the acceptable range and 47.6 % of the test results fell above the acceptable range, totally 71.4 % of the results fell out of the acceptable range.

Similarly, for Total Cholesterol (A), 50 % of the reported values fell below the acceptable range and also no value left above the acceptable range and for Total Cholesterol (B), 33.3 % of the test results fell below the acceptable range and 33.3 % of the test results fell above the acceptable range, totally 66.6 % of the results fell out of the acceptable range.

DISCUSSION

The main purpose of this study was to assess the accuracy and precision of the west Amhara clinical chemistry laboratories which are also on HIV monitoring tests for ART programs in addition to their general roles. All of the participating laboratories in this assessment scheme completed the survey except where some tests were not performed due to the lack of reagent and improper condition for the specimen in the laboratories. Not all laboratories in the west Amhara region can deliver all the chemistry measurements for estimation of liver and kidney functions. Only 213 values from the expected 324 values requested in the design were reported and 64. 7 % of the 213 values reported fell outside of the allowable limits of errors for the chemistry tests of the control specimen used based on the stated value. It was found that there was a lack of accuracy and precision in measurements from these laboratories.

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Table 4. Summary of the results of all test values obtained from eight government hospital based laboratories and a regional medical research laboratory in western region in Amhara National Regional State, Bahir Dar, 2011.

Component	Sample	tated Value	Mean Value	No. of Values Reported	Range	Median	SD	Allowable Limit of error (%)	* % of Unacc values	* % of Unacc. Values
SGOT/AST	A	35.7	35.5	27	27.5-48.6	35	52.5	10	37	37
	B	152	152.2	27	112-330.6	134.6	54.9	10	74	74
SGPT/ALT	A	32.2	30.8	27	22.5-41.7	30.7	4.3	10	48	48
	B	146	143	27	85-324.2	111.9	51.8	10	85	81.4
ALP	A	218	220	12	88.2-322.4	175.2	81.7	10	75	75
	B	526	510	12	152.1-683	426.7	200	10	75	75
Creatinine	A	1.68	1.6	15	0.46-1.8	1.56	0.54	10	53	60
	B	4.55	4.8	15	1.01-4.8	3.7	1.31	10	80	80
BUN	A	64.6	62	18	0-73	54	20	10	61.8	49.4
	B	147	136.1	21	26.1-180	150	48	10	71.4	62
Total Cholesterol	A	169	164	6	127-179	163	19.3	7	50	33
	B	252	244	6	209-268	250.5	24	7	66.7	66.7
Average									**64.7**	**61.8**

**The last two columns give the percentage of values classified as unacceptable.*

The medical laboratory surveys in the US classified a laboratory as performing satisfactorily only when 10% or less of the reported values fell out of the allowable limits (21). The Majority of medical laboratories in west Amhara were found to be out of the standards even in the old Good Clinical Laboratory Practice. Some of the laboratories did not have adequate reagents and chemicals to do all the necessary tests and thus health decisions were made based on incomplete laboratory test results. In another study done by Belete Tegbaru on the status of HIV screening laboratories in Ethiopia indicates that there is poor laboratory management and lack of follow- up in many laboratories (5). Inter-laboratory comparison conducted to evaluate participant laboratories based only on analytical performances as in this work and previous studies is actually is not sufficient for a comprehensive EQA program. A more comprehensive EQA would also include the evaluation of the ability of test interpretation, advice for clinicians on laboratory requests and diagnosis, evaluation of method performance; presence of continuous education, training and help available in the system The Ministry of Health and the regional health bureaus should start the implementation of Laboratory Quality Management System to reinforce the movement towards quality and standardized medical laboratories. Health care organizations must focus on the continuous improvement of quality. A regular survey on the performance of the medical laboratories in health sector can exert a considerable influence on the thinking of the participant laboratory personnel in their work. Investments in education and training should be made to support continuous improvement, recognition should be provided for all health care workers including medical laboratory technologists, clinical laboratory scientists and an open dialogue should be maintained between customers and suppliers for better. Laboratory Quality Management Systems appreciate the need for regular quality control and quality assessment schemes in medical laboratories.

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