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Evaluation of an External Quality Assessment Program for HIV Testing in Tigray North Ethiopia 2016

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Abstract

Background: Point-of-care diagnostic tests (POCTs) are increasingly used in both developing and developed countries. They allow same day testing and treatment at remote locations where no laboratory support is available. Quality control measures, which are routinely used in laboratories, have not been widely implemented for POCTs. This aimed to assess the integrity of the entire laboratory testing process, and aims to educate and improve performance in quality of HIV rapid testing**.**

Methods: A health facility based cross section study was conducted from April to June 2016.Randomly selected health facilities were participated in the external quality assessment. Onsite evaluation and panel test were used to collect data using structured checklists and formats. Data was entered and analyzed using SPSS version 16.

Results: Between April to June 2016, a total of 60 health facilities (145 testing points) from governmental health facilities (hospitals and health centers) were participated in the study. Among the participated testing points 41% have no designated area, 40% have no clean water for hand washing and 51% have no national test algorithm. The average performance of testing points was varies from 89.6% to 99.1% (Laboratory 99.1%, ANC 90.4%, TB clinic 91.4% and VCT 89.6%). In a multivariable logistic regression model, didn't follow national testing algorithm to report client test results have statistical significance.

Conclusions: High quality test results underpin accurate diagnosis and appropriate treatment for patients. But in the study area the score of proficiency testing result and coverage of training is slightly low comparing to other findings. Therefore following national testing algorithm to report client test results, training and monitoring are critical points to improve the proficiency testing score of testing points.

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Background

Point-of-care diagnostic tests (POCTs) are increasingly used in both developing and developed countries [1]. They allow same day testing and treatment at remote locations where no laboratory support is available. Quality control measures, which are routinely used in laboratories, have not been widely implemented for POCTs. The World Health Organization and US Centers for Disease Control and Prevention advocates the implementation of POCT with a quality assurance method in place [2].

The World Health Organization (WHO) defines External Quality Assessment (EQA) as a system for objectively checking a laboratory's performance using an external agency or facility [3]. EQA participation is associated with improved laboratory performance over time and is a requirement for accreditation [4]. However, many professionals in Sub-Saharan Africa (SSA) countries are unable to effectively implement quality improvement programs and many countries remain without an accredited clinical laboratory [5]. Establishing, maintaining and demonstrating the accuracy of diagnostic tests is a major challenge for most laboratories in SSA, and the complexity and cost of setting up and main training quality assurance systems mean that very few laboratories, mainly tertiary or privately owned, can achieve these standards [6,7]. The common perception that EQA is costly or unnecessary has hindered the widespread enrolment of laboratories into EQA programs [8].EQA can be applied in three main ways, each with advantages and disadvantages: 1) Proficiency testing (PT), where an external provider sends samples of undisclosed results to laboratories or individual testers and provides feedback on results; 2) Rechecking or retesting samples in higher level or peer laboratories (inter-laboratory comparison); 3) On-site assessment by approved evaluators [3].

Health service utilization to human immunodeficiency (HIV) has expanded rapidly in Ethiopia. National efforts to scale up care and treatment services for individuals with HIV depend on efficient laboratory services, including HIV testing, which is the main entry point to access to care and treatment. In spite of increased access to HIV counseling and testing in developed countries, most people living with HIV in low and middle-income countries are unaware of their aerostats [9].

While available rapid diagnostic tests (RDTs) for HIV have high sensitivity and specificity when performed correctly, incorrect use can result in incorrect results, with serious consequences [10]. EQA is critical to assess the quality of laboratory performance and to ensure accuracy and reliability of laboratory results [11].This aimed to assess the integrity of the entire laboratory testing process, to educate and improve performance in quality of HIV rapid testing.

Methods

Study area

The study was conducted in Tigray region which is located at a distance of 600 km northeast of Addis Ababa.Tigray is bordered by Eritre to the north, Suda to the west, the Afar Regio to the east, and the Amhara Regio to the south and southwest.

Study design, period and Study subject

A health facility based cross section study was conducted from April to June 2016.Randomly selected health facilities were selected. Sixty hospitals and health centers (145 testing points) were participated in this study.

Data collection and quality control methods

Proficiency test, standard checklist and on site observation were used during the specified time to asses overall quality HIV rapid test including HIV testing, HIV testing methods used, utilization of standard operating procedures (SOPs), internal and external quality control utilization.

Data processing and analysis

The quality of data was checked by reviewing the questionnaire for consistency and completeness. Data were entered, cleared and analyzed using SPSS version 16.

Result

A total of 145 testing points from governmental health facilities (hospitals and health centers) participated in the study. Among the participated testing points 41% have no designated area, 40% have no clean water for hand washing and 51% have no national test algorithm (table 1).

Table 1. General back ground characteristics of testing points in HIV testing

characteristics	Yes N (%)	No N (%)
Designated area for HIV testing	86 (59)	59 (41)
Availability of clean water and soap for hand washing	87 (60)	58 (40)
Availability of national test algorithm	94 (64.8)	51 (35.2)
Sop for each HIV rapid test	72 (49.7)	73 (50.3)
Kits and supplies used within their expiry date	139 (96)	6 (4)
IQC practice	65 (45)	80 (55)
Training for HIV rapid test	81 (56)	64 (44)
Clean and organized working area	132 (91)	13 (9)
Appropriate disinfectants	110 (76)	35 (24)
Waste segregation	101 (70)	44(30)
kits stored according to manufacturer recommendation	137 (94.5)	8 (5.5)
Inventory management	59 (41)	86 (59)
job aids on specimen collection	52 (36)	93 (64)
Availability of sufficient kits and supplies	122 (84)	23 (16)
Labeling with client identification number	12 (89)	16 (11)
Availability of timer	44 (30)	101 (70)
testing procedures adequately followed	108 (74.5)	37 (25.5)
Following the national testing algorithm to report the client test result	128 (88)	17 (12)

Table 2. Association of health service providers with HIV rapid test PT results

Characteristics	Response categories	PT result		Crude OR (95% CL)	P-value
		Meet the standard	Below the standard		
Testing points	laboratory	36(97.3)	1(2.7)	**Reference**	
	ANC	29(76.3)	9(23.7)	11.172(1.34, 93.37)	.026
	TB	29(82.9)	6(17.1)	7.45(.85, 65.41)	.070
	VCT	26(74.3)	9(25.7)	12.462(1.486, 104.51)	.020
Availability of national test algorithm	Yes	83(88.3)	11(11.7)	Reference	
	No	37(72.5)	14(27.5)	2.86(1.19,6.89)	.019
Sop for each HIV rapid test	Yes	64(88.9)	8(11.1)	Reference	
	No	56(76.7)	17(23.3)	2.43(.97,6.10)	.057
Kits and supplies used within their expiry date	Yes	115(82.7)	24(17.3)	Reference	
	No	5(83.3)	1(16.7)	.96(.11,8.60)	.97
IQC practice	Yes	59(90.8)	6(9.2)	Reference	
	No	61(76.2)	19(23.8)	3.06(1.14,8.20)	.026
Training for HIV rapid test	Yes	67(82.7)	14(17.3)	Reference	
	No	53(82.6)	11(17.2)	.99(.42,2.37)	.99
kits stored according to manufacturer recommendation	Yes	115(83.9)	22(16.1)		
	No	5(62.5)	3(37.5)	3.14(.70,14.10)	.14
job aids on specimen collection	Yes	48(92.3)	4(7.7)	Reference	
	No	72(77.4)	21(22.6)	3.50(1.13,10.83)	.030
Labeling with client identification number	Yes	110(85.3)	19(14.7)	Reference	
	No	10(62.5)	6(37.5)	3.47(1.13,10.68)	.030
Availability of timer	Yes	42(95.5)	2(4.5)	Reference	
	No	78(77.2)	23(22.8)	6.17(1.39,27.55)	.017
testing procedures adequately followed	Yes	96	12	Reference	
	No	24	13	4.3(1.8,10.7)	.002
Following the national testing algorithm to report the client test result	Yes	111(86.7)	17(13.3)	Reference	
	No	9(52.9)	8(47.1)	5.80(1.97,17.10)	.001

PT result of testing points

Most (82.8%) of the testing points score above the expected standard. From the total testing points 118 (81.4%) testing points score 100%, 6 (4.2%) testing points score 33%, 19 (13%) testing points score 67% and 2 (1.4%) testing points score 83%.The average performance of testing points was varies from 89.6% to 99.1(Laboratory 99.1%, ANC 90.4%, TB 91.4% and VCT 89.6%).

Factors associated with poor HIV rapid test PT performance

In a univariable logistic regression analysis, have no national algorithm in testing sites has high risk (odd ratio 2.86) to report false client results than having national test algorithm at P value (0.03). Using timer to report client result has reduced false HIV results six times than not using timer (P value 0.015). An adequately following test procedure during HIV testing has great advantage. Because it reduces false negative results 4 times than not adequately following test procedure (P value 0.002) (Table 2).

In a multivariable logistic regression model, didn't follow national testing algorithm to report client test results has statistical significance (Table 3).

Discussion

External quality assessments is a method used for assessing laboratory and health care professionals' performance and allows for the evaluation of inter-laboratory proficiency tests and the identification of related problems. Accordingly, it affords grounds for corrective and preventive actions on a regular basis [10].Measures to control the quality of result in HIV diagnostic laboratories are extremely important, because of the consequence of either false Positive or false negative results are huge [9].

This study demonstrates low (56%) coverage of HIV training in the testing points. This is different from a study conducted in south Ethiopia which was 85% [11]. This difference may be due to difference in sample size and characteristics of study participants, our study participants were laboratories and other health professionals whom perform HIV rapid test in TB clinic, VCT, ANC but their study participants were only laboratory and their samples were only 20 health facilities. From the assessed testing points, 64 (44%) health professionals' who conduct HIV testing were found to have no trained in HIV testing. This is incomparable with study conducted in Ethiopia, which reported only14% were found to have no trained in HIV testing [11]. In this study 12% study participants didn't follow national test algorithm. This is in line with study conducted in Ethiopia, which demonstrates 10% of the study participants didn't follow national test algorithm. Our finding demonstrated that 50% testing points have no SOP for each testing points. In contrast to this findings study conducted in Ethiopia and South East Asia reported that from assessed laboratories 0% and 8% did not have SOPs respectively [11,12].

The average score of the testing points were 92.7%.This slightly lower than nine year survey conducted in Africa WHO region which indicated that 98.9% [13]. This deference may be due to study participant difference and method used for HIV testing. Because our study participants included all testing points and they performed HIV testing using HIV rapid test but their study participants' only laboratory professionals and they used HIV rapid test and ELISA to perform HIV rapid testing. Our findings demonstrated that 82.8% of testing points score 80 and above this lower than study conducted by Jean Louis and his colleagues which was 97.5% [13].

Conclusions and recommendations

High quality test results underpin accurate diagnosis and appropriate treatment for patients. But in the study area the score of PT result and coverage of training is slightly low comparing to other findings. Therefore following national testing algorithm to report client test results, training and monitoring are critical points to improve the PT score of testing points.

Declaration

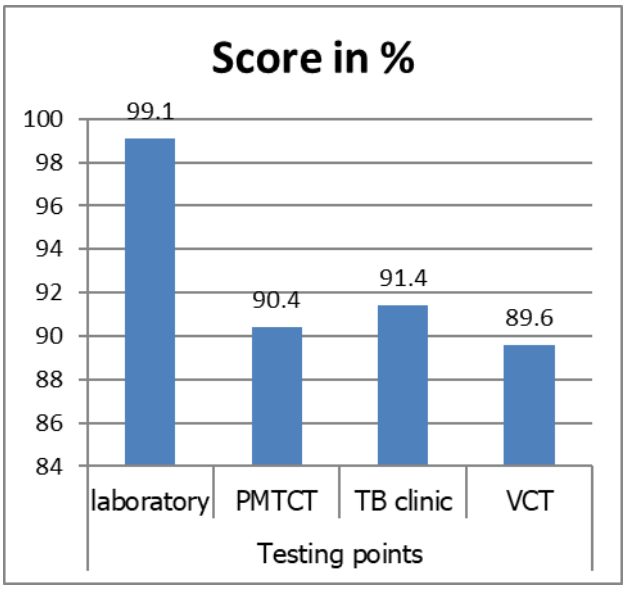
Ethical approval and consent to participate

Ethical approval was obtained from Tigray regional health bureau and permission was obtained from each health facilities before conducting this study.

Table 3. Factors associated with poor HIV rapid test PT performance

characteristics	Response categories	PT result		Crude OR (95% CL)	Adjusted OR (95% CL)	P-value
		Meet the standard	Below the standard			
Testing points	laboratory	36(97.3)	1(2.7)	Reference	Reference	
	ANC	29(76.3)	9(23.7)	11.172(1.34, 93.37)	3.58(.30,42.22)	.311
	TB	29(82.9)	6(17.1)	7.45(.85, 65.41)	2.70(.20,35.05)	.454
	VCT	26(74.3)	9(25.7)	12.46 (1.49, 104.51)	5.71(.46,71.01)	.175
Availability of national test algorithm	Yes	83(88.3)	11(11.7)	Reference	Reference	
	No	37(72.5)	14(27.5)	2.86(1.19,6.89)	2.06(.69,6.22)	.198
IQC practice	Yes	59(90.8)	6(9.2)	Reference	Reference	
	No	61(76.2)	19(23.8)	3.06(1.14,8.20)	1.80(.50,6.52)	.374
job aids on specimen collection	Yes	48(92.3)	4(7.7)	Reference	Reference	
	No	72(77.4)	21(22.6)	3.50(1.13,10.83)	1.70(.38,7.68)	.492
Labeling with client identification number	Yes	110(85.3)	19(14.7)	Reference	Reference	
	No	10(62.5)	6(37.5)	3.47(1.13,10.68)	2.05(.48,8.74)	.332
Availability of timer	Yes	42(95.5)	2(4.5)	Reference	Reference	
	No	78(77.2)	23(22.8)	6.17(1.39,27.55)	3.17(.45,22.18)	.246
testing procedures adequately followed	Yes	96	12	Reference	Reference	
	No	24	13	4.3(1.8,10.7)	1.29 (.35,4.73)	.701
Following the national testing algorithm to report the client test result	Yes	111(86.7)	17(13.3)	Reference	Reference	
	No	9(52.9)	8(47.1)	5.80(1.97,17.10)	11.57(2.46,54.35)	.002

Figure 1. Average performance of testing points in %



Consent to publish

Not applicable

Availability of data and materials

All data and materials are available in SPSS and excel. We can avail our raw data for all who need it.

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Competing interests

The authors declare that they have no competing interests.

Authors' contribution

GT and GG designed the study, participated in data collection, analysis, interpretation, and write-up, drafted the manuscript and critically revised the manuscript. Both authors read and approved the final manuscript.

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