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#### ABSTRACT

**Background:** The consequences of HIV misdiagnosis leading to misclassification and unnecessarily treating HIV-negative persons have many important ethical, legal, and health system consequences. However, WHO recommends HIV retesting for verification for all newly diagnosed cases by a second tester, so as to rule out potential misdiagnosis and its subsequent implications. The aim of this study was to ascertain the uptake and implementation of HIV re-testing for verification in some health facilities in the littoral region of Cameroon.

**Methods:** The study design consisted of a retrospective review of HIV testing registers and HIV stock cards and also a cross sectional survey on the level of knowledge of HIV testers. The study was conducted from December 2018 to January 2019. A structured questionnaire was used to capture information on the testers' knowledge on the national algorithm for HIV diagnosis using rapid test. Stock cards were used to determine the number of test kits used and the number of tests done. The national HIV testing register was used to estimate the expected number of test that should have been used following the national testing algorithm. Data analysis was done with SPSS version 20. Proportions were calculated for categorical variables. While difference in proportions were compared with the Chi-square tests.

**Results:** Out of the 84 testers recruited in the study, 11 (13.1%) were not health personnel, while 65(77.4) were laboratory technician/Scientist. Up to 42(50%) of the testers had received a comprehensive training on laboratory quality assurance and HIV testing. The proportion of testers who knew the type of HIV rapid testing algorithm used in Cameroon was significantly higher 37(56.1%) among testers who were trained, compared to those who were not trained 5(27.8%) (p = 0.033). However, majority of participants who did not understand the concept of testing for verification were those who had not been trained, 83.3% compared to 16.7% who were trained (p = 0.001). Out of the 17 testing sites enrolled in the study, only 8 sites were effectively doing retesting for verification. Stocks out of HIV test kits as well as the site for which testing was done, were found to be associated with the uptake of retesting for verification.

**Conclusion:** The findings of this study suggest that, the uptake and implementation of HIV retesting for verification is low. Stock outs and the site for which retesting for verification is done, are associated with retesting for verification uptake. Therefore, there is need for a regular policy while ensuring the availability of functional procurement systems to avoid frequent stock-outs of test kits.

Key word: HIV Retesting for Verification, Knowledge, Testing Algorithm, Cameroon

#### **INTRODUCTION**

The risk of misclassification of HIV test results leading to initiating HIVnegative individuals on ART is not hypothetical. <sup>[1,2]</sup> The consequences of HIV misdiagnosis leading to misclassification and unnecessarily treating HIV-negative persons have many important ethical, legal,

and health system consequences. <sup>[3]</sup> HIV rapid tests results can be misclassified (false positive or false negative) due to use of expired test kits, lack of quality assurance procedures and deviation from the national testing algorithm or inherent limitations of the HIV rapid tests. In 2016 WHO recommended that all people living with HIV should start ART early ('Test and Treat'), regardless of WHO clinical stage or CD4 cell count.<sup>[4]</sup> Then came the Joint United Nations Program on HIV/AIDS (UNAIDS) target of '90-90-90' by 2020 to accelerate progress towards ending the epidemic by 2030. <sup>[5]</sup> AIDS These approaches promoted the scale up of HIV testing and expansion to out of laboratory testing. To ensure quality scaling up of HIV testing, WHO recommends the retesting for verification purposes of all newly diagnosed HIV cases by a second tester using a different sample from the same patient.<sup>[6]</sup>

Many countries with Cameroon inclusive adopted the WHO retesting for verification strategy to ensure HIV-negative individuals are not place on lifelong ART. As of 2014, only 20% of testing strategies followed current WHO recommendations. [3,7] Despite adoption of retesting for verification by many HIV endemic countries, limited and slow uptake due to cost perceived high of re-testing, overstretched health workers, poor system capacity and uncertainty about how to implement the verification testing was observed in some of these countries.<sup>[6]</sup> WHO information note in 2014 reminded Ministries of Health and National AIDS Control programs to retest all persons newly diagnosed as HIV positive, with a second specimen before ART initiation, to rule out potential misdiagnosis.<sup>[8]</sup>

Retesting for verification started in Cameroon in 2017 after adoption and contextualizing to retesting of same sample by a second tester, as part of national algorithm for HIV rapid testing in adults. In order to capture this aspect of verification testing in Cameroon, Global Health Systems Solutions (GHSS) an implementing partner

of CDC, redesigned national Quality Assurance logbooks for rapid diagnosis in Cameroon to include a portion for verification testing. With the Scale up of HIV testing in regions with high burden, HIV testing is increasingly done by a variety of lay providers. <sup>[9]</sup> However there is still limited data to ascertain on the uptake and implementation of HIV re-testing for verification in Cameroon and specifically the staff's knowledge on the HIV rapid testing national algorithm as well as the possible factors affecting retesting for verification uptake.

### **METHODS**

#### Study design

The study had both a retrospective and a cross sectional design, conducted from December 2018 to January 2019.The retrospective aspect of the study involved the review of HIV testing registers for the number of test done and HIV reagent stock cards for the number of test kits used from April to September 2018. The cross sectional survey was design to assess the level of knowledge of HIV testers on the national algorithm in Cameroon for HIV diagnosis using rapid test. For health facilities with multiple HIV testing sites, testers from three high volume testing sites were surveyed.

### Study Area

Douala is the economic capital of Cameroon and the regional capital of the Littoral Region of the country. The city of Douala is the most populated urban centre in Cameroon, <sup>[10]</sup> with about 2, 768 436 habitants. According to the 2011 Cameroon Demographic and Health Survey, the prevalence of HIV/AIDS reached 4.6% for people aged 15 to 49 years making the Littoral region one of the four regions in Cameroon with the highest HIV burden. Women were particularly affected, with a prevalence of 6.4% as opposed to 2.6% for men <sup>[11]</sup> The Littoral is also one of the Regions prioritized for the implementation of HIV/AIDS interventions.

#### **Study population**

The study was conducted in some health districts that have been identified for HIV burden in the Littoral region of Cameroon namely: Deido, Mbangue, Logbaba, Cite de Palmier. Participants included in the retrospective part were individuals who were tested with the HIV rapid diagnostic test kit in the selected rapid tested in the selected health facilities between April and September 2018 while those involved in the survey were HIV testers working in three high volume testing sites.

#### Data collection

Data was collected using a structured questionnaire which captured information on testers' knowledge on the HIV national rapid testing algorithm, and demography. The numbers of tests done and number of positive cases diagnosed per site were collected from the laboratory HIV testing quality assurance register with the help of a checklist. The checklist was also used to collect data on the number of test kits used within the study period.

#### Data analysis

Data collected using questionnaires and checklists was entered into Epi-info 7 and exported to SPSS version 20 (IBM, Chicago, IL) for analysis. The number of testing sites doing retesting for verification was determined by comparing the number of test kits used to the number of test kits the site was expected to use for the number of tests they performed. Descriptive statistics were expressed as percentages, while the difference in proportions within groups was compared with the chi-square tests. A p value of 0.05was considered statistically significant.

#### Data archiving

To ensure security of the data collected after data entry and upon completion of the study, all questionnaires and checklists are stored in special cabinets at the headquarters of the hosting institutions for the study. These files will be retained for a 10 year period and thereafter discarded.

#### **Ethical Considerations**

Administrative authorizations for this study were obtained from the regional delegation of Public Health for the Littoral Region and the directors of all the health facilities involved. Ethical clearance for the study was obtained from the Cameroon Baptist Convention Health Service (CBCHS) Institutional Review Board. Written informed consent was obtained from all participants before enrolment. All registers from which data was collected did not have names of patients and any information obtained was treated with strict confidentiality by assigning codes as names to each of the health facilities.

#### RESULTS

#### **Characteristics of the study population**

The study was conducted in 7 health facilities among which 5 were government owned and two were faith based. Within the facilities enrolled, 17 HIV testing sites participated in the study with 9 (52.9%) being laboratories. A total of 84 HIV testers were enrolled with 52(61.9%) of them being females. Looking at the testers professional background, majority 65(77.4%) were laboratory technician or Scientist while the least were counsellors 3(3.6%) and other (accounting clerk. teacher and administrative clerk) 3(3.6%). Participants with at least a university degree or diploma were the most represented 55(65.5%) while those with secondary level of education were least represented 7(8.3%) as shown on Table 1.

Table 1: Distribution	on of the	e study	population
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Factor	Category	Number
		Enrolled (%)
Type of facility	Faith base	2(28.5)
	Government	5(71.4)
Testing site	Blood bank	2 (11.8)
	Laboratory	9(52.9)
	Care and treatment Centre	2 (11.8)
	Others	4(23.5)
Tester sex	Female	52(61.9)
	Male	32(38.1)
Tester profession	Psychosocial worker	5 (6.0)
	Counsellor	3(3.6)
	Lab technician/Scientist	65(77.4)
	Nurse	8(9.5)
	Others	3(3.6)
Level of education	High school	22 (26.2)
	Secondary	7(8.3)
	University	55(65.5)

# Knowledge of HIV Testers on the National Testing Algorithm

Among the 84 testers enrolled, 42(50%) had received a comprehensive training on quality assurance and HIV testing. Eighty three (98.8%) of the participants were aware of the existence of national Algorithm on HIV rapid testing in the country. The proportion of participants who knew the type of testing algorithm (serial) used for HIV diagnosis in Cameroon was significantly higher 37(56.1%) among participants who were trained compared to those who didn't 5(27.8%) (p = 0.033). No significant association was found between those who were trained and those who were not trained with respect to test kits combination, results interpretation and handling of inconclusive cases. However, majority of participants who did not understand the concept of verification testing were those who had not been trained 83.3% compared to 16.7% who were trained. This difference was statistically significant (p = , 0.001) as shown on table 2.

Table 2: Testers knowledge on the national algorithm for HIV rapid diagnostic testing

Variable	Category	Number enrolled (H)	Trained on HIV	Not Trained on HIV	p-
		N = 84	testing (%H)	testing (%H)	value
Type of Algorithm	Serial	66	37(56.1)	29(43.9)	0.033
	Parallel/ don't	18	5(27.8)	13(72.2)	
	know				
First line tests	Knew	75	37 (49.3)	38 (50.7)	0.72
	Didn't know	9	5 (55.6)	4 (44.4)	
Second line tests	Knew	68 (81.0)	36(52.9)	32(47.1)	0.27
	Didn't know	16 (19.0)	6(37.5)	10(62.5)	
1st and 2nd Test Interpretation	Correctly	69(85.2)	35(50.7)	34(49.3)	0.57
_	Wrongly	15(17.9)	7(46.7)	8(53.3)	
Interpretation of an inconclusive	Correctly	50(59.5)	26(52.0)	24(57.1)	0.66
test results	Wrongly	34(40.5)	16(47.1)	18(52.9)	
Handling of in conclusive test	Correctly	80(95.2)	40(50)	40(50)	1
results	Wrongly	4(4.8)	2(50)	2(50)	
Knowledgeable about	Yes	66(78.6)	39(59.1)	27(40.9)	0.001
verification testing	No	18(21.4)	3(16.7)	15(83.3)	]
Overall		84	42(50)	42(50)	-

# Up take of verification testing and associated factors

When the number of HIV test done were matched with the number of test kits used, it was observed that among the 17 HIV testing sites enrolled, 8(47.1%) used less than the expected number of the first line test (Alere Determine) while 5(29.4%) used less than the expected number of the second line test (Ora Quick or KHB Shanghai) as reported in figure 1.

Out of the 17 sites involved in the study, 8 were doing HIV retesting for verification (sites that had used the expected number of first and second line test kits). For HIV testing sites that were not doing verification testing, no association was observed between sites that were doing verification and sites that were not doing it with respect to type of sample used, whether the tester is trained on HIV testing or not and the type of facility. Other findings revealed that, all the 8 testing sites effectively doing retesting for verification send their patient or their sample to a different testing site for retesting to be done. This was found to be statistically significant (p = 0.006).



Figure 1: Proportion of site that used the expected number of test kits and those that didn't use the expected number of test kits

Furthermore, among the 9 sites that reported stock out (mostly determine), 7(77.8%) were doing verification testing while, of the 8 sites that did not report any stock outs, only 1(12.5%) was doing verification

testing. This observation showed a significant association (p = 0.007) (Table 3). With the sites doing verification testing, no discordance was observed between the first tester and the second tester (verification).

Factor	Category	Number enrolled	Doing Verification (%)	Not doing verification (%)	P-value
Type of sites w	Faith based	4	2(50.0)	2(50.0)	0.893
	Government	13	6(46.2)	7(53.8)	
HCT Training	Trained	12	4(33.3)	8(66.7)	0.079
	Not trained	5	4(80)	1(20)	
Sample	Capillary	10	6(60)	4(40)	0.201
	Venous	7	2(28.6)	5(71.4)	
Where verification is done	Same site	5	0(0)	5(100)	0.006
	A different site	12	8(66.7)	4(33.3)	
Availability of test	Stock out	9	7(77.8)	2(22.2)	0.007
	No stock out	8	1(12.5)	7(87.5)	

Table 3:	Factors	affecting	verification	testing	
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#### DISCUSSION

As HIV screening becomes more widely required and more commonly conducted, the use of rapid tests kits have scaled up. A primary concern about rapid testing is the poor testing sensitivity and the unacceptable high rate of false positive results. Retesting for verification aims at ruling out possible technical or clerical errors, including specimen mix-up through mislabeling and transcription errors, as well as random error either by the provider or the test device. <sup>[12]</sup> This study was designed to identify the uptake level of HIV re-testing for verification, the staff's knowledge on the HIV rapid testing national algorithm as well as the possible factors affecting retesting for verification uptake.

In this study, out of the 17 sites doing HIV rapid testing, 8(47.1%) sites were identified to be doing re-testing for Verification. This low uptake of retesting for verification could be explained by the fact that there is no policy in place to ensure health facilities implement the strategy, and also to sanction defaulters. In addition to that, the frontline implementation of this strategy is championed by implementing partners while the ministry of health with greater authority over the health facilities is not very active. Further findings illustrated that, retesting for verification was associated with tests kits stock-out as 7 out of 9 testing sites that reported stock out were doing retesting for verification. Therefore, it could

be possible that in an attempt to avoid stock out and service interruption, facilities failed to implement retesting for verification, which requires additional test kits. It has previously been reported that, Stock outs of HIV test kits and consumables such as lancets, alcohol swabs, or specimen transfer devices, are some of the biggest sources of poor quality and client dissatisfaction with HIV counseling and testing. <sup>[6,13]</sup> It is important to note that more sites had used the expected number of the second line test kits (OraQuick or KHB Shanghai) than the expected first line test kits (Alere Determine). This implies that, these sites did verification using only the second line. Furthermore, the findings also revealed that more sites reported stock outs for the first line test than the second line test. Frequent stock outs of the first line test kits could be explained by the fact that one of the first line test kit (HIV Unigold) on the national testing algorithm is not available for use in the country. Also, the second line test kits are only used when the 1<sup>st</sup> line test is reactive thus the high rate of use of the 1<sup>st</sup> line test kits.

The level of testers' knowledge on the national algorithm was the same among those who had received comprehensive training on quality assurance and HIV testing, as well as those who had not. This could be due to the fact that majority of the trained testers were trained more than 2 years ago and received any refresher

training. WHO recommends that testers should participate in a refresher training that includes a practicum every two years.<sup>[14]</sup> Nonetheless, there are no national policies enforcing in Cameroon regular comprehensive training on quality assurance and HIV testing. Furthermore, some of the trained testers are frequently transferred to facilities different health and are occasionally being replaced by staffs who haven't received training. With the scale up of HIV testing, the number of people who are now able to receive testing has drastically increased. Problematically, the number of medical professionals available to administer the tests and interpret the results has not increased proportionately, leaving clinic staff with less training and experience to run testing centers in some areas. <sup>[15]</sup> Also, although majority (98.9%) of the testers in this study were aware of the existence of the national algorithm for HIV rapid diagnostic testing, the proportion of testers who knew the type of testing algorithm (serial) used for HIV diagnosis in Cameroon was significantly higher among 37(56.1%) participants who were trained, as well as majority of participants who understood the concept of verification testing. This further emphasizes that, scaling up of retesting for verification requires effective capacity building and periodic supportive supervision to ensure services are consistently of high quality and that they meet the required standards. <sup>[11]</sup>

### CONCLUSION

The current findings on implementation of HIV retesting for verification showed that just 47% percent of testing sites involved in the study are effectively doing retesting, with major challenges being inadequate trained staff, absence of refresher training to already trained staff as well as frequent stock out of test kits. In other to avoid misclassification and unnecessarily treating HIV-negative persons, there is a need of policies enforcing regularly comprehensive training of testers on the quality assurance and HIV testing as well as ensuring the availability of supplies in a functional procurement and inventory management systems, to avoid frequent stock-outs of test kits.

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