

Research Article



Usability of three finger-stick whole blood HIV self-testing kits among men who have sex with men and female sex workers in Yaounde and Douala, Cameroon

JP Yves Awono Noah^{1,6*}, Justin Ndié^{1,6}, Francis Ateba Ndongo^{1,8}, Rogacien Kana^{1,6}, Onesimus Yongwa², Martial Bonyohe¹, Plessy Hedgar Mboussam², Tatiana Palisson Avang¹, Fatima Moulioum¹, Félicité Tabala Naah¹, Gutenberg Tchikangni², Audrey Djomo Nzaddi³, Alice Ketchaji⁴, Carelle Djofang Yepndo⁴, Gildas Nguemkam¹, Charles Baudelaire Ndindjock IV², Brice Seukam², Yagaï Bouba³, Ernest Désiré Mvilongo Anaba³, Rina Estelle Djoukwe⁵, Serge Billong^{4,7}, Karin Hatzold¹⁰, Annie Michele Salla², Jérôme Ateudjieu^{1,9}, Anne Cécile Zoung - Kanyi Bissek^{1,7}

Abstract

Background: The use of fingerstick HIV self-testing (HIVST) represents a novel approach to improving HIV screening, particularly among at-risk populations. However, there is currently a paucity of empirical evidence on its usability in Cameroon, necessitating the development of robust empirical evidence before this approach can be scaled up.

Objective: This study assessed the usability of three HIVST kits among men who have sex with men (MSM) and female sex workers (FSWs) in Cameroon.

Materials and Methods: An observational study was conducted in 14 community-based organisations (CBOs) in Yaoundé and Douala between the 11th and 22nd of June 2022. The study population consisted of FSWs and MSM aged 21 years and over who agreed to participate in the study. Once recruited, participants received counselling, unassisted finger-stick whole blood HIV self-testing and condoms. Data was collected using an administered questionnaire. Three finger-stick whole blood HIV self-testing kits were used in the study: Mylan, Sure Check and Check Now. The analysis was conducted using SPSS 27 software and the main outcomes were presented with a 95% confidence interval (95% CI).

Results: Of the 815 participants who completed the HIV blood selftest, the median age was 27 years and 56.1% were FSWs. One in ten participants had never undergone an HIV test. The successful test performance for the Check Now, Sure Check and Mylan tests were 98.5%, 97.8% and 94.7%, respectively. In addition, the proportions of correct interpretation of results were 83.1%, 79.3% and 79.8%. The agreement between a participant's blood-based HIV self-test result and those of trained investigator-observers results was moderate with Check Now (κ =0.486; 95% CI: 0.366-0.605; p=0.001), whereas agreement with Sure Check (κ =0.36) and Mylan (κ =0.372) was low. Similarly, the proportions of good usability were 82.0%, 77.9% and 75.3 respectively. On multivariate analysis, participants who had difficulty drawing blood with the micropipette were more likely to fail the self-test (aOR=0.1; 95% CI: 0.0-0.3; P = 0.005).

Conclusion: The use of fingerstick whole blood HIV self-testing kits by key populations in Cameroon is a viable method of HIV testing. However, issues have been identified with regard to interpretation, thereby underscoring the necessity for further training in order to enhance the accuracy of these tests and optimise the effectiveness of HIV prevention interventions.

Affiliation:

¹Operational Health Research Division - Ministry of Public Health, Cameroon

²Cameroon Social Marketing Association, Cameroon ³Central Technical Group - National AIDS Control Committee, Cameroon

⁴Department of Disease Control, Epidemics and Pandemics - Ministry of Public Health, Cameroon

⁵Directorate of Pharmacy, Medicines and

Laboratories - Ministry of Public Health, Cameroon ⁶Media Convergence Health Research Centre,

Cameroon

⁷University of Yaounde I, Faculty of Medicine and Biomedical Sciences, Cameroon

⁸Faculty of Medicine, University of Garoua,

Cameroon

⁹Department of Public Health, University of Dschang, Cameroon

¹⁰Population Services International, Cameroon

*Corresponding author:

JP Yves Awono Noah, Operational Health Research Division - Ministry of Public Health, Cameroon.

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Introduction

Cameroon is the second most affected country by Human Immunodeficiency Virus (HIV) infection in the West and Central Africa Region, according to the 2018 UNAIDS. The HIV prevalence in general population progressively decreased from 5.4% in 2004 to 2.7% in 2018 [1] but remain high in specific groups, such as Female Sex Workers (FSWs) with a prevalence of 24.3% and Men who have Sex with Men (MSM) with a prevalence of 20.7% [2]. The criminalisation of homosexuality and prostitution results in a reduction in the number of individuals in this specific group who undergo HIV testing. The National Strategic Plan 2021-2023 (PSN 2021-2023) for the control of HIV and sexually transmitted infections (STIs) in Cameroon is considering the use of HIV self-testing (HIVST) among key populations. This approach is supported by the HIV Self-Testing Africa Initiative (STAR) project, funded by Unitaid from June 2020 to June 2022. HIVST has shown promising uptake by otherwise underserved priority groups [3]. Research in Cameroon among MSM and FSWs, suggesting the potential uptake of oral fluid based HIVST so Cameroon has approved guidelines for oral fluid-based HIVST to reach those at high risk who may not otherwise test [4]. However, before introducing and scaling up fingerstick whole blood HIVST, usability needs to be addressed. HIV self-tests kits should undergo virological and clinical evaluation for pre-market approval. These includes: (i) evaluation by trained users in a controlled environment; (iia) observed evaluation of untrained users interpreting a panel of contrived test results in a controlled setting; (iib) observed evaluation of untrained users, with high risk of HIV, performing the Rapid Diagnostic Test (RDT) and interpreting the test results in a controlled setting and (iii) established performance of the test system as a whole in the hands of untrained intended and expected users in the actual intended use (in-home) setting as a measure of clinical utility [5–7]. For instance, there is no specific performance threshold for in vitro diagnostic devices (IVDs) used for selftesting. Rather, these devices will be assessed based on their usability and appropriateness for the self-testing population [8–10]. Currently, no local study has been published on this strategic option. This study assesses the usability of three fingerstick whole blood HIVST kits among MSM and FSWs in Yaounde and Douala.

Methodology

Ethical considerations

This study obtained ethical approval from the National Ethics Committee for Human Health Research of Cameroon (reference numbers 2022/04/1448/CE/CNERSH/SP) and

Administrative Research Authorisation (reference numbers 031-16-22). Written informed consent was obtained from all participants.

Type of study

A cross-sectional was conducted in 14 communitybased organisations (CBOs) in Yaounde and Douala from November 2021 to 22 July 2022.

Selection of the study population

The study involved individuals aged 21 and above, who were MSM or FSWs, and reported an unknown HIV status or had tested HIV-negative for more than three months. The study excluded those who had previously participated in pilot studies for oral fluid-based HIVST, were currently undergoing pre-exposure prophylaxis (PrEP) or antiretroviral treatment or had any extenuating condition that might impair the testing process.

Site selection

The study was conducted in Cameroon's Yaounde and Douala cities, focusing on Community-Based Organisations (CBOs) with high key populations densities and their leaders' willingness to participate.

Sample size and sampling

The study's sample size was determined based on the WHO's recommended criteria [11] and the proportion of HIV testing in previous national or regional studies for each target group. So, we estimated a minimum of 785 study participants (423 for FSWs and 362 for MSM). The study utilized a voluntary sampling technique, which is particularly useful for sensitive topics like sexual behaviour [12], and participants were informed and invited two days prior to data collection through peer leaders/educators. The study used three HIV self-testing kits: Atomo Mylan, Chembio Sure Check, and Abott Check Now, with participants drawing one kit at random from each CBO to ensure fair use. Each HIV Self-Test device included the manufacturer's instructions for use and other kit components.

Type of blood-based HIV Self-test kits

The study utilized three blood-based HIV self-testing (HIVST) kits: Mylan HIV Self-Test (Atomo Diagnostics Pvty. Ltd), Sure Check HIV Self-Test (Chembio Diagnostic Systems, Inc), and Check NowTM HIV Self-Test (Abbott Rapid Diagnostics Jena GmbH). Each device came with the manufacturer's IFUs and other kit components. For memory, participants did not receive any additional user aids, demonstrations, or assistance. To ensure a fair number of HIVST kits were used in the evaluation, in each CBO, each triad of participants drew one of the three devices according to the probabilities 1/3, 1/2 and 1/1.

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Data collection

Data collection was carried out by a research team comprising of twenty healthcare staff who were trained to perform fingerstick whole blood HIV self-tests, including laboratory technicians and nurses. The study was conducted over a period of nine months, from November 2021 to July 2022, with data collection taking place over eight days from 11 to 22 June 2022. The interviewers were paired up for the purpose of the study. In order to conduct the survey, each pair of interviewers observed approximately 10 participants per day, for a maximum of 30 minutes per test, including passing the questionnaire, observing the test performance, and interpreting the results. To ensure confidentiality, a confidential setting was established for conducting data collection and HIV blood self-testing procedures in each community-based organization selected for the survey. Additionally, data collectors introduced themselves to every participant at the beginning of the process. Authorisations for the study were distributed and the purpose was highlighted. Participants were then given an information leaflet and their informed consent was obtained. Information about their eligibility for the study was also collected. Pre- and post-test counselling was provided to each participant by CBO managers and staff. Finally, the recruited participant was given a fingerstick whole blood HIVST kit to carry out the blood self-test procedure. The HIV self-testing was conducted unassisted, with participants instructed to use only the Instructions For Use (IFUs) contained in the self-test packaging (Supplemental materials S1-S3). The investigators' role was limited to observing the procedure without providing any assistance to the participants. It was not permitted for the participant to pose questions to the study team member. This was done to ascertain the extent to which the participant was able to adhere to the instructions on the label without professional assistance, as they would have to do at home. The test was conducted on site, with both the participants and two trained investigator-observers interpreting the results. Each investigator-administered the product-specific semistructured questionnaire to one participant at a time. The questionnaire assessed the usability of fingerstick whole blood HIVST kits and was based on WHO prequalification documentation [9,13–15]. The questionnaire covered the socio-demographic characteristics, lifetime history of participants' HIV testing, the HIV self-testing process, test results, waste management, and participants' opinions about the device and IFUs. It was pretested to 43 participants, including 19 MSM and 24 FSWs, using the Kobo Collect application on tablets. Condoms were offered to participants after receiving their test results. If participant of the study had a reactive test, they were directed to their CBO's supervising health facility for confirmation according to the national algorithm for HIV testing and management.

Data processing and statistical analysis

The main outcome variable for this study was "usability", a binary variable (Good; Bad). It was a composite variable of "performance of HIV self-test (Success; Failure) and "correct interpretation of the HIV self-test result (Correct; Incorrect)" by participants. If both were true, usability was considered good, otherwise, it was considered bad. The secondary outcome was "performance of the HIV self-test", a binary variable (Success; Failure); the successful performance of the HIV self-test was determined by the presence of the control strip. Tests that did not produce a control line were identified as "Invalid" and reported as a failure. The interpretation of the HIV self-test result was considered accurate (correct) only in cases where the participant's interpretation aligned perfectly with that of the trained observers. After data was collected with the Kobo Collect application, it was imported into SPSS (version 27) for analysis. Analysis excluded observations with missing data. Median with Inter-Quartile Range (IQR) were used to describe continuous variables and proportions for categorical variables. The level of agreement between reactive (positive), non-reactive (negative), and invalid HIV self-test results interpretation between participants and observing healthcare staff was assessed using Cohen's Kappa (κ) . The concordance was interpreted using the Landis and Koch scale [16]. A multivariate logistic regression analysis with enter method was employed to estimate the adjusted odds-ratio (aOR) and 95% confidence interval (95% CI) for the outcome's variables. All tests were two-sided, with p < 0.05 indicating statistical significance. The variables included in the analysis were city, type of key population, age, education, employment, living status, ever HIV tested, and frequent errors made during self-testing process. The results were presented using tables ...

Results

Demographic characteristics and HIV testing history of MSM and *FSWs*

Out of the 820 participants, data on the type of test used was missing for 5. Then data were analysed for 815 participants. The study analyzed data from 815 participants, revealing that 56.7% were residents of Douala, with 98.2% being Cameroonian, 56.1% were FSWs, with a median age of 27. Many had completed secondary education (58.9%), with unemployed individuals accounting for 43.2%. Many were single (78%), and 10% had never been tested for HIV before the test was carried out as part of this study. The study utilized 280 Chembio Sure Check HIV Test, 272 Abbott Check Now HIV Self-Test, and 263 Mylan HIV Self-Test (Table 1).



Table 1: Distribution of finger-stick whole blood HIV s	self-tests based on participants'	sociodemographic characteris	stics and testing history.
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Characteristics	Chembio Sure Check HIV Test (N=280) n(%)	Abbott Check Now HIV Self-Test (N=272) n(%)	Atomo Mylan HIV Self-Test (N=263) n(%)	Overall (N=815) n(%)
City				
Yaoundé	120 (42.9)	118 (43.4)	115 (43.7)	353 (43.3)
Douala	160 (57.1)	154 (56.6)	148 (56.3)	462 (56.7)
Nationality				
Foreign	6 (2.1)	2 (0.7)	7 (2.7)	15 (1.8)
Cameroonian	274 (97.9)	270 (99.3)	256 (97.3)	800 (98.2)
Type of population				
FSWs	157 (56.1)	127 (46.7)	173 (65.8)	457 (56.1)
MSM	123 (43.9)	145 (53.3)	90 (34.2)	358 (43.9)
Age (in years)				
Median (IQR)	26 (22-34)	26.5 (22-32)	27 (23-34)	27 (22-34)
Education				
None	15 (5.4)	10 (3.7)	16 (6.1)	41 (5.0)
Elementary	52 (18.6)	43 (15.8)	46 (17.5)	141 (17.3)
Second level	162 (57.9)	167 (61.4)	151 (57.4)	480 (58.9)
Advanced	51 (18.2)	52 (19.1)	50 (19.0)	153 (18.8)
Employment status	n=280	n=272	n=262	n=814
Self-employed	93 (33.2)	88 (32.4)	97 (37)	278 (34.2)
Unemployed	124 (44.3)	112 (41.2)	116 (44.3)	352 (43.2)
Employed in private sector	55 (19.6)	67 (24.6)	45 (17.2)	167 (20.5)
Employed in public sector	8 (2.9)	5 (1.8)	4 (1.5)	17 (2.1)
Marital status				
Single	216 (77.1)	213 (78.3)	206 (78.6)	635 (78)
Divorced	11 (3.9)	5 (1.8)	9 (3.4)	25 (3.1)
Widowed	3 (1.1)	1 (0.4)	4 (1.5)	8 (1)
Cohabiting	28 (10)	34 (12.5)	32 (12.2)	94 (11.5)
Married	22 (7.9)	19 (7)	11 (4.2)	52 (6.4)
History of HIV testing				
Yes	255 (91.4)	239 (87.9)	239 (90.9)	733 (90)
No	24 (8.6)	33 (12.1)	24 (9.1)	81 (10)

Usability of fingerstick whole blood HIV self-testing kits by study participants

The majority of participants,790 (96.9%; 95% CI: 95.5-98.0) successfully performed finger-stick whole blood HIV self-testing and obtained a valid an interpretable result. A significant proportion of participants, 222 (79.3%; 95% CI: 74.1-83.9) for Chembio Sure Check HIV Self-Test, 226 (83.1%; 95% CI: 78.1-87.3) for Abbott Check Now HIV Self-Test and 210 (79.8%; 95% CI: 74.5-84.5) for Mylan HIV Self-Test, interpreted the results correctly based on the IFUs. All three devices achieved comparable rates of good usability. Chembio had a rate of 77.9% (95% CI: 72.5-82.6) for 218 participants, Abbott had a rate of 82.0% (95% CI: 76.9-86.4) for 223 participants, and Mylan had a rate of 75.3% (95% CI: 69.6-80.4) for 198 participants. Overall, the errors commonly made while using the self-test were, in order of occurrence: insufficient collection/addition of blood to the well (26.6%), incorrect positioning of the self-test device (21.5%) and incorrect volume of blood drawn with 12% (Table 2).



Table 2: Ability to	perform HIV	self-testing in	exact com	pliance with	the leaflet.
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Characteristics	Chembio Sure Check HIV Self-Test (N=280)	Abbott Check Now HIV Self-Test (N=272)	Atomo Mylan HIV Self-Test (N=263)	Total (N=815)
	n (% [95% Cl])	n (% [95% CI])	n (% [95% CI])	n (% [95% CI])
Performance of the HIV self-test				
Success	273 (97.8 [94.9-99.0])	268 (98.5 [96.3-99.6])	249 (94.7 [91.2-97.1])	790 (96.9 [95.5-98.0])
Failure	7 (2.5)	4 (1.5)	14 (5.3)	25 (3.1)
Interpretation of the HIV self-test result by MSM and FSWs				
Correct	222 (79.3 [74.1-83.9])	226(83.1[78.1-87.3])	210(79.8[74.5-84.5])	658 (80.7[77.9-83.4])
Not correct	58 (20.7)	46 (16.9)	53(20.2)	157 (19.3)
Usability of the HIV self-test				
Good	218 (77.9 [72.5-82.6])	223 (82.0 [76.9-86.4])	198 (75.3 [69.6-80.4])	639 (78.4 [75.4-81.2])
Bad	62 (22.1)	49 (18)	65 (24.7)	176 (21.6)
Frequent errors made during self-testing process	n=270	n=260	n=252	n=782
Incorrect volume of blood drawn (tube over/underfilled)	24 (8.9)	34(13.1)	36 (14.3)	94 (12.0)
Insufficient blood collected/added to the well (difficulty in drawing blood)	62 (23)	70 (26.9)	76 (30.2)	208 (26.6)
Incorrect positioning of the device	60 (23.8)	51 (19.6)	57 (21.1)	168 (21.5)

With regards to the agreement on result interpretation between participants and healthcare workers trained as HIV testing counsellors (as presented in Table 3), it was observed that the positive agreement percentages were 94.4%, 100%, and 66.7% for Sure Check HIV, Mylan, and Check Now, respectively; the percentages of agreement for negative cases were 79.1%, 82.8% and 81.2% respectively, for invalid cases 50%, 42.9% and 75.0%. The three fingerstick whole blood HIVST kits demonstrated varying levels of total agreement, with percentages ranging from 79.28% to 83.39%. But note that controlling for chance, the overall concordance rates are 34.6, 48.6 and 37.2 percent respectively. This indicates a low overall agreement for Sure Check (x=0.346; 95% CI: 0.226-0.465; P<0.001) and Mylan (ĸ=0.372; 95% CI: 0.244-0.499; P<0.001) and a moderate agreement for Check Now (κ=0.486; 95% CI: 0.366-0.605; P<0.001).

Factors associated with successful performance of blood-based HIV self-testing, correct interpretation of the blood-based HIV self-testing and good usability

Performance of the fingerstick whole blood HIV self-testing kits

The secondary outcome was to assess the ability of participants to successfully perform the fingerstick whole blood HIV self-testing. The univariate analysis using simple logistic regression (Supplement material S4) revealed that several variables were significantly associated with the successful performance of the fingerstick whole blood HIV self-testing. These included the city (Douala), the type of participant (MSM, FSWs), age, the HIV self-testing kit (Sure Check, Check Now Mylan), and the presence of insufficient blood collected or added to the well (difficulty in drawing blood: yes, no). However, in the multivariate analysis using the logistic regression model, only the variables "city" and "insufficient blood collected/added to the well (difficulty in drawing blood)" were found to be associated with the successful performance of the fingerstick whole blood HIV self-testing. Indeed, the successful performance of the fingerstick whole blood HIV self-testing was higher among participants from the City of Douala than among those from the city of Yaounde (98.1% versus 95.5%; aOR: 4.1 [95% CI: 1.5-11.1; P = 0.005), with 310% greater odds of success. Those participants who demonstrated difficulty in drawing blood using the micro pipette were more likely to fail the self-test (91.8% versus 98.6%; aOR: 0.1 [95% CI: 0.0-0.3]; P = 0.005), with 90% lower odds of successful performance (Table 4).

Interpretation of fingerstick whole blood HIV self-testing kits by participants

In univariate analysis (Supplement material S4), variables such as city, type of participant, education and employment status were found to be significantly associated with correct interpretation of the fingerstick whole blood HIV self-testing

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Table 3: Results of HIV self-tests interpreted by participants with those interpreted by pairs of trained health workers.

Characteristics	Chembio Sure Check HIV Test N=280	Abbott Check Now HIV Self-Test N=271	<i>Mylan HIV Self-Test</i> N=262
Both participants and trained health workers interpreted self-test results			
Positive agreement	17	25	8
Negative agreement	201	198	190
Invalid agreement	4	3	12
Positive disagreement	1	0	4
Negative disagreement	53	41	42
Invalid disagreement	4	4	4
Percentage of agreement			
Positive agreement percentage	94.4%	100%	66.7%
Negative agreement percentage	79.1%	82.8%	81.2%
Invalid agreement percentage	50%	42.9%	75.0%
Total agreement percentage	79.28%	83.39%	80.15%
Cohen's Kappa (standard error)	0.346 (0.061)	0.486 (0.061)	0.372 (0.065)
95% CI of Cohen's Kappa (Ib - ub)	(0.226-0.465)	(0.366-0.605)	(0.244-0.499)
Ρ	<0.001**	<0.001**	<0.001**

P: significance level; **: <0.01; 95% CI: 95% confidence interval; lb : lower bound; ub: upper bound;

kits by participants. In multivariate analysis (Table 4), these variables were also found to be significantly associated with correct interpretation of the fingerstick whole blood HIV selftesting. It seems that participants from the City of Douala were more likely to correctly interpret the fingerstick whole blood HIV self-testing than those from the City of Yaoundé. In fact, the correct interpretation was 91.8% versus 66.3% (aOR: 6.7 (95% CI: 4.2–10.5); P < 0.001), with 570% greater odds of correct interpretation. The correct interpretation was higher among MSM than among FSWs. This is evidenced by the fact that 84.6% of MSM were able to correctly interpret the results, compared to 77.7% of FSWs. This difference in results is reflected in an adjusted odds ratio of 1.9 (95% CI: 1.1-3.0; P = 0.008), which suggests that there is a 90% increased likelihood of correct interpretation among MSM. As Table 4 indicates, participants with a minimum of an elementary education demonstrated a greater capacity for accurate interpretation of results than those with no formal education. In fact, the correct interpretation was 85.1% (aOR: 5.6 (95% CI: 2.4–13.2); P < 0.001), 81.5% (aOR: 4.2 (95%) CI: 2.0-8.9); P < 0.001) and 80.4% (aOR: 3.7 (95% CI: 1.5-8.8); P = 0.003) versus 58.5%, with 460%, 320% and 270% increasing chance of correct interpretation respectively for elementary school, second level and advanced. Additionally,

it seems that those employed in the public sector may have found interpreting the results of the self-test more challenging with 52.9% of correct interpretation (aOR: 0.2 (95% CI: 0.0-0.7); P = 0.017) compared to those who identified as self-employed (86.9%) (Table 4).

Usability of fingerstick whole blood HIV self-testing kits

Finally, for the primary outcomes (usability), the results of the univariate analysis (Supplement material S4) indicated a potential association between the "good usability" and the blood-based HIV self-testing kit, " Check Now" with a crude odds ratio (OR) of 1.4 (95% CI: 0.9-2.2; P=0.059). However, this tendance did not persist in the multivariate analysis. Multivariate analysis showed a significant positive association with the city of Douala (aOR=8.1 (95% CI: 5.2-12.7); p<0.001), being MSM (aOR=2.3 (95% CI: 1.4-3.6); p<0.001) and level of education (elementary (aOR=5.5 (95% CI: 2.3-12.7); p<0.001), second level (aOR=4.1 (95% CI: 1.9-8.7); p<0.001) and advanced (aOR=3.4 (95% CI: 1.4-8.1); p=0.004). However, there was a significant negative association with public sector employment (aOR=0.2 (95% CI: 0.0-0.7); p=0.014) and age (aOR=0.97 (95% CI: 0.94-0.99; p=0.045). In fact, higher age subjects (by on year) have 5% lower odds of having good usability when compared to the lower age subjects (Table 4).

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 Table 4: Multivariate logistic regression of factors associated with successful performance of blood-based HIV self-testing, correct interpretation of the blood-based HIV self-testing and good usability. actors associated with successful completion of all stages of blood self-testing.

Characteristics	Succes: HIV	sful performance o V self-test (N=779)	of the	Corre HIV s	ect interpretation of self-test result (N=8	f the 312)	Go HIV	od usability of the self-test kit (N=812	2)
	n (%)	aOR (95% CI)	Р	n (%)	aOR (95% CI)	P	n (%)	aOR (95% CI)	P
City									
Yaoundé	337 (95.5)	1	1	234 (66.3)	1	1	218 (61.8)	1	1
Douala	453 (98.1)	4.1 (1.5-11.1)	0.005**	424 (91.8)	6.7 (4.2-10.5)	<0.001**	421 (91.1)	8.1 (5.2-12.7)	<0.001**
Type of population									
FSWs	436 (95.4)	1	1	355 (77.7)	1	1	338 (74.0)	1	1
MSM	354 (98.9)	2.5 (0.6-9.4)	0.163	303 (84.6)	1.9 (1.1-3.0)	0.008**	301 (84.1)	2.3 (1.4-3.6)	<0.001**
Education									
None	40 (97.6)	1	1	24 (58.5)	1	1	23 (56.1)	1	1
Elementary	135 (95.7)	0.8 (0.0-8.2)	0.909	120 (85.1)	5.6 (2.4-13.2)	<0.001**	116 (82.3)	5.5 (2.3-12.7)	<0.001**
Second level	465 (96.9)	0.6 (0.0-5.5)	0.698	391 (81.5)	4.2 (2.0-8.9)	<0.001**	380 (79.2)	4.1 (1.9-8.7)	<0.001**
Advanced	150 (98.0)	0.8 (0.0-11.3)	0.929	123 (80.4)	3.7 (1.5-8.8)	0.003**	120 (78.4)	3.4 (1.4-8.1)	0.004**
Living status									
Living alone	649 (97.2)	1	1	546 (81.7)	1	1	533 (79.8)	1	1
living with partner	140 (95.9)	1.1 (0.4-3.4)	0.766	111 (76.0)	1.2 (0.7-1.9)	0.440	105 (71.9)	1.1 (0.7-1.9)	0.487
Employment status									
Self-employed	266 (95.7)	1	1	241 (86.7)	1	1	233 (83.8)	1	1
Unemployed	342 (97.2)	2.0 (0.7-5.4)	0.173	272 (77.3)	0.7 (0.4-1.2)	0.239	264 (75.8)	0.8 (0.5-1.3)	0.496
Employed in private sector	165 (98.8)	4.6 (0.8-24.0)	0.068	135 (80.8)	0.7 (0.4-1.3)	0.404	133 (79.6)	0.9 (0.5-1.6)	0.754
Employed in public sector	16 (94.1)	0.9 (0.0-13.9)	0.943	9 (52.9)	0.2 (0.0-0.7)	0.017*	8 (47.1)	0.2 (0.0-0.7)	0.014*
HIV self-testing kits									
Mylan	249 (94.7)	1	1	210 (79.8)	1	1	198 (75.3)	1	1
Sure Check	273 (97.5)	1.5 (0.5-4.1)	0.414	222 (79.3)	0.9 (0.5-1.4)	0.663	218 (77.9)	1.1 (0.7-1.7)	0.631
Check Now	268 (98.5)	3.0 (0.9-10.0)	0.063	226 (83.1)	1.1 (0.6-1.7)	0.681	223 (82.0)	1.3 (0.8-2.1)	0.186
Has already been tested for HIV									
No	79 (97.5)	1	1	68 (84.0)	1	1	67 (82.7)	1	1
Yes	710 (96.9)	1.1 (0.2-6.2)	0.870	589 (80.4)	0.8 (0.4-1.6)	0.573	71 (77.9)	0.8 (0.4-1.6)	0.558
Incorrect positioning of the device									
No	594 (96.7)	1	1		NA	NA		NA	NA
Yes	163 (97.0)	1.1 (0.3-3.5)	0.752		NA	NA		NA	NA
Insufficient blood collected / added to the well (difficulty in drawing blood)									
No.	566 (08 6)	1	1		NA	NA		NA	NA
Voo	101 (01 0)		ı مر			NA NA			
res	191 (91.8)	0.1 (0.0-0.3)	<0.001***		NA	NA		NA	NA
Incorrect volume of blood drawn (tube over / underfilled)									
No	669 (97.2)	1	1		NA	NA		NA	NA
Yes	88 (93.6)	0.5 (0.2-1.6)	0.327		NA	NA		NA	NA
	median (IQR)]	. ,		median (IQR)]			median (IQR)]		
Age in years	26.5 [22-33]	0.97 (0.92-1.03)	0.399	26 [22-33]	0.97 (0.95-1.00)	0.113	22 [26-32]	0.97 (0.94-0.99)	0.045*

N: total number of subjects in multivariate analysis; n: number of subjects in category; %: percentage; P: significance level; *: <0.01; ** <0.05; aOR: adjusted Odds Ratio; 95% CI: 95% confidence interval for the Odds Ratio; NA: Not Applicable.



Discussion

This study assessed the usability of Mylan HIV Self-Test, Chembio Sure Check HIV Test and Abbott Check Now HIV Self-Test in Cameroon, the first assessment of their usability in Central Africa, following previous studies in South Africa and Vietnam [17,18].

In our study, the majority of participants successfully performed fingerstick whole blood HIV self-testing, consistent with previous field experiences in various regions, demonstrating the ability of lay adults to perform immunochromatographic finger-stick whole-blood self-tests [17–29]. Micro pipettes are often criticized for their laborious nature in HIV self-testing in sub-Saharan Africa, Asia, America, Europe, and Australia due to the steps involved in self-lancing, sample collection, and transfer [17,19,24-27,30-33]. This study has demonstrated that the difficulty associated with obtaining blood samples has a significant negative influence, as well as the place of residence has a significant positive influence on the successful performance of the fingerstick whole blood HIV self-test. It is important to note that, in contrast to this, none of the studies which evaluated the successful performance of self-tests tested the influence of that common error that could have been made in the performance result. It is notable that age, level of education and lifetime history of HIV testing were not found to be associated with successful HIV self-testing performance. This is consistent with findings from a previous study [22], but inconsistent with another study [33].

It is currently well established that the ability to correctly interpret self-test results is considered a crucial step in self-testing [34,35]. Our study found that most participants correctly interpreted their blood-based HIV self-test results, with an overall accuracy of 78.5%. However, the percentage agreement for positive, negative, and invalid results is below the Blood Products Advisory Committee's threshold of 98%, with an acceptable level of agreement for weak positive devices at 95%.[6]. Our findings contrast with previous studies in Vietnam, South Africa, Canada, Central African Republic, Kenya, Australia, France, and Democratic Republic of the Congo, which showed positive, negative, and invalid agreement between 90.2% and 100% depending the blood based HIV self-testing kits [17-19,23,26-28,36]. Invalid results are either indicative of deficiencies in the quality control procedures employed during the manufacturing process or the consequence of insufficient sample volumes [34]. Our study found that lay users' interpretation of bloodbased HIVST results was significantly less accurate than trained health staff, with Cohen's k values ranging from 0.346 to 0.486. This result is slightly contrasting with prior study conducted in Central Africa of which Cohen's ĸ value ranging from 0.44 to 0.84 [19,20,23,24,29]; the observed disparity may be due to the distinct characteristics of the target populations, blood-based HIV self-testing kits, selftesting approach (assisted or unassisted), and study design (observational or randomised). In fact, a randomized clinical trial in Africa found good concordance ($\kappa = 0.69$) with direct assisted HIVST (DAH) while moderate concordance ($\kappa = 0.44$) was observed with unassisted HIVST (UH) [29].

The multivariate analysis revealed that the city (Douala), the type of participant (MSM) and education (elementary to advanced) were significantly positively associated with correct interpretation. Indeed, a randomized controlled trial conducted in Uganda reported that FSWs often incorrectly interpret HIV self-test results [34]. A study conducted in Central Africa revealed an association between place of residence and correct interpretation of RDT for self-testing [24]. Similarly, numerous studies have indicated that educational level is a primary sociological factor in the interpretation of the results of HIV self-testing [19,20,24,30,32,35,37,38]. However, in our study, employment status was negatively associated with correct interpretation.

Regarding usability of the blood-based HIV self-test kits, in different studies, the authors used three definitions of "usability" for the blood-based HIV self-test kits, with "very easy" or "easy" responses indicating positive usability outcomes [25,27,28,33,36,39]; with a developed checklist, identifying critical items and calculating the usability rate using this checklist [18,19,21,23,24,26]. The third defined the concept of usability as the successful performance of the self-test and the correct interpretation of the results [17,20,29]. Our study found good usability with a range of 75.3% to 82.0% depending on blood-based HIVST kits, consistent with previous studies ranging from 43% to 97.6% [17-21,23-29,33,36,39]. The results of the univariate analysis indicated a potential association between the "good usability" and the blood-based HIV self-testing kit, "Abbott Check Now HIV Self-Test". However, this association did not persist in the multivariate analysis. These findings contradict those of study conducted in Vietnam [17], which indicated in multivariate analysis a significant inverse correlation between usability and Sure Check, INSTI, and BIOSURE, in contrast to Check Now. In our series, analysis showed a significant positive association with the city of Douala, being MSM and level of education. The outcome of the current study is consistent with that of previous investigations, which have identified educational level as a key barrier to HIVST. In addition, the execution and interpretation of HIVST results were found to pose challenges among those with a low educational background [17,19]. Previous study also revealed an inverse association between usability and employment status [17]. The results of our study indicated in multivariate analysis, a significant negative association between older age and good usability, which is consistent with previous findings [33].



It is acknowledged that there are certain limitations to this study. Firstly, the sample was selected from a specific population of individuals who consented to the usability assessment of finger-prick whole-blood HIV self-tests, in accordance with WHO guidance. Therefore, it is possible that the sample is not entirely representative of the wider population. Secondly, the involvement of healthcare observers in self-testing environments may introduce a potential bias into the study design. The usability of blood based HIVST at home or outside CBOs/clinical settings may be different.

Conclusion

The study found high success rates and good usability of blood-based HIV testing among key populations in Yaounde and Douala. The Abbott Check Now HIV Self-Test was slightly suitable for unassisted use. These results could promote the spread of blood-based testing and oral fluidbased testing, increasing uptake and access to essential HIV prevention services. However, difficulties with interpretation and usability enhancements are needed. Ministrie of Public Health and country programs should consider both bloodbased and oral fluid-based HIV testing options.

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Competing interests:

The authors have declared that no competing interests exist.

Data sharing Statement: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate: Each participant provided written informed consent prior to the interview and no nominal information was reported on the questionnaire. The study was approved by the National Health Research Ethics Committee in Cameroon (reference numbers 2022/04/1448/CE/CNERSH/SP).

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SUPPLEMENTARY FILES

S1 File. Public Report for SURE CHECK HIV Self-Test (PQDx 0). (PDF)





S2 File. Public Report for CheckNOW HIV Self-Test (PQDx 048). (PDF)











S4 Table. Univariate logistic regression of factors associated with successful performance of blood-based HIV self-testing, correct interpretation of the blood-based HIV self-testing and good usability. (DOCX). N: total number of subjects include in univariate analysis; n: number of subjects in category; %: percentage; P: significance level; *: <0.01; ** <0.05; cOR: crude Odds Ratio; 95% CI: 95% confidence interval for the Odds Ratio

Characteristics	Successful performance of the HIV self-test			Correct interpretation of the HIV self-test result			Good usability of the HIV self-test kit		
	n (%)	cOR (95% CI)	Р	n (%)	cOR (95% CI)	Р	n (%)	cOR (95% CI)	Р
City (N=815)									
Yaoundé	337 (95.5)	1	1	234 (66.3)	1	1	218 (61.8)	1	1
Douala	453 (98.1)	2.3 (1.0-5.4)	0.039*	424 (91.8)	5.6 (3.8-8.4)	<0.001**	421 (91.1)	6.3 (4.3-9.3)	<0.001**
Type of population (N=815)									
FSWs	436 (95.4)	1	1	355 (77.7)	1	1	338 (74.0)	1	1
MSM	354 (98.9)	4.2 (1.4-12.5)	0.008**	303 (84.6)	1.5 (1.1-2.2)	0.013*	301 (84.1)	1.8 (1.3-2.6)	<0.001**
Education (N=815)									
None	40 (97.6)	1	1	24 (58.5)	1	1	23 (56.1)	1	1
Elementary	135 (95.7)	0.5 (0.0-4.8)	0.599	120 (85.1)	4.0 (1.8-8.7)	<0.001**	116 (82.3)	3.6 (1.7-7.7)	<0.001**
Second level	465 (96.9)	0.7 (0.1-6.0)	0.807	391 (81.5)	3.1 (1.6-6.0)	<0.001**	380 (79.2)	2.9 (1.5-5.7)	<0.001**
Advanced	150 (98.0)	0.8 (0.1-12.3)	0.849	123 (80.4)	2.9 (1.3-6.0)	0.005**	120 (78.4)	2.8 (1.3-5.8)	0.005**
Living status (N=814)									
Living alone	649 (97.2)	1	1	546 (81.7)	1	1	533 (79.8)	1	1
living with partner	140 (95.9)	0.6 (0.2-1.7)	0.425	111 (76.0)	0.7 (0.4-1.0)	0.114	105 (71.9)	0.6 (0.4-0.9)	0.037*
Employment status (N=814)									
Self-employed	266 (95.7)	1	1	241 (86.7)	1	1	233 (83.8)	1	1
Unemployed	342 (97.2)	1.5 (0.6-3.6)	0.320	272 (77.3)	0.5 (0.3-0.8)	0.003**	264 (75.8)	0.5 (0.3-0.8)	0.008**
Employed in private sector	165 (98.8)	3.7 (0.8-16.8)	0.088	135 (80.8)	0.6 (0.3-1.0)	0.100	133 (79.6)	0.7 (0.4-1.2)	0.266
Employed in public sector	16 (94.1)	0.7 (0.0-5.9)	0.761	9 (52.9)	0.1 (0.0-0.4)	<0.001**	8 (47.1)	0.1 (0.0-0.4)	<0.001**
HIV self-testing kits (N=815)									
Mylan	249 (94.7)	1	1	210 (79.8)	1	1	198 (75.3)	1	1
Sure Check	273 (97.5)	2.1 (0.8-5.5)	0.096	222 (79.3)	0.9 (0.6-1.4)	0.871	218 (77.9)	1.1 (0.7-1.7)	0.479
Check Now	268 (98.5)	3.7 (1.2-11.5)	0.021*	226 (83.1)	1.2 (0.8-1.9)	0.335	223 (82.0)	1.4 (0.9-2.2)	0.059
Has already been tested for HIV(N=814)									
No	79 (97.5)	1	1	68 (84.0)	1	1	67 (82.7)	1	1
Yes	710 (96.9)	0.7 (0.1-3.3)	0.741	589 (80.4)	0.7 (0.4-1.4)	0.437	71 (77.9)	0.7 (0.4-1.3)	0.319



Incorrect positioning of the device (N=782)									
No	594 (96.7)	1	1						
Yes	163 (97.0)	1.0 (0.4-2.9)	0.854						
Insufficient blood collected / added to the well (difficulty in drawing blood)									
No	566 (98.6)	1	1						
Yes	191 (91.8)	0.1 (0.0-0.3)	<0.001**						
Incorrect volume of blood drawn (tube over / underfilled) (N=782)									
No	669 (97.2)	1	1						
Yes	88 (93.6)	0.4 (0.1-1.0)	0.069						
Age in years	median (IQR)]		Р	median (IQR)]		Р	median (IQR)]		Р
(N=815)	26.5 [22-33]	0.95 (0.91-0.99)	0.035*	26 [22-33]	0.98 (0.96-1.00)	0.098	22 [26-32]	0.97 (0.95-0.99)	0.019*

N: total number of subjects include in univariate analysis; n: number of subjects in category; %: percentage; P: significance level; *: <0.01; ** <0.05; cOR: crude Odds Ratio; 95% CI: 95% confidence interval for the Odds Ratio

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