

RESEARCH ARTICLE

# Ability to use oral fluid and fingerstick HIV self-testing (HIVST) among South African MSM

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## Abstract

### Background

HIV self-testing (HIVST) may increase HIV testing uptake, facilitating earlier treatment for key populations like MSM who experience barriers accessing clinic-based HIV testing. HIVST usability among African MSM has not been explored.

### Methods

We assessed usability of oral fluid (OF) and fingerstick (FS; blood) HIVST kits during three phases among MSM with differing degrees of HIVST familiarity in Mpumalanga, South Africa. In 2015, 24 HIVST-naïve MSM conducted counselor-observed OF and FS HIVST after brief demonstration. In 2016 and 2017, 45 and 64 MSM with experience using HIVST in a pilot study chose one HIVST to conduct with a counselor-observer present. In addition to written, the latter group had access to video instructions. We assessed frequency of user errors and reported test use ease, changes in error frequency by phase, and covariates associated with correct usage using log-Poisson and Gaussian generalized estimating equations.

### Results

Among OF users (n = 57), 15–30% committed errors in each phase; however, observers consistently rated participants as able to test alone. Among FS users (n = 100), observers noted frequent errors, most commonly related to blood collection and delivery. We found suggestive evidence (not reaching statistical significance) that user errors decreased, with 37.5%, to 28.1%, and 18.2% committing errors in phases I, II, and III, respectively (p-value:0.08), however observer concerns remained constant. Ease and confidence using HIVST increased with HIV testing experience. Participants using three HIVST were more likely (RR:1.92, 95% CI:1.32, 2.80) to report ease compared to those without prior HIVST experience. Never testers (RR:0.66, 95% CI:0.44–0.99) reported less ease performing HIVST compared to participants testing in the past six months.

## OPEN ACCESS

**Citation:** Lippman SA, Gilmore HJ, Lane T, Radebe O, Chen Y-H, Mlotshwa N, et al. (2018) Ability to use oral fluid and fingerstick HIV self-testing (HIVST) among South African MSM. PLoS ONE 13(11): e0206849. <https://doi.org/10.1371/journal.pone.0206849>

**Editor:** Hong-Van Tieu, New York Blood Center, UNITED STATES

**Received:** June 1, 2018

**Accepted:** October 19, 2018

**Published:** November 8, 2018

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**Data Availability Statement:** Data cannot be shared publicly based on confidentiality concerns due to the sensitive nature of the research data and because participants were assured in the consent form that ‘only study managers and investigators will have access to data files’. This assurance may have impacted an individual’s decision to join the study and the UCSF Institutional Review Board will honor that assurance. Those who wish to request access to this data may contact: Laurie Herraiz, RD, CCRP, CIP Director, Human Research Protections Program University of California San

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**Funding:** This research was supported by a grant from the National Institutes of Health ([www.nih.gov](http://www.nih.gov); R21MH103038 to SAL) and in part by the President's Emergency Plan for AIDS Relief through the US Department of Health and Human Services and the Centers for Disease Control and Prevention South Africa Country Office under the terms of a Cooperative Agreement ([www.cdc.gov](http://www.cdc.gov); U2GHH000251 to TEL). HIV self-testing kits were donated by Atomo Diagnostics and OraSure Technologies, Inc. The funders and test kit donors had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing interests:** Test kit manufacturers Atomo Diagnostics and OraSure Technologies, Inc. donated test kits to the research study, but did not provide any additional funding and had no input into the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

## Conclusions

MSM were able to perform the OF test. Fingerstick test performance was less consistent; however preference for fingerstick was strong and performance may improve with exposure and instructional resources. Continued efforts to provide accessible instructions are paramount.

## Introduction

In South Africa, with the largest HIV-positive population globally [1], HIV testing falls far below levels necessary to reduce new infections, particularly among men, who test half as frequently as women [2]. Nationally, approximately one-third of men have never tested [3] and only 37.8% of HIV-positive men are aware of their status [4]. Men who have sex with men (MSM) are no exception: as few as one-fourth of HIV-positive MSM in Mpumalanga Province are aware of their sero-status [5], despite prevalence as high as 28% and incidence of 12.5/ per 100 person years [5, 6]. Data from across sub-Saharan Africa has documented structural barriers to accessing testing services for men. In addition to the cost of travel to clinics, others may be working, traveling for work, or have livelihoods that make clinic attendance difficult. [7, 8] Logistical barriers can be further heightened among men by norms of masculinity that envision clinics and health seeking as feminine [7, 9, 10]. Stigma associated with 'emasculating' health seeking behavior and HIV infection associated with risk-taking can deter seeking care [11, 12]. For MSM the experienced stigma and discrimination associated with sexual orientation and HIV act as further deterrents to seeking services in public clinics [13, 14].

HIV self-testing (HIVST) offers an alternative to clinic-based testing, with potential to increase testing uptake and frequency, thus facilitating earlier diagnosis and HIV treatment initiation as well as knowledge of status that encourages safer sexual behavior [15–17]. In 2016 the World Health Organization (WHO) published guidelines [18] recommending HIVST to reach high HIV risk populations, including MSM; the Government of South Africa has echoed support of this strategy in the recently published National Guidelines for HIV Self Screening [19]. Acceptability of HIVST among MSM following self-testing experiences is high for both oral fluid (OF) [15, 20, 21] and blood-based fingerstick (FS) tests [22–24]. Furthermore, HIVST kits, essentially equivalent to antibody lateral flow devices used in healthcare settings, have been found to have high sensitivity and specificity when supervised [25, 26]. Sensitivity may be slightly lower (bottom range in one systematic review was 92.9%) in unsupervised settings [25], signaling some potential for under diagnosis (or false negatives) if not used correctly. A second systematic review noted that individuals' performance of unassisted HIVST is highly comparable to performance by health care workers, indicating that HIVST can be utilized accurately [27]. Less data is available, however, about unassisted test utilization among key populations in sub-Saharan Africa, who have the greatest need for alternative approaches to HIV testing.

Over several phases of research, we aimed to assess the acceptability, feasibility, uptake, and ability of MSM to conduct OF and FS HIVST in a high prevalence area of South Africa. We have reported on the high acceptability and uptake of HIVST and testing preferences elsewhere [24]. Here we report findings on ability to use HIVST, including frequency and characteristics of user errors and reported ease of use in three MSM groups with varying levels of HIVST exposure. We also assess individuals' ability to recognize their own capacity for correct

utilization and explore factors associated with correct use and comfort with self-testing in order to inform targeted distribution and materials development.

## Materials and methods

### Setting and participants

The study took place among MSM in two high HIV prevalence districts, Gert Sibande and Ehlanzeni, South Africa, which were also known to have sizeable LGBT populations, and where community partnerships for research with these populations were already extant. [28]. The majority of participants were recruited from MSM not known to be HIV-positive who had participated in the Mpumalanga Men's Study (MpMS) [5], cross-sectional integrated bio-behavioral surveys conducted between 2013–2015 using respondent-driven sampling (RDS) [29]. Additional Ehlanzeni participants were recruited via a newly-conducted RDS scheme, designed to mimic MpMS recruitment. All participants were assigned male sex at birth, ages 18 and over, sexually active with another man in the six months prior to recruitment, who reported HIV-negative or unknown HIV status [5, 24].

### Materials

Two self-testing kits were utilized. The OraQuick HIV-1/2 Rapid Antibody Test (OraSure Technologies, Bethlehem, Pennsylvania, US), approved by the United States FDA for over-the-counter sales in 2012, [30] uses oral fluid swabs from upper and lower gums that is placed into a pre-filled tube of reagent for 20 minutes. Test sensitivity and specificity are 99.3% and 99.8% in a laboratory setting, and 93.0% and 99.98% in self-testing studies [25, 30, 31]. The AtomoRapid HIV-1/2 Antibody Test (Atomo Diagnostics, Sydney, Australia) uses whole blood and has a built-in lancet and specimen collection window. Users prick themselves using the trigger lancet, collect blood (~5 µL) into the onboard collection tube that uses a rotating arm to pull the sample onto a test window, then deliver two drops of reagent, provided in the test package, and wait 15 minutes to read the results. Sensitivity and specificity of the AtomoRapid with professional use are 100.0% and 99.6%, respectively [32]. The AtomoRapid is CE Marked (approved in Europe), has been given ERP Category 3 approval by the Global Fund, and has been submitted for WHO prequalification with approval anticipated later this year; in sum, although not available on shelves, its approval process toward commercial marketing is progressing rapidly. The OraQuick is fully WHO pre-qualified. Both tests are read using a testing window with a control line indicating adequate specimen collection and a test line; user instructions have images of how to interpret the test window for negative, positive, and invalid results.

### Procedures

This study was conducted among MSM with varying exposure to HIVST over three phases of research (Fig 1).

Phase I was conducted between February and March 2015 and included 24 participants (12 in each site) selected from a random stratified sample of MpMS participants by age (18–24, 25 or older) and education level (some tertiary vs. some secondary). The sample size was selected to ensure that we could identify difficulties with test conduct with diverse users in order to improve instructional materials for the next phases of the study. In a single visit, participants provided written informed consent, viewed a brief demonstration on use of both HIVST kits by a trained counselor, completed an observed testing experience using both OF and FS self-tests, and answered an interviewer-administered acceptability survey. Test-use

STUDY PHASE	PHASE I	PHASE II	PHASE III
<b>Location</b>	Gert Sibande & Ehlanzeni	Gert Sibande	Ehlanzeni
<b>Dates</b>	Recruited for single visit February-March 2015	Recruited May-June 2015; follow-up through January 2016	Recruited August-October 2016; follow-up through May 2017
<b>Sample size</b>	24 participants enrolled; 24 underwent observed self-testing	55 participants enrolled; 45 underwent observed self-testing	72 participants enrolled; 64 underwent observed self-testing
<b>Visit schedule</b>	Single visit	Enrollment, 3 & 6 month follow-up visits	Enrollment, 3 & 6 month follow-up visits
<b>Procedures / data collected</b>	<ul style="list-style-type: none"> <li>• Test demonstration;</li> <li>• Test conduct under observation;</li> <li>• Acceptability survey</li> </ul>	<ul style="list-style-type: none"> <li>• Test demonstration;</li> <li>• 6 months of utilization &amp; distribution;</li> <li>• Test conduct under observation (6 month visit);</li> <li>• Behavioral and acceptability surveys</li> </ul>	<ul style="list-style-type: none"> <li>• Test demonstration;</li> <li>• 6 months of utilization &amp; distribution;</li> <li>• Test conduct under observation (6 month visit);</li> <li>• Behavioral and acceptability surveys</li> </ul>
<b>HIVST kit used</b>	Both oral fluid & fingerstick kits	Kit of choice; could change at mid-point	Kit of choice; could change at mid-point
<b>Available resources for test conduct</b>	Manufacturer draft Instructions for use (IFU); Counselor demonstration prior to use	Manufacturer draft Instructions for use (IFU); Counselor demonstration at enrollment & 3 months if requested; Call line	Manufacturer Instructions for use (IFU); Counselor demonstration at enrollment & 3 months if requested; Call line; Manufacturer video instructions

Fig 1. Description of study phases.

<https://doi.org/10.1371/journal.pone.0206849.g001>

order was randomly assigned. Counselors recorded testing errors on an observation checklist. Feedback from these sessions informed minor revisions to testing and educational materials for phases II and III of the study, in which we aimed to follow a combined 125 participants between the sites.

**Phase II**—included recruitment between May and June 2015 of randomly-selected MpMS participants not known to be HIV-positive in the Gert Sibande district. Study staff phoned those selected to assess initial eligibility as well as interest in participating. In total 55 MSM were enrolled, provided written informed consent, and underwent HIV rapid-testing with the counselor to confirm HIV-negative status at enrollment. Participants responded to a brief interviewer-administered behavioral survey, watched a demonstration on how to use both self-tests, and chose which test they would like to take home with them. Each participant received five tests (either OF or FS) to use themselves and to share with partners and others with whom they felt safe and comfortable testing. Participants were provided logs to document test use, a list of local psycho-social and medical resources and referrals, including a 24-hour study hotline, and condoms and lubricant. Participants returned three months following enrollment to deliver test logs, receive up to four additional tests, and complete an acceptability survey. Six months following enrollment, participants returned to deliver test logs, complete a behavioral and acceptability survey that included reported testing experiences, and conduct an HIVST with the kit of their choice under counselor observation. Counselors recorded testing errors on an observation check-list.

**Phase III**—included recruitment of MpMS participants not known to be HIV-positive as well as recruitment of MSM through the new RDS scheme between August and October 2016

in the district of Ehlanzeni. Participants were screened by phone (MpMS) or in-person (new RDS) to assess eligibility and study interest. In total 72 HIV-negative MSM were consented and enrolled. All procedures were identical to phase II, except that phase III participants were shown manufacturers' instructional videos about the HIVST at enrollment. Additionally, in phase III the FS manufacturer revised their Instructions for Use (IFU) and participants were provided a weblink to access the instructional videos. Return visits three and six months after enrollment were equivalent to phase II, with the exception that phase III participants could choose to watch the videos at the study office during the three month visit.

Self-test performance was validated in all phases using external quality assurance agents; both the OF and FS tests validated at all time-points on the quality assurance schedule. All procedures were approved by the University of California San Francisco Committee on Human Research, the University of the Witwatersrand's Human Research Ethics Committee, the Mpumalanga Department of Health and Social Development Research Committee, and the Centers for Disease Control's Center for Global Health, Human Research Protection Office.

## Measures & analysis

Frequency and type of testing errors observed are described for each test as well as summary indicators regarding a) proportion of participants making an error, b) proportion of participants for whom the observer was concerned about their ability to perform the test alone, and c) proportion of participants who had to repeat the test due to errors rendering the test invalid. Errors are divided into those that are unlikely to, or might, impact test results.

We explored reported self-testing experiences using Likert-scale questions on the acceptability (phase I) and three- and six-month surveys (phases II-III) regarding the ease or difficulty of collecting the sample, conducting test procedures, and interpreting test results, referent to the test utilized. We also asked about participants' confidence in completing the test correctly and trust of results. We created a summary indicator variable for 'ease of and comfort with testing' that included those who responded 'somewhat easy' or 'very easy' and 'somewhat comfortable' or 'very comfortable' to all the above questions. During the observed test in phases II-III, participants were given an option to use either test kit; as a result some participants utilized a kit during observation that they had not used previously. We restricted data on reported experience to include only participants who were observed and reported on the same test kit (e.g. we assess observed OF with reported experience using OF) to facilitate comparing correct use during observation and reported ease and comfort, resulting in fewer observations in the reported experience data.

Observation check-list data was captured on paper, entered into Excel, and content re-verified. Surveys were conducted in QDS (Questionnaire Development System) and exported to R (R Foundation for Statistical Computing, Vienna, Austria) for analysis. Frequency tables were generated to describe population demographics and behaviors, observed testing errors, and testing experiences by phase. We examined associations between user characteristics and research phase using Fisher's exact tests (Table 1). We used Gaussian generalized estimating equations (GEE) to test for trends in testing errors and observer concerns over the phases, treating phase as a linear exposure (Table 2). We also assessed characteristics associated with correct usage during observation and reported ease and comfort testing. For these analysis with binary outcomes, we used a log-Poisson GEE when data included repeated measures (including phase I participants), and used a Poisson-based generalized linear model with a log link function when repeated measures were not involved (no phase I observations) (Table 3). Finally, we assessed participants' observed ability to conduct the test as compared to their

**Table 1. Baseline characteristics of HIVST study populations participating in observed testing, Mpumalanga, South Africa.**

Respondent characteristics	Phase 1: 2015 HIVST naïve (n = 24)		Phase 2: 2016 HIVST experienced (Gert Sibande) (n = 45)		Phase 3: 2017 HIVST experienced (Ehlanzeni) (n = 64)	
	n	%	n	%	n	%
<b>Age</b>						
18–24	10	41.7	30	66.7	44	68.8
25–39	14	58.3	15	33.3	20	31.2
<b>Highest level of education*</b>						
Primary or secondary	9	37.5	16	35.6	40	62.5
Matric (high school graduate)	10	41.7	23	51.1	18	28.1
Some college or technical school	5	20.8	6	13.3	6	9.4
<b>Paid work in the past six months?</b>						
Yes	11	45.8	13	28.9	22	34.4
No	13	54.2	32	71.1	42	65.6
<b>Sexual identity*</b>						
Gay/homosexual	12	50.0	7	15.6	26	40.6
Bisexual	10	41.7	34	75.6	38	59.4
Straight	2	8.3	3	6.7	0	0
Transgender <sup>‡</sup>	0	0	1	2.2	0	0
<b>HIV testing history<sup>†*</sup></b>						
Never tested	7	29.2	7	15.6	9	14.1
Tested in past 6 months	7	29.2	9	20.0	36	56.2
Tested 6–12 months ago	6	25.0	24	53.3	5	7.8
Tested >12 months ago	4	16.7	5	11.1	14	21.9
<b>Current regular male sexual partner</b>						
Yes	17	70.8	35	77.8	54	84.4
No	7	29.2	10	22.2	10	15.6
<b>Number of partners in the last six months</b>						
0	0	0	2	4.4	1	1.6
1	12	50	30	66.7	37	57.8
≥2	12	50	13	28.9	26	40.6

\* differences by study phase ( $p \leq .05$ );

<sup>‡</sup> Participant identified their sexual identity as transgender;

<sup>†</sup> Reported HIV testing behaviors prior to participation in our HIV testing research initiatives, including MpMS.

<https://doi.org/10.1371/journal.pone.0206849.t001>

stated ease and comfort in order to explore whether participants can recognize their own ability to conduct self-tests.

## Results

All men reached for recruitment during phase I agreed to participate in the study, resulting in 24 enrolled with complete study procedures. Among 58 eligible participants contacted in phase II, 55 (95%) enrolled; follow-up data (at three months, six months, or both) was captured for 51 participants, with 45 completing observed testing. In phase III, 72 (90%) of 80 eligible potential participants enrolled, with follow-up data on 65 participants and observed testing experiences for 64 (Fig 1).

While there was no upper age bound for recruitment, the RDS samples were all under the age of 40. Most participants did not have paid work and were under the age of 25, with 41.7%,

**Table 2. Participant performance utilizing HIV self-tests under observed and non-observed conditions and reported acceptability indicators among MSM in Mpu-malanga, South Africa.**

Observed self-testing	Phase 1 <sup>‡</sup> : Self-test naïve; following brief instructions				Phase 2 <sup>§</sup> : 6 months following HIVST distribution				Phase 3 <sup>§</sup> : 6 months following HIVST distribution			
	Oral (n = 24)		Blood <sup>#</sup> (n = 24)		Oral (n = 13)		Blood (n = 32)		Oral (n = 20)		Blood (n = 44)	
	n	%	n	%	n	%	n	%	n	%	n	%
Minor observed errors / challenges												
Did procedures out of order	1	4.2	2	8.3	1	7.7	0	0	4	20.0	0	0
Didn't place tube in stand properly	4	16.7			1	7.7			2	10.0		
Forgot to clean finger			1	4.2			1	3.1			0	0
Spilled test tube contents (partial)	1	4.2			0	0			1	5.0		
Major observed errors / challenges												
Touched pad	0	0			1	7.7			0	0		
Errors timing results (waits too little / too long)	1	4.2	0	0	0	0	1	3.1	0	0	0	0
Lancet error (failed to remove tab / ejected lancet)			4	16.7			4	12.5			5	11.4
Error delivering blood to kit			5	20.8			4	12.5			3	6.8
Diluent Errors (too few / many drops)			4	16.7			0	0			1	2.3
Participants committing errors	4	16.7	9	37.5	2	15.4	9	28.1	6	30.0	8	18.2
Observer concern with participant's ability to perform test alone	0	0	4	16.7	0	0	5	15.6	0	0	6	13.6
Test invalid; had to repeat test	0	0	1	4.2	0	0	0	0	0	0	0	0
Tested positive	0	0	1	4.2	0	0	2	6.2	0	0	4	9.1
<b>Reported self-testing experience</b>	<b>N = 24</b>		<b>N = 23<sup>#</sup></b>		<b>N = 8<sup>§</sup></b>		<b>N = 30<sup>§</sup></b>		<b>N = 17<sup>§</sup></b>		<b>N = 39<sup>§</sup></b>	
Ease/difficulty collecting sample?												
Very easy	22	91.7	16	69.6	8	100	21	70.0	17	100	34	87.2
Somewhat easy	1	4.2	3	13.0	0	0	9	30.0	0	0	4	10.3
Difficult (somewhat + very)	1	4.2	4	17.4	0	0	0	0	0	0	1	2.6
Ease/difficulty conducting test?												
Very easy	20	83.3	19	82.6	7	87.5	20	66.7	16	94.1	34	87.2
Somewhat easy	2	8.3	3	13.0	1	12.5	10	33.3	1	5.9	5	12.8
Difficult (somewhat + very)	2	8.3	1	4.3	0	0	0	0	0	0	0	0
Reported ease/difficulty interpreting result?												
Very easy	19	79.2	20	87.0	8	100	29	96.7	17	100	38	97.4
Somewhat easy	4	16.7	2	8.7	0	0	1	3.3	0	0	0	0
Difficult (somewhat + very)	1	4.2	1	4.3	0	0	0	0	0	0	1	2.6
Trust results?												
Yes	24	100	23	100	7	87.5	30	100	17	100	39	100
No	0	0	0	0	1	12.5	0	0	0	0	0	0
Confident you did test correctly?												
Very confident	21	87.5	20	87.0	8	100	28	93.3	17	100	37	94.9
Somewhat confident	3	12.5	3	13.0	0	0	2	6.7	0	0	2	5.1
Not confident	0	0	0	0	0	0	0	0	0	0	0	0

<sup>‡</sup> Participants used both kits;

<sup>§</sup> Participants used kit of their choosing;

<sup>§</sup> Includes participants reporting experiences on test kit used during observation;

<sup>#</sup> One participant in phase I was not asked about blood testing experiences due to interviewer error.

<https://doi.org/10.1371/journal.pone.0206849.t002>

**Table 3. Factors associated with correct HIVST usage and reported comfort and ease among MSM in Mpumalanga, South Africa.**

Respondent characteristics	Correct usage during observed test N = 157				Reported comfort + ease N = 141 <sup>^</sup>			
	n	%	RR (95% CI)	p-value	n	%	RR (95% CI)	p-value
<b>Age</b>								
18–24	94	87.2	1.00	0.09	83	63.9	1.00	0.97
25–39	63	76.2	0.87 (0.74, 1.02)		58	65.5	1.00 (0.77, 1.28)	
<b>Highest level of education</b>								
Primary or secondary	74	82.4	1.00	0.97	62	74.2	1.00	0.20
Matric (high school graduate)	61	83.6	1.01 (0.87, 1.18)		57	59.6	0.83 (0.63, 1.08)	
Some college or technical school	22	81.8	0.99 (0.80, 1.23)		22	50.0	0.74 (0.48, 1.13)	
<b>Recruitment Site</b>								
Gert Sibande	69	78.3	1.00	0.19	61	55.7	1.00	0.05
Ehlanzeni	88	86.4	1.11 (0.95, 1.28)		80	71.2	1.30 (1.0, 1.71)	
<b>Paid work in the past six months?</b>								
No	100	85.0	1.00	0.36	93	66.7	1.00	0.34
Yes	57	78.9	0.93 (0.79, 1.09)		48	60.4	0.87 (0.65, 1.16)	
<b>Sexual identity</b>								
Gay/homosexual	57	84.2	1.00	0.65	54	59.3	1.00	0.26
Bisexual	92	83.7	0.99 (0.87, 1.14)		81	70.4	1.16 (0.89, 1.51)	
Straight	7	57.1	0.68 (0.30, 1.53)		5	20.0	0.37 (0.06, 2.17)	
Transgender <sup>‡</sup>	1	100	-		1	100	-	
<b>HIV testing history</b>								
Tested in past 6 months	59	84.7	1.00	0.60	53	77.4	1.00	0.07
Tested 6–12 months ago	41	87.8	1.04 (0.89, 1.21)		38	63.2	0.82 (0.61, 1.08)	
Tested >12 months ago	27	77.8	0.92 (0.73, 1.15)		23	52.2	0.68 (0.45, 1.04)	
Never tested	30	76.7	0.90 (0.71, 1.15)		27	51.9	0.66 (0.44, 0.99)	
<b>Number of self-testing kits used</b>								
0	52	78.8	1.00	0.68	47	48.9	1.00	<0.01
1–2	91	84.6	1.07 (0.91, 1.27)		80	68.8	1.42 (0.97, 2.07)	
3	14	85.7	1.09 (0.84, 1.40)		14	92.9	1.92 (1.32, 2.80)	
<b>N = 109</b>				<b>N = 94</b>				
Phases II & III only <sup>§</sup>	n	%	RR (95% CI)	p-value	n	%	RR (95% CI)	p-value
<b>Number of HIV tests ever</b>								
0	5	100	1.00	1.0	5	100	1.00	0.24
1–5	57	84.2	0.84 (0.34, 2.12)		46	76.1	0.76 (0.30, 1.94)	
6+	47	83.0	0.83 (0.33, 2.11)		43	65.1	0.65 (0.25, 1.69)	
<b>Use of cell phone to access internet</b>								
Yes	79	86.1	1.00	0.55	69	73.9	1.00	0.61
No	30	80.0	0.93 (0.58, 1.48)		25	68.0	0.92 (0.53, 1.59)	
<b>Used HIVST with someone else there?</b>								
Yes	26	84.6	1.00	1.00	23	78.3	1.00	0.60
No	83	84.3	1.00 (0.62, 1.61)		71	70.4	0.90 (0.53, 1.54)	

<sup>^</sup> Reported comfort/ease limited to those reporting on the same test used during observation, resulting in fewer data points: some participants chose to utilize tests for observation that they had not reported using during the study;

<sup>‡</sup> Participant identified their sexual identity as transgender;

<sup>§</sup> questions not asked during phase I.

<https://doi.org/10.1371/journal.pone.0206849.t003>



66.7%, and 68.8% of the phase I-III samples, respectively, being between the ages of 18–24 (Table 1). Most participants identified as bisexual or gay, though the distribution of sexual identities varied across phases. Testing history also varied by phase. Prior to participation in the joint research initiatives (MpMS and the HIVST study), the majority of participants had HIV-tested before, largely within the last 12 months, though never testing was as high as 29% in phase I, and only 14% in phase III. Between 71% and 84% of participants reported having a regular male sexual partner at the time of study enrollment. There were no differences in age, education, sexual identity, or HIV testing history between those returning for follow-up and those who did not (data not shown).

### Test usability

Observed OF testing included 57 tests, with 24, 13, and 20 participants observed in phases I-III, respectively. Most recorded errors were minor (Table 2), the most common being conducting procedures out of order (e.g. collecting the sample before opening the tube) and not placing the tube securely. All users of the OF tests had valid results. Observers were universally confident that users would be able to conduct the OF test correctly in an unobserved setting. Frequency of errors did not decrease over the study phases. Similarly, among the 24 (phase I), eight (phase II), and 18 (phase III) participants observed conducting an OF and who reported on their OF self-testing experience, all but one in phase I reported it was very easy to collect the sample and interpret the result, and only two in phase I reported the test being difficult to conduct. One participant in phase II stated they did not trust the result. Participants were confident in their ability to use the OF test: 87.5% in phase I and 100% in phases II-III felt very confident they used the OraQuick test correctly.

Observed FS testing included 100 user-conducted tests, including 24, 32, and 44 participants in phases I-III, respectively. Major errors with the FS test were more frequent as compared to OF. The most common included lancet errors ( $n = 13$ ), errors delivering blood to the kit ( $n = 12$ ), and diluent errors ( $n = 5$ ). During phase I, 16 errors were made by nine individuals (37.5%) and counselors noted concerns about four participants (16.7%) being able to perform the test alone. In phases II-III, participants committed fewer errors on the FS test, with nine (28.1%) committing errors in phase II and eight (18.2%) in phase III (Table 2). While fewer people committed errors in the later phases of the study (test for trend  $p$ -value: 0.08), the proportion of participants for whom observers registered concerns remained consistently between 13% and 17% over all phases. While 13 participants had to use an external lancet, only one participant (phase I) had to repeat the entire test due to invalid results; this occurred after delivering only one drop of diluent (vs. recommended two). Overall seven participants tested positive on the blood test and were referred to a local MSM-friendly clinic [33]. Among 92 participants who were observed conducting the FS test and reported FS testing experiences, four (17.4%) during phase I and one in phase III (2.6%) reported difficulty collecting the sample and interpreting the results. Only one participant in phase I also reported difficulty conducting the test. All participants trusted the blood test results and 87%, 93%, and 95% felt very confident they used the blood test correctly in phases I-III, respectively (Table 2).

Among participants who were observed utilizing the OF and reported on using OF tests, level of agreement between reported ease and comfort and correct observed use was high. Only one participant who reported ease and comfort was observed making a mistake (positive predictive value (PPV) of reported ability 97.1%). Participants' ability to discern their own skill on the FS test was lower, with ten participants who reported ease and comfort having an observed mistake by the counselor (PPV 82.1%).

Younger age was the only characteristic marginally associated with correct observed use ( $p = .09$ ); education level was not associated with correct use (Table 3). Participant characteristics associated with stated ease and comfort included Ehlanzeni recruitment site ( $p = .05$ ) and having more testing experiences. Compared to those who had tested in the past six months, those who had never HIV-tested were 66% less likely (RR 0.66, 95% 0.44–0.99) to report ease and comfort with test use. Similarly, compared to those who had tested in the past six months, those who had tested more than one year ago reported less ease and comfort (RR 0.68, 95% CI 0.45–1.04), though this did not reach statistical significance. Additionally, those who had conducted three or more self-tests were more likely to report ease and comfort self-testing as compared to those who had not used HIVST prior to observation (RR: 1.92, 95% CI 1.32–2.80).

## Discussion

We found that overall South African MSM with differing degrees of experience and familiarity with HIVST were universally able to successfully use OraQuick OF test. Most errors were unlikely to render tests invalid. Participants were confident about using the OF tests, finding them easy to use. Our findings are comparable to recent studies conducted in sub-Saharan Africa. In a general population in Kwa-Zulu Natal, only .09% of OF testers had to repeat testing due to errors following a self-testing demonstration [34]. In a Ugandan fishing community [35], observers noted errors among 19% of participants but most tests were still successfully conducted, similar to our findings. However in the Uganda study, only three-quarters of users found the test easy [35], notably lower than our sample; however our participants appeared to test more frequently and therefore may have more comfort testing. Fewer user errors were reported in general populations studies in Kenya [36] and Malawi [37], with similar levels of acceptability and reported ease as our findings. Additionally, studies conducted in Africa have demonstrated a sensitivity of self-conducted OF testing at 90% or higher with specificity consistently at or above 95% [34–38], with one study conducted among healthcare workers in South Africa demonstrating lower sensitivity, primarily due to poor reading of (and lack of instructions around) weak positives [39].

While most MSM participants in our study could also perform the Atomo Diagnostics FS test, errors were more common, resulting in about one-sixth of users rated as unable to conduct the test alone. Though there has been collectively less research in Africa regarding blood-based HIVST, a recent study undertaken in the Central African Republic using a different FS test [40] found that while almost all participants could conduct the test, only 78.2% of lay users performed a FS test without error. Also similar to our findings, participants had the most trouble using the lancet. [40] A study in Cape Town [41] assessed usability of the Atomo test among young people (16–24 years), noting errors in only 3.6% of users, a much lower prevalence of errors as compared to our findings. This may be due to more intensive training prior to use; our training was a brief demonstration of the test and a review of the IFU. Like our sample, errors in Cape Town were largely related to blood draw and delivery to the device. In a multi-country study using 4 fingerstick HIVST prototypes, Peck et al. found that less than half performed the tests without errors, with only 61% able to collect a sample [42]; however users were not given training or instructions prior to use and the written instructions provided were not final manufacturer instructions.

Overall, our study and the majority of the evidence gathered around HIVST usability in Africa indicate that FS tests will require more instruction than what is currently included in the package insert. We did find evidence that fewer participants made errors on FS testing and more reported ease and comfort with FS testing in the later cohorts with additional degrees of exposure to HIVST and access to instructional videos. This was also observed in the Kenya OF

testing study; the authors noted that confidence in the ability to perform and interpret tests appeared to increase with testing experience [36]. These findings highlight the importance of continuing to develop resources for blood-based HIVST to ensure correct use, particularly in light of the evidence of improved test performance when using blood-based specimens [43, 44]. We believe that the instructional videos helped users in phase III, but note that our population did not report accessing the videos outside of the study office, as few had internet access or mobile device data plans. As a result, resources are needed that do not require internet connections or use large amounts of mobile data. Additionally, while we provided a hotline, calls for assistance were limited to two participants who called for further instruction, suggesting that while important to offer, participants may not utilize such a resource.

In terms of associations with correct test use and comfort conducting the tests, we found some evidence that younger participants conducted the tests with fewer errors, which has been noted in previous research [45]. We also found that recent exposure to clinic-based testing and more exposure to self-testing resulted in more reported confidence in conducting HIVST, though the same was not true with observed test performance. This increased confidence could be due to having a recent seronegative test result and therefore feeling less nervous and more focused while conducting HIVST. Increased comfort with increased HIVST exposure is also likely a result of gaining practice and familiarity with procedures, including steps such as pricking the finger, which can be daunting. Generally HIVST testing confidence has been demonstrated to be higher than the proportion of people conducting the tests correctly [26]. Our findings and past research [42] suggests that users overestimate their abilities to conduct HIVST alone, making improved instructional resources even more urgent.

This is among the first studies of both OF and FS HIVST use among sub-Saharan African MSM. Limitations include potential biases inherent in the use of counselor-observers, as being observed could lead to participant discomfort. Additionally, the sample size is small and skewed towards a young MSM population; however, results revealed a number of important findings and next steps towards improving diagnostic capacity in this high risk population.

## Conclusions

Against the backdrop of both structural barriers to clinic-based testing as well as feared and experienced stigmatization in public health care settings, [13, 14] MSM have evidenced a clear need and reported a resounding support for HIVST in two high prevalence districts of South Africa. While utilization errors were observed, particularly on the fingerstick test, increasing experience and exposure to HIVST is likely to decrease utilization errors. Further optimization of test devices to facilitate sample collection, improved supporting materials and instructions for use, and use of demonstration videos and Smartphone applications that can be downloaded and used offline (i.e. do not require ongoing use of network data), should improve usability and decrease frequency of errors. Rapid progress in HIVST quality will also be spurred by the growing number products entering the market and the increasing number of countries, including South Africa, producing regulatory policies [46] and stepping up monitoring systems to ensure device quality and appropriate instructions for use. Even with areas for improvement, HIVST are safe, acceptable, and feasible to use and will benefit populations like MSM that require alternatives to clinic-based HIV testing.

## Acknowledgments

**Disclaimer:** This research has been supported in part by the President's Emergency Plan for AIDS Relief through the US Department of Health and Human Services and the Centers for Disease Control and Prevention South Africa Country Office under the terms of the

Cooperative Agreement Number U2GGH000251. The contents of this manuscript are solely the responsibility of the authors and do not necessarily represent the official views of the US Centers for Disease Control and Prevention or the US Government.

We thank the study teams: Amukelani Bilankulu, Fikile Cibi, Nokuthula Boyisi, and Nkosi-nathi Zuma in Gert Sibande; Bongani Mabasa and Simphiwe Thabede in Ehlanzeni; and Angel Thomo who worked at both sites. We thank Helen Struthers, Helen Savva, Emily Agnew, and Tom Osmand for supporting the study. We thank Adrian Puren and Beverly Singh at NICD for test validation and controls provision.

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