Accuracy of Oral HIV Self-tests in Kenya

Ann E. Kurth, New York University
Abraham M. Siika, AMPATH/Moi University School of Medicine
Edwin Were, AMPATH/Moi University School of Medicine
Violet Naanyu, AMPATH/Moi University School of Medicine
Wilfred Emonyi, AMPATH/Moi University School of Medicine (Lab)
John E. Sidle, Indiana University School of Medicine
Charles M. Cleland, New York University (Statistician)
Stephen Macharia, AMPATH/Moi Teaching and Referral Hospital
Edwin Sang, AMPTH
Nok Chhun, New York University

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About 3ie

The International Initiative for Impact Evaluation (3ie) was set up in 2008 to meet growing demand for more and better evidence of what development interventions in low- and middle-income countries work and why. By funding rigorous impact evaluations and systematic reviews and by making evidence accessible and useful to policymakers and practitioners, 3ie is helping to improve the lives of people living in poverty.

About the HIV Self-Testing Thematic Window

Thematic Window 2 on HIV self-testing in Kenya is structured under two phases—phase 1, which funded formative research and phase 2, which will be informed by results from the first phase and will fund pilot interventions and their impact evaluations. 3ie identified key questions related to HIV self-tests by reviewing relevant literature and by meeting with key stakeholders in Kenya. 3ie and Kenya's National AIDS and STI Control Programme selected six of these questions in a request for applications under phase 1. The call was open to organisations implementing HIV and AIDS programmes in Kenya.

About this report

This report has been submitted in partial fulfilment of the requirements of a grant issued under the HIV Oral Self-Testing Thematic Window. 3ie is making this final report available to the public as it was received without any further changes. All content is the sole responsibility of the authors and does not represent the opinions of 3ie, its donors or its board of commissioners. Any errors and omissions are the sole responsibility of the authors. All affiliations of the authors listed in the title page are those that were in effect at the time the report was accepted. Any comments or queries should be directed to the corresponding author, Ann Kurth at akurth@nyu.edu.

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FINAL REPORT

Accuracy of Oral HIV Self-tests in Kenya

Project Description, Findings, and Recommendations

Principal Investigators:
Ann E. Kurth, New York University
Abraham M. Siika, AMPATH/Moi University School of Medicine

Co-Investigators:
Edwin Were, AMPATH/Moi University School of Medicine
Violet Naanyu, AMPATH/Moi University School of Medicine
Wilfred Emonyi, AMPATH/Moi University School of Medicine (Lab)
John E. Sidle, Indiana University School of Medicine
Charles M. Cleland, New York University (Statistician)

Project Director:
Nok Chhun, New York University

Project Coordinator:
Stephen M. Macharia, AMPATH/Moi Teaching and Referral Hospital

Data Manager:
Edwin Sang, AMPATH

1. Project Description and Data

(i) BACKGROUND

Knowledge of HIV status is key to earlier access to HIV treatment and prevention services. As an HIV prevention strategy, voluntary counseling and testing (VCT) is cost effective (Menzies et al., 2009; Sweat et al., 2000). It is also the fundamental entry point to an effective seek, test, treat and retain (STTR) paradigm, which has the potential to bend the curve of the HIV pandemic (Granich, Gilks, Dye, De Cock, & Williams, 2009). In resource limited settings such as in sub-Saharan Africa, the shortage of health care workers has been identified as a barrier in the effort to scale up HIV prevention and treatment services (WHO, 2010). According to population-based surveys in low- and middle-income countries (LMIC), the median percentage of people living with HIV who know their status is estimated at <40% (WHO, 2010). Given the public health implications of unknown HIV status, availability of self-testing for rapid scale up of HIV testing is compelling; increasing awareness of HIV status is an important step towards reducing HIV transmission and enabling antiretroviral therapy (ART) that reduces mortality as well as secondary HIV transmission.

Data from studies conducted in Malawi (Choko et al., 2011) and the US (Gaydos et al., 2011) show that self-testing in the general population is feasible, acceptable, and accurate. Availability of self-testing is one of several options to increase access to testing especially in higher-risk subpopulations that may not access current forms of HIV testing, such as HIV-discordant couples, men who have sex with men (MSM), sex workers (SWs), people who inject drugs (PWID), and high-risk youth. Currently available options include voluntary counseling and testing (VCT), provider-initiated counseling and testing (PICT), home-based counseling and testing (HBCT), and self-testing home specimen collection. In the US, where approximately 1 in 5 people do not know that they are infected (CDC, 2011), the Food and Drug Administration (FDA) approved the OraQuick In-Home HIV test kit, the first HIV self-test (HST) kit for sale directly to consumers over-the-counter (OTC) and online (FDA, 2012). The target population for this test is individuals who would not normally access HIV testing services for a variety of reasons that may

include privacy concerns, stigma, or other barriers to accessing HIV services. The US HST kit contains extensive resources such as detailed instructions on use, test result interpretation, and access to a customer support center (available 24/7) for any HIV/AIDS questions and referral to a health care provider in their area if needed. However, such an approach has not yet been implemented as a standard option for non-health professionals in LMIC countries, e.g., sub Saharan Africa, where two-thirds of all people living with HIV infection globally reside.

Kenya has been a leader in innovative approaches to HIV prevention and care. The recent KAIS (NASCOP, September 2013) national survey found that levels "of HIV testing have increased with 72% of adults aged 15-64 years in 2012 reporting ever having been tested for HIV, a significant increase from 34% in 2007." Ambitious population coverage targets for HIV serostatus knowledge have been set, yet even with large-scale home-based counseling and testing (HBCT) programs, voluntary counseling and testing (VCT) scale up, and other approaches, there still remains a coverage gap as noted by KAIS (one that is larger for men than women). This suggests that HST has a place as part of a comprehensive testing strategy. Kenya has successfully piloted HST among health workers (Kalibala et al., 2011) and is the first African country to develop policy guidelines (NASCOP, 2009) around HST for the general public.

(ii) AIMS AND OBJECTIVE

Our objective was to evaluate the performance and accuracy parameters of oral fluid HIV self-testing in the general population of Kenya. The study aims were to determine (1) the ability of participants with unknown HIV status to correctly perform and interpret a rapid oral fluid (OF) HIV test and to determine accuracy of HST results compared to staff/lab testing (i.e., sensitivity and specificity measures of validation), and (2) participant attitudes towards OF self-testing (i.e., OF HST acceptability and feasibility). A secondary objective included exploring linkage to care (i.e. whether the proportion of those who attend clinic within one month of their confirmed positive HIV result differed between individuals who tested using the OF HST in comparison to those who tested through regular VCT).

(iii) STUDY DESIGN

Participants

Study participants were recruited from three sites, a health care facility that has expanded beyond HIV-only care provision and two community partner sites in Eldoret, Kenya from November 11 – 29, 2013. Eligibility criteria included (1) adults (≥18 years old), (2) who do not know their HIV status because they have never tested or their last HIV test was negative, and (3) live within one hour of travel time to Eldoret town. Participants received 250 Kenyan shillings (equivalent to 3.00 USD) for their time and to reimburse their transportation costs. All study procedures were approved by the Institutional Research and Ethics Committee (Moi University IREC, #1029) and the University Committee on Activities Involving Human Subjects (NYU UCAIHS, #13-9670).

Recruitment

Participant recruiment occurred at AMPATH's clinic buildings in Eldoret; these facilities are part of AMPATH's primary care network. The two additional community partner sites are workplace settings, ensuring that our sample is drawing from the general population, and that self-testing occurs in a more natural, less clinical environment. All three sites are located in Eldoret, in areas considered to be a peri-urban/urban setting. We recruited using three teams based at each site following a recruitment algorithm; study flyers with mobile contact numbers so that interested individuals can contact the study team directly. At the health facility we also used provider word of mouth and staff referrals to recruit individuals of unknown or never tested HIV status and serodiscordant couples. For the additional sites outside of AMPATH, the engaged organizations publicized the study with their members, posted study flyers on site, and provided a confidential space where the study team could recruit, enroll, and perform study procedures with interested members. Prior to project roll-out, we engaged stakeholders at each site to introduce the study objectives and procedures to ensure community acceptance. AMPATH, as in the past, conducted community outreach and health information sessions at these sites.

Study Procedures

We conducted a prospective validation study comparing self-administered OF HST to staff-administered OF and rapid fingerstick (FS) test; all preliminary positives, invalids, and a proportion of the negatives were validated using an enzyme-linked immunosorbent assay (ELISA). We also assessed HST steps to understand errors in a subset of individuals. The study was conducted in two arms. Arm 1 consisted of the total study sample of N=240 (self-test validation) and Arm 2 participants (self-test usability) were a subset of the N=240 who agreed to be videotaped while performing the steps of the self-testing.

All participants conducted an OF self-test, followed by staff administered OF and FS. The only difference between the two arms is that Arm 2 participants' self-testing performance was video streamed which enabled study staffers to monitor the steps, in a separate area, in real time using a standardized checklist (see Figure 1). Only participants enrolled from the health facility site were asked to be part of the self-test usability component of the study; every participant was asked at the time of informed consent until N=20 were enrolled.

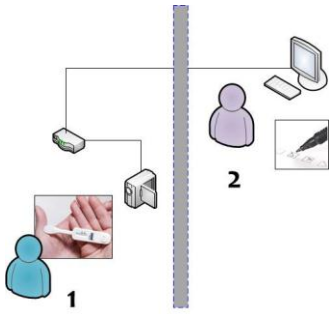


Fig. 1 – HST Real-Time Data Capture
1. User performs steps
2. Staff monitors steps by streaming video noting on checklist

The study was conducted over a single, supervised session and enrollment was done with written informed consent of each participant. Following informed consent, study staff administered a pre-HST questionnaire to collect basic demographic information and to assess risks, HIV test history, and HIV self-testing importance, confidence, and concerns. Afterwards, participants performed the self-testing in a private space, using a pictorial instruction sheet with both English and Kiswahili language text and icons (adapted from OraQuick with input from PATH, see Appendices), without supervision from study staff members. The OraQuick ADVANCE Rapid HIV 1/2 Antibody Test (OraSure Technologies), a rapid point-of-care oral fluid test kit approved for use in Kenya (and the only WHO-approved self-test commercially available at the time of this study), was used. After OF self-specimen collection, participants informed the study staffer that they completed the HST by interpreting their results aloud. Afterwards, study staff administered a post-HST questionnaire to collect information about participant experience using the self-

test kit, how HST should be packaged or made available, possible reasons people may or may not use HIV prevention and treatment services, as well as some of the same information that was collected during the pre-test questionnaire. Study staff then collected an OF sample and a blood FS sample (the Alere Determine HIV-1/2; Alere Medical Co.) and conducted parallel OF and rapid HIV tests. A blood specimen was drawn for ELISA confirmatory testing (Vironostika HIV Uni-Form II Ag/Ab; bioMérieux Inc.**)** of any preliminary HIV-positive, discrepant, or indeterminate/invalid OF/FS test results and a proportion of OF negative results. Post-test counseling was provided according to Kenya Ministry of Health guidelines, after completion of all study procedures. All preliminary HIV-positives were notified of the confirmed HIV-positive status once ELISA results were available and referrals to appropriate HIV care were made.

Linkage to care was assessed with a one month follow-up phone questionnaire of all participants confirmed by ELISA to be HIV-positive. Up to four phone calls were made to determine HIV-positive participants' uptake of referrals made and any clinic visit, whether CD4 count was assessed, and/or ART initiated. Participant self-reports were validated by checking the electronic health record system (AMRS[1]). Medical record review was also conducted to determine whether the proportion of those who sought care one month post HIV confirmed positive result differed in comparison to those who tested through regular VCT.

Sample Size Determination

We were originally approved to collect a sample of N=180, with the option to try to accrue 240 if time and resources allowed. Assuming sensitivity of .96 and specificity of .99, and an undiagnosed HIV prevalence of 20%, the total maximum sample size of up to N≤240 (minimum N=180) provides adequate (≥80%) power to detect key errors in HIV self-testing steps during this usability/validation pilot, including specimen collection and interpretation. For sensitivity, a null hypothesis of *Se*=.80 can be rejected with 82% power when the true value is .96; for specificity, a null hypothesis of *Sp*=.80 can be rejected with 99% power when the true value is .99. To convey the precision this sample size provides, a point estimate of *Se*=.94 would

[1] http://www.ampathkenya.org/our-programs/research-informatics/medical-informatics/

have a 95% confidence interval ranging from .819 to .985, and a point estimate of *Sp*=.97 would have a 95% confidence interval ranging from .858 to .999.

For the videotaping we set out to attain a sample of 10 males and 10 females. Samples of this size have been shown to have sufficient power to detect the large majority of usability problems (Faulkner, 2003).

(iv) DATA COLLECTION

Pre-HST Questionnaire

A structured, paper-based questionnaire was completed. It was administered verbally with results recorded by trained study staff. The questionnaire collected basic demographics (age, sex, education level, occupation/income) and briefly assessed risks, HIV test history, a Likert scale of HIV self-testing importance and confidence and top three concerns about testing HIV-positive (stigma, confidentiality concerns, relationship problems, treatment access, and open-ended 'other').

HST Procedures

We used the OraQuick HIV-1/2 Rapid Antibody Test (OraSure Technologies) approved for use in Kenya.

Post-HST Questionnaire

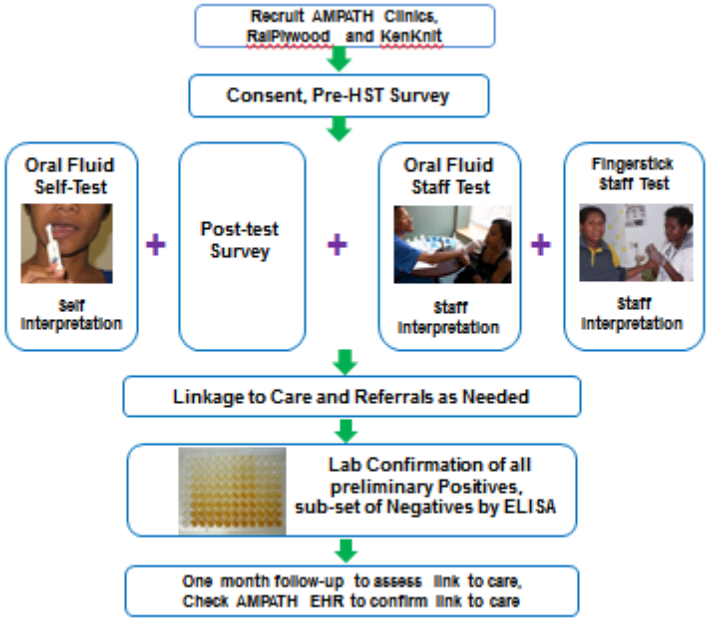
The post-test was a paper-based questionnaire administered verbally by trained study staff. The post-HST questionnaire repeated HST confidence/importance scales from the pre-test, and additionally collected information from the following domains: optimal Approach (how do participants think HST should be marketed), Feasibility/Acceptability (compare their experience and project what other population groups might encounter), Availability (where should HST tests be made available), Accuracy (assessment of their experience and potential user issues), Linkage to Care (what do they think will be barriers/facilitators for HIV prevention or treatment services for themselves and for others); Cost (price point and subsidization opinions); Harms (what main concerns do they have for themselves/others; Benefits (what advantages do they see from HST for themselves, others). These *HST session debriefing* data provide insights into perceptions of self-administered tests (ease of use, acceptability), perceptions of staff-administered tests,

exploration of HST facilitators and barriers, and recommendations for HST distribution. At session end, participants were allowed a question and answer period during which study staffers responded to queries on HIV testing and provided referrals and linkage to care as needed.

One month post HST

The purpose of the one month post HST survey is to assess linkage to care by determining HIV-positive participants' uptake of referrals made and any clinic visit, whether CD4 count was assessed, and/or ART initiation. Self-reports will be validated by checking the electronic health record system (AMRS) as described/permissioned in the consent. Figure 2 (right) summarizes the study procedures.

Fig. 2 – Study Flow



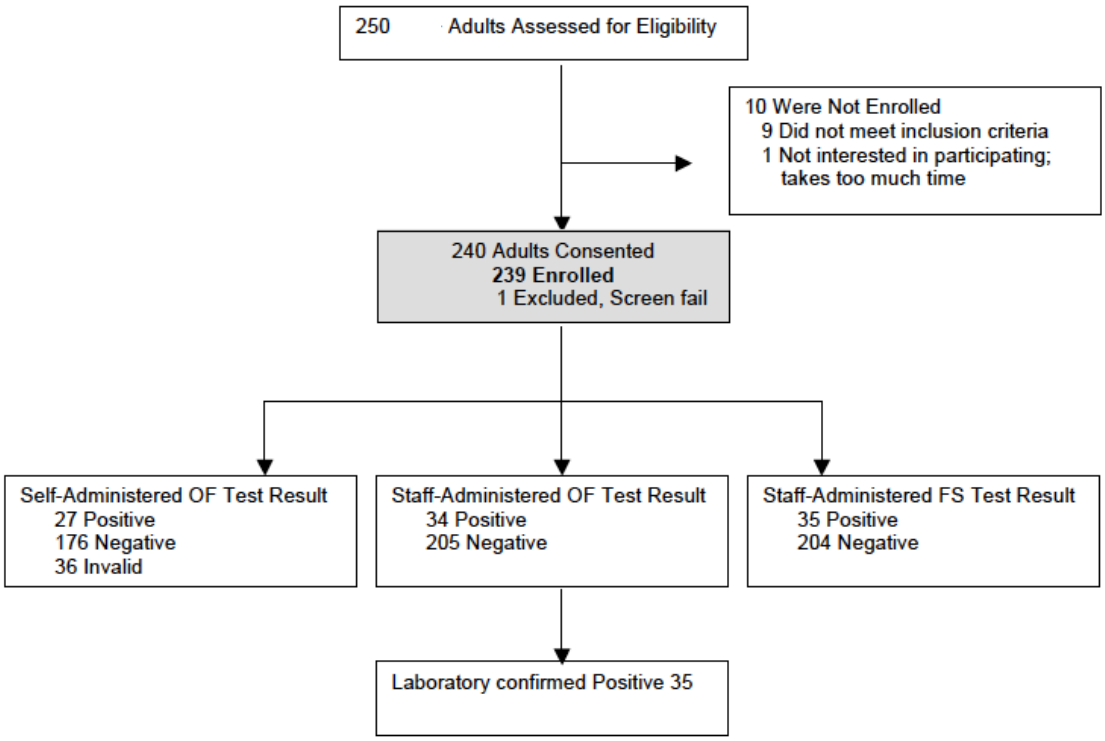
Statistical Analysis

Statistical analysis was conducted using Stata 13.1 (Stata Corporation, College Station, Texas). Distributions of participants' characteristics and oral fluid (OF) HIV self-testing (HST), staff finger stick (FS), and ELISA laboratory results were assessed using contingency tables. With ELISA and staff FS as gold standards, the performance of the rapid OF HST diagnostic test was estimated using the *diagt* module in Stata (Seed, 2001). Prevalence of HIV infection was based on staff finger stick (FS) results, since staff FS results were very accurate relative to ELISA results (sensitivity and specificity both 100%) and available for all participants. Determination of the accuracy of oral fluid (OF) HIV self-testing (HST) was based on comparison with both the FS and the ELISA blood test as the gold standard. **Sensitivity** is the percentage of

individuals with HIV infection (based on ELISA or FS) whom rapid OF HST correctly identified as having infection; this is also known as the true positive rate. **Specificity** is the percentage of individuals without HIV infection (based on ELISA or FS) whom rapid OF HST correctly identified as being free of infection; this is also known as the true negative rate. Sensitivity was estimated as the proportion of positive ELISA (or staff FS) results that were also positive by OF HST. Specificity was estimated as the proportion of negative ELISA (or staff FS) results that were also negative by OF HST. Additional measures of diagnostic accuracy describe those who did and did not receive a positive OF HST result; **positive predictive value** (PPV) represents the percentage of individuals with a positive OF HST result who actually had HIV infection, while **negative predictive value** (NPV) represents the percentage of individuals with a negative OF HST result who did not have HIV infection.

(v) RESULTS

Fig. 3 – Enrollment



Sample

We were able to enroll above our originally targeted sample, to a total of n = 240. Figure 3 outlines the status of enrollees. One study participant enrolled who was HIV-positive; this individual was removed from the analysis.

As seen in Table 1, the sample was approximately one third female (32.6%) and two-thirds males (67.4%). Many participants (90%) had HIV tested before, while 10% (n = 23) reported having never tested previously. A handful (n=8 females, 3%) said that they had done any kind of self-test before, in this case an over the counter pregnancy test. Mean age was 33, and mean education was 12 years. Two thirds of the sample were laborers. Most participants (88%) were in a relationship, though we saw only six out of this group who came in with a partner as part of a discordant couple.

Table 1. Demographic Characteristics

	Sites			
	Site 1 (n=77)	Site 2 (n=73)	Site 3 (n=89)	Overall (n=239)
Age	30.86 (8.86)	40.38 (10.05)	36.74 (8.00)	35.96 (9.69)
Gender Male	39 (50.65)	44 (60.27)	78 (87.64)	161 (67.36)
Gender Female	38 (49.35)	29 (39.73)	11 (12.36)	78 (32.64)
Highest Education Level	12.18 (3.86)	11.79 (2.66)	12.13 (2.77)	12.04 (3.13)
Relationship Status				
Single (no current main relationship)	14 (18.18)	2 (2.74)	13 (14.61)	29 (12.13)
Currently married (certificate or custom), one wife/husband	38 (49.35)	57 (78.08)	34 (38.20)	129 (53.98)
Currently married, more than one wife/husband	0 (0.00)	5 (6.85)	5 (5.62)	10 (4.18)
Currently living with a woman/man as if married	1 (1.30)	0 (0.00)	35 (39.33)	36 (15.06)
Currently in a relationship but not living with partner	18 (23.38)	4 (5.48)	1 (1.12)	23 (9.62)
Divorced	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Widow/ widower	3 (3.90)	2 (2.74)	1 (1.12)	6 (2.51)
Separated	3 (3.90)	3 (4.11)	0 (0.00)	6 (2.51)
If in relationship, came into study with partner				
No	40 (70.18)	66 (100)	74 (98.67)	180 (90.91)
Yes	17 (29.83)	0 (0.00)	1 (1.33)	18 (9.09)
S/he is my main partner	16 (94.12)	N/A	1 (100.00)	17 (94.44)
S/he is my other type of partner	1 (5.88)	N/A	0 (0.00)	1 (5.56)
If came with partner, partner's HIV status				
I don't know, but think may be HIV-positive	0 (0.00)	N/A	0 (0.00)	0 (0.00)
I don't know, but think may be HIV-negative	9 (52.94)	N/A	0 (0.00)	9 (50.00)
I know is HIV positive	5 (29.41)	N/A	1 (100.00)	6 (33.33)
I know is HIV negative	3 (17.65)	N/A	0 (0.00)	3 (16.67)
Household monthly income				
None	16 (21.05)	0 (0.00)	1 (1.12)	17 (7.14)

< 1,000 Ksh	1 (1.32)	0 (0.00)	0 (0.00)	1 (0.42)
1,000 – 4,999 Ksh	7 (9.21)	2 (2.74)	0 (0.00)	9 (3.78)
5,000 – 9,999 Ksh	22 (28.95)	30 (41.10)	3 (3.37)	55 (23.11)
10,000 – 19,999 Ksh	16 (21.05)	38 (52.06)	70 (78.65)	124 (52.10)
20,000 – 49,999 Ksh	12 (15.79)	3 (4.11)	15 (16.85)	30 (12.61)
50,000 – 100,000 Ksh	2 (2.63)	0 (0.00)	0 (0.00)	2 (0.84)
>100,000 Ksh	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Occupation				
Professional/technical/managerial	23 (29.87)	6 (8.22)	14 (15.73)	43 (17.99)
Clerical	0 (0.00)	6 (8.22)	4 (4.49)	10 (4.18)
Sales and services	6 (7.79)	3 (4.11)	0 (0.00)	9 (3.77)
Skilled manual	10 (12.99)	43 (58.90)	56 (62.92)	109 (45.61)
Unskilled manual	18 (23.38)	15 (20.55)	14 (15.73)	47 (19.67)
Domestic service	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Agriculture	3 (3.90)	0 (0.00)	0 (0.00)	3 (1.26)
Student	15 (19.48)	0 (0.00)	0 (0.00)	15 (6.28)
Other	2 (2.60)	0 (0.00)	1 (1.12)	3 (1.26)

Cell contents are count of participants with percentages in parentheses.

Sexual risk-taking was very common (Table 2), with 81% acknowledging sex without a condom in the last month. Of those with a main sex partner, two-thirds said their partners had been HIV tested, with 7% of those reporting that the partner's status was HIV-positive (8/9 of those were on ART). Mean number of sex partners in the last month was 1.35, indicating some possible sexual concurrency, a factor thought to contribute to HIV epidemic spread. Around six percent of participants said they had traded sex for drugs, money, food, clothing, shelter, or any other goods in the last 30 days. Almost half (45%) said they were less concerned about HIV than they used to be, though 91% acknowledged being "very worried about getting HIV". HIV stigma was still prevalent (60% "worried about what people in the community will think if I have HIV") but not universal.

Table 2. Sex Risk Behaviors

	Sites			
	Site 1 (n=77)	Site 2 (n=73)	Site 3 (n=89)	Overall (n=239)
Sex without condom in last 12 months				
Yes	58 (75.33)	61 (84.72)	73 (82.02)	192 (80.67)
No	19 (24.68)	11 (15.28)	16 (17.98)	46 (19.33)
One person consider as main sexual partner in past 30 days				
Yes	60 (77.92)	63 (86.30)	77 (86.52)	200 (83.68)
No	17 (22.08)	10 (13.70)	12 (13.48)	39 (16.32)
Main partner ever tested for HIV				

Yes	23 (38.33)	44 (69.84)	61 (79.22)	128 (64.00)
No	8 (13.33)	9 (14.29)	10 (12.99)	27 (13.50)
I don't know	29 (48.33)	10 (15.87)	6 (7.79)	45 (22.50)
If yes, test results were:				
HIV results were positive	6 (26.09)	0 (0.00)	3 (4.92)	9 (7.03)
If positive, on ARVs?				
Yes	6 (100.00)	N/A	2 (66.67)	8 (88.89)
No	0 (0.00)	N/A	0 (0.00)	0 (0.00)
I don't know	0 (0.00)	N/A	1 (33.33)	1 (11.11)
HIV results were negative	16 (69.57)	42 (95.46)	55 (90.16)	113 (88.28)
Neither of us knows the results	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
I do not know his/her results/HIV status	1 (4.35)	2 (4.55)	3 (4.92)	6 (4.69)
Other people you had sex with in past 30 days				
Number of persons	1 (1.30)	2 (2.74)	13 (14.61)	16 (6.70)
	2 (2.60)	2 (2.74)	2 (2.25)	6 (2.51)
	0 (0.00)	1 (1.37)	0 (0.00)	1 (0.42)
I don't know	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
None	74 (96.10)	68 (93.15)	74 (83.15)	216 (90.38)
Average number of sex partners, last mo (N=23)	1.67 (0.58)	1.80 (0.84)	1.13 (0.35)	1.35 (0.57)
HIV status of these other partners				
Number who were HIV positive	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Number who were HIV negative	0 (0.00)	0 (0.00)	0.80 (0.56)	0.52 (0.59)
Number who you did not know their status	1.67 (0.58)	1.80 (0.84)	0.33 (0.49)	0.83 (0.89)
Traded sex for drugs, money, food , clothing, shelter, or any other goods in the last 30 days				
Yes	14 (18.18)	0 (0.00)	0 (0.00)	14 (5.86)
No	63 (81.82)	73 (100.00)	89 (100.00)	225 (94.14)
Agreement with the following statements:				
I'm less worried about HIV infection than I used to be				
Strongly Agree/ Agree	29 (37.66)	50 (68.49)	25 (28.09)	104 (43.52)
New HIV treatments will take the worry out of sex				
Strongly Agree/ Agree	6 (7.79)	44 (60.27)	16 (17.98)	66 (27.62)
If a cure for AIDS were announced, I would stop practicing safe sex (using a condom)				
Strongly Agree/ Agree	1 (1.30)	32 (43.84)	4 (4.49)	37 (15.48)
HIV/AIDS is a less serious threat than it used to be because of new treatments				
Strongly Agree/ Agree	29 (37.66)	44 (60.27)	32 (35.96)	105 (43.93)
I am very worried about getting HIV				
Strongly Agree/ Agree	77 (100.00)	57 (78.08)	85 (95.51)	219 (91.63)
Is I was/am HIV positive I would be/am very worried about passing HIV				
Strongly Agree/ Agree	73 (94.81)	70 (95.89)	86 (96.63)	229 (95.82)
I am worried about what people in the community will think if I have HIV				
Strongly Agree/ Agree	21 (27.27)	45 (61.64)	77 (86.52)	143 (59.83)
I am not worried about pregnancy because of available HIV treatments.				
Strongly Agree/ Agree	1 (2.63)	18 (62.07)	9 (81.82)	28 (35.90)

Cell contents are count of participants with percentages in parentheses.

Most (90%) had tested for HIV before, with a mean of 3.77 tests taken (SD 2.30), most had tested within the last year (Table 3). Previous test sites included VCT (61%), with 31% tested at a hospital and 4% at home. Reasons for not testing included fear and perceived low risk. Concerns about testing HIV positive included stigma, abandonment and violence (all over 50%), with confidentiality as the main/top reason for not having HIV tested before.

Table 3. Exposure to Services, HIV Test History, Perceptions, and Concerns

	Sites			
	Site 1 (n=77)	Site 2 (n=73)	Site 3 (n=89)	Overall (n=239)
Ever tested for HIV				
Yes	77 (100.00)	63 (86.30)	76 (85.39)	216 (90.38)
No	0 (0.00)	10 (13.70)	13 (14.61)	23 (9.62)
Number of times tested for HIV	3.55 (2.02)	2.48 (1.38)	5.04 (2.53)	3.77 (2.30)
How long ago was most recent test	10.81 (13.81)	17 .83 (17.16)	11.87 (26.04)	12.34 (20.42)
Most recent HIV test result				
Positive	0 (0.00)	1 (1.59)	0 (0.00)	1 (0.46)
Negative	77 (100.00)	62 (98.41)	76 (100.00)	215 (99.54)
Didn't get result	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Location where last tested for HIV				
VCT (stand-alone sites)	24 (31.17)	1 (1.59)	20 (26.32)	45 (20.83)
VCT (mobile sites)	23 (29.87)	13 (20.64)	53 (69.74)	89 (41.20)
Hospital or doctor's office	24 (31.17)	40 (63.49)	1 (1.32)	65 (30.09)
Antepartum clinic	6 (7.79)	0 (0.00)	1 (1.32)	7 (3.24)
Addiction treatment center	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Home	0 (0.00)	8 (12.70)	1 (1.32)	9 (4.17)
Other	0 (0.00)	1 (1.59)	0 (0.00)	1 (0.46)
If never tested, reasons why (check all that apply)				
I thought I had a low change of getting HIV	0 (0.00)	6 (60.00)	1 (7.69)	7 (30.43)
Too expensive	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Takes too much time/inconvenient	0 (0.00)	1 (10.00)	4 (30.77)	5 (21.74)
I am afraid of knowing that I may have HIV	0 (0.00)	2 (20.00)	6 (46.15)	8 (34.78)
There is no cure so it doesn't matter	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
I don't know where to get tested	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
I'm afraid that my results may be known to other people	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Other	0 (0.00)	1 (10.00)	3 (23.08)	4 (17.39)
Ever used self-tests in the past				
Yes	7 (9.09)	1 (1.39)	0 (0.00)	8 (3.36)
No	70 (90.91)	71 (98.61)	89 (100.00)	230 (96.64)
Concerns about testing HIV positive (check all that apply)				
Fear of stigma	73 (94.81)	42 (57.53)	41 (46.07)	156 (65.27)
Fear of abandonment	72 (93.51)	32 (43.84)	44 (49.44)	148 (61.93)

Fear of family violence	37 (48.05)	53 (72.60)	27 (30.34)	117 (48.95)
Confidentiality concerns	70 (90.91)	54 (73.97)	36 (40.45)	160 (66.95)
Access to treatment if you are HIV positive	11 (14.29)	65 (89.04)	9 (10.11)	85 (35.57)
Other	2 (2.60)	9 (12.33)	28 (31.46)	39 (16.32)
Top three ranked reasons				
1.	Confidentiality Concerns	Access to Treatment	Fear of Abandonment	Confidentiality Concerns
2.	Fear of Stigma	Confidentiality Concerns	Confidentiality Concerns	Fear of Stigma
3.	Fear of Abandonment	Fear of Stigma	Fear of Stigma	Fear of Abandonment

Cell contents are count of participants with percentages in parentheses.

Outcomes of the various HIV tests are shown below.

Fig. 4 – Number of Results Indicating HIV Infection Across Different Testing Methods

Population	OF Self +	OF Staff +	FS Staff +	Lab +
Overall	27	34	35	35
Male	16	19	19	19
Female	11	15	16	16

There were 36 invalid self-tests (15% of the total sample).

As seen in Table 4, the importance of having access to a HST increased before vs. after the person conducted their own self-test, going from a mean of 8.1 to 8.6 (ascending scale 0 to 10). Confidence in doing the self-test correctly rose from 6.0 to 7.9 and ability to read results correctly from 6.1 to 8.1. Only 11 people (4.6% overall) thought that doing the HST was 'very difficult or difficult' while 94% 'strongly agreed or agreed' that HST was acceptable.

Table 4. Pre and Post HST Importance, Confidence, and Acceptability*

	Sites							
	Site 1 (n=77)		Site 2 (n=73)		Site 3 (n=89)		Overall (n=239)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Importance of having access to an HIV self-test kit	8.23 (1.05)	8.90 (0.80)	9.51 (1.20)	9.77 (0.49)	6.82 (2.19)	7.37 (2.48)	8.10 (1.95)	8.59 (1.89)
Confident that will use/used the self-test correctly	3.10 (2.27)	7.99 (1.36)	8.37 (0.99)	8.48 (0.97)	6.82 (2.04)	7.34 (2.65)	6.09 (2.86)	7.90 (1.92)
Confident that will be able/read results correctly	2.97 (2.24)	8.26 (1.61)	8.18 (1.02)	8.59 (0.80)	7.16 (2.16)	7.64 (2.69)	6.13 (2.92)	8.14 (1.96)
Think/feel using this test will be/was difficult[±]	2 (2.60)	0 (0.00)	4 (5.48)	0 (0.00)	5 (5.62)	11 (12.36)	11 (4.60)	11 (4.60)
Think/feel that HIV self-testing will be/is acceptable[±±]	77 (100.0)	77 (100.0)	73 (100.0)	73 (100.0)	78 (87.64)	75 (84.27)	228 (95.40)	225 (94.14)

[±]Responses have been dichotomized as proportion who said using HST was 'very difficult or difficult' (vs. 'not difficult, easy, very easy')
± Responses have been dichotomized as proportion who 'strongly agreed or agreed' HST was acceptable (vs. strongly disagree, disagreed, or neither agreed or disagreed)
*****Numbers represent ratings averaged on an ascending scale 0 to 10

Test Performance Video Data

Twenty individuals were videotaped during their HST. Data from the observation checklist were entered into an excel database and data were analyzed for common user errors. Video observation demonstrated that all participants reviewed the instruction sheet prior to performing the self-test. Problems noted covered a range of issues, some minor (e.g., twisting rather than popping the cap, n=14) and others less so (e.g., placing swab in the buffer solution before sample collection, n=3). These errors are similar to those that have been noted in a 3-country videotaped HST study conducted by PATH (consultants J. Lim and R. Peck on our study team, publication forthcoming June 2014). In addition, although not captured during the videotaping session, or from the post-HST questionnaire, research assistant field notes anecdotally describe one participant drinking the buffer solution. Outcomes from the test performance video data are shown below (Figure 5). The same individual could have made multiple errors.

Fig 5. HIV Infection Across Different Testing Methods for Video Participants

Case	Sex	OF Self	OF Staff	FS Staff	ELISA	User Errors
1	M	N	N	N	-	Difficulty putting bottle in stand (holder)/Did not put bottle in stand Did not swab between teeth and gums
2	F	N	N	N	-	Difficulty opening bottle Difficulty putting bottle in stand (holder)/Did not put bottle in stand Put swab on table Tongue touched swab
3	F	N	N	N	N	Difficulty opening packet Difficulty opening bottle Holds swab in mouth Waited < 20 minutes to read results
4	M	N	N	N	-	Difficulty opening bottle Difficulty putting bottle in stand (holder)/Did not put bottle in stand Placed stand in wrong position Spilled solution Waited < 20 minutes to read results
5	M	I	N	N	N	Difficulty opening bottle Collected sample with finger instead of using swab Placed finger in buffer solution before collecting sample with finger Placed swab in buffer solution before collecting sample Spilled solution Waited < 20 minutes to read results
6	M	N	P	P	P	Difficulty opening bottle Put swab on table
7	M	N	N	N	-	Difficulty opening bottle Waited < 20 minutes to read results
8	F	N	N	N	-	Difficulty opening bottle Difficulty putting bottle in stand (holder)/Did not put bottle in stand Placed swab in stand Placed swab in buffer solution before collecting sample Illiteracy Did not keep swab in bottle for the entire time Waited < 20 minutes to read results
9	M	N	N	N	-	Difficulty opening bottle Put swab on table
10	M	N	N	N	-	Placed stand in wrong position
11	F	N	N	N	-	Difficulty opening bottle Waited < 20 minutes to read results
12	F	N	N	N	-	Difficulty opening packet Difficulty opening bottle Touched bottom of swab with fingers Used finger to swab with desiccant Collected sample with finger instead of using swab Placed swab in buffer solution without collecting sample Did not keep swab in bottle for the entire time Added desiccant to solution Poured solution into stand Spits into bottle Illiteracy
13	M	N	N	N	-	Difficulty opening bottle Put swab on table Waited < 20 minutes to read results
14	F	N	N	N	-	Put swab on table Waited < 20 minutes to read results
15	M	N	N	N	-	Placed swab in stand Touched bottom of swab with fingers Waited < 20 minutes to read results
16	F	N	N	N	-	Difficulty opening bottle Put swab on table Added desiccant to solution Used swab as stirrer Did not keep swab in bottle for the entire time Waited < 20 minutes to read results
17	F	N	N	N	-	Waited < 20 minutes to read results
18	F	N	N	N	N	Difficulty opening bottle Waited < 20 minutes to read results
19	F	N	N	N	-	Difficulty putting bottle in stand (holder)/Did not put bottle in stand
20	M	N	N	N	N	Difficulty opening bottle Waited < 20 minutes to read results

Overall, videotaped participants' OF result was in agreement with staff administered FS. However, among this videotaped group there was one HST OF invalid result and one OF result misinterpretation (i.e., positive result read as negative), both among male participants. The study staffer confirmed OF positive interpretation when the participant left the room. The errors performed by the participant with the invalid result include, sample collection with his finger instead of using the swab, placing his finger in the buffer solution before collecting the sample with his finger, placing the swab in the buffer solution prior to sample collection, and spilling the buffer solution.

During the test preparation, participants experienced difficulty opening the packet (n=2), opening the bottle (n=14), and placing the bottle in the stand (n=5). Components not found on the instruction sheet, i.e., the desiccant packet, caused errors among some participants, which included adding the desiccant to the solution (n=2), and swabbing with the desiccant (n=2). Sixty-five percent (13/20) read the results before twenty minutes, although this did not include the participant who misread his results. Two women in the video sample were illiterate. Some of their errors included difficulty putting the bottle in the stand, placing the swab in the stand rather than the bottle, touching the bottom of the swab with fingers, using finger to swab with desiccant, collecting sample with finger instead of using swab, dipping the swab into the buffer solution before sample collection, adding desiccant to the solution, spitting into the bottle, and pouring the solution into the stand (Figure 6).

Fig 6. List of HST User Errors

Video Observation User Errors	N
Test Preparation	
Difficulty opening packet	2
Difficulty opening bottle	14
Difficulty putting bottle in stand (holder)/Did not put bottle in stand	5
Placed stand in wrong position	2
Placed swab in stand	2
Placed swab on table	6
Sample Collection	
Did not swab between teeth and gums	1
Touched bottom of swab with fingers	2
Tongue touched swab	1
Holds swab in mouth	1
Used finger to swab with desiccant	1

Collected sample with finger instead of using swab	2
Placed swab in buffer solution before collecting sample	2
Placed swab in buffer solution without collecting sample	1
Placed finger in buffer solution before collecting sample with finger	1
General other errors	
Added desiccant to solution	2
Used swab as stirrer	1
Spilled solution	2
Poured solution into stand	1
Spits into bottle	1
Illiteracy	2
Did not keep swab in bottle for the entire time	3
Timing	
Waited < 20 minutes to read results	13

Prevalence

We show here prevalence of HIV infection based on staff finger stick (FS) results, since staff FS results were equivalent to the ELISA laboratory blood test (sensitivity and specificity both 100%) and available for all participants. A total of 35 of 239 participants were positive for HIV infection, indicating **prevalence** of just under 15% (**0.146**; 95% CI: 0.107 – 0.197, Fig. 7).

Fig. 7 – HIV Prevalence

	Sample Size	Infections	Point Estimate	95% CI Lower	95% CI Upper
Overall	239	35	0.146	0.107	0.197
Male	161	19	0.118	0.077	0.177
Female	78	16	0.205	0.130	0.308
Age < 25	31	3	0.098	0.033	0.245
Age ≥ 25	208	32	0.154	0.111	0.209

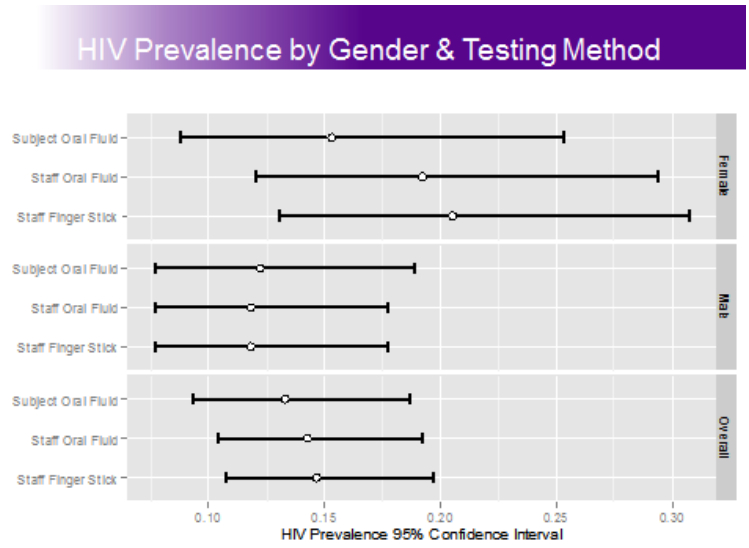


Fig. 8 shows HIV prevalence by type of test done and by sex of the study participant.

Sensitivity and Specificity

Determination of the accuracy of oral fluid (OF) HIV self-testing (HST) was based on comparison with the ELISA blood test and staff FS rapid HIV testing. Sensitivity was estimated as the proportion of positive ELISA (or staff FS) results that were also positive by OF HST. Specificity was estimated as the proportion of negative ELISA (or staff FS) results that were also negative by OF HST. Among the 239 OF HIV self-testing results, 36 (15.1%; 95% CI: 11.1% - 20.1%) were invalid. Among the invalid OF HST results, only one participant was from the videotaped cohort; invalid results were more likely among participants not videotaped, but this difference was not statistically significant (OR = 3.60; p = 0.3251 by Fisher's Exact Test). Participants with an invalid test did recognize that something had gone wrong with their test and did not misinterpret the result as either negative or positive. Invalid results were excluded from analysis of accuracy. Among 29 participants with positive ELISA results, 3 false negatives were observed for OF HST (**Sensitivity = .897**; 95% CI: 0.726 – 0.978). Among 49 participants with negative ELISA results, 1 false positive was observed for OF HST (**Specificity = 0.980**; 95% CI: 0.891 – 0.999). Among 29 participants with positive staff FS results, 3 false negatives were observed for OF HST (Sensitivity = .897; 95% CI: 0.726 – 0.978). Among 174 participants with negative staff FS results, one false positive was observed for OF HST (Specificity = 0.994; 95% CI: 0.968 – 0.999). All participants positive by FS were confirmed by

ELISA, which identified exactly the same people as having HIV infection. However, only a sample of negatives was confirmed by ELISA, hence the slight difference in specificity.

Negative and positive predictive values for OF HST relative to ELISA and staff FS results were estimated as well. Among 51 participants with a negative OF HST result, 48 were also negative by ELISA (**NPV = 0.941**; 95% CI: 0.838 – 0.988). Among 27 participants with a positive OF HST result, 26 were also positive by ELISA (**PPV = 0.963**; CI: 0.810 – 0.999). Among 176 participants with a negative OF HST result, 173 were also negative by staff FS (NPV = 0.983; 95% CI: 0.951 – 0.996). Among 27 participants with a positive OF HST result, 26 were also positive by staff FS (PPV = 0.963; CI: 0.810 – 0.999).

When the videotaped cohort (n=20) is excluded from the analysis, sensitivity is slightly higher (Sensitivity = .929; 95% CI: 0.765 – 0.991), and specificity is slightly lower (Specificity = 0.978; 95% CI: 0.885 – 0.999). None of the video-taped participants had a positive OF HST, therefore positive predictive value remains the same (PPV = 0.963; CI: 0.810 – 0.999). Negative predictive value is slightly higher (NPV = 0.957; 95% CI: 0.855 – 0.995).

Invalids

As previously mentioned, among the 239 OF HIV self-testing results, 36 (15.1%; 95% CI: 11.1% - 20.1%) were invalid. By design, samples positive by OF HST were over-sampled for ELISA confirmatory testing, so it is not feasible to use ELISA results to compare HIV prevalence among participants with and without invalid OF HST results. When staff finger-stick results (available for all participants) are used as a gold standard for HIV infection, those with invalid self-testing results had slightly increased odds of infection, but the difference was not statistically significant (OR = 1.20; p = 0.7977 by Fisher's Exact Test).

In our study sample, participants recruited from Site 3 had increased odds of an invalid test result (OR = 6.76; p < 0.001 by Fisher's Exact Test), and being male also increased the odds of an invalid test result (OR = 2.74; p = 0.033 by Fisher's Exact Test). Age and education were not significantly associated with the odds of an invalid OF HST result. Participants who had never tested before had increased odds of

an invalid result, but this finding was only marginally significant (OR = 2.81; p = 0.0579 by Fisher's Exact Test).

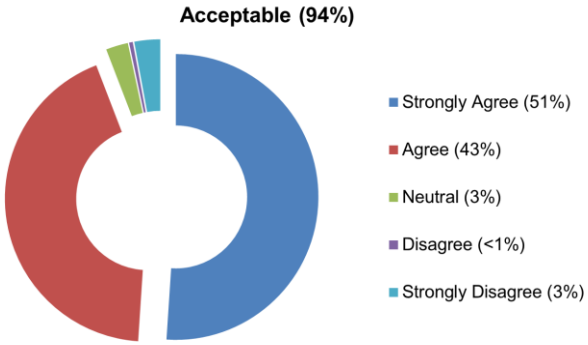
Figure 9 shows diagnostic accuracy by gender and level of education. Power to detect differences in sensitivity or specificity based on participant characteristics is low. The sample size for cases with infection is 29, and for cases without infection is 49. Also, because the number of diagnostic errors among those with a valid OF HST result is very small (one false positive and three false negatives), it is nearly impossible to identify statistically significant predictors of diagnostic error/accuracy. For these reasons, we do not disaggregate accuracy by additional participant characteristics and do not attempt to identify participant characteristics related to diagnostic accuracy/errors.

Figure 9. Disaggregation of Accuracy by Sex and Education Level

Female	
Sensitivity	.917
Specificity	1
Positive Predictive Value	1
Negative Predictive Value	.941
Male	
Sensitivity	.882
Specificity	.970
Positive Predictive Value	.938
Negative Predictive Value	.941
Lower Education	
Sensitivity	.818
Specificity	1
Positive Predictive Value	1
Negative Predictive Value	.714
Higher Education	
Sensitivity	.944
Specificity	.977
Positive Predictive Value	.944
Negative Predictive Value	.977

HST Acceptability

Almost all participants said that use of the HST was acceptable (94%, see figure) and confidence in the ability to perform and interpret the self-test appeared to increase with exposure to actually doing the test, as noted in Table 4 results drawn from the post-HST behavioral questionnaire closed-ended/quantified questions (see Appendices for survey instrument). Themes identified from the open-ended data fields in the post-HST behavioral questionnaire (Table 5) found that the large majority (71%) said that the HST experience was likeable.



Most participants (94%) said that they would use a self-test in the future.

Detailed data summaries below are from the open-ended data fields in the post-HST questionnaire:

Table 5 "How was your experience using the self-test?", "What did you like about this test?" "What did you think/feel was difficult about doing the test?" – Most (n=194) said that the HST was acceptable; about equal numbers said the test was hard (n=52) as said it was easy (n=45). The most commonly noted 'likeable' aspects of the HST were instructions that were easily understood (N=103) and that it was stress-free (n=74) and painless (N=70). The most common reasons for liking the self-test (asked among those who said they liked the self-test) was easily understood instructions (n=79). Nearly half the sample (n=100, 42%) reported that they had no difficulties during the self-test. Of those who described having problems, common issues were unclear test result interpretation (n=49), first time use and fear of making a mistake (n=35), opening the bottle (n=29), swabbing (n=27), opening the test kit packet (n=10), and illiteracy (n=10).

Table 5. Post-HST Survey Findings – Qualitative Themes Around HST Experience

A.	**Self-test experience**	**N**
	Nice, excellent, likeable	164
	Difficult	52
	Simple/Easy	45
	Clear charts/instructions	26
	No testing assistant/All alone	23
	Facilitated knowledge of HIV status	21
	Painless	20
	Daunting task	14
	Fast, saves time	12
	Easy to interpret results	11
	Confidential	9
	Convenient	6
	Accurate	2
	Safe	1
B.	**Likeable aspects of the self-test**	
	Easily understood charts/instructions	103
	Simple, stress-free	74
	Painless	70
	Do self-test on your own	69
	No blood sample/sharps	33
	Confidential	31
	Fast	30
	Facilitates knowledge of HIV status	22
	Liked nothing	17
	Convenient	12
	Use of English and Kiswahili in instructions	12
	Kit packaging	9
	No expertise needed	8
	Validity	3
C.	**Difficulties experienced during self-test**	
	None	100
	Unclear test result interpretation chart/diagrams	49
	First time use and fear of making a mistake	35
	Opening bottle	29
	Swabbing	27
	Opening packet	12
	Illiteracy	10
	Putting the bottle in the stand	9
	Timing the steps (long waiting periods)	9
	Opening swab packaging	5
	Putting swab in solution	4
	Everything was difficult	4
	Fear that the swab may have infections	2
	Unclear arrows in the instructions	2
	No demonstration of self-test before-hand	2
	Bottom part of swab not soft for those with gum problems	1
	Too many procedures	1
	Lack of information on what to do with the desiccant	1
D.	**Reasons for liking the self-test**	
	Easily understood instructions	79

Simple, stress-free	74
No testing assistant (alone)	69
Painless	69
Clear charts and pictures	60
Easy result interpretation	36
Confidential	31
Saves time	30
No risks (no sharps used)	23
No blood sample	12
Convenient	12
No expertise needed	7
Tamper proof packaging	5
Packaging safe from elements (rain)	5
Validity (all procedures by one 'handler')	3
Can do home test with partner	1
Light package/kit	1

Table 6 "If people have problems doing the test, what type of help would they like?", "If you were to conduct a self-test, where would you like to buy or pick up (if free or government subsidized) the test?" – The most preferred support that respondents would like to see for HST was a 24 hour call service to a skilled health worker (n=128), with the next most common support being access to a pharmacist (n=35) or doctor/health facility (n=30). Most would prefer to get HST kits at a chemist/ Pharmacy (N=143) or a health facility (n=101); informal access points were much less preferred.

Table 6. Post-HST Survey Findings – Qualitative Themes Around HST Preferences

		N
A.	**Preferred help during the self-test**	
	24 hour call service to a skilled health worker	128
	Access to skilled pharmacist	35
	Access to a doctor when ready to see one	30
	Access to a health facility when ready to use one	27
	Text message service	8
	Internet support/kit information	7
	ST with a doctor present	6
	Access to a contact at the kit issuing outlet	5
	Access to counseling service	4
	Availability of extensive instructions	1
B.	**Preferred test kit pick up point**	
	Chemist/ Pharmacy	143
	Health facility	101
	Shops	8
	Pubs	4

Table 7 "Would you recommend this test to others? Why or why not?" – The top reasons to recommend a HST to others were that it facilitates knowledge of HIV status (n=91), is simple to use (n=88), not requiring any assistance (n=38), and that it is confidential (n=35). The only two reasons noted (by very few participants) for not recommending self-test included a concern that people will get false results (n=5) or mess up procedures (n=4).

Table 7. Post-HST Survey Findings – Qualitative Themes Around HST Recommendation

		N
A.	**Reasons for recommending self-test**	
	Facilitates knowledge of HIV status	91
	Simple	88
	No testing assistant needed	38
	Confidential	35
	Saves time	24
	Convenient	24
	Painless, no pricks/sharps	24
	No expert staff/knowledge needed	16
	Accurate	10
	Easily understood instructions	8
	No blood sample	6
	Decongest hospitals	4
	Easy result interpretation	3
	Useful for those who fear hospital testing	3
	Can be done at home	3
	It is safe	2
	Can be done at own's convenient time	2
	Safer than the Determine method	1
B.	**Reasons for not recommending self-test**	
	People will get false results	5
	People can mess up procedures	4

Table 8 "What do you think are some of the challenges of HIV self-testing" – Interestingly, the main concern or challenge noted around HST was illiteracy (n=72); 49 people said they foresaw no challenges.

Table 8. Post-HST Survey Findings – Qualitative Themes Around HST Challenges

Self-test challenges	N
Illiteracy	72
None	49
Wrong result interpretation	43
No counseling	32
Extreme outcome if positive	25
Availability of ST kit	17
No information on what to do after a positive test	17
Disabled cannot use it	13

Fear to know HIV status	11
Extreme reaction due to absence of Counselor	11
Fear to do the test	7
Timing the steps (lengthy)	6
Unclear result interpretation diagrams	3
Opening bottle	3
Cost of self-test kit	1
Lack of awareness of ST method	1
Swabbing	1
Fear to buy the kit	1

Table 9 "What do you think are some of the benefits of HIV self-testing?" – Benefits of HST are that it is confidential (n=127), facilitates serostatus knowledge (n=114), and is fast, saving time (n=68).

Table 9. Post-HST Survey Findings – Qualitative Themes Around HST Benefits

Benefits of HIV self-testing	N
Confidential	127
Facilitate knowledge of HIV status	114
Fast, saves time	68
Simple, easy to use	66
Painless, No pricking	44
Convenient	31
No blood samples	23
No expert staff needed	22
Useful for those who fear hospital testing	20
Encourages personal reflection on life	14
Reliable	13
No injuries	13
No benefits	7
Facilitates timely HIV care uptake	6
No blood lost	4
Easily understood instructions for the literate	4
No transport costs incurred	4
One can easily help another person test at home	2
Reduces stigma	2
No testing assistant needed	2
Kit is portable	1
One can test anywhere	1
Provides opportunity for testing individual to control disclosure of results	1

Table 10 "What price would you be willing to pay for the self-test? – Affordability was the main theme, mentioned by n=192 participants. The mean price that people said they were willing to pay was 111 Kenyan shillings (range 0-1000 Ksh), with females mean being 78 Ksh and males 158 Ksh, though the

median price was 50 Ksh for both males and females. Mean price among those under age 25 was 56 Ksh and for those 25 Ksh and over was 120 Ksh.

Table 10. Post-HST Survey Findings – Qualitative Themes Around HST Price Factors

Factors influencing price preference	N
Affordable	192
Encourage HIV testing by all	55
To meet costs of producing the self-test kit	5
Government recommended price	5
To discourage self-testing	4
For government to gain revenue	1

Table 11 – Easy availability of ST kits was preferred (n=68), with smaller numbers (n=27-28) also mentioning presence of skilled staff and of extensive self-test information and support, within market centers/places.

Table 11. Post-HST Survey Findings – Qualitative Themes Around HST Pick Up Site Factors

Factors influencing choice of test kit pick up point	N
Easily available	68
Presence of skilled staff	27
Presence of extensive self-test information and support	26
Within market centers/places	26
Access all day	17
Facilities offering HIV services	14
Facilities with good storage	14
Strategically located	10
Confidentiality	5
Some rarely visit health facilities	3
Areas frequented by sexually active people	3
Government recommended points	2
Requires little time	2
Facilities with controlled pricing of goods	2
Where few people are involved when providing this service	1

Tables 12, 13 "Once you got the self-test results, what would you do?" "who would you tell?" – Almost half said they would wait, then repeat the test (n=109) and would maintain negative status, avoid risks (n=101). Sixty-six said that they would repeat the test with a skilled health worker or get support from a health worker of facility (n=34). Notably, only 10 people (4.1%) spontaneously said that they would show their results to a sex partner. When asked directly about disclosure following a HST, the most

common response was to tell a wife (n=84), followed by 'nobody" (n=58), husband (n=38), or sex partner (n=23).

Table 12. Post-HST Survey Findings – Qualitative Themes Around Post HST Actions

Action after self-test	N
Wait, then repeat test	109
Maintain negative status, avoid risks	101
Repeat test with skilled health worker	66
Get psychological support from skilled health workers	34
Go to health facility for support/advice/treatment	34
Show results to sex partner	10
Encourage others to test	9
No comment	3
Contact family doctor	1
Confide in close relative/friend	1
Avoid spreading HIV	1

Table 13 "In your opinion, how should self-testing be done in practice?" – The most common approach recommended was to do general HST awareness and education campaigns (n=77) in a variety of settings including community/mobile outreach (n=44) and in health facilities (N=43). Only 18 people mentioned the model of in-person counseling prior to giving a ST kit.

Table 13. Post-HST Survey Findings – Qualitative Themes Around Post HST Disclosure

People to disclose test results to	N
Wife	84
Nobody	58
Husband	38
Sex partner	23
Parents	8
Boyfriend	8
Children	7
Friend	7
Girlfriend	6
Family	4
Brother	3
Sister	3
Guardian	1

Table 14 – In terms of supporting people following a HST, most supported counseling (n=168), followed by ART medication availability (n=94).

Table 14. Post-HST Survey Findings – Qualitative Themes Around How to Promote HST	
How to do self-testing in practice	**N**
Create self-test awareness & educate people on the procedures	77
Current method (what was experienced) is good	47
In community/mobile outreaches	44
In health facilities	43
Counseling prior to giving ST kit	18
At household level	13
Anywhere private	7
Train individuals to do on their own	5
Avail kits widely	4
At church	2
Don't know	2
Through schools	1
Provide monthly testing services	1
Provide written test results	1
Limit self-test to the literate	1
Ensure access to counseling service	1

Table 15-17 "What would be the easiest way for people to receive lab validation of their preliminary positive HIV self-test results?" "How else do you think you could be supported after receiving your HIV self-test results?" – To encourage post-preliminary testing confirmation, respondents recommended: Call client to come for results (n=77) or give client a due-date for results (n=56) though others said that people should take their own initiative to visit clinic (n=55). Only 22 mentioned text messaging to encourage clients to come for results. Most recommended counseling support (n=168).

Table 15. Post-HST Survey Findings – Qualitative Themes, How to Do Post HST Support	
Other ways to support individuals after receiving results	**N**
Counseling	168
Provision of HIV medications	94
None/no comment	16
HIV education by skilled health workers	7
Food support	7
Psychosocial support	5
Get linked to relevant support groups	5
Support from family members	4
Don't know	3
Provide condoms	2
Facilitate repeat tests every three months	2
Encouragement from friends	1
Appointment	1
Do follow-up of clients	1
Job	1
Get linked to relevant NGO Support	1
School fees support	1

Table 16. Post-HST Survey Findings – Qualitative Themes, How to Ensure HST Test Result Confirmation

Easiest way for people to receive lab validation feedback	N
Call client to come for results	77
Give client a due-date for results	56
Own initiative to visit clinic	55
Text message client to come for results	22
Where they got the ST kit	6
Follow up the Clients	4
Text message results to client if its negative	1
Increase labs in the community & use them to give feedback	1
Don't know	1

Table 17. Post-HST Survey Findings – Qualitative Themes, Other Ways to Support People After Self-Testing

Other ways to support individuals after receiving results	N
Counseling	168
Provision of HIV medications	94
None/no comment	16
HIV education by skilled health workers	7
Food support	7
Psychosocial support	5
Get linked to relevant support groups	5
Support from family members	4
Don't know	3
Provide condoms	2
Facilitate repeat tests every three months	2
Encouragement from friends	1
Appointment	1
Do follow-up of clients	1
Job	1
Get linked to relevant NGO Support	1
School fees support	1

Table 18 "What would be the easiest way for people testing HIV-positive to link to HIV care if they need it?" – Most people (n=177) wanted a referral to a health facility offering HIV care; a handful advocated for more HIV clinics (n=33). Tellingly, very few mentioned wanting follow-up from health providers or a phone line to call (n=1).

Table 18. Post-HST Survey Findings – Qualitative Themes, How to Encourage Linkage to Care

Easiest way to link people to HIV care	N
Refer to health facility offering HIV care	177
Increase number of HIV clinics	33
Have health care workers follow them up	9
Have specific contacts at the HIV clinic	7
Do phone follow up of clients	6

HIV care centers should be well advertised	5
Have HIV care at chemists too	3
Mobile HIV clinics	2
Provide transport support to health facility	2
Give clients a phone line to call	1
Use referral cards (refer them for care)	1
Own Initiative	1
Don't know	1

Tables 19 and 20 lay out reasons why people would or would not be willing to use a HST test in the future (the majority expressed interest in doing so). Table 21, reasons why they think others would use HST in future, highlights that knowledge of serostatus appears to be valued highly (n=189).

Table 19. Post-HST Survey Findings – Qualitative Themes Around Using HST in Future

Reasons for considering self-test in future	N
Facilitates knowledge of HIV status	93
Simple, easy to use	70
It is clean – no infections	62
Accurate	39
Confidential	35
Convenient	30
Painless/no pricks	23
No testing assistant (alone)	22
It will hopefully be available	21
I have seen it and am now skilled to use it	19
No experts needed	14
No hospital visits	13
Results are easily interpreted	12
Easily understood procedures/instructions	12
Self-test will facilitate repeat/routine testing	12
Can test anywhere	9
Sexually active people can do routine tests	8
Fast	6
No injuries	4
I am literate and thus can do self-test	3
No side effects	3
No blood sample	2
Short procedures	2
Charts are well elaborated	2
Reduces stigma	1
The kit is portable	1

Table 20. Post-HST Survey Findings – Qualitative Themes Around Not Using HST in Future

Reasons for not considering self-test	N
Already knows HIV status	6
Will mess up/do incorrect procedures	6

Since it is new, one needs assistance	5
Illiteracy	3
Prefer test facilitated by a healthcare worker	1
Inaccessibility of self-test kits	1

Table 21. Post-HST Survey Findings – Qualitative Themes Around Why Others Might Use HST

Why others will consider self-test	N
Facilitates knowledge of HIV status	189
Confidential	66
No testing assistant (alone)	27
Responsibility as sex partners	19
Encourages life decisions	16
To be aware of new testing methods & experiment on ST	10
Painless/no pricks	9
Useful for those who fear hospital testing	9
Simple, easy to use	5
Facilitates timely HIV care	4
Easily understood instructions	4
Fast, no queues	4
To take away anxiety associated with unknown HIV status	2
Can test anywhere	2
Less anxiety when doing it alone	2
Useful for those too busy to go to the hospital	2
Reduces stigma	2
No expert staff needed	1
Charts are well elaborated	1
Convenient	1

Linkage to Care

All those confirmed to be HIV-positive were informed of the HIV result and actively referred to HIV care at AMPATH facilities. The rate of linkage that we observed in our study will be compiled once the one-month follow-up period has passed. We will assess how many of the 35 confirmed HIV-positives referred attended a clinic appointment within one month. We will not be able to assess how many of these had a CD4 test ordered, as there were CD4 test supply stockouts at AMPATH during the timeperiod of this study. Similarly, we will assess whether antiretroviral therapy (ART) was started in this group but do not expect this to occur within a one-month timeframe following a single clinic visit given the CD4 test stockouts and since clinicians may wait on test results before initiating treatment.

Implications of these key results are discussed in Section 2.

2. Data Interpretation

Sample

The demographics of enrolled participants reflected expectations and the patterns seen in Kenya, comprising more females (who had higher prevalence of HIV) than males.

Results Indicating HIV Infection Across Different Testing Methods

Of note, 7.7% (n=6) women and 18.6% (n=30) of the men had invalid HSTs ($p<0.03$, OR 2.7). This may suggest less familiarity with health tests among men (many women reported having done OTC pregnancy test, e.g.).

Prevalence

The higher prevalence seen in our sample as compared with that found in the province during the KAIS 2012 household survey suggests that somewhat higher-risk individuals self-selected to participate in the study, which may be a selection bias but which at least indicates an interest in HST among this epidemiologically and clinically important subgroup of the general adult population.

Sensitivity and Specificity

The sensitivity was somewhat lower than expected. However, it was nearly 90%, and positive predictive value at this prevalence was reasonable at 96%. This does underscore the need for improved instructions for the self-test kits, particularly for men who had an invalid test rate that was more than double that of women.

HST Acceptability

Most participants found the HST to be acceptable, and said they would use the HST in future if it were to become available.

SUMMARY

This HIV self-test validation study conducted among a general population sample in western Kenya found an overall HIV prevalence of 15%. By way of comparison, the KAIS 2012 national household survey found that HIV prevalence in the North Rift Province where the study took place (Eldoret is in Uasin Gishu County) was 3.1%. This suggests that HST is of interest to individuals, including some in the general population who may have a somewhat higher HIV risk (i.e., not just low risk 'worried well' testers) – an important population to reach. We were able to recruit a larger-than-required sample in a short period of time, another indication of interest in HST. Confidence in conducting the HST was good, as noted by positive responses and Likert scale scores after having done the HIV self-test.

In terms of HIV self-test performance, sensitivity in this general population sample (89.7%) was somewhat lower than originally hypothesized (a priori expected 96%) though this level is not dissimilar to that published in the Malawi study by Choko et al. Specificity of HST was high (98%). These data provide initial insights into the challenges and opportunities for HIV self-testing availability in Kenya.

3. Recommendations

Our study showed:

1. **There is a clear interest in, and good acceptability of, HIV self-testing (HST) among general population. HST may particularly reach men and at risk people within the broader adult population.**

   - We were able to enroll quickly
     - N = 239 eligible people in 3 weeks
   - Strong interest among men, who tend not to interact with VCT/health system
     - 66% were men
   - Qualitative data showed interest, acceptability, value, perceived utility of HST
   - Higher HIV prevalence was identified in this group than in the general surrounding geographic area
     - Nearly 5 times higher HIV (~15% vs 3%)

2. **General population adults can conduct the HIV self-test. Sensitivity was reasonable, though lower than expected or perhaps, ideal. Strategies to increase sensitivity/predictive value should be considered in any roll-out.**

    - Study hypothesis was that sensitivity would be 96%; we saw lower than that, sensitivity of 89.87% in one observed (but not staff facilitated or trained) session
    - Specificity was reasonable, as was positive predictive value
    - Subgroup sensitivity may be higher for those with higher education, and for females, though power was too limited to statistically test this. Potentially, factors such as literacy and previous exposure to health tests may influence HST performance
        - This suggests the need for educational campaigns and individual test kit instruction that reduces the likelihood of doing the self-test wrong (i.e., invalids as well as sensitivity performance)

3. If HST is rolled out in Kenya, there will need to be clear instructions and possibly, user training in some form

- Simplify HST steps if possible, reduce user errors
  - N=20 videos taped session revealed a range of user errors
- ADD very specific directions about what to do when user gets an invalid self-test result
  - 15% of our sample self-tests were invalid, twice as high among men as among women
- Training helps
  - Staff oral fluid (OF) tests done after one practice session were more accurate than individual participants' self OF tests being done for the first time
  - Potentially, distribute HSTs to clinics where individuals could have staff supervision of first tests, then self-test in future without. However, this adds health system costs and the study qualitative data showed little user support for this model
  - Costs of staff/health system involvement in teaching or supervising people to do HIV self-tests will have to be weighed against possible more likely user error, and more false negatives, of unsupervised HST use
- Best venue (e.g., point of purchase, clinical setting, other) and modalities (e.g., paper text/icons, digital, group instruction) of HST preparation/ education remain to be determined

4. The need for OF self-tests to be confirmed will have health system implications

- Will this take place in VCTs, HIV care sites/clinics, all of the above?
  - In this small study sample, research assistant fingerstick (FS) results were equivalent to lab-based ELISA results
- Qualitative survey data provides good information regarding potential HST consumer preferences, e.g., people say they would like to receive phone calls to return to clinic for test results on given dates.

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Appendices

A. Patient Instruction Handout

B. Pre-HST questionnaire

- Basic demographics (age, sex, education level, occupation/income); HIV risks, HIV testing history, a Likert scale of HIV self-testing importance and confidence, concerns about testing HIV-positive (e.g., stigma, confidentiality concerns, relationship problems, treatment access, etc.)

C. Post-HST questionnaire

- Debriefing domains include: optimal approach, feasibility/acceptability, availability, linkage to care, cost, harms, benefits etc.

D. Video Checklist

E. One month post-HST follow-up phone survey

REFERENCES

CDC. (2011). New Hope for Stopping HIV. CDC Vital Signs. Available at http://www.cdc.gov/VitalSigns/pdf/2011-12-vitalsigns.pdf.

Choko, A. T., Desmond, N., Webb, E. L., Chavula, K., Napierala-Mavedzenge, S., Gaydos, C. A., . . . Corbett, E. L. (2011). The uptake and accuracy of oral kits for HIV self-testing in high HIV prevalence setting: a cross-sectional feasibility study in Blantyre, Malawi. *PLoS Med, 8*(10), e1001102. doi: 10.1371/journal.pmed.1001102

Faulkner, L. (2003). Beyond the five-user assumption: benefits of increased sample sizes in usability testing. *Behav Res Methods Instrum Comput, 35*(3), 379-383.

FDA. (2012). OraQuick In-Home HIV test kit. Available at http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm310436.htm. Summary of safety and effectiveness available at fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM312534.pdf.

Gaydos, C. A., Hsieh, Y. H., Harvey, L., Burah, A., Won, H., Jett-Goheen, M., . . . Rothman, R. E. (2011). Will patients "opt in" to perform their own rapid HIV test in the emergency department? *Ann Emerg Med, 58*(1 Suppl 1), S74-78. doi: 10.1016/j.annemergmed.2011.03.029

Granich, R. M., Gilks, C. F., Dye, C., De Cock, K. M., & Williams, B. G. (2009). Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model. *Lancet, 373*(9657), 48-57. doi: 10.1016/S0140-6736(08)61697-9

Kalibala, S., Tun, W., Muraah, W., Cherutich, P., Oweya, E., & Oluoch, P. (2011). Knowing myself first: Feasibility of self-testing among health workers in Kenya. Naironi: Population Council.

Menzies, N., Abang, B., Wanyenze, R., Nuwaha, F., Mugisha, B., Coutinho, A., . . . Blandford, J. M. (2009). The costs and effectiveness of four HIV counseling and testing strategies in Uganda. *AIDS, 23*(3), 395-401. doi: 10.1097/QAD.0b013e328321e40b

NASCOP. (2009). Guidelines for HIV Testing and Counseling in Kenya. Nairobi: Kenya.

NASCOP. (September 2013). Kenya AIDS Indicator Survey 2012: Preliminary Report. Nairobi, Kenya.

Seed, P. (2001). DIAGT: Stata module to report summary statistics for diagnostic tests compared to true disease status. Statistical Software Components, S423401, Boston College Department of Economics, revised 19 Feb 2010.

Sweat, M., Gregorich, S., Sangiwa, G., Furlonge, C., Balmer, D., Kamenga, C., . . . Coates, T. (2000). Cost-effectiveness of voluntary HIV-1 counselling and testing in reducing sexual transmission of HIV-1 in Kenya and Tanzania. *Lancet, 356*(9224), 113-121. doi: 10.1016/S0140-6736(00)02447-8

WHO. (2010). Towards Universal Access: Scaling up priorities HIV/AIDS interventions in the health sector: progress report 2010. Available at http://whqlibdoc.who.int/publications/2010/9789241500395_eng.pdf.