Acceptability and feasibility of HIV self-testing among men who have sex with men in Peru and Brazil

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Abstract

HIV self-testing has the potential to increase testing frequency and uptake. This pilot study assessed the feasibility and acceptability of HIV self-testing in a sample of sexually active men who have sex with men in Peru and Brazil. Participants were trained to use a whole blood rapid HIV self-test and instructed to use the self-test monthly during this three-month study. Test acceptability was measured with self-reported use of the test at the one-month and three-month study visits, and test feasibility was assessed by direct observation of self-test administration at the final three-month visit. A total of 103 participants (52 in Peru and 51 in Brazil) were enrolled, and 86% completed the three-month study. Nearly all participants reported use of the self-test (97% at one-month and 98% at three-month visit), and all participants correctly interpreted the self-administered test results when observed using the test at the final study visit. HIV self-testing with a blood-based assay was highly acceptable and feasible. HIV self-testing may have the potential to increase testing frequency and to reach high-risk men who have sex with men not currently accessing HIV-testing services.

Keywords

HIV; viral disease; homosexual; diagnosis; South America; screening

Introduction

In Peru and Brazil, men who have sex with men (MSM) have the highest HIV prevalence and incidence compared to other HIV transmission groups.[1–3] HIV prevention strategies currently available are inadequate to control the spread of new infections among MSM, thus new interventions are needed. Vital to any prevention strategy is HIV testing, the primary gateway into HIV care and treatment. Studies have suggested that a substantial proportion of new infections come from persons unaware of their HIV infection,[4,5] and that increased testing alone could reduce new infections by as much as one-third in one year under optimal circumstances.[6] HIV self-testing kits, now available over the counter (OTC) in many Western countries, have the potential to increase the proportion of people tested, increase testing frequency, and encourage earlier detection of HIV and thus earlier treatment.

Prior research in Brazil has documented the feasibility and acceptability of home-based self-collection of biologic specimens for other sexually transmitted diseases,[7] as well as hypothetical interest in HIV self-testing.[8] Recently, high-risk MSM and transgender women in Peru reported a relatively low rate of willingness to use home-based HIV tests for regular HIV testing (Lama JR, personal communication); however, there are no published studies to date documenting experiences with HIV self-testing in South America. We conducted a three-month longitudinal pilot study to evaluate the feasibility and acceptability of HIV home testing among MSM in Peru and Brazil using a fingerstick whole blood assay. We chose a whole blood rather than an oral secretion home-based test because of its increased sensitivity during acute infection. We hypothesised that feasibility and acceptability for HIV self-testing would be high in a sample of sexually active MSM.

Methods

Study sample

Participants were enrolled at one study site in Rio de Janeiro, Brazil and two sites in Lima, Peru. These sites were selected because of their participation in the Prevention Umbrella for MSM in the Americas, a larger multi-site international study designed to explore optimal combination HIV prevention strategies for MSM. Recruitment occurred through community outreach and online and print advertisements. Participants were eligible for inclusion if they were HIV-uninfected, male sex at birth and currently identified as male, at least 18 years of age, a resident of Lima or Rio de Janeiro, able to read in Spanish or Portuguese, and willing to provide informed consent. To target MSM at high risk for HIV-acquisition, men who reported anal sex with two or more male partners or any unprotected anal sex with male partners in the preceding six months were eligible for inclusion. HIV status was confirmed with a rapid HIV test prior to enrollment.[9,10]

Study design

This three-month, longitudinal study included three in-person study visits. Following consent at the initial visit, participants completed a Computer Assisted Self-Interview (CASI) to assess demographics, health care utilisation, HIV risk behaviours, and HIV testing history and attitudes. Training on the use of the test kit was then conducted by a member of the study staff and included direct observation of participants using the Clearview COMPLETE HIV–1/2 Assay prior to distribution of the whole blood rapid HIV self-test. This assay was chosen because of its high sensitivity and specificity. Participants were instructed to use the kit prior to their one-month, in-person follow-up visit. All test kits had written instructions that included pictures, pre- and post-test counselling materials, a list of local HIV/AIDS resources, and condoms. Participants were asked to contact a 24-h telephone support line for any positive or invalid test results, procedural questions, technical support, counselling, or to request new test kits. Monthly SMS text message and email reminders to use the self-test were provided for participants with mobile phones or e-mail access.

At the one-month study visit, participants completed a CASI questionnaire about their self-testing experience, including questions about ease of use, confidence in results, and willingness to test again. Participants were given two additional kits and instructed to test monthly. Monthly testing was used to maximise participant experience using the test device. At the three-month final study visit, a CASI was used to assess test acceptability, as well as history, attitudes, and barriers to home testing and HIV risk behaviours. Participants were asked to use the self-test independently during this final visit while being directly observed and assessed by a trained study staff member; participants did not receive assistance from study staff while conducting the test.

Measures and statistical analyses

Our primary dependent variables were testing acceptability and testing feasibility. Acceptability was measured with the self-reported use of the test at the one-month and three-month study visits. Self-testing feasibility was assessed at the three-month visit; participants were classified as using the test incorrectly if errors were made during self-test administration that resulted in an inaccurate result. Questions regarding use of the test kit and trust in the results were asked using a 4-point Likert scale and made into dichotomous variables. Willingness to recommend the test to a friend and desire to use the test in the future were asked as yes/no questions. Statistical analyses were performed using SAS® software version 9.3.

Results

One hundred and three participants enrolled (52 in Peru and 51 in Brazil), 92 (89%) returned for the one-month visit, and 89 (86%) completed the three-month study visit. At study entry, about half (49%) of the study participants were 25 years old or younger, and 25% had 10 years of education or fewer (Table 1). Forty-six participants (45%) had not been tested for HIV in the preceding year, and 16% had never been tested for HIV prior to study participation. In the three months prior to study enrolment, 59% reported anal sex without a

condom, 17% were diagnosed with a sexually transmitted infection, and 40% reported sexual activity while under the influence of alcohol. A history of exchange sex was also common (28%).

Test acceptability was high, with 98% (90/92) reporting use of the self-test at the one-month visit, and 97% (86/89) reporting use of the kit at the final three-month study visit. Reasons cited for not using the test included loss of the test, forgetfulness, lack of time, lack of perceived risk for HIV, and desire to avoid using the lancet to draw blood. At the final study visit, 92% (82/89) of study participants reported feeling comfortable collecting their own blood specimens, 91% (81/89) found it easy to obtain blood, and 98% (87/89) described test interpretation as straight forward; 99% (88/89) reported that they trust future results if the test were used again. All participants (89/89) noted that they would recommend the test to a friend, and 99% (88/89) reported that they would use the kit themselves were they available in the future. No participants reported giving the tests to people outside of the study.

A large majority (86%) of the tests were completed in participants' homes, and a few were used at the homes of partners (7%), friends (3%), and relatives (2%). A few kits were also used at places of work (3%). While most participants reported performing the test alone (68%), some also had partners or spouses (15%), other relatives (8%), or friends (7%) with them.

Two new HIV infections were diagnosed during the study. One participant in Brazil had a positive result while learning to use the self-test kit during the initial study visit; this individual was linked to care and did not complete the remainder of the study. In Peru, a second participant noted positive results with the home self-test between his one-month and three-month study visits. This positive test was not reported to the study team until the three-month visit, five days after his initial positive self-test result. The participant was successfully linked to care. The 24-h telephone support line was only used for logistical questions such as rescheduling study appointments or requesting additional self-test kits.

All participants interpreted the results correctly when observed using the self-test at the final study visit. While no errors were made that impacted test results, 28 (31%) participants made minor errors during testing: 20 (22%) did not clean their finger with alcohol and/or allow time for the alcohol to dry, 12 (13%) did not dispose of the first drop of blood as recommended by the test instructions, and 10 (11%) had difficulty pushing the test device into the test holder.

Discussion

In this study of sexually active HIV-uninfected MSM in Peru and Brazil, HIV self-testing with a blood-based assay was both highly acceptable and feasible. Nearly all participants reported use of the self-test, very few participants had concerns with fingerstick blood collection, and all participants correctly interpreted the self-administered test results. Many participants cited lack of time, privacy concerns, and stigma/discrimination as reasons for not getting tested in the year prior to study participation. Importantly, HIV self-testing may

mitigate these frequently cited barriers by eliminating travel time and waiting at clinics as well as concerns surrounding confidentiality.

Our study findings are consistent with a community-based study of HIV self-testing with oral fluid in Malawi that found high levels of test acceptability and a 99% concordance between the self and laboratory performed tests.[11] In contrast, however, another study that included both HIV-infected and uninfected men and women in Singapore using a different blood-based self-test found that 85% of study participants did not perform all test steps correctly. Consequently, the majority (56%) of participants had invalid results.[12] This result may be the result of differences in test characteristics and ease of use, study population, or the level of test instruction included in this study.

Several limitations should be acknowledged when interpreting these results. First, while efforts were made to obtain a diverse sample of MSM in regard to age, education, and ethnicity, our sample did not include MSM from outside major urban areas in Peru and Brazil or MSM who reported lower risk sexual behaviours for HIV-acquisition. Second, we likely also missed MSM who may be fearful of HIV testing, who may not self-identify as gay or bisexual, and who are homeless, marginally housed, or youth living with parents, thus further limiting the generalisability of our findings. Consequently, stigma and discrimination may play important roles in test acceptability and feasibility that were not observed in our study. Third, it is uncertain how many participants were invited to participate in this study and refused (a measure of uptake), thus the response rate is unknown and the refusal rate may have introduced a self-selection bias. In addition, social desirability bias may have resulted in the over-reporting of test use. Finally, our results likely overestimate test acceptability and feasibility, as real-world implementation of HIV self-testing will likely not involve SMS and email reminders or in-person test education and feedback. Cost of the test also has potential to limit uptake.

The U.S. Food and Drug Administration approved the in-home, oral fluid OraQuick test in the United States in 2012.[13] However, a recent systematic review and meta-analysis concluded that OraQuick In-Home HIV Test has lower sensitivity and positive-predictive value as compared to tests that used fingerstick blood.[14] In fact, a model of HIV transmission dynamics suggested that replacing clinic-based testing with the OraQuick In-Home HIV Test may result in increased HIV prevalence in some populations because of the relative decrease in test sensitivity soon after infection.[15] This increased sensitivity for early infection would be critical if home self-testing were integrated into an HIV pre-exposure prophylaxis delivery program.

We observed high feasibility, acceptability, and interest in HIV self-testing with a blood-based assay among at-risk MSM study participants in Peru and Brazil. Our study findings make fingerstick whole blood self-testing an appealing alternative to oral fluid in Peru and Brazil, where OTC self-test kits are not yet being considered by regulatory agencies. Access to low-cost, affordable HIV self-testing offers potential both to increase testing frequency and to reach MSM not currently accessing HIV-testing services. Ongoing efforts will be needed to confirm self-test accuracy outside of a trial setting, and to ensure individuals with positive test results are successfully linked to care for confirmatory testing and treatment.

Acknowledgments

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Table 1

Baseline demographics, HIV testing history and attitudes, and HIV risk behaviours (N = 103).

	Peru n = 52 (%)	Brazil n = 51 (%)	Total N = 103
Age			
18–20	12 (23)	8 (16)	20 (19)
21–25	20 (38)	10 (20)	30 (29)
>25 years old	20 (38)	33 (65)	53 (51)
Race/ethnicity			
Mestizo/Pardo/Mixed race	40 (77)	18 (35)	58 (56)
White	8 (15)	19 (37)	27 (26)
Black	3 (6)	13 (25)	16 (16)
Indigenous/other	1 (2)	1 (2)	2 (2)
Residence			
Own house or apartment	26 (50)	30 (59)	56 (54)
At a rented apartment/room	13 (25)	14 (27)	27 (26)
At a relatives or friend's house	12 (23)	7 (14)	19 (18)
Live alone			
Yes	8 (16)	9 (18)	17 (17)
Work status			
Full-time job	28 (54)	25 (49)	53 (51)
Part-time/hourly work	12 (23)	6 (12)	18 (17)
Student	8 (15)	3 (6)	11 (11)
Unemployed/other	4 (8)	17 (33)	21 (20)
Years of school			
1–5	9 (18)	4 (8)	13 (13)
6–10	5 (10)	8 (16)	13 (13)
11–12	11 (22)	16 (31)	27 (27)
13–16	18 (37)	13 (25)	31 (31)
>16	6 (12)	10 (20)	16 (16)
Marital status			
Single/separated/divorced	49 (94)	38 (75)	87 (84)
Married or living together	3 (6)	12 (24)	15 (15)
Sexual orientation			
Homosexual/Gay	36 (69)	42 (82)	78 (76)
Bisexual	14 (27)	7 (14)	21 (20)
Other	2 (4)	2 (4)	4 (4)
Time since last HIV test			
In the last 3 months	8 (16)	16 (31)	24 (24)
3–6 months	6 (12)	9 (18)	15 (15)
6–12 month	9 (18)	7 (14)	16 (16)
1–2 years	12 (24)	5 (10)	17 (17)
>2 years	7 (14)	6 (12)	13 (13)

	Peru *n* = 52 (%)	Brazil *n* = 51 (%)	Total *N* = 103
Never tested	8 (16)	8 (16)	16 (16)
Reasons cited for not testing/delaying testing:			
Confidentiality/Stigma/Discrimination			
Didn't want others to know getting testing	9 (17)	7 (14)	16 (15)
Didn't want health records to show results	6 (11)	0 (0)	6 (6)
Concern for stigma/discrimination from health centre	8 (15)	1 (2)	9 (9)
Concern for stigma/discrimination from community	9 (17)	3 (6)	12 (12)
Worried about being seen at testing centre	10 (19)	2 (4)	12 (12)
Didn't want others to know the results	8 (15)	4 (8)	12 (12)
Convenience			
Didn't have time	21 (40)	13 (25)	34 (33)
Location inconvenient for testing	7 (13)	3 (6)	10 (10)
Other reasons			
Negative prior experiences with HIV test	3 (6)	2 (4)	5 (5)
Didn't want to receive HIV counselling	3 (6)	1 (2)	4 (4)
Didn't feel comfortable with staff at clinic	4 (8)	1 (2)	5 (5)
Didn't feel at risk for HIV	11 (21)	5 (10)	16 (15)
Didn't want to know results	7 (13)	3 (6)	10 (10)
Too expensive	4 (8)	0 (0)	4 (4)
Condoms with male partners in the last 3 months			
Never	9 (18)	6 (12)	15 (15)
Less than half the time	8 (16)	10 (20)	18 (18)
About half the time	3 (6)	2 (4)	5 (5)
Over half the time	10 (20)	11 (22)	21 (21)
Always	20 (39)	22 (43)	42 (41)
HIV-positive or unknown HIV status partner in the last 3 months			
Yes	33 (63)	38 (75)	71 (69)
STI diagnoses in the last 3 months			
Yes	10 (19)	7 (14)	17 (17)
Sex while drunk in the last 3 months			
Yes	22 (45)	19 (35)	40 (40)
Ever received money or gifts in exchange for sex			
Yes	11 (21)	18 (35)	29 (28)

STI: sexually transmitted infection. Percentages may not add to 100% because of rounding.