Title: Feasibility and economic costs of Syphilis self-testing to expand test uptake among gay, bisexual, and transgender men: Results from a randomised controlled trial in Zimbabwe

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Abstract

Background

Access to syphilis testing and treatment is frequently limited for men who have sex with men (MSM). A two-armed randomised controlled trial (RCT) compared feasibility and costs of facility-based syphilis testing with self-testing among MSM in Zimbabwe.

Methods

This RCT was conducted in Harare with participants randomised 1:1. Syphilis self-testing was offered in community-based settings. The primary outcome was the relative proportion of individuals taking up testing. Total incremental economic provider and user costs, cost per client tested, diagnosed and treated were assessed using ingredients-based costing in 2020 US dollars.

Results

A total of 100 men were enrolled. The two groups were similar in demographics. The mean age was 26 years old. Overall 58% (29/50) and 74% (37/50) of facility and self-testing arm participants respectively completed syphilis testing. 28% of facility arm participants had a reactive test with 50% of them returning for confirmatory testing yielding 28% reactivity. In the self-testing arm, 67% returned for confirmatory testing with a reactivity of 16%. . Total provider costs were $859 and $736, and cost per test $30 and $15 for respective arms. Cost per reactive test was $107 and $123 and per client treated $215 and $184, respectively. The syphilis test kit was the largest cost component. Total user cost per client per visit was $9.

Conclusion

Syphilis self-testing may increase test uptake among MSM in Zimbabwe. However, some barriers limit uptake including lack of self-testing and poor service access. Bringing syphilis testing services to communities, simplifying service delivery, increasing self-testing access through community-based organizations are useful strategies to promote health-seeking behaviours among MSM.

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Key words

Syphilis, syphilis self-testing, facility-based syphilis testing, Men who have sex with men, MSM, hidden populations, self-care products, sexually transmitted infections, Zimbabwe, costs of syphilis-testing, syphilis testing barriers

Summary of text

Access to syphilis testing and treatment for men who have sex with men (MSM) is frequently limited. A two-armed randomised controlled trial compared feasibility and costs of facility-based syphilis testing with self-testing among MSM in Zimbabwe. Overal 58% and 74% of facility and self-testing arm participants took up and subsequently completed syphilis testing, respectively. Syphilis self-testing can increase test uptake among MSM in Zimbabwe. However, some barriers limit uptake including lack of self-testing and poor service access.

Background

Delayed diagnosis of syphilis and ongoing transmission is an urgent global public health problem, it is not only responsible for high rates of neonatal deaths but predisposes many to HIV (human immunodeficiency virus) infection. ~~particularly among~~ Men who have sex with men (MSM) are particularly affected by this delayed diagnosis of syphilis (Hawkes et al., 2013) (2). ~~Additionally, many men who have sex with men also have sex with women~~(3). A systematic review of the prevalence of syphilis among MSM found a global pooled prevalence of 7.5% (95% CI: 7.0-8.0). A 2020 study found high rates of syphilis among MSM in two of Zimbabwe's largest cities, Harare and Bulawayo (5.5% and 5.6% respectively) (4). A 2020 study found high rates of syphilis among MSM in two of Zimbabwe's largest cities, Harare and Bulawayo (5.5% and 5.6% respectively) (4).

Despite the high prevalence of syphilis among MSM, they remain largely neglected in sexual health research in low- and middle- income countries (LMIC) (5).

Access to healthcare by MSM is frequently limited by cultural taboos, stigma and discrimination (6). In Zimbabwe, same-sex acts are punishable by one year in prison (7). MSM in Zimbabwe often suffer from violence, public outing, police harassment and blackmail because of their sexual orientation (8). MSM also experience cultural, religious and social stigma from healthcare professionals (9). Access to appropriate sexual health services is therefore limited, with the recent COVID-19 pandemic making facility-based care even more difficult. (4)

Regular testing is key to controlling syphilis transmission and reducing morbidity through timely diagnosis and treatment (10). While pregnant women are routinely tested for syphilis, there are no public programs in Zimbabwe focused on syphilis control among MSM despite the high rates of syphilis. Physicians do not routinely ask about same-sex behaviour or recommend syphilis testing for MSM (11). Syphilis self-testing may be an effective way to increase test uptake among MSM communities by providing out-of-facility testing opportunities (12). Self-testing involves individuals collecting their own blood specimen, performing the test using a disposable device and interpreting the results in private. The syphilis self-test kit is a rapid test that detects treponemal antibodies in under thirty minutes (13). These point-of-care testing devices for syphilis are readily available in the private sector. The tests are currently used as rapid syphilis tests and can be adapted for individual, home-based use (14).

However, whilst regular syphilis self-testing testing maybe good in increasing access to testing, treponemal only rapid tests will only be able to detect new syphilis infections and fail to detect syphilis infections in those previously treated for syphilis.

We assessed context-specific facilitators and barriers and evaluated the usability of syphilis self-testing in MSM (15). In our formative research, we found that MSM were willing to use self-test kits and that this method provided privacy, convenience, autonomy and reduced the potential for social and healthcare provider stigma (16). There is extensive evidence on the effectiveness and acceptability of HIV self-testing in LMICs, but data on syphilis self-testing is limited (17). As a result of this research gap, the World health Organization (WHO) has only given a conditional recommendation for the use of self-testing for syphilis diagnosis, even though it could potentially help to curb the syphilis epidemic in low-resource settings (18).

In a two-arm randomised controlled trial (RCT), we assessed the effectiveness of syphilis self-testing uptake compared to facility-based syphilis testing among MSM in Zimbabwe. Alongside the RCT, we undertook an analysis of the economic costs of syphilis self-testing both from provider and client perspectives.

Methods

Study design

This RCT, conducted between October 2019 and July 2020, compared syphilis self-testing to facility-based testing. Participants were randomised 1:1 to either the syphilis self-testing or facility-based testing group. The study was conducted in Harare, Zimbabwe by Pangaea Zimbabwe AIDS Trust (PZAT, a Zimbabwean local registered non-profit organization working to improve the health and well-being of people in Zimbabwe (19). The organization works with MSM among other population groups.

Ethical Approval

The study received ethical approval from the Medical Research Council of Zimbabwe (MRCZ) (MRCZ/2533) and the ethics committee at the London School of Hygiene & Tropical Medicine (LSHTM). All participants provided written informed consent. The study was registered on clinicaltrials.gov (NCT04480749).

Syphilis testing in Zimbabwe

Facility-based syphilis testing used a lateral-flow point-of-care blood-based assay to detect treponemal antibodies. Syphilis self-testing was not available at facilities during the RCT. For the RCT, the study team used rapid treponemal syphilis tests manufactured by SD Biosensor. Syphilis tests were individually repackaged in a Ziplock bag and included capillary pipettes, lancets, alcohol swab and testing device (supplement 1- testing instructions on paper and video – supplement 2).

Study procedures

Recruitment

Eligible participants were enrolled in Harare between October 1st and December 19th, 2019. Pre-screening was conducted on the phone with actual recruitment conducted in person. Participants had to: be 16 years or older; residing in Harare and planning to remain there for the next six months; be born biologically male; have no history of syphilis testing in the past 12 months; have at least one sexual risk factor (defined as condomless anal sex with a man in the last three months), in a non-monogamous relationship with a man, more than three male sexual partners in the past three months, previously diagnosed with a sexually transmitted infection (including syphilis), or

currently taking oral pre-exposure prophylaxis willing to provide a mobile phone number (for follow-up) and to give informed consent. Fliers outlining the study and the eligibility criteria were distributed to community-based organizations working with MSM. Interested men contacted study staff via dedicated phone numbers.

Randomization

An individual randomization sequence was computer generated. Each number was assigned to either facility-based testing or syphilis self-testing. The number and assigned arm were inserted in envelopes and sealed. The envelopes were stacked with participants asked to pick an envelope which contained printed cards assigning them to either of the study arms. Participants assigned to the self-testing arm were given a syphilis self- test kit and general information sheet (supplement 1) on syphilis. In addition, participants could access an instructional video via WhatsApp on their personal devices or programme tablets if they did not have a smart phone (supplement 2). Self-testing arm participants needing assistance with the test could elect to self-test at the community based organization site in a private area but with a programme officer on hand to assist if needed. Participants assigned to the facility-testing arm were given a referral slip to take to the facility for testing (Study flowchart, Annex 1). Facility health care providers had been sensitized and received specific training on provision of syphilis testing. Participants in both arms received $10 USD for time spent completing the enrolment process. Enrolment in the study occurred at a local non-profit organization in Harare that typically works with the MSM community. Staff also knew the individuals, which removed the possibility of participants enrolling twice.

Data Collection

At baseline we collected data on demographics, sexual behavior and previous HIV and syphilis testing. This included age, sexual orientation, marital status, educational attainment, living arrangements, disclosure of sexual orientation to a healthcare provider and or family member, sexual roles, number of sexual partners in the past six months, relationship type (long-term, short-term) with each sexual partner, condom use, history of STIs, group sex and substance use. Data was captured electronically on tablets using Open Data Kit.

Sample size calculation

The sample size was determined by the available budget.

Follow-up

Data logs were created for nurses at the facility to capture facility-testing arm participant data and those who tested positive. Data was compiled on a weekly basis from the facility, capturing identification numbers of participants who came to the facility and their syphilis test results. Self-testing arm participants were asked to send a picture of their test results via WhatsApp or bring their test kits to the program office. Participants in both the self-testing and facility arms with reactive syphilis test results were followed up by the study team and referred back to the health facility for further blood samples to test for Treponema Pallidum Hemagglutination (TPHA) and Rapid Plasma Reagin (RPR) tests. Following enrolment blood samples were processed at Multi-tech Diagnostics, a commercial pathology laboratory. Participants with positive results for both TPHA and RPR tests had treatment administered according to STI (20,21). In both arms participants with reactive tests were followed-up at 48 hours, and then 3 and 6 months. Part of the follow-up took place in the context of COVID-19 (beginning March 2020), layered with lock-down restrictions on movement. Laboratory samples for those with reactive tests were scheduled

based on specific laboratory sample pick up days and therefore not always feasible to have on the day of the reactive test.

Lost-to-follow-up

Participants who enrolled but failed to either self-test or attend facility-testing were followed-up by phone beginning at 48 hours and then weekly thereafter up to three times, and if not-contactable were then considered lost-to-follow-up. If a participant responded positively to a follow up call, then the normal process, as described above, would be followed.

Statistical analysis

We report descriptive statistics for demographic characteristics, substance use, sexual behaviour, history of HIV and syphilis testing. The primary outcome was the difference in the proportion of individuals who undertook a syphilis test between study arms between October 2019 and July 2020. Syphilis test uptake was assessed by photo-verification (among those with a smartphone), receipt of the completed test kit or telephone call. Secondary outcomes included the proportion of individuals who tested positive by either self-testing or facility-based testing, associated costs of delivery and those who reported engaging in condomless sex. We used an intention to treat approach to analyze the primary and secondary outcomes. The analysis was conducted using STATA version 15 (StataCorp, Texas, USA).

Economic cost analysis

An ingredients-based costing exercise estimated the incremental economic cost of syphilis self-test kit distribution (Appendix 1). Standard costing guidelines were used to estimate the total cost,

and cost per client tested for syphilis, per syphilis diagnosis and per person treated in the facility based and self-test arms (22–24). Consistent with other self-testing studies, (25–27) costs of training and start-up (venue and reimbursement expenses), staffing and supplies for demand creation, self-testing, initial facility and confirmatory tests (including laboratory tests) and treatment were estimated. We also administered a short exit/telephone interview to 10 clients who had accessed syphilis testing at the facility to measure user costs in terms of productivity losses (lost income) and other out-of-pocket expenses (OOPEs) incurred seeking syphilis testing. OOPE's included transportation for the self-test kit collection, initial facility-test and confirmatory testing, food, and or other payments incurred. Costs are presented in 2020 United States Dollars (US$). The US$ has been part of the official basket of currencies in use in Zimbabwe since 2009.

Results

Of 104 MSM approached and screened, 100 MSM enrolled, with 50 participants assigned to each arm. The four individuals who screened out were ineligible based on age and not planning to stay in Harare for the next six months. 66/100 men had primary outcome data available at six months and 34/100 were lost to follow up. Potential participants were identified and referred to PZAT by community-based organizations (CBOs) working with MSM. The mean age was 26 years (SD 5.72). Overall, 40% of participants reported taking HIV pre-exposure prophylaxis at the time of enrolment. Most of the participants (81%) had never been married while 13% were separated or divorced and 6% engaged or married. Just under a third of the participants (30%) reported having achieved tertiary level of education whilst 48% had completed secondary education. Most participants identified as gay (49%), followed by bisexual (31%) and transgender (19%). (Table

1). The primary outcome (syphilis testing uptake) was assessed by photo-verification in 33 individuals, receipt of test kit in 4 individuals and clinic records in 29 individuals.

Table 1. Socio-demographics characteristics of gay, bisexual, and transgender MSM who enrolled in the syphilis self-testing randomised controlled trial 2020-2021 in Harare, Zimbabwe.

	Total N=100 (%)	**Facility testing arm N=50 (%)**	**Self-testing arm N=50 (%)**
Age (years)			
>24	37 (37)	14 (28)	23 (46)
>=24 & <30	39 (39)	22 (44)	17 (34)
>=30 & <40	20 (20)	12 (24)	8 (16)
>=40 &<50	4 (4)	2 (4)	2 (4)
Mean (SD)			
Marital status			
Engaged or married	6 (6)	3 (6)	3 (6)
Never married	81(81)	42 (84)	39 (78)
Separated or divorced	13 (13)	5 (10)	8 (16)
Highest education			
High school or below	22 (22)	9 (18)	13 (26)
Secondary school	48 (48)	23 (46)	25 (50)
Tertiary or beyond	30 (30)	18 (36)	12 (24)
Spoken to family member about sexual orientation			
No	43 (43)	24 (48)	19 (38)
Yes	57 (57)	26 (52)	31 (62)
Spoken to a physician about sexual orientation			
No	42 (42)	22 (44)	20 (40)
Yes	58 (58)	28 (56)	30 (60)
Ever tested for HIV			

No	2 (2)	0 (0)	2 (4)
Yes	98 (98)	50 (100)	48 (96)
Ever used an HIV self- test			
No	32 (32)	15 (30)	17 (34)
Yes	66 (66)	35/50 (70)	31 (62)
	2 (2)	0	2 (4)
Ever tested for syphilis			
No	75 (75)	37 (74)	38 (76)
Yes	25 (25)	13 (26)	12 (24)
Primary identification			
Bisexual	31 (31)	16 (32)	15 (30)
Gay	49 (49)	26 (52)	23 (46)
Transgender	19 (19)	7 (14)	12 (24)
Unsure, other	1 (1)	1 (2)	0
Spoken to a physician - sexual orientation			
No	42/100 (42)	22/50 (44)	20 (40)
Yes	58/100 (58)	28/50 (56)	30 (60)
Spoken to a family member - sexual orientation			
No	43 (43)	24 (48)	19 (38)
Yes	57 (57)	26 (52)	31 (62)

Two thirds of participants (68%) were living with family; only 8% were living with an intimate male partner. Just over half of the participants (58%) had spoken to a physician and/or a family member about their sexual orientation. 98 participants reported ever testing for HIV (98%) and 66 had previously performed an unsupervised HIV self-test (66%). Only 25% of the participants had ever tested for syphilis, most commonly through a community-based organization. One individual had tested for syphilis using a self-test kit prior to this study. Among those who reported ever testing for syphilis, six had a reactive test and had been treated before. Based on their serological data and clinical history, the clinician decided that further syphilis treatment was not necessary for these six individuals.

Table 2. Syphilis uptake outcomes

	Total (N=100)	**Facility testing arm (N=50)**	**Self-testing arm (50)**
Tested for syphilis	66/100 (66%)	29/50 (58%)	37/50 (74%)
Had a reactive syphilis test	14/66 (21%)	8/29 (28%)	6/37 (16%)
Treated for syphilis	8/14 (57%)	4/8 (50%)	4/6 (67%)

In the self-testing arm 37/50 MSM (74%) completed a syphilis self-test (see consort diagram, annex 2). Among individuals in the control arm, 29 participants (58%) accessed facility-based syphilis testing (Absolute difference 16%, 95% CI -4% to +36%, p = 0.14). Six participants in the self-test arm and eight in the facility-testing arm had a reactive syphilis test result. Of these, four in each arm returned for confirmatory testing. None of the participants reported having received prior syphilis treatment.

One participant reported that they had been pressured to take a syphilis test by their regular male sexual partner. Two participants had difficulties conducting the syphilis self-test alone and sought assistance from a staff member. After additional support both participants were able to use the self-test kit. There were no adverse events experienced because of MSM participating in the study.

Economic cost results

Total provider programme costs were US$736 for the self-testing intervention and US$859 for facility-based syphilis testing (Table 3). The cost per self-test was US$15 compared to US$30 per facility-based test reflecting the impact of freeing up health providers time as clients test themselves. Cost per reactive client was US$123 compared to US$107 per facility-based test due to the lower number of syphilis positive clients. Cost results per client treated were US$183 versus US$215 in the self-testing and facility arms respectively. The largest cost component for each of the arms was the initial screening test (31% for self-testing arm vs 33% in facility). In the self-testing arm confirmatory testing contributed 27% (personnel 7% + supplies 20%), demand creation 26% (personnel 17% + supplies 9%) and training and start-up 15%. Confirmatory testing

contributed 30% (personnel 8% + supplies 22%) and demand creation 28% (personnel 15% + supplies 8%) for the facility test. Training and start-up costs were 11% of total costs.

Self-reported user costs were collected through exit interviews with 10 men. Transport costs contributed nearly half of the user costs, (52% in self-testing vs 44% in the facility arm, respectively). On average transport cost was $1.90 each way for self-test kit collection and the initial facility test. Clients returned for confirmatory testing and upon a confirmed positive result for a single dose of treatment; i.e. men needed to take three trips to receive treatment. Food and other expenses averaged $2.12 per visit. We also assessed productivity losses incurred whilst seeking syphilis testing, with average self-reported lost income estimated at US$0.76 per hour. This was multiplied by the estimated time for travel (79 minutes one-way) and at the facility (56 minutes). In total each visit incurred an average lost income of US$3.32. The total user cost per client per visit was US$9 for self-testing and US$12 for facility testing. Attending the three visits needed to receive syphilis treatment would consume almost 92% of client's weekly income (average weekly earnings = $30.30).

Table 3. Provider total and cost per kit distributed (US$)

Input categories	Facility testing	%	Self-testing	%
Training & start-up costs	$ 110	13%	$ 110	15%
Demand Creation - Personnel	$ 125	15%	$ 125	17%
Demand Creation - Supplies	$ 67	8%	$ 67	9%
Initial test - Personnel	$ 166	19%	$ -	0%
Initial syphilis test - Supplies	$ 121	14%	$ 229	31%
Confirmatory testing - Personnel	$ 69	8%	$ 51	7%
Confirmatory syphilis test (including laboratory tests) - Supplies	$ 192	22%	$ 144	20%
Treatment - Personnel	$ 8	1%	$ 8	1%
Treatment - Supplies	$ 2	0%	$ 2	0%
Total programme cost	**$ 859**	**100%**	**$ 736**	**100%**
People tested/ # Kits distributed	29		50	
Cost per kit distributed	$29.61		$14.71	
# Positive/reactive client	8		6	

Cost per positive/reactive client	$107.35	$122.60
# Clients treated	4	4
Cost per client treated	$214.69	$183.90

Discussion

Our study found that promoting syphilis self-testing among MSM through Community Based Organisation distribution may increase syphilis test uptake compared to offering facility-based syphilis testing. This finding, where syphilis self-testing was seen to be more acceptable and accessible to MSM, is consistent with studies reporting results of HIV (13,28) and hepatitis C virus self-testing (16). Syphilis self-testing may decrease stigma associated with testing and increase ease of use compared to facility-based testing. Lastly, syphilis self-testing allows the tester to decide when, where, and with whom they test. The higher uptake of syphilis testing in the self-testing arm is consistent with our previous qualitative study suggesting that facility-based services may be avoided by some MSM (Sri-Pathmanathan et al., 2021) due to stigma and discrimination as well as cultural taboos of being an MSM (Ndione, 2022). A key consideration for the current study is that facility-testing for syphilis amongst MSM is not standard of care (SOC) in Zimbabwe and is only routinely provided to pregnant women. Thus, facility-based testing did not represent a true "control" group within the context of this study since it was only feasible due to extensive training and sensitization.

We observed poor rates of linkage to care after a positive syphilis self-test in both arms of the study. This finding of poor linkage to care among MSM, is in line with other studies (Peeling et al., 2017) that showed poor linkage to care for syphilis treatment among MSM. Linkage to care has also been shown to be problematic especially for diseases where patients are asymptomatic. This may be related to stigma associated with hospitals, homophobic clinical environments, and

related linkage costs. Future studies may need to focus on how to strengthen linkages to syphilis care as a critical public health intervention.

Syphilis prevalence among MSM in the study was high at 21% (14/66), higher than that reported in a global syphilis systematic review (7.5%) and in the Zimbabwe 2020 study (5.5%) (4,29)

Costs of syphilis self-testing Societal costs of syphilis self-testing in the community appear lower cost than for facility testing. This is in part due to reductions in the cost of personnel as clients test themselves, reducing the high costs of health providers' time. Though the numbers are small, we saw that men who used a self-test kit could find their way to the facility for confirmatory testing and treatment. Further analysis of the linkage to care in larger samples is important to fully ascertain the cost-effectiveness of self-testing.

Clients however incur substantial costs in accessing testing services related to transport and productivity losses as well as food and other expenses particularly due to the need for multiple visits. Client costs have been shown to discourage care seeking most critically among low-income earners, impeding continuity of treatment and care even where services are provided at no user fee and can consign already poor clients to deeper levels of poverty (Bien-Gund et al., 2019b; World Health OrgranizationOrganization, 2019b). Future distribution should consider having the initial screening done in communities so that user costs can be significantly reduced with only those with a reactive test needing to visit facilities. This would both widen access to testing and reduce user costs and pressures on facility-based services. Furthermore, as the self-testing intervention develops into a fully-fledged community-based distribution model higher numbers of kits

delivered where they are needed most may potentially result in even greater cost reductions. More generally, facility testing algorithms should aim for same day testing and treatment, to ensure treatment of all those with a positive test and reduce user costs.

Our study has several limitations. First, we did not anticipate the high rates of syphilis testing observed in the facility arm. This may have been related to the intensive health care worker training provided to health care workers and the buy-in from the facility and free travel to the facilities. As a result of this, our study was not adequately powered to detect a difference in the two arms. Second, a key consideration for the current study is that facility-testing for syphilis amongst MSM is not standard of care (SOC) in Zimbabwe. However, we did not feel it was ethical to recruit patients into a syphilis testing study and offer no route to testing for participants. In addition, COVID-19 restrictions during the study period impacted on the ability of men to travel to the non-profit organization or the facility. COVID-19 concerns may have made it less likely for people to attend the facility and decreased linkage to care in both arms.

There are challenges associated with potential use of treponemal only rapid tests as the self-tests, as these would no longer be helpful for those with previously treated for syphilis. Thus, the use of dual and non-treponemal tests may need to be developed into self-tests.

In conclusion, this RCT demonstrates the feasibility and potential to increase syphilis testing uptake among MSM through a CBO delivered self-testing model. Such efforts need to be augmented with broader policies supporting MSM to screen and test for STIs in LMIC settings. Bringing health services to the people and communities, most importantly to those who need them

the most, simplifying service delivery, increasing self-care products, and increasing service access through CBOs can be a useful strategy to promote health seeking behaviors among hidden populations such as MSM.

Key messages

What is already known on this topic:

Current facility-based syphilis-testing protocols limit access to testing due to associated stigma and financial costs.

What the study adds:

Syphilis self-testing through community- based distribution was feasible among MSM and it increased access to testing among this population group.

We observed poor linkage to care for syphilis treatment among MSM who had a reactive test result.

How this study might affect research, practice or policy:

Community-based syphilis testing reached more MSM at lower costs relative to facility-based syphilis testing.

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Conflict of interest

The authors declare they have no conflict of interest.

Contributors

JDT, MM, FT, RF, KK and IM designed the study, DN, CM, GC and TM analysed the data under the supervision of JDT and FT. DN and CM wrote the initial manuscript. All authors were involved in revising the manuscript and approved the final version.

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