Katrina Ortblad
Daniel Kibuuka Musoke
Thomson Ngabirano
Catherine Oldenburg
Till Bärnighausen

Direct provision versus facility collection of HIV tests

Impacts of self-testing among female sex workers in Uganda

November 2018

Impact Evaluation Report 84

HIV and AIDS

3ie 10 YEARS
International Initiative for Impact Evaluation

About 3ie

The International Initiative for Impact Evaluation (3ie) promotes evidence-informed equitable, inclusive and sustainable development. We support the generation and effective use of high-quality evidence to inform decision-making and improve the lives of people living in poverty in low- and middle-income countries. We provide guidance and support to produce, synthesise and quality-assure evidence of what works, for whom, how, why and at what cost.

3ie impact evaluations

3ie-supported impact evaluations assess the difference a development intervention has made to social and economic outcomes. 3ie is committed to funding rigorous evaluations that include a theory-based design, and use the most appropriate mix of methods to capture outcomes and are useful in complex development contexts.

About this report

3ie accepted the final version of the report, *Direct provision versus facility collection of HIV tests: impacts of self-testing among female sex workers in Uganda,* as partial fulfilment of requirements under grant TW2.2.23 awarded through the HIV Self-Testing Evidence Programme. The content has been copy-edited and formatted for publication by 3ie to the extent possible. Some departures from 3ie standards for formatting or copy-editing were unavoidable.

The 3ie technical quality assurance team for this report comprises Anna C Heard, Eric W Djimeu, Annette N Brown, Priyanka Dubey, an anonymous external reviewer and Emmanuel Jimenez, with overall technical supervision by Marie Gaarder. The 3ie editorial production team for this report comprises Sahib Singh and Akarsh Gupta, with Beryl Leach providing overall editorial supervision.

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 also the sole responsibility of the authors. All affiliations of the authors listed in the title page were in effect at the time the report was accepted. Please direct any comments or queries to the corresponding author, Katrina Ortblad at katort@uw.edu. This trial is registered at ClinicalTrials.gov (NCT02846402).

3ie received funding for the HIV Self-Testing Evidence Programme from the Bill & Melinda Gates Foundation.

Suggested citation: Ortblad, K, Musoke, DK, Ngabirano, T, Oldenburg, C and Bärnighausen, T, 2018, *Direct provision versus facility collection of HIV tests: impacts of self-testing among female sex workers in Uganda.* 3ie Impact Evaluation Report 84. New Delhi: International Initiative for Impact Evaluation (3ie). Available at: https://doi.org/10.23846/TW2IE84

Cover photo: Jennifer Huxta

Direct provision versus facility collection of HIV tests: impacts of self-testing among female sex workers in Uganda

Katrina Ortblad
Harvard TH Chan School of Public Health

Daniel Kibuuka Musoke
International Research Consortium

Thomson Ngabirano
Uganda Health Marketing Group

Catherine Oldenburg
University of California, San Francisco

Till Bärnighausen
Heidelberg University

Impact Evaluation Report 84

November 2018

Acknowledgments

The authors would like to acknowledge the study participants who took time participating in this study, the peer educators who recruited participants and conducted visits, the research assistants who collected these data, and administrative staff at both the Uganda Health Marketing Group and the International Research Consortium who kept the study on schedule. The authors would like to also acknowledge the study's Scientific Oversight Committee for participation in the interim report and monitoring adverse events, as well as the Ugandan Ministry of Health for assistance with necessary approval. Finally, the authors would like to acknowledge the International Initiative for Impact Evaluation (3ie) for funding the research.

Summary

HIV self-testing allows for HIV testing away from a health facility and without interaction with a health provider. It may be particularly useful for female sex workers (FSWs) – who are recommended to test for HIV every three months – by reducing HIV testing barriers for this population (i.e. provider stigma and discrimination). The objective of this study was to explore the effectiveness of different HIV self-testing delivery methods on HIV testing and their linkage to care outcomes among FSWs.

The study design was a 1:1:1 cluster randomized controlled trial implemented in Kampala, Uganda. FSW peer educator groups (one peer educator and eight FSWs) were randomized into one of three study arms: (1) *direct provision* of HIV self-tests; (2) provision of coupons for free *facility collection* of HIV self-tests; and (3) *standard-of-care* HIV testing. All participants received four peer educator visits, wherein peer educators distributed condoms and referred participants to free HIV testing services. In the two intervention arms, peer educators distributed HIV self-tests/coupons during their first and fourth visits (three months apart). The participants completed baseline assessments and two follow-up assessments (which occurred one month after the first peer educator visits, and again after four months).

We randomized 120 peer educator groups (960 participants) from 18 October to 16 November 2016. Participant follow-up was 96.4 per cent (925/960) at one month and 89.6 per cent (860/960) at four months after the first visits. Our primary outcomes were any HIV testing at one month and at four months. Our secondary outcomes were repeat HIV testing, facility-based testing, self-test use, seeking HIV-related medical care, and antiretroviral therapy initiation. Repeat HIV testing and facility-based testing were not pre-specified outcomes, but instead were added to understand the intervention effects on frequent testing and to quantify substitution effects, respectively.

Overall levels of HIV testing among participants were high across the study arms. At one month after the first visit, 95.2% (275/289) of participants in the direct provision arm, 80.4% (258/321) of participants in the facility collection arm, and 71.5% (226/316) of participants in the standard-of-care arm had tested for HIV. At four months, there was almost complete testing coverage among participants in the HIV self-testing intervention arms (direct provision: 99.6%, 261/262; facility collection: 97.0%, 288/297), and 87.1 per cent (263/302) of participants in the standard-of-care arm had tested for HIV since the start of the study.

Participants in the direct provision arm were significantly more likely to have tested for HIV than those in the standard-of-care arm (at one month: risk ratio (RR) 1.33, 95% confidence interval (CI) 1.17–1.52, $p < 0.001$; at four months: RR 1.14, 95% CI 1.07–1.22, $p < 0.001$) and those in the facility collection arm (at one month: RR 1.18, 95% CI 1.07–1.31, $p = 0.001$; at four months: RR 1.03, 95% CI 1.01–1.05, $p = 0.02$). At four months, participants in the direct provision arm were significantly more likely to have tested twice for HIV than those in the standard-of-care arm (RR 1.51, 95% CI 1.29–1.77, $p < 0.001$) and those in the facility collection arm (RR 1.22, 95% CI 1.04–1.49, $p = 0.001$). Participants in the HIV self-testing arms almost completely replaced facility-based testing with self-testing. At one month, fewer participants in the intervention arms had sought medical care for HIV than in the standard-of-care arm, but this difference was

not significant and disappeared by four months. There were no statistically significant differences in antiretroviral therapy initiation across study arms. Two adverse events related to HIV self-testing were reported: interpersonal violence and mental distress.

Our study found HIV self-testing to be safe and effective at increasing recent and frequent testing among FSWs. Additionally, we found the delivery model to be important: the direct provision of HIV self-tests was more effective in increasing recent and frequent HIV testing among FSWs than collecting HIV self-tests at health facilities (the standard approach of countries that have already implemented HIV self-testing). HIV self-testing can play an important role in HIV prevention interventions that require frequent testing, i.e. treatment-as-prevention, behavioral change for transmission reduction, and potentially pre-exposure prophylaxis.

Contents

Summary ii
List of figures and tables v
Abbreviations and acronyms vi
1. Introduction 1
1.1 Background 1
1.2 Research objectives 1
1.3 Theory of change 2
2. Background 2
2.1 Ethics 2
2.2 Study setting 2
2.3 Study design 3
2.4 FSW peer educators 3
3. Methodology 4
3.1 Participant recruitment and eligibility 4
3.2 Randomization 4
3.3 Interventions 4
3.4 Assessments 7
3.5 Outcomes 7
3.6 Sample size calculation 7
3.7 Data quality control 8
3.8 Statistical analysis 8
3.9 Cost-effectiveness methodology 9
3.10 Qualitative methods 9
4. Results 10
4.1 Participant recruitment and flow 10
4.2 Baseline characteristics 11
4.3 Implementation activities 13
4.4 Primary outcome 15
4.5 Secondary outcomes 18
4.6 Sensitivity analyses 18
4.7 Adverse events 24
4.8 Cost-effectiveness 24
4.9 Qualitative analysis 26
5. Discussion 30
5.1 Summary of main results 30
5.2 Strengths and limitations 33
5.3 Stakeholder engagement 34
6. Specific findings for policy and practice 35
7. Conclusions 35
Online appendices 36
References 37

List of figures and tables

Figure 1: Flow of study participants 11
Figure 2: Implementation activities reported by participants at four months 13
Figure 3: Effect size estimates for impact of HIV self-testing on HIV self-testing outcomes at (a) one month and (b) four months 16
Figure 4: Study team at the Uganda HIV self-testing national dissemination event in Kampala, July 2017 34
Figure 5: Front page of the local newspaper the morning after Uganda's HIV self-testing national dissemination event 35

Table 1: Description of study procedures 6
Table 2: Participant baseline descriptive characteristics 12
Table 3: HIV testing and linkage to care: self-reported outcomes at one month and at four months 15
Table 4: Effect size estimates, risk ratios: HIV self-testing on HIV testing and linkage to care outcomes 17
Table 5: Sensitivity analysis: pooled HIV self-test arms versus the standard-of-care arm – percentages and effect size estimates, risk ratios 20
Table 6: Sensitivity analysis: the proportion of participants in a peer educator group reporting each outcome – effect size estimates, percentage points (PP) 21
Table 7: Sensitivity analysis: effect modification, recent HIV testing at baseline – effect size estimates, risk ratios 22
Table 8: Sensitivity analysis: linkage to care outcomes among only participants who report testing HIV positive – conditional effect size estimates, risk ratios 23
Table 9: Incremental cost-effectiveness of HIV self-testing at four months* 25
Table 10: SWOT analysis for HIV self-testing among FSWs 26

Abbreviations and acronyms

ART	Antiretroviral therapy
CI	Confidence interval
FSW	Female sex worker
HIVST	HIV self-testing
ITT	Intention to treat
IQR	Interquartile range
MARPI	Ministry of Health's Most at Risk Population Initiative
MOH	Ministry of Health
PPP	Power purchasing parity
PrEP	Pre-exposure prophylaxis
RR	Risk ratio
SSA	Sub-Saharan Africa
SWOT	Strengths, weaknesses, opportunities and threats
TasP	Treatment-as-prevention

1. Introduction

1.1 Background

HIV testing is the important first stage of both the HIV treatment and prevention cascades. In the treatment cascade, HIV testing is essential first to know one's HIV status, and subsequently for linkage to care, antiretroviral therapy (ART) initiation and viral suppression (UNAIDS 2014b; Cohen et al. 2011; Donnell et al. 2010). In Sub-Saharan Africa (SSA), an estimated 70–80% of people living with HIV know their status (UNAIDS 2014b; Haber et al. 2017; Iwuji et al. 2016a; Kranzer et al. 2012; Nsanzimana et al. 2015), which is below the desired 90% outlined in the first of UNAIDS' ambitious 90-90-90 HIV treatment targets (UNAIDS 2014b; Fox and Rosen 2017).

Frequent HIV testing is recommended for key populations that face the highest risk of infection. Female sex workers (FSWs) and their clients are the largest of these populations in SSA, with FSWs experiencing approximately five times the HIV prevalence of the general population (Baral et al. 2012; WHO 2016; UNAIDS 2014a; Shannon et al. 2015). The World Health Organization (WHO) recommends that FSWs test for HIV every three months (Cohen et al. 2011; WHO 2016; CDC 2014; WHO 2015; Donnell et al. 2010); however, barriers to HIV testing for FSWs often include healthcare provider stigma and discrimination, transport costs, and inconvenient location and opening hours of testing centers (Chanda et al. 2017b; WHO 2016; Napierala Mavedzenge et al. 2013; UNAIDS 2014a). HIV self-testing may affect HIV testing among FSWs as it does not require interaction with a healthcare provider or travel to a facility, and can be carried out in any location at any time.

Despite these advantages, few countries in SSA have introduced HIV self-testing due to safety concerns and an overall lack of evidence that it is effective, especially among key populations (e.g. FSWs) (Brown et al. 2014; Napierala Mavedzenge et al. 2013). Frequently cited concerns related to HIV self-testing are that testing outside a health facility and decoupling testing from counseling may result in social or emotional harms or poor linkage to care among individuals who test HIV positive (Brown et al. 2014). However, a number of explorative studies in SSA have shown high acceptability of HIV self-testing and good test performance (Brown et al. 2016; Choko et al. 2011, 2015; Figueroa et al. 2015; Krause et al. 2013; Kumwenda et al. 2014; Mokgatle and Madiba 2017; Mugo et al. 2017; Pai et al. 2013; Pérez et al. 2016; Zerbe et al. 2015). Recent HIV self-testing trials have demonstrated HIV self-testing to be effective among members of the general population and two subpopulations (Ayles et al. 2017): namely the male partners of women at antenatal care clinics (Gichangi et al. 2016; Johnson et al. 2017; Masters et al. 2016; Thirumurthy et al. 2016) and men who have sex with men (Jamil et al. 2017; Johnson et al. 2017; Katz et al. 2015; Wang et al. 2016, 2018). This trial (Ortblad et al. 2017), alongside a similar trial by the same team in Zambia (Chanda et al. 2017a), is the first to explore the effect of HIV self-testing among FSWs in SSA.

1.2 Research objectives

We conducted a three-arm cluster randomized controlled trial to explore the effect of HIV self-testing delivery models on recent and repeat HIV testing among FSWs in Kampala, Uganda as compared with standard care. The effectiveness of HIV self-testing will likely

depend on the delivery approach. In this study, we thus aimed to establish the effectiveness of two different HIV self-testing delivery models: (1) *direct provision* of an oral HIV self-test from a peer educator; and (2) the provision of a coupon from a peer educator for *facility collection* of an HIV self-test.

1.3 Theory of change

We hypothesized that HIV self-testing would increase HIV testing among FSWs because it may address some of their often-cited barriers (Chanda et al. 2017b; WHO 2016; Napierala Mavedzenge et al. 2013; UNAIDS 2014a). The direct provision of HIV self-tests to FSWs fully realizes the advantages of self-testing because FSWs do not have to travel to health facilities, arrive during facility hours, or interact with a healthcare provider. Facility-based collection of HIV self-tests still enables FSWs to freely choose the time and place of testing; however, they must travel to a healthcare facility during opening hours to collect the self-test. For this reason, we hypothesized that HIV testing would be lower among FSWs in the facility collection arm compared with the direct provision arm. We included the facility collection arm in the study because it closely resembles the HIV self-testing model that has been adopted by Kenya and South Africa – countries that have already rolled out HIV self-testing – and will likely be adopted by other SSA countries considering HIV self-testing in the near future (HIVST.org 2017).

However, the same barriers that may have prevented FSWs from testing at healthcare facilities (Chanda et al. 2017b; WHO 2016; Napierala Mavedzenge et al. 2013; UNAIDS 2014a) remain in the presence of HIV self-testing when it comes to linkage to care. For this reason, we hypothesized that linkage to care would be lower among participants who received one of the HIV self-testing interventions compared with those who HIV tested at standard healthcare facilities. The direct provision of HIV self-tests to FSWs completely decouples HIV testing from the healthcare system where counseling and HIV treatment services are provided. Without counseling and proximity to HIV treatment services, mental distress may be more common and links to care may be delayed. We hypothesized that participants who received HIV self-tests directly would be less likely to link to care than those who collected self-tests from healthcare facilities because, unlike those who had to collect self-tests, they did not have to overcome some potential barriers to accessing healthcare facilities.

2. Background

2.1 Ethics

The study received ethical approval from the Mildmay Uganda Research Ethics Committee (REF 0105-2016) and the Office of Human Research Administration at the Harvard T.H. Chan School of Public Health (IRB16-0885). The study was also registered with the Ugandan National Council of Science and Technology (HS3006). All participants provided written informed consent.

2.2 Study setting

Uganda is a country in eastern SSA with a population HIV prevalence of 7 per cent (UNAIDS 2017). This study was conducted in Uganda's capital city of Kampala, which has an estimated 13,000 FSWs. Approximately one in three FSWs in Kampala is HIV

positive (CDC, 2010). The Ugandan Ministry of Health (MOH) prioritizes FSWs for health and HIV prevention interventions. Through the MOH's Most at Risk Population Initiative (MARPI), FSWs in Kampala have access to a number of free HIV testing options including facility-based testing and home- or work-based testing (which often operate through moonlight clinics). There are also four FSW-focused non-governmental organizations operating within Kampala, which help to provide health services and economic opportunities to FSWs and have created FSW peer networks. The Ugandan MOH is very interested in HIV self-testing but has not yet issued any guidelines (Ugandan MOH 2016; HIVST.org 2017).

2.3 Study design

We used a three-arm cluster randomized controlled health systems trial to explore how different HIV self-testing delivery models effect HIV testing and linkage to care outcomes. Our clusters were one FSW peer educator and eight FSW participants. Our study arms were: (1) *direct provision* of an HIV self-test; (2) a coupon for *facility collection* of an HIV self-test; and (3) *standard-of-care* HIV testing and counseling. All study arms received four peer educator visits, including condom distribution and referral to free HIV testing services. In the HIV self-testing intervention arms, peer educators additionally distributed HIV self-test/coupons at the first and fourth peer educator visits (i.e., month zero and month three). Our trial can be found in the clinical trials registry and database run by the United States National Library of Medicine at the National Institutes of Health, ClinicalTrials.gov (NCT02846402).

2.4 FSW peer educators

Peer educators were used in this study to ensure feasibility of FSW recruitment and trust among members of our study population. FSW peer educators may be particularly effective at recruiting FSWs who might not normally utilize the health system and therefore would particularly benefit from HIV self-testing. FSWs also tend to trust other FSWs, and trust is important when introducing a new technology that might be perceived as dangerous or threatening (Medley et al. 2009). Additionally, peer educators have previously been used as a platform for delivering health services to FSWs in Uganda, and thus are a realistic future platform for the delivery of HIV self-tests (George and Blankenship 2015).

The Kampala-based FSW non-governmental organizations and Ugandan Ministry of Health's Most at Risk Population Initiative (MARPI) clinics helped us to recruit peer educators for this study who had previously worked with them and were trusted and respected within the local FSW community. All peer educators completed a two-day training where they learned study procedures. At this training they also had the opportunity to use the oral HIV self-test and were instructed on how to conduct it, interpret the results, and link to care following potential results.

We paid the peer educators UGX90,000 for each of their four visits. This is equivalent to approximately USD25 at market exchange rates or approximately USD79 after adjusting for purchasing power parity (PPP) in Uganda (World Bank, 2017). As a reference, the majority of FSW participants in our study made between PPP-adjusted USD100 and 440 per month, and the median price participants charged for vaginal sex with a condom was

approximately PPP-adjusted USD6 (interquartile range: approximately PPP-adjusted USD4–9).

3. Methodology

3.1 Participant recruitment and eligibility

The peer educators recruited potential study participants. We encouraged peer educators to recruit FSWs whom they already knew, to ensure trust, which was particularly important for this study because HIV self-testing is a new technology that might be perceived as harmful. Potential participants were referred to research assistants who first conducted a phone screening followed by an in-person eligibility assessment and enrollment.

Eligible participants: (1) were 18 years or older; (2) reported exchanging sex (vaginal/anal/oral) for money, goods or other items of value in the past month; (3) self-reported never having tested for HIV or testing HIV negative at their last test (more than three months prior); and (4) were Kampala based.

3.2 Randomization

Peer educator participant groups were randomized 1:1:1 to each of the three study arms. The author, Catherine Oldenburg, developed the randomization list using R Studio software (Version 3.3.1, The R Foundation for Statistical Computing, Vienna, Austria). The assignment to study arms was not masked. Sealed randomization envelopes were opened by a peer educator and research assistant after all eight participants were enrolled within a peer educator group. Research assistants, peer educators and participants were not aware of study arm assignment prior to opening the randomization card.

3.3 Interventions

The study interventions, as well as assessments, are described in chronological order in Table 1. Research assistants enrolled eligible participants after first explaining the study and having participants sign informed consent. At enrollment, research assistants gave all participants a referral card for free facility-based HIV testing and a study card.

The referral card could be exchanged at 10 private healthcare facilities participating in our study; all were affiliated with our implementing partner – the Uganda Health Marketing Group. Two of these ten healthcare facilities provided ART. While facility-based HIV testing is free for FSWs at the MARPI healthcare facilities in Kampala, it might be difficult for participants to reach these facilities; they differ from the self-test distribution locations in the facility collection arm. Since we were distributing free HIV self-tests to participants in the intervention arms, it was important that facility-based HIV testing was free to participants in our standard-of-care arm.

The study card given to participants at enrollment included a toll-free hotline number. Participants were instructed to call this number for referral to free HIV testing and treatment services and to report potential adverse events. Participants in the HIV self-testing intervention arms were additionally encouraged to call this number if they had any

questions or concerns related to HIV testing. Individuals working at the hotline received training on HIV self-testing and the study procedures prior to participant enrollment.

Throughout the duration of the study, participants in all study arms were scheduled to complete four peer educator visits (Table 1). At all visits, peer educators were instructed to distribute condoms, refer participants to standard HIV testing services and screen for potential adverse events. The first peer educator visit was a group visit, and all subsequent ones were on an individual level (to ensure the confidentiality of participants who tested HIV positive or wanted to report adverse events).

In the first visit, peer educators randomized to the HIV self-testing intervention arms instructed participants on how to use the oral HIV self-test, interpret the results, and link to care following potential results. Participants were instructed to get a confirmatory test at a health facility if they self-tested HIV positive, and to test again in three months if they self-tested HIV negative. Research assistants attended all first peer educator visits to ensure quality and consistency of information transmitted to study participants.

In the intervention arms, oral HIV self-tests or coupons for oral HIV self-tests were distributed by peer educators to participants shortly after enrollment (first visit) and again three months later (fourth visit). Participants in the intervention arms were to receive only two HIV self-tests or coupons over the duration of the study. We used the OraQuick Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, PA) for this study, which came with written and pictorial instructions (available in both English and Luganda).

Participants in the facility collection arm could exchange their HIV self-test coupon for a physical test at the 10 Kampala-based healthcare facilities participating in our study (described above). Representatives from these facilities were trained on oral HIV self-test use, study procedures and FSW sensitization prior to participant enrollment.

Table 1: Description of study procedures

Month[1]	Activity	Assessment	Description[2]
	Enrollment	*Baseline* assessment	• Participants received referral card for free standard-of-care testing at 10 participating private health facilities and a study contact card, including a hotline number.
0	Randomization		• Peer groups (one peer educator, eight participants) were 1:1:1 randomized to: (1) *direct provision* of an HIV self-test; (2) a coupon for *facility collection* of an HIV self-test;[3] and (3) *standard-of-care* HIV testing services.
0	1st peer educator visit		• ***All study arms:*** Peer educator distributed condoms and referred participants to standard HIV testing services (group visit). • ***Intervention arms:*** Peer educators additionally trained participants on how to use oral HIV self-tests and then delivered one HIV self-test (*direct provision* arm) or one HIV self-test coupon (*facility collection* arm) to each participant.
0.5	2nd peer educator visit		• ***All study arms:*** Peer educators distributed condoms, referred participants to standard HIV testing services, and screened for adverse events (individual visit).
1		*Follow-up* assessment	• Research assistants conducted the first quantitative follow-up assessment.
1.5	3rd peer educator visit		• ***All study arms:*** *Same as 2nd peer educator visit.*
3	4th peer educator visit		• ***All study arms:*** *Same as 1st peer educator visit, but an individual visit.* • ***Intervention arms:*** Peer educators additionally delivered a second HIV self-test (*direct provision* arm) or a second HIV self-test coupon (*facility collection* arm) to each participant.
4		*Follow-up* assessment	• Research assistants conducted the final quantitative follow-up assessment.

[1] Timeline begins once participants in the *standard-of-care* arm were randomized and participants in the *direct provision* and *facility collection* arms received their first HIV self-test or coupon.

[2] Intervention descriptions relevant to all study participants unless specified otherwise.

[3] HIV self-test coupons were redeemable for a free HIV self-test at one of 10 private healthcare facilities situated throughout Kampala. All private healthcare facilities were affiliated with our implementing partner, the Uganda Health Marketing Group.

3.4 Assessments

Throughout the duration of the study, participants completed a baseline assessment (post-enrollment, pre-randomization) and two follow-up assessments (one month and four months after the first peer educator visit), as illustrated in Table 1. Questions related to sociodemographic characteristics, sex work history, HIV testing (timing and location) and intimate partner violence were included in the baseline assessment. Identical questions on HIV testing and intimate partner violence were included in the follow-up assessments. In the intervention arms, participants were additionally asked about HIV self-test use. All participants who reported testing HIV positive were asked linkage to care questions. Research assistants collected de-identified electric data in face-to-face interviews using the CommCare data collection platform (Dimagi Inc, Cambridge, MA). As compensation for their time, participants received UGX16,500 upon completion of each assessment. This is equivalent to approximately PPP-adjusted USD14 (World Bank, 2017).

3.5 Outcomes

Our pre-specified primary outcomes were any HIV testing following the first peer educator visit, measured at one month and at four months. Pre-specified secondary outcomes included HIV self-test use (intervention arms only) and seeking HIV-related medical care and ART initiation at one month and at four months. In addition to these pre-specified outcomes, we analyzed repeat HIV testing at four months (i.e. testing twice since the first peer educator visit) and facility-based HIV testing at one month and at four months. The former was added to understand the effects of the intervention on frequent testing and the latter was added to quantify substitution effects. Facility-based testing included HIV testing at any public or private healthcare facility.

Adverse events were carefully screened for by peer educators, research assistants and individuals working at the toll-free hotline. These included physical, sexual or verbal assault; unintentional HIV status disclosure; and self-harm.

3.6 Sample size calculation

Power calculations were performed using methods for cluster randomized controlled trials in Stata 13.1 (StataCorp, College Station, TX). Our study was powered on our primary outcome: any HIV testing in the past month at the one-month assessment. We assumed that 60 per cent of participants in our standard-of-care arm would have this outcome by one month. This assumption was based on a Zambian FSW behavioral survey that found 80 per cent HIV testing in the past year among FSWs in Livingstone, which has a number of ongoing FSWs health interventions similar to Kampala (Family Health International 2009). We assumed HIV testing would be lower among study participants in our standard-of-care arm compared with participants in the Zambian survey, as a result of our inclusion criteria and short follow-up period. Additionally, we assumed that 25 per cent of our sample would be lost to follow-up because FSWs are a highly mobile population.

We estimated that 960 participants (120 peer educator groups), with 320 participants (40 peer educator groups) per arm, would detect a risk ratio of 1.25 in the pooled HIV self-testing arms compared with the standard-of-care arm (90% power, 0.05 type I error

probability and 0.02 intracluster correlation). This sample size was also estimated to yield 90 per cent power to detect a risk ratio of 1.18 or larger in the direct provision arm compared with the facility collection arm. We did not power our study to measure statistically significant differences in linkage to care outcomes.

3.7 Data quality control

To ensure data quality, we appointed one team leader for every three research assistants, as well as a project manager that oversaw the team leaders. These team leaders tracked where and when research assistants were conducting participant interviews and made unannounced visits to research assistants in the field to ensure that everything was going as planned. Research assistants were instructed to upload their data to CommCare's cloud storage daily. During the periods of ongoing data collection, the author Katrina Ortblad checked the quality of incoming data daily. If a quantitative interview was not complete, responses looked abnormal, or the interview was not conducted within the scheduled time frame, Katrina Ortblad emailed the team leader responsible for that interview and they followed up on the issue. The Harvard research team and Ugandan project manager conducted weekly Skype calls to discuss data quality and study logistics.

To measure intervention activities, research assistants called peer educators after each scheduled peer educator visit to determine if the visit occurred. Research assistants marked these data in a peer educator visit tracking sheet. At four months, research assistants asked participants if they had received condoms from their peer educator at each peer educator visit. Participants in the intervention arms were additionally asked how many HIV self-tests or coupons they had received from their peer educator over the duration of the study and what they had done with each of these self-tests or coupons.

3.8 Statistical analysis

Our pre-specified analysis was a mixed-effect multilevel regression model with a peer educator random effect. We calculated risk ratios for all primary and secondary outcomes using mixed-effects linear models (i.e. Poisson distribution, log link, robust standard errors) (Zou 2004) with a study arm fixed effect and peer educator random effect. We chose to use modified Poisson models over log-binomial models because they generate similar results and converge more easily when study outcomes are relatively common (Zou 2004). All statistical tests were two sided ($p < 0.05$ was considered statistically significant) and there were no adjustments for multiple comparisons. All analyses were conducted at the unit of the individual and were intention-to-treat (ITT), complete-case analyses. We included all participants in our linkage to care analyses because analyses that are conditional on events that occur after randomization (e.g. self-reported HIV-positive test results) can suffer from selection bias.

We conducted four sensitivity analyses. First, we pooled outcomes in the two HIV self-testing intervention arms and calculated risk ratios that compared this pooled arm with the standard-of-care arm using the mixed-effects linear models described above. Second, we calculated the proportion of participants that presented each outcome in a peer educator group and used generalized linear models with study arm fixed effects to calculate risk differences for each outcome. Third, for the HIV testing outcomes, we

conducted a subgroup analysis where we calculated risk ratios (mixed-effects linear models described above) for participants that tested for HIV within the past 12 months, and more than 12 months ago, at baseline. Fourth, for the linkage to care outcomes, we limited the sample to participants who reported testing HIV positive at their last test, and calculated risk ratios using the mixed-effects linear models described above.

We used Stata 13.1 (StataCorp, College Station, TX) for all analyses.

3.9 Cost-effectiveness methodology

We calculated the incremental cost-effectiveness of our HIV self-testing delivery models using administrative data on costs and evidence generated from this study regarding the effectiveness of providing HIV self-tests directly or providing coupons for facility collection of HIV self-tests. We calculated the incremental cost-effectiveness for the following outcomes: any HIV testing (at one month and at four months), repeat HIV testing (at four months), HIV-positive status (at four months), seeking medical care for HIV (at four months) and ART initiation (at four months)

We took the provider perspective of a non-governmental organization with an ongoing FSW peer educator program and accounted for all running costs related to implementation activities including materials and salaries. Materials cost included HIV testing referral cards, coupons and HIV self-tests. The oral HIV self-tests in this study were purchased from OraSure for approximately USD7.4 each (including shipping and tax). We included the salaries for implementation management, FSW peer educators and hotline staff. We additionally included costs related to car hire, airtime and support of participating private health facilities. We did not include start-up costs related to recruiting and training FSW peer educators in our cost-effectiveness analysis.

3.10 Qualitative methods

We conducted structured qualitative interviews on a random 5 per cent (N = 48) of study participants at the baseline assessment and again at the four-month assessment (with the same participants). The structured qualitative interview guides asked participants about their perceptions related to HIV self-testing, including concerns and opportunities for the new HIV testing technology. The guides also asked participants to describe their experiences with HIV self-testing (for those randomized to the HIV self-testing intervention arms). Interviews were conducted in local languages and audio recorded. Research assistants transcribed and translated the audio recordings.

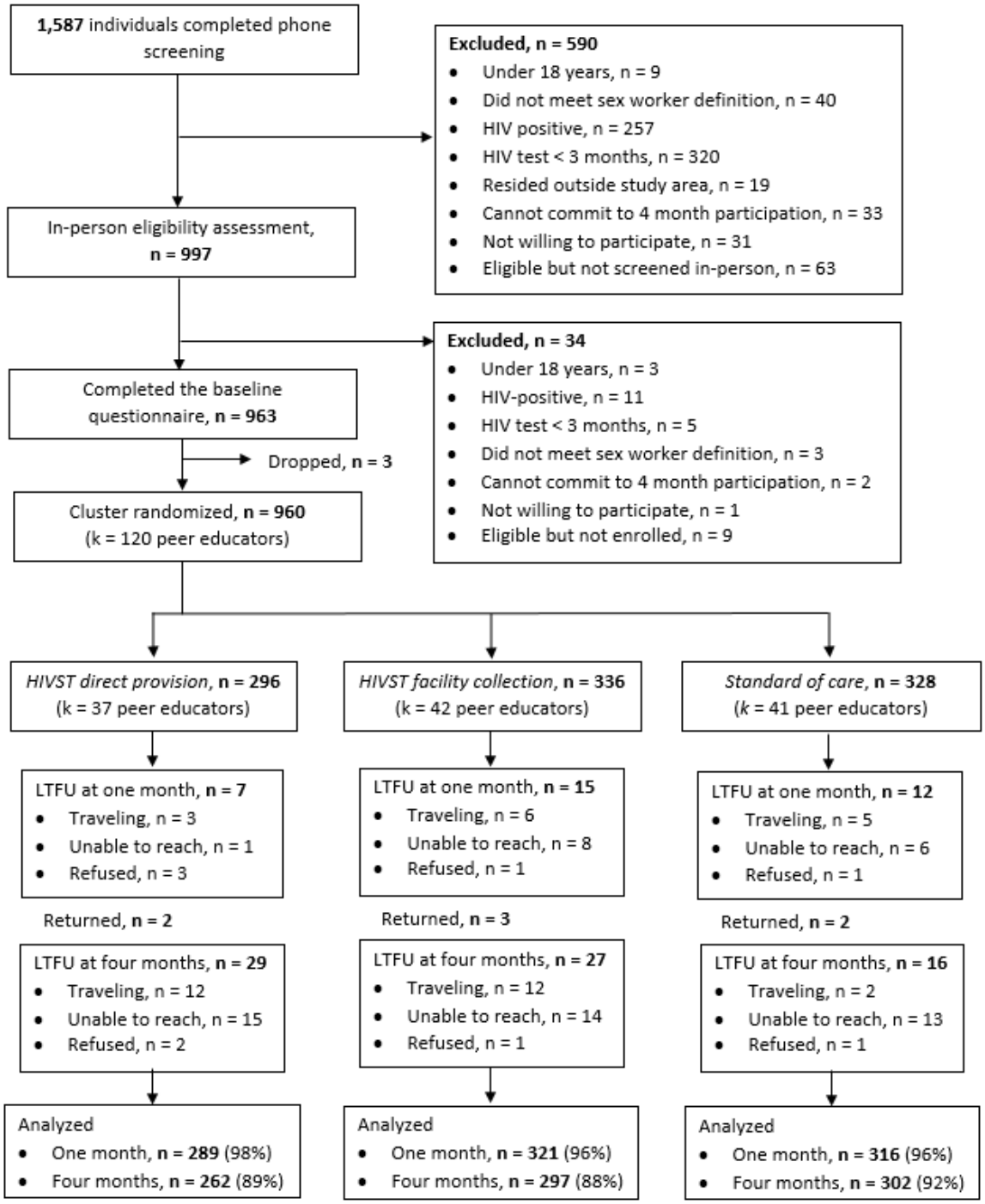
We used grounded theory to develop a codebook from the qualitative interviews (Creswell 2013). A team of two qualitative research assistants and two supervisors completed a two-day training on the codebook in Kampala, Uganda. The coders manually coded hard copies of the qualitative transcripts, which were transferred to the qualitative research software ATLAS.ti (Berlin, Germany). New codes were added to the codebook as they were identified throughout the coding process; previously coded transcripts were recoded to incorporate these new codes. The supervisors reviewed the work of the coders at the end of each day to ensure quality. To explore the effect of HIV self-testing among FSWs, we conducted a strengths, weaknesses, opportunities and threats (SWOT) analysis (Creswell 2013).

4. Results

4.1 Participant recruitment and flow

From October to November 2016, research assistants screened 1,587 potential participants for eligibility over the phone. Among those, 997 were invited for an in-person eligibility assessment, and 960 participants (separated into 120 peer educator groups) were enrolled and randomized, as illustrated in Figure 1. The most common reasons for exclusion were recent HIV testing (less than three months ago, as was the case for 52%, or 325/624) and self-reported HIV-positive status (43%, 267/624). Three participants dropped out prior to randomization because the peer educator who recruited them left the study and had to be replaced. Thirty-seven peer educator groups (296 participants) were randomized to the direct provision arm, 42 peer educator groups (336 participants) to the facility collection arm, and 41 peer educator groups (328 participants) to the standard-of-care arm. Participant retention at one month and at four months was 96 per cent (925/960) and 90 per cent (860/960), respectively. There was no statistically significant difference in loss to follow-up across study arms.

Figure 1: Flow of study participants



4.2 Baseline characteristics

Baseline characteristics of the 960 randomized participants were balanced across the three study arms, as seen in Table 2. The median age of participants was 28 years (interquartile range [IQR]: 24 to 32 years). The majority of participants had a primary partner (59%, 568/960) and could read and write (85%, 819/960). On an average working night, participants reported a median of five clients (IQR: 4 to 7 clients) and 40 per cent (388/960) reported not using a condom with at least one of these clients. The majority of participants self-reported testing for HIV in the past 12 months (66%,

630/960) and testing at a healthcare facility at their last HIV test (72%, 692/960). Only 6 per cent (56/960) of participants self-reported never testing for HIV. Self-reported intimate partner violence, either physical or sexual, in the past 12 months was common among study participants (47%, 455/960; physical 36%, 349/960; sexual 30%, 288/960).

Table 2: Participant baseline descriptive characteristics

Characteristic	*Direct provision* (N = 296)	*Facility collection* (N = 336)	*Standard-of-care* (N = 328)
Age (median, IQR)	28 (24–32)	28 (25–32)	28 (24–32)
Have primary partner	186 (62.8%)	193 (57.4%)	189 (57.6%)
Can read and write	255 (86.2%)	279 (83.0%)	285 (87.7%)
Education			
No formal	24 (8.1%)	35 (10.4%)	20 (6.1%)
Primary/Junior	121 (40.9%)	155 (46.1%)	161 (49.1%)
Secondary	143 (48.3%)	136 (40.5%)	144 (43.9%)
Vocational	2 (0.7%)	6 (1.8%)	0
Tertiary	6 (2.0%)	4 (1.2%)	3 (1.0%)
Own mobile phone	289 (97.6%)	311 (92.6%)	310 (94.5%)
Monthly income, USD[1]			
No income	4 (1.4%)	0	1 (0.3%)
< $35.67	63 (21.3%)	76 (22.9%)	51 (15.5%)
$35.67–$74.32	90 (30.4%)	117 (35.2%)	125 (38.1%)
$74.32–$148.64	104 (35.1%)	107 (32.2%)	117 (35.6%)
$148.64–$297.28	31 (10.5%)	25 (7.5%)	29 (8.8%)
> $297.28	4 (1.4%)	7 (2.1%)	3 (0.9%)
Years in sex work (median, IQR)	5 (3–8)	5 (3–8)	5 (3–8)
Clients per night (median, IQR)	5 (4–7)	5 (4–7)	5 (4–7)
Inconsistent condom use with clients	125 (42.7%)	141 (42.3%)	122 (37.2%)
Timing of last HIV test			
>3-6 months	108 (36.7%)	119 (35.6%)	123 (37.5%)
>6-12 months	90 (30.6%)	88 (26.4%)	102 (31.1%)
>12-24 months	46 (15.7%)	68 (20.4%)	42 (12.8%)
>24 months	30 (10.2%)	42 (12.6%)	42 (12.8%)
Never tested	20 (6.8%)	17 (5.1%)	19 (5.8%)
Last HIV test facility-based[2]	230 (77.7%)	229 (68.2%)	233 (71.0%)
Intimate partner violence, past 12 months			
Physical	102 (34.5%)	132 (39.3%)	115 (35.1%)
Sexual	89 (30.1%)	105 (31.3%)	94 (28.7%)
Any	141 (47.6%)	167 (49.7%)	147 (44.8%)

[1] Price categories in US dollars (USD); 10 October 2016 exchange rate (USD1 = UGX3,363.85).
[2] Includes public and private sector or antenatal care clinic; other locations included home, work and other.

4.3 Implementation activities

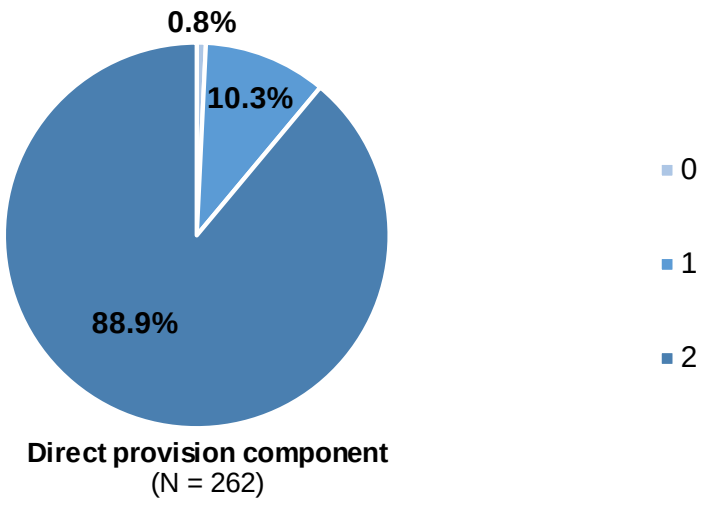
All intervention activities and assessments went as planned. We only had one peer educator drop out of the study and this occurred prior to randomization. That peer educator was replaced and eight new participants were recruited and enrolled. All assessments occurred on schedule with the exception of the four-month assessment, which was delayed by two weeks due to budget logistics.

All peer educators completed four peer educator visits over the duration of the study. Figure 2 shows the number of HIV self-tests or HIV self-test coupons that participants in the HIV self-testing intervention arms reported receiving from their peer educator at four months. Among participants in the direct provision arm, 88.9 per cent (233/262) reported receiving two HIV self-tests. Among participants in the facility collection arm, 89.9 per cent (267/297) reported receiving two HIV self-test coupons from their peer educator and 72.4 per cent (215/297) reported exchanging two coupons for HIV self-tests at participating health facilities. Only 1.1 per cent (3/262) of participants in the direct provision arm and 0.7 per cent (2/297) of participants in the facility collection arm reported receiving more than two HIV self-tests or coupons from their peer educator (Figure 2). The vast majority of participants reported receiving condoms at every peer educator visit (direct provision 76.0%, 199/262; facility collection 73.1%, 217/297; standard-of-care 76.7%, 231/301); there were no statistically significant differences in this outcome across study arms.

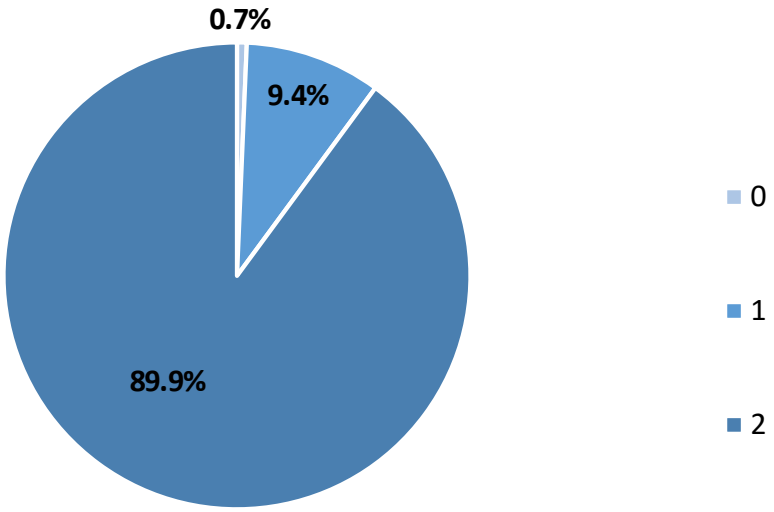
One unexpected event that occurred during implementation was that some peer educators in the HIV self-testing facility collection arm took the coupons for participants in their group and picked up HIV self-tests at participating health facilities on their participants' behalf. We followed up with health facilities to determine the prevalence of this and found it to be rare. We also found that participants had a strong preference for public MARPI health facilities for HIV testing and linkage to care; thus, few participants used the HIV self-test referral cards we gave them for free HIV testing at the participating private health facilities.

Figure 2: Implementation activities reported by participants at four months

a. Number of HIV self-tests participants received from their peer educator[1]

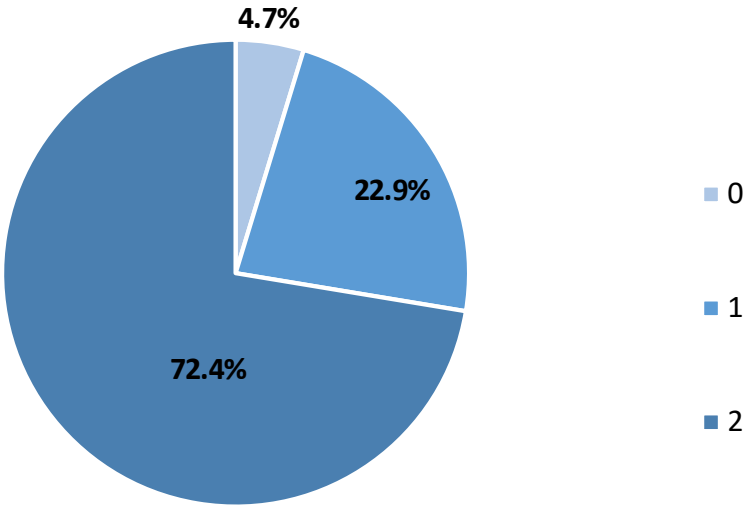


b. Number of coupons participants received from their peer educator[2]



Facility collection component
(N = 297)

c. Number of HIV self-tests picked up at healthcare facility[3]



Facility collection component
(N = 297)

[1] Participants in the direct provision arm were to receive two HIV self-tests from their peer educator over the duration of the study; 1.1 per cent (3/262) of participants in this arm reported receiving more than two HIV self-tests at four months.
[2] Participants in the facility collection arm were to receive two coupons for HIV self-tests from their peer educator over the duration of the study; 0.7 per cent (2/297) of participants reported receiving more than two coupons.
[3] Participants had to have received a coupon from their peer educator to pick up an HIV self-test from a healthcare facility. Picking up HIV self-tests at a healthcare facility occurs along the causal pathway to HIV testing for participants in the facility collection arm.

4.4 Primary outcome

Any HIV testing at one month (past month) was highest in the direct provision arm (95.2%, 275/289), as compared with the facility collection arm (80.4%, 258/321) and standard-of-care arm (71.5%, 226/316) (Table 3). Participants in the direct provision arm were 1.18 times (95% confidence interval (CI) 1.07 to 1.31, $p = 0.001$) and 1.33 times (95% CI 1.17 to 1.51, $p < 0.001$) as likely to test for HIV in the past month as participants in the facility collection arm and standard-of-care arm, respectively (Figure 3a and Table 4). There were no statistically significant differences in HIV testing at one month between participants in the facility collection arm and standard-of-care arm (Table 4).

Any HIV testing at four months (past four months) was again greatest in the direct provision arm (99.6%, 261/262), followed by the facility collection arm (97.0%, 288/297) and standard-of-care arm (87.1%, 263/302) (Table 3). Participants in both HIV self-testing arms were significantly more likely to have tested for HIV in the past four months than participants in the standard-of-care arm (direct provision risk ratio (RR): 1.14 times, 95% CI 1.07 to 1.22, $p < 0.001$; facility collection RR: 1.11, 95% CI 1.04 to 1.19, $p = 0.002$) (Table 4). Participants in the direct provision arm were significantly more likely to have tested for HIV in the past four months than participants in the facility collection arm (RR: 1.03 times, 95% CI 1.01 to 1.05, $p = 0.02$) (Table 4).

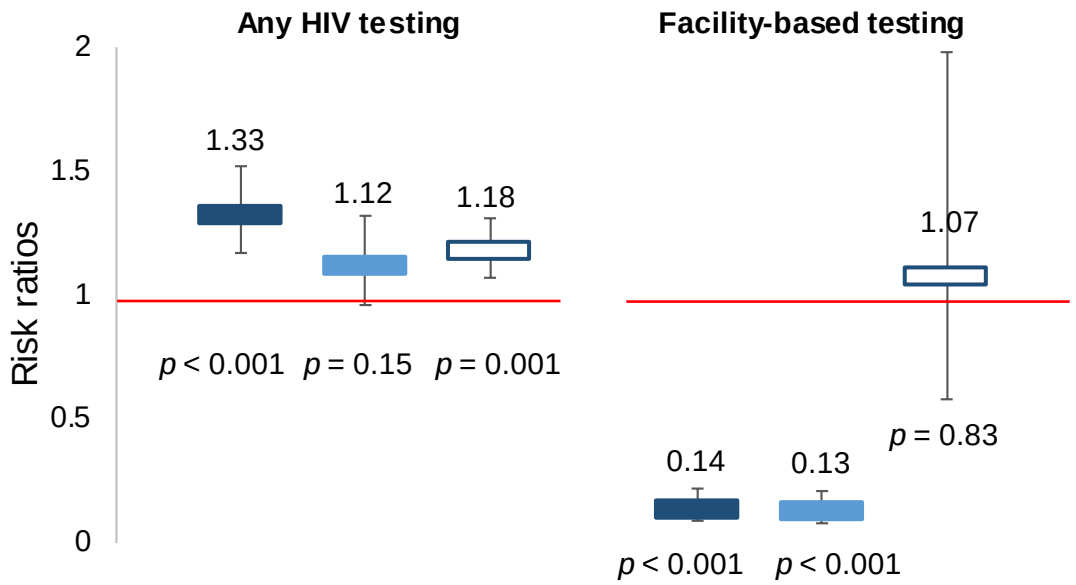
Table 3: HIV testing and linkage to care: self-reported outcomes at one month and at four months

	One month			Four months		
Outcome[1]	***Direct provision***	***Facility collection***	***Standard-of-care***	***Direct provision***	***Facility collection***	***Standard-of-care***
HIV testing						
HIV testing, any*	275/289 (95.2%)	258/321 (80.4%)	226/316 (71.5%)	261/262 (99.6%)	288/297 (97.0%)	263/302 (87.1%)
HIV tested twice	---	---	---	228/262 (87.0%)	212/287 (71.4%)	174/302 (57.6%)
HIV self-test use	272/289 (94.1%)	250/321 (77.9%)	0/316 (0%)	258/262 (98.5%)	279/297 (93.9%)	5/302 (1.7%)
Used self-test twice	---	---	---	218/262 (83.2%)	202/297 (68.0%)	---
Facility-based testing	27/289 (9.3%)	28/321 (8.7%)	211/316 (66.8%)	56/262 (21.4%)	75/297 (25.3%)	259/302 (85.8%)
Tested at a facility twice	---	---	---	4/262 (1.5%)	9/297 (3.0%)	136/302 (45.0%)
HIV positive, last test result[2]	39/287 (13.6%)	54/312 (17.3%)	39/301 (13.0%)	44/260 (16.9%)	80/289 (27.7%)	53/294 (18.0%)
Linkage to care[3]						
Seek HIV-related medical care	17/287 (5.9%)	13/312 (4.2%)	25/301 (8.3%)	27/260 (10.4%)	37/289 (12.8%)	37/294 (12.6%)
ART initiation	13/287 (4.5%)	10/312 (3.2%)	13/301 (4.3%)	19/260 (7.3%)	27/289 (9.3%)	24/294 (8.2%)

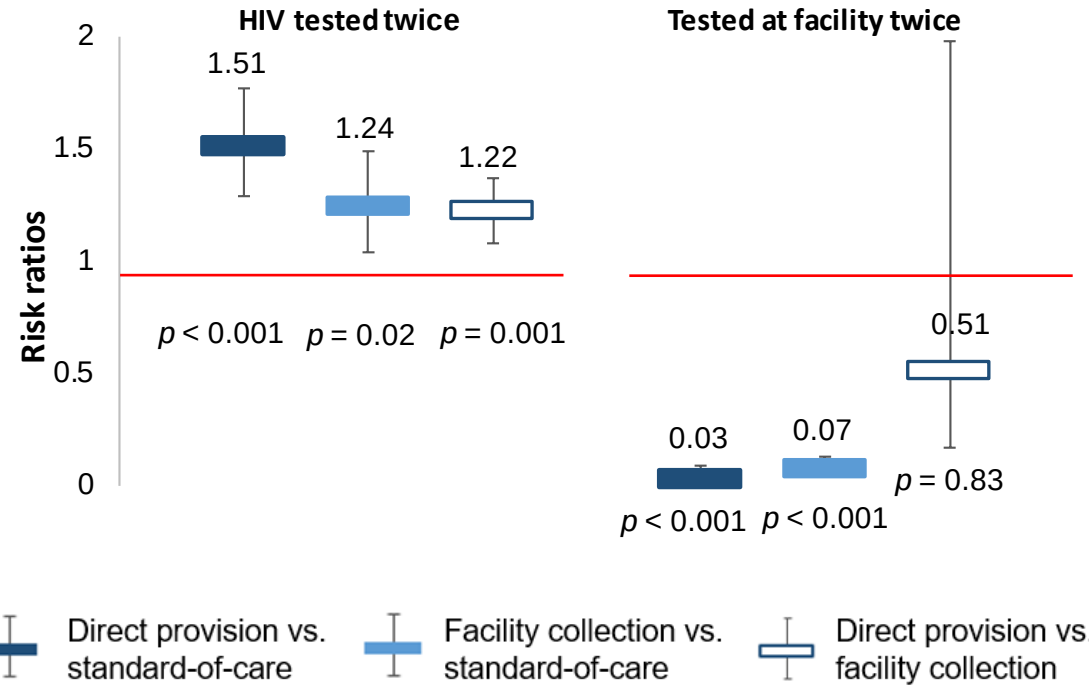
* Pre-specified primary outcomes.
[1] All testing and linkage to care outcomes reported since study start.
[2] Among participants that shared their test result.
[3] For these outcomes, participants had to report both testing HIV positive and seeking HIV-related medical care or initiating ART.

Figure 3: Effect size estimates for impact of HIV self-testing on HIV self-testing outcomes at (a) one month and (b) four months

(a) One-month effect size estimates



(b) Four-month effect size estimates



Note: All outcomes are since the study start; facility-based testing includes private and public health facilities. Comparisons between study arms: direct provision versus standard-of-care (dark grey), facility collection versus standard-of-care (light grey), direct provision versus facility collection (hollow grey).

Table 4: Effect size estimates, risk ratios: HIV self-testing on HIV testing and linkage to care outcomes

Outcome[2]	Assessment	*Direct provision vs. standard-of-care* RR (95% CI)	*p*-value[1]	*Facility collection vs. standard-of-care* RR (95% CI)	*p*-value[1]	*Direct provision vs. facility collection* RR (95% CI)	*p*-value[1]
HIV testing							
HIV testing, any	One month*	1.33 (1.17 to 1.51)	< 0.001	1.12 (0.96 to 1.32)	0.148	1.18 (1.07 to 1.31)	0.001
	Four months*	1.14 (1.07 to 1.22)	< 0.001	1.11 (1.04 to 1.19)	0.002	1.03 (1.01 to 1.05)	0.015
HIV tested twice	Four months	1.51 (1.29 to 1.77)	< 0.001	1.24 (1.04 to 1.49)	0.021	1.22 (1.08 to 1.37)	0.001
HIV self-test use	One month	---		---		1.21 (1.09 to 1.35)	0.001
	Four months	---		---		1.05 (1.01 to 1.09)	0.010
Used self-test twice	Four months	---		---		1.22 (1.06 to 1.40)	0.005
Facility-based testing	One month	0.14 (0.09 to 0.22)	< 0.001	0.13 (0.08 to 0.21)	< 0.001	1.07 (0.58 to 1.98)	0.827
	Four months	0.25 (0.18 to 0.34)	< 0.001	0.29 (0.23 to 0.37)	< 0.001	0.85 (0.59 to 1.22)	0.373
Tested at facility twice	Four months	0.03 (0.01 to 0.09)	< 0.001	0.07 (0.04 to 0.13)	< 0.001	0.51 (0.17 to 1.53)	0.227
HIV positive, last test result	One month	1.05 (0.62 to 1.75)	0.866	1.27 (0.74 to 2.19)	0.386	0.82 (0.48 to 1.41)	0.476
	Four months	0.95 (0.62 to 1.48)	0.835	1.53 (1.00 to 2.36)	0.050	0.62 (0.41 to 0.94)	0.025
Linkage to care[3]							
Seek HIV-related medical care	One month	0.65 (0.30 to 1.41)	0.275	0.50 (0.24 to 1.04)	0.063	1.30 (0.54 to 3.15)	0.557
	Four months	0.83 (0.49 to 1.41)	0.482	1.01 (0.62 to 1.65)	0.967	0.82 (0.46 to 1.44)	0.488
ART initiation	One month	0.99 (0.37 to 2.67)	0.991	0.76 (0.29 to 2.02)	0.585	1.30 (0.46 to 3.73)	0.619
	Four months	0.91 (0.46 to 1.81)	0.879	1.15 (0.63 to 2.10)	0.646	0.79 (0.41 to 1.54)	0.490

* Pre-specified primary outcomes.

[1] Multilevel mixed-effects generalized linear models (Poisson distribution); study arm fixed effect, peer educator random effect.

[2] All testing and linkage to care outcomes reported since study start; self-reported.

[3] Reported testing HIV positive and currently receiving medical care or ART for their HIV.

4.5 Secondary outcomes

Participants in the HIV self-testing arms were significantly more likely to test for HIV twice since the start of the study than those in the standard-of-care arm (direct provision RR: 1.51, 95% CI 1.29 to 1.77, $p < 0.001$; facility collection RR: 1.24, 95% CI 1.04 to 1.49, $p = 0.02$) (Figure 3b and Table 4). Participants in the direct provision HIV self-testing arm were 1.22 times (95% CI 1.08 to 1.27, $p = 0.001$) as likely to test for HIV twice since the start of the study as those in the facility collection HIV self-testing arm (Figure 3b and Table 4).

Facility-based HIV testing (i.e. public or private sector) was significantly lower in the HIV self-testing arms compared with the standard-of-care arm at one month and at four months. At four months, participants in the direct provision arm were 0.25 times (95% CI 0.18 to 0.34, $p < 0.001$) as likely to test at a health facility as those in the standard-of-care arm, while participants in the facility collection arm were 0.29 times (95% CI 0.23 to 0.37, $p < 0.001$) as likely (Figure 3b and Table 4). There were no statistically significant differences in facility-based testing between the direct provision and facility collection arms at one month and at four months (Table 4).

There are no statistically significant differences in testing HIV positive at the last test (self-reported) across study arms at one month; however, at four months, significantly more participants in the facility collection arm reported testing HIV positive, compared with those in the standard-of-care arm (RR 1.53, 95% CI 1.00 to 2.36, $p = 0.05$) and direct provision arm (RR 1.61, 95% CI 1.06 to 2.43, $p = 0.03$), respectively (Table 4). This outcome did not significantly differ between the direct provision and standard-of-care arm at four months.

Few participants reported seeking medical care for HIV or ART initiation across study arms (Table 3). There were no statistically significant differences in the linkage to care outcomes (i.e. seeking HIV-related medical care or ART initiation) across study arms at one month and at four months in the ITT analysis (Table 4).

4.6 Sensitivity analyses

In our first sensitivity analysis – which pooled outcomes across HIV self-testing arms and calculated risk ratios for this pooled arm compared with the standard-of-care arm – the significance of our effect size estimates was consistent with those calculated in our main analysis (Table 5). Participants in the pooled HIV self-testing arm were 1.22 times (95% CI 1.07 to 1.40, $p = 0.004$) as likely to have tested for HIV in the past month as those in the standard-of-care arm, and 1.13 times (95% CI 1.05 to 1.21, $p < 0.001$) as likely to have tested for HIV in the past four months as those in the standard-of-care arm.

The significance of the effect size estimates calculated in our main analysis was also confirmed by our second sensitivity analysis, which generated group-level outcomes (i.e. the proportion of participants in a peer educator group presenting an outcome) and then calculated risk differences for these outcomes using generalized linear models (Table 6). In this analysis, at one month, participants in the direct provision arm were 24.4 per cent (95% CI 14.1% to 34.7%, $p < 0.001$) and 14.5 per cent (95% CI 4.2% to 24.8%, $p = 0.01$) more likely to have tested for HIV in the past month than the standard-of-care arm and facility collection arm, respectively. At four months, participants in the direct provision

arm were 13.1 per cent (7.9% to 18.4%, $p < 0.001$) more likely and participants in the facility collection arm were 10.7 per cent (5.6% to 15.7%, $p < 0.001$) more likely to have tested for HIV in the past four months than participants in the standard-of-care arm.

There were no differences in the significance of our HIV testing outcomes in the sensitivity analysis, which measured effect sizes among participants who reported testing for HIV in the past 12 months at baseline, and participants who reported testing for HIV more than 12 months ago at baseline. Among participants who reported testing for HIV in the past 12 months at baseline, those in the HIV self-testing intervention arms were more likely to have tested for HIV at one month (direct provision RR: 1.27, 95% CI 1.12 to 1.46, $p < 0.001$; facility collection RR: 1.08, 95% CI 0.91 to 1.29, $p = 0.36$) and at four months (direct provision RR 1.10 95% CI 1.05 to 1.17, $p < 0.001$; facility collection RR 1.07, 95% CI 1.01 to 1.14, $p = 0.02$), compared with those in the standard-of-care arm (Table 7). The same is true for participants who reported testing for HIV more than 12 months ago at baseline (Table 7).

In the sensitivity analysis that limited the sample size to participants who self-reported testing HIV positive and then calculated risk ratios for linkage to care outcomes, significantly fewer participants in the facility collection arm sought HIV-related medical care at one month and at four months than in the standard-of-care arm (one-month RR: 0.38, 95% CI 0.21 to 0.67, $p = 0.001$; four-month RR: 0.66, 95% CI 0.47 to 0.94, $p = 0.02$) (Table 8). There were no statistically significant differences in seeking HIV-related medical care between the direct provision arm and the standard-of-care arm, nor the direct provision arm and the facility collection arm at one month and at four months. There were also no statistically significant differences in ART initiation across study arms at one month and at four months, which is consistent with the effect size estimates calculated in the main analysis for this outcome.

Table 5: Sensitivity analysis: pooled HIV self-testing (HIVST) arms versus the standard-of-care arm – percentages and effect size estimates, risk ratios

Outcome[2]	Assessment	*Pooled HIVST arms*	*Standard-of-care*	RR[1] (95% CI)	*p*-value
HIV testing					
HIV testing, any	One month*	533/610 (87.4%)	226/316 (71.5%)	1.22 (1.07 to 1.40)	0.004
	Four months*	549/559 (98.2%)	263/302 (87.1%)	1.13 (1.05 to 1.21)	< 0.001
HIV tested twice	Four months	440/559 (71.3%)	174/302 (57.6%)	1.37 (1.16 to 1.60)	< 0.001
Facility-based testing	One month	55/610 (9.0%)	211/316 (66.8%)	0.13 (0.10 to 0.19)	< 0.001
	Four months	131/559 (23.4%)	259/302 (85.8%)	0.27 (0.23 to 0.33)	< 0.001
Tested at facility twice	Four months	13/559 (2.3%)	136/302 (45.0%)	0.05 (0.03 to 0.09)	< 0.001
HIV positive, last test result[3]	One month	93/599 (15.5%)	39/301 (13.0%)	1.16 (0.73 to 1.84)	0.520
	Four months	124/549 (22.6%)	53/294 (18.0%)	1.26 (0.85 to 1.86)	0.244
Linkage to care[4]					
Seek HIV-related medical care	One month	30/559 (5.0%)	25/301 (8.3%)	0.57 (0.30 to 1.06)	0.073
	Four months	64/549 (11.7%)	37/294 (12.6%)	0.92 (0.60 to 1.41)	0.711
ART initiation	One month	23/599 (3.8%)	13/301 (4.3%)	0.87 (0.38 to 2.01)	0.746
	Four months	46/549 (8.4%)	24/294 (8.2%)	1.04 (0.60 to 1.80)	0.894

* Pre-specified primary outcomes.

[1] Multilevel mixed effects generalized linear models (Poisson distribution, log link, robust standard errors), study arm fixed effect, peer educator random effects; intention-to-treat analyses.

[2] All testing and linkage to care outcomes reported since study start; self-reported.

[3] Among participants that shared their test result. [4] For these outcomes, participants had to report both testing HIV positive and seeking HIV-related medical care or initiating ART. These outcomes were measured among all participants randomized, as defined by the intention-to-treat analysis.

Table 6: Sensitivity analysis: the proportion of participants in a peer educator group reporting each outcome – effect size estimates, percentage points (PP)

Outcome[2]	Assessment	*Direct provision vs. standard-of-care* PP[1] (95% CI)	*p*-value	*Facility collection vs. standard-of-care* PP[1] (95% CI)	*p*-value	*Direct provision vs. facility collection* PP[1] (95% CI)	*p*-value
HIV testing							
HIV testing, any	One month*	24.4 (14.1 to 34.7)	< 0.001	9.9 (-0.1 to 19.9)	0.053	14.5 (4.2 to 24.8)	0.006
	Four months*	13.1 (7.9 to 18.4)	< 0.001	10.7 (5.6 to 15.7)	< 0.001	2.5 (-2.7 to 7.8)	0.354
HIV tested twice	Four months	29.7 (18.9 to 40.4)	< 0.001	15.2 (4.8 to 25.6)	0.004	14.5 (3.8 to 25.2)	0.008
HIV self-test use	One month	---		---		15.9 (8.8 to 22.9)	< 0.001
	Four months	---		---		3.8 (0.0 to 7.6)	0.050
Used self-test twice	Four months	---		---		24.9 (6.4 to 43.3)	0.008
Facility-based testing	One month	-56.6 (-66.1 to -47.0)	< 0.001	-57.1 (-66.4 to -47.9)	< 0.001	0.6 (-8.9 to 10.0)	0.907
	Four months	-64.2 (-72.8 to -55.7)	< 0.001	-60.2 (-68.6 to -51.9)	< 0.001	-4.0 (-12.5 to 4.5)	0.359
Tested at facility twice	Four months	-320.9 (-389.4 to -252.3)	< 0.001	-310.3 (-376.7 to -243.9)	< 0.001	-10.6 (-78.8 to 57.5)	0.760
HIV positive, last test result	One month	1.2 (-6.3 to 8.8)	0.747	4.6 (-2.7 to 11.9)	0.218	-3.3 (-10.8 to 4.1)	0.382
	Four months	0.3 (-9.4 to 10.0)	0.951	9.5 (0.1 to 18.9)	0.047	-9.2 (-18.9 to 0.4)	0.061
Linkage to care[3]							
Seek HIV-related medical care	One month	-2.0 (-6.8 to 2.8)	0.411	-3.3 (-8.0 to 1.3)	0.154	1.4 (-3.4 to 6.1)	0.575
	Four months	-0.9 (-8.3 to 6.5)	0.812	0.3 (-6.9 to 7.4)	0.942	-1.2 (-8.5 to 6.2)	0.757
ART initiation	One month	0.5 (-3.5 to 4.4)	0.811	-0.4 (-4.2 to 3.4)	0.835	0.9 (-3.0 to 4.8)	0.658
	Four months	0.8 (-6.0 to 7.6)	0.817	1.6 (-4.9 to 8.2)	0.629	-0.8 (-7.5 to 5.9)	0.812

* Pre-specified primary outcomes.

[1] Multilevel mixed effects generalized linear models, study arm fixed effect; intention-to-treat analyses.

[2] All testing and linkage to care outcomes reported since study start; self-reported.

[3] For these outcomes, participants had to report both testing HIV positive and seeking HIV-related medical care or initiating ART. These outcomes were measured among all participants randomized, as defined by the intention-to-treat analysis.

Table 7: Sensitivity analysis: effect modification, recent HIV testing at baseline – effect size estimates, risk ratios

Outcome[2]	Assessment	*Direct provision vs. standard-of-care* RR (95% CI)	*p*-value[1]	*Facility collection vs. standard -of-care* RR (95% CI)	*p*-value[1]	*Direct provision vs. facility collection* RR (95% CI)	*p*-value[1]
Last HIV test, < 12 months at baseline							
HIV testing, any	One month*	1.27 (1.12 to 1.46)	< 0.001	1.08 (0.91 to 1.29)	0.361	1.18 (1.04 to 1.34)	0.012
	Four months*	1.10 (1.05 to 1.17)	< 0.001	1.07 (1.01 to 1.14)	0.021	1.03 (1.00 to 1.06)	0.079
HIV tested twice	Four months	1.41 (1.20 to 1.66)	< 0.001	1.16 (0.95 to 1.41)	0.154	1.22 (1.05 to 1.42)	0.01
HIV self-test use	One month	---		---		1.22 (1.07 to 1.49)	0.004
	Four months	---		---		1.05 (1.00 to 1.10)	0.028
Used self-test twice	Four months	---		---		1.28 (1.07 to 1.52)	0.007
Facility-based testing	One month	0.11 (0.06 to 0.18)	< 0.001	0.09 (0.05 to 0.17)	< 0.001	1.20 (0.54 to 2.65)	0.658
	Four months	0.22 (0.15 to 0.32)	< 0.001	0.27 (0.20 to 0.36)	< 0.001	0.81 (0.51 to 1.30)	0.39
Tested at facility twice	Four months	0.02 (0.01 to 0.10)	< 0.001	0.06 (0.03 to 0.15)	< 0.001	0.40 (0.08 to 2.01)	0.268
Last HIV test, > 12 months at baseline							
HIV testing, any	One month*	1.44 (1.20 to 1.73)	< 0.001	1.20 (0.97 to 1.48)	0.096	1.20 (1.07 to 1.35)	0.002
	Four months*	1.25 (1.09 to 1.43)	0.001	1.21 (1.06 to 1.39)	0.006	1.03 (1.00 to 1.06)	0.062
HIV tested twice	Four months	1.77 (1.38 to 2.27)	< 0.001	1.43 (1.09 to 1.87)	0.011	1.24 (1.06 to 1.45)	0.007
HIV self-test use	One month	---		---		1.20 (1.07 to 1.35)	0.001
	Four months	---		---		1.04 (0.99 to 1.10)	0.114
Used self-test twice	Four months	---		---		1.22 (0.95 to 1.33)	0.181
Facility-based testing	One month	0.21 (0.11 to 0.40)	< 0.001	0.20 (0.11 to 0.39)	< 0.001	1.05 (0.45 to 2.45)	0.91
	Four months	0.30 (0.21 to 0.43)	< 0.001	0.31 (0.24 to 0.41)	< 0.001	0.97 (0.63 to 1.49)	0.88
Tested at facility twice	Four months	0.05 (0.01 to 0.22)	< 0.001	0.08 (0.03 to 0.21)	< 0.001	0.70 (0.14 to 3.56)	0.67

* Pre-specified primary outcomes.

[1] Multilevel mixed effects generalized linear models (Poisson distribution); study arm fixed effect, peer educator random effect.

[2] All testing and linkage to care outcomes reported since study start; self-reported.

[3] Reported testing HIV positive and currently receiving medical care or ART for their HIV.

Table 8: Sensitivity analysis: linkage to care outcomes among only participants who report testing HIV positive – conditional effect size estimates, risk ratios

Outcome[2]	Assessment	*Direct provision vs. standard-of-care* RR[1] (95% CI)	*p*-value	*Facility collection vs. standard-of-care* RR[1] (95% CI)	*p*-value	*Direct provision vs. facility collection* RR[1] (95% CI)	*p*-value
Linkage to care,[3] unadjusted							
Seek HIV-related medical care	One month	0.68 (0.39 to 1.20)	0.182	0.38 (0.21 to 0.67)	0.001	1.81 (0.87 to 3.75)	0.111
	Four months	0.88 (0.62 to 1.24)	0.461	0.66 (0.47 to 0.94)	0.021	1.33 (0.88 to 2.01)	0.182
ART initiation	One month	1.00 (0.49 to 2.04)	1.00	0.56 (0.25 to 1.23)	0.146	1.80 (0.77 to 4.20)	0.173
	Four months	0.95 (0.57 to 1.59)	0.856	0.75 (0.46 to 1.22)	0.240	1.28 (0.76 to 2.15)	0.352
Linkage to care,[3] adjusted[4]							
Seek HIV-related medical care	One month	0.72 (0.45 to 1.17)	0.186	0.41 (0.23 to 0.75)	0.004	1.75 (0.87 to 3.52)	0.114
	Four months	0.86 (0.63 to 1.18)	0.365	0.66 (0.47 to 0.94)	0.020	1.30 (0.86 to 1.97)	0.208
ART initiation	One month	1.10 (0.56 to 2.16)	0.782	0.61 (0.26 to 1.44)	0.260	1.81 (0.78 to 4.17)	0.165
	Four months	0.97 (0.59 to 1.57)	0.886	0.77 (0.49 to 1.22)	0.270	1.25 (0.75 to 2.09)	0.390

[1] Multilevel mixed effects generalized linear models (modified Poisson distribution), study arm fixed effect, peer educator random effect, robust standard errors; intention-to-treat analyses.

[2] All testing and linkage to care outcomes reported since study start; self-reported.

[3] For these outcomes, participants had to report both testing HIV positive and seeking HIV-related medical care or initiating ART.

[4] Analysis adjusted for age,[2] highest level of education and monthly income.

4.7 Adverse events

Two adverse events relating to HIV self-testing were reported throughout the duration of the study: (1) interpersonal violence from a sexual partner upon discovery of the HIV self-test (facility collection arm); and (2) mental distress following a perceived HIV-positive test result (the participant was later confirmed HIV negative with blood-based rapid testing at a health facility) (direct provision arm).

Two additional events relating to study participation, but not HIV self-testing, were reported throughout the duration of the study. Both entailed interpersonal violence related to FSW status disclosure in the direct provision arm. No adverse events related to study participation were reported in the standard-of-care arm.

All adverse events were reported to the study's Scientific Oversight Committee within 24 hours and the study Institutional Review Boards.

4.8 Cost-effectiveness

Table 9 shows the effectiveness and cost of the HIV self-testing interventions and standard-of-care at four months. The cost per participant in the standard-of-care arm was USD30. At approximately USD7 per self-test (what we paid for a self-test), the cost per participant in the direct provision arm was USD44 and the cost per participant in the facility collection arm was USD46. The facility collection arm cost more than the direct provision arm because of additional costs supporting the healthcare facilities involved in the study and the minimal cost of coupons.

Table 9: Incremental cost-effectiveness of HIV self-testing at four months*

	Direct provision	*Facility collection*	*Standard-of-care*
Effectiveness			
Number of participants	296	336	328
Number of peer educators	37	42	41
HIV testing, any (one month)	95%	80%	72%
HIV testing, any (four months)	100%	97%	87%
HIV tested twice	87%	71%	58%
Number tested in population of 1,000			
HIV testing, any (one month)	952	804	715
HIV testing, any (four months)	996	970	871
HIV tested twice	870	714	576
Itemized running costs, USD			
Car	$435	$494	$482
Referral cards	$11	$13	$13
Coupons	$0	$19	$0
Oral HIV self-tests	$4,381	$4,973	$0
Private clinic support	$0	$427	$0
Hotline support	$112	$127	$124
Management salaries	$4,522	$5,126	$5,005
Peer educator salaries	$3,676	$4,172	$4,073
Cumulative costs, USD			
Total	$13,137	$15,351	$9,697
Cost/participant	$44	$46	$30
Cost for population of 1,000	$44,380	$45,686	$29,563
Incremental cost effectiveness, USD			
HIV testing, any (one month)	$63	$181	*ref*
HIV testing, any (four months)	$119	$163	*ref*
HIV tested twice	$50	$117	*ref*

* All outcomes reported at four months with the exception of HIV testing, which is reported at both one month and four months.

In a pseudo-population of 1,000 FSWs, at one month, 237 additional FSWs tested for HIV with direct provision of HIV self-tests and 89 additional people tested for HIV with facility collection of self-tests, compared with standard-of-care. At four months, 125 additional FSWs tested for HIV and 294 additional FSWs tested for HIV twice with direct provision, while 99 additional FSWs tested for HIV and 138 additional FSWs tested for HIV twice with facility collection, compared with standard-of-care. In this pseudo-population of 1,000, direct delivery of HIV self-tests cost USD14,817 more than referral to standard HIV testing services, and facility collection of HIV self-tests cost USD16,124 more.

The incremental cost-effectiveness for each additional FSW who tested for HIV is USD63 with direct provision and USD181 with facility collection at one month (Table 9). At four months, the incremental cost-effectiveness for each additional FSW who tested for HIV is USD119 with direct provision and USD163 with facility collection. The incremental cost-effectiveness for each FSW who tested twice for HIV at four months was USD50 with direct provision and USD117 with facility collection, compared with referral to standard HIV testing services. Direct provision of HIV self-tests is more cost-

effective than facility collection due to lower overall costs for this delivery method and larger effect estimates compared with referral to standard-of-care HIV testing services.

4.9 Qualitative analysis

We limited our qualitative analysis to the FSWs who were in the HIV self-testing intervention arms (N = 30) because only these participants were asked questions related to experiences of HIV self-testing. The median age of these FSWs was 30 years (IQR 26 to 33 years), 83 per cent (25/30) self-reported the ability to read and write, and 36 per cent (8/22) were biologically confirmed to be living with HIV. The majority of participants (60%, 18/30) were in the direct provision arm and the rest were in the facility collection arm. Almost all participants completed both baseline and four-month qualitative interviews (97%, 29/30), and almost all participants used an HIV self-test at least once (97%, 29/30) throughout the duration of the study.

Table 10 outlines the findings from our SWOT analysis on the strengths, weaknesses, opportunities and threats of HIV self-testing among FSWs in Kampala, Uganda (Creswell 2013).

Table 10: SWOT analysis for HIV self-testing among FSWs

Strengths	**Weaknesses**
• Privacy • No injection (i.e. oral fluid) • Convenience • Simple to use • Empowerment • Reduction in HIV risk-related sexual behaviors	• Not seen by a healthcare provider • Do not receive counseling • Difficulties interpreting the test results • Incorrect self-test use
Opportunities	**Threats**
• Testing others (e.g. clients, other sexual partners, children) • Serosorting • Secondary distribution of self-tests • Accessing individuals who have never tested for HIV	• Mistrust of the new technology • Reduced linkage to care • Testing others against their will • Suicide/depression • Misunderstanding of HIV transmission • False assurance of HIV status

Strengths

We identified a number of strengths related to HIV self-testing among FSWs through the qualitative interviews. A frequently identified strength of HIV self-testing was that it prevented FSWs from having to be seen testing at the healthcare facility and enabled them to process the results of their HIV self-test in private.

> HIV testing has always been there but people were scared since it would be done in hospitals and they feared for their privacy but now this new method is good because it is private so people will like it very much. — Direct provision arm, 26 years old

FSWs were also enthusiastic about an HIV self-test that did not draw blood, for many feared being 'injected' by a needle.

> Swabbing the gum is so easy unlike pricking with the old method. I really have phobia for injections and so do many people out there. Even when the veins disappear, you can still take the test because your gum will always be there. — Direct provision arm, 40 years old

Another strength of HIV self-testing that was often described is the ability to circumvent the need to go to a healthcare facility and to wait in line, receive repeated counseling, face judgement/stigma from healthcare providers, and spend money on transportation.

> It is time saving. This is because waking up in the morning to go to hospital so that you can get tested, and then at times you find many people in line too and you end up spending hours out there is tiring. With this new method, all you do is get the test, sit somewhere and perhaps watch television as you wait for the kit to give you the results. — Direct provision arm, 30 years old

Many FSWs described feelings of empowerment related to HIV self-testing and HIV status knowledge (acquired through testing) that influenced their condom use with clients.

> I liked it because you get to test yourself alone and you can make your own life-changing decisions just there by yourself minus anyone knowing about it. — Direct provision arm, 26 years old

> I feel like my risk has gone down ever since I took the test. It is like what I told you earlier that when you get to know your status, there are certain changes that you make in your life. You become more cautious and careful when it comes to sex so that you maintain your status and not get infected. — Facility collection arm, 37 years old

Weaknesses

We also identified a number of potential weaknesses related to HIV self-tests through the qualitative interviews. Some FSWs were concerned that they were no longer interacting with healthcare providers who could provide counseling (especially if they tested HIV positive) and address other health issues, such as sexually transmitted infections.

> I can test myself yet I may not get adequate counselling. But when I go to a health facility and they test me and tell me that I am sick [with HIV], I get counselled and at times they can start you on drugs. — Facility collection arm, 35 years old

> Because you are alone, you don't have anyone to talk to in the very moment just in case the results are positive and you are feeling so low. Self-counseling is kind of hard to do for many people. — Direct provision arm, 30 years old

Another identified weakness of HIV self-testing was that the accuracy of the test relies on FSWs' correct self-test use and interpretation of results. FSWs who self-tested for HIV might have developed false perceptions of their HIV status if they incorrectly used the self-test or incorrectly interpreted the self-test results.

> Since you are doing the test by yourself, it is easy to think that you did it incorrectly and start to doubt yourself and the results at large. — Direct provision arm, 30 years old

> Where you view the number from, that area between the numbers is confusing. I wish they had done it in an easier way. But it is not easy to know where it ends between those numbers [reading results not easy]. — Facility collection arm, 38 years old

Opportunities

One of the opportunities for HIV self-tests often described by FSWs was the ability to test other individuals for HIV. FSWs were particularly interested in testing their sexual partners, including clients. Many FSWs said it would be great to test a client who demanded 'live sex' (i.e. sex without a condom) to confirm he is HIV negative before engaging in that activity. Other FSWs reported using the HIV self-tests to test their primary sexual partners (i.e. non-client partners) and children for HIV.

> HIV self-testing will also come in handy for those clients who insist on not using condoms because you can always have the kit in your purse and when he insists, you ask him to open his mouth for testing first before you can have sexual intercourse. If he refuse, then you can conclude that he probably has a disease that he was trying to hawk into your life. —— Direct provision arm, 30 years old

> I want to use [HIV self-testing] because you can convince your partner and tell him that; 'instead of going to a health facility and have our blood taken off, I have my thing here. Let us test ourselves and see.' — Facility collection arm, 35 years old

> When you are home, you can conduct the test by yourself and on your children without them knowing what you are doing to them because it could worry them. — Direct provision arm, 30 years old

Since HIV self-testing does not have to be conducted by a trained professional, self-tests can be distributed throughout existing social networks as a means of accessing individuals who might have never otherwise tested for HIV. Individuals who previously were not interested in HIV testing might also be drawn to it for the first time through self-tests due to the increased privacy and convenience.

> If [HIV self-testing] is at facilities near me, I would take just one. If I have friends who also want some then I can pick for them as well. — Direct provision arm, 26 years old

> Especially that people who have been previously scared of being tested will have an opportunity to test themselves. — Direct provision arm, 31 years old

Threats

We additionally identified a number of potential threats to HIV self-testing uptake among FSWs throughout the qualitative interviews. One of the most commonly cited threats was mistrust of the new HIV testing technology. A number of FSWs discussed concerns that

people would not believe the results of an HIV test that used oral fluid instead of blood. Other FSWs were concerned that the technology itself would harm them in some way.

> I had that thing [HIV self-test] at home. I at first didn't take it seriously and wondered whether it really works. I spent with it two days before using it. But later on I decided to use it and see if it is accurate. — Facility collection arm, 35 years old

> I was hearing some rumors and so I got scared; that the HIVST kit is not yet legally in use, and some other people were saying that we are going to run mad after use. — Direct provision arm, 30 years old

> I was scared about the kit and I thought it could cause cancer to me since I had never used it. — Facility collection arm, 33 years old

Another threat we identified is using self-tests to test other individuals for HIV against their will. This could potentially be done by tricking others into thinking they are testing for something else (e.g. cancer, STIs), or potentially using violence to test others.

> Because you can have a partner and decide to buy about two kits without letting him know of it. I think men have not yet learnt of them. Then you tell him that I want to rub this thing [test kit] into you and see. You try to deceive him and see what comes out of him. — Direct provision arm, 30 years old

Since HIV self-testing uses oral fluid instead of blood, there is the potential that the testing technology may result in false perceptions of HIV transmission among FSWs. This could possibly reverse years of work around HIV education within the FSW community and increase stigma and discrimination among individuals living with HIV.

> We have grown up being told that there is no HIV in saliva and that is why many people kiss the infected and get away with it. Now out of the blue, you guys come and say that HIV can be detected from the gum. Trust me you are going to have a lot of trouble explaining yourselves to the masses so that they understand you. — Direct provision arm, 40 years old

Finally, many FSWs were excited about testing themselves for HIV shortly after a condom breaks with a client they suspect to be living with HIV. Unfortunately, oral HIV self-tests cannot detect these very early infections and thus individuals who test themselves shortly after an HIV risk-related encounter might develop false reassurance of their HIV status.

> I would consider using it because as I told you as a FSW we believe in condom use, but there are times when the condom may burst, so in such a moment, I will need to take a self-test before proceeding to the health facility so in that way that is helpful. HIVST is useful in times of accidents. — Direct provision arm, 30 years old

5. Discussion

5.1 Summary of main results

We find that oral HIV self-testing is safe and effective at increasing recent HIV testing among FSWs without any discernable detrimental effect on linkage to care. In our study in Kampala, Uganda, the provision of HIV self-tests significantly increased the likelihood that FSWs participated in HIV testing within one month (our primary outcome), and additionally resulted in almost universal HIV testing at four months. Within a four-month period, FSWs in the HIV self-testing arms were also significantly more likely to have tested twice for HIV than those in the standard-of-care arm. Universal and repeated HIV testing is particularly important for FSWs, because of the high risk of HIV acquisition they face in their daily lives (Baral et al. 2012; Shannon et al. 2015).

With regard to their own health, frequent HIV testing will allow FSWs to detect HIV infection early and initiate treatment without delay. Frequently repeated HIV testing is also a prerequisite for pre-exposure prophylaxis (PrEP), which is becoming increasingly available to FSWs in SSA. PrEP requires frequent HIV testing to detect breakthrough infections (WHO 2015). Our results suggest that HIV self-testing could be a viable approach to ensure that FSWs who are taking PrEP regularly check their HIV status (Ngure et al. 2017). The viability of combining PrEP and HIV self-testing, however, will depend on the biological performance of HIV self-tests in detecting HIV among PrEP users (Suntharasamai et al. 2015), as well as the ability for oral HIV antibody-based self-tests to accurately detect early HIV infection (Stekler et al. 2013). However, if the availability of HIV self-testing increases the likelihood of HIV testing, even with PrEP, the benefits should be weighed.

With regard to the health of others, frequent HIV testing is necessary for successful treatment-as-prevention (TasP) and positive prevention strategies (Bunnell et al. 2006b; Kennedy et al. 2010). Frequent testing will ensure early detection of HIV infection, which is needed for early treatment initiation and behavior change to prevent onward HIV transmission. FSWs have larger numbers of sex partners than most other populations (Shannon et al. 2015) and thus are at higher risk of spreading the virus following infection (Baral et al. 2012; Shannon et al. 2015; UNAIDS 2014a). Early treatment initiation and behavior change following infection is thus particularly important for FSWs. Our results suggest that HIV self-testing could play an important role in achieving the frequent repeat testing necessary for successful TasP and positive prevention strategies among FSWs.

While our findings indicate that HIV self-testing is effective overall in increasing recent and frequent HIV testing, one of the two delivery models that we tested – direct provision of HIV self-tests – is substantially more effective than the facility collection model. This result is highly plausible, as direct provision of HIV self-testing eliminates more potential barriers to HIV self-testing than facility collection. Direct provision requires neither an interaction with a health worker, nor money nor time. In contrast, facility collection requires FSWs to interact with health workers, implying the potential risk of provider stigma. Moreover, collection of HIV self-tests from a healthcare facility requires FSWs to travel during operating hours, thereby incurring monetary transport and time costs that are similar to those of facility-based testing.

We included the facility collection arm in our study because it more closely resembles the likely default strategy to HIV self-testing that governments in SSA will choose. In fact, in South Africa (South African Pharmacy Council 2013) and Kenya (Kenyan MOH 2015), HIV self-tests have already become available for over-the-counter purchase in pharmacies (HIVST.org 2017). Our results show that for FSWs even such 'passive' provision coupons for facility collection of HIV self-tests is inferior to the 'active' delivery of HIV self-tests through peer educators. In adopting HIV self-testing policies, governments in SSA should consider peer-supported strategies of direct HIV self-test delivery for FSWs as well as for other key populations that are likely to face provider stigma and to lack money for frequent travel to healthcare facilities. A peer-supported HIV testing strategy for FSWs is feasible because peer educators have previously been used to successfully deliver health services to FSWs in Uganda and other SSA settings (George and Blankenship 2015; Medley et al. 2009).

Another important secondary finding of our study is that HIV self-testing interventions not only increase overall HIV testing, but also lead to a very high degree of substitution of facility-based testing with self-testing. At one month, less than 10% of all testing was facility based in the self-testing intervention arms, while more than 60% of testing was facility based in the standard-of-care arm; at four months, about one quarter of all testing was facility based in the self-testing arms, while more than 80% was facility based in the standard-of-care arm. This substitution has several important implications. First, it signals a high degree of acceptance of HIV self-testing among FSWs in Uganda, which bodes well for future routine government roll-out of HIV self-testing strategies in the country. Second, in the direct provision arm, the large substitution effect implies savings of money and time that would have been spent on facility-based HIV testing. These savings are an additional benefit of peer-provided HIV self-testing, especially since FSWs are a very poor population (Shannon et al. 2015).

Substituting facility-based testing with self-testing, however, also raises concerns related to the sensitivity of oral antibody-based testing and self-testers' ability to correctly interpret results. Since the oral antibody-based self-tests are not as sensitive at detecting early HIV infection as the blood-based antigen tests found at healthcare facilities (Stekler et al. 2013), substituting blood-based antigen tests with oral antibody-based self-tests may delay HIV diagnosis. Delayed HIV diagnosis, especially among a population of FSWs with many sexual partners, is concerning because it may delay linkage to care and ART initiation, and contribute to increased HIV transmission (Donnell et al. 2010). Unlike facility-based HIV testing, the sensitivity and specificity of self-testing relies on testers' correct interpretation of self-test results. While previous studies have found participant-interpreted self-test results to be highly sensitive and specific (Asiimwe et al. 2014; Choko et al. 2011, 2015; Kurth et al. 2016), it is possible that characteristics of FSWs, such as low health literacy (Ngugi et al. 2012; Scorgie et al. 2012; Shannon et al. 2015) and higher substance use (Chersich et al. 2014; Lancaster et al. 2017; White et al. 2016) increase their likelihood of misinterpreting self-test results. Misinterpretation could lead to false perceptions of HIV status, which may delay linkage to care, result in unnecessary mental distress or stigma (Scorgie et al. 2013), or change HIV prevention behaviors (e.g. condom use) (Bunnell et al. 2006a; Kabiru et al. 2010; L'akoa et al. 2013; Naigino et al. 2017).

The large substitution effects, however, also raise worries of potential negative consequences for linkage to care. Self-testing will typically take place outside a healthcare facility and often far from the closest facility where HIV treatment and other services are available. Moreover, self-testing will generate an HIV test result without accompanying pre- and post-test counselling by a specifically trained health worker, as is the standard in facility-based testing. Both of these characteristics of self-testing could decrease linkage to care. In our main ITT analysis, however, we find that linkage to care remains largely unaffected by the substitution of facility-based testing with self-testing. While we fail to detect significant effects of the HIV self-testing interventions on linkage to care, this finding is comparatively weak because we lack sufficient power to reject the negative effect hypothesis.

In our linkage to care sensitivity analysis, where we limited our sample to individuals who self-reported testing HIV positive, we found that fewer participants in the facility collection arm sought HIV-related medical care than in the standard-of-care arm, and this difference was statistically significant. It is possible that FSWs in this arm used limited financial resources to travel to healthcare facilities to collect the HIV self-tests and did not have money or time to return for linkage to care. However, because this analysis is conditional upon an outcome that occurs after randomization, the results are likely biased. Randomization only ensures that we are comparing 'like' and 'like' in the ITT analysis. HIV testing is necessary for participants to discover that they are HIV positive. Since HIV testing was higher among participants in the HIV self-testing arms, we would expect more participants in those arms to report testing HIV positive. At four months, significantly more participants in the facility collection arm reported testing HIV positive than in the standard-of-care arm (there were no statistically significant differences between the direct provision arm and standard-of-care arm). Different selection into the denominator (e.g. testing HIV positive) across study arms is likely to bias effect size estimation in the conditional analysis. The results from this sensitivity analysis should be interpreted with caution.

Future studies are needed to provide stronger tests of this hypothesis. These will require substantial investment because, compared with previous studies (Gichangi et al. 2016; Johnson et al. 2017; Masters et al. 2016; Thirumurthy et al. 2016), this study included a large number of people who tested HIV positive (a total of 177 across the three arms) and were thus eligible for linkage. Until better evidence becomes available, HIV self-testing policies for FSWs should ideally include strong linkage interventions, because baseline linkage in this population was low and any delays in linkage to care are problematic for a population with a high number of partners. (The median number of clients per night was five among the FSWs in this study.) Linkage-enhancing interventions could include counseling by peer educators (Arem et al. 2011; Chang et al. 2010), home- and community-based ART (Iwuji et al. 2016b; Kipp et al. 2010) and financial incentives (Bassett et al. 2015; Govindasamy et al. 2014).

In our qualitative analysis, we identified a number of future opportunities and threats for HIV self-testing among FSWs. In this study, we only explored the effect of HIV self-testing among FSWs when tests were provided for personal use. In the future, FSWs could be given more than one HIV self-test to distribute to clients, other sexual partners, friends and family members. This distribution might allow us to access individuals who might not have otherwise traveled to healthcare facilities to test for HIV or selected to

test for HIV in front of other individuals. One commonly identified threat of HIV self-testing among FSWs was mistrust of the HIV self-testing technology. Thus, it may be especially important to distribute HIV self-tests via trusted FSW social networks, such as peer educators, to ensure rumors do not spread that prevent FSWs from using the HIV testing technology. It will also be important to clarify the window period in which HIV self-tests can detect HIV infection, and any misconceptions about oral fluid and HIV transmission during any pre-test training sessions.

5.2 Strengths and limitations

Our study has a number of important strengths, including the testing of two different HIV self-testing delivery models, a large sample size, low loss to follow-up, and the exclusive focus on FSWs – all of which means it provides an important contribution to literature on HIV self-testing among key populations. Randomization at the level of participant-peer educator groups also helped prevent spillover of the HIV self-testing interventions across study arms. Additionally, this design took advantage of existing peer educator networks in Kampala, enhancing the real-world applicability of the intervention.

Our study also has a number of limitations. First, we rely on self-reported outcomes, which could potentially be biased by social desirability and other reporting distortions. For example, participants who received an HIV self-test in the direct provision arm might feel shame for not using it and report HIV testing even if they did not actually test. Second, we only followed participants for four months, which is a relatively short duration. Participants who received an HIV self-test coupon might have needed a longer period of time to collect the self-test from a healthcare facility. Similarly, participants who tested HIV positive might have needed a longer period of time to link to care. Any delays in linkage to care for FSWs, however, are concerning because they have approximately five sexual partners on an average working night.

Based on the nature of our study design, the external validity of our results may additionally be limited. Since all participants in our study received peer educator inventions (which included condom distribution and encouragement to test for HIV), we were unable to measure the effect of HIV self-testing in the absence of these peer educator activities. The peer educator interventions may have increased HIV testing and linkage to care across study arms, thereby biasing our effect size estimates towards the null. Peer educators also reached out to FSWs within their social network and may have selected FSWs who they knew were more interested in HIV testing and likely to participate in the study – again inflating the effect of HIV self-testing among Kampala-based FSWs and biasing our findings towards the null. This study was able to take advantage of previously trained FSW peer educators, which may not exist in other settings. Peer educators can be expensive to train from scratch and support over time, which may additionally limit the scalability of our findings. FSWs in urban Kampala may also have better access to health services than FSWs in other settings as a result of MARPI, which provides FSWs with specialized HIV services. This might explain why HIV testing in the standard-of-care arm was so high at both one and four months.

5.3 Stakeholder engagement

We engaged stakeholders throughout the duration of the study. During the development stage, we met with members of the HIV prevention group from the MOH, as well as leaders of sex worker peer organizations (Women's Organization Network for Human Rights Advocacy and Health and Development Support Initiative). Prior to enrolling the first participants, we additionally met with members from these organizations and individuals from the Kampala City Council Authority, the Virus Research Institute, the National Drugs Authority and MARPI. Individuals from these organizations were invited to join the study's Scientific Oversight Committee, which was notified of all reported adverse events and met once to review an interim analysis. Individuals from MARPI were invited to assist with the two-day FSW peer educator training.

The results of this study were presented at meetings with the MOH and an HIV self-testing national dissemination event, entitled 'Improving access to HIV testing through self-testing: from research to policy to implementation'. The meetings and national dissemination were well attended and the MOH plans to move forward and incorporate HIV self-testing into their national HIV testing guidelines based on the results of this and other studies. Geoffrey Taasi from the MOH has helped to interpret study results and situate them in the context of the MOH's developing HIV self-testing strategy. He has presented the study results at international HIV conferences and is a co-author on a number of forthcoming publications related to HIV self-testing.

Figure 4: Study team at the Uganda HIV self-testing national dissemination event in Kampala, July 2017

Figure 5: Front page of the local newspaper the morning after Uganda's HIV self-testing national dissemination event

6. Specific findings for policy and practice

HIV self-testing, as compared with standard HIV testing and counseling services, increases universal and frequent HIV testing among Kampala-based FSWs without negatively affecting linkage to care outcomes. The uncertainty in our linkage to care outcomes, however, was large; thus, linkage to care following HIV self-testing remains an important concern when rolling out national HIV self-testing interventions.

Based on the results of this study, we have three recommendations for governments hoping to improve HIV testing outcomes among FSWs:

1. *Consider HIV self-testing* to increase universal and frequent HIV testing coverage among FSWs.
2. *Distribute HIV self-tests to FSWs directly using peer educators* for higher universality and frequent HIV testing coverage.
3. *Pair HIV self-testing with linkage to care enhancing interventions* to reduce potential delays in linkage to care that may be caused by self-testing.

In this study, we were unable to measure the effect of HIV self-testing in the absence of FSW peer educators, who encouraged all participants to test for HIV. It may be difficult to generalize study results to other SSA settings that have less-developed peer educator networks and fewer free HIV testing services for FSWs.

7. Conclusions

In sum, oral HIV self-testing could be an important arm of HIV policies to achieve near-universal and frequent HIV testing among FSWs. In designing HIV self-testing policies for FSWs, governments should consider direct provision of HIV self-tests to FSWs, rather than merely making HIV self-tests available in healthcare facilities. HIV self-testing policies for FSWs should be accompanied by strong interventions to support linkage to care.

Online appendices

Note to readers: These appendices are available online only and have not been copy-edited or formatted.

Online appendix A: Baseline questionnaire

http://www.3ieimpact.org/sites/default/files/2019-01/tw2223-hivst-hspot-appendix-a-baseline-questionnaire_0.pdf

Online appendix B: One-month follow-up questionnaire

http://www.3ieimpact.org/sites/default/files/2019-01/tw2223-hivst-hspot-appendix-b-one-month-questionnaire.pdf

Online appendix C: Four-month follow-up questionnaire

http://www.3ieimpact.org/sites/default/files/2019-01/tw2223-hivst-hspot-appendix-c-four-month-questionnaire_0.pdf

References

Arem, H, Nakyanjo, N, Kagaayi, J, Mulamba, J, Nakigozi, G, Serwadda, D, Quinn, TC, Gray, RH, Bollinger, RC, Reynolds, SJ and Chang, LW, 2011. Peer health workers and AIDS care in Rakai, Uganda: a mixed methods operations research evaluation of a cluster-randomized trial. *AIDS Patient Care STDs*, 25(12), pp.719–24. doi:10.1089/apc.2010.0349

Asiimwe, S, Oloya, J, Song, X and Whalen, CC, 2014. Accuracy of un-supervised versus provider-supervised self-administered HIV testing in Uganda: a randomized implementation trial. *AIDS and Behavior*, 18(12), pp.2477–84. doi:10.1007/s10461-014-0765-4

Ayles, H, Floyd, S, Mulubwa, C, Hensen, B, Schaap, A, Phiri, B, Shanaube, K, Simwinga, M, Bond, V, Fidler, S, Hayes, R and Mwinga, A, 2017. Increasing knowledge of HIV status among men: a cluster-randomised trial of community-based distribution of oral HIV self-test kits nested in four HPTN 071 communities in Zambia. Presented at the 9th International AIDS Society Conference on HIV Science, Paris, France.

Baral, S, Beyrer, C, Muessig, K, Poteat, T, Wirtz, AL, Decker, MR, Sherman, SG and Kerrigan, D, 2012. Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *The Lancet Infectious Diseases,* 12(7), pp.538–49. doi:10.1016/S1473-3099(12)70066-X

Bassett, IV, Wilson, D, Taaffe, J and Freedberg, KA, 2015. Financial incentives to improve progression through the HIV treatment cascade. *Current Opinion in HIV and AIDS,* 10(6), pp.451–63. doi:10.1097/COH.0000000000000196

Brown, AN, Djimeu, EW and Cameron, DB, 2014. A review of the evidence of harm from self-tests. *AIDS and Behavior*, 18(4), pp.445–49. doi:10.1007/s10461-014-0831-y

Brown, W, Carballo-Diéguez, A, John, RM and Schnall, R, 2016. Information, motivation, and behavioral skills of high-risk young adults to use the HIV self-test. *AIDS and Behavior*, 20(9), pp.2000–09. doi:10.1007/s10461-016-1309-x

Bunnell, R, Ekwaru, JP, Solberg, P, Wamai, N, Bikaako-Kajura, W, Were, W, Coutinho, A, Liechty, C, Madraa, E, Rutherford, G and Mermin, J, 2006a. Changes in sexual behavior and risk of HIV transmission after antiretroviral therapy and prevention interventions in rural Uganda. *AIDS (London, England)*, 20(1), pp.85–92.

Bunnell, R, Mermin, J and Cock, KMD, 2006b. HIV prevention for a threatened continent: implementing positive prevention in Africa. *JAMA,* 296(7), pp.855–58. doi:10.1001/jama.296.7.855

CDC, 2010. *The Crane Survey Report: High risk group surveys conducted in 2008/9, Kampala, Uganda.* Makerere University School of Public Health, Ugandan Ministry of Health, and PEPFAR, Centers for Disease Control and Prevention.

CDC, 2014. *Preexposure prophylaxis for the prevention of HIV infection in the United States - 2014; a clinical practice guideline*. Atlanta, GA: Centers for Disease Control and Prevention.

Chanda, M, Ortblad, K, Mwale, M, Chongo, S, Kanchele, C, Kamungoma, N, Fullem, A, Dunn, C, Barresi, L, Harling, G, Barnighausen, T and Oldenburg, C, 2017a. HIV self-testing among female sex workers in Zambia: A cluster randomized controlled trial. *PLoS Med*, 14(11), p. e1002442.

Chanda, M, Perez-Brumer, A, Ortblad, K, Mwale, M, Chongo, S, Kamungoma, N, Kanchele, C, Barresi, L, Barnighausen, T and Oldenburg, C, 2017b. Barriers and facilitators to HIV testing among Zambia female sex workers in three transit hubs. *AIDS Patient Care STDs*, 31(7), pp.290–96.

Chang, LW, Kagaayi, J, Nakigozi, G, Ssempijja, V, Packer, AH, Serwadda, D, Quinn, TC, Gray, RH, Bollinger, RC and Reynolds, SJ, 2010. Effect of peer health workers on AIDS care in Rakai, Uganda: a cluster-randomized trial. *PloS One*, 5(6), p. e10923.

Chersich, MF, Bosire, W, King'ola, N, Temmerman, M and Luchters, S, 2014. Effects of hazardous and harmful alcohol use on HIV incidence and sexual behaviour: a cohort study of Kenyan female sex workers. *Globalization and Health,* 10(22). doi:10.1186/1744-8603-10-22

Choko, AT, Desmond, N, Webb, EL, Chavula, K, Napierala-Mavedzenge, S, Gaydos, CA, Makombe, SD, Chunda, T, Squire, SB, French, N, Mwapasa, V and Corbett, EL, 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), p.e1001102. doi:10.1371/journal.pmed.1001102

Choko, AT, MacPherson, P, Webb, EL, Willey, BA, Feasy, H, Sambakunsi, R, Mdolo, A, Makombe, SD, Desmond, N, Hayes, R, Maheswaran, H and Corbett, EL, 2015. Uptake, accuracy, safety, and linkage into care over two years of promoting annual self-testing for HIV in Blantyre, Malawi: a community-based prospective study. *PLoS Med*, 12(9), p.e1001873. doi:10.1371/journal.pmed.1001873

Cohen, MS, Chen, YQ, McCauley, M, Gamble, T, Hosseinipour, MC, Kumarasamy, N, Hakim, JG, Kumwenda, J, Grinsztejn, B, Pilotto, JHS, Godbole, SV, Mehendale, S, Chariyalertsak, S, Santos, BR, Mayer, KH, Hoffman, IF, Eshleman, SH, Piwowar-Manning, E, Wang, L, Makhema, J, Mills, LA, de Bruyn, G, Sanne, I, Eron, J, Gallant, J, Havlir, D, Swindells, S, Ribaudo, H, Elharrar, V, Burns, D, Taha, TE, Nielsen-Saines, K, Celentano, D, Essex, M and Fleming, TR, 2011. Prevention of HIV-1 infection with early antiretroviral therapy. *New England Journal of Medicine*, 365(6), pp.493–505. doi:10.1056/NEJMoa1105243

Creswell, J, 2013. *Research design: qualitative, quantitative, and mixed methods approaches.* 4th ed. London: SAGE Publications.

Donnell, D, Baeten, JM, Kiarie, J, Thomas, KK, Stevens, W, Cohen, CR, McIntyre, J, Lingappa, JR and Celum, C, 2010. Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. *Lancet*, 375 (9731), pp.2092–98. doi:10.1016/S0140-6736(10)60705-2

Family Health International, 2009. *Behavioral Surveillance Survey Zambia, 2009: Female sex workers in border and transportation routes with trend analysis 2000-2009*. Zambia: Family Health International.

Figueroa, C, Johnson, C, Verster, A and Baggaley, R, 2015. Attitudes and acceptability on HIV self-testing among key populations: a literature review. *AIDS and Behavior*,19(11), pp.1–17. doi:10.1007/s10461-015-1097-8

Fox, MP and Rosen, S, 2017. A new cascade of HIV care for the era of "treat all." *PLoS Medicine*, 14(4), p.e1002268. doi:10.1371/journal.pmed.1002268

George, A and Blankenship, KM, 2015. Peer Outreach Work as Economic Activity: Implications for HIV Prevention Interventions among Female Sex Workers. *PLoS ONE*, 10(3), p.e0119729. doi:10.1371/journal.pone.0119729

Gichangi, A, Wambua, J, Gohole, A, Mutwiwa, S, Njogu, R and Bazant, E, 2016. Provision of oral HIV self-test kits triples uptake of HIV testing among male partners of antenatal care clients: results of a randomized trial in Kenya. Presented at the 21st International AIDS Conference, Durban, South Afirca.

Govindasamy, D, Meghij, J, Negussi, EK, Baggaley, RC, Ford, N and Kranzer, K, 2014. Interventions to improve or facilitate linkage to or retention in pre-ART (HIV) care and initiation of ART in low- and middle-income settings – a systematic review. *Journal of the International AIDS Society*, 17(1), pp.19032. doi:10.7448/IAS.17.1.19032

Haber, N, Tanser, F, Bor, J, Naidu, K, Mutevedzi, T, Herbst, K, Porter, K, Pillay, D and Bärnighausen, T, 2017. From HIV infection to therapeutic response: a population-based longitudinal HIV cascade-of-care study in KwaZulu-Natal, South Africa. *Lancet HIV*, 4(5), pp.PE223-E230. doi:10.1016/S2352-3018(16)30224-7

HIVST.org. HIV self-testing research and policy hub: Uganda, 2017. URL: hivst.org (accessed 9/8/17)

Iwuji, C, Orne-Gliemann, J and Balestre, E, 2016a. *The impact of universal test and treat on HIV incidence in a rural South African population: ANRS 12249 TasP trial*, *2012-2016.*

Iwuji, CC, Orne-Gliemann, J, Larmarange, J, Okesola, N, Tanser, F, Thiebaut, R, Rekacewicz, C, Newell, M-L, Dabis, F and ANRS 12249 TasP trial group, 2016b. Uptake of home-based HIV testing, linkage to care, and community attitudes about ART in rural KwaZulu-Natal, South Africa: descriptive results from the first phase of the ANRS 12249 TasP cluster-randomised trial. *PLoS Medicine*, 13(8), p.e1002107. doi:10.1371/journal.pmed.1002107

Jamil, MS, Prestage, G, Fairley, CK, Grulich, AE, Smith, KS, Chen, M, Holt, M, McNulty, AM, Bavinton, BR, Conway, DP, Wand, H, Keen, P, Bradley, J, Kolstee, J, Batrouney, C, Russell, D, Law, M, Kaldor, JM and Guy, RJ, 2017. Effect of availability of HIV self-testing on HIV testing frequency in gay and bisexual men at high risk of infection (FORTH): a waiting-list randomised controlled trial. *Lancet HIV*, 4(6), pp.e241–e250. doi:10.1016/S2352-3018(17)30023-1

Johnson, CC, Kennedy, C, Fonner, V, Siegfried, N, Figueroa, C, Dalal, S, Sands, A and Baggaley, R, 2017. Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis. *Journal of International AIDS Society*, 20(1), pp.21594. doi:10.7448/ias.20.1.21594

Kabiru, CW, Luke, N, Izugbara, CO and Zulu, EM, 2010. The correlates of HIV testing and impacts on sexual behavior: evidence from a life history study of young people in Kisumu, Kenya. *BMC Public Health*, 10, p.412. doi:10.1186/1471-2458-10-412

Katz, D, Golden, M, Hughes, J, Farquhar, 2015. HIV self-testing increases HIV testing frequency among high-risk men who have sex with men: a randomized controlled trial. Presented at the 8th Conference on HIV pathogenesis, treatment, and prevention, Vancouver, Canada.

Kennedy, CE, Medley, AM, Sweat, MD and O'Reilly, KR, 2010. Behavioural interventions for HIV positive prevention in developing countries: a systematic review and meta-analysis. *Bulletin of the World Health Organization*, 88(8), pp.615–23. doi:10.1590/S0042-96862010000800014

Kenyan Ministry of Health, 2015. *The Kenya HIV Testing Services Guidelines*. Nairobi: Kenyan Ministry of Health.

Kipp, W, Konde-Lule, J, Saunders, LD, Alibhai, A, Houston, S, Rubaale, T, Senthilselvan, A, Okech-Ojony, J and Kiweewa, F, 2010. Results of a community-based antiretroviral treatment program for HIV-1 infection in Western Uganda. *Current HIV Research*, 8(2), pp.179–85.

Kranzer, K, Govindasamy, D, Ford, N, Johnston, V and Lawn, SD, 2012. Quantifying and addressing losses along the continuum of care for people living with HIV infection in sub-Saharan Africa: a systematic review. *Journal of the International AIDS Society*, 15. doi:10.7448/ias.15.2.17383

Krause, J, Subklew-Sehume, F, Kenyon, C and Colebunders, R, 2013. Acceptability of HIV self-testing: a systematic literature review. *BMC Public Health* 13, p.735. doi:10.1186/1471-2458-13-735

Kumwenda, M, Munthali, A, Phiri, M, Mwale, D, Gutteberg, T, MacPherson, E, Theobald, S, Corbett, L and Desmond, N, 2014. Factors shaping initial decision-making to self-test amongst cohabiting couples in urban Blantyre, Malawi. *AIDS and Behavior*, 18 Suppl 4, S396-404. doi:10.1007/s10461-014-0817-9

Kurth, AE, Cleland, CM, Chhun, N, Sidle, JE, Were, E, Naanyu, V, Emonyi, W, Macharia, SM, Sang, E, Siika, AM, 2016. Accuracy and acceptability of oral fluid HIV self-testing in a general adult population in Kenya. *AIDS and Behaviour*, 20(4), pp.870–79. doi:10.1007/s10461-015-1213-9

L'akoa, RM, Noubiap, JJN, Fang, Y, Ntone, FE and Kuaban, C, 2013. Prevalence and correlates of depressive symptoms in HIV-positive patients: a cross-sectional study among newly diagnosed patients in Yaoundé, Cameroon. *BMC Psychiatry*, 13, p.28. doi:10.1186/1471-244X-13-228

Lancaster, KE, Lungu, T, Mmodzi, P, Hosseinipour, MC, Chadwick, K, Powers, KA, Pence, BW, Go, VF, Hoffman, IF, Miller, WC, 2017. The association between substance use and sub-optimal HIV treatment engagement among HIV-infected female sex workers in Lilongwe, Malawi. *AIDS Care*, 29(2), pp.197–203. doi:10.1080/09540121.2016.1211244

Masters, SH, Agot, K, Obonyo, B, Mavedzenge, SN, Maman, S, Thirumurthy, H, 2016. Promoting partner testing and couples testing through secondary distribution of HIV self-tests: a randomized clinical trial. *PLoS Medicine*, 13(11), p.e1002166. doi:10.1371/journal.pmed.1002166

Medley, A, Kennedy, C, O'Reilly, K and Sweat, M, 2009. Effectiveness of peer education interventions for HIV prevention in developing countries: a systematic review and meta-analysis. *AIDS Education and Prevention*, 21(3), pp.181–206. doi:10.1521/aeap.2009.21.3.181

Mokgatle, MM and Madiba, S, 2017. High acceptability of HIV self-testing among technical vocational education and training college students in Gauteng and north west province: what are the implications for the scale up in South Africa? *PLoS ONE*, 12(1), p.e0169765. doi:10.1371/journal.pone.0169765

Mugo, PM, Micheni, M, Shangala, J, Hussein, MH, Graham, SM, Wit, TFR de and Sanders, EJ, 2017. Uptake and acceptability of oral HIV self-testing among community pharmacy clients in Kenya: a feasibility study. *PLoS ONE*, 12(1), p.e0170868. doi:10.1371/journal.pone.0170868

Naigino, R, Makumbi, F, Mukose, A, Buregyeya, E, Arinaitwe, J, Musinguzi, J and Wanyenze, RK, 2017. HIV status disclosure and associated outcomes among pregnant women enrolled in antiretroviral therapy in Uganda: a mixed methods study. *Reproductive Health,* 14, p.107. doi:10.1186/s12978-017-0367-5

Napierala Mavedzenge, S, Baggaley, R and Corbett, EL, 2013. A review of self-testing for HIV: research and policy priorities in a new era of HIV prevention. *Clinical Infectious Diseases*, 57(1), pp.126–38. doi:10.1093/cid/cit156

Ngugi, EN, Roth, E, Mastin, T, Nderitu, MG and Yasmin, S, 2012. Female sex workers in Africa: epidemiology overview, data gaps, ways forward. *SAHARA-J: Journal of Social Aspects of HIV/AIDS* 9(3), 148–53. doi:10.1080/17290376.2012.743825

Ngure, K, Heffron, R, Mugo, N, Thomson, KA, Irungu, E, Njuguna, N, Mwaniki, L, Celum, C and Baeten, JM, 2017. Feasibility and acceptability of HIV self-testing among pre-exposure prophylaxis users in Kenya. *Journal of the International AIDS Society*, 20(1), p.21234. doi:10.7448/IAS.20.1.21234

Nsanzimana, S, Kanters, S, Remera, E, Forrest, JI, Binagwaho, A, Condo, J and Mills, EJ, 2015. HIV care continuum in Rwanda: a cross-sectional analysis of the national programme. *The Lancet HIV*, 2(5), pp.e208-215. doi:10.1016/S2352-3018(15)00024-7

Ortblad, K, Kibuuka Musoke, D, Ngabirano, T, Nakidende, A, Magoola, J, Kayiira, P, Taasi, G, Barresi, L, Haberer, JE, McConnell, M, Oldenburg, C and Barnighausen, T, 2017. Direct provision versus facility collection of HIV self-tests among female sex workers in Uganda: a cluster-randomized controlled health systems trial. *PLoS Medicine,* 14(11), p.e1002458. doi:10.1371/journal.pmed.1002458

Pai, NP, Sharma, J, Shivkumar, S, Pillay, S, Vadnais, C, Joseph, L, Dheda, K and Peeling, RW, 2013. Supervised and unsupervised self-testing for HIV in high- and low-risk populations: a systematic review. *PLoS Medicine*, 10(4), p.e1001414. doi:10.1371/journal.pmed.1001414

Pérez, GM, Cox, V, Ellman, T, Moore, A, Patten, G, Shroufi, A, Stinson, K, Cutsem, GV and Ibeto, M, 2016. "I know that I do have HIV but nobody saw me": oral HIV self-testing in an informal settlement in South Africa. *PLoS ONE*, 11(4), p.e0152653. doi:10.1371/journal.pone.0152653

Scorgie, F, Chersich, MF, Ntaganira, I, Gerbase, A, Lule, F and Lo, Y-R, 2012. Socio-demographic characteristics and behavioral risk factors of female sex workers in sub-saharan Africa: a systematic review. *AIDS and Behaviour*, 16(4), pp.920–33. doi:10.1007/s10461-011-9985-z

Scorgie, F, Nakato, D, Harper, E, Richter, M, Maseko, S, Nare, P, Smit, J, Chersich, M, 2013. "We are despised in the hospitals": sex workers' experiences of accessing health care in four African countries. *Culture, Health and Sexuality*, 15(4), pp.450–65. doi:10.1080/13691058.2012.763187

Shannon, K, Strathdee, SA, Goldenberg, SM, Duff, P, Mwangi, P, Rusakova, M, Reza-Paul, S, Lau, J, Deering, K, Pickles, MR and Boily, M-C, 2015. Global epidemiology of HIV among female sex workers: influence of structural determinants. *The Lancet*, 385(9962), pp.55–71. doi:10.1016/S0140-6736(14)60931-4

South African Pharmacy Council, 2013. *Annexure A: Rules Relating to Good Pharmacy Practice*. South Africa: The South African Pharmacy Council.

Stekler, JD, O'Neal, JD, Lane, A, Swanson, F, Maenza, J, Stevens, C, Coombs, RW, Dragavon, JA, Swenson, PD, Golden, MR and Branson, BM, 2013. Relative accuracy of serum, whole blood, and oral fluid HIV tests among Seattle men who have sex with men. *Journal of Clinical Virology*, 58 (Suppl 1), pp.e119-122. doi:10.1016/j.jcv.2013.09.018

Suntharasamai, P, Martin, M, Choopanya, K, Vanichseni, S, Sangkum, U, Tararut, P, Leelawiwat, W, Anekvorapong, R, Mock, PA, Cherdtrakulkiat, T, Leethochawalit, M, Chiamwongpaet, S, Gvetadze, RJ, McNicholl, JM, Paxton, LA, Kittimunkong, S and Curlin, ME, 2015. Assessment of oral fluid HIV test performance in an HIV pre-exposure prophylaxis trial in Bangkok, Thailand. *PLoS ONE*, 10(12), p. e0145859. doi:10.1371/journal.pone.0145859

Thirumurthy, H, Masters, SH, Mavedzenge, SN, Maman, S, Omanga, E and Agot, K, 2016. Promoting male partner HIV testing and safer sexual decision making through secondary distribution of self-tests by HIV-negative female sex workers and women receiving antenatal and post-partum care in Kenya: a cohort study. *The Lancet HIV*, 3(6), pp.e266-274. doi:10.1016/S2352-3018(16)00041-2

Ugandan Ministry of Health (MOH), 2016. *Consolidated Guidelines for Prevention and Treatment of HIV in Uganda.* Kampala: Ugandan Ministry of Health.

UNAIDS, 2014a. *The Gap Report*. Geneva: UNAIDS. Available at: <http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport/> [Accessed 18 September 2018].

UNAIDS, 2014b. *90–90–90 – An ambitious treatment target to help end the AIDS epidemic.* Geneva: UNAIDS. Available at: <http://www.unaids.org/sites/default/files/media_asset/90-90-90_en.pdf> [Accessed 18 September 2018].

UNAIDS, 2016. *Global AIDS Update 2016*. Geneva: UNAIDS.

UNAIDS, 2017. *Ending AIDS: Progress Towards the 90-90-90 Targets.* Geneva: UNAIDS. Available at: <http://www.unaids.org/sites/default/files/media_asset/Global_AIDS_update_2017_en.pdf> [Accessed 18 September 2018].

Wang, Z, Lau, J, Ip, M and Ho, S, 2016. A randomized controlled trial evaluating the efficacy of promoting HIV self-testing and online real-time counseling on increasing HIV testing among men who have sex with men in Hong Kong. Presented at the International Congress of Behavioral Medicine, Melbourne, Australia.

Wang, Z, Lau, J, Ip, M, Ho, S, Phoenix, K, Latkin, C, Ma, Y and Kim, Y, 2018. A randomized control trial evaluating efficacy of promoting home-based HIV self-testing with online counseling on increasing HIV testing among men who have sex with men. *AIDS and Behavior*, 22(1), pp.190–201. doi:10.1007/s10461-017-1887-2.

White, D, Wilson, KS, Masese, LN, Wanje, G, Jaoko, W, Mandaliya, K, Richardson, BA, Kinuthia, J, Simoni, JM and McClelland, RS, 2016. Alcohol use and associations with biological markers and self-reported indicators of unprotected sex in human immunodeficiency virus-positive female sex workers in Mombasa, Kenya. *Sexually Transmitted Diseases*, 43(10), pp.642–47. doi:10.1097/OLQ.0000000000000502

World Bank Group, 2017. PPP conversion factor, GDP (LCU per international $), n.d. Washington DC, USA.

WHO, 2015. *Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV*. Geneva: World Health Organization. Available at: <http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/> [Accessed 18 September 2018].

WHO, 2016. *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*. Geneva: World Health Organization.

Zerbe, A, DiCarlo, A, Mantell, J, Remien, R, Morris, D, Frederix, K, 2015. Acceptability and uptake of home-based HIV self-testing in Lesotho. 19th Conference on Retroviruses and Opportunistic Infections. 23–26 February 2015. Seattle, WA.

Zou, G, 2004. A modified poisson regression approach to prospective studies with binary data. *American Journal of Epidemiology*, 159(7), pp.702–06.

Other publications in the 3ie Impact Evaluation Report Series

The following reports are available from http://www.3ieimpact.org/evidence-hub/impact-evaluation-repository

Increasing female sex worker HIV testing: effects of peer educators and HIV self-tests in Zambia, 3ie Impact Evaluation Report 83. Chanda, MM, Ortblad, KF, Mwale, M, Chongo, S, Kanchele, C, Kamungoma, N, Fullem, A, Bärnighausen, T and Oldenburg, CE, 2018.

Community delivery of antiretroviral drugs: a non-inferiority matched-pair pragmatic cluster-randomized trial in Dar es Salaam, Tanzania, 3ie Impact Evaluation Report 82. Francis, JM, Geldsetzer, P, Asmus, G, Ulenga, N, Ambikapathi, R, Sando, D, Fawzi, W and Bärnighausen, T, 2018.

Nourishing the future: targeting infants and their caregivers to reduce undernutrition in rural China, 3ie Impact Evaluation Report 81. Cai, J, Luo, R, Li, H, Lien, J, Medina, A, Zhou, H and Zhang, L, 2018.

Impacts of the World Food Programme's interventions to treat malnutrition in Niger. 3ie Impact Evaluation Report 80. Brück, T, Ferguson, NTN, Ouédraogo, J and Ziegelhöfer, Z, 2018.

Impact evaluation of the World Food Programme's moderate acute malnutrition treatment and prevention programmes in Sudan. 3ie Impact Evaluation Report 79. Guevarra, E, Mandalazi, E, Balegamire, S, Albrektsen, K, Sadler, K, Abdelsalam, K, Urrea, G and Alawad, S, 2018.

Impact evaluation of WFP's programs targeting moderate acute malnutrition in humanitarian situations in Chad. 3ie Impact Evaluation Report 78. Saboya, M, Rudiger, J, Frize, J, Ruegenberg, D, Rodríguez Seco, A and McMillon, C, 2018.

Improving midday meal delivery and encouraging micronutrient fortification among children in India, 3ie Impact Evaluation Report 77. Shastry, GK, Berry, J, Mukherjee, P, Mehta, S and Ruebeck, H, 2018.

Evaluation of infant development centres: an early years intervention in Colombia, 3ie Impact Evaluation Report 76. Andrew, A, Attanasio, O, Bernal, R, Cordona, L, Krutikova, S, Heredia, DM, Medina, C, Peña, X, Rubio-Codina, M and Vera-Hernandez, M, 2018.

Can the wounds of war be healed? Experimental evidence on reconciliation in Sierra Leone. 3ie Impact Evaluation Report 75. Cilliers, J, Dube, O and Siddiqi, B, 2018.

Impact evaluation of the Menabe and Melaky development programme in Madagascar, 3ie Impact Evaluation Report 74. Ring, H, Morey, M, Kavanagh, E, Kamto, K, McCarthy, N, Brubaker, J and Rakotondrafara, C, 2018.

Impact evaluation of the Smallholder Dairy Commercialization Programme in Kenya, 3ie Impact Evaluation Report 73. Bonilla, J, McCarthy, N, Mugatha, S, Rai, N, Coombes, A and Brubaker, J, 2018.

Impact and adoption of risk-reducing drought-tolerant rice in India, 3ie Impact Evaluation Report 72. Yamano, T, Dar, MH, Panda, A, Gupta, I, Malabayabas, ML and Kelly, E, 2018.

Poverty and empowerment impacts of the Bihar Rural Livelihoods Project in India, 3ie Impact Evaluation Report 71. Hoffmann, V, Rao, V, Datta, U, Sanyal, P, Surendra, V and Majumdar, S 2018.

How should Tanzania use its natural gas? Citizens' views from a nationwide Deliberative Poll, 3ie Impact Evaluation Report 70. Birdsall, N, Fishkin, J, Haqqi, F, Kinyondo, A, Moyo, M, Richmond, J and Sandefur, J, 2018.

Impact evaluation of the conditional cash transfer program for secondary school attendance in Macedonia, 3ie Impact Evaluation Report 69. Armand, A and Carneiro, P, 2018.

Age at marriage, women's education, and mother and child outcomes in Bangladesh, 3ie Impact Evaluation Report 68. Field, E, Glennerster, R, Nazneen, S, Pimkina, S, Sen, I and Buchmann, N, 2018.

Evaluating agricultural information dissemination in western Kenya, 3ie Impact Evaluation Report 67. Fabregas, R, Kremer, M, Robinson, J and Schilbach, F, 2017.

General equilibrium impact assessment of the Productive Safety Net Program in Ethiopia, 3ie Impact Evaluation Report 66. Filipski, M, Taylor, JE, Abegaz, GA, Ferede, T, Taffesse, AS and Diao, X, 2017.

Impact of the Uddeepan programme on child health and nutrition in India, 3ie Impact Evaluation Report 65. Kochar, A, Sharma, A and Sharma, A, 2017.

Evaluating oral HIV self-testing to increase HIV testing uptake among truck drivers in Kenya, 3ie Impact Evaluation Report 64. Kelvin, EA, Mwai, E, Romo, ML, George, G, Govender, K, Mantell, JE, Strauss, M, Nyaga, EN and Odhiambo, JO, 2017.

Integration of EPI and paediatric HIV services for improved ART initiation in Zimbabwe, 3ie Impact Evaluation Report 63. Prescott, M, Boeke, C, Gotora, T, Mafaune, HW, Motsi, W, Graves, J, Mangwiro, A and McCarthy, E, 2017.

Increasing male partner HIV testing using self-test kits in Kenya, 3ie Impact Evaluation Report 62. Gichangi, A, Korte, JE, Wambua, J, Vrana, C and Stevens, D, 2017.

Evaluating the impact of community health worker integration into prevention of mother-to-child transmission of HIV services in Tanzania, 3ie Impact Evaluation Report 61. Nance, N, McCoy, S, Ngilangwa, D, Masanja, J, Njau, P and Noronha, R, 2017.

Using HIV self-testing to promote male partner and couples testing in Kenya, 3ie Impact Evaluation Report 60. Thirumurthy, H, Omanga, E, Obonyo, B, Masters, S and Agot, K, 2017.

Increasing male partner HIV self-testing at antenatal care clinics in Kenya, 3ie Impact Evaluation Report 59. Gichangi, A, Korte, JE, Wambua, J, Vrana, C and Stevens, D, 2017.

Impact of free availability of public childcare on labour supply and child development in Brazil, 3ie Impact Evaluation Report 58. Attanasio, O, Paes de Barros, R, Carneiro, P, Evans, D, Lima, L, Olinto, P and Schady, N, 2017.

Estimating the effects of a low-cost early stimulation and parenting education programme in Mexico, 3ie Impact Evaluation Report 57. Cardenas, S, Evans, D and Holland, P, 2017.

The Better Obstetrics in Rural Nigeria study: an impact evaluation of the Nigerian Midwives Service Scheme, 3ie Impact Evaluation Report 56. Okeke, E, Glick, P, Abubakar, IS, Chari, AV, Pitchforth, E, Exley, J, Bashir, U, Setodji, C, Gu, K and Onwujekwe, O, 2017.

The Productive Safety Net Programme in Ethiopia: impacts on children's schooling, labour and nutritional status, 3ie Impact Evaluation Report 55. Berhane, G, Hoddinott, J, Kumar, N and Margolies, A, 2016.

The impact of youth skills training on the financial behaviour, employability and educational choice in Morocco, 3ie Impact Evaluation Report 54. Bausch, J, Dyer, P, Gardiner, D, Kluve, J and Mizrokhi, E, 2016.

Using advertisements to create demand for voluntary medical male circumcision in South Africa, 3ie Impact Evaluation Report 53. Frade, S, Friedman, W, Rech, D and Wilson, N, 2016.

The use of peer referral incentives to increase demand for voluntary medical male circumcision in Zambia, 3ie Impact Evaluation Report 52. Zanolini, A, Bolton, C, Lyabola, LL, Phiri, G, Samona, A, Kaonga, A and Harsha Thirumurthy, H, 2016.

Using smartphone raffles to increase demand for voluntary medical male circumcision in Tanzania, 3ie Impact Evaluation Report 51. Mahler, H and Bazant, E, 2016.

Voluntary medical male circumcision uptake through soccer in Zimbabwe, 3ie Impact Evaluation Report 50. DeCelles, J, Kaufman, Z, Bhauti, K, Hershow, R, Weiss, H, Chaibva, C, Moyo, N, Braunschweig, E, Mantula, F, Hatzold, K and Ross, D, 2016.

Measuring the impact of SMS-based interventions on uptake of voluntary medical male circumcision in Zambia, 3ie Impact Evaluation Report 49. Leiby, K, Connor, A, Tsague, L, Sapele, C, Koanga, A, Kakaire, J and Wang, P, 2016.

Assessing the impact of delivering messages through intimate partners to create demand for voluntary medical male circumcision in Uganda, 3ie Impact Evaluation Report 48. Semeere, AS, Bbaale, DS, Castelnuovo, B, Kiragga, A, Kigozi, J, Muganzi, A, Kambugu, A and Coutinho, AG, 2016.

Optimising the use of economic interventions to increase demand for voluntary medical male circumcision in Kenya, 3ie Impact Evaluation Report 47. Thirumurthy, H, Omanga, E, Rao, SO, Murray, K, Masters, S and Agot, K, 2016.

The impact of earned and windfall cash transfers on livelihoods and conservation in Sierra Leone, 3ie Impact Evaluation Report 46. Bulte, E, Conteh, B, Kontoleon, A, List, J, Mokuwa, E, Richards, P, Turley, T and Voors, M, 2016.

Property tax experiment in Pakistan: Incentivising tax collection and improving performance, 3ie Impact Evaluation Report 45. Khan, A, Khwaja, A and Olken, B, 2016.

Impact of mobile message reminders on tuberculosis treatment outcomes in Pakistan, 3ie Impact Evaluation Report 44. Mohammed, S, Glennerster, R and Khan, A, 2016.

Making networks work for policy: Evidence from agricultural technology adoption in Malawi, 3ie Impact Evaluation Report 43. Beaman, L, BenYishay, A, Fatch, P, Magruder, J and Mobarak, AM, 2016.

Estimating the impact and cost-effectiveness of expanding access to secondary education in Ghana, 3ie Impact Evaluation Report 42. Dupas, P, Duflo, E and Kremer, M, 2016.

*Evaluating the effectiveness of computers as tutors in China, 3*ie Impact Evaluation Report 41. Mo, D, Bai, Y, Boswell, M and Rozelle, S, 2016.

Micro entrepreneurship support programme in Chile, 3ie Impact Evaluation Report 40. Martínez, CA, Puentes, EE and Ruiz-Tagle, JV, 2016.

Thirty-five years later: evaluating the impacts of a child health and family planning programme in Bangladesh, 3ie Impact Evaluation Report 39. Barham, T, Kuhn, R, Menken, J and Razzaque, A, 2016.

Effectiveness of a rural sanitation programme on diarrhoea, soil-transmitted helminth infection and malnutrition in India, 3ie Impact Evaluation Report 38. Clasen, T, Boisson, S, Routray, P, Torondel, B, Bell, M, Cumming, O, Ensink, J, Freeman, M and Jenkins, M, 2016.

Evaluating the impact of vocational education vouchers on out-of-school youth in Kenya, 3ie Impact Evaluation Report 37. Hicks, JH, Kremer, M, Mbiti, I and Miguel, E, 2016.

Removing barriers to higher education in Chile: evaluation of peer effects and scholarships for test preparation, 3ie Impact Evaluation Report 36. Banerjee, A, Duflo E and Gallego, F, 2016.

Sustainability of impact: dimensions of decline and persistence in adopting a biofortified crop in Uganda, 3ie Impact Evaluation Report 35. McNiven, S, Gilligan, DO and Hotz, C 2016.

A triple win? The impact of Tanzania's Joint Forest Management programme on livelihoods, governance and forests, 3ie Impact Evaluation Report 34. Persha, L and Meshack, C, 2016.

The effect of conditional transfers on intimate partner violence: evidence from Northern Ecuador, 3ie Impact Evaluation Report 33. Hidrobo, M, Peterman, A and Heise, L, 2016.

The effect of transfers and preschool on children's cognitive development in Uganda, 3ie Impact Evaluation Report 32. Gillian, DO and Roy, S, 2016.

Can egovernance reduce capture of public programmes? Experimental evidence from India's employment guarantee, 3ie Impact Evaluation Report 31. Banerjee, A, Duflo, E, Imbert, C, Mathew, S and Pande, R, 2015.

Improving maternal and child health in India: evaluating demand and supply strategies, 3ie Impact Evaluation Report 30. Mohanan, M, Miller, G, Forgia, GL, Shekhar, S and Singh, K, 2016.

Smallholder access to weather securities in India: demand and impact on production decisions, 3ie Impact Evaluation Report 28. Ceballos, F, Manuel, I, Robles, M and Butler, A, 2015.

What happens once the intervention ends? The medium-term impacts of a cash transfer programme in Malawi, 3ie Impact Evaluation Report 27. Baird, S, Chirwa, E, McIntosh, C and Özler, B, 2015.

Validation of hearing screening procedures in Ecuadorian schools, 3ie Impact Evaluation Report 26. Muñoz, K, White, K, Callow-Heusser, C and Ortiz, E, 2015.

Assessing the impact of farmer field schools on fertilizer use in China, 3ie Impact Evaluation Report 25. Burger, N, Fu, M, Gu, K, Jia, X, Kumar, KB and Mingliang, G, 2015.

The SASA! study: a cluster randomised trial to assess the impact of a violence and HIV prevention programme in Kampala, Uganda, 3ie Impact Evaluation Report 24. Watts, C, Devries, K, Kiss, L, Abramsky, T, Kyegombe, N and Michau, L, 2014.

Enhancing food production and food security through improved inputs: an evaluation of Tanzania's National Agricultural Input Voucher Scheme with a focus on gender impacts, 3ie Impact Evaluation Report 23. Gine, X, Patel, S, Cuellar-Martinez, C, McCoy, S and Lauren, R, 2015.

A wide angle view of learning: evaluation of the CCE and LEP programmes in Haryana, 3ie Impact Evaluation Report 22. Duflo, E, Berry, J, Mukerji, S and Shotland, M, 2015.

Shelter from the storm: upgrading housing infrastructure in Latin American slums, 3ie Impact Evaluation Report 21. Galiani, S, Gertler, P, Cooper, R, Martinez, S, Ross, A and Undurraga, R, 2015.

Environmental and socioeconomic impacts of Mexico's payments for ecosystem services programme, 3ie Impact Evaluation Report 20. Alix-Garcia, J, Aronson, G, Radeloff, V, Ramirez-Reyes, C, Shapiro, E, Sims, K and Yañez-Pagans, P, 2015.

A randomised evaluation of the effects of an agricultural insurance programme on rural households' behaviour: evidence from China, 3ie Impact Evaluation Report 19. Cai, J, de Janvry, A and Sadoulet, E, 2014.

Impact of malaria control and enhanced literacy instruction on educational outcomes among school children in Kenya: a multi-sectoral, prospective, randomised evaluation, 3ie Impact Evaluation Report 18. Brooker, S and Halliday, K, 2015.

Assessing long-term impacts of conditional cash transfers on children and young adults in rural Nicaragua, 3ie Impact Evaluation Report 17. Barham, T, Macours, K, Maluccio, JA, Regalia, F, Aguilera, V and Moncada, ME, 2014.

The impact of mother literacy and participation programmes on child learning: evidence from a randomised evaluation in India, 3ie Impact Evaluation Report 16. Banerji, R, Berry, J and Shortland, M, 2014.

A youth wage subsidy experiment for South Africa, 3ie Impact Evaluation Report 15. Levinsohn, J, Rankin, N, Roberts, G and Schöer, V, 2014.

Providing collateral and improving product market access for smallholder farmers: a randomised evaluation of inventory credit in Sierra Leone, 3ie Impact Evaluation Report 14. Casaburi, L, Glennerster, R, Suri, T and Kamara, S, 2014.

Scaling up male circumcision service provision: results from a randomised evaluation in Malawi, 3ie Impact Evaluation Report 13. Thornton, R, Chinkhumba, J, Godlonton, S and Pierotti, R, 2014.

Targeting the poor: evidence from a field experiment in Indonesia, 3ie Impact Evaluation Report 12. Atlas, V, Banerjee, A, Hanna, R, Olken, B, Wai-poi, M and Purnamasari, R, 2014.

An impact evaluation of information disclosure on elected representatives' performance: evidence from rural and urban India, 3ie Impact Evaluation Report 11. Banerjee, A, Duflo, E, Imbert, C, Pande, R, Walton, M and Mahapatra, B, 2014.

Truth-telling by third-party audits and the response of polluting firms: Experimental evidence from India, 3ie Impact Evaluation Report 10. Duflo, E, Greenstone, M, Pande, R and Ryan, N, 2013.

No margin, no mission? Evaluating the role of incentives in the distribution of public goods in Zambia, 3ie Impact Evaluation Report 9. Ashraf, N, Bandiera, O and Jack, K, 2013.

Paying for performance in China's battle against anaemia, 3ie Impact Evaluation Report 8. Zhang, L, Rozelle, S and Shi, Y, 2013.

Social and economic impacts of Tuungane: final report on the effects of a community-driven reconstruction programme in the Democratic Republic of Congo, 3ie Impact Evaluation Report 7. Humphreys, M, Sanchez de la Sierra, R and van der Windt, P, 2013.

The impact of daycare on maternal labour supply and child development in Mexico, 3ie Impact Evaluation Report 6. Angeles, G, Gadsden, P, Galiani, S, Gertler, P, Herrera, A, Kariger, P and Seira, E, 2014.

Impact evaluation of the non-contributory social pension programme 70 y más in Mexico, 3ie Impact Evaluation Report 5. Rodríguez, A, Espinoza, B, Tamayo, K, Pereda, P, Góngora, V, Tagliaferro, G and Solís, M, 2014.

Does marginal cost pricing of electricity affect groundwater pumping behaviour of farmers? Evidence from India, 3ie Impact Evaluation Report 4. Meenakshi, JV, Banerji, A, Mukherji, A and Gupta, A, 2013.

The GoBifo project evaluation report: Assessing the impacts of community-driven development in Sierra Leone, 3ie Impact Evaluation Report 3. Casey, K, Glennerster, R and Miguel, E, 2013.

A rapid assessment randomised-controlled trial of improved cookstoves in rural Ghana, 3ie Impact Evaluation Report 2. Burwen, J and Levine, DI, 2012.

The promise of preschool in Africa: A randomised impact evaluation of early childhood development in rural Mozambique, 3ie Impact Evaluation Report 1. Martinez, S, Naudeau, S and Pereira, V, 2012.

Female sex workers are at higher risk for acquiring HIV than others. In many countries, including Uganda, sex work is illegal and stigmatized. Reaching them with HIV testing services can be difficult; HIV self-testing is a way for people to test with privacy at a location of their choosing. This study tested two different delivery methods using peer educators who were former and current female sex workers with connections in their community. The study found that direct provision was more effective than either referral or the offer of a coupon. There was no difference in accessing medical care after the test between the different groups.

Impact Evaluation Series

International Initiative for Impact Evaluation
202-203, Rectangle One
D-4, Saket District Centre
New Delhi – 110017
India

3ie@3ieimpact.org
Tel: +91 11 4989 4444

www.3ieimpact.org