Direct provision versus facility collection: a randomized controlled health systems trial of HIV self-testing among female sex workers in Uganda

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Note to readers

This impact evaluation has been submitted in partial fulfilment of the requirements of grant TW2.2.23 issued under Thematic Window 2. This version is being published online as it was received. A copy-edited and formatted version will be available in the 3ie Impact Evaluation Report Series in the near future. All content is the sole responsibility of the authors and does not represent the opinions of 3ie, its donors or its board of commissioners. Any errors and omissions are the sole responsibility of the authors. All affiliations of the authors listed in the title page are those that were in effect at the time the report was accepted. Any comments or queries should be directed to the corresponding author, Katrina Ortblad at katrina.ortblad@mail.harvard.edu. This trial is registered at ClinicalTrials.gov (NCT02846402).

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Summary

HIV self-testing allows for HIV testing away from a health facility, without interaction with a health provider. It may be particularly useful for female sex workers (FSWs), who are recommended to test for HIV every 3 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 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, 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 where peer educators distributed condoms and referred participants to free HIV testing services. In the intervention arms, peer educators distributed HIV self-tests/coupons at the first and fourth peer educator visits (three months apart). The participants completed baseline assessments and two follow-up assessments, one month and four months following the first peer educator visits.

We randomized 120 peer educator groups (960 participants) from October 18 to November 16, 2016. Participant follow-up was 96.4% (925/960) at one month and 89.6% (860/960) at four months. 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 ART initiation. Repeat HIV testing and facility-based testing were not pre-specified outcomes but 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 study arms. At one month, 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% (263/302) of participants in the standard-of-care arm tested had tested for HIV since the start of the study.

Participants in the peer provision arm were significantly more likely to have tested for HIV than those in the standard-of-care arm (one month: RR 1.33, 95% CI 1.17-1.52, $p<0.001$; four month: RR 1.14, 95% CI 1.07-1.22, $p<0.001$) and those in the facility collection arm (one month: RR 1.18, 95% CI 1.07-1.31, $p=0.001$; four month: RR 1.03, 95% CI 1.01-1.05, $p=0.02$). At four months, participants in the peer 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 ART 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 HIV self-testing delivery model to matter – direct provision of

HIV self-tests was more effective at 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 (TasP), behavioral change for transmission reduction, and potentially pre-exposure prophylaxis (PrEP).

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Abbreviations and acronyms

ART	Antiretroviral treatment
CI	Confidence interval
FSW	Female sex worker
HIVST	HIV self-testing
HTC	HIV testing and counseling
IPV	Intimate partner violence
IQR	Interquartile range
PrEP	HIV pre-exposure prophylaxis
SSA	Sub-Saharan Africa
TasP	HIV 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 for HIV status knowledge, and subsequently for linkage to care, antiretroviral therapy (ART) initiation and viral suppression (UNAIDS, 2017; Cohen et al., 2011; Donnell et al., 2010). In sub-Saharan Africa (SSA), an estimated 70-80% of people living with HIV know their HIV status (UNAIDS, 2017; Haber et al., 2017; C. Iwuji et al., 2016; 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 – have 90% of all people living with HIV know their HIV status (UNAIDS, 2017; Fox and Rosen, 2017).

Frequent HIV testing is recommended for key populations that face the highest risk of HIV infection. Female sex workers (FSWs) and their clients are the largest of these key populations in SSA. In sub-SSA, FSWs have approximately five times the prevalence of HIV compared to the general population (Baral et al., 2012; WHO, 2016; UNAIDS, 2014; Shannon et al., 2015). The World Health Organization recommends that FSWs test for HIV every three months (Cohen et al., 2011; WHO, 2016; CDC, 2014; WHO, 2015; Donnell et al., 2010). 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., 2017; WHO, 2016; Napierala Mavedzenge et al., 2013; UNAIDS, 2014). HIV self-testing may affect HIV testing among FSW because: it does not require an interaction with a healthcare provider; it does not require travel to a facility; and it can be carried out in any space and at any time.

Despite these advantages, few countries in SSA have introduced HIV self-testing because of concerns related to safety 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). Often cited concerns related to HIV self-testing are that testing outside a health facility and decoupling testing and counseling may result in social or emotional harms or poor linkage to care among individuals who test HIV-positive (Brown et al., 2014). 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 sub-populations (Ayles et al., 2017): the male partners of women at antenatal care clinic (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, 2017). This trial (Ortblad et al., 2017), with a similar trial by the same team in Zambia (Chanda et al., 2017a), are 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 compared to standard of care. The effectiveness of HIV self-testing will likely depend on the

approach that is used to deliver it. In this study, we thus aim to establish the effectiveness of two different HIV self-testing delivery models: (1) direct peer provision of an oral HIV self-test, and (2) peer provision of a coupon, exchangeable at ten specified private healthcare facilities throughout Kampala for collection of an oral 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 barrier to HIV testing (Chanda et al., 2017; WHO, 2016; Napierala Mavedzenge et al., 2013; UNAIDS, 2014). 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, but they but 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 to 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 ("Policy & Regulations for HIVST," 2017).

The same barriers that may have prevented FSWs from testing at healthcare facilities (Chanda et al., 2017; WHO, 2016; Napierala Mavedzenge et al., 2013; UNAIDS, 2014), however, 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 to 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 linkage 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 from the Office of Human Research Administration (OHRA) 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% (UNAIDS, 2017). This study was conducted in Uganda's capital city, Kampala, which has an estimated 13 thousand FSWs.

About one in three FSWs in Kampala is HIV-positive (*The Crane Survey: Female sex workers (FSW) in Kampala*, 2009). The Ugandan Ministry of Health (MOH) priorities FSWs for health and HIV prevention interventions. Through the Most at Risk Population Initiative (MAPRI), 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 (NGOs) operating within Kampala. These NGOs help 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 HIV self-testing guidelines (Ugandan MOH, 2016; "Policy & Regulations for HIVST," 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 arm received four peer educator visits, including condom distribution and referral to free HIV testing services. In the HIV self-testing interventions arms, peer educators additionally distributed HIV self-test/coupons at the first and four peer educator visit (three months apart). 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 for this study for 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 thus especially 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 been previously 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 NGOs and MAPRI clinics helped us recruit peer educators for this study. We recruited peer educators that had previously worked with these organizations 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 the self-test, interpret the results, and link to care following potential results.

We paid the peer educators 90,000 UGX for each of their four visits. This is equivalence to ~25 USD at market exchange rates or ~79 USD after adjusting for purchasing power (PPP) in Uganda (World Bank, 2017). As a reference, the majority of FSW participants in our study made between 100 to 440 PPP-adjusted USD per month and the median price participants charged for vaginal sex with a condom was ~6 PPP-adjusted USD (interquartile range: ~4 to ~9 PPP-adjusted USD).

3. Methodology

3.1. Participant recruitment and eligibility

The peer educators recruited potential study participants. We encouraged peer educator to recruit FSWs they already knew to ensure trust, which was particularly important for this study because HIV self-testing is 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 were: (1) 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 (>3 months prior), and (4) Kampala-based.

3.2. Randomization

Peer educator-participant groups were randomized 1:1:1 to one of three study arms. The author CEO developed the randomization list in R Studio (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 to 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 ten 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 MARPI healthcare facilities within Kampala, it might be difficult for participants to reach these facilities and these facilities differ from where self-tests were distributed 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 they 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 individual visits (to ensure the confidentiality of participants who tested HIV-positive or wanted to report adverse events).

At the first peer educator 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 test again in three months if they self-tested HIV-negative. Research assistants attended all of the first peer educator visits to ensure quality and consistency of information being 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 peer educator visit) and again three months later (fourth peer educator visit). Participants in the intervention arms were to only receive 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 ten 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 ten 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, 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]Interventions 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 ten 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), **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 16,500 UGX upon completion of each assessment. This is equivalent to ~14 purchasing power parity (PPP)-adjusted USD (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), 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 later 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% 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% 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 to participants in this survey as a result of our inclusion criteria and short follow-up period. Additionally, we assumed that 25% of our sample would be lost to follow-up because FSWs are a highly mobile population.

We estimated that 960 participants (120 peer educators groups), 320 participants (40 peer educator groups) per arm, would detect a risk ratio of 1.25 in the pooled HIV self-testing arms compared to 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% power to detect a risk ratio of 1.18 or

larger in the direct provision arm compared to 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 had one team leader for every three research assistants and 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 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 KFO checked the quality of the incoming data daily. If a quantitative interview was not complete, responses looked abnormal, or the interview was not conducted within the scheduled time frame, KFO 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 this data in a peer educator visit tracking sheet. At four months, research assistants asked participants if they 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 received from their peer educator over the duration of the study and what they did 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 (Poisson distribution, log link, robust standard errors) (Zou, 2004) with a study arm fixed effect and peer educator random effect. We choose 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 sub-group analysis where we calculated risk ratios (mixed-effects linear models described above) for participants that tested for HIV in the past 12 months and more than 12 months ago at baseline. Fourth, for the linkage to care outcomes, we limited the sample to just participants who reported testing HIV-positive at 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 the administrative data we kept on costs and evidence generated from this study on 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 an NGO 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 ~7.4 USD (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% (N=48) of study participants at the baseline assessment and again at the four-month assessment (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 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 and then these were transferred to ATLAS.ti (Berlin, Germany), a qualitative research software. 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 SWOT analysis: strengths, weaknesses, opportunities, and threats (Creswell, 2013).

4. Results

4.1. Participant recruitment and flow

From October to November 2016, 1,587 potential participants were screened for eligibility by research assistants over the phone. Among those, 997 were invited for an in-person eligibility assessment and 960 participants (120 peer educator groups) were enrolled and randomized, **Figure 1**. The most common reasons for exclusion were recent HIV testing (<3 months) (52%, 325/624) and self-reported HIV-positive status (43%, 267/624). Three participants dropped prior to randomization because the peer educator who recruited them left the study and had to be replaced. 37 peer educator groups (296 participants) were randomized to the peer provision arm, 42 peer educator groups (328 participants) to the facility pick-up arm, and 41 peer educator groups (336 participants) to the standard-of-care arm. Participant retention at one month and at four months was 96% (925/960) and 90% (860/960), respectively. There were no statistically significant difference in loss to follow-up across study arms.

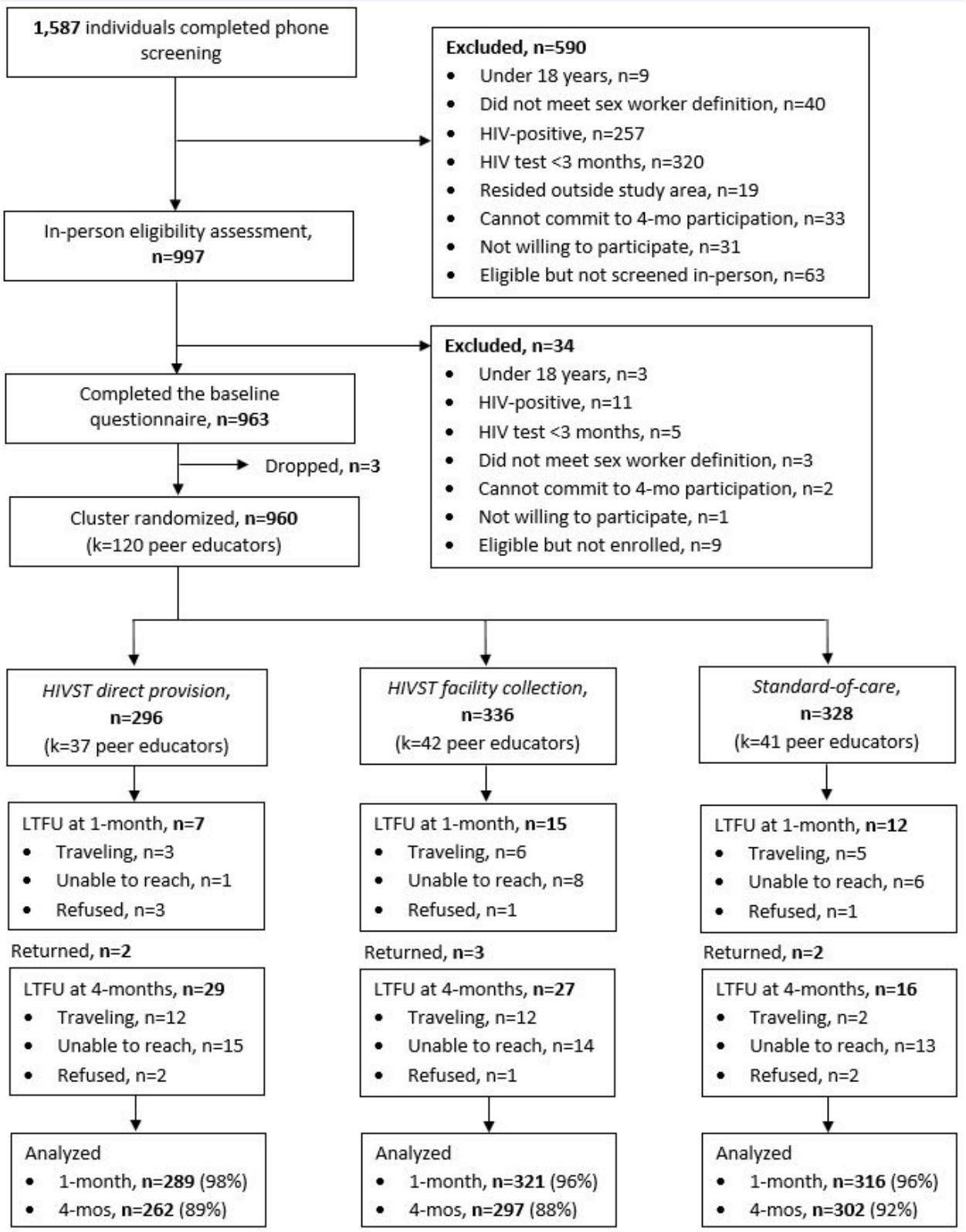

Figure 1. Flow of study participants.

4.2. Baseline characteristics

Baseline characteristics of the 960 randomized participants were balanced across the three study arms, **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 (59.2%, 568/960) and could read and write (85.7%, 819/960). On an average working night, participants reported a median of 5 clients (IQR: 4 to 7 clients) and 40.8% (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 (58.9%, 630/960) and testing at a healthcare facility at their last HIV test (72.1%, 692/960). Only 5.9% (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 (47.5%, 455/960; physical 36.4%, 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 (83.3%)	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 (15.6%)
$35.67-$74.32	90 (30.4%)	117 (35.2%)	125 (38.3%)
$74.32-$148.64	104 (35.1%)	107 (32.2%)	117 (35.9%)
$148.64-$297.28	31 (10.5%)	25 (7.5%)	29 (8.9%)
>$297.28	4 (1.4%)	7 (2.1%)	3 (0.9%)
Years in sex work (med, IQR)	5 (3 to 8)	5 (3 to 8)	5 (3 to 8)
Client per night (med, IQR)	5 (4 to 7)	5 (4 to 7)	5 (4 to 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 (35.3%)
Sexual	89 (30.1%)	105 (31.3%)	94 (28.8%)
Any	141 (47.6%)	167 (49.7%)	147 (45.1%)

[1]Price categories in US dollars (USD); October 10th, 2016 exchange rate (1 USD = 3363.85 Ugandan Shillings).
[2]Includes public and private sector, or antenatal care clinic, other locations included: home, work, 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 by a new peer educator 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 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% (233/262) reported receiving two HIV self-tests from their peer educator. Among participants in the facility collection arm, 89.9% (267/297) reported receiving two HIV self-test coupons from their peer educator and 72.4% (215/297) reported exchanging two coupons for HIV self-tests at participating health facilities. Only 1.1% (3/262) of participants in the direct provision arm and 0.7% (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 all participants reported receiving condoms at every peer educator visit (peer provision 76.0%, 199/262; facility pick-up 73.1%, 217/297; standard-of-care 76.7%, 231/301); there were no statistically significant differences in this outcome across study arms.

An unexpected event that occurred during implementation was that some peer educators in the HIV self-testing facility pick-up arm took the coupons for participants in their group and picked up HIV self-tests at a 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.

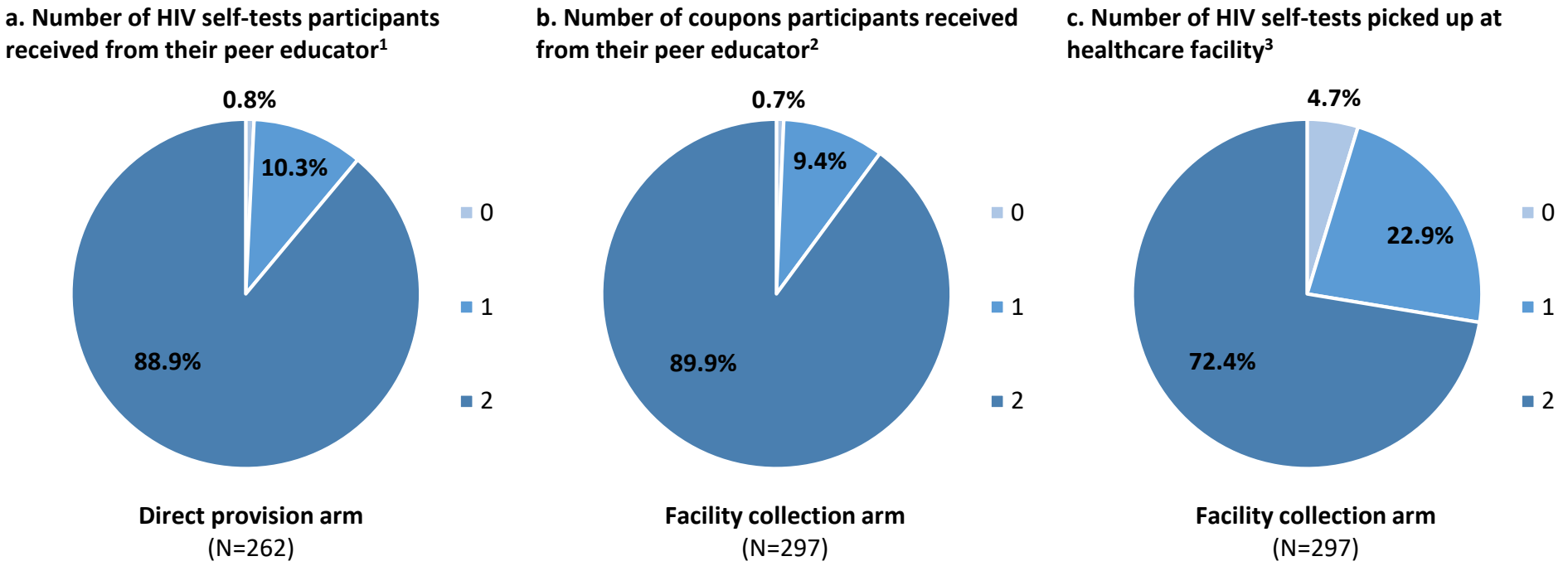

Figure 2. Implementation activities reported by participants at four months

[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% (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% (2/297) of participants reported receiving more than two coupons

[3]Picking up HIV self-test at a healthcare facility is along the causal pathway to HIV testing for participants in the facility collection arm. Participants had to have received a coupon from their peer educator to pick-up a HIV self-test from a healthcare facility.

4.4. Primary outcome

Any HIV testing at one month (past month) was highest in the direct provision arm (95.2%, 275/289) compared to the facility collection arm (80.4%, 258/321) and standard-of-care (71.5%, 226/316) arm, **Table 3**. Participants in the direct provision arm were 1.18 times (95% CI 1.09 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 compared to participants in the facility collection arm and standard-of-care arm, respectively, **Figure 3 & 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 peer 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 of the HIV self-testing arms were significantly more likely to test for HIV in the past four months compared to participants in the standard-of-care arm (direct provision RR: 1.11, 95% CI 1.04 to 1.19, p = 0.002; facility collection RR: 1.14 times, 95% CI 1.07 to 1.22, $p < 0.001$), **Figure 3 & Table 4**. Participants in the direct provision arm were significantly more likely to test for HIV in the past four months compared to participant in the facility collection arm (RR 1.03, 95% CI 1.01 to 1.05, p = 0.02), **Figure 3 & Table 4**.

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

Outcome[1]	One month			Four months		
	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	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[2]						
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]For these outcomes, participants had to report both testing HIV-positive and seeking HIV-related medical care or initiating ARTs.

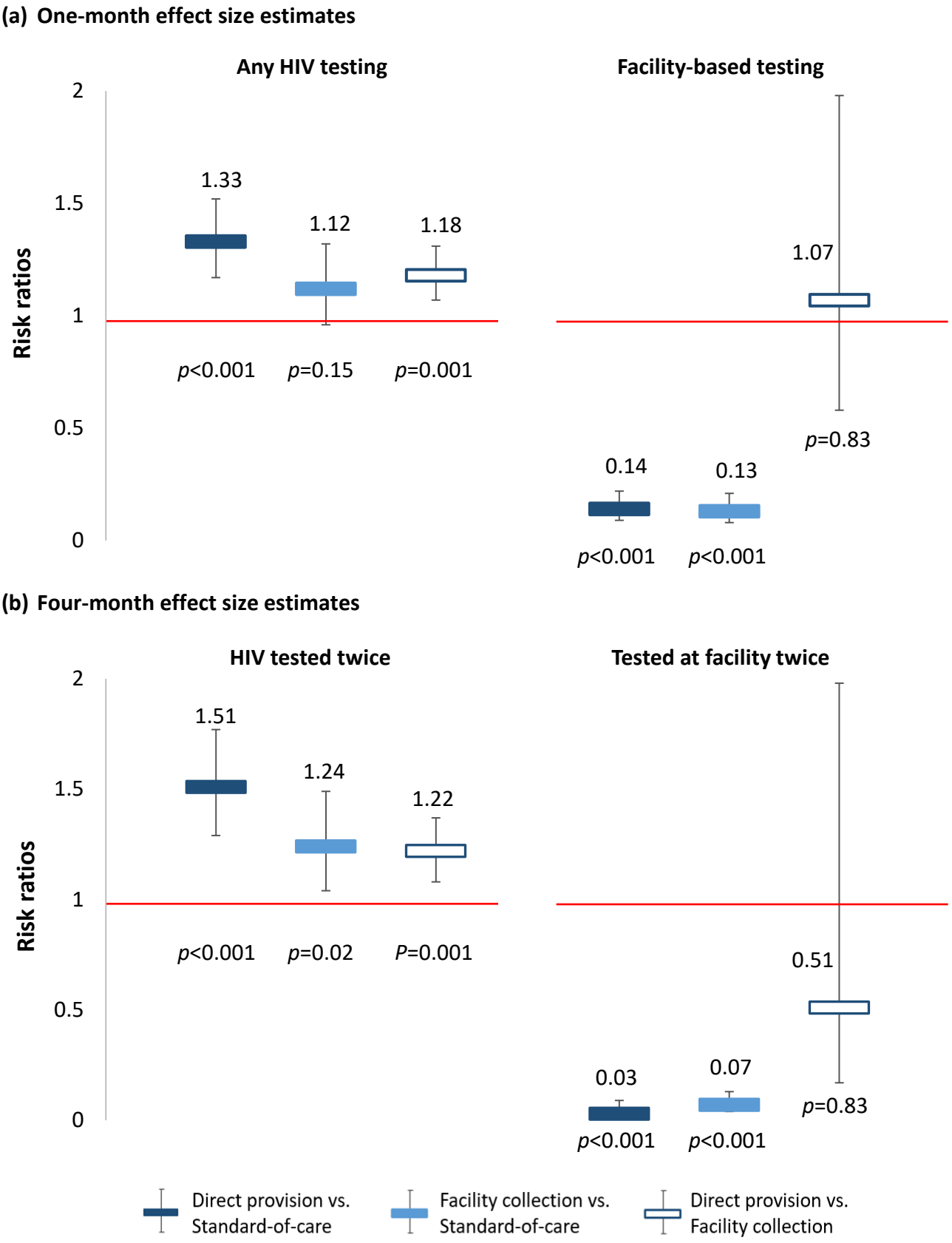

Figure 3. Effect size estimates for impact of HIV self-testing on HIV self-testing outcomes at (a) one month and (b) four months. All outcomes since study-start; facility-based testing includes private and public health facilities. Comparisons between study arms: direct provision versus standard-of-care (dark blue), facility collection versus standard-of-care (light blue), direct provision versus facility collection (hollow blue).

Table 4. Effect size estimates, risk ratios (RR): 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 1.52)	<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 (0.30-1.41)	0.275	0.50 (0.24-1.04)	0.063	1.30 (0.54-3.15)	0.557
	Four months	0.83 (0.49-1.41)	0.482	1.01 (0.62-1.65)	0.967	0.82 (0.46-1.44)	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 ARTs 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 compared to 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 2 & Table 4.** Participants in 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 compared to those in the facility collection HIV self-testing arm, **Figure 2 & Table 4**.

Facility-based HIV testing (i.e., public of private sector) was significantly less in the HIV self-testing arms compared to the standard-of-care arm at one month and at four months, **Figure 2 & Table 4.** At four months, participants in the direct provision arm and facility collection arm were 0.25 times (95% CI 0.18 to 0.34, $p < 0.001$) and 0.29 times (95% CI 0.23 to 0.37, $p < 0.001$) as likely to test at a health facility compared to those in the standard-of-care arm, respectively, **Figure 2 & 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 no statistically significant differences in testing HIV-positive at 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 to 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, $p = 0.03$), **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 to the standard-of-care arm, the significance of our effect size estimates were consistent with those calculated 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 test for HIV in the past month compared to those in the standard-of-care arm at one month, and 1.33 times (95% CI 1.05 to 1.21, $p < 0.001$) as likely to test for HIV in the past four months compared to the standard-of-care arm at four months.

The significance of our 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, participants in the direct provision arm were 24.4% (95% CI 14.1% to 34.7%, $p < 0.001$) and 14.5% (95% CI 4.2% to 24.8%, $p = 0.01$) more likely to test for HIV in the past month compared to the standard-of-care arm and facility collection arm at one month, respectively. At four months, participants in the direct provision arm were 13.1% (7.9% to 18.4%, $p < 0.001$) more likely and participants in the facility

collection arm were 10.7% (5.6% to 15.7%, $p < 0.001$) more likely to test for HIV in the past four months compared to participants in the standard-of-care arm.

There were no differences in the significance of our HIV testing outcomes in the sensitivity analysis that measured effect sizes among participants who reported testing for HIV in the past 12 months at baseline and participants that 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 test for HIV since the start of the study 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 1.11, 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 to 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 few participants in the facility collection arm sought HIV-related medical care at one month and at four months compared to 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 at 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-test arms versus the standard-of-care arm – percentages and effect size estimates, risk ratios (RR)

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

Abbreviations: CI = confidence interval; sig = significance; p-val = p-value.

*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 ARTs. 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 (RR)

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 ARTs 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 (RR)

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 (0.39-1.20)	0.182	0.38 (0.21-0.67)	0.001	1.81 (0.87-3.75)	0.111
	Four months	0.88 (0.62-1.24)	0.461	0.66 (0.47-0.94)	0.021	1.33 (0.88-2.01)	0.182
ART initiation	One month	1.00 (0.49-2.04)	1.00	0.56 (0.25-1.23)	0.146	1.80 (0.77-4.20)	0.173
	Four months	0.95 (0.57-1.59)	0.856	0.75 (0.46-1.22)	0.240	1.28 (0.76-2.15)	0.352
Linkage to care[3], adjusted[4]							
Seek HIV-related medical care	One month	0.72 (0.45-1.17)	0.186	0.41 (0.23-0.75)	0.004	1.75 (0.87-3.52)	0.114
	Four months	0.86 (0.63-1.18)	0.365	0.66 (0.47-0.94)	0.020	1.30 (0.86-1.97)	0.208
ART initiation	One month	1.10 (0.56-2.16)	0.782	0.61 (0.26-1.44)	0.260	1.81 (0.78-4.17)	0.165
	Four months	0.97 (0.59-1.57)	0.886	0.77 (0.49-1.22)	0.270	1.25 (0.75-2.09)	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 ARTs.
[4]Analysis adjusted for age, age^2, highest level of education and monthly income.

4.7. Adverse events

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

Two additional events related to study participation, but not HIV self-testing were reported throughout the duration of the study. Both of these events were interpersonal violence related to FSW status disclosure and both were 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 $30 USD. At ~$7 USD per self-test (what we paid for self-test), the cost per participant in the direct provision arm was $44 USD and the cost per participant in the facility collection arm was $46 USD. 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 1000			
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	$4381	$4973	$0
Private clinic support	$0	$427	$0
Hotline support	$112	$127	$124
Management salaries	$4522	$5126	$5005
Peer educator salaries	$3676	$4172	$4073
Cumulative costs, USD			
Total	$13,137	$15,351	$9,697
Cost/participant	$44	$46	$30
Cost for population of 1000	$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 1000 FSWs, 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 to standard-of-care at one month. 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 compare to standard-of-care. In this pseudo population of 1000, direct delivery of HIV self-test was $14,817 USD more than referral to standard HIV testing services and facility collection of HIV self-tests was $16,124 USD more.

The incremental cost-effectiveness for each additional FSW who tested for HIV is $63 USD with direct provision and $181 USD with facility collection at one month, **Table 9**. At four months, the incremental cost-effectiveness for each additional FSW who tested for HIV is $119 USD with direct

provision and $163 for facility collection. The incremental cost-effectiveness for each FSW who tested twice for HIV at four months was $50 with direct provision and $117 with facility collection compared to referral to standard HIV testing services. Direct provision of HIV self-test is more cost effective that facility collection of HIV self-tests because overall costs for this delivery method were lower and the effect estimates were larger compared to 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 HIV self-testing. The median age of these FSWs was 30 years (IQR 26 to 33 years), 86% (25/30) self-reported the ability to read and write, and 36% (8/22) were biologically confirmed to be living with HIV. The majority of the 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 • Don't 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. An often 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*

Not having to go to a healthcare facility and spend time waiting in line, receive repeated counseling, face judgement/stigma from healthcare providers, and spend money on transportation was another often described strength of HIV self-testing.

> "*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-test 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 also 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" (e.g., sex without a condom) to confirm he is HIV-negative before engaging in that activity. Other FSWs described 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, HIV self-tests can be distributed throughout existing social networks to access individuals who might have never otherwise tested for HIV. Individuals who previously were not interested in HIV testing, might also be interested in testing for HIV for the first time with a self-test because of the increased privacy and convenience of HIV self-testing.

> *"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 threats to HIV self-testing 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 threat that the testing technology may result in false perceptions of HIV transmission among FSWs. This could potentially 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 test twice for HIV compared to 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).

For 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 pre-requisite for PrEP, which is becoming increasingly available to FSWs in sub-Saharan Africa. PrEP requires frequent HIV testing to detect break-through 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 accuracy detect early HIV infection (Stekler et al., 2013). If HIV self-testing availability increases the likelihood of HIV testing, however, even with PrEP, the benefits should be weighed.

For the health of others, frequent HIV testing is necessary for successful 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 are thus at very risk of spreading the virus following infection (Baral et al., 2012; Shannon et al., 2015; *The Gap Report*, 2014). 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 overall effective in increasing recent and frequent HIV testing, the effectiveness of one of the two delivery models that we tested – direct provision of HIV self-tests – is substantially better than the effectiveness of the other model – facility collection of HIV self-tests. This result is highly plausible. 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 or time, for HIV testing. In contrast, facility collection requires FSWs to interact with health workers, implying the potential risk of provider stigma. Moreover, to collect an HIV self-test in a healthcare facility FSWs still need to travel to a facility during operating hours, incurring monetary transport and time cost that are similar to 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 sub-Saharan Africa will chose. 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 sub-Saharan Africa 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 lack the 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 Ugandan and other sub-Saharan African settings. (George and Blankenship, 2015; Medley et al., 2009)

Another important secondary finding of our study is that the 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 ten percent of all testing was facility-based in the self-testing intervention arms, while more than sixty percent 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 eighty percent 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 saving of money and time, which 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 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 self-test 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 of self-test results 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 the worry 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 to 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 compared to those 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 the remaining money or time to return to the healthcare facilities for linkage to care. However, because this analysis conditions on 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 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 compared to those in the standard-of-care arm (there were no statistically significant differences between the peer 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 studies will require substantial investments because compared to previous studies (Gichangi et al., 2016; Johnson et al., 2017; Masters et al., 2016; Thirumurthy et al., 2016), in this study a large number of people (a total of 177 across the three arms) tested HIV-positive 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 (C. C. Iwuji et al., 2016; 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 given to them 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-test 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, which leads to an important addition to the 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 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 a HIV self-test in the direct provision arm might feel shame for not using the self-test 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 of follow-up time. Participants who received a 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 around 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 the 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, biasing our effect size estimates towards the null. The 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 the Ugandan Ministry of Health's Most at Risk Population Initiative (MARPI) that 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 of the study we meet with members in the HIV prevention group from the Ugandan Ministry of Health, as well as leaders of sex workers peer organizations (WONETHA and HEDSI). Prior to enrolling the first participant we additionally met with members from these organizations as well as individuals from the Kampala City Council Authority, the Virus Research Institute (UVRI), the National Drugs Authority (NDA), and MARPI. A number of individuals from these various organization were invited to be on the study's scientific oversight committee, which was notified of all reported adverse events and meet once to review an interim analysis. Individuals from MAPRI were invited to assist with the two-day FSW peer educator training.

The results of this study were presented at invited meetings at the Ugandan Ministry of Health and at an HIV self-testing national dissemination event titled "Improving access to HIV testing through self-testing: from research to policy to implementation." The meetings and national dissemination were well attended and the Ugandan Ministry of Health plans to move forward and incorporated HIV self-testing into their national HIV testing guidelines based on the results of this and other studies. Geoffrey Taasi, from the Ministry of Health, has helped us interpret study results and situate them in the context of the Ministry of Health'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, compared to 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 FSW.

2. *Distribute HIV self-tests to FSWs directly using peer educators* for higher universal 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 sub-Saharan African 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 component of HIV policies to achieve near-universal and frequent HIV testing among FSWs. In designing HIV self-testing policies for FSWs, governments should consider peer 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 appendixes

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

Online appendix A – Baseline questionnaire
http://www.3ieimpact.org/media/filer_public/2018/06/27/tw2223-hivst-hspot-appendix-a-baseline-questionnaire.pdf

Online appendix B – One-month follow-up questionnaire
http://www.3ieimpact.org/media/filer_public/2018/06/27/tw2223-hivst-hspot-appendix-c-four-month-questionnaire.pdf

Online appendix C - Four-month follow-up questionnaire
http://www.3ieimpact.org/media/filer_public/2018/06/27/tw2223-hivst-hspot-appendix-b-one-month-questionnaire.pdf

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