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# Increasing HIV self-testing and linkage to care for partners of women in antenatal care in Uganda

July 2019

Impact Evaluation Report 102

**HIV and AIDS**

3ie International Initiative for Impact Evaluation

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Finally, the study participants who consented to participate in this study, women and their partners, are greatly appreciated.

## Summary

Couples testing is a critical intervention to the attainment of the United Nations' 90–90–90 targets toward ending HIV by 2030. In Uganda, the couples testing rate was only 16 percent in 2011. The World Health Organization strongly recommends HIV self-testing (HIVST) as an approach with the potential to improve uptake of couples and partner HIV testing. In this study, we proposed to deliver HIVST kits to partners through pregnant women attending antenatal care to eradicate several supply and demand barriers to couples testing.

We implemented a phased cluster randomized controlled trial among pregnant women attending antenatal care at Mpigi Health Centre Level 4, and at Entebbe and Nakaseke hospitals, to determine the uptake of HIV testing in the male partners and assess the linkage to care among HIV-positive partners across the two study arms.

We randomized clinic days to intervention or control. Women in both arms received health education and were encouraged to bring their partners to test at the facility. Women in the intervention arm were additionally given HIVST kits to deliver to their partners. We conducted structured interviews with women at baseline, month 1 and month 3 post-enrollment, and with the men at one month and three months after the women's enrollment.

We also conducted a long-term, follow-up sub-study on HIV-positive men and discordant couples at six months and up to 24 months post-enrollment.

The primary outcomes were self-reported HIV testing, post-test linkage to care (defined by self-reported registration at an HIV clinic) and strategies for coping with discordant status reported by the woman or her male partner across month 1 and month 3 follow-ups and up to 24 months.

We conducted key informant interviews with healthcare providers and in-depth interviews with selected women, their male partners, family members, HIV-positive men and discordant couples who used the kits. We collected cost data to estimate the cost impact of HIVST, relative to public health benefits, and the corresponding cost to the medical system required to test an additional partner and detect each additional case of HIV. All primary outcomes are based on intention to treat.

We recruited 1,618 women – 333 women in 59 clusters (20.6%) from Nakaseke, 558 women in 108 clusters (34.5%) from Mpigi and 727 women in 180 clusters (44.9%) from Entebbe. The mean age of the pregnant women was 25.2 years (standard deviation = 5.5), and the majority were cohabitating (1,258 of 1,618, or 79.0%). The male partners' mean age was 32.2 years (standard deviation = 8.1). Overall, the randomized intervention and control groups were comparable, with no statistically significant differences observed between groups beside male religion, which could be due to small sample sizes in certain categories.

We observed a dramatic increase in male partner testing in the intervention arm, with a nearly four times higher proportion of male partners testing. Overall, considering reports of testing from the women's and men's reports across month 1 and month 3, 626 of 816 (76.7%) tested for HIV in the intervention group versus 278 of 742 (37.5%) in the control

group. Furthermore, 562 (73.3%) in the intervention arm tested as couples, compared to 186 (30.8%) in the control arm.

Over the entire follow-up period, based on the women's and men's reports, 42 HIV-positive men were identified in the intervention arm and 11 were identified in the control group. Based on the month 1 and month 3 follow-ups, we observed 10 of 42 men in the intervention arm and 5 of 11 in the control group linked to care ($p = 0.09$). In extended follow-up in phase 3 of the study, focusing on men who had tested HIV-positive in the intervention arm, we found that 21 of 42 men eventually went for confirmatory testing.

*Qualitative results:* We conducted 85 qualitative interviews to explore six thematic areas:

- motivation to test;
- anticipated fears and barriers to HIVST;
- strategies used by women in delivering HIVST kits to their partners;
- experiences in using HIVST kits;
- social consequences of HIVST; and
- positive outcomes and benefits of HIVST.

Although women initially had fears about how to introduce the HIVST kits to their partners, they affirmed that the kits encouraged men to test for HIV and helped the women to learn their male partners' HIV status. They and their partners found it easy to use the kits, but were skeptical about the simple test kit's ability to test for HIV.

Women who enjoyed good relationships with their partners introduced the kits on the same day, but many women took some time to consider which strategies to use. HIVST was reported to increase the number of men escorting their wives or partners to health facilities and testing for HIV, besides improving the quality of their relationships.

In phase 3, we conducted 25 in-depth interviews to explore the coping mechanisms of HIV-discordant couples after they learned about their discordant status, and seven in-depth interviews to explore factors that facilitated or inhibited HIV-positive men from linking to HIV care.

Our findings on coping mechanisms show that although individuals in HIV-discordant relationships were initially afraid of separating, no separations occurred. Also, although some participants developed suicidal ideations, no suicides were reported. Two main factors enabled individuals in HIV-discordant relationships to cope with their HIV serodiscordance – post-test counseling support from health professionals and psychosocial support from relatives and close friends.

With regard to linkage to HIV care, we found that post-test counseling played a key role in supporting initiation of and retention in HIV care among those who were still in care at the end of the follow-up period. However, lack of HIV status disclosure to the sexual partner was a deterrent to retention in care among those who had initiated HIV care. HIV-positive men who did not link to HIV care cited two main reasons for their failure to do so: (a) they were not yet ready to commit to lifelong antiretroviral therapy – influenced by misconceptions about antiretroviral therapy from their close friends (for example, that taking HIV drugs would make one become "fat and black"); and (b) the feeling that they were still healthy and did not need to initiate HIV treatment at the time. This second

observation coincides with men's beliefs that seeking healthcare when one is still strong projects men as weak and less resilient. This keeps men away from HIV treatment programs until they have developed advanced HIV-related disease.

The total cost of the intervention was US$15,717.27, and US$5,826.10 for the control. In the intervention arm, the biggest cost driver was the HIVST kits (60.2% of the total cost), followed by above-site costs (20.6%) of the intervention. Above-site costs were the biggest cost driver in the control arm (55% of total cost), followed by facility personnel time (27% of total cost).

The cost per partner tested was US$30.30 for the intervention and US$31.20 for the control, while the cost per HIV-infected person identified was US$462.30 for the intervention and US$582.60 for the control. Comparing intervention with control, the incremental cost per additional partner tested (incremental cost-effectiveness ratio [ICER]) was US$29.80 and the ICER per additional partner testing HIV-positive was US$412.10).

In the sensitivity analysis, reducing the unit cost of self-testing kits by half reduced the cost per partner tested and the cost per HIV-positive partner identified by 30 percent (to US$21.20 and US$323.30, respectively). The ICERs of partner testing and of identifying HIV-positive partners were reduced by 48 percent (to US$15.60 per extra person tested and US$215.30 per extra HIV-positive person identified). The ICER for identifying HIV-positive partners and the cost per HIV-positive person identified were also sensitive to the proportion of partners who tested HIV-positive. Doubling this proportion reduced the ICER and cost per HIV-positive partner identified by a further 50 percent (ICER = US$107.60 per incremental HIV-positive partner identified).

Our results demonstrate an enormous increase in partner and couples HIV testing when oral self-testing was available at home. However, our results do not show that men testing positive through HIVST are as likely to link to care as men who test positive at a clinic. We recommend that the Ugandan government consider this model of HIVST as an effective approach to improving male partner and couples testing. We further recommend additional interventions to enhance linkage to care for partners who test HIV-positive through HIVST. Reducing the cost of test kits and targeting the intervention at settings with higher HIV prevalence is important for the cost-effectiveness of HIVST.

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## List of figures and tables

## Abbreviations and acronyms

| | |
|---|---|
| ANC | antenatal care |
| HC4 | Health Centre Level 4 |
| HTS | HIV testing services |
| HIVST | HIV self-testing |
| ICC | intraclass correlation |
| ICER | incremental cost-effectiveness ratio |
| PCR | polymerase chain reaction |
| PMTCT | prevention of mother-to-child transmission |
| RR | risk ratio |
| SD | standard deviation |
| WHO | World Health Organization |

# 1. Introduction

Uganda is one of the three countries that account for 48 percent of all new HIV infections in Sub-Saharan Africa (UNAIDS 2014). Twenty-one countries, including Uganda, are committed to a global plan to eliminate HIV by 2030 and to the United Nations 90–90–90 targets toward ending HIV. The first "90" focuses on ensuring that all people with HIV know their status by 2020; however, testing remains low among certain populations, including men (UNAIDS 2016).

HIV transmission from mother-to-child is the second most-common route of HIV infection, after heterosexual transmission, in Uganda (Ministry of Health et al. 2011). However, only 8 percent of pregnant women attending antenatal care (ANC) tested HIV-positive in 2014 (Uganda AIDS Commission and Ministry of Health 2015). Furthermore, couples testing is only 16 percent (Byamugisha et al. 2011) and partner testing has remained persistently low over the years, even though studies have reported that pregnant women who are aware of their partners' HIV status have beneficial outcomes, including improved prevention of mother-to-child transmission (PMTCT) and higher rates of delivery in health facilities. Therefore, approaches that increase uptake of HIV testing services (HTS) among partners of pregnant women may improve PMTCT and other maternal health outcomes.

The World Health Organization (WHO) has recommended HIV self-testing (HIVST) as an approach with the potential to improve uptake of couples and partner testing services (WHO 2016), acting as an entry point into couples or partner HTS.

HIVST refers to a process in which a person collects their specimen (oral fluid or blood), performs a test and interprets the result, often in private or with someone they trust (WHO 2015). It is an emerging approach that can extend HTS to people who may be unable or reluctant to attend existing HTS and to people who frequently retest (WHO 2016). HIVST could reach individuals at high risk of HIV infection who experience barriers to conventional HTS, since HIVST offers a private, autonomous and confidential alternative to facility-based tests (Mavedzenge et al. 2013).

## 1.1 Study justification

Although the WHO and the Uganda PMTCT policy recommend couples and/or partner HIV testing at ANC, couples testing through provider-initiated testing and counseling for pregnant women (Matida et al. 2011; Hensen et al. 2012; WHO 2007), only 16 percent of couples have been tested together (Byamugisha et al. 2011).

This HIVST study is positioned to provide strong and timely evidence to inform national and global HTS guidelines. The revised Uganda HIV testing policy guidelines, launched in January 2017, recommend HIVST only under study and pilot projects and indicate a need to adjust these provisions based on findings from ongoing studies, including this ANC partner testing study (Ministry of Health 2010).

Findings from this pilot could thus inform decisions on HIVST and adjustments to the new policy. Furthermore, Uganda is facing scarcities in human resources for health. HIVST could substantially reduce the burden on healthcare workers to reach and test the male partners and other family members of ANC clients.

### 1.2 Primary research hypothesis and study objectives

We hypothesized that the intervention group (HIVST) would have significantly higher male partner testing rates than the comparison group.

We had five research objectives – two primary and three secondary objectives.

Primary objectives:

1. to determine the uptake of HIV testing and number of new HIV infections identified in the two study arms; and
2. to assess the linkage to care among HIV-positive partners across the two study arms.

Secondary objectives:

3. to assess the acceptability of partner or couples HIVST among HIV-positive and HIV-negative women attending ANC (document the proportion of women accepting HIVST kits to take home, those who eventually deliver them, partners and family members testing, and HIV-positive partners or family members receiving confirmatory HIV testing);
4. to document the disclosure rates and positive and negative outcomes (positive outcomes including partners' support for women, and negative outcomes including social harms) of partner HIV testing across the two arms; and
5. to determine the cost-effectiveness of HIVST for male partner testing during ANC.

## 2. Background

Uganda is among the 22 high-HIV burden countries that account for 90 percent of pregnant women who need antiretroviral drugs for PMTCT (WHO 2011). The standard of care in Uganda does not yet include HIVST, but includes a universal opt-out system for clinic-based, rapid HIV testing by women enrolled in ANC.

More than 90 percent of women agree to receive HTS as part of ANC (Mumtaz et al. 2013; Uganda AIDS Commission 2011). HTS for couples and partners increases HIV testing among men; reduces the risk of HIV acquisition and transmission by pregnant women and their partners (Msuya et al. 2008); and improves women's and infants' use of services (Bajunirwe and Muzoora 2005) and their retention in care and adherence to antiretroviral drugs (Conkling et al. 2010).

Men play an important role in women's risk of acquiring HIV (Msuya et al. 2008) and in prevention, in terms of condom use in the couples' relationships (Farquhar et al. 2004; Desgrées-Du-Loû et al. 2009). Men also play a role in women's use of services, including testing for HIV (Maman et al. 2001; Bajunirwe and Muzoora 2005; Baiden et al. 2005; Peltzer et al. 2008) and obtaining follow-up results (Peltzer et al. 2008). Male partners influence women's treatment decisions regarding delivery in a health facility and whether they receive medication and adhere to it (Conkling et al. 2010; Peltzer et al. 2008). Thus, involvement and testing of male partners enhances outcomes for women and their infants.

In addition, partner testing is an efficient and effective way of identifying additional people with HIV who could benefit from treatment. Couples testing and partner testing

help more people know their HIV status, particularly men, who in generalized epidemic settings are substantially less likely to test than women. Thus, mothers attending ANC are encouraged to bring their partners to be tested. However, in countries with high HIV prevalence, Uganda included, HIV testing rates for men are generally lower than for women. This is because HTS are conducted mainly at ANC and other clinics, where the routine offer of HIV testing is generally the norm (WHO 2015). In most countries, the proportion of couples and partners who test together is less than 20 percent (WHO 2014).

This study was implemented in three health facilities supported by Mildmay Uganda – Entebbe and Nakaseke hospitals and Mpigi Health Center Level 4 (HC4) in Uganda's Central region. Uganda is in East Africa, bordering Kenya to the east, Tanzania and Rwanda to the south, South Sudan to the north and the Democratic Republic of the Congo to the west (UNAIDS 2014). HIV prevalence in Uganda is 7.3 percent in the general population, 8.3 percent among women and 6.1 percent among men; Central region has a higher overall HIV prevalence of 10.9 percent.

## 2.1 The HIV self-testing intervention

This pilot intervention involved delivery of HIVST kits to partners through eligible pregnant women who received ANC services at the three study sites. ANC clinic days were randomly allocated to two arms – standard of care as the control, which included education for women to encourage their partners to test at the health facility, and the intervention, which included providing women with up to four HIVST kits to deliver to their male partners and other adult family members in the household. Although the primary study outcome was male partner testing, we also collected information on testing by other adult members of the household.

- Control (standard of care): As the women waited to receive health services, facility staff provided routine health education about encouraging their partners to come for HIV testing. We conducted screening to identify eligible women for the study. We conducted baseline interviews with eligible women who consented, as they waited for the clinicians' review. At month 1 and month 3 after the baseline assessments, we conducted follow-up interviews with the women and their male partners.
- Intervention (HIVST): In addition to general health education, women received additional information on HIVST. We gave each woman one to four kits, depending on how many adults – including their sexual partners – lived in their household. We conducted follow-up interviews at month 1 and month 3 to assess the use of the kits and conduct confirmatory testing.

We conducted study activities in two phases: (1) the planning and preparatory phase; and (2) project implementation.

### *2.1.1 Planning and preparatory phase (Phase 1)*

*Adaptation of HIV self-testing protocols:* While engaging the nurses at each of the facilities, the study team developed data collection tools, reviewed the ANC clinic flow and identified stages for integration of the HIVST study.

*Development of HIVST materials:* The study team worked with the HIVST manufacturer, Mildmay Uganda and the Ministry of Health to develop HIVST educational and informational materials for the study participants to use. We included the following information in the materials: main modes of HIV transmission; the value of HIV testing; and what they should do if they had a negative or positive HIV test, including confirmatory testing, evaluation and linkage to care in the event of a positive self-test. We translated the study materials into Luganda, the local language in the study area.

*Identification of the study/data advisory board:* The study team conducted stakeholder analysis to identify new and already-identified stakeholders. The stakeholders formed the advisory board for the study.

*Stakeholder engagement:* We conducted a series of meetings at national, district and facility levels. The objectives of these meetings were to promote government buy-in, through the Ministry of Health, and to enable entry into the districts and facilities. Stakeholders who participated in the meetings included the ministry and district health teams, including district health officers, district- and village-level focal persons for the elimination of mother-to-child transmission; the health facility in-charge; hospital superintendents; and Ministry of Health representatives from the AIDS control program (particularly those coordinating the elimination of mother-to-child transmission and HIV counseling and testing services).

*Orientation of staff and all health workers at the selected health facilities:* The study team oriented health facility staff, including nurses and midwives, on the HIVST intervention to ensure all health workers at the facility were competent in supporting implementation and follow-up of study participants.

*Staff recruitment and training:* We recruited one study coordinator to lead coordination and implementation of study activities across sites. At the start of the study, we recruited three site coordinators, who doubled as midwives and trained counselors for the study, and nine research assistants. We recruited three more research assistants to support follow-up activities, due to overlap between recruitment and follow-up.

### *2.1.2 Phase 2: Project implementation*

This phase involved screening participants for eligibility, recruiting women and men into the study, and conducting month 1 and month 3 follow-ups.

*Screening and selection of participants eligible for the study:* Together with the health workers at the ANC, all pregnant women received health education upon arrival at the ANC clinic. The nurse informed the women about this study, focusing on partner HIV testing. As the women waited for their clinical examination, existing and new ANC attendees were screened for eligibility.

We administered baseline interviews to all eligible women who consented to participate. We obtained a list of household members from all women in the intervention arm to determine the number of adults in the household and, hence, the number of kits to give each woman. We provided HIVST procedures and information, test kits and pre- and post-test information, referral resource lists for women in the intervention arm and a month 1 follow-up date for each woman and her partner.

Women allocated to the intervention arm watched a video, translated into Luganda, that presented information on HIVST procedures. The purpose of the video was to enhance the women's perception of the procedures and enable them to explain the procedures to their partners and other adults in the household.

The women and their partners in the standard of care arm received a month 1 follow-up date. We also conducted follow-up interviews at month 1 and month 3.

## 2.2 Polymerase chain reaction sub-study

At the month 1 follow-up visit – which may have been some weeks after the test was performed, and well outside the approved window for reading the test – we asked each HIVST participant to bring the used test kits back to the clinic. In the questionnaire, we asked participants to inspect the used kit and interpret the test result displayed on the window of the test device.

The interviewers also recorded their own reading of the used test kit result. We interpreted results as negative if only one "control" band was displayed, positive if two bands ("control" and "test") were displayed, however faint the test line was, and invalid if it could not be interpreted. All those individuals whose kits had two bands were noted and sent for a confirmatory test using the rapid blood test.

At the month 1 follow-up visit, some used test kits showed weak positive "test" bands indicating HIV positivity. In many cases, the participant had read the tests as negative when they had first performed the test. The majority of the confirmatory test results conducted on participants with weak bands were negative. This discrepancy was attributed either to user error or to the kit.

Recognizing the importance of correct diagnosis for these individuals, and the importance of understanding the differential performance of the HIV testing systems, we prepared a list of individuals with weak positive bands on HIVST and held engagement meetings with the Uganda national health laboratory services team, with the help of the Ministry of Health.

To capture individuals' experiences and allow direct comparison between testing modalities, we designed a polymerase chain reaction (PCR) sub-study, in which we planned to re-contact participants with weak positive bands on HIVST. In this PCR sub-study, we tested three methods simultaneously – HIVST, standard of care rapid testing and using a blood sample for PCR gold standard testing.

### *2.2.1 Re-contacting participants*

Using the study tracking forms, we retrieved the telephone numbers of all participants whose HIVST kits had weak bands (whether or not they had interpreted the results as positive or negative). The study team designed two separate messages, one to use over the phone and another at the facility, and a checklist for the PCR sub-study.

Both messages were translated into Luganda to maintain uniformity. Site coordinators assigned to the three study sites underwent a one-day refresher training to familiarize themselves with the scripts and checklist. We reached out to all participants with telephone contacts and made appointments for re-testing and brief interviews.

### *2.2.2 Procedures for re-testing*

While at the facility, we offered participants more information about the objective of the study and asked them how they stored their kits after the initial test. This was followed by a repeat oral self-test under the observation of the trained site coordinator, who doubled as counselor.

After reading the oral self-test results, the participants were led to the laboratory for a rapid blood-based HIV test, following the national algorithm. A laboratory technician drew one blood sample to use for the rapid test and the DNA/PCR test. Clearly labeled samples were delivered to the national laboratory, using hub riders, after two days of sample collection for up-country sites and every day for Entebbe Hospital.

## 2.3 Study extension to oversample HIV-positive women

In the preliminary analysis of phase 1 results, the number of male partners of HIV-positive women reached was too small, at 32 of 77 (41.6%), to permit meaningful statistical comparisons. With support from the International Initiative for Impact Evaluation, the study was extended for seven months (November 2017 to June 2018) to over-sample HIV-positive participants, increase the number of positives and increase power to assess linkage to care across the two study arms. The request to extend the study was approved by the Makerere University School of Public Health Higher Degrees Research and Ethics Committee.

In line with the initial study procedures, we enrolled an additional 104 pregnant women (84 HIV-positive and 20 HIV-negative) in this extension to increase the number of index HIV-positive women. This increased the sample size in the intervention arm from 777 to 847, and in the control arm from 737 to 771. We recruited the 20 HIV-negative women to reduce stigmatization that might have resulted from enrolling only HIV-positive women.

We conducted structured interviews with 104 pregnant women at baseline, one month and three months post-baseline, and with their male partners at three months after enrollment of the women. We collected quantitative data using paper copies and later entered the data in the REDCap system.

## 2.4 Study extension to assess long-term linkage to care for HIV-positive men and coping among discordant couples who self-tested for HIV

Results from phases 1 and 2 demonstrated potentially poor linkage to care among male partners who self-tested for HIV. This was partly attributable to the short follow-up period that characterized phase 1 and 2 sub-studies. Although the scientific literature is sparse on the subject of linkage to care among individuals using HIVST, we expected to see an increase over time, underscoring the importance of a longer follow-up period to accurately determine linkage to care for HIV-positive men who self-tested.

Qualitative findings from a formative study conducted prior to the implementation of the current trial indicated that participants were afraid that HIVST could result in marital instability, due to the absence of pre- and post-test counseling, especially if one of the partners was HIV-positive (Matovu et al. 2017). Previous studies have found that marital dissolution is more likely in HIV-discordant couples than in concordant HIV-negative or concordant HIV-positive couples (de Walque and Kline 2012).

Although we saw only minor incidents of marital instability among couples enrolled into the HIVST study in phases 1 and 2, we anticipated that HIV-discordant couples who self-tested for HIV might have experienced challenges in ensuring marital stability, compared with other types of couples. Furthermore, we also anticipated greater challenges in cases where the female partner was HIV-positive than in those where the male partner was. These observations informed the need to conduct longer-term follow-up of couples in HIV-discordant relationships.

All men who tested positive in HIVST, as well as HIV-discordant couples, were identified and extracted from the main phase 1 and 2 databases. Using information from the clients' tracking forms, we sought to identify and interview all HIV-positive men and HIV-discordant couples who were enrolled in phases 1 and 2 to determine their linkage to care and explore their coping mechanisms following HIVST. Couples who were found to have coping issues were referred to organizations that deal with domestic violence-related challenges.

We collected quantitative data using interviewer-administered questionnaires and used in-depth interview guides to collect qualitative data.

## 2.5 Theory of change and key assumptions

The theory of change that guided this study is shown in Figure 1.

We made several key assumptions in developing our theory of change. First, we assumed that the counseling and training provided to the women in the intervention arm would increase their motivation and self-efficacy to take the self-testing kits home and present them to their husbands.

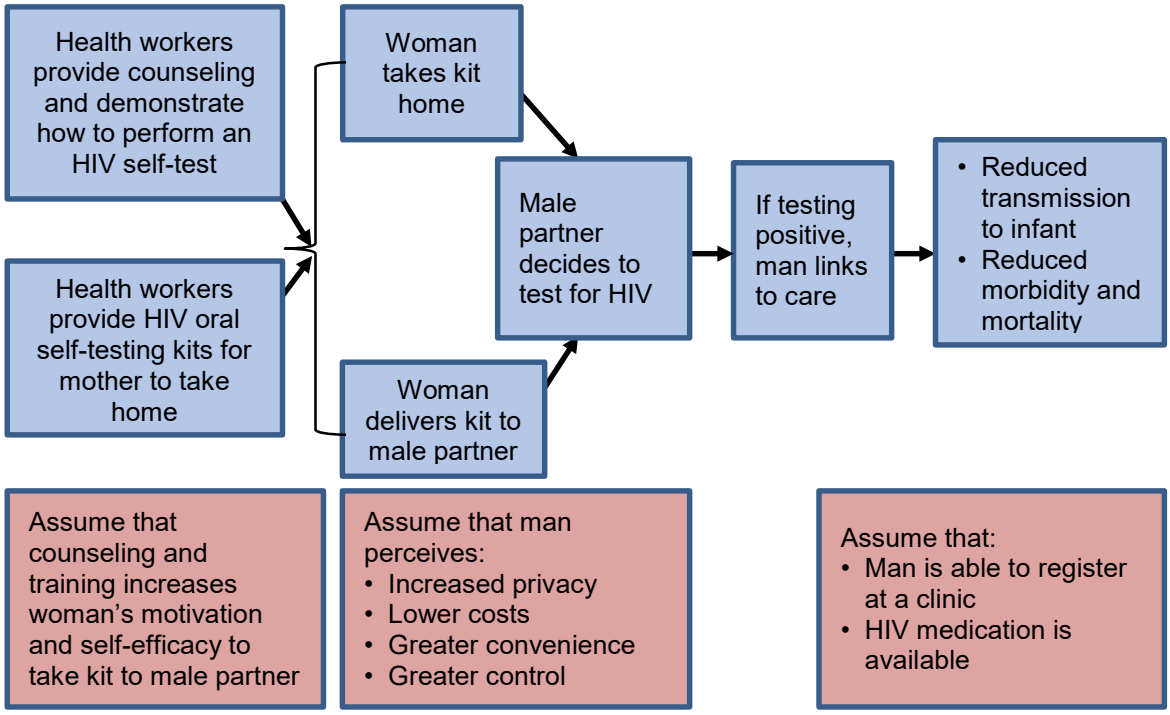
We assumed that having a self-testing kit would mitigate against common barriers to HIVST among men, including lost work time, transportation costs and stigma. We assumed that self-testing would reduce these barriers by increasing the men's sense of privacy, convenience and low cost associated with HIV testing, leading to an increased likelihood of HIV testing.

Furthermore, we assumed that having an HIV kit would increase the men's sense of self-efficacy, control and ownership of the process of HIV testing, increasing the likelihood that they would test. Our theory of the health impact of testing rested on the assumption that men testing positive were able to link to care and that medication was available.

In previous research with pregnant women delivering kits to their male partners (Gichangi et al. 2017), we found very high rates of couples testing and, consequently, very high rates of disclosure. Thus, previous research supports the hypothesis that home-based self-testing may result in high rates of disclosure, as well as linkage to care.

Based on our theory of change, we formulated hypotheses that the impact of the intervention might vary by age, marital status, education and religious affiliation, because these factors could be related to the women's self-efficacy and motivation to take the kits home and present them to the men, as well as the men's likelihood to respond positively and test for HIV. In addition, we planned to test for differential effects by study site, because these and other factors might differ across sites.

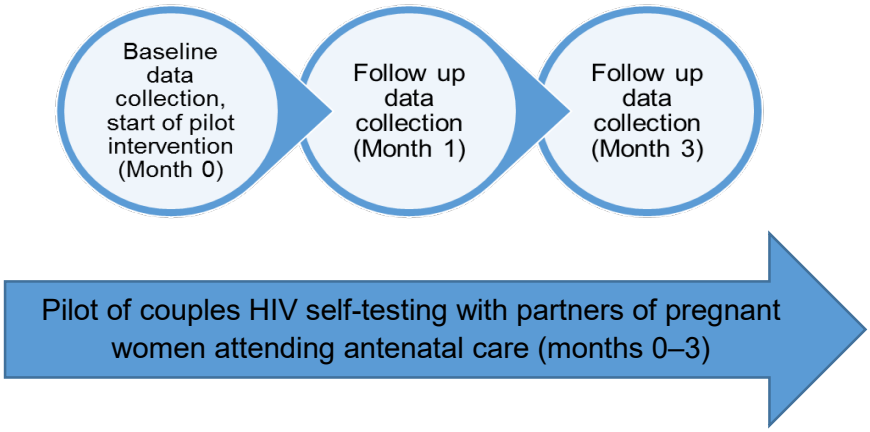
**Figure 1: Theory of change**




## 2.6 Study time frame

In planning the time frame for the anticipated effects, most men were expected to test with the self-testing kit within the first month after pregnant female partners presented the kits. The study was therefore designed with two follow-up visits – a one-month follow-up to try to capture the anticipated early uptake and a three-month follow-up to provide a somewhat longer-term perspective on uptake of HIV testing during pregnancy. However, a longer follow-up, after three months, was conducted for the men who tested HIV-positive and the serodiscordant couples, as described in Section 2.4.

**Figure 2: Study time frame**




### *2.6.1 Month 0*

Month 0 was characterized by preparatory activities that included completing protocol and data collection tools, study registration, obtaining Institutional Review Board approval, stakeholder analysis and engagement, and establishing and meeting of the

Ministry of Health oversight committee. Additionally, we performed pre-implementation site visits to facilities and protocol adoption. Protocol development involved designing facility-specific patient flow charts and the enrollment protocol, which included educational materials and referral resource lists.

Other activities included translation of HIVST kit user information and HIVST kit procurement, recruitment and training of staff, purchasing and programming of tablets for data collection, pilot testing of tools and orientation of providers at the selected facilities.

Screening, identification and enrollment of eligible women were scheduled to start in January 2016 and end in March 2016. These activities were delayed for two to four months by unforeseen hitches, which included:

- change of study site from Mityana to Nakaseke Hospital, because another study that involved the same population was due to start in Mityana. This was to avoid contamination and over-burdening of the pregnant women. Among the other facilities supported by Mildmay Uganda, Nakaseke was selected because it had the highest outpatient department and ANC attendance, which was desirable to achieve the recruitment targets. The change was made after Institutional Review Board approval of the protocol amendment;
- shipment of HIVST kits to Uganda was delayed by three months. This time was used to train interviewers and prepare health facilities for the study. We rolled out the study on 25 July 2016, as soon as the HIVST kits arrived; and
- lower daily ANC attendance coupled with one clinic's running four ANC days a week instead of five – as well as many women's having partners who had tested in the previous six months – reduced the number of eligible women per clinic day and consequently reduced daily enrolments. Recruitment for phases 1 and 2 went on for three months instead of the planned two months.

#### *2.6.2 Follow-up visits (month 1, month 3 and long-term follow-up)*

During month 1 and month 3 follow-ups, the teams concentrated on conducting follow-up interviews. However, this activity was delayed because of the overlap with enrollment, which increased workload. Month 3 follow-up for phase 1 was completed in February 2017, and phase 2 follow-up began in November 2017 and was completed in May 2018. Long-term follow-up began in July 2018 and was completed in October 2018.

### 2.7 Primary and secondary outcomes of interest

The study had two primary outcomes: (1) uptake of HIV testing by the male partners, and (2) linkage to care among HIV-positive partners across the two study arms. Secondary outcomes included the number of HIV infections identified in the two study arms, negative social outcomes, costing analysis of HIVST and coping skills for discordant couples who self-tested for HIV.

## 3. Data and methods

### 3.1 Research ethics

We obtained approval to conduct this study from Makerere University School of Public Health's Higher Degrees, Research and Ethics Committee (Protocol Number 392), the Uganda National Council for Science and Technology (Protocol Number HS 2022) and

the Medical University of South Carolina. All participants consented to participate, and interviewers emphasized that participation was voluntary and participants were free to opt out at any time.

To maximize the study protocol's relevance for scale-up by the Uganda Ministry of Health, study participants received only minimal compensation for their participation. Those whose follow-up dates coincided with a regular ANC visit, or those with an interview conducted at home or over the telephone, received 5,000 Ugandan shillings, equivalent to about US$1.40, for their time. Those who came to the facility to provide an interview on a day that was not a regular ANC visit were compensated an average of 15,000 Ugandan shillings, equivalent to US$4.20, for their time and transportation costs.

## 3.2 Power calculation and sample size determination

We estimated our sample size based on a power calculation for a superiority test between the intervention and the control to determine whether HIVST availability resulted in a significant increase in HIV testing uptake by male partners. We considered our study design to be a cluster-randomized trial, although we did not expect our clusters would have any substantial intraclass correlation (ICC). The women coming to a clinic on any given day might have been equally likely to come on a different day; therefore, our clusters were not correlated in the usual sense.

Our estimates assumed that the proportion of male partners testing in the control arm would be similar to the average reported proportion of 11.6 percent currently estimated for Mildmay Uganda clinics. We hypothesized that arm 2 (the intervention group, with self-testing kits) would have the highest rate of male partner HIV testing. We determined that an improved proportion of 20 percent was the minimum that would justify scaling up the program to the national level in Uganda, and calculated the sample size to detect this effect.

With the cluster-randomized design, each facility would have three data collectors, each expected to recruit and interview 5 women per day at the ANC clinic; thus, each cluster was estimated as 15 participants (1 cluster per facility per day). With a cluster size of 15, and male partner testing rates of 11.6 percent versus 20 percent, we estimated that with 50 clusters (750 women or couples) per arm, we would have this statistical power:

- 0.89 with ICC = 0.07;
- 0.93 with ICC = 0.05;
- 0.96 with ICC = 0.03; and
- 0.99 with ICC < 0.01.

With an assumed 10 percent attrition rate, the above sample size would have more than 80 percent power to detect the 20 percent uptake. With a total of 100 clusters across three facilities, 750 women were estimated to be recruited in 8 weeks.

### *3.2.1 Phase 2 sample size*

An additional 120 women (100 HIV-positive and 20 HIV-negative), with equal numbers per arm, were recruited in this 7-month extension, in an attempt to reach more partners of HIV-positive women. The HIV-negative women were enrolled to reduce stigma resulting from enrolling only HIV-positive women. In other words, if we only enrolled HIV-positive women in the study, then any woman enrolling in the study could be identified as

HIV-positive, which would be stigmatizing. This additional enrollment increased the total sample size from 750 to 810 in each study arm.

Again, we considered all women recruited each day from each study clinic to constitute one cluster. However, because this phase of the study focused primarily on HIV-positive women, many clusters were very small, with only one or two women. The design of our study and the small size of the clusters led us to expect a very small ICC. Nevertheless, we continued to consider the essential design of our study to be a cluster-randomized trial for purposes of the primary analysis.

#### *3.2.2 Phase 3 sample size*

In the self-testing arm during phase 1 and phase 2 of the study, 42 men tested positive for HIV. Of these men, one died after testing positive. The team planned to follow up with all remaining 41 men in the self-testing arm who had tested positive for HIV (34 in phase 1 and 7 in phase 2) and assess coping skills among 75 discordant couples.

We further planned to conduct 27 in-depth interviews with nine purposely selected HIV-positive men (three who linked to care and are still in care, three who linked but dropped out and three who had not linked into care at the time of follow-up); and nine purposely selected couples (three with HIV-positive male partners and six with HIV-positive female partners).

### 3.3 Sampling strategy, recruitment and participants' assignment to study arms

To minimize contamination between study arms, we used clinic day as the unit of randomization, rather than individual randomization. We anticipated that this strategy would reduce contamination, because women coming to the clinic on a given day usually spent multiple hours at the clinic together in the waiting area and might be expected to talk and compare notes about the study. Each day in each clinic was a separate cluster.

All women recruited from a particular clinic on a particular day were randomized to the same study arm. We randomized clinic day clusters to two study arms – control for standard of care and the other one for the HIVST intervention. A biostatistics doctoral student from Dr Korte's department generated the list of random numbers used to assign each sequential clinic day to either the control or intervention. We generated separate lists of random numbers to choose participants for eligibility screening each day from the study clinics.

Each morning during recruitment, the study coordinator unmasked the clinic day allocation and random number list for the cluster (clinic day), and communicated this to the study team at each of the facilities. All three facilities were randomized each day to the same study arm. This randomization strategy was designed to ensure that any site differences would not bias our findings.

At cluster level, a site coordinator generated a sampling frame daily as the women sequentially registered for the ANC clinic arrived. The site coordinator then used the list of simple random numbers received from the study coordinator to pick out women whose registered number matched the random one for screening and enrollment if they were

eligible. Women who declined or were not eligible were replaced with the next random number from the recruitment list.

Depending on the number of women registering at the clinic each day, and on eligibility criteria, some women may not have been approached on some days if the recruitment limit had already been filled for that day. On the other hand, clinic attendance on some days at the smaller sites was lower than expected, leading us to recruit every eligible, willing woman at the clinic that day. Participants were not aware of the study arm to which they were assigned, leaving no room for them to influence their randomization assignment. Furthermore, study staff did not know until each morning whether that day would be an intervention day or a control day.

In the last phase of recruitment, we recruited providers, women, men and other family members for in-depth interviews.

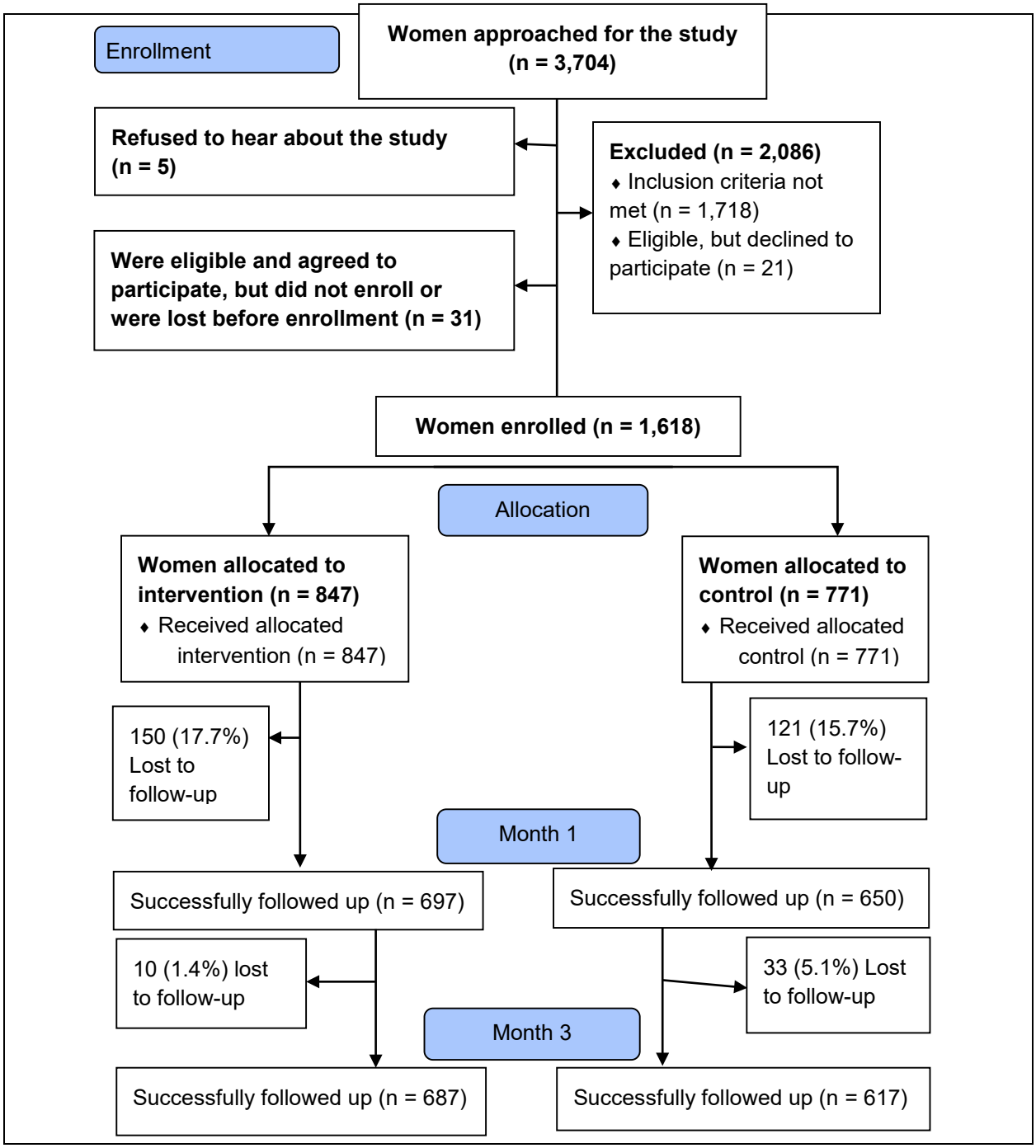
### 3.4 Inclusion and exclusion criteria

Every pregnant woman attending ANC in Mpigi HC4, Entebbe and Nakaseke hospitals was eligible for participation if she had a male partner she saw at least once a week, if the male partner was at least 18 years old, if his HIV status was negative or unknown and if he had not tested for HIV in the past six months.

Women were asked about intimate partner violence, but concern about intimate partner violence did not constitute an exclusion criterion. However, women were free to decline study participation for any reason, and participants were carefully monitored for instances of intimate partner violence throughout the study. Specifically, during follow-up interviews, women were asked if they experienced any form of intimate partner violence, and those reporting that they had experienced physical or sexual violence were referred to MIFUMI, an organization involved in gender-based violence prevention and psychosocial activities in Central region, for further support.

MIFUMI works closely with Mildmay Uganda to address gender-based violence issues reported by Mildmay's clients. Given the fears about potential violence associated with HIVST, all women were provided with information on existing referral networks and the site coordinator's telephone contact, and they were encouraged to call the site coordinator whenever they experienced any form of violence. The site coordinator supported women experiencing intimate partner violence to link to MIFUMI or any other organization of their choice.

**Figure 3: CONSORT flow diagram showing the participants' enrollment and follow-up trajectory (phase 1)**




## 3.5 Sources and methods of data collection

At the beginning of the study, we used Android tablet computers to collect data. We used the REDCap system, including a secure server at the Medical University of South Carolina, and an offline Android application that could be used with the tablets. With this system, interviewers were able to collect data on the tablets whether or not they had a network connection. If a network connection was available, then interviewers could synchronize data on the tablet with the server.

The REDCap system encountered several serious challenges relating to the use of the tablets. As data collection proceeded, the study coordinator and interviewers at all three study sites reported problems with long wait times as the tablets attempted to synchronize and update the data.

After follow-up visits had begun, we realized that some of the data had not been synchronized with the server. We then used paper records to collect data while working to isolate the problem, and eventually decided to continue collecting data on paper. For the remainder of the study, we used the online REDCap system to enter data from paper copies.

### *3.5.1 Quantitative data collection methods*

We used interviewer-administered questionnaires to collect quantitative data, including cost, and we used key informant interviews and in-depth interviews to collect qualitative data.

We used the following tools to collect different information:

- pre-enrolment screening questionnaire in ANC clinic – demographic and behavioral information used to screen the women for eligibility to join the study;
- baseline questionnaire (administered as soon as participants consented) – basic background characteristics from the women about themselves and their families, also used to determine how many kits the women would take home for adult family members;
- tracking tool – information used for contacting participants for follow-up in the field to ensure retention in the study, including the residence and particular features around the residence, preferred mode of follow-up and available contacts that could be used to trace the participants;
- female follow-up questionnaire (for ANC clients at month 1 and month 3) – behaviors, attitudes, communication, HIVST experiences and other relevant parameters for male partners and other adult family members;
- male follow-up questionnaire – similar to the female questionnaire, but specific to male partners;
- long-term follow-up questionnaire – HIV testing behaviors, shame and internalized stigma, and coping mechanisms for discordant couples; the information was similar, but specific to the sex of respondents; and
- costing tools – facility and volunteer time, facility-level assessment of monthly resources, HIVST kit log, above-site coordination and supervision costs for Mildmay Uganda and management costs for investigators.

### *3.5.2 Qualitative data collection methods for phase 1*

We conducted in-depth interviews after the main study outcome had been ascertained; in other words, after the last follow-up visits. During the in-depth interviews, we explored:

- the anticipated fears/barriers that women had in mind on being asked to introduce the HIVST kits to their male partners;
- the strategies they used to deliver the kits to their male partners; and
- what happened after HIVST, including any negative or positive social outcomes post-testing.

We explored similar issues among male partners (for example, men's initial thoughts about HIVST when their partners introduced the kits to them) to triangulate the data obtained from female partners, and to capture their perceptions and experiences regarding HIVST. Specifically, we explored whether men were comfortable receiving HIVST kits from their female partners or whether it would have been better if the men had introduced the kits to their female partners.

The information generated from these in-depth interviews is relevant for our understanding of the quantitative results (which will be reported elsewhere) and for greater understanding of the assumptions underlying the theory of change that informed the design of the intervention. All data collected were recorded on digital recorders with permission from the participants. Interviews lasted about 1–2 hours. All participants who consented to be interviewed and who actually participated in the interviews were compensated for their time and had their travel costs refunded.

#### *3.5.3 Qualitative data collection methods for phase 3*

We conducted in-depth interviews with 27 purposely selected respondents to explore HIVST behaviors and experience, linkage to care for HIV-positive men only, and coping mechanisms and changes in sexual behaviors for discordant couples. All interviews were audio-recorded and lasted 90 minutes, on average.

## 3.6 Strategies to avoid bias and address spill-over and contamination

To avoid contamination between the two study arms, they were randomized by clinic day. Enrolling all women who came on a particular day in the same arm minimized social interaction and thus contamination between study arms.

To avoid selection bias, study arm was randomly assigned. Eligible women who chose to enroll were compared to those who did not using data from the screening and pre-enrollment questionnaires to evaluate possible selection bias.

To assess whether participants in the control arm bought kits from those in the intervention arm or elsewhere, we included a question about HIV testing from any source in the follow-up questionnaires. The data were incorporated into the main analysis of HIV testing and sub-analyses conducted to evaluate HIV testing via the self-testing kit, clinical testing, home-based testing by a community health worker or any other means of HIV testing.

We were also concerned about social desirability bias, where women enrolled in the intervention arm might report that their partner had tested when they had not. The number of kits issued to women was based on the number of adults in the households and labeled. Women were asked to bring back used kits at the follow-up visit, and interviewers verified whether they had done so. Before asking whether a partner had tested, study staff told each woman that they understood that the woman's partner might not have tested for HIV.

## 3.7 Data quality control measures

Prior to implementation, experienced interviewers with a university education were recruited and trained for five days in research and interview skills and in the details of the

study, including data collection tools. The study tools were piloted and corrections made before full implementation. During implementation, each site team met every day after work to discuss unusual cases. The interviewers and investigators met weekly to discuss emerging issues, and weekly supportive supervision visits were conducted to offer additional timely assistance to the sites.

Initially, tablets with programmed skip patterns in the questionnaires enhanced the quality of data collected. After we switched to paper data collection, we continued to monitor data issues and quality control through team meetings and regular monitoring of the data entered into REDCap.

We conducted refresher training for the three best-performing interviewers before implementing the phase 2 and 3 sub-studies. Emerging issues were addressed mainly during supervision visits and through telephone calls and emails.

## 3.8 Problems or challenges

The following challenges were encountered during the study span:

- Change of study site: before we began data collection, another study targeting HIV-infected pregnant women in Mityana Hospital was discovered. There was a serious risk that HIVST interventions might influence the other study outcomes, and vice versa. We assessed alternative sites and selected Nakaseke Hospital to replace Mityana Hospital;
- Late delivery of kits: OraQuick kits were received in Uganda on 12 July 2016. This delayed the launch of data collection activities;
- Low enrollment pace: enrollment pace was lower than expected for various reasons. One facility (Entebbe) ran ANC clinics four days a week instead of five, like the other clinics. Nakaseke had a lower patient load with smaller clusters, and the partner testing reported at screening was generally higher than previously estimated, based on routine facility data. This extended the enrollment period from the planned 8 weeks to 12 weeks, creating a longer overlap between recruitment and follow-up interviews and increasing the load of interviews;
- Network and connectivity problems: Internet challenges were encountered in all sites, especially in Nakaseke. This affected data synchronization, and we changed the mode of data collection to hard copies;
- Access to women's partners: a few HIV-positive women denied interviewers access to their partners; and
- Loss to follow-up: some couples had moved to unknown destinations; hence, we were unable to follow up with them.

## 3.9 Data analysis methods

### *3.9.1 Evaluation strategy*

Our primary analysis for estimating the impact of the intervention was to perform a comparison of the primary outcome (male partner testing) in the intervention group versus the control group. In addition to unadjusted analyses comparing these two groups, we fit log-linear models with and without accounting for clustering by clinic day, and testing for covariate imbalance at baseline.

We accounted for clustering using a random effect for clinic day, because this was the unit of group-level randomization across clinics. In addition, we included study site as a fixed effect and tested study site (as well as other pre-determined, hypothesized effect modifiers) for multiplicative interactions with intervention assignment.

We used log-binomial models to enable estimation of the relative risk, which we judged the most appropriate measure of association in this longitudinal study with interval-based assessment of a high-prevalence outcome measure (HIV testing).

### *3.9.2 Tests for differential attrition*

We evaluated follow-up in the intervention and control groups by assessing the proportion of participants returning for each follow-up visit. Overall, we achieved a good follow-up rate, with 1,244 of 1,514 (82.2%) women returning for the month 1 interview and 1,207 of 1,514 (79.7%) returning for the month 3 interview in phase 1. In phase 2, 103 of 104 (99.0%) women returned for month 1 and 99 of 104 (95.2%) returned for month 3. We compared the attrition rates using a chi-square test of two proportions and found no difference in attrition by study arm.

Follow-up rates were somewhat lower for men, with approximately 1,110 of 1,514 (73%) and 1,054 of 1,514 (70%) men participating in month 1 and month 3, respectively, in phase 1; and 88 of 104 (85%) and 69 of 104 (66.3%) men participating in month 1 and month 3, respectively, in phase 2.

### *3.9.3 Primary specifications*

The final analysis consisted of participants with sufficient follow-up data to be included in the primary analysis. To be included in the final analysis, participants needed to complete at least one of the two follow-up interviews. In random-effects log-binomial models accounting for clustering by clinic day, we estimated the risk ratio for HIV testing among male partners, comparing the two study arms. The primary outcome measure was the woman's self-report about whether her male partner had tested for HIV since the beginning of the study.

Overall, we also conducted analyses accounting for the reports of each woman and man, by considering a man to have tested if either he or the woman reported that he had done so. Although our primary outcome was the woman's report, we constructed the male and female combined outcome to provide a more sensitive measure, accounting for men who reported having tested for HIV but had not revealed this to the women.

### *3.9.4 Balance tables*

We assessed possible imbalances between the intervention and control groups by comparing baseline sociodemographic characteristics of participants. We used t-tests and chi-square tests, as appropriate, to test for any differences in these variables, using a nominal p-value of 0.05 to denote statistical significance.

### *3.9.5 Data cleaning*

We had major problems with the electronic tablets used for data capture and spent considerable effort making sure we recovered all data that could be recovered from them. In data cleaning, we merged and sorted data from several sources (properly synchronized data, tablet logs, emergency data dumps and data entered separately from paper records) to produce a data set with complete data for each participant.

In univariate and bivariate analyses, the data management team cleaned the data to check for outliers. Outliers and implausible values were very rare in the data set, due to electronic data entry and limits placed on variables to be entered. We did not impute any values for missing data. We conducted the analysis as we had planned in the initial protocol.

### *3.9.6 Qualitative data analysis*

The team had all digitally recorded interviews transcribed verbatim and translated from Luganda to English prior to data analysis. Initially, researchers manually read through 10 transcripts to identify emerging themes based on the primary objective of the study; namely, to document perceptions, HIVST delivery strategies and post-test experiences of women and men with regard to HIVST.

The team coded each emerging theme as belonging to perceptions, strategies or experiences through a process of constant comparison and consensus building. They assigned a code to each theme and used these codes to review the remaining 22 transcripts to identify perceptions, strategies or post-test experiences pertaining to HIVST, while noting down any other emerging themes along the way.

At the end of the analysis, we categorically grouped all emerging themes into four main themes: (a) perceptions about HIVST; (b) strategies women used to deliver the kits to their male partners; (c) experiences of using HIVST kits; and (d) post-test experiences following HIVST.

We conducted data analysis inductively, following a thematic framework approach. The team followed similar procedures (initial reading of the transcripts to identify emerging themes, grouping themes into meaningful codes and using the codes to review the 25 transcripts) in conducting analyses for coping mechanisms and linkage to care at the end of the phase 3 follow-up visit.

### *3.9.7 Cost-effectiveness analysis*

Costing was done from the provider perspective, taking into account only costs borne by the study team toward service provision, using a six-month time horizon. Cost categories were:

- above-facility personnel costs and operational costs for supervision of facility staff
- facility personnel time costs
- training costs
- above-site assets (used by above-facility supervisors)
- facility assets
- facility operational cost
- facility supplies.

Above-facility personnel included supervisors who visited facilities to supervise implementation of services. Above-site operational costs and assets included costs incurred by above-site personnel to coordinate and supervise implementation of activities. Facility personnel costs included:

- time spent by personnel to conduct health education
- counseling of mothers

- screening for eligibility of self-testing
- training of mothers on HIVST
- follow-up with mothers, partners and family members
- linkage of partners and family members to care
- testing partners and family members
- distribution of self-test kits
- mobilization
- organizing patient flow at the facility.

On a daily basis, staff responded to a questionnaire to indicate how much time they spent doing the above activities. The total amount of staff time spent was multiplied by the unit hourly personnel cost to obtain the total cost of staff time. Costing used a micro-costing approach with identification of resource inputs, quantifying resources, obtaining unit cost for each resource and obtaining costs. Annualized costs of capital costs were determined using a 3 percent discount rate and halved to reflect a six-month cost.

The useful life of capital assets was based on estimates from Kenya. Assets bought in past years were evaluated at 2016 values, prior to being annualized. Training costs were annualized, assuming that major retraining would be done after two years of the initial training as a consequence of staff turnover or policy changes.

The cost of the intervention was evaluated as cost per partner tested and cost per HIV-positive partner identified. Incremental cost-effectiveness ratios (ICERs) were based on incremental costs between intervention and control arms and incremental effects, including incremental number of partners tested and partners identified as HIV-positive:

(total costs in intervention – total cost in control) / (total number tested or positive intervention – total number tested or positive control)

We were unable to assess cost per HIV-positive person linked to care, due to incomplete linkage data.

We performed one-way sensitivity analyses using the cost of self-testing kits and HIV prevalence among partners tested.

# 4. Results

## 4.1 Quantitative findings

We approached and screened 3,704 women and enrolled 1,618 women in the study; 847 women were enrolled in the intervention arm and 771 in the control arm. The imbalance in recruitment between study arms was due to random variation in the group assignment of clinic days to either intervention or control. We recruited a similar number of clusters (clinic days) at each site. This required extending recruitment at Entebbe Hospital, because this site had only four ANC clinic days a week, compared with five days at the other clinics.

About 82.3 percent of women in the intervention arm and 84.3 percent in the control arm were successfully followed up at month 1. Some 81.5 percent of women enrolled in the intervention arm and 80.0 percent of women enrolled in the control arm were followed up

at month 3. Of the male partners 1,198 (640 intervention and 558 control) were followed up at month 1 and 1,123 (589 intervention and 534 control) were followed up at month 3.

Attrition was higher than predicted – 18.5 percent in the intervention arm and 20.2 percent in the control arm, compared with the 10 percent assumed in our power calculations. However, we compared the attrition rates using a chi-square test of two proportions and found no difference in attrition by study arm (p-value = 0.50). Follow-up rates were high enough to suggest that the study attrition was unlikely to have substantially biased our findings.

In our study, we did not believe there was any systematic bias influencing which participants with whom we were able to follow up. Therefore, we believe the results among the participants who completed follow-up are a good representation of the results we would have found if we had been able to achieve 100 percent follow-up.

Although attrition was higher than expected, the observed effect size was also higher. Therefore, our study had adequate power to show a significant effect.

Women in the intervention arm received up to four oral self-testing kits in phase 1, depending on the number of adult household members, and two kits in phase 2. Overall, 1,815 kits were distributed to women randomized in the intervention arm. Of these, 1,442 (79.4%) were used and returned, 149 (8.2%) were returned unused and 244 (13.4%) were not returned.

#### *4.1.1 Baseline characteristics*

Characteristics of women at baseline, and male partners at the month 1 follow-up, are presented in Tables 1 and 2, respectively, stratified by intervention assignment.

No important differences were noted between study sites. Large numbers of participants declined to answer questionnaire items pertaining to religion and employment status. Overall, randomized intervention and control groups were comparable, with no statistically significant differences observed between groups.

**Table 1: Baseline characteristics of participating women by intervention or control**

| Characteristic | Intervention (n = 847, 52.3) n (%) | Control (n = 771, 47.7) n (%) | Total (n = 1,618) n (%) | p-value |
|---|---|---|---|---|
| Age (years), mean ±SD | 25.1 ± 5.5 | 25.4 ± 5.5 | 25.2 ± 5.5 | 0.79 |
| *Missing* | 9 (1.1) | 12 (1.6) | 21 (1.3) | |
| Age (years), range | 15–43 | 15–49 | 15–49 | 0.70 |
| *15–19* | 120 (14.3) | 105 (13.8) | 225 (14.1) | |
| *20–24* | 330 (39.4) | 281 (37.0) | 611 (38.3) | |
| *25–29* | 219 (26.1) | 206 (27.1) | 425 (26.6) | |
| *30–49* | 169 (20.2) | 167 (22.0) | 336 (21.0) | |
| *Missing* | 9 (1.1) | 12 (1.6) | 21 (1.3) | |
| Female level of education | | | | 0.55 |
| *No formal education* | 13 (1.6) | 13 (1.6) | 29 (1.8) | |
| *Nursery* | 3 (0.4) | 1 (0.1) | 4 (0.3) | |
| *Primary* | 328 (39.2) | 312 (41.2) | 640 (40.2) | |
| *Post-primary/vocational* | 39 (4.7) | 35 (4.6) | 74 (4.7) | |
| *Secondary (A or O level)* | 384 (45.9) | 343 (45.3) | 727 (45.6) | |
| *College (middle level)* | 45 (5.4) | 38 (5.0) | 83 (5.2) | |
| *University* | 22 (2.6) | 12 (1.6) | 34 (2.1) | |
| *Don't know* | 2 (0.2) | 0 (0) | 2 (0.1) | |
| *Missing* | 11 (1.3) | 14 (1.8) | 25 (1.5) | |
| Religion | | | | 0.59 |
| *Catholic* | 97 (40.6) | 84 (42.4) | 130 (39.4) | |
| *Protestant* | 62 (25.9) | 42 (21.2) | 78 (23.4) | |
| *Pentecostal* | 29 (12.1) | 30 (15.2) | 49 (14.7) | |
| *Muslim* | 46 (19.3) | 35 (17.7) | 66 (19.8) | |
| *Other* | 5 (2.1) | 7 (3.5) | 10 (3.0) | |
| *Missing* | 608 (71.8) | 573 (74.3) | 1,181 (73.0) | |
| Employment status | | | | 0.57 |
| *Employed for wages* | 35 (14.6) | 20 (10.1) | 55 (12.5) | |
| *Self-employed* | 63 (26.3) | 49 (24.6) | 112 (25.5) | |
| *Student* | 3 (1.3) | 1 (0.5) | 4 (0.9) | |
| *Out of work (unemployed)* | 33 (13.8) | 33 (16.6) | 66 (15.0) | |
| *Housewife* | 74 (37.2) | 74 (37.2) | 159 (36.2) | |
| *Other* | 22 (11.1) | 22 (11.1) | 439 (9.8) | |
| *Missing* | 607 (71.7) | 572 (74.2) | 1,179 (72.9) | |
| Marital status | | | | 0.10 |
| *Currently married* | 121 (14.5) | 142 (18.7) | 263 (16.5) | |
| *Cohabiting* | 679 (81.3) | 579 (76.4) | 1,258 (79.0) | |
| *Never married* | 33 (4.0) | 34 (4.5) | 67 (4.2) | |
| *Divorced/separated* | 2 (0.2) | 3 (0.4) | 5 (0.3) | |
| *Missing* | 12 (1.4) | 13 (1.7) | 25 (1.5) | |
| Health facility | | | | 0.95 |
| *Nakaseke Hospital* | 177 (20.9) | 156 (20.2) | 333 (20.6) | |
| *Mpigi HC4* | 292 (34.5) | 267 (34.6) | 559 (34.6) | |
| *Entebbe Hospital* | 378 (44.6) | 348 (45.1) | 726 (44.9) | |

Notes: SD = standard deviation. [a] Columns may not total to 100 due to missing values. Chi-square values are based on available data and exclude missing. Fisher's exact test was used as needed when one or more cells was less than 5. * statistical significance at $p < 0.05$. ** statistical significance at $p < 0.01$.

**Table 2: Month 1 characteristics of male partners of women attending antenatal care by intervention or control**

| Characteristic | Intervention (n = 847, 52.3) n (%) | Control (n = 771, 47.7) n (%) | Total (n = 1,618) n (%) | p-value |
|---|---|---|---|---|
| Age (years), mean ±SD | 31.9 ± 8.2 | 32.6 ± 7.9 | 32.2 ± 8.1 | 0.33 |
| Range | 18–68 | 19–64 | 18–68 | |
| Age (years) | | | | 0.36 |
| *15–24* | 106 (16.9) | 77 (14.0) | 183 (15.5) | |
| *25–34* | 324 (51.6) | 278 (50.6) | 602 (51.1) | |
| *35–44* | 146 (23.3) | 148 (26.90) | 294 (25.0) | |
| *45–68* | 52 (8.3) | 47 (8.6) | 99 (8.4) | |
| *Missing* | *212 (25.0)* | *216 (28.0)* | *440 (27.2)* | |
| Level of education | | | | 0.54 |
| *No formal education* | 24 (3.8) | 16 (2.9) | 40 (3.4) | |
| *Primary* | 267 (42.1) | 228 (41.1) | 495 (41.6) | |
| *Post-primary/vocational* | 38 (6.0) | 418 (7.4) | 79 (6.4) | |
| *Secondary (A or O level)* | 239 (37.6) | 206 (37.1) | 445 (37.4) | |
| *College (middle level)* | 44 (6.9) | 34 (6.1) | 78 (6.6) | |
| *University* | 23 (3.6) | 30 (5.4) | 53 (4.5) | |
| *Missing* | *199 (25.6)* | *213 (28.9)* | *428 (26.5)* | |
| Religion | | | | 0.046 |
| *Catholic* | 168 (38.3) | 169 (45.0) | 337 (41.4) | |
| *Protestant/other Christian* | 115 (26.2) | 104 (27.7) | 219 (26.9) | |
| *Pentecostal* | 16 (3.6) | 5 (1.3) | 21 (2.6) | |
| *Born again* | 45 (10.3) | 26 (6.9) | 71 (8.7) | |
| *Muslim* | 89 (20.3) | 716 (18.9) | 160 (19.6) | |
| *No religion* | 1 (0.2) | 0 (0) | 1 (0.1) | |
| *Other* | 5 (1.1) | 1 (0.3) | 6 (0.7) | |
| *Missing* | *408 (48.2)* | *395 (51.2)* | *803 (49.6)* | |
| Employment status | | | | 0.96 |
| *Employed for wages* | 134 (30.7) | 119 (31.7) | 253 (31.2) | |
| *Self-employed* | 231 (53.0) | 198 (52.8) | 429 (52.9) | |
| *Business partnership* | 26 (6.0) | 20 (5.3) | 46 (5.7) | |
| *Student* | 1 (0.2) | 0 (0) | 1 (0.1) | |
| *Out of work (unemployed)* | 3 (0.7) | 4 (1.1) | 7 (0.9) | |
| *Retired* | 1 (0.2) | 1 (0.3) | 2 (0.3) | |
| *Other* | 40 (9.2) | 33 (8.8) | 73 (9.0) | |
| *Missing* | *411 (48.5)* | *396 (51.4)* | *807 (52.2)* | |
| Marital status | | | | 0.11 |
| *Currently married* | 84 (13.2) | 101 (18.2) | 185 (15.6) | |
| *Cohabiting* | 531 (83.6) | 439 (79.1) | 970 (81.5) | |
| *Never married* | 12 (1.9) | 11 (2.0) | 23 (1.9) | |
| *Widowed* | 2 (0.3) | 0 (0) | 2 (0.2) | |
| *Divorced or separated* | 6 (0.9) | 4 (0.7) | 10 (0.8) | |
| *Missing* | *212 (25.0)* | *216 (28.0)* | *428 (26.5)* | |

A slight difference may be seen with educational attainment in women, with 22 of 847 (2.6%) completing university in the intervention arm versus 12 of 771 (1.6%) in the control arm. A slight difference may also be seen with reported religious affiliation in men, with 168 of 847 (38.3%) Catholics in the intervention arm versus 169 of 771

(45.0%) in the control arm, although the difference was largely in the distribution of different types of Christianity (fewer Pentecostal and born-again Christians).

At baseline, the mean age for male partners was 32.2 (8.1) and slightly more than half (602 of 1,198, or 51.1%) were between 25 and 34 years of age. The majority were cohabiting (970 of 1,198, or 81.5%), more than half were self-employed (429 of 1,198, or 52.9%) and almost half were Catholics (337 of 1,198, or 41.4%). The two study groups did not differ significantly.

### *4.1.2 Male partners' uptake of HIV testing*

In our primary comparison between intervention and control arms, the focus was on the woman's report of her male partner's having used the oral self-testing kit to test for HIV (Table 3). We present results for month 1 interviews, month 3 interviews and cumulative measures looking across both time points. In addition, we present results for the woman's report, the man's report and measures we constructed based on both reports.

In all combined measures, we took the most optimistic assumption. For example, if either partner reported that the man had tested, then we classified the man as having tested in the combined measure. At month 1 and at month 3, we attempted to contact all enrolled participants to ask about HIV testing, confirmatory testing and linkage to care.

**Table 3: Primary outcome tables by intervention arm and follow-up time point – woman's report of male partner testing**

| **Month 1 woman's report** | | | | |
|---|---|---|---|---|
| | **Since your last interview, has your partner tested for HIV?** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 477 (81.1) | 216 (29.4) | 693 | 3.9 (3.28–4.67) |
| Control, n (%) | 111 (18.9) | 520 (70.7) | 631 | |
| Total[a] | 588 (44.4) | 736 (55.6) | 1,324 | |
| *Missing* | | | *294* | |
| **Month 3 woman's report** | | | | |
| | **Since your last interview, has your partner tested for HIV?** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 171 (29.1) | 416 (70.9) | 587 | 1.31 (1.07–1.61) |
| Control, n (%) | 116 (22.2) | 407 (77.8) | 523 | |
| Total | 287 (25.4) | 823 (74.6) | 1,110 | |
| *Missing* | | | *508* | |
| **Combined month 1 and month 3 woman's report** | | | | |
| | **Male tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 567 (70.4) | 238 (29.6) | 805 | 2.57 (2.26–2.91) |
| Control, n (%) | 201 (27.5) | 531 (72.5) | 732 | |
| Total | 768 (50.0) | 769 (50.0) | 1,537 | |
| *Missing* | | | *81* | |

Note: [a] Columns may not total to 100 due to missing values.

In month 1, 477 of 693 women (81.1%) reported that their male partners had tested in the intervention arm, versus 111 of 631 (18.9%) in the control arm (RR 3.9, 95% CI: 3.28–4.67). At the month 3 follow-up, women were asked whether their male partners

had tested since the last interview; 171 of 587 (29.1%) and 116 of 523 (22.2%) reported testing in the intervention and control group, respectively (RR 1.31, 95% CI: 1.07–1.61).

Looking across both follow-up time points, we defined a cumulative measure (as described above in 4.1.2) based on reported testing at either time point. For the purposes of the cumulative measure, we considered the male partner not to have tested if the response was “no/don’t know” at month 1 and either missing or “no/don’t know” at month 3. Based on this definition, the woman’s cumulative report regarding whether her male partner had tested for HIV during the entire 3-month follow-up period was 567 of 805 (70.4%) in the intervention group versus 201 of 732 (27.5%) in the control group (RR 2.57, 95% CI: 2.26–2.91).

Some 99 percent of the women at baseline and 88.9 percent of the men at their first interview (month 1 follow-up) reported having ever been previously tested for HIV. However, 34 men (16 in the intervention arm and 18 in the control arm) were tested for the first time during the study period (RR 2.08; 95% CI: 1.19–3.63).

When combining the woman’s and man’s reports for testing for HIV across the whole study period, we found that 626 of 816 (76.7%) in the intervention group versus 278 of 742 (37.5%) in the control group had tested for HIV (Table 4).

**Table 4: Primary outcome tables by intervention arm, combined woman’s and man’s report of male partner testing**

| | Tested | Did not test | Total n | p-value |
|---|---|---|---|---|
| Intervention, n (%) | 626 (76.7) | 190 (23.3) | 816 | < 0.01 |
| Control, n (%) | 278 (37.5) | 464 (62.5) | 742 | |
| Total, n (row %) | 904 (58.0) | 654 (42.0) | 1,558 | |

To explore heterogeneity of effects, we analyzed the group differences, stratified by pre-specified potential effect modifiers: woman’s age, woman’s educational attainment, woman’s employment status, study site and woman’s baseline HIV status. We had intended to also assess religious affiliation, but were unable to do so due to large amounts of missing data for the women’s religious affiliation.

To explore effect modification by age, we stratified the age of the ANC client into four categories: 15–19 years, 20–24 years, 25–29 years and 30–49 years, as Table 5 shows. We saw very little effect modification by age, with very similar risk ratios (RRs) in the four categories: 2.61, 2.34, 2.77 and 2.67, respectively.

**Table 5: Primary outcome table for combined month 1 and month 3 woman's report by allocation day and woman's age**

| **Age 15–19 years** | | | | |
|---|---|---|---|---|
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 83 (72.8) | 31 (27.2) | 114 | 2.61 (1.86–3.67) |
| Control, n (%) | 27 (27.8) | 70 (72.2) | 97 | |
| Total | 110 (52.1) | 101 (47.9) | 211 | |
| *Missing* | | | *14* | |
| **Age 20–24 years** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 223 (70.6) | 93 (29.4) | 316 | 2.34 (1.93–2.84) |
| Control, n (%) | 82 (30.2) | 190 (69.8) | 272 | |
| Total | 305 (51.9) | 283 (48.1) | 588 | |
| *Missing* | | | *23* | |
| **Age 25–29 years** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 149 (72.0) | 58 (28.0) | 207 | 2.77 (2.15–3.58) |
| Control, n (%) | 49 (25.9) | 140 (74.1) | 189 | |
| Total | 198 (50.0) | 198 (50.0) | 396 | |
| *Missing* | | | *29* | |
| **Age 30–49 years** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 105 (65.6) | 55 (34.4) | 160 | 2.67 (1.99–3.58) |
| Control, n (%) | 40 (24.5) | 123 (75.5) | 163 | |
| Total | 145 (44.9) | 178 (55.1) | 323 | |
| *Missing* | | | *13* | |

To explore effect modification by education, we stratified the ANC client's educational attainment into three categories – none/primary, secondary/vocational and college/university – as Table 6 shows. We saw little effect modification by educational level, with very similar RRs in the three categories: 2.44, 2.72 and 2.25, respectively.

**Table 6: Primary outcome tables for combined month 1 and month 3 woman's report by allocation day and woman's educational level**

| **None/primary** | | | | |
|---|---|---|---|---|
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 220 (68.3) | 102 (31.7) | 3225 | 2.44 (2.01–2.96) |
| Control, n (%) | 867 (28.0) | 221 (72.0) | 307 | |
| Total | 306 (48.7) | 323 (51.4) | 629 | |
| *Missing* | | | *44* | |
| **Secondary/Vocational** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 291 (71.5) | 116 (28.5) | 407 | 2.72 (2.26–3.27) |
| Control, n (%) | 95 (26.2) | 267 (73.8) | 362 | |
| Total | 386 (50.2) | 383 (49.8) | 769 | |
| *Missing* | | | *32* | |
| **College/University** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 46 (71.93) | 18 (28.1) | 64 | 2.25 (1.46–3.46) |
| Control, n (%) | 16 (32.0) | 34 (68.0) | 50 | |
| Total | 62 (54.4) | 52 (45.6) | 114 | |
| *Missing* | | | *3* | |

To explore effect modification by ANC client's employment status, we created three categories – employed for wages, self-employed and other – as Table 7 shows.

The very low prevalence of employment limited our statistical power to detect an interaction by employment status; however, we did see some differences in the observed impact of self-testing in these categories. Among ANC clients employed for wages, 14 of 31 male partners in the intervention arm, versus 6 of 17 in the control arm, tested for HIV during the 3-month follow-up period (RR 1.18, 95% CI: 0.73–1.90).

Interestingly, among ANC clients who were self-employed, 41 of 56 male partners in the intervention arm, versus 7 of 39 in the control group, tested for HIV (RR 3.06, 95% CI: 1.93–4.84). Among ANC clients who were neither employed for wages nor self-employed, 90 of 119 male partners in the intervention arm, versus 35 of 111 in the control arm, tested for HIV (RR 2.81, 95% CI: 2.00–3.95).

**Table 7: Primary outcome tables for combined month 1 and month 3 woman's report by allocation day and woman's employment status**

| **Employed for wages** | | | | |
|---|---|---|---|---|
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention day, n (%) | 14 (45.2) | 17 (54.8) | 31 | 1.27 (0.60–2.71) |
| Control day, n (%) | 6 (35.3) | 11 (64.7) | 17 | |
| Total | 20 (41.7) | 28 (57.1) | 48 | |
| *Missing* | | | *7* | |
| **Self-employed** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention day, n (%) | 41 (73.2) | 15 (26.8) | 56 | 4.08 (2.05–8.12) |
| Control day, n (%) | 7 (17.9) | 32 (82.0) | 39 | |
| Total | 48 (50.5) | 47 (49.5) | 95 | |
| *Missing* | | | *17* | |
| **Other** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention day, n (%) | 90 (75.6) | 29 (24.4) | 111 | 2.81 (2.00–3.95) |
| Control day, n (%) | 35 (31.5) | 76 (68.5) | 119 | |
| Total | 125 (54.4) | 105 (45.6) | 230 | |
| *Missing* | | | *42* | |

To explore site differences, we evaluated the intervention impact separately at Entebbe, Mpigi and Nakaseke (Table 8).

We observed comparable uptake of HIV testing in the intervention arm at the different study sites, but substantially higher testing at Nakaseke in the control arm, contributing to a lower observed intervention impact at that study site. Specifically, the RRs were 1.87 for Nakaseke, 2.97 for Mpigi and 2.71 for Entebbe.

**Table 8: Primary outcome tables for combined month 1 and month 3 woman's report by allocation day and facility**

| **Nakaseke** | | | | |
|---|---|---|---|---|
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention day, n (%) | 115 (67.7) | 55 (32.3) | 170 | 1.87 (1.47–2.36) |
| Control day, n (%) | 54 (36.2) | 95 (63.8) | 149 | |
| Total | 169 (53.0) | 150 (47.0) | 319 | |
| *Missing* | | | *14* | |
| **Mpigi** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention day, n (%) | 199 (70.8) | 82 (29.2) | 281 | 2.97 (2.36–3.75) |
| Control day, n (%) | 61 (23.8) | 195 (76.2) | 256 | |
| Total | 260 (48.4) | 277 (51.6) | 537 | |
| *Missing* | | | *22* | |
| **Entebbe** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention Day, n (%) | 253 (71.5) | 101 (28.5) | 354 | 2.71 (2.24–3.29) |
| Control Day, n (%) | 86 (26.3) | 241 (73.7) | 327 | |
| Total | 339 (49.8) | 342 (50.2) | 681 | |
| *Missing* | | | *45* | |

To explore effect modification by woman's baseline HIV status, we stratified the ANC clients' baseline HIV status into three categories – HIV-positive, HIV-negative and did not receive last HIV test result – as Table 9 shows.

We saw some effect modification by baseline HIV status, with RRs in the three categories of 2.76, 2.52 and 3.6, respectively. However, these subgroup differences should be interpreted with caution, due to the small number of women in the "did not receive last HIV test result" category.

Finally, we used multivariable log-binomial models to estimate adjusted RRs and to explore subgroup heterogeneity. We fit models with clustering to account for the group-randomized study design. Overall, no covariates were imbalanced at baseline and ICCs were low, so the adjusted results with clustering were comparable to the unadjusted results shown below.

**Table 9: Primary outcome tables for combined month 1 and month 3 woman's report by allocation day and woman's baseline HIV status**

| **Positive HIV baseline status** | | | | |
|---|---|---|---|---|
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 65 (67.7) | 31 (32.3) | 96 (62.8) | 2.76 (1.71–4.43) |
| Control, n (%) | 14 (24.6) | 43 (75.4) | 57 (37.3) | |
| Total | 79 (51.6) | 74 (48.4) | 153 (100) | |
| *Missing* | | | *8* | |
| **Negative HIV baseline status** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 471 (71.0) | 192 (29.0) | 663 (51.3) | 2.52 (2.21–2.89) |
| Control, n (%) | 177 (28.1) | 453 (71.9) | 630 (48.7) | |
| Total | 648 (50.1) | 645 (49.9) | 1293 (100) | |
| *Missing* | | | *67* | |
| **Did not receive last HIV test result** | | | | |
| | **Male partner tested at month 1 and/or month 3** | | | |
| | **Yes** | **No** | **Total** | **RR (95% CI)** |
| Intervention, n (%) | 9 (60.0) | 6 (40.0) | 15 (45.5) | 3.6 (1.18–10.95) |
| Control, n (%) | 3 (16.7) | 15 (83.3) | 18 (54.6) | |
| Total | 12 (36.4) | 21 (63.6) | 33 (100) | |
| *Missing* | | | *1* | |

We found that male partners in the intervention arm were much more likely to test for HIV than men in the control arm, with an RR (95% CI) of 2.6 (2.3, 2.9) after controlling for the woman's baseline HIV status, employment status and study site. Regarding subgroup differences in intervention impact, we found significant site differences (interaction p-value < 0.01 for Mpigi versus Nakaseke, and p = 0.02 for Entebbe versus Nakaseke).

We also found possible subgroup differences by woman's employment status, with an interaction p-value of 0.05 for a difference in intervention impact comparing self-employed versus employed for wages, and p = 0.10 for other employment status versus employed for wages.

In addition, although no significant interaction was detected between the intervention arm and woman's baseline HIV status, we explored stratified RRs by HIV status, because this was a major secondary question of interest. Adjusted RRs, stratifying by study site, were 1.9 (1.5, 2.3) for Nakaseke, 3.0 (2.4, 3.7) for Mpigi and 2.7 (2.2, 3.3) for Entebbe. Adjusted RRs, stratifying by woman's employment status, were 1.3 (0.61, 2.9) for employed for wages, 3.6 (1.9, 7.1) for self-employed and 2.6 (2.3, 2.9) for other employment status. Finally, adjusted RRs, stratifying for woman's baseline HIV status, were 2.8 (1.7, 4.4) for women who were HIV-positive and 2.5 (2.2, 2.9) for women who were HIV-negative or whose status was unknown.

### *4.1.3 HIV case finding*

When combining the woman's and man's reports across the whole study period, 53 men tested positive of the 904 who reported testing, with 42 in the intervention arm and 11 in the control arm. In Table 10, we show overall testing results among the 904 who reported testing.

**Table 10: Results of man's HIV testing, combined across woman's and man's report and month 1 and 3, stratified by allocation day**

| Study arm | Missing | Positive | Negative | Indeterminate | Did not receive result | Total | p-value |
|---|---|---|---|---|---|---|---|
| Intervention, n (%) | 6 (1.0) | 42 (6.7) | 569 (90.9) | 6 (1.0) | 3 (0.5) | 626 | 0.02 |
| Control, n (%) | 10 (3.6) | 11 (4.0) | 254 (91.4) | 1 (0.4) | 2 (0.7) | 278 | |
| Total, n (row %) | 16 (1.8) | 53 (5.9) | 823 (91.0) | 7 (0.8) | 5 (0.6) | 904 | |

### *4.1.4 Confirmatory testing and linkage to care among male partners*

As Table 11 shows, after 1 month of follow-up, of 307 men who tested using oral self-testing, 26 (almost 9%) went for confirmatory testing, and 281 did not.

**Table 11: Confirmatory testing for male partners who used HIVST as reported by woman in month 1**

| HIVST result | Confirmatory testing, n (%) | No confirmatory testing, n (%) | Total | p-value |
|---|---|---|---|---|
| Positive | 4 (25.0) | 12 (75.0) | 16 | 0.06 |
| Negative | 22 (7.8) | 262 (92.3) | 284 | |
| Indeterminate | 0 (0) | 7 (100) | 7 | |
| Total | 26 (8.5) | 281 (91.5) | 307 | |

Of the men who tested positive on the HIVST, 4 of 16 (25.0%) went for confirmatory testing, compared with 22 of 284 (7.8%) of the men testing negative and zero of 7 (0%) of the men who tested indeterminate in HIVST. Even with our small sample size, this difference in confirmatory testing was substantial enough to show borderline statistical significance ($p = 0.06$).

Furthermore, this difference in rates of confirmatory testing was in the expected direction, with those testing positive appearing to have higher rates of confirmatory testing than those with negative or indeterminate results with the self-testing kit.

Based on the combined woman's and man's reports at both time points (Table 12), 472 men used the HIVST and answered the confirmatory testing question. Of those 472, 102 went for confirmatory testing and 356 did not. Of the men testing positive in HIVST, 11 of 26 (42.3%) went for confirmatory testing, compared with 89 of 436 (20.4%) of the men testing negative and 2 of 5 (40%) of the men testing indeterminate (p-value < 0.01).

**Table 12: Confirmatory testing for male partners who used HIVST, as reported by woman or man, month 1 or 3**

| HIVST result | Missing | Went for confirmatory test | Did not go for confirmatory test | Total | p-value |
|---|---|---|---|---|---|
| Missing, n (%) | 2 (100.0) | 0 (0) | 0 (0) | 2 | < 0.01 |
| Positive, n (%) | 0 (0) | 11 (42.3) | 15 (57.7) | 26 | |
| Negative, n (%) | 12 (2.8) | 89 (20.4) | 335 (76.8) | 436 | |
| Indeterminate, n (%) | 0 (0) | 2 (40.0) | 3 (60.0) | 5 | |
| Did not receive results, n (%) | 0 (0) | 0 (0) | 3 (100.0) | 3 | |
| Total, n (row %) | 14 (3.0) | 102 (21.6) | 356 (75.4) | 472 | |

Linkage to care among male partners testing positive for HIV was evaluated based on the woman's report and the man's report. Based on the woman's report (Table 13), during the first month of follow-up, 12 men in the intervention arm and two men in the control arm tested positive, with one from the intervention group and two from the control group linking to care.

**Table 13: Linkage to care for male partners as reported by woman, stratified by intervention arm and follow-up period**

| Variable | Yes | No | Total | p-value |
|---|---|---|---|---|
| Month 1 woman's report | | | | |
| Intervention day, n (%) | 1 (8.3) | 11 (91.7) | 12 | 0.03 |
| Control day, n (%) | 2 (100) | 0 (0) | 2 | |
| Total | 3 (21.4) | 11 (78.6) | 14 | |
| Month 3 woman's report | | | | |
| Intervention day, n (%) | 1 (14.3) | 6 (85.7) | 7 | 0.08 |
| Control day, n (%) | 2 (100) | 0 (0) | 2 | |
| Total | 3 (33.3) | 6 (66.7) | 9 | |
| Combined month 1 and month 3 woman's report | | | | |
| Intervention day, n (%) | 2 (10.5) | 17 (89.5) | 19 | < 0.01 |
| Control day, n (%) | 4 (100) | 0 (0) | 4 | |
| Total | 6 (26.1) | 17 (73.9) | 23 | |

Note: Chi-square values are based on available data and exclude missing. Fisher's exact test was used as needed when one or more cells were less than 5.

Over the entire three-month follow-up period, based on the woman's report, 19 men in the intervention arm and 4 men in the control arm tested positive, but only 6 men linked to care, with a significant difference between the study groups: 2 (10.5%) in the intervention arm and 4 (100%) in the control arm linked to care (Fisher's exact test, $p < 0.01$).

Based on the man's report, however, we did not observe a significant difference between groups. As Table 14 shows, 29 men (24 in the intervention arm and 5 in the control arm) tested positive over the entire three-month follow-up period. Of the 29 who tested positive, 10 (41.7%) men in the intervention arm and 3 (60%) men in the control arm linked to care.

**Table 14: Linkage to care for male partners as reported by man, stratified by intervention arm and follow-up period**

| Variable | Yes | No | Total | p-value |
|---|---|---|---|---|
| Month 1 male partner's report | | | | |
| Intervention day, n (%) | 6 (30.0) | 14 (70.0) | 20 | 0.31 |
| Control day, n (%) | 3 (60) | 2 (40) | 5 | |
| Total | 9 (36.0) | 16 (64.0) | 25 | |
| Month 3 male partner's report | | | | |
| Intervention day, n (%) | 6 (85.7) | 1 (12.5) | 7 | 1.00 |
| Control day, n (%) | 1 (100) | 0 (0) | 1 | |
| Total | 7 (87.5) | 1 (12.5) | 8 | |
| Combined month 1 and month 3 male partner's report | | | | |
| Intervention day, n (%) | 10 (41.7) | 14 (58.3) | 24 | 0.63 |
| Control day, n (%) | 3 (60) | 2 (40) | 5 | |
| Total | 13 (44.8) | 16 (55.2) | 29 | |

Note: Chi-square values are based on available data and exclude missing. Fisher's exact test was used as needed when one or more cells were less than 5.

When we combined men's and women's reports (Table 15), we found that 53 men (42 in the intervention arm and 11 in the control arm) tested positive over the entire three-month follow-up period. Of the 53 who tested positive by any means and answered the linkage to care question, 10 (23.8%) men in the intervention arm and 5 (45.5%) men in the control arm linked to care.

**Table 15: Linkage to care for male partners as reported by either woman or man, combining month 1 and 3, stratified by intervention arm**

| Study arm | Missing | Registered for care | Did not register for care | Total | p-value |
|---|---|---|---|---|---|
| Intervention, n (%) | 9 (21.4) | 10 (23.8) | 23 (54.8) | 42 | 0.09 |
| Control, n (%) | 4 (36.4) | 5 (45.5) | 2 (18.2) | 11 | |
| Total, n (row %) | 13 (24.5) | 15 (28.3) | 25 (47.2) | 53 | |

Note: Chi-square values are based on available data and exclude missing. Fisher's exact test was used as needed when one or more cells were less than 5.

### *4.1.5 Long-term follow-up (phase 3): confirmatory testing and linkage to care*

As described above, in phase 3 of the study, we sought to re-contact couples in which the male partner had tested positive for HIV through self-testing, to enable longer-term follow-up of linkage to care outcomes. Participants were contacted after a range of 5 to 26 months after baseline (mean 13.8 ± 8.0 months).

In phases 1 and 2, we identified a total of 26 men testing positive; however, 2 of these men did not use the self-testing kits and 1 died during follow-up. Of the remaining 23 men, we interviewed 18 in phase 3 for the long-term follow-up interview (78% retention).

As Tables 10 and 12 show, based on the man's report and the woman's report across months 1 and 3, there were 42 men in the intervention arm who tested positive, of whom 26 used the self-testing kit and answered the question about confirmatory testing. In months 1 and 3, based on the combined responses from the man and the woman, we ascertained that 11 of these 26 men went for confirmatory HIV testing at the clinic (Table 12).

Similarly, of the 42 men testing positive in the intervention arm, we ascertained that 10 men registered in HIV care (Table 15), with 23 failing to register in care and 9 missing. Therefore, in the extended follow-up, we were particularly interested in the men who, by the month 3 interview, had not yet reported confirmatory testing or linkage to care.

In Table 16, we summarize confirmatory testing results from phase 3 of the study, based on the 26 men who had tested positive via HIVST. Overall, we found a notable increase in men going for confirmatory testing during the extended follow-up period, bringing the proportion from 11 of 26 to 16 of 26.

**Table 16: Confirmatory testing at long-term follow-up (at long-term visit and cumulative) for male partners testing positive by HIVST**

| | Missing | Went for confirmatory test | Did not go for confirmatory test | Total |
|---|---|---|---|---|
| **Long-term visit** | | | | |
| Woman's report | 21 (80.8%) | 4 (15.4%) | 1 (3.8%) | 26 |
| Partner's report | 19 (73.1%) | 7 (26.9%) | 0 (0%) | 26 |
| Combined | 19 (73.1%) | 7 (26.9%) | 0 (0%) | 26 |
| **Cumulative** | | | | |
| Woman's report | 0 (0%) | 12 (46.2%) | 14 (53.8%) | 26 |
| Partner's report | 5 (19.2%) | 13 (50.0%) | 8 (30.8%) | 26 |
| Combined | 0 (0%) | 16 (61.5%) | 10 (38.5%) | 26 |

Among the 15 men who tested positive with HIVST but did not go for confirmatory testing during the first three months, we found that 3 men had gone for confirmatory testing based on the woman's report. However, based on the man's report, and looking across both the woman's report and the man's report, we found that 5 of the 15 men had gone for confirmatory testing between the month 3 visit and the long-term visit.

Looking across all three study visits, therefore, we found that 16 of the 26 men eventually went for confirmatory testing. Finally, among all 42 men who tested positive in the intervention arm, we found that 21 eventually went for confirmatory testing, with 15 failing and 6 missing.

Regarding linkage to care, in Table 17 we summarize results from the long-term visit and updated cumulative results for linkage to care among men testing positive via HIVST.

**Table 17: Linkage to HIV care at long-term follow-up (at long-term visit and cumulative) for male partners testing positive by HIVST**

| | Missing | Linked to HIV care | Did not link to HIV care | Total |
|---|---|---|---|---|
| **Long-term visit** | | | | |
| Woman's report | 22 (84.6%) | 3 (11.5%) | 1 (3.8%) | 26 |
| Partner's report | 20 (76.9%) | 5 (19.2%) | 1 (3.8%) | 26 |
| Combined | 20 (76.9%) | 5 (19.2%) | 1 (3.8%) | 26 |
| **Cumulative** | | | | |
| Woman's report | 10 (38.5%) | 3 (11.5%) | 13 (50.0%) | 26 |
| Partner's report | 12 (46.2%) | 7 (26.9%) | 7 (26.9%) | 26 |
| Combined | 4 (15.4%) | 7 (26.9%) | 15 (57.7%) | 26 |

Overall, among all men testing positive in the intervention arm, whether or not they used HIVST, when including the longer-term follow-up we found an increase from 10 of 42 (Table 15) to 14 of 42 (with 21 failing to link to care and 7 missing), demonstrating a meaningful proportion of men who did link to care after the month 3 visit.

In comparison, among 11 men testing positive in the control arm, 5 men linked to care during the first three months of follow-up, with only 2 failing and 4 missing. Therefore, linkage to care among men testing positive via HIVST continued to lag behind linkage among men who tested positive at the clinic in the control arm.

#### *4.1.6 Secondary outcomes: passing the kit to the male partner and testing as a couple among HIV-positive and -negative women attending antenatal care*

Overall, 651 of 662 (98.3%) women took the HIV oral self-testing kit home; 597 of 647 (92.1%) women passed the kits on to their partners and the majority of the women who passed the kits to their partners passed them on the same day (239 of 497, 40.0%) or within the first week (254 of 597, 42.6%).

As Table 18 shows, based on the combined woman's report and man's report, approximately three quarters (562 of 767, or 73.3%) in the intervention arm reported to have tested as a couple. The difference in couples testing was statistically different at all follow-up points but highest within the month 1 women's report, with 419 of 573 (73.1%) versus 45 of 241 (18.7%).

**Table 18: HIV self-testing as a couple among pregnant woman attending antenatal care and their male partners**

| Variable | Yes | No | Total | p-value |
|---|---|---|---|---|
| **Month 1 woman's report** | | | | |
| **Did you test together as a couple?** | | | | |
| Intervention arm, n (%) | 419 (73.1) | 154 (26.9) | 573 | < 0.0001 |
| Control arm, n (%) | 45 (18.7) | 196 (81.3) | 241 | |
| Total | 464 (57.0) | 350 (43.0) | 814 | |
| *Missing* | | | *804 (49.7)* | |
| **Month 3 woman's report** | | | | |
| **Did you test together as a couple?** | | | | |
| Intervention arm, n (%) | 100 (33.3) | 200 (66.7) | 300 | 0.003 |
| Control arm, n (%) | 54 (22.0) | 192 (78.1) | 246 | |
| Total | 154 (28.2) | 392 (71.8) | 546 | |
| *Missing* | | | *1,072 (66.3)* | |
| **Combined month 1 and month 3 woman's and man's report** | | | | |
| **Did you test together as a couple?** | | | | |
| Intervention arm, n (%) | 562 (73.3) | 205 (26.7) | 767 | < 0.0001 |
| Control arm, n (%) | 186 (30.8) | 418 (69.2) | 604 | |
| Total | 748 (54.6) | 623 (45.4) | 1,371 | |
| *Missing* | | | *247 (15.3)* | |

#### *4.1.7 Disclosure rates and outcomes of partner HIVST across the two arms (positive including partner support for women and negative events, including social harms)*

A third of the women (533 of 1,562, or 34.1%) reported having disclosed their HIV status at baseline. Their disclosure rates at the subsequent follow-up points were higher than their male partners' (Table 19).

A comparison of disclosure rates by arm reveals meaningful differences, but must take into account the fact that many more couples in the intervention arm tested together. Therefore, tables 19 and 20 refer only to those couples who did not test together.

**Table 19: Disclosure rates from woman to man in baseline report**

| Baseline woman's report | Yes | No | Only tested today | Total | p-value |
|---|---|---|---|---|---|
| Intervention, n (%) | 270 (32.8) | 238 (28.9) | 315 (38.3) | 823 | 0.38 |
| Control, n (%) | 263 (35.6) | 216 (29.2) | 260 (35.2) | 739 | |
| Total | 533 (34.1) | 454 (29.1) | 575 (36.8) | 1,562 | |

As Table 20 shows, disclosure rates were generally comparable across arms, although more men in the control arm reported having disclosed to their partners than their counterparts in the intervention arm. During month 1, 214 of 309 (69.3%) men in the control arm and 105 of 164 (64.0%) in the intervention arm disclosed their test results to their partners, although the difference was not statistically significant.

Disclosure by men increased by more than 10 percent (to 38 of 46, or 82.6%) in the control arm and by 8 percent (to 27 of 39, or 69.2%) in the intervention arm at month 3.

**Table 20: Disclosure rates in man's report, stratified by arm and follow-up period**

| **Month 1 man's report** | | | | |
|---|---|---|---|---|
| | **If you didn't test with your partner, did you disclose your results to her?** | | | |
| | **Yes** | **No** | **Total** | **p-value** |
| Intervention day, n (%) | 105 (64.0) | 59 (36.0) | 164 | 0.25 |
| Control day, n (%) | 214 (69.3) | 95 (30.7) | 309 | |
| Total | 319 (67.4) | 154 (32.6) | 473 | |
| *Missing* | | | *1,145* | |
| **Month 3 man's report** | | | | |
| | **If you didn't test with your partner, did you disclose your results to her?** | | | |
| | **Yes** | **No** | **Total** | **p-value** |
| Intervention day, n (%) | 27 (69.2) | 12 (30.8) | 39 | 0.15 |
| Control day, n (%) | 38 (82.6) | 8 (17.4) | 46 | |
| Total | 65 (76.5) | 20 (23.5) | 85 | |
| *Missing* | | | *1,533* | |

As Table 21 shows, more women in the intervention arm (66 of 277, or 23.8%) than in the control arm (75 of 563, or 13.3%) reported that their partners disclosed their test results at month 1. At month 3, slightly more women in the intervention arm (94 of 487, or 19.3%) reported partners' disclosure, compared with those in the control arm (64 of 454, or 14.1%). Although the difference in disclosure rates among women was statistically significant at month 1, the difference was comparable at month 3 and across all follow-up points among men.

**Table 21: Disclosure rates in woman's report, stratified by arm and follow-up period**

| **Month 1 Woman's report** | | | | | |
|---|---|---|---|---|---|
| **If you didn't test as a couple, did your partner disclose to you his test results?** | | | | | |
| | **Yes** | **No** | **Don't know** | **Total** | **p-value** |
| Intervention day, n (%) | 66 (23.8) | 120 (43.3) | 91 (32.8) | 277 | < 0.01 |
| Control day, n (%) | 75 (13.3) | 275 (48.8) | 214 (37.9) | 564 | |
| Total | 141 (16.8) | 395 (47.0) | 305 (36.3) | 841 | |
| *Missing* | | | | *777* | |
| **Month 3 woman's report** | | | | | |
| **If you didn't test as a couple, did your partner disclose to you his test results?** | | | | | |
| | **Yes** | **No** | **Don't know** | **Total** | **p-value** |
| Intervention day, n (%) | 94 (19.3) | 222 (45.6) | 171 (35.9) | 487 | 0.09 |
| Control day, n (%) | 64 (14.1) | 227 (50) | 163 (35.9) | 454 | |
| Total | 158 (16.8) | 449 (47.7) | 334 (35.5) | 941 | |
| *Missing* | | | | *677* | |

### *4.1.8 Positive and negative social outcomes*

In the questionnaires, we asked women and their partners about positive and negative social outcomes at baseline and throughout the follow-up period. Negative social outcomes were of interest to address the concern that stress associated with HIV testing, and conflict related to the woman's bringing a kit home, might result in social harms. On the other hand, positive social outcomes were of interest to investigate whether successful HIV testing, and possibly increased self-efficacy associated with HIVST, might improve the relationship or have other beneficial social outcomes.

We assessed the women's questionnaire regarding how the men responded to the idea of HIV testing, and found minimal negative outcomes. Overall, of those who answered the question at the month 1 interview, the largest percentage of women reported the men to be happy (45.0%), with 20.5% "not sure" and 7.9%, 4.6%, 4.3%, 0.5%, and 17.2% of the women describing the men as "did not want to talk," "angry," "fearful," "violent" and "other," respectively.

The majority of the men (66.4% overall, similar between study arms) did not change in the way they supported their pregnant partners. The most common support given to the women was money to attend ANC clinic; this was reported by 452 of 847 (52.3%) of the women in the intervention arm and 413 of 771 (47.8%) in the control arm (Table 22).

Many of the study participants (22 of 45 women, or 48.9%; and 17 of 41 men, or 41.5%) had considered ending the relationship after they learned of the discordant status. However, few actually left the relationship.

Overall, women were significantly more likely than men to share their discordant status with others, with somewhat higher rates of disclosure (not statistically significant) to parents and friends. However, men were somewhat more likely than women to share the discordant status with other relatives (not statistically significant).

**Table 22: Partner support based on woman's report**

| *Row % for month 1 & 3 separately* | **Month 1** | | **Month 3** | |
|---|---|---|---|---|
| | **Intervention (n = 847)** | **Control (n = 771)** | **Intervention (n = 847)** | **Control (n = 771)** |
| **How has your partner supported you towards attending antenatal care, after your last interview? (Row percentages; women could choose more than one)** | | | | |
| Money to attend ANC, n (%) | 452 (52.3) | 413 (47.8) | 305 (52.8) | 273 (47.2) |
| Escorts me to attend ANC, n (%) | 47 (56.6) | 36 (43.4) | 46 (56.1) | 36 (43.9) |
| ANC reminders, n (%) | 213 (49.9) | 214 (50.1) | 126 (52.7) | 113 (47.3) |
| Does not support me to attend ANC, n (%) | 31 (50.0) | 31 (50.0) | 28 (50.9) | 27 (49.1) |
| **In your assessment, how has the support from your husband changed, if at all? (Column percentages)** | | | | |
| Not changed, n (%) | 475 (68.6) | 412 (64.0) | 346 (59.2) | 281 (54.8) |
| Improved, n (%) | 167 (24.1) | 174 (27.0) | 180 (30.8) | 188 (36.7) |
| Reduced, n (%) | 47 (6.8) | 54 (8.4) | 59 (10.1) | 44 (8.6) |
| Not sure, n (%) | 3 (0.4) | 4 (0.6) | n/a | n/a |

As Table 23 shows, at month 1, according to the woman's report, a higher proportion reported their partners' humiliating them or threatening to harm them (34 of 690 versus 10 of 643, p = 0.0006). However, only a few of these women reported this to be related to the HIV testing (8 of 32 versus 1 of 10, p = 0.42), providing no clear support for the concern that HIVST might lead to gender-based violence.

Furthermore, only two couples in the intervention arm were reported to have separated during the study period, with no other intimate partner violence registered.

**Table 23: Social harms based on woman's report**

| *Row % for month 1 and 3 separately* | **Month 1** | | **Month 3** | |
|---|---|---|---|---|
| | **Intervention (n = 847)** | **Control (n = 771)** | **Intervention (n = 847)** | **Control (n = 771)** |
| Partner humiliated or threatened to harm you | 34 (4.9%) | 10 (1.6%) | 13 (2.2%) | 12 (2.3%) |
| *Related to HIV testing?* | 8 (0.9%) | 1 (0.2%) | 2 (0.4%) | 2 (0.4%) |
| Physical harm | 16 (2.3%) | 7 (1.1%) | 11 (1.9%) | 4 (0.8%) |
| *Related to HIV testing?* | 4 (0.5%) | 1 (0.2%) | 1 (0.2%) | 0 (0.0%) |
| Worried partner may harm you | 13 (1.9%) | 11 (1.7%) | 15 (2.6%) | 4 (0.8%) |

### *4.1.9 Coping strategies among discordant couples*

In phase 3 (long-term follow-up), we enrolled discordant couples to assess coping strategies, in addition to confirmatory testing and linkage to care, as summarized above. In Table 24, we summarize reported impacts on the relationship and coping strategies discordant couples employed.

**Table 24: Discordant couples – relationship outcomes and strategies for coping**

| | Woman | Male partner | p-value |
|---|---|---|---|
| Thought of quitting relationship? | 22/45 (48.9%) | 17/41 (41.5%) | 0.49 |
| Quit the relationship? | 4/22 (21.7%) | 2/16 (12.5%) | 0.64 |
| Share discordant status with anyone? | 28/48 (58.3%) | 11/40 (27.5%) | 0.004 |
| *Parents* | 11/28 (39.3%) | 3/11 (27.3%) | 0.71 |
| *Friends* | 9/28 (32.1%) | 2/11 (18.2%) | 0.46 |
| *Religious leaders* | 0/28 (0%) | 0/11 (0%) | 1.0 |
| *Other relative* | 9/28 (32.1%) | 6/11 (54.6%) | 0.28 |
| *Children* | 0/28 (0%) | 0/11 (0%) | 1.0 |
| How they were supported | | | |
| *Encourage to stay in relationship* | 22/28 (78.6%) | 10/11 (90.9%) | 0.65 |
| *Link to discordant couples' club* | 0/28 (0%) | 0/11 (0%) | 1.0 |
| *Link to HIV counselor* | 1/28 (3.6%) | 0/11 (0%) | 1.0 |
| *Encourage to leave relationship* | 3/28 (10.7%) | 1/11 (9.1%) | 1.0 |
| *Did not support me* | 1/28 (3.6%) | 0/11 (0%) | 1.0 |
| Coping strategies (Likert scale [1 = agree, 5 = disagree]: Mean, SD) | | | |
| *Solve our problems by discussing* | 1.9 (1.2) | 1.8 (1.2) | 0.71 |
| *Concerned about preventing HIV transmission* | 1.9 (1.0) | 1.8 (0.96) | 0.87 |
| *Big challenge is uncertainty of HIV* | 3.1 (1.7) | 3.2 (1.4) | 0.73 |
| *Discordance brought us closer* | 3.3 (1.6) | 3.2 (1.5) | 0.84 |
| *Discordance causes emotional distance* | 3.1 (1.7) | 3.7 (1.4) | 0.09 |
| *We always use condoms* | 3.3 (1.7) | 2.7 (1.6) | 0.09 |
| *I stay because of our children* | 3.1 (1.9) | 3.5 (1.7) | 0.36 |

We observed no differences between women and men regarding the reaction of those with whom they shared news of their discordant relationship. Most women and men reported that the individual encouraged them to stay in the relationship. Few were linked to discordant couples' clubs or HIV counselors.

Regarding coping strategies, women and men reported their agreement with different statements using a Likert scale, in which 1 indicated strong agreement and 5 indicated strong disagreement (Table 24). Overall, we found that both men and women tended to agree that they had solved their problems through discussion, that they were concerned about preventing HIV transmission and that the uncertainty of having HIV presented a major concern in their lives.

We found no strong agreement or disagreement with the idea that HIV brought them emotionally closer or that HIV induced emotional distance between the woman and her male partner. However, men were somewhat less likely to agree that having HIV created an emotional distance between the partners ($p = 0.09$).

Men were somewhat more likely than women to report that they always used condoms during sexual intercourse ($p = 0.09$). Finally, we found no strong agreement or disagreement with the idea that the respondent should have left the discordant relationship, but did not do so for the sake of their children.

#### *4.1.10 Polymerase chain reaction results*

We identified 186 participants in the intervention arm who reported testing negative with the oral self-testing kit, but whose kits appeared to show a weak positive band when they returned for a follow-up visit. We invited these 186 individuals to participate in a PCR testing study to confirm their results and to better understand the performance of different HIV testing modalities.

One hundred fifty of 186 (80.7%) people participated in this sub-study and more than half were women (96 of 150, or 64%). As described in section 3 (methods), these individuals underwent repeat supervised oral testing, standard rapid blood-based testing and blood was taken for PCR testing. Nearly all of these individuals were confirmed negative on retesting, with 140 concordant negative on observed oral self-testing, rapid blood-based and PCR tests.

Five other participants were found to be HIV-positive, with concordant results from all three methods. Lastly, five participants had discordant results: two oral self-testing results were in agreement with PCR and two with the rapid blood test. As part of this sub-study, participants were asked to interpret their oral self-testing result, under observation. About 139 oral testing results were interpreted correctly by the participants, six were wrongly interpreted and five were missing participants' interpretation.

Of the six wrongly interpreted results, four were wrongly interpreted as positive and two as negative; all four results that were wrongly interpreted as positive tested negative in PCR. Of the two wrongly interpreted as negative, one interpreted as indeterminate by the interviewer tested negative and the second interpreted as negative by both the interviewer and participant tested positive on PCR. Four of the six (66.7%) wrongly interpreted results were for women.

### 4.2 Qualitative results

Eighty-five individuals were interviewed. Of these, 70 were in-depth interview participants and 15 were key informants (Table 25). Of the 70 in-depth interview participants, 11 were family members of women whose male partners self-tested for HIV, 15 were male partners who used the kit, 15 were male partners who refused to use the kit and 12 were women whose male partners refused to use the kit to test for HIV.

Of the 15 key informants, 9 were nurse counselors, 2 were expert clients and 4 were other types of participants. All interviews were conducted at the end of the last quantitative follow-up visit; in other words, at the end of the follow-up period.

**Table 25: Number of participants interviewed for the qualitative study by study site and category of participant**

| Study site | Entebbe | | | Mpigi | | | Nakaseke | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| | IDI | KII | Total | IDI | KII | Total | IDI | KII | Total | |
| Participant category | | | | | | | | | | |
| *In-depth interviews* | | | | | | | | | | |
| Family member | 5 | | 5 | 4 | | 4 | 2 | | 2 | 11 |
| Men who refused HIVST | 5 | | 5 | 6 | | 6 | 4 | | 4 | 15 |
| Men who self-tested | 6 | | 6 | 5 | | 5 | 4 | | 4 | 15 |
| Women whose partners refused HIVST | 5 | | 5 | 5 | | 5 | 2 | | 2 | 12 |
| Women whose partners self-tested | 5 | | 5 | 5 | | 5 | 7 | | 7 | 17 |
| Subtotal | 26 | | 26 | 25 | | 26 | 19 | | 19 | 70 |
| *Key informant interviews* | | | | | | | | | | |
| Nurse counselor | 0 | 2 | 2 | 0 | 3 | 3 | | 4 | 4 | 9 |
| Expert client | 0 | 0 | 0 | 0 | 2 | 2 | | 0 | 0 | 2 |
| Other (not specified) | 0 | 3 | 3 | 0 | 0 | 0 | | 1 | 1 | 4 |
| Total | 0 | | | | 5 | 5 | | 5 | 5 | 6 |
| Overall total | 26 | 5 | 5 | 25 | 5 | 30 | 19 | 5 | 24 | 85 |

Note: IDI = in-depth interview and KII = key informant interview.

Study findings were grouped into six a priori and emerging themes: (a) motivation for HIVST; (b) anticipated fears/initial barriers to HIVST; (c) strategies women used in delivering HIVST kits to their male partners; (d) experiences in using HIVST kits; (e) social consequences associated with HIVST; and (f) positive outcomes/benefits of HIVST.

These findings support our initial assumptions, as envisaged in the theory of change, and partly explain the high HIVST rates reported by women in the quantitative section of this report.

### *4.2.1 HIV self-testing facilitates male partner and couples' HIV testing*

Evidence from prior research suggests that men are less likely than women to test for HIV (largely because they do not have time to go to health facilities to test (Camlin et al. 2016b). We explored participants' perceptions as to whether the presence of the HIVST kits in the home could have motivated men to test for HIV.

In response, women indicated that the HIVST kit not only helped encourage men to test for HIV, but also helped the women learn about their male partners' HIV infection status (some men learned they were HIV-positive after using the kit), which they might not have known had the kit not been brought home.

> [I]f I had not taken it, even my husband would not have come to the facility to be tested, but I took it and told him that once it comes two lines, it means you have HIV and if it come with one line, it means you don't have HIV; and when we came here and the lab tested him, and they called him and he came, they drew blood from us and on that very day he started on medication, which he didn't know. And if I had not taken that kit, he didn't have the idea in his mind to come to hospital to test for HIV, but the oral kit influenced him to come to the hospital so that he

> knows the truth with his status, and after that day, he started getting treatment. — *HIV-negative woman in an HIV-discordant relationship whose male partner self-tested for HIV, age 34, Nakaseke Hospital*

Women also indicated that the presence of the kits in the home motivated them to test together with their male partners. This was likely the case because women and their partners were able to use the test kits at home, something that would be difficult if men were asked to go to the health facilities to test for HIV with their female partners.

#### *4.2.2 Anticipated fears or barriers that women faced before delivering HIVST kits*

Female participants narrated how they were initially scared of how best to introduce the HIVST kits to their male partners. Most thought their male partners would "ask me what I had brought home" and that they were likely to refuse to use the kits.

There were initial doubts about the ability of the HIVST kit to detect HIV antibodies given that participants were used to a blood-based test, rather than a test kit that uses mucosal fluids.

> The first time I heard about HIV self-testing, the issue that came into my mind was that the kits will not work. This is because personally, I was used to the old method of pricking with a needle. So, I wondered and thought [about] how this method will test for HIV, yet there is no blood involved. — *HIV-positive female partner in an HIV-discordant relationship whose male partner self-tested for HIV, age 33, Mpigi HC4*

When asked if the HIVST kit performed as expected, participants indicated that when they self-tested using the HIVST kit, their HIV results were similar to those they got when they were tested at the ANC clinic using a blood-based rapid HIV test; that is, the test yielded HIV-positive results that they already knew, having tested previously through ANC.

#### *4.2.3 Strategies women used to introduce HIV self-testing kits to their male partners or to make them use the kits at home*

Women used several strategies to introduce HIVST kits to their male partners. Some women, particularly those whose relationships with their husbands/male partners were good, introduced the kit on the same day and told their partners the kits were meant for HIVST. In the majority of cases, however, women thought of innovative strategies that would enable them to deliver the kits to their male partners without causing trouble for themselves.

Most of the strategies used were positive: enlisting the support of a health worker in convincing the male partner to use the kit; asking that the HIVST kits be sent to the male partners by the health workers; and waiting for "opportune moments."

Other strategies used to convince their partners to use the tests or ensure their partners tested were less honest. Only a few women reported using these strategies, but they are important to mention: concealing some information about the HIVST kit from the male partner (for example, telling the male partner the kit was for HIVST but not telling them how the results should be interpreted); lying about the purpose of the kit (for example, telling the male partner the HIVST kit was meant to test all "blood-related" diseases in

the body); and controlling the HIVST process (for example, one woman swabbed the male partner and conducted the self-testing exercise herself instead of teaching her partner how to do it on his own):

> I told him that he would do it wrongly, so I asked him to allow me [to] do it for him. He asked me to teach him how he should do it and I told him that he would not afford to do it and he was convinced. So he allowed me to do it [perform HIVST] for him. — *HIV-negative female partner who self-tested with her HIV-negative male partner, age 20 years, Entebbe Hospital*

#### *4.2.4 Experiences with using HIV self-testing kits*

Participants indicated that HIVST was easy to perform because of its convenience; that is, it could be done at home or in any other private place, and in a much simpler way than conventional HIV testing processes.

> I think it's a simple process, because when you go for testing at a health facility, you must wait till when you're called for your HIV test results, but in self-testing, it's you who controls the entire process. For the conventional HIV testing, it's the health provider who sees your test results first before you do. Secondly, before they give you your results, again they first take you through counseling, which can make you think that you're HIV-positive. For HIV self-testing, you get to know your test results without going through counseling again – that stress! — *Female partner who self-tested with male partner, age 20 years, Entebbe Hospital*

One man said he was not sure that just a simple test kit – the one he received from his wife – could really detect HIV antibodies. He said he still carried these thoughts even after performing the test.

> I was asking myself, saying, "Is this really true?" Can really a person just get that spoon and pass it in the gum and then … [spreading his hands] tests for HIV? Still that was running in my mind – wondering … and up to now, am still not convinced, because she told me that, you know, the saliva settles there and the person who is positive, there is this and that – she is not a nurse, she is … [laughs] so you have to know am still asking myself, really. — *Male partner who self-tested for HIV, 38 years, Entebbe Hospital*

This male participant indicated that he knew HIV antibodies could only be detected through blood, rather than through oral mucosal fluids. He reasoned that oral mucosal fluids, which he constantly referred to as saliva, were "too acidic" for HIV to survive. As such, there was no way "saliva" could have antibodies for HIV, even if someone were HIV-positive. Even after performing the test and testing negative, this participant indicated that he still had doubts as to whether the oral HIVST kit could detect HIV antibodies in mucosal fluids.

#### *4.2.5 Women's experiences after using the kits*

We asked women what happened when they delivered and/or eventually used the HIVST kits with their male partners. All women whose male partners self-tested for HIV reported that they did not experience any dire social consequences arising from testing with them. Instead, they reported more positive experiences.

In an in-depth interview with an HIV-positive woman in an HIV-discordant relationship, we asked her what had happened to their relationship after the husband knew his HIV-negative status and the woman's HIV-positive status. She responded that although she feared what the husband might do after learning that she was HIV-positive, he did not "show any anger":

> We had tested together some time back. But for me I had taken a period of three months since I had last tested. But we had tested together sometime back through the mobile testing services that had come to our village and we were both negative. I was surprised when I tested this time and the results had changed. So, maybe the virus was just not detected that time. My greatest fear was that it was going to be trouble the moment he learns about it. But he did not show me any anger. Nothing happened. — *HIV-positive woman in an HIV-discordant relationship whose male partner self-tested for HIV, age 25, Mpigi HC4*

This woman indicated that instead of the relationship's developing cracks, her husband started to support her the moment he learned of her HIV-positive status. He supported her with money for transport to the clinic and reminded her of when to take her drugs to improve adherence.

> Since that time, he asks me when I am going for treatment and he gives me transport. He is very interested in knowing my return date whenever I come from the facility to enable him [to] plan for the transport … He always reminds me to take my medication on time. — *HIV-positive woman in an HIV-discordant relationship whose male partner self-tested for HIV, age 25, Mpigi HC4*

In another interview, an HIV-negative woman whose male partner tested HIV-positive was asked what she thought following the knowledge of her partner's HIV-positive status. She indicated that although knowledge of her male partner's results caused her stress at the beginning, she was eventually able to cope with the situation and they still live with him.

#### *4.2.6 Positive outcomes/benefits of HIV self-testing*

Participants who tested together for HIV indicated that the use of HIVST kits helped improve the quality of their relationships.

> It built the confidence between the two of us because – I do not know whether she misunderstood or that that is exactly what you told her, but she told me that "we have to do it when we are two." I do not know because I was not there in the first place, when she was bringing the kits … but it builds the confidence. — *Male partner who self-tested for HIV, 38 years, Entebbe Hospital*

> I didn't trust him. Even when we were going to have sex I would be scared, thinking that I would contract HIV from him at that time. But after HIV self-testing, I gained confidence in him and stopped worrying. — *HIV-negative female partner who self-tested with her HIV-negative male partner, age 20 years, Entebbe Hospital*

A nurse counselor at Mpigi shared similar benefits of HIVST. When asked what observations she had seen at the health facility since HIVST had been initiated, she reported that there had been an increase in the number of men escorting their wives to the health facility, in addition to an increase in the number of men testing for HIV.

> What I can say is that HIV self-testing has increased the number of men testing for HIV, which was not the case before. According to my observation, the study has also improved on the number of men who escort their wives for antenatal care, unlike before. The number has gone up. — *Nurse counselor, Mpigi HC4*

### *4.2.7 Coping mechanisms of HIV-discordant couples*

We followed up with 18 individuals in HIV discordant relationships (nine couples) and interviewed them about how they had coped with their HIV serodiscordant status since they had last self-tested for HIV. Six of the couples had an HIV-infected female partner and three had an HIV-infected male partner.

It is important to note that 11 of these 18 individuals had previously tested for HIV and were already aware that they were living in an HIV-discordant relationship, so they had most likely overcome the initial emotions and fears associated with serodiscordance.

Only seven individuals indicated that they had learned their HIV-discordant status after they self-tested for HIV. Even then, we did not find any major differences in the way the two sets of couples coped with HIV discordance, probably because most, if not all, of them had already passed the most critical/difficult stage in appreciating their HIV-discordant status, and because of the long period since they had last self-tested for HIV. The follow-up visit to assess coping mechanisms among HIV-discordant couples happened 6–18 months after the couples had last self-tested for HIV.

Nevertheless, study findings provide insights into what goes through the minds of individuals the moment they learn that they are in an HIV-discordant relationship and how they eventually cope with the situation. The findings present scenarios that can happen in any relationship, regardless of the method of HIV testing used.

We grouped study findings into four main areas:

- initial reactions when members of the couple learned for the first time that they were HIV discordant;
- how individuals coped with their HIV-discordant status and managed to live together until time of interview;
- current thoughts and fears about HIV discordance; and
- advice to couples in other HIV-discordant situations.

*Initial reactions about HIV serodiscordance*. Our findings suggested that three things happened the moment individuals learned of their serodiscordant status for the first time: (a) HIV-positive women feared they would be chased from their homes, while HIV-negative women thought of separating from their HIV-infected partners; (b) some participants developed suicidal ideations, although these cleared after they were counseled; and (c) some participants reported changes in the way they related sexually.

The majority of HIV-positive women with HIV-negative male partners were scared that their male partners would throw them out of the home, although many attested to the fact that this did not happen.

> What came to my mind, at heart I was so scared and worried and had this feeling that since he had found out that I am HIV-positive while he is HIV-negative, he might overreact and, in the end, we [would] separate, but all in all, I was also relieved after knowing the truth about his status and became strong and ready to go by whichever decision he would make. To my surprise, he did not react like I had expected, because he chose to stay with me and support me in my situation. *— HIV-positive female partner, age 35, Mpigi HC4*

Likewise, HIV-negative women with HIV-positive partners initially thought of separating from their HIV-positive male partners, but decided to stay in the relationship after being counseled by health workers. A female participant from Entebbe Hospital narrated how she had had repeated impulses to separate from her HIV-positive husband, but "cooled down" after she was counseled by health workers, deciding to stay in the relationship.

> What came to my mind … I thought of walking away and abandoning him, I thought of separating from him, I even didn't want to have a glance at him at that time, but I cooled down. Such thoughts would come and I felt so stressed; I was pregnant [at the time] and felt stressed. But I decided to calm down by myself; the health workers had tried to counsel me that this was possible – I could stay like that and look after my children. Generally, I got a very big challenge and if it was not [for] the fact that I was strong, I would not have tolerated it at all, or would have packed my bags and separated from him. *— HIV-negative female partner, age 25, Entebbe Hospital*

Two HIV-positive men indicated that they initially thought of committing suicide due to being HIV infected while their partners were HIV-negative, and due to the fact that their HIV-negative partners were threatening to leave them.

An HIV-positive man from Entebbe Hospital narrated how he felt life was no longer "worth living" since his partner, who could have counseled him, was threatening to leave him. However, when these individuals received counseling from their relatives and health workers, they let go of the idea of committing suicide.

> I had decided to commit suicide. I got that thought so often because of three reasons: first was because I had found myself infected with HIV; second was I was no longer working; and thirdly, my wife who would have counseled me was continuously threatening to abandon me. Whenever I thought of all these, I felt like I was not worth living but I dropped the decision because of the thorough counseling I received from my aunt and my parents, and also the fact that my wife eventually decided to stay with me in our relationship and we look after our children. *— HIV-positive male partner, age 30, Entebbe Hospital*

The majority of HIV-negative participants with HIV-infected partners narrated how learning about their HIV serodiscordant status created an emotional distance between them. The idea of resorting to regular condom use with their marital partners was so

difficult and painful that some participants took a long time to engage in sex with their HIV-positive partners.

In a few couples, HIV-negative men refused to use condoms and continued to have “live” (unprotected) sex, which put them at risk of HIV infection. A 34-year-old, HIV-negative male participant from Entebbe Hospital narrated how they no longer had sex as regularly as they used to (before he learned his wife was HIV-positive), since the “love has reduced.”

> Hmm, life changed a bit. Our life was very good before I learnt that my partner was HIV-positive, but when I did, just like you know, the love reduced a bit and became measurable because before, we both thought that we were HIV-negative and we used to have live sex. We could have it like three or more times but now, it has reduced. We can have it like once in a week or not even having it at all because we rarely think about that. It is because the love has reduced. Nothing else changed. The way we treat and care for each other is still the same. I still love her. — *HIV-negative male partner, age 34, Entebbe Hospital*

*How couples coped with their HIV-discordant status.* HIV-positive individuals in serodiscordant relationships were initially concerned that they would separate or thought of committing suicide, while others had to grapple with changes in the way their partners related to them sexually.

To cope with these thoughts and changes in their lives, participants highlighted the important role of counseling from professional health workers and psychosocial support from relatives and friends. The following quotations highlight the importance that counseling played in these people’s lives and how it helped them cope with HIV discordance.

> I received some counseling. What I really got out of this counseling was to ensure that my partner takes medicine. This was something important I got, because I leant that when she takes her medicine, the virus will become dormant. And, secondly, not to stress her and keep reminding her that you are HIV-positive because, just that you have come at a time when she is just recovering from an illness. She had an illness, which affected her, but before that she was very healthy that no one could even suspect that she is HIV-positive. When she goes to pick [up] her medicine, one could think that she is taking the child for immunization, but she would be getting her medicine. So, what I got from this counseling is that I don’t make my partner worried and stressed. This also helped us to stay together because of the fact that you are aware of her status and you know how to support her to stay healthy. — *HIV-negative male partner, age 47, Nakaseke Hospital*

> Yes, especially me … It took me time to accept that I would stay with her in our relationship and I still remain HIV-negative. It took time. The health worker assured me that it was possible, so long as she adhered to her drugs as prescribed; it was possible that she could live long and I can also stay negative. The counseling partly helped because according to my understanding, I had made my own decisions about what would happen [getting HIV-infected] … They

> continued to strengthen me that it was possible to remain in this relationship when you are still HIV-negative. — *HIV-negative male partner, age 45, Mpigi HC4*

As already noted, some individuals indicated that they were supported to cope with their HIV-discordant status by people in their social networks, including parents, aunts, siblings and, to some extent, close friends to whom they had disclosed their HIV status.

When asked whether disclosing to these people had helped them cope in any way, most participants indicated that they had received support from those to whom they had disclosed, including support to stay together with their partners and to start or continue to take HIV treatment if they were HIV infected.

> I told my mother and elder brother, who is a pastor. I opened up to my mother, since she is an adult and can understand; she advised that I should continue taking drugs and look after my children. She strengthened me and that is why I am still living too. I further explained to them about my wife's [HIV-negative] status, too, and they were eager to know if she would be willing to [stay with] me, they had that thought [in their] mind, too. I told them that currently I had not sensed any changes, but since we all have different plans hidden in our heart, I may be here, proud that she may stay with me forever, when she has a different plan in the long run. — *HIV-positive male partner, age 48, Entebbe Hospital*

When asked what their source of hope for a healthy future was, despite being in an HIV-discordant relationship, HIV-negative participants indicated that the fact that their HIV-positive partners were already receiving HIV treatment was a great source of hope. Being on treatment would help them remain healthy and strong. Likewise, HIV-positive individuals reported that being on HIV treatment would help them live a longer life and "be able to take care of my children."

> What gives me hope is being on treatment and to be of importance to my children. What gives me hope is that I am going to be healthy and alive, and I will be able to take care of my children when I promptly take my medicine. Also, the fact that my partner takes good care of me, but even if he doesn't take care of me, I have hope that when I am healthy, I can provide everything I want for myself. — *HIV-positive female partner, aged 34, Nakaseke Hospital*

*Current thoughts and fears about HIV discordance.* Although the majority of couples indicated that they were coping well with HIV discordance, a few HIV-negative individuals indicated that they sometimes feared that their partners might one day infect them with HIV, especially if they refused to use a condom. This is a natural feeling of desperation that calls for individuals in HIV-discordant relationships to receive ongoing support counseling.

> Maybe what can come on my mind is, sometimes I can sit down and think that since he is sick (i.e. HIV-positive), one day I will also wake up when he has infected me. If he wakes up one morning and [refuses] to use a condom and forces me into sex, won't I risk my life getting infected? Sometimes I get those worries, but I try so hard to remain strong. — *HIV-negative female partner, age 25–34, Entebbe Hospital*

When asked what their hardest moment had been since they learned they were HIV-positive while their partners were HIV-negative, some HIV-positive individuals expressed fear and skepticism regarding what their partners thought about them

> The hardest thing is, sometimes when we are discussing family issues and I get imaginations of what he may be thinking about me in regards to our different status, because he does not talk about it. Secondly, sometimes when I am going to get my drugs at the health facility and I do not have transport, I find it hard turning to him for assistance; sometimes I feel like I am a burden and he may complain and get fed up of such a situation. — *HIV-positive female partner, age 32, Mpigi HC4*

*Advice to other couples in HIV-discordant relationships.* When asked what advice they would give to other HIV-discordant couples for coping with HIV infection, most participants suggested that such couples should endeavor to avoid getting into arguments with each other about who brought HIV into the home, and try to support each other to live harmoniously without pointing fingers.

> Some suggested that the HIV-negative partner should support the HIV-positive partner to not only link to HIV care, but also to continue taking their HIV medication as prescribed. I would advise the one who is negative … that you encourage your partner to always go back to the health facility on the return date given and to also make sure that the medicine given is taken as instructed. The other thing is a challenge of getting so worried about the fact that you are positive and your partner is negative, and you start thinking that he will even leave me, but leaving your partner after going through so much trouble together, I don't see that as right … Lastly, the advice I would give to discordant couples is that the partner who is infected should also take trouble to take his medicine, instead of feeling low about themselves, saying that after all I am already infected. The more they continue being reluctant about care, the more their lives will be in danger. Actually, in most cases, people who drop off care get worse and some of them even lose their lives. — *HIV-negative male partner, age 45, Nakaseke Hospital*

#### *4.2.8 Linkage to HIV care among HIV-positive individuals*

Interviews were conducted with seven HIV-positive men to explore:

- issues that had supported them to link to and remain in HIV care, among those who had linked to care and were still in care;
- issues that had led them to drop out of care, among those who had initiated care but dropped out; and
- issues that had inhibited them from linking to HIV care, among those who had not yet initiated HIV care.

We have grouped study findings into three main themes: issues that influence linkage to and retention in HIV care; issues that led HIV-positive men who enrolled into HIV care to drop out; and issues that inhibited HIV-positive men who have yet to link to HIV care.

*Issues that influenced linkage to and retention in HIV care.* Three HIV-positive men had initiated care after HIVST and were still in HIV care at the time of interview. We asked

these men what had helped them link to care in the first place when other men had failed to do so. Men cited the role of counseling they had received from health workers and encouragement from their relatives as key factors.

> I realized that my life was deteriorating and yet my children needed me. Secondly, how my aunt and other health workers counseled me. When I thought about all this, I realized that my people still needed me, and I also had more reasons to continue living. During counseling, they showed me examples of some people who had lived for many years, yet they were in my situation. So, all this gave me hope to start on drugs. — *HIV-positive male partner, age 34, Entebbe Hospital*

When asked what had made them continue with their HIV treatment when others sometimes dropped out, men cited two main reasons for keeping in HIV care – support from their wives or female sexual partners, and a love of life; in other words, the need to remain alive and strong.

> What you should know is that our wives play a big role in our lives, communicate through women … when these women are attending antenatal services, the men do not escort them and tend to be so busy. I personally would have opposed the idea if my wife was not among those who had counseled me to initiate drugs. — *HIV-positive male partner, age 30, Entebbe Hospital*

> And what has helped me to be on care for the last two years is because I love my life. Ever since I started treatment, there is a lot of improvement in my life. I used to constantly fall sick but that stopped when I started on care. I could be attacked by fever, strong cough and other illnesses constantly. Also, what has helped me stay on care is the fact that I know that I am not alone, but there are many other people who are on care like me, this makes me stronger. Also, my wife … reminds me to take my medicine. — *HIV-positive male partner, age 29, Nakaseke Hospital*

*Issues that led HIV-positive men who had enrolled into HIV care to drop out.* In interviews with one participant from Mpigi, who had initiated HIV care but dropped out, we found that inability to disclose his HIV status to his new partner was the main reason he had dropped out of care. This participant informed us that he feared that continuing to take his HIV medicines could reveal his hidden HIV-positive status to his new wife.

> What made me drop off care is the fact that I had got a wife during that time and I did not know how I was going to handle being on care without her finding out. So, I decided to drop out of care. I was afraid she would discover the medicine. Secondly, the health workers that are working under the HIV care program … come from the areas we live in. Sometimes we might not be [on] par with that person and because you have your misunderstandings, he starts to spread rumors about your life, because he is already aware that I am on care so he decides to tell people about it. That kind of condition also forced me to drop off care. — *HIV-positive male partner, age 25, Mpigi HC4*

*Issues that have inhibited HIV-positive men to link to HIV care.* Three men who had not yet initiated HIV care were interviewed to document reasons for their failure to link to

care. When asked why they had never initiated care after self-testing for HIV, the men cited reasons such as not being ready to start lifelong HIV treatment (largely driven by misconceptions they had picked up from fellow men – see below) and the perception that they were still healthy and did not see the need to start HIV treatment at the time.

> … the truth is that this [starting HIV treatment] is not something that one can just adopt like that. I have spent two years but I am yet to initiate HIV care. The main reason is the tablets! Taking those tablets is not easy. We are told that when you start on the treatment, you have started. There is no stopping. It is like eating food; the truth is you have started so, for that matter, you really have to get ready for it after doing some observation. When I start, I don't want to stop. This is the arrangement I have. I want to go and do a confirmatory test; then I start on the treatment. I am afraid of starting and then drop-out. — *HIV-positive male partner, age 31, Entebbe Hospital*

> I have not yet put my mind to it. I have not yet felt like it in my heart. Secondly, what is stopping me is because there is nothing I feel about my health that needs me to start treatment. To me, I am still healthy and do not see any reason as to why I should start treatment when I don't have any sickness I am feeling in my life that needs medication. I just feel that it is not yet time for me to start on medication; when time comes, I will start. — *HIV-positive male partner, age 30, Nakaseke Hospital*

Other reasons men had not started on HIV treatment related to misconceptions from participants' social networks. For instance, a participant from Mpigi narrated how he had heard from his friends that taking HIV medication requires a lot of money to buy food and that individuals taking HIV medication become "fat and black," something he says discouraged him from starting treatment.

> There was some guy I spoke to who is on care and he gave me that information. He told me that when he enrolled to care, he had to sell his piece of land because he used to eat a lot and yet he didn't have the money. So that is the problem. He told me that if you have to enroll into care, you need to first prepare some money for yourself, money that is not for solving other problems [but for buying food] … He further said that being on treatment makes you weak and at the same time makes you eat too much. There is too much desire for food. The other thing is when people start on treatment, they become fat and yet I don't want to become fat … Imagine a person becoming so fat with a very big belly and then he turns black like charcoal, e … What is in this world? I have never admired becoming fat. That is what I am worried of … — *HIV-positive male partner, age 44, Mpigi HC4*

## 4.3 Cost-effectiveness analysis results

Table 26 shows the cost of the intervention by cost categories.

**Table 26: Distribution of costs by category**

| | Intervention | | Control | |
|---|---|---|---|---|
| | Cost (US$) | % of total | Cost (US$) | % of total |
| Above-site personnel costs | 1,926.80 | 12.3% | 1,926.79 | 33% |
| Above-site operational costs | 1,296.20 | 8.3% | 1,296.20 | 22% |
| Facility personnel time costs | 2,016.50 | 12.8% | 1,599.80 | 27% |
| Training costs | 73.40 | 0.5% | 48.90 | 1% |
| Above-site assets | 330.10 | 2.1% | 330.10 | 6% |
| Facility asset costs | 141.80 | 0.9% | 141.80 | 2% |
| Facility operational costs | 482.50 | 3.1% | 482.50 | 8% |
| Facility supplies (self-testing kits) | 9,450.0 | 60.2% | - | 0% |
| Total | 15,717.30 | 100 | 5,826.10 | 100 |

In the base-case analysis, the total cost for intervention was US$15,717.27 and US$5,826.10 for the control. In the intervention arm, the biggest cost driver was the HIVST kits (60.2% of the total cost), followed by above-site costs of the intervention (20.6%), which largely covered operational costs, training coordination and personnel time.

In the control arm, above-site costs were the biggest cost driver (55% of total cost), followed by facility personnel time costs (27% of total cost).

We computed facility personnel time from the time they spent on activities related to recruitment, follow-up with recruited participants and linkage to care of those who tested HIV-positive. Their time was spent on health education, counseling women, screening for eligibility of self-testing, training women on HIVST, follow-up with women, partners or family members, linkage of partners and family members into care, testing of partners and family members, distributing the self-testing kits, mobilization and organizing patient flow at the facility.

The cost per partner tested was US$30.30 for the intervention and US$31.20 for the control, while the cost per HIV-infected person identified was US$462.30 for the intervention and US$582.60 for the control. Comparing intervention with control, the ICER per additional partner tested was US$29.80 and the ICER per additional partner testing HIV-positive was US$412.10. In a one-way sensitivity analysis, reducing the unit cost of the self-testing test kits by half reduced the cost per partner tested, and the cost per HIV-positive partner identified, by 30 percent – to US$21.20 and US$323.30, respectively.

The ICERs of partner testing and identifying HIV-positive partners were reduced by 48 percent, to US$15.60 per extra person tested and to US$215.26 per extra HIV-positive person identified. The ICER for identifying HIV-positive partners and the cost per HIV-positive person identified were also sensitive to the proportion of partners who tested HIV-positive.

Doubling the proportion of HIV-positive partners reduced the ICER and cost per HIV-positive partner identified by another 50 percent (ICER = $107.60 per incremental HIV-partner identified), as Table 27 shows.

**Table 27: Cost-effectiveness and incremental cost-effectiveness of self-testing on partners testing and identification of HIV-positive partners**

| | | | Partner testing | | | | Partners testing HIV-positive | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Cost (US$) | Cost difference (US$) | Partners tested | Cost per partner tested | Partner testing difference | ICER | Number HIV-positive | Cost per new HIV-positive partner | Difference number HIV-positive | ICER |
| Control | 5,826.1 | 0 | 187 | 31.2 | - | - | 10 | 582.61 | - | - |
| Intervention | 15,717.3 | 9,891.2 | 519 | 30.3 | 332 | 29.8 | 34 | 462.27 | 24 | 412.13 |
| Sensitivity analysis on cost of self-testing kits | | | | | | | | | | |
| Control | 5,826.1 | 0 | 187 | 31.2 | 0 | | 10 | 582.6 | - | - |
| Intervention (cost of self-testing kits halved $1) | 10,992.5 | 5,166.2 | 519 | 21.2 | 332 | 15.6 | 34 | 323.3 | 24 | 215.26 |
| Sensitivity analysis on joint effect of doubling proportion of partners who tested HIV-positive and reduction in cost of self-testing kits | | | | | | | | | | |
| Control | 5,826.1 | 0 | 186 | 31.2 | 0 | - | 20 | 582.6 | - | - |
| Intervention (cost kits = 50% & double HIV-positive proportion) | 10,992.5 | 5,166.2 | 503 | 21.2 | 332 | 15.6 | 68 | 161.7<br>251.3 | 48 | 107.6 |

# 5. Discussion

## 5.1 Uptake of HIV testing services by male partners of pregnant women

In this study, a convincing and impressive increase in male partner testing was demonstrated, resulting from provision of HIV oral self-testing kits through the female partner enrolled in ANC. During the first month of follow-up, HIV testing uptake was almost four times higher in the self-testing arm. Considering the women's and men's reports across the entire follow-up period, 76.7 percent in the intervention arm tested, compared with 37.5 percent in the control group.

The large increase in testing uptake was seen in couples where the woman was HIV-negative and where the woman was HIV-positive. HIVST also led to a significant increase in couples testing, with 73 percent in the intervention arm testing as couples, compared with 31 percent in the control arm. Qualitative findings further highlighted improved male partner testing, with respondents asserting that the number had gone up and their relationships have improved.

These results show that HIV oral self-testing may have the potential to be an important tool for increasing HIV testing rates in male partners of pregnant women and couples testing in Uganda – and likely in other important populations around Uganda.

Among the men who received the HIVST kits, 94 percent used them to test for HIV (based on the woman's report). The resistance to testing among some men could be due to men's chauvinistic tendencies, since they received the test kits from their female partners; to fear of testing; or to the men's perception that their HIV status was implied in their female partner's status.

Similar results were found in Kenya, with 90.8 percent partner testing in the HIVST arm, compared with 51.7 percent (Masters et al. 2016), and a meta-analysis in which HIVST doubled the uptake of HIV testing among men, compared with standard HTS (Johnson et al. 2017). Such an increase in HIV testing uptake has important public health implications, if it can be achieved at population level and reach those with undiagnosed HIV infection. This increase is also critical for the success of PMTCT programs.

Contrary to this study's findings, HIVST use was low in Malawi in the first and second years (46.1% and 43.8%, respectively) in a community-based prospective study (Choko et al. 2015).

## 5.2 Linkage to care

Regarding linkage to care, we were concerned that individuals who had not previously tested for HIV, but agreed to use self-testing, might be more difficult to link to care if they tested positive for HIV. Although we had limited statistical power to evaluate linkage to care, the results of our study are consistent with the hypothesis that men who tested positive via self-testing might be less likely to link to care than men testing at a clinic.

Notably, based on this study, two to three times as many male partners tested positive in the self-testing arm than in the control arm. However, the proportion of men who went for

confirmatory testing and linkage to care was low enough that the intervention arm did not show a great improvement in the number of HIV-positive men linked to care.

This is similar to what was found in an RCT in Kenya, where women reported that 25 percent (n = 2 of 8) of their male partners in the HIVST group linked to confirmatory testing at a 3-month follow-up, and then to care, while in the control group, all 4 male partners diagnosed HIV-positive linked to care (Masters et al. 2016). These findings underscore the need for further research in this area, and careful monitoring of people using self-testing as the practice is rolled out on a larger scale.

It is possible that individuals who test positive through self-testing and do not immediately link to care could still change their sexual behavior to reduce the risk of transmitting HIV to sexual partners. Our extended follow-up period revealed that a meaningful proportion (approximately 10%) of men testing positive through HIVST showed delayed linkage to care after our month 3 visit, highlighting the importance of longer follow-ups to better understand long-term linkage to and retention in care for individuals testing positive through HIVST.

Linkage to care in a study in Malawi was 41.7 percent in the researchers' first estimate, but increased to 56.3 percent after adding those who had already initiated antiretroviral therapy by one year (Choko et al. 2015). Additionally, it may be useful to develop and test interventions to improve overall linkage to care after HIVST.

Our study findings reflect a higher percentage (45.5%) of men linked to care in the control arm, compared with the intervention arm (23.8%). This could be due to the men's not being ready to commit to long-term treatment, inconvenience of accessing clinics (travel, wait, opportunity costs), fear or avoidance of a needle stick or privacy concerns; whereas those who test at a clinic are already there and are, therefore, easier to enroll in immediate treatment.

Approximately 31 percent of men who tested positive on self-testing were assessed for antiretroviral therapy eligibility, but only 19.2 percent were initiated on treatment in Malawi (Maheswaran et al. 2016), and no partner of pregnant women attending ANC in Kenya came for confirmatory testing or was even linked to care (Masters et al. 2016).

As part of phase 3, we interviewed HIV-positive men who had linked to HIV care to document the factors that facilitated the linkage. We asked those who had linked to care whether they were still in care (and what had helped them remain in care). We also interviewed men who had linked to care but dropped out, as well as those who had never linked to care since they self-tested for HIV. Our findings show that provision of post-test counseling support is crucial for enhanced linkage to and retention in HIV care.

Individuals who were able to link to care cited the counseling support that they received from professional health workers, coupled with psychosocial support from their relatives, as having been crucial for their ability to link to and remain in HIV care. HIV-positive men who remained in care also cited the role that their spouses or female sexual partners played in supporting them to remain in care, highlighting the importance of tapping into nontraditional support mechanisms (including working with spouses or female partners) to improve retention in HIV care among HIV-positive men. However, lack of HIV status

disclosure and fear of being seen by people who reside in the same community as HIV-positive men acted as a deterrent to retention in HIV care.

HIV-positive men who did not link to HIV care cited two main reasons: (a) they were not ready to commit to life-long HIV treatment – possibly driven by misconceptions from their peers (for example, beliefs that being on HIV treatment makes one “fat and black”); and (b) the feeling that they (HIV-positive men) were still strong and did not need to start HIV treatment at the time.

The issue of men’s still feeling strong as a deterrent to engaging in HIV care has been cited in previous studies (Nyamhanga et al. 2013; Camlin et al. 2016a; Gregson et al. 2011; Musheke et al. 2016), and borders on what has come to be known as “hegemonic masculinity norms,” in which men project themselves as being strong and resilient, whereas those who seek HIV care services are seen as weak or not “man enough” (Siu et al. 2013).

Studies have also documented the fact that men tend to be less represented in health facility settings where HIV treatment and other HIV services are provided (Nyamhanga et al. 2013; Camlin et al. 2016a), suggesting a need for alternative models of reaching HIV-positive men and linking them to care, including the provision of home-based antiretroviral therapy, which has been proven to be successful in several settings (Govindasamy et al. 2014).

Overall, few women in the intervention and control groups reported any negative social outcomes related to HIV testing, similar to what was reported in a meta-analysis on HIVST (Johnson et al. 2017). Although there seems to be much anxiety that HIVST could exacerbate or bring about intimate partner violence, this does not seem to be the case. However, more research is needed to critically study this in larger-scale programs and studies.

## 5.3 Strategies for delivering HIV self-testing kits

In general, women used positive strategies to deliver HIVST kits to their male partners, but some used less honest methods. Our qualitative findings show that HIVST was accepted and associated with positive benefits, including a chance to learn about the partner’s HIV status and to disclose HIV status.

Women used a number of positive strategies to deliver the kits to their male partners: enlisting the support of a health worker in convincing the male partner to use the kit; asking that the HIVST kits be sent to the male partners by the health workers; and waiting for “opportune moments.”

Some women used less-than-honest methods to convince their male partners to use the kits, including (a) concealing some information about the HIVST kit from the male partner (for example, telling the male partner that the kit was for HIVST, but not telling him how the results should be interpreted); (b) lying about the purpose of the kit (for example, telling the male partner the HIVST kit was meant to test all “blood-related” diseases in the body); and (c) controlling the HIVST process (for example, one woman swabbed the male partner and conducted the self-testing exercise herself instead of teaching her partner how to do it on his own).

The use of these methods raises a number of public health implications. For instance, a woman's controlling the HIVST process denies the man the opportunity to conduct the test himself (the essence of self-testing) and implies a sign of coercion from the female partner. Although the number of women who used these undesirable strategies was quite small – three or four women – we thought it important to report them, since they have serious implications for HIVST.

## 5.4 Coping mechanisms of HIV-discordant couples after HIV self-testing

In interviews, we observed that the majority (11 of 18) of individuals in HIV-discordant relationships had previously tested for HIV and were aware of their HIV-discordant status by the time they self-tested for HIV. As a result, many had been able to move beyond the most critical or difficult stages in the coping process and had settled down with their partners. This observation was true for those who first learned of their serodiscordant status when they self-tested, since the follow-up visits were made 6–18 months post-test. Thus, we were not able to link any coping mechanisms observed to HIVST.

However, we still inquired how individuals in HIV-discordant relationships coped with HIV discordance by asking them to take us back in time to when they first learned of their serodiscordance and how they had coped with their different HIV statuses thereafter. We thought this would still be important for programs intending to assist couples in coping with HIV-discordant status. Our findings have a number of program implications:

1. In line with the quantitative findings, our qualitative findings show that HIV-positive women were initially afraid their partners would chase them from the house, whereas HIV-negative women thought of separating from their HIV-positive partners, possibly to avoid HIV infection. Initially, 48.9 percent of women and 41.5 percent of men in HIV-discordant relationships thought of ending the relationship, but the majority of individuals who initially had these thoughts did not separate.

   In the qualitative interviews, we found that individuals who had thought of separation continued with the relationship. These individuals mentioned that counseling from professional counselors, coupled with psychosocial support from relatives and close friends, had helped them stay together. These findings suggest that HIV-discordant couples can be supported to remain together through counseling support, reinforced with psychosocial support from nontraditional sources of support, including relatives and friends.

2. Couples reported that learning about their HIV-discordant status initially created an emotional distance between partners. This manifested through reduced frequency of sexual intercourse and disgust associated with always using condoms with their marital partners, something they were not used to. Initially, couples found it hard to cope with condom use at every sexual encounter, resulting in reduced frequency of sex for some couples.

   In a few couples, HIV-negative men refused to use condoms and continued to have unprotected sex, which put them at risk of HIV infection. These findings highlight a need for ongoing supportive counseling to assist couples to explore

nonpenetrative forms of sexual satisfaction, if they are unable to use condoms every time they have sex, to reduce the risk of HIV infection.

3. Some participants – particularly HIV-positive men – thought of committing suicide after they learned of their HIV-discordant status. They were counseled out of these thoughts by health providers and relatives, and no suicide was reported. This finding reinforces the need to provide appropriate post-test counseling support to HIV-discordant couples to help them appreciate their serodiscordant status and plan how to cope with it thereafter.

4. Two mechanisms were cited as the main factors that enabled individuals to cope with HIV serodiscordance: post-test counseling support from health workers and psychosocial support from their mothers, sisters, other siblings and close friends after they disclosed their HIV-discordant status to them. As we note in the quantitative findings, 78.6 percent of women and 90.9 percent of men in HIV-discordant relationships reported that these friends and family members encouraged them to stay in their relationships. These approaches should be maximized in supporting HIV-discordant couples to cope with their different HIV statuses.

## 5.5 Cost-effectiveness analysis

We showed that the cost of the intervention was driven mainly by the cost of the self-testing kits, and that the cost-effectiveness of the intervention would be very sensitive to lowering the cost of test kits and using the intervention in priority populations with higher HIV prevalence, such fishing communities and sex workers and their partners. Partner HIV and sexually transmitted infection notification programs are needed.

In another report, we will provide detailed sensitivity analyses examining the effect of joint distribution of all parameters using probabilistic methods. We will use generic outcomes, such as QALYs and DALYs, to provide for comparability of results across interventions. Because of incomplete data on linkage to care, we did not have sufficient data to assess cost-effectiveness with respect to linkage to care.

## 5.6 Conclusion and recommendations for policy and practice

Our results demonstrate a significant increase in individual and couples HIV testing when oral self-testing is available at home. This option appears to break down several barriers to testing, including time and effort required to attend clinic, expense associated with attending clinic, lack of privacy, lack of control and fear of stigma. HIVST also does not seem to increase negative social harms, compared with the standard of care, and could reduce providers' workload by screening HIV-negative individuals through HIVST.

However, our results do not show that men testing positive through self-testing are as likely to link to care as men who test positive at a clinic. This question clearly deserves further study; better understanding of longer-term linkage to care among those who test positive through oral self-testing will be extremely important in planning public health programs in Uganda and other countries. Advocacy for reducing the cost of test kits, along with targeting the intervention to settings with higher HIV prevalence, will be important for scale-up.

We have the following recommendations for policy and practice:

- HIVST should be integrated as one of the recognized approaches for HIV testing;
- Additional support may be required to ensure linkage to care for individuals who test HIV-positive through HIVST, including provision of home-based antiretroviral therapy initiation; and
- Further evaluations, and research with larger numbers and longer-term follow-up of newly diagnosed HIV-positive individuals, are needed to ascertain better the linkage to and retention in care and social harms following HIVST.

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