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Promoting partner and couples HIV testing using self-test kits in Kenya

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About this report

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Using HIV self-testing to promote male partner and couples testing in Kenya

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Summary

Effective demand creation strategies are needed to increase uptake of HIV testing among men in eastern and southern Africa. The objective of this study was to understand whether providing HIV self-test kits to pregnant women and new mothers could lead to higher rates of HIV testing among their male partners than clinic-based HIV testing.

This study was a randomized trial implemented in Kisumu, Kenya. Antenatal and postpartum women aged 18–39 years were randomized in a 1:1 ratio to one of two groups, an HIV self-testing group (n = 303) or a comparison group (n = 297). Participants in the HIV self-testing group received two oral fluid-based HIV test kits, were instructed on how to use them, and encouraged to give a test kit to their male partner or use both test kits for couples testing. Participants in the comparison group received an invitation card for clinic-based HIV testing and were encouraged to give the card to their male partner, a practice used in many clinics.

The primary outcome was partner testing within three months of enrolment in the trial. The secondary outcome was couples testing within the same period.

Between 11 June and 16 October 2015, 600 participants were enrolled (303 in the intervention group, 297 in the comparison group). Among 570 participants with follow-up data, partner HIV testing was more likely in the HIV self-testing group (90.8%, 258 out of 284) than in the comparison group (51.7%, 148 out of 286). In unadjusted modified Poisson regression, the percentage point difference of 39.1% was statistically significant (95% CI 32.4%–45.8%, $p < 0.001$). Couples testing was also significantly more likely in the HIV self-testing group than the comparison group (percentage point difference = 42.1%, 95% CI 34.7%–49.6%, $p < 0.001$).

One concern about providing multiple self-tests to women has been the possibility of intimate partner violence due to women giving their partners self-tests and the possibility of people learning their HIV status in the absence of a counselor. However, intimate partner violence was extremely rare in both of our study groups. One participant in the HIV self-testing group and one in the comparison group reported intimate partner violence associated with discussion of HIV testing.

This approach, providing multiple self-tests to women to enhance partner testing, warrants further consideration as countries develop HIV self-testing policies and seek new ways to promote male partner testing, which can ultimately increase the effectiveness of preventing mother-to-child transmission of HIV, and HIV treatment.

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Abbreviations and acronyms

ANC	Antenatal care
CI	Confidence interval
HIVST	HIV self-testing
HTC	HIV testing and counseling
IPV	Intimate partner violence
NASCOP	National AIDS and STI Control Programme
PPC	Postpartum care
RA	Research assistant
SD	Standard deviation
SSA	Sub-Saharan Africa

1. Introduction

Increasing the uptake of HIV testing and counseling (HTC) in Sub-Saharan Africa (SSA) is essential for improving the effectiveness of HIV treatment and preventing new HIV infections. Although Kenya has nearly met its target of 80 percent coverage of HTC among adults, uptake of HTC among men, uptake of repeat testing and knowledge of HIV status among HIV-infected persons remain low (Baggaley et al. 2012; Kenya National Bureau of Statistics and ICF Macro 2010).

Whereas early diagnosis and treatment reduces transmission (Donnell et al. 2010; Cohen et al. 2011; Baeten et al. 2012), improves survival and reduces long-term morbidity (Cohen et al. 2011; Jaen et al. 2008; Kitahata et al. 2009), late diagnosis is more common and a major contributor to high rates of early mortality in African HIV care programs (Rosen et al. 2007; When to Start Consortium et al. 2009). Low HTC uptake limits the impact of combination HIV prevention, including treatment as prevention strategies.

Existing efforts to encourage women to refer their male partners for HTC and thereby address the male testing gap have had limited success (Farquhar et al. 2004; Msuya et al. 2008). Low uptake of HIV testing among men and among couples in Kenya is concerning in light of data indicating that 4 in 10 new HIV infections occur within stable heterosexual partnerships and the majority of persons in serodiscordant relationships (where one partner is HIV positive and the other is not) are unaware of their HIV status (Gelmon et al. 2009).

Although HTC is available free of charge in most places, for many individuals and couples the barriers to testing include: stigma; fear of prognosis; lack of awareness of HIV risk; inconvenience; fear of disclosure; transportation costs; opportunity costs such as time off work; and behavioral factors such as a tendency to put off behaviors with immediate costs and delayed benefits (Hutchinson et al. 2004; Obermeyer and Osborn 2007).

Moreover, despite the benefits of couples testing – a greater likelihood of mutual HIV status disclosure and reduced HIV transmission (Allen et al. 2003) – the majority of HIV testing takes place alone and not with sexual partners (NASCOP 2014a). Couples testing is recommended by the National Aids and STI Control Programme (NASCOP) in Kenya (NASCOP 2015).

One promising new technology that is growing in popularity in SSA to address low HTC is HIV self-testing (HIVST). Previous studies on HIVST in SSA have shown that it is highly acceptable and accurate (Choko et al. 2011; Choko et al. 2015). Innovative use of HIV self-tests provides an opportunity to address the challenges of low uptake of HIV testing among men and couples.

A promising but under-explored use of self-testing is providing multiple HIV self-tests to individuals who are then encouraged to distribute the self-tests in their sexual networks. Given the low uptake of HTC by men and couples, and the high risk of HIV infection among individuals in stable heterosexual partnerships, an especially promising use of self-testing could lie in the initiation of partner testing or couples testing by providing multiple self-tests to index individuals who are in stable partnerships (Myers et al. 2013).

We conducted a randomized controlled trial in Kenya that examined whether providing HIV self-test kits can improve HIV testing uptake among partners of women receiving antenatal care (ANC) and postpartum care (PPC) services relative to clinic referral testing.

2. Intervention, theory of change and research hypotheses

The intervention was developed on the basis of a prior pilot project that our team implemented in the study area. We developed training materials for self-tests as well as scripts for research assistants (RAs) to use when providing female study participants with self-tests. Staff training lasted one week and was supplemented by periodic refresher trainings.

During the training, all study materials were presented to RAs involved in the study. These RAs had previously participated in a different study on self-testing distribution, so were already well versed on the procedure. All RAs reviewed standard operating procedures and questionnaires as a team. Mock interviews were staged, mimicking different types of participants they may encounter.

After completing a baseline questionnaire and randomization, women in the HIVST group received two OraQuick Rapid HIV 1/2 Tests and instructions for use for themselves and their partners. They received training on the proper use of the HIV self-test, including a demonstration. Participants were counseled about the importance of partner testing and received suggestions on broaching the sensitive topic of HIV testing. They also received a referral card counseling them on where they could go for confirmatory testing in case of a positive result.

The control group represents the current standard of care, in which women are encouraged to refer their partner for HTC during ANC and PPC visits. However, members of this group also received a referral card, which is generally not provided in standard care in Kenya. Women in the control group were counseled on the importance of partner testing. They were given HTC referral cards to present to their partner. The referral cards summarized the information presented to the participants. They also mentioned the three study sites and encouraged the recipient to get screened at one of these sites and to present the referral card.

When developing the interventions, we consulted various community stakeholders, and national and provincial HIV testing task forces. We also obtained support from local Ministry of Health officials and a community advisory board. Our theory of change was based on the underlying goal of increasing HIV testing rates among males.

There are multiple barriers to HIV testing for men, largely due to testing services taking place at specific sites. Men traditionally interact with the health system less than women. Given this dichotomy, we theorized that women – who interact with the health system and receive HIV testing due to their exposure to the system – may be a useful conduit through which to reach men. Additionally, we assumed that offering women HIV self-tests to distribute to their partners – which remove many of the barriers of clinic-based testing, including stigma and inconvenience – would improve testing uptake.

Given this theory, we chose to utilize a randomized controlled trial design to test our initial hypothesis that the partners of participants receiving HIVST kits would be more likely to test for HIV than partners of participants receiving referral cards. Additionally, we hypothesized that couples testing would be more likely in the HIVST group than the referral group.

3. Study setting and participant recruitment

3.1 Study setting

The study took place in Kisumu County, in the Nyanza region of western Kenya, alongside Lake Victoria. Kisumu County is the primary urban and commercial area in the region and is one of the counties with the highest adult HIV prevalence in Kenya, at 19.3 percent (NASCOP 2014b). The city of Kisumu is located within Kisumu County and is the third largest city in Kenya. The study was conducted in collaboration with Impact Research and Development Organization.

3.2 Participant recruitment and flow

The study received approval from the Ethics and Research Committee at Kenyatta National Hospital/University of Nairobi and the Office of Human Research Ethics at the University of North Carolina at Chapel Hill. Between 11 June and 16 October 2015, study participants were recruited from three sites. These three sites were chosen to maximize generalizability of the patient populations in western Kenya, including urban and rural.

Trained RAs screened all ANC and PPC women who visited the three sites for study eligibility. All women were invited to enrol in the study if they met the following eligibility criteria: being between 18 and 39 years of age, having an HIV-negative primary partner, primarily residing in or around Kisumu and having no intention of leaving the area for the duration of the follow-up period (three months). In addition, women recruited in the ANC clinic were only eligible if they were less than or equal to 20 weeks into gestation. Women recruited in the PPC clinic were only eligible if they had given birth between six weeks and 12 months before.

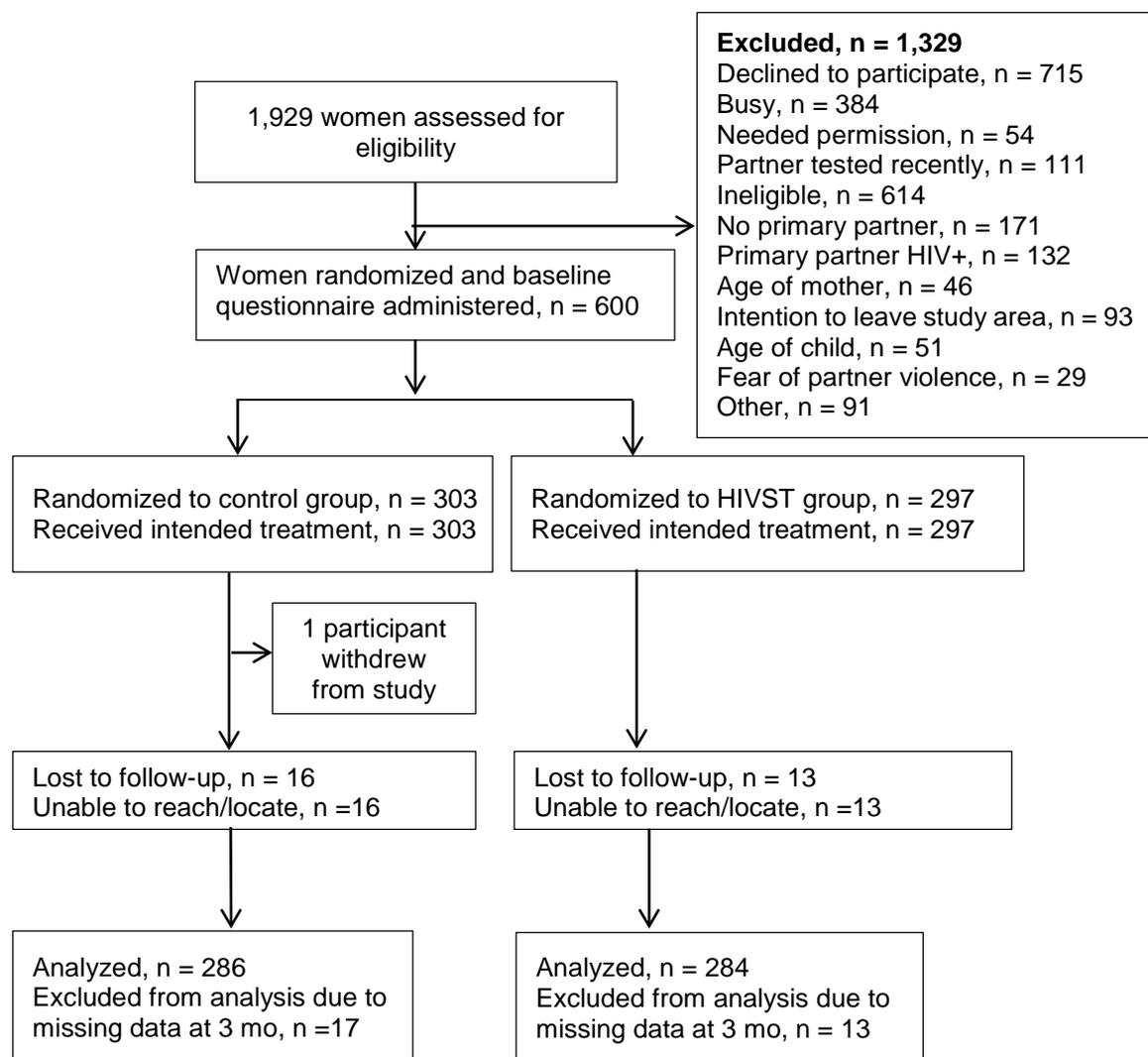
The use of gestational criteria attempted to ensure that female participants stayed enrolled in their respective clinic throughout the entire study period, while the postpartum period was chosen to reach women who may have resumed sexual activity and would still be attending the clinic with their infant children. Eligibility was determined during the informed consent process and using a short screening questionnaire. Following enrolment, study RAs administered a short baseline questionnaire that captured information on study participants' demographics, sexual behavior, HIV testing behavior and partner HIV testing.

At the end of the baseline questionnaire, study participants were randomized in a 1:1 ratio to either an HIVST group or a control group. Randomization was performed using sealed envelopes and balanced block randomization (block size = 20). The sealed envelopes were offered to participants sequentially, revealing the study group assignment to the participant and RA at the same time. Study participants and study staff were not blinded to group assignment because knowledge of the group was necessary

for study interventions to take place. Participants were informed about the two groups they could possibly be randomized to during the informed consent process.

The follow-up period lasted three months. During the follow-up period, we contacted study participants each month to determine if their partner went for HIV testing at the clinic (control group) or if they had given an HIV self-test kit to their partner or another individual (HIVST group). If they had, the RAs scheduled and conducted a follow-up interview. Participants received KSH 200 (approximately USD 2) compensation for their time at both baseline and follow-up interviews.

Figure 1: Study flowchart



4. Methodology: evaluation design and implementation

Power calculations were performed using the `sampsi` command in Stata version 13.1. These calculations suggest that with 20 percent of male partners in the control group seeking either partner or couples HTC at the Lumumba Health Centre within three months, a sample size of 200 women per group (400 women in total) will provide adequate statistical power to conduct pair-wise comparisons. A sample size of 200

women in the intervention group and 200 women in the control group will provide 90% power to detect a difference in the use of partner or couples HTC as small as 15%, and 80% power to detect a difference in partner or couples HTC as small as 13%.

The unit of analysis was the study participant. All outcomes were self-reported. The primary, pre-specified outcome was the participant's report of their primary partner testing for HIV within three months of their enrolment in the study. The outcome was coded as a binary variable equal to 1 if the participant reported that her partner had undergone HIV testing at study clinics within three months of enrolment and 0 if the participant did not.

The primary analysis compared HIV testing uptake with the control group using an unadjusted modified Poisson regression with robust standard errors (Zou 2004). We also conducted adjusted analyses but results were consistent across the two models, and therefore we present results from the unadjusted analyses here. We chose the modified Poisson because of its ability to handle extremely common data and produce relative risks. Participants who were not successfully followed up were not included in the final analysis, as we had no way of determining their or their partners' HIV testing outcomes.

In secondary analyses, we examined the impact of the intervention on the following six outcomes reported by participants:

1. discussion of HIV testing with partner;
2. couples testing for HIV;
3. couples testing among participants whose partner tested for HIV;
4. awareness of partner's HIV test result;
5. awareness of partner's HIV test result among participants whose partner tested for HIV; and
6. partner's HIV test result.

Discussion of HIV testing was defined as having occurred if the participant reported that she and her partner had talked about HIV testing since enrolment in the study. Couples testing was defined as having occurred when a participant reported that she had tested together with her partner at the same time. Awareness of partner's HIV test result was defined as the participant having learned her partner's HIV status.

Additionally, we examined whether partners of participants in the HIVST group who tested positive sought confirmatory testing, and whether partners in both groups who received a positive result were reported to be in care at the time of follow-up. We also assessed levels of intimate partner violence (IPV) at baseline and follow-up to assess a common concern of whether the distribution of self-tests by women to their partners, as well as the possibility of learning HIV status in the absence of a counselor, present any additional risks to women. We did this using questions adapted from the Kenya Demographic and Health Survey that asked whether participants experienced physical, emotional, verbal or sexual violence from their partner in the last 12 months. Participants were coded as having experienced IPV if they responded affirmatively to any of the IPV questions.

In order to better understand potential differences in intervention effectiveness in certain populations, we conducted exploratory subgroup analyses in which we ran the same

modified Poisson regression model on certain subpopulations and compared the intervention effectiveness among those populations.

We did this for four variables:

1. study site;
2. whether a study participant's partner had ever tested for HIV;
3. whether a study participant's partner had tested for HIV in the past 12 months;
and
4. whether a participant had experienced IPV in the 12 months prior to baseline.

All statistical tests were two-sided and the significance level was set at $p < 0.05$. All outcomes were assessed by intention-to-treat analysis. No adjustment was made for multiple testing since the secondary analyses were considered exploratory. Statistical analyses were performed using Stata 14.1.

5. Results

5.1 Participant recruitment and flow

Between 11 June and 16 October 2015, a total of 1,929 women were screened for participation in the study. Among those, 614 (32%) were ineligible, 715 declined to participate (37%), and 600 (31%) were enrolled in the study and randomized (see Figure 1). Reasons for ineligibility included: having no primary partner (28%); having an HIV-positive partner (22%); intending to leave the study area during the follow-up period (15%); age of the participant (8%); age of the participant's child (8%); and fear of IPV due to discussing HIV testing with their partner (5%).

Commonly reported reasons for refusal to participate in the study included women reporting that they were 'in a hurry' or 'too busy' (384 out of 715, 53.7%), needing permission from their partner to enrol in a study (54 out of 715, 7.6%), and reporting that their partner had tested recently and therefore did not have any interest in participating in the study (111 out of 715, 15.5%).

Follow-up interviews were conducted until 15 January 2016. One participant from the comparison group withdrew from the study during the follow-up period. Of the 600 participants who were enrolled, follow-up was completed for 570 (95%), comprising 286 (94.4%) in the comparison group and 284 (95.6%) in the HIVST group. In an attrition analysis, there were no significant differences in baseline characteristics between participants who were followed up and those who were not.

The total life of the grant was approximately 21 months. Originally, it was set to finish by the end of December 2015, but we received a no-cost extension that let the grant run until the end of June 2016. This time was used to finish up follow-up data collection, conduct analyses and work on publications from the study.

5.2 Baseline data

Participants in the two study groups had largely similar characteristics (see Table 1). Their mean age was 24 years and the vast majority were married. Participants' self-reported sexual behavior and their reports of their partner's HIV testing history were similar in both groups (see Table 2). Nearly four percent of all participants self-reported

being HIV positive. The majority of participants reported that their partner had tested for HIV in the past year (56%), and only a small percentage of participants (14%) had heard of HIVST prior to the study. Nearly 30 percent of participants reported experiencing IPV in the 12 months prior to enrolment.

Table 1: Baseline characteristics of study participants

	Comparison, n (%) (n = 286)	Self- testing, n (%) (n = 284)	P- value*
Age, mean (SD)	24.2 (4.3)	24.2 (4.5)	0.973
Monthly earnings (USD), median (IQR)	0 (0–30)	0 (0–40)	0.269
Ethnic group			
Luo	221 (77)	219 (77)	0.964
Luhya	33 (12)	43 (15)	0.206
Other	32 (11)	22 (8)	0.161
Education			
Some primary or completed	138 (48)	143 (50)	0.616
Some secondary education	133 (47)	120 (42)	0.307
Completed secondary or greater	15 (5)	21 (7)	0.291
Married	266 (93)	266 (94)	0.754
Occupation			
Non-manual	74 (26)	83 (29)	0.371
Manual	19 (7)	28 (10)	0.163
Housewife/unemployed	193 (67)	173 (61)	0.102

Note: For all variables, frequencies are presented with percentages in parentheses. Monthly earnings are in USD equivalents, reported as median with interquartile range (IQR) in parentheses.

*P-value from Mann-Whitney tests for continuous variables and Chi-square for indicator variables. SD = standard deviation.

Table 2: Attitudes and knowledge of HIV and self-reported sexual behavior

	Comparison, n (%) (n = 286)	Self- testing, n (%) (n = 284)	P- value*
Age at first intercourse, mean (SD)	17.7 (2.8)	17.9 (2.5)	0.320
Number of times been tested for HIV in last year, mean (SD)	2.8 (1.4)	2.8 (1.5)	0.939
Self-reported HIV positive	10 (3.5)	13 (4.6)	0.501
Condom used during last sex	54 (19)	46 (16)	0.400
Had at least 1 other sexual partner in past year	4 (1)	5 (2)	0.725
Had heard of HIVST prior to study	39 (14)	41 (14)	0.783
Primary partner ever been tested for HIV			
Yes	220 (77)	216 (76)	0.807
No	19 (7)	21 (7)	0.726
Don't know	47 (16)	47 (17)	0.970
Primary partner has been tested for HIV in the past year			
Yes	173 (60)	149 (52)	0.373
No	35 (12)	42 (15)	0.053
Don't know	78 (27)	93 (33)	0.154
Know partner's HIV status	192 (67)	194 (68)	0.764
Experienced IPV in past year	76 (27)	78 (27)	0.811

Note: For all variables, frequencies are presented with percentages in parentheses.

*P-value from Mann-Whitney tests for continuous variables and Chi-square for indicator variables.

5.3 Primary outcome: partner HIV testing

Male partner testing within three months of enrolment in the study was higher in the HIVST group (258 out of 284, 90.8%) than the comparison group (148 out of 286, 51.7%), as shown in Table 3. The percentage point difference of 39.1% between the two groups was statistically significant (95% CI, 32.4%–45.8%, $p < 0.001$).

Table 3: Effects of HIVST within three months

	Comparison, n (%) (n = 286)	Self- testing, n (%) (n = 284)	Absolute difference percentage points (95% CI)*	P- value*
Primary endpoint				
Male partner HIV testing	148 (51.7)	258 (90.8)	39.1 (32.4 to 45.8)	< 0.001
Secondary outcomes				
Discussed HIV testing with partner	276 (96.5)	271 (95.4)	-1.1 (-4.3 to 2.2)	0.512
Couples testing for HIV	95 (33.2)	214 (75.4)	42.1 (34.7 to 49.6)	< 0.001
Couples testing for HIV conditional on partner HIV testing*** (n = 148 and n = 258)	95 (64.2)	214 (82.9)	18.8 (9.8 to 27.8)	< 0.001
Aware of partner's HIV test result	145 (50.7)	255 (89.8)	39.1 (32.3 to 45.9)	< 0.001
Aware of partner's HIV test result conditional on partner HIV testing*** (n = 148 and n = 258)	145 (98.0)	255 (98.8)	0.9 (-1.8 to 3.5)	0.519
Partner tested HIV positive	4 (1.4)	8 (2.8)	1.4 (-0.9 to 3.8)	0.239

Note: *Estimates and confidence intervals (CI) are marginal effects from unadjusted modified Poisson regression.

**Estimates and CI are risk ratios from unadjusted modified Poisson regression.

***Model includes the subset of participants whose partner tested for HIV.

5.4 Secondary analyses

Over 95% of participants in both groups reported discussing HIV testing with their partner since enrolling in the study, and there was no significant difference between the two groups (difference = -1.1%, 95% CI -4.3% to 2.2%, p = 0.512).

Participants in the HIVST group were more likely to test as a couple than participants in the comparison group (difference = 42.1%, 95% CI 34.7% to 49.6%, p < 0.001). In addition, among participants whose partner tested for HIV during the follow-up period, couples testing was more likely in the HIVST group than the comparison group (difference = 18.8%, 95% CI 9.8% to 27.8%, p < 0.001).

At follow-up, participants in the HIVST group were more likely to know their partner's HIV status than those in the comparison group (difference = 39.1%, 95% CI 32.4% to 45.8%, p < 0.001). However, among participants whose partner tested for HIV during the follow-up period, participants' awareness of their partner's HIV status did not differ significantly between the two groups (difference = 0.9%, 95% CI -1.8% to 3.5%, p < 0.519), suggesting that the increase in awareness of partner HIV status in the HIVST group was driven by the greater likelihood of partner testing having occurred rather than a greater likelihood of becoming aware if a partner did get tested.

Among participants whose partner tested for HIV, almost all were aware of their partner's HIV test result (98.0% in the comparison group, 98.8% in the HIVST group). A small number of participants in both groups reported that their partner tested HIV positive (1.4% in the comparison group, 2.8% in the HIVST group). Among the eight partners who tested positive in the HIVST group, two went for confirmatory testing, were confirmed positive and were linked to care. Among the four partners who tested positive in the comparison group, three were reported to have sought HIV care at the time of the three-month interview. No participants in either group reported experiencing IPV due to HIV testing.

5.5 Heterogeneity of intervention effectiveness

For all participant subgroups examined, participants in the HIVST group reported more partner testing than participants in the comparison group. While partner testing was significantly more likely in the HIVST group than the comparison group at all three study sites, the HIVST intervention was more effective in promoting partner testing in the hospital setting than the urban health clinic setting ($p < 0.001$).

There was no difference in intervention effectiveness by partner HIV testing status in the 12 months prior to baseline ($p = 0.172$). Similarly, we found no difference in intervention effectiveness between participants who had experienced IPV at baseline and those who had not ($p = 0.111$).

Table 4: Comparison of intervention effectiveness in participant subgroups

Subgroup	HIV testing uptake		Effect of HIVST		
	Comparison, no./total no. (%)	Self-testing, no./total no. (%)	Absolute difference, percentage points (95% CI)*	P-value for subgroup up*	P-value for interaction**
Study site					
Urban clinic	80/120 (66.7)	117/129 (90.7)	24.0 (14.2 to 33.9)	< 0.001	–
Hospital	47/122 (38.5)	97/105 (92.4)	53.9 (43.8 to 63.9)	< 0.001	< 0.001
Semi-urban clinic	21/44 (47.7)	44/50 (88)	40.3 (22.9 to 57.7)	< 0.001	0.093
Partner tested for HIV in 12 months prior to enrolment in study					
Tested ≥ 1 time	102/173 (59)	142/149 (95.3)	36.3 (28.3 to 44.4)	< 0.001	–
Did not test	16/35 (45.7)	37/42 (88.1)	42.4 (23.1 to 61.7)	< 0.001	0.389
Don't know if tested	30/78 (38.5)	79/93 (84.9)	46.5 (33.5 to 59.5)	< 0.001	0.057
Had experienced IPV at baseline	114/210				
No	(54.3)	185/206 (89.8)	35.5 (27.6 to 43.4)	< 0.001	–
Yes	34/76 (44.7)	73/78 (93.6)	48.9 (36.4 to 61.3)	< 0.001	0.111

Note: *Estimates and CI are marginal effects from a modified Poisson regression of outcome on study group for the subgroup described.

**P-value from the interaction coefficient between the subgroup and first category (urban clinic, yes tested in past 12 months, no IPV).

In in-depth interviews with nine HIV-positive women in the HIVST group, all but one reported that their partner was receptive to HIVST, none of them reported having experienced IPV and all participants' partners (n = 9) tested HIV negative. Women commonly wanted their partners to test for their own benefit.

I started to tell him that “You should also know your status”...so that we can help each other...and he can start taking care of his life.... I told him he should also know his status since we have sex and I am positive. – Anonymous, female

5.6 Cost-effectiveness

Using the evidence generated in this study on the effectiveness of providing HIV self-tests, as well as administrative data we kept on the costs of implementing the intervention, we were able to determine the incremental cost-effectiveness of the demand creation interventions assessed in this study.

The cost-effectiveness results (see Table 5) show that the HIVST intervention is highly cost-effective. In a population of 1,000 male partners, study results suggest 390 additional partners would be tested for HIV as a result of providing HIV self-tests to women attending ANC and PPC clinics. The total cost of this intervention would be USD 10,545, indicating an incremental cost-effectiveness of USD 27 per partner who tested for HIV.

This value is highly dependent on the cost of HIV self-tests. We assume a unit cost of USD 10, which we procured the tests for in the study. However, with mass distribution costs may be lower, improving the cost-effectiveness of the intervention. Also, we presume the cost of getting tested is zero, but obviously this is a simplification because there is an expense associated with more traditional forms of testing. Accounting for these costs would further improve the cost-effectiveness of the intervention.

Given the data on the sizable HIV prevention benefits of testing, this suggests that demand creation interventions, such as the ones implemented in this study, warrant strong consideration by programs and countries seeking to increase HIV testing.

If implemented at scale and over a longer duration of time, it is plausible that providing HIVST kits would be even more cost-effective, as some of the fixed costs of developing and initiating the intervention could be distributed over a greater number of partners. The cost-effectiveness of the intervention will also be enhanced if adjustments are made for the fact that effective demand creation interventions can lead to efficiency gains at clinics, since staff are less likely to be under-utilized.

Table 5: Intervention cost-effectiveness inputs and results

	Control	HIVST
Effectiveness		
# of tests in 3-month period	148	258
# of participants in study group	286	284
Percentage of group participants tested	52%	91%
Projected # of partners tested if implemented in community of 1,000	520	910
Costs		
Cost of setting up and maintaining HIVST distribution for 3 months	\$0	\$500
Personnel time for distributing self-tests at facility (5% effort for 3 months)		\$45
Referral card printing costs	\$15	\$0
Test costs	\$0	\$10,000
Total costs	\$15	\$10,545
Incremental cost-effectiveness		
Cost per additional partner tested		\$27
Unit cost of printing referral cards		\$0.05
Unit cost of HIV self-test		\$10

6. Discussion

Providing multiple self-tests to female participants led to the secondary distribution of the self-tests to their male partners and ultimately achieved higher HIV testing among their male partners and higher rates of couples HIV testing than a more conventional approach of giving women invitation cards for their male partners to test at health facilities.

In the group that received multiple self-tests, partner testing occurred for 90% of participants and couples testing for 75% of them. To our knowledge, this is the first randomized trial to test whether secondary distribution of HIV self-tests promotes partner and couples testing. In subgroup analyses, the intervention was more effective than the partner invitation approach, even among female participants who reported a history of IPV and among those whose partners had not gone for HIV testing in the past 12 months.

Male partner testing was nearly universal among women who received multiple self-tests. This striking result is consistent with findings from a pilot study we previously conducted in the study region, in which male partner testing was reported to have occurred for 91% of women seeking ANC and 86% of women receiving PNC (Thirumurthy et al. 2016). The study results are also consistent with the high acceptability of self-testing that has been documented in SSA and elsewhere (Choko et al. 2011; Napierala Mavedzenge et al. 2013; Figueroa et al. 2015).

Uptake of partner testing in the comparison group was similar to that found in a recent study of HIV testing using invitation cards in the same region of Kenya (Osoti et al. 2014). In that study, pregnant women receiving home-based HIV testing by counselors had higher levels of male partner testing than a comparison group of pregnant women who received clinic invitation cards for their partner (36% in the comparison group). This supports our finding that HIVST can help overcome barriers associated with clinic-based testing.

Further, a study in Malawi found a similar uptake of partner HIV testing among participants who received invitation cards for their partner (52%) (Rosenberg et al. 2015). The similarity in male partner testing levels in the comparison group of our study with those reported in two other studies of the partner invitation approach provide further support for the validity of the measures obtained in our study.

There was no significant difference in the effectiveness of our intervention based on whether partners had tested for HIV in the 12 months prior to baseline. This result is highly encouraging since it suggests that HIVST is an effective way to increase HIV testing in hard to reach populations such as men who do not regularly test for HIV.

In addition, the large differences in testing in this hard to reach population, between the HIVST and comparison group, were observed in all subgroups, suggesting that the HIVST intervention overcame many of the barriers that high-risk men have to HIV testing. Overall, the high levels of partner testing achieved in the HIVST group are consistent with results from various studies that have shown extremely high acceptability of HIVST in SSA (Choko et al. 2015; Napierala Mavedzenge et al. 2013; Figueroa et al. 2015; Johnson et al. 2014).

From a policy standpoint, providing self-tests to women in clinic settings is likely to have substantial appeal because it not only promotes male partner testing but also helps women learn their partners' HIV status. The intervention's feasibility is enhanced by the fact that pregnant and postpartum women represent an 'easy to reach' segment of the population by virtue of their higher utilization of health services.

Couples testing, which is recommended by the World Health Organization and the Kenyan Ministry of Health, is another important benefit of the intervention. Individuals who test as a couple and mutually disclose their HIV status are more likely than those testing alone to adopt a range of HIV prevention and care behaviors (Allen et al. 2003). Despite these benefits, only 37.2% of people who have tested for HIV in Kenya reported ever having tested together with a sexual partner (Ng'ang'a et al. 2014).

The uptake of couples testing observed among female participants given multiple self-tests in this study was higher than the uptake reported from our pilot study in the study area, in which ANC and PPC women tested as couples 47% and 58% of the time respectively (Thirumurthy et al. 2016). The difference is most likely due to the strong emphasis we placed on partner testing in our initial interviews with participants, something we did not do in the pilot study.

This study has limitations. First, we relied on self-reported data for the main outcomes. This is a common limitation in many studies involving HIVST due to the private manner in which self-tests are meant to be used. Despite the potential for self-reporting to be associated with reporting bias, we believe that reporting bias was minimal given the consistency of our results for HIV testing uptake with other studies conducted in SSA (Choko et al. 2011; Choko et al. 2015; Thirumurthy et al. 2016; Rosenberg et al. 2015; Osoth et al. 2014). In addition, any bias in reporting of HIV testing uptake is unlikely to be differential by study group, thereby maintaining the validity of examining the difference in HIV testing uptake between study groups.

Second, our study did not include women who knew that their partner was HIV positive because we believed that a partner testing intervention would have little additional benefit to them. This feature of the study design, coupled with high rates of HIV testing in the urban study setting (Kimanga et al. 2014), likely led to relatively few HIV-positive partners being identified in this study. This also limited our ability to make statistical inferences with respect to confirmatory testing and linkages to care. More research is needed to assess levels of confirmatory testing and linkages to care following HIVST rigorously, as well as to understand the decision-making process around whether to seek these services.

Finally, not all women seeking ANC and PPC agreed to participate in the study. While this likely has little impact on the difference in levels of HIV testing among female participants' partners, it does potentially limit the generalizability to the population of pregnant and postpartum women. More studies are necessary to assess the generalizability of the intervention to other populations and settings outside western Kenya. However, to the extent that men experience similar barriers to clinic-based HIV testing elsewhere, the results from this study should apply in other settings.

Implementation of the intervention was fairly straightforward. Although a large number of women declined to participate in the study, the majority of decliners said they could not participate because they were in a hurry and lacked time. Very few said that they declined because of the study goals. Once study participants were enrolled, follow-up data collection was somewhat difficult. To counteract this, we employed a number of strategies to ensure low attrition, including setting up appointments, home visits, and telephone interviews when all in-person options were unavailable.

One lesson learned was that different RAs had valuable insights on contacting hard to reach individuals. It was helpful to get all of the RAs together every month or so to share experiences and ensure that everyone was utilizing best practices.

One concern about providing multiple self-tests to women has been the possibility of IPV due to women giving their partners self-tests and the possibility of people learning their HIV status in the absence of a counselor. However, IPV was extremely rare in both of our study groups. The study demonstrates the safety of the intervention and confirms findings from other studies that self-testing can be undertaken without resulting in adverse events (Napierala Mavedzenge et al. 2013). This is an encouraging result that supports the greater use of approaches that provide multiple self-tests to women to enhance partner testing and ultimately increase the effectiveness of preventing mother-to-child transmission of HIV, and HIV treatment.

This study provides key insights into the secondary distribution of self-tests to sexual partners, a behavior that may become common in many populations in SSA and elsewhere as HIV self-tests become more widely available. Studies in the US have begun to explore the feasibility of this approach among key populations such as men who have sex with men (Carballo-Diequez et al. 2012a; Carballo-Diequez et al. 2012b). Our study shows how and why countries should consider using self-tests to achieve key HIV prevention objectives. Implementing this intervention at scale is likely to be feasible as the primary requirements are that clinic staff are trained in explaining self-test use to women and that health facilities are equipped with self-tests.

Future studies must examine confirmatory testing and linkages to care following self-testing to ensure that those who test HIV positive seek care. A limitation of partners distributing self-tests is the inability to ensure that people who test HIV positive engage in confirmatory testing. Although this is important, it is a factor in all self-testing studies and not specific to partner test distribution. Another limitation of partner testing is that it fails to reach men who are not in partnerships, a group that could have a high burden of HIV. Innovative strategies are needed to target these single males.

Additionally, more research is needed to understand how partners distributing self-tests would interact with the widespread availability of self-tests. It is unclear how partner distribution would be affected by universal availability. It is also unclear whether men, if they were offered HIV self-tests, would use them in the same way as the female participants in this study.

With regards to implementation of the intervention, there were various lessons learned and challenges worth noting. First, we requested participants in the HIVST group to return their used test kits when meeting study staff to help us corroborate the self-reported information with physical evidence. In practice, it was difficult to obtain the used test kits for various reasons, such as the tests having been thrown away or left at home. Similarly, participants in the comparison group were asked to encourage their partner to bring their clinic testing referral card, but in practice this was not done nearly as often as clinic testing was reported.

Second, follow-up data collection produced some challenges. To increase participation in follow-up surveys, we utilized phone interviews and participant tracking. Both methods helped to ensure low loss to follow-up. Finally, we were fortunate to have study staff who are trained HIV counselors to recruit study participants. These staff members were able to draw upon their experiences to counsel participants regarding their reservations about HIV testing. They were an invaluable resource and the study's success was due to their efforts.

The preliminary results of the study have been presented multiple times to audiences in Kenya, including NASCOP, the US Centers for Disease Control and Prevention and KEMRI. The study was accepted for an oral presentation at the International AIDS Society Conference in Durban in July 2016. Investigators from the study were invited to share their results at steering committee meetings and to contribute to national policy guideline formulation surrounding HIVST in Kenya. The primary findings of this study were published in *PLoS Medicine* in November 2016 (Masters et al. 2016).

In conclusion, providing HIV self-tests to women seeking ANC and PPC led to a higher uptake of partner testing and couples testing. This approach warrants further consideration as countries develop HIVST policies and seek new ways to promote partner testing.

Online appendices

Note to the reader: Online appendices are provided as received from the authors. These have not been copy-edited or formatted by 3ie.

Appendix A: Baseline questionnaire can be accessed here.

<http://www.3ieimpact.org/sites/default/files/2019-01/ie60-appendix-a.pdf>

Appendix B: Follow-up questionnaire can be accessed here.

<http://www.3ieimpact.org/sites/default/files/2019-01/ie60-appendix-b.pdf>

Appendix C: Screening questionnaire can be accessed here.

<http://www.3ieimpact.org/sites/default/files/2019-01/ie60-appendix-c.pdf>

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Despite progress in recent years, men in Sub-Saharan Africa have lower HIV testing rates than women. Nearly half of all HIV-positive individuals remain unaware of their HIV status. This represents a key barrier to meeting the UNAIDS 90-90-90 targets for HIV elimination. Achieving higher rates of partner and couples HIV testing among pregnant and postpartum women in Sub-Saharan Africa is essential for the success of combination HIV prevention, including the prevention of mother-to-child transmission. This impact evaluation assessed the effect of secondary distribution of HIV self-test kits to women to provide to their male partner on their testing rates. The study found that providing women with multiple HIV self-tests is more effective at promoting partner and couples testing than the conventional strategy based on partner invitations to clinic-based testing.

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