Anthony Gichangi
Jeffrey E Korte
Jonesmus Wambua
Caroline Vrana
Danielle Stevens

Increasing male partner HIV testing using self-test kits in Kenya

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Anthony Gichangi
Jhpiego, an affiliate of Johns Hopkins University

Jeffrey E Korte
Medical University of South Carolina

Jonesmus Wambua
Jhpiego

Caroline Vrana
Medical University of South Carolina

Danielle Stevens
Medical University of South Carolina

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Summary

Kenya has approximately 1.6 million people living with HIV, and a little over 100,000 new HIV infections occurred in 2013. Of these infections, 11,000 are attributed to mother-to-child transmission, according to the 2014 Kenya HIV progress report (NACC 2014). To accelerate the elimination of mother-to-child transmission, the Kenyan Ministry of Health (MOH) has introduced HIV testing to all pregnant women attending antenatal care (ANC), using the opt-out approach. The 2012 Kenya AIDS Indicator Survey reported that uptake of HIV testing at ANC was about 94.4 per cent.

All women who are identified as HIV positive are immediately enrolled on highly active antiretroviral therapy. Despite the nearly universal uptake of HIV testing among ANC clients, testing among their male partners is low. Based on undocumented programmatic evidence, only about six per cent of partners of ANC clients in Kenya's former Eastern and Central Provinces accept HIV testing. Globally, male involvement is a critical success factor in the elimination of mother-to-child transmission of HIV (Morfaw et al. 2013). Male partner testing with disclosure of results allows couples to make informed decisions about HIV prevention.

We conducted an individually randomized impact evaluation to determine if provision of oral HIV self-test kits, with improved information cards, to male partners of ANC clients is a viable way of improving partner testing rates. We recruited 1,410 women from 14 ANC clinics in the former Eastern and Central Provinces of Kenya in 2015. Pregnant women were randomized at their first ANC visit to one of three study arms: Arm 1, Arm 2 or Arm 3.

In Arm 1 (standard of care group), women randomized into this group were provided with the standard ANC, which includes HIV counseling and testing, and the standard MOH letter inviting their partners to come to the ANC clinic to discuss the health of their family.

In Arm 2 (information control group), women randomized into this group were provided with the standard ANC, including HIV counseling and testing, and an improved letter. This was male-friendly in design, specific about the purpose of the visit (i.e. to have an HIV test), and included some messaging on HIV discordancy and transmission from mother to child.

In Arm 3 (intervention group), women randomized into this group were provided with the standard ANC, including HIV counseling and testing, and the improved letter provided to women in Arm 2. Women in Arm 3 were also provided with two oral HIV self-test kits to take home and test with their partner. In addition, women were provided with information on how the HIV self-test kit works, how to approach their partner and what to do after testing. The primary study outcome was reported as HST by the woman's male partner, within a three-month study follow-up period.

Of the 1,410 women enrolled at baseline, a total of 1,215 (86 per cent) were successfully followed up at endline. In addition, 1,133 men were followed up. A total of 1,106 couples were reached in the follow-up. Overall, we found that in the intervention group (Arm 3), 82.6% of the male partners tested for HIV during the follow-up period, compared with 37.0% in Arm 2 and 28.3% in Arm 1. Among the men who were in the self-testing group (Arm 3), 86.6% of them reported testing at home and 81.6% reported testing together

with their partner. Regarding the usability of the test kit, 81.4% of the men reported that it was very easy to read the instructions, 80% reported that it was very easy to take the swab, and 90% reported that it was very easy to read the results. From the focus group discussion with women in the intervention group (Arm 3), privacy and testing together at home were reported as the key drivers of the uptake of self-testing. Stigma, the dismissive nature of men and busy schedules were reported as barriers explaining why men would not go to test at the ANC clinic.

The study demonstrates that the oral HIV self-test kit has the potential to increase access to testing among male partners of ANC clients, therefore increasing a couple's HIV status awareness and preventing potential infection to mother and child if the male partner is HIV positive. These promising results suggest that the inclusion of oral self-test kits in a national HIV program may dramatically increase testing among male partners of pregnant women.

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List of figures and tables

Abbreviations and acronyms

ANC	Antenatal care
FGDs	Focus group discussions
HST	HIV self-testing
HTC	HIV testing and counseling
MOH	Ministry of Health
NASCOP	National AIDS & STI Control Programme
PMTCT	Prevention of mother-to-child transmission (of HIV)
VCT	Voluntary counseling and testing

1. Introduction

1.1 Background

Kenya is a country of approximately 42 million people (KNBS and ICF Macro 2010), with an estimated HIV prevalence of 5.6 per cent, according to the Kenya AIDS Indicator Survey 2012 (NASCOP 2013). It is estimated that there are about 1.6 million people living with HIV in Kenya, with over 100,000 new HIV infections occurring annually (NACC 2014). Currently, about 72% of Kenyans report having been tested for HIV at least once in their lifetime and about 47% of all HIV-positive individuals are aware of their status (NASCOP 2013).

It is generally accepted that knowledge of one's HIV-positive status is the key entry point to all HIV prevention and treatment services. People who are aware that they are HIV positive are less likely to engage in risky sexual behaviors or more likely to use protection with their sexual partners (Marks et al. 2005). They are also more likely to seek treatment services early, increase their life expectancy and improve their quality of life.

In fact, even among key populations, such as commercial sex workers, those who know their correct HIV status are less likely to engage in risky sexual activities and more likely to reduce the number of sexual partners that they have (Weinhardt et al. 1999). Even without HIV prevention counseling, knowledge of HIV status has a significant effect on behaviors, especially for those who are HIV positive (Marks et al. 2005). Therefore, providing HIV testing services to the majority of the population remains the cornerstone in prevention of new HIV acquisition and transmission.

Upon realizing the importance of knowledge of HIV status for HIV prevention and treatment, Kenya's MOH – through its technical arm, NASCOP – has been at the forefront of designing and implementing programs aimed at increasing knowledge of HIV status. Kenya, as provided for in the *National HIV Testing and Counselling Guidelines* (NASCOP 2016), has approved the use of diverse HIV testing and counseling (HTC) strategies in different contexts. This includes a provision for HST. In addition, in 2016, NASCOP, through its technical working group, developed an operational guideline for HST to guide the implementation of the self-testing policy.

HST is a type of HIV test that can be conducted in private (e.g. at home) by anyone and without any medical supervision. In 2012, the US Food and Drug Administration authorized the sale and use of home HIV self-test kits. The Kenyan MOH has approved the use of oral HIV self-test kits for the general population in accordance with agreed-upon guidelines. The current recommendation for self-testing in Kenya is to utilize the self-test as an initial screening. Clients testing negative are advised to consider retesting after 4 to 12 weeks to account for the 3-month window period of HIV. Clients testing positive should go for a confirmatory test at a health facility.

1.2 HIV self-testing

Self-testing offers the potential for more people to know their HIV status by circumventing some of the common barriers, such as stigma, lack of privacy, long

distances to health facilities, lack of client autonomy, and poor access to health facilities or stand-alone voluntary counseling and testing (VCT) centers (Ganguli et al. 2009). KAIS 2012 sought to determine the acceptance rates of HST in Kenya and found that over 70.7 per cent of Kenyans would test themselves if such kits were available to them. It also found that over 3.5 per cent of Kenyans have tested themselves at least once.

While some key stakeholders still have questions about how best to implement HST, there is a growing evidence base that suggests implementation is feasible. A study conducted in Blantyre, Malawi (Choko et al. 2011) found that supervised self-testing was highly accurate, with clear and concordant results for 99.2 per cent of participants. Overall sensitivity for self-test self-read was 97.9%, with specificity of 100%. In another study conducted in Singapore, investigators aimed to assess the accuracy and user-acceptability of HST using an oral fluid-based HIV rapid test kit with only visual instructions, followed by healthcare worker testing (Ng et al. 2012). Self-testing was associated with very high sensitivity (97.4%) and high specificity (99.9%). These findings indicate that unsupervised self-testing is very accurate even among untrained individuals. A systematic review conducted in 2013 (Pant Pai et al. 2013) on supervised and unsupervised HST in both low- and high-risk populations showed that both supervised and unsupervised testing strategies were highly acceptable, preferred and more likely to result in partner self-testing. In addition, in the Malawi study, the vast majority (98.5 per cent) of the participants rated the self-test as very easy (Choko et al. 2011).

A study conducted in Kenya (Kalibala et al. 2011) on self-testing among health workers in seven district-level hospitals, preceded by a one-month pilot test in two other hospitals, found that approximately nine out of ten health workers who attended the information session on HST took the test with them after the session. Of those who took the test kits, the majority (85 per cent) tested themselves. Most (72 per cent) tested within one day of receiving the HST kit. The majority (64%) of health workers with partners indicated that their partners used the HST kits to test themselves, and among them, almost all (96%) tested within one week of receiving the test kit. Qualitative results on the same study revealed that, while many of the health workers and their partners tested together, those couples who did not test together still revealed their test results to their partners.

These studies demonstrate that HST has a great potential to increase HIV testing in the population due to high acceptability. In our current study, we have tried to answer the question of whether HST is feasible among male partners of clients of ANC clinics. Specifically, we evaluated the impact on male partner HIV testing rates of offering HIV self-test kits to male partners through their pregnant female partners.

1.3 Kenya prevention of mother-to-child transmission program

According to KAIS 2012, up to 6.5 per cent of Kenya's pregnant women are living with HIV (NASCOP 2014), and there were approximately 100,000 new infections in 2013 (NACC 2014). Of those, about 11,000 were infants who became HIV infected through mother-to-child transmission (NACC 2014). Overall, 4.8 per cent of all married and cohabitating couples are sero-discordant (one partner is HIV positive while the other is HIV negative). Among HIV-negative pregnant women, 1.3 per cent reported having a

partner who was HIV positive. About two-fifths (42.2 per cent) of pregnant women did not know their partner's HIV status. Among all women and men in Kenya, women were more likely to have ever been tested for HIV than men (80% compared with 63%) (NASCOP 2014). Therefore, it is critical for men and women to understand the importance of HIV testing, even if their partners are negative, in order to eliminate new pediatric and adult HIV infections.

In Kenya, ANC clinics are a nearly universal entry point to HTC for pregnant women. Nearly all (95.4 per cent) of Kenyan pregnant women aged 15–54 years had at least one ANC visit in 2012 as part of the national HIV guidelines and quality of care standards. In Kenya, a facility-based rapid diagnostic HIV test is offered at no cost to every client who comes to an ANC clinic as part of the national prevention of mother-to-child transmission (PMTCT) program. Of those who went to ANC clinics at least once, 94.4 per cent accepted HTC in 2012 (NASCOP 2013).

PMTCT of HIV, when undertaken as part of routine ANC for pregnant women, can offer important HTC services, linkages to care and treatment if needed, and help to prevent infant exposure to HIV during pregnancy, delivery and breastfeeding. Elimination of mother-to-child transmission is a priority for the Kenyan government. The national HIV program strives to encourage HIV testing for both ANC clients and their male partners. As a standard practice, when a woman visits an ANC clinic for the first time, she is taken through the standard clinical and laboratory examinations. At this stage, the woman is issued with a Mother and Child Health Booklet, to be used to collect antenatal and postnatal care information. After these examinations, pregnant women are offered a health talk on nutrition, hygiene, general health issues, and HIV and AIDS. Thereafter, women are offered pre-test HIV counseling and an HIV test, and the vast majority of women do agree to be tested. Depending on the outcome of the HIV test, post-test HIV counseling is offered and, subsequently, the woman is told that it is important to have her partner tested for HIV in order to protect the baby's health. The woman is also encouraged to bring her partner along to the next ANC clinic visit.

Because of the high coverage of HIV testing among pregnant women in Kenya, ANC clinics could be an important entry point for HTC among male partners as well, either in the context of clinic-based testing or self-testing. Currently, according to UNICEF, Kenya has an annual birth rate of approximately 1.5 million (2013).

1.4 Study justification and rationale

Despite the near-universal uptake of HIV testing among ANC clients, testing among their male partners is low. Based on undocumented programmatic evidence, only about six per cent of partners of ANC clients in Kenya's former Eastern and Central Provinces accept HIV testing. Globally, male involvement is a critical success factor in eliminating mother-to-child transmission (Morfaw et al. 2013), and male partner testing with disclosure of results allows couples to make informed decisions about prevention. It also enables people living with HIV to access HIV clinical care, including antiretroviral therapy, preserving their own health and reducing the likelihood of onward transmission, especially to partners who are HIV negative and then also to their babies. Male involvement in PMTCT improves adherence and retention in care and is associated with lower mother-to-child transmission rates. Partner testing is equally important for women

who test negative for HIV at their first ANC visit. There are high rates of HIV acquisition among pregnant and postpartum women as shown in studies from western Kenya, Botswana and Rakai, Uganda (Drake et al. 2014). Women who sero-convert during pregnancy or while breastfeeding are at high risk of transmitting the virus to their fetuses or infants due to the high viral load associated with acute HIV infection.

The provision of oral HIV self-tests, with a convenient, private distribution method (through female partners), may be a way to reach male partners who are not willing to accompany their female partners to the ANC clinic for testing. The goal of our study was to explore male partner testing, and how this may be improved by providing oral HIV self-test kits. We framed our work on a robust theory of change, and have tested critical aspects of our theory, including barriers, facilitators and other dynamics of male partner HIV testing.

One of the major critical goals in eliminating mother-to-child transmission is to increase male partner testing rates. In this study, we sought to determine if provision of oral HIV self-test kits (with improved information cards) to male partners of women attending ANC clinics is a viable way to improve male partner testing rates.

1.5 Study description

The key objective of the intervention was to increase HIV testing rates among male partners of pregnant women attending ANC clinics. The intervention consisted of training pregnant women in the use of the oral HIV self-test kits, and offering the women strategies for persuading their male partners to use the kit. Each pregnant woman was provided with two kits to take home so that the couple would have the option of testing together.

This study had three arms, comprising one intervention group (Arm 3) and two control groups (Arm 1 and Arm 2). We used two control groups in order to isolate the effect of providing improved information. While planning the study, we determined that standard care in Kenya involved the provision of an information card for ANC clients to take home to their male partners. The information card was produced by the Kenyan MOH and provided an invitation for the male partner to come to the clinic to discuss the health of the family, but did not specifically mention HIV. We hypothesized that HIV testing in male partners might be separately impacted by: (1) improved information and focus on HIV, and (2) the act of providing oral HIV self-test kits. To isolate these two effects and to be able to focus specifically on the individual effect of providing the oral HIV self-test kits, we decided to include a second control group (Arm 2). In this study arm, participants were provided with the standard care and an improved information card to take home to the male partner, with explicit mention of HIV and the importance of HIV testing by the father of the baby during pregnancy. In summary, Arm 1 women (standard of care) were provided with the usual standard of care, including the standard information card to take home. Arm 2 women (standard of care plus improved information control group) were provided with the usual standard of care and an improved information card to take home. Arm 3 women (intervention group) received the standard care and the improved information card, plus training with two oral HIV self-test kits to take home.

In all three study arms, women completed a baseline questionnaire assessing important socio-demographic and clinical factors, factors relating to HIV testing, partner communication around HIV testing and gender equity within the relationship. Women in all three study arms were followed up for three months, the primary outcome of the study being the woman's self-report regarding any HIV testing by her male partner (oral self-test kit, clinic-based testing or other testing venue). In addition, we sought to recruit all the male partners, have them complete a similar baseline questionnaire, determine whether they had self-reported on HIV testing, and follow them up for three months.

1.6 Study hypotheses

Based on national data on male testing, as well as on data from male partner testing at ANC clinics, we estimated before conducting the study that male partners of women in the standard of care group would have HIV testing rates of six per cent. We further estimated that male partners with the improved card would have HIV testing rates statistically similar to the standard of care group (HIV testing rate not greater than 11 per cent). Finally, we estimated that male partners in the intervention arm with the improved card and oral HIV self-test kits would have statistically higher HIV testing rates of 20 per cent.

1.7 Study objectives

The primary study objective was to determine if provision of oral HIV self-test kits, with improved information cards, to male partners of ANC clients is a viable way to improve partner testing rates.

The secondary study objectives were as follows:

- To determine barriers and drivers of HIV testing among male partners of ANC clients in former Eastern and Central Provinces;
- To determine the acceptance rates for couple testing and disclosure of HIV status; and
- To determine the rates of confirmatory testing among clients who self-test for HIV at home.

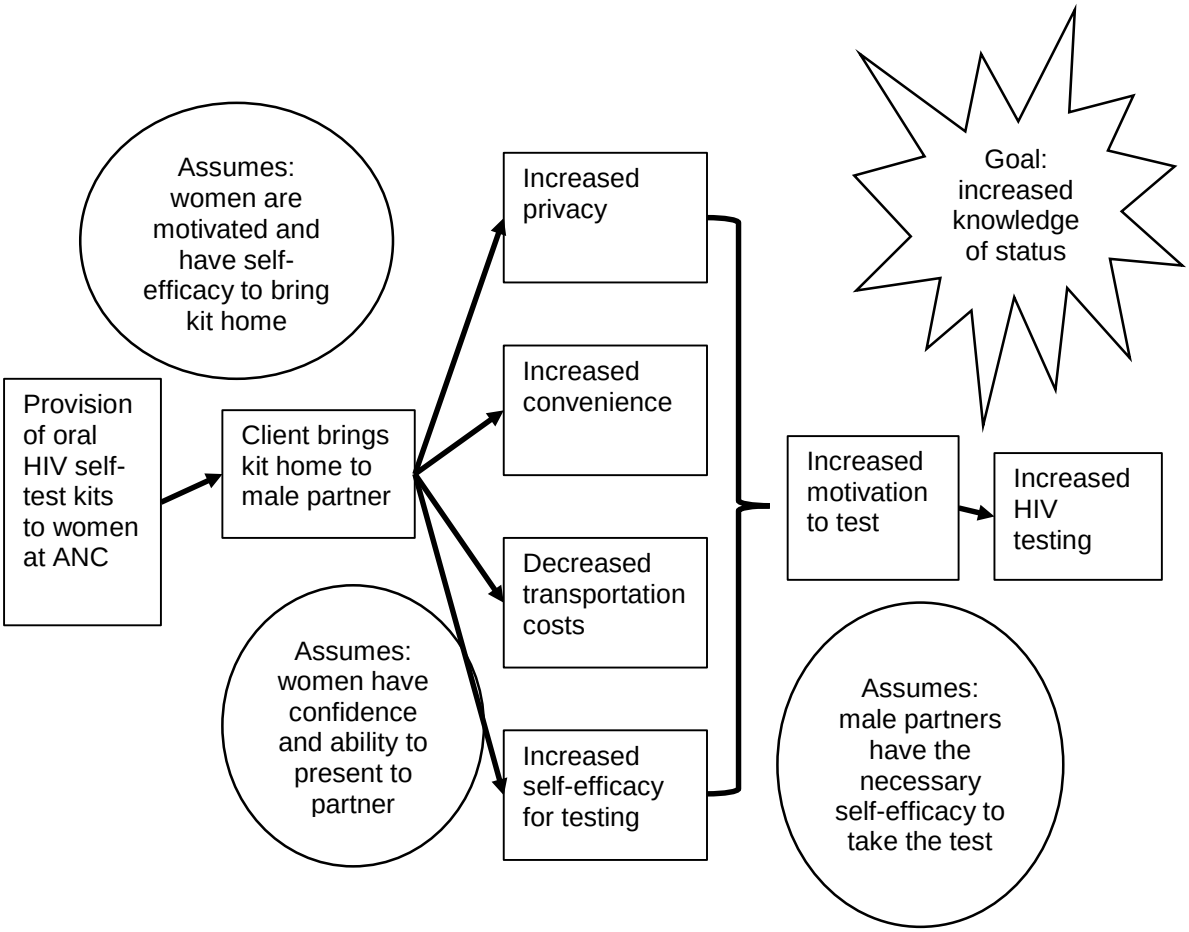
1.8 Primary outcome of interest

The primary outcome of interest in this study was any self-reported HIV testing by the male partner of the ANC client using an oral HIV self-test kit or through clinic-based testing.

1.9 Theory of change

Nested within several behavior change theories, including the AIDS Risk Reduction Model and the theory of planned behavior, the proposed intervention considered the importance of couple dynamics, social norms and environmental factors on utilization of HIV testing services among male partners of pregnant women. Figure 1 shows our theory of change diagram. It gives a connection between project inputs and outcomes, as well as the potential long-term public health impact beyond the life of the project.

Figure 1: Theory of change



1.10 Sample size determination

1.10.1 Quantitative component

The sample size calculation was made by comparing Arm 1 with Arm 2, and Arm 2 with Arm 3. We did not perform a sample size calculation for Arm 1 versus Arm 3, as it was expected that the difference between the two groups would always be larger than any other comparison. In all sample size calculations, we assumed a 5% level of significance and 80% minimum power.

Arm 1 versus Arm 2 sample sizes were calculated based on an *equivalence test*. We assumed that 5% would be the limit of equivalence; that is, any difference exceeding 5% would make the two groups not equivalent. If there was no difference between Arm 1 and Arm 2, then 950 ANC clients (475 per group) would be required to be 80% sure that the limits of a two-sided 95% confidence interval (CI) would exclude a difference between the two groups of more than 5%.

Arm 2 versus Arm 3 sample sizes were calculated based on a *superiority test.* We assumed that Arm 3 would have an uptake of partner HIV testing of 20%, while Arm 2 would reach at least 11% (the upper limit of equivalence). Based on these assumptions, 500 ANC clients (250 per group) would be required to have an 80% chance of detecting, with significance at the 5% level, an increase in the partner HIV testing measure from 11% in Arm 2 to 20% in Arm 3.

To achieve balance among the study arms, we planned to recruit an equal number of participants in all groups. Since a higher sample size was required for the equivalence test than for the superiority test, recruiting equal numbers in each group allowed us to have greater statistical power to evaluate a possibly superior HIV testing rate in Arm 3 compared with Arm 1 or Arm 2. In addition, the increased sample size allowed comparable statistical power in each group to evaluate the heterogeneity of effects (i.e. effect modification).

Considering that each of the three study arms had 475 enrolled and consented ANC clients, the sample had 1,425 enrolled participants (ANC clients). A survey (in person) involved interviewing 1,425 male partners three months after randomization of the ANC clients.

1.11 Study implementation

Jhpiego and the Medical University of South Carolina implemented the intervention in five counties in the former Eastern and Central Provinces of Kenya. In January 2015, Working in close collaboration with the Kenyan MOH and county authorities, Jhpiego and the Medical University of South Carolina identified 14 intervention sites with a high volume of ANC clients as well as the necessary human resources and infrastructure to support the study activities. The health facilities that were selected for the intervention were part of APHIAplus KAMILI, the existing Jhpiego-led project that was funded by USAID. Ethical approval was obtained from the Kenyan Institutional Review Board in June 2015, as were letters of approval from national and county ministries of health. The study was conducted between July 2015 and February 2016.

After the 14 intervention sites were selected, study nurses were recruited and trained. Research assistants who were also nurses recruited 1,410 pregnant women attending their first ANC visit, against the target of 1,425 clients, in the 14 health facilities with high client volume and individually randomized them each of the three study arms. Enrollment was completed in November 2015. For women who were randomized to the intervention group (Arm 3), the intervention was added to the end of the standard first ANC visit. The intervention consisted of a brief orientation on the use of the oral HIV self-test kit, and brief counseling on strategies for introducing the kit to the male partner. ANC clients were then each provided with two oral self-test kits for them to test together with their male partner at home.

Several other key activities were conducted during the study implementation period, including formation of study steering committee and formation of the data safety monitoring board. There was continuous supervision of research nurses in all the 14 study sites, and continuous sharing of work progress with NASCOP and the donor. Focus group discussions (FGDs) were conducted among a subset of enrolled ANC women who had received the oral HIV self-test kits. Study research assistants followed up with participants and their male partners three months after enrollment with an endline survey.

2. Data and methods

Researchers obtained ethical clearance from institutional review boards from the Johns Hopkins School of Public Health, the Kenya Medical Research Institute's Scientific, Ethics and Research Unit, and the Medical University of South Carolina before implementation of the study. Kenya's MOH also issued a letter of approval to carry out the study within the 14 intervention facilities. In addition to this, all study staff underwent training on human subject research.

2.1 Quantitative data

Baseline data on ANC clients was collected during the recruitment period. The information collected focused on socio-demographic characteristics, reproductive health of women, HIV information and knowledge of partner status. Follow-up data was collected three months later separately for men and women. The information collected included socio-demographic characteristics of men, HIV information and knowledge of partner status, confirmation of HIV testing, disclosure of results, linkage to HIV care for those who tested HIV positive, information on the oral HIV self-test kit and satisfaction with testing. Women were also asked whether they had faced any gender-based violence within the three months of the study and if it was related to HIV testing. Both men and women were also interviewed on gender equity.

2.2 Qualitative data

Qualitative data was collected at the end of the project to investigate the drivers and barriers to HIV testing among male partners with the aim of explaining quantitative results in the theory of change. We used FGDs only among women, due to cultural barriers among men making it difficult to elicit information in this way. During the FGDs, we collected qualitative data from women on the most important reasons that they had for wanting their male partner to be tested, the most significant challenges that may make it difficult for the man to be tested, and community beliefs regarding HIV testing. We sought information from the women about their own perceptions, as well as their partners' perceptions, of drivers and barriers to HIV testing. FGDs of up to eight women each were carried out among the study arm that received oral HIV self-test kits. The FGD participants comprised both younger and older women regardless of their HIV status or that of their partners. The FGDs were conducted in all five counties in order to represent various cultural groups and regions.

2.3 Identification strategy and randomization

In each study clinic, clients at their first ANC visit were screened for eligibility and, upon consent, individually randomized into one of the three study arms. For the purposes of practical randomization, each study arm was assigned a sticker of a particular color, distinct from the others (yellow for Arm 1, green for Arm 2 and blue for Arm 3). Stickers for all study arms were prepared, based on the projected number of clients to be recruited from each facility. The stickers were put in non-transparent envelopes and sealed. At the facility, these envelopes were thoroughly shuffled in a basket and the research assistant randomly picked from the basket to assign a group to each ANC client in the study. After randomization, the stickers were put in their Mother and Child Health

Booklets so that other health workers could easily identify them as participating in the study without compromising confidentiality. At the randomization stage, women were informed that the purpose of the study was to investigate how best to encourage HIV testing among male partners of ANC clients. To reduce contamination bias, we did not inform women in the two control groups (Arms 1 and 2) that the study was about HST; rather, we described the study as focused on HIV testing in male partners.

2.4 Recruitment strategy

2.4.1 ANC clients

ANC clients were identified at the time they came for registration for the first ANC visit to receive the Mother and Child Health Booklet by the study nurse (research assistant). The study nurse approached the ANC client (the pregnant woman) after registration and informed her about the ongoing study to increase male partner HIV testing at ANC clinics. The ANC clients willing to participate in the study were then screened for eligibility and those who qualified were enrolled in the study.

2.4.2 Women for qualitative focus group

A subset of enrolled participants was selected and invited at the end of the study to participate in an FGD. The ANC clients were notified of this possibility at the first consent (for the whole study). At the end of the study, the selected ANC clients were contacted by phone and invited for the FGD.

2.4.3 Men's survey

During the recruitment of the ANC client, it was mentioned that the study staff desired to talk to their male partner regarding HIV testing in general. If the woman was willing to let us contact her partner, we asked her whether she preferred to let us know when to talk to her partner, or whether she would prefer us to talk to him directly. In addition, we asked the woman whether we may approach the male partner if he accompanied her to the clinic for the next ANC visit. If she was willing for us to contact him directly, we asked for her partner's telephone number and directions to his residence. The study nurse called the man or, with the help of the community health worker, located the man's residence, recruited him, sought his consent and conducted the survey. Alternatively, if the male partner accompanied the client to the follow-up ANC visit, or the birth at the clinic, the study nurse approached and recruited him.

2.4.4 Inclusion and exclusion criteria

Table 1 shows the inclusion and exclusion criteria used for the ANC clients and their male partners.

Table 1: Inclusion and exclusion criteria

Inclusion criteria for women	1. First ANC visit in this pregnancy 2. Age 18+ years
Exclusion criteria for women	1. No current male partner, or does not have at least weekly contact with partner 2. Woman who reported that her partner is HIV positive 3. Woman who reported that her partner has tested within last three months 4. Woman is concerned for her safety or feels at risk of gender-based violence if she asks her partner to self-test, or woman currently does not feel safe at home to encourage HIV testing
Inclusion criteria for men	1. Male partner of the ANC client enrolled in the study 2. Has personal contact with the woman at least once per week 3. Has cognitive ability to respond to the survey questions, which was assessed by talking to the client
Exclusion criteria for men	1. Unwilling to participate in the study

2.4.5 Strategies for bias control

The following potential biases were identified in the study.

1. There may have been a bias arising from the tendency for study staff to more aggressively follow up women and their male partners in one of the study arms regarding partner testing or another study outcome. This is because the study staff knew the group to which each participant was randomized and participants knew what they were being offered, although the study staff did not talk to them about the group they belonged to and what each group was getting.
2. Women and their male partners in the intervention arm (with oral HIV self-test kits) may have felt social desirability bias to report testing for HIV.

To control the first bias, investigators emphasized to study staff the importance of unbiased follow-up and equal outcome assessment in all groups. In addition, study staff stressed to participants the importance of answering all questions honestly. To reduce the social desirability bias, study staff expressed the need to understand if the woman's partner had not tested for HIV.

2.5 Data quality control measures

During data collection, several measures were put in place to ensure data quality control. These included:

- Regular and ongoing data quality spot checks at site level by both the principal investigator and APHIAplus KAMILI, as well as MOH staff involved in PMTCT activities;
- Hiring of research assistants with a clinical or nursing background to oversee the recruitment and follow-up process on a daily basis in order to maintain integrity of data; and

- Training of study staff on data collection techniques and introducing them to the study protocol, tools of data collection and consent forms.

Tablets were used for data collection and entry. The data collection questionnaire was programmed in the tablets with inbuilt skip patterns that enhanced quality.

2.6 Data analysis

The primary comparison between groups was analyzed using chi-square tests of the association and the results were interpreted as statistically significant if the p-value of the test was less than 0.05. The effects of the intervention were quantified using the difference in proportion and were reported with the associated 95 per cent confidence level for the difference. Subgroup analyses were conducted for specific subgroups to determine if there was a differential effect of the intervention by subgroups. We fit logistic regression models to investigate independent factors associated with male partner testing and to control for possible imbalances between different arms at baseline. We used the model to investigate the unadjusted and adjusted association between demographic and other factors in relation to male partner testing.

3. Results

3.1 Enrolment and follow-up

The study enrolled a total of 1,410 women at baseline, from whom a total of 1,215 (86 per cent) were successfully followed up during endline. In addition, 1,133 men were followed up. A total of 1,106 couples were reached in the follow-up. Each of the three arms had a target sample size of 475 women. However, in Arm 1, a total of 471 (99.2 per cent) women were enrolled. Of these women, a total of 406 (85.5%) were followed up with 375 (79.6%) men and 365 (76.8%) couples reached in Arm 1. In Arm 2, 467 (98.3%) women were recruited, of whom 387 (82.9%) were followed up. For men, 362 (77.5%) were also followed up, with a total of 352 (75.4%) couples reached. In Arm 3, 472 (99.4%) of the women were recruited, of whom 422 (89.4%) were followed up, with 396 (84.0%) men followed up and 389 (82.4%) couples reached. Table 2 shows the number (percentage) of people enrolled, followed up and reached by the study.

Table 2: Number (percentage) of people enrolled, followed up and reached by the study

	Arm 1 (N=475)	Arm 2 (N=475)	Arm 3 (N=475)	Total	P-value
Women enrolled	471 (99.2)	467 (98.3)	472 (99.4)	**1,410**	
Women followed up	406 (85.5)	387 (82.9)	422 (89.4)	**1,215**	**0.961**
Men followed up	375 (79.6)	362 (77.5)	396 (84.0)	**1,133**	
Couples reached	365 (76.8)	352 (75.4)	389 (82.4)	**1,106**	

3.2 Demographic characteristics

3.2.1 Characteristics of women enrolled

Table 3 shows the demographic characteristics of the women enrolled in the study. Women had relatively low levels of education (52% to 59% with primary education or

less) and employment; the majority were Protestant, married and aged 18–34 years. Table 3 provides evidence that the women were randomly allocated among the three study arms.

Table 3: Demographic characteristics of women enrolled in the study: number (percentage)

	Arm 1 (N=471)	Arm 2 (N=467)	Arm 3 (N=472)	P-value
Level of education				
Primary	279 (59.2)	265 (56.7)	247 (52.3)	0.0962
Secondary	192 (40.8)	202 (43.3)	225 (47.7)	
Religion				
Catholic	83 (17.6)	103 (22.1)	107 (22.7)	0.251
Protestant	382 (81.1)	355 (76.0)	359 (76.1)	
Other	6 (1.3)	9 (1.9)	6 (1.3)	
Employment				
Self-employed	160 (34.0)	159 (34.0)	145 (30.7)	0.687
Employed	70 (14.9)	74 (15.8)	83 (17.6)	
Unemployed	241 (51.2)	234 (50.1)	244 (51.7)	
Marital status				
Single	5 (1.1)	9 (1.9)	8 (1.7)	0.751
Cohabitating	58 (12.3)	49 (10.5)	54 (11.4)	
Currently married	408 (86.6)	409 (87.6)	410 (86.9)	
Age (years)				
18–24	206 (43.7)	188 (40.3)	182 (38.6)	0.24
25–34	224 (47.6)	242 (51.8)	237 (50.2)	
≥ 35	41 (8.7)	37 (7.9)	53 (11.2)	
Wealth				
Lowest	87 (23.8)	77 (21.9)	109 (28.0)	0.521
Second lowest	87 (23.8)	90 (25.6)	97 (24.9)	
Second highest	99 (27.1)	93 (26.4)	88 (22.6)	
Highest	92 (25.2)	92 (26.1)	95 (24.4)	

3.2.2 Characteristics of men enrolled

Table 4 shows the demographic characteristics of the men enrolled in the study. Most men had secondary-level education, and we noted higher educational attainment in the men enrolled in the intervention arm (Arm 3). Specifically, about two-thirds (66%) of the men in Arm 3 had secondary-level education, compared with 55% and 58% in Arm 1 and Arm 2 respectively. In addition, men in Arm 3 were slightly more likely to be employed (48%) compared with those in Arm 1 and Arm 2 (43% and 41% respectively). Nearly half of the enrolled men were self-employed, with the majority of them being Protestant and aged 18–34 years. Overall, Table 4 demonstrates balance across the study arms for most measures.

Table 4: Demographic characteristics of men enrolled in the study: number (percentage)

	Arm 1 (N = 471)	Arm 2 (N = 467)	Arm 3 (N = 472)	P-value
Level of education				
Primary	168 (44.8)	151 (41.7)	134 (33.8)	0.006
Secondary	207 (55.2)	211 (58.3)	262 (66.2)	
Religion				
Catholic	120 (32.0)	106 (29.3)	109 (27.5)	0.614
Protestant	241 (64.3)	246 (68.0)	272 (68.7)	
Other	14 (3.7)	10 (2.8)	15 (3.8)	
Employment				
Self-employed	183 (48.8)	182 (50.3)	188 (47.5)	0.07939
Employed	160 (42.7)	147 (40.6)	189 (47.7)	
Unemployed	32 (8.5)	33 (9.1)	19 (4.8)	
Marital status				
Cohabitating	41 (10.9)	43 (11.9)	42 (10.6)	0.8424
Currently married	333 (88.8)	318 (87.8)	354 (89.4)	
Missing	1 (0.3)	1 (0.3)	0 (0.0)	
Age (years)				
18–24	30 (8.1)	26 (7.2)	24 (6.2)	0.638
25–34	243 (65.9)	242 (67.2)	248 (64.3)	
≥ 35	96 (26.0)	92 (25.6)	114 (29.5	
Wealth				
Lowest	87 (23.8)	77 (21.9)	109 (28.0)	0.521
Second lowest	87 (23.8)	90 (25.6)	97 (24.9)	
Second highest	99 (27.1)	93 (26.4)	88 (22.6)	
Highest	92 (25.2)	92 (26.1)	95 (24.4)	

3.2.3 Male partner testing history

Table 5 shows the number (percentage) of men who ever tested for HIV and the time of the last test. Prior to the study, slightly more men in Arm 3 had ever tested for HIV before (92% compared with 86% in Arm 2 and 84% in Arm 1). However, substantially more men in Arm 3 reported having tested within the last five months.

Table 5: Number (percentage) of men who ever tested for HIV and time of the last test

	Arm 1 (N = 471)	Arm 2 (N = 467)	Arm 3 (N = 472)	P-value
Ever tested for HIV				
Yes	314 (83.7)	311 (85.9)	365 (92.2)	0.009
No	61 (16.3)	51 (14.1)	31 (7.8)	
Total	**375 (100)**	**362 (100)**	**396 (100)**	
When was the last HIV test?				
Less than 3 months ago	67 (21.3)	106 (34.2)	174 (47.7)	<0.001
3–5 months ago	44 (14.0)	47 (15.2)	87 (23.8)	
6–11 months ago	42 (13.4)	30 (9.7)	25 (6.8)	
1–2 years ago	79 (25.2)	65 (21.0)	31 (8.5)	
More than 2 years ago	78 (24.8)	59 (19.0)	47 (12.9)	
Don't know	4 (1.3)	3 (1.0)	1 (0.3)	
Total	**314 (100)**	**310 (100)**	**365 (100)**	

3.3 Primary outcome: HIV testing

3.3.1 HIV testing reported by male partners

After receiving consent from the ANC clients to contact their male partners, we contacted the men approximately three months after the initial ANC visit. We administered the three-month follow-up questionnaire to assess whether the men reported testing for HIV during the follow-up period, and details of testing behavior.

Table 6: Number (percentage) of men who reported testing for HIV in the three-month follow-up period

	Arm 1 (N = 375)	Arm 2 (N = 362)	Arm 3 (N = 396)
Tested for HIV in the last three months	106 (28.3)	133 (36.7)	327 (82.6)
P-value for the comparisons	0.01*		<0.001**

* two-sided proportions test comparing Arm 1 and Arm 2
** one-sided (greater than) test of superiority of Arm 3 compared with Arm 2

Table 6 shows that 82.6% of the men in the self-testing intervention group (Arm 3) tested for HIV in the three months after the woman's ANC visit, compared with only 36.7% in the information control group (Arm 2) and 28.3% in the standard of care control group (Arm 1). Over half of the men in the intervention arm reported taking an HIV confirmatory test, while among the women testing at home, 32 per cent reported that their male partners went for a confirmatory test at the facility.

Table 7: Location of HIV testing among male partners

	Arm 1 (N = 106)	Arm 2 (N = 133)	Arm 3 (N = 327)	P-value
Clinic or VCT center	105 (99.1)	130 (97.7)	43 (13.4)	<0.001
Home	1 (0.9)	3 (2.3)	278 (86.6)	

In relation to the location of HIV testing (Table 7), over 85 per cent of men in the intervention group (Arm 3) took the test at home, while nearly everyone in the control groups (Arm 1 and Arm 2) went to the clinic or VCT center. All the respondents in Arm 3 who tested at home said that they used the oral HIV self-test kits provided to the ANC clients. One male partner in Arm 2 said that he bought the test kit to self-test. Of the 278 male partners testing at home, 72 per cent said that they went for a confirmatory test at the health facility.

3.3.2 Characteristics of men self-reporting within three months of the partner's clinic visit

There was no association between the demographic characteristics of study participants and the study arms among men who tested within three months of the partner's clinic visit. Wealth quantiles were computed using the socio-economic information collected. Wealth1 represents those who were well off economically while Wealth4 represents those who were worse off economically. A significant association was found between wealth category and the study arm of the study participants. Among those self-testing, the majority were in wealth quintile 1 (30.4%) and wealth quintile 2 (25.5%) respectively. Table 8 shows the demographic characteristics and wealth of male partners tested for HIV.

Table 8: Demographic characteristics of male partners tested for HIV: number (percentage)

	Arm 1 (N = 106)	Arm 2 (N = 133)	Arm 3 (N = 327)	P-value
Level of education				
Primary	37 (34.9)	39 (29.3)	103 (31.5)	0.6519
Secondary	69 (65.1)	94 (70.7)	224 (68.5)	
Religion				
Catholic	27 (25.5)	45 (33.8)	89 (27.2)	0.4756
Protestant	77 (72.6)	84 (63.2)	226 (69.1)	
Other	2 (1.9)	4 (3.0)	12 (3.7)	
Employment				
Self-employed	55 (51.9)	70 (52.6)	151 (46.2)	0.2826
Employed	43 (40.6)	55 (41.4)	162 (49.5)	
Unemployed	8 (7.5)	8 (6.0)	14 (4.3)	

	Arm 1 (N = 106)	Arm 2 (N = 133)	Arm 3 (N = 327)	P-value
Marital status				
Cohabitating	6 (5.7)	12 (9.0)	35 (10.7)	0.2978
Currently married	100 (94.3)	121 (91)	292 (89.3)	
Age (years)				
18–24	6 (5.7)	11 (8.3)	18 (5.6)	0.23
25–34	74 (70.5)	93 (69.9)	202 (63.3)	
≥ 35	25 (23.8)	29 (21.8)	99 (31.1)	
Wealth				
Lowest	45 (42.9)	35 (26.5)	98 (30.4)	<0.001
Second lowest	34 (32.4)	42 (31.8)	82 (25.5)	
Second highest	14 (13.3)	36 (27.3)	67 (20.8)	
Highest	12 (11.4)	19 (14.4)	75 (23.3)	

3.3.3 Male partner HIV testing outcomes as reported by women

Table 9 shows the results of logistic regression for uptake of HIV testing by the male partner as reported by the female partner. In the bivariate analysis, study arm, education and wealth were strongly related to the uptake of male partner testing. The unadjusted odds of a male partner testing for HIV were almost 11 times higher (10.8; 95% CI: 7.67 to 15.2) in Arm 3 compared with Arm 1, while the unadjusted odds of a male partner testing for HIV decreased by wealth quartile and increased with more education. Adjusting for confounders (including education and wealth), the association between study arm and testing was slightly stronger, with the odds ratio, comparing Arm 3 with Arm 1, increasing to 11.5 (95% CI: 8.0 to 16.5) in the multivariate analysis.

Table 9: Determinants of uptake of HIV testing among male partners: number (percentage)

	Unadjusted			Adjusted		
	Odds ratio	95% CI		Odds ratio	95% CI	
Age						
18–24	1.00			1.00		
25–34	1.35	0.84	2.17	1.15	0.65	2.02
>=35	1.22	0.74	0.02	1.05	0.57	1.92
Study arm						
Arm 1	1.00			1.00		
Arm 2	1.46	1.07	2.00	1.48	1.07	2.05
Arm 3	10.80	7.67	15.20	11.52	8.03	16.53
Employment						
Employed	1.00			1.00		
Unemployed	0.51	0.32	0.83	1.12	0.63	2.01
Self-employed	0.90	0.71	0.16	1.19	0.88	1.60

Religion						
Catholic	1.00			1.00		
Other	1.11	0.57	2.16	1.40	0.64	3.07
Protestant	1.30	1.00	1.68	1.19	0.88	1.62
Wealth index						
Lowest	1.00			1.00		
Second lowest	0.70	0.49	0.98	0.76	0.51	1.13
Second highest	0.41	0.29	0.58	0.42	0.28	0.62
Highest	0.33	0.23	0.47	0.33	0.21	0.50
Education						
Primary	1.00			1.00		
Secondary (A or O level)	2.01	1.58	2.57	1.62	1.19	2.19

3.3.4 Couple HIV testing

Table 10 shows the number (percentage) of women who reported discussing HIV and testing with their partners. In each of the three arms of the study, over 95 per cent of the women reported discussing HIV testing with their partners.

Table 10 also shows the number of women who tested together with a partner. In Arm 3, more than three-quarters (79.1 per cent) of women reported that they had tested together with their partner. More than one-third (36.7%) and one-quarter (28.1%) of the women in Arm 2 and Arm 1 respectively reported testing together with their partner or knowing that the partner had tested.

Table 10: Number (percentage) of women who reported discussing HIV and testing with their partners

	Arm 1 (N = 406) N (%)	Arm 2 (N = 387) N (%)	Arm 3 (N = 422) N (%)	P-value
Discussed HIV testing with partner				
No	13 (3.2)	16 (4.1)	9 (2.1)	0.262
Yes	393 (96.8)	371 (95.9)	413 (97.9)	
Tested together with partner				
No	297 (73)	251 (64.9)	88 (20.9)	<0.001
Yes	109 (27)	136 (35.1)	334 (79.1)	
Tested together with partner or knows partner tested				
No	292 (71.9)	245 (63.3)	87 (20.6)	<0.001
Yes	114 (28.1)	142 (36.7)	335 (79.4)	
Total	**406 (100)**	**387 (100)**	**422 (100)**	

Table 11: Male partner self-reports testing with female partner or alone

	Arm 1 (N = 375) N (%)	Arm 2 (N = 362) N (%)	Arm 3 (N = 396)
Male partner self-reports testing with female partner	106 (28.3)	133 (36.7)	323 (81.6)
Male partner self-reports testing with female partner or alone	106 (28.3)	133 (36.7)	327 (82.6)

Note: the numbers are the same in Arms 1 and 2 because all of the men self-reported testing with their partner; none said they tested alone. In Arm 3, four reported testing alone.

The ANC clients and their male partners were separately asked if they had tested together or knew whether their partner had been tested. As shown in Table 12 below, there was strong agreement between the members of the couple regarding self-reported partner testing. We calculated the Kappa statistic to compare the reports from the female and male partners: this test statistic ranges from 0–1, with a value of 1 indicating perfect agreement between the two partners. Results indicate a strong agreement in all three arms, as shown by the Kappa agreement statistic.

Table 12: Number (percentage) of couples in agreement on HIV testing by the male partner

Study arm		Woman reported knowing the partner tested for HIV N (%)	Kappa
Arm 1 (N=105)	Partner reported testing for HIV	98 (93.3)	0.90 (0.84–0.94) P-value < 0.001
Arm 2 (N=132)		116 (87.9)	0.80 (0.74–0.87) P-value < 0.001
Arm 3 (N=322)		310 (96.3)	0.82 (0.75–0.90) P-value < 0.001

3.4 Usability of test kits

In the follow-up survey, men and women were interviewed privately about their experiences with HIV testing, including oral self-testing for those participants who used this method. Table 13 illustrates the usability of oral HIV self-test kits, in terms of whether it was very difficult, somewhat difficult, neither easy nor difficult (or don't know), somewhat easy, or very easy to: (i) understand the instructions for using the kit, and (ii) obtain the sample (gum line swab) for the test kit. People reported it was very easy to understand the instructions (81%), obtain the sample (82% for women and 80% for men), and read the test results (92% for women and 89% for men). In addition, it was somewhat easy to take the sample for a further 11% of women and 15% of men.

Table 13: Usability of oral HIV self-test kits by sex: number (percentage)

	Women (N = 351) N (%)	Men (N = 324) N (%)	P-value
Ease or difficulty of understanding the instructions for using the kit			
Neither difficult nor easy or don't know	12 (3.4)	8 (2.5)	0.199
Somewhat difficult	6 (1.7)	2 (0.6)	
Somewhat easy	39 (11.1)	50 (15.5)	
Very easy	294 (83.8)	262 (81.4)	
Ease or difficulty of obtaining sample for the test kit			
Neither difficult nor easy or don't know	12 (3.4)	13 (4)	0.297
Very difficult	0 (0.0)	1 (0.3)	
Somewhat difficult	5 (1.4)	2 (0.6)	
Somewhat easy	39 (11.1)	49 (15.2)	
Very easy	295 (84)	258 (79.9)	
Ease or difficulty of reading the test results			
Neither difficult nor easy or don't know	8 (2.3)	7 (2.2)	0.608
Somewhat difficult	1 (0.3)	1 (0.3)	
Somewhat easy	19 (5.5)	26 (8)	
Very easy	320 (92)	289 (89.5)	

3.5 Gender equity

A set of questions on gender equity in the household were asked in order to determine whether gender-based violence was experienced by the study participants during the study period. Men were asked whether they either: did not know, somewhat agree, somewhat disagree, strongly agree or strongly disagree for each question. For ease of analysis, the above responses were collapsed into two: agree or disagree, as shown in Table 14. Only 16.9% of the men interviewed agreed that there are times when a woman deserves to be beaten, while the majority (83%) disagreed with that view. In relation to unfaithfulness, only 15% of men agreed that it is all right for a man to beat his wife for being unfaithful, with 85% disagreeing. A greater proportion of men (95.8%) disagreed that a man can hit his wife if she does not agree to have sex with him, and over 71% of men disagreed that use of violence against the wife is a matter that should not be discussed outside the couple.

Table 14: Gender equity among male respondents

	Arm 1 (N=373) N (%)	Arm 2 (N=361) N (%)	Arm 3 (N=396) N (%)	Total (N=1,130) N (%)	P-value
There are times when a woman deserves to be beaten					
Agree	74 (20)	50 (14)	68 (17)	190 (17)	0.195
Disagree	299 (80)	311 (86)	327 (83)	937 (83)	
A woman should tolerate violence to keep her family together					
Agree	92 (25)	67 (19)	59 (15)	218 (19)	0.008
Disagree	281 (75)	294 (81)	337 (85)	912 (81)	
It is all right for a man to beat his wife if she is unfaithful					
Agree	62 (17)	58 (16)	51 (13)	171 (15)	0.483
Disagree	311 (83)	303 (84)	345 (87)	959 (85)	
A man can hit his wife if she doesn't agree to have sex with him					
Agree	21 (6)	12 (3)	15 (4)	48 (4)	0.438
Disagree	352 (94)	349 (97)	381 (96)	1,082 (96)	
A man using violence against his wife is a matter not to be discussed outside the couple					
Agree	119 (32)	101 (28)	108 (27)	328 (29)	0.516
Disagree	254 (68)	260 (72)	288 (73)	802 (71)	

3.6 Themes from focus group discussions

To create a robust analysis of the FGDs, framework analysis was used to create themes that can be used to gain an understanding of barriers and drivers of HIV testing among male partners of ANC clients from the ANC client's perspective. All of the quotations in this section are from female participants in the intervention arm.

3.6.1 Drivers of HIV testing among male partners of ANC clients

'Importance of privacy surrounding HIV test'

One of the most important themes that emerged from the analysis was the importance of privacy, both when doing the HIV testing and also when receiving the results:

> For me I think the price won't be a problem as long as it has privacy. — Female, older than age 25, Embu country

And another one remarked:

> He may fear to go to the nearby clinic because maybe the doctor that you will get there, lives in your area or he knows you. Yes you are told that there is privacy, but how sure are you that he is not going to share with somebody else? — Female, younger than age 25, Embu County

Both of these emerged to be important indicators of whether a man would decide to take an HIV test or not, in their partners' opinions. One of the barriers to making the decision to take an HIV test, which was mentioned by multiple participants across FGDs in both

former Eastern and Central Provinces, is directly related to who will know of the result. Several FGD participants reported that their partners did not trust the doctors to keep results to themselves and feared that their communities might find out if they were found to be HIV positive, which could lead to stigmatization. Even if the results were negative participants feared that, as they were seen to be taking the HIV test, they could face stigmatization anyway.

'Testing at home together'
Another theme, which builds on the issue of privacy and was coded multiple times, is the importance for the male partner of testing alongside the ANC service user. Many of the women who were from the sample of survey respondents given an oral HIV self-test kit found success, although sometimes begrudgingly so, in getting their partners to test for HIV. However, the men were rarely willing to take the test themselves without their partner taking the test with them. Yet the men would often still not be persuaded to travel to an ANC clinic together with their partner to take the test:

> Between the two processes, at home and at the hospital, it is easier to do it at home because if both of you are given, you are both going to test yourself together. — Female, younger than age 25, Kitui County

3.6.2 Barriers to HIV testing among male partners of ANC clients
'Stigma, fear and misinformation about HIV in the community'
As focus group respondents were reporting both stigma and misinformation about HIV, it is clear that one barrier to men testing for HIV is education about the virus in the community and what can be done to prevent but also treat it:

> Others think that it is something shameful. — Female, older than age 25, Embu County

> Fear is what makes it hard in my community to take the HIV test. — Female, younger than age 25, Kiambu County

> Many people don't believe that HIV exists. They think it is about poison.' — Female, younger than age 25, Kiritiri County

'Male partners dismissive of women asking them to take the test'
Some women reported during the focus group session that, when they were negotiating with their partners to take the HIV test, the men would not take them seriously – this was for both the ANC clinic users and some of the oral HIV self-test kit users:

> My husband just laughs and thinks that I am foolish. — Female, younger than age 25, Kiambu County

> He tells me that that is for the women and not the men. — Female, younger than age 25, Kitui County

This gendered relationship is a strong barrier to having men test themselves for HIV as, if they do not take their partners seriously or believe that it is not something a man should take, then even if they are sent HIV self-test kits they may choose to ignore them.

'Access barriers for men: income, workload and distance'

The last theme was barriers to access for men to receive HIV testing. This included income, workload and distance to a clinic. Several women in the focus group said that the journey to the nearest ANC clinic was too expensive or it was too far away for their partners to visit to have the test as their work schedules were extensive:

> In the communities, there are those people who live far away from the hospitals. When people are far away, they will not want to go and take those kits. — Female, older than age 25, Meru County

These were from groups who did not receive the oral HIV self-test kits. Although these access barriers exist now, they are barriers that could be overcome with the HIV self-test kits for service users of ANC clinics. However, it is important to note that, although some FGD respondents mentioned the price as a key factor in deciding whether they should take the test or not, others disagreed and said that privacy was a bigger barrier than cost:

> It will depend with the price. If it is readily affordable, they will take it. — Female, older than age 25, Murange County

4. Discussion and conclusion

This study was implemented to address low testing rates among the male partners of ANC clients in former Eastern and Central Provinces. Randomization appears to have been mostly successful as most demographic and clinical characteristics of the ANC clients and their male partners did not differ significantly across the study arms. The only exceptions were education (p=0.10 for women, p=0.06 for men), employment (p=0.08 for men) and proportion of male partners who had tested previously (p=0.009). However, the associations between these possibly imbalanced covariates and the outcome of HIV testing are not strong enough to produce substantial confounding of our main result, which in fact was strengthened slightly and remained extremely strong and highly significant after controlling for covariates.

In this study, female participants gave oral HIV self-test kits to their male partners to test themselves in their own free time either at home or at a clinic. We found a remarkably high uptake of HIV testing (88%) in Arm 3 – where the ANC clients were given self-test kits to go and test together with their partners – compared with Arm 1 of the study, where they were just given the standard care and asked to bring their partners for testing at the facility. An overwhelming majority of women in all three study arms reported that they spoke with their partners about HIV. In particular, the study findings showed that 98 per cent of women in Arm 3 discussed HIV testing with their partners, creating an opportunity to present the HIV self-test kit and test together as a couple, or give a kit to the male partner to use by himself. We found that, of those couples testing together, 95% of women in Arm 3 reported testing together with their partners at home and only 5% reported testing together at the clinic. This finding differs significantly from the results of KAIS 2012, which show that 51.5 per cent of women interviewed reported knowledge of partner status in the last year.

We observed that couples in the HST intervention group (Arm 3) were slightly more likely to test with their partners than couples in other arms: 99.7% (334/335) versus 95.8%

(136/142) in Arm 2 and 96.5% (110/114) in Arm 1. However, the result was not significant. This difference may underscore the barriers removed by self-testing (e.g. inconvenience and lack of privacy). In testing among couples where women reported testing together and their partners were asked separately if they had tested, there was very high agreement between the man and woman regarding whether the male partner tested. Using the male partner's report of testing as the gold standard, among couples in which the male partner tested, we found that 94%, 87% and 97% of women in Arms 1, 2 and 3 respectively correctly reported that their partners had tested. Both reports from the male and female partner indicated a 2.5- to 3-fold increase in the proportion of the male partners who tested for HIV, showing that giving the oral HIV self-test kit to the male partner increased the chances of him testing, compared with the control arms referring him to seek testing services elsewhere.

Among those who tested at home, 99.7 per cent (in Arm 3) reported testing themselves, underscoring the finding that participants were willing to try the oral HIV self-test kits. Furthermore, our questionnaire data assessing ease of use and our qualitative data both suggest that almost all participants found the oral HIV self-test kits easy to use.

The realization that HTC is the only entry to care and treatment services within the HIV response has led to several measures being adopted to scale up the knowledge of HIV status, including formulation of HIV testing protocols, guidelines and quality assurance mechanisms. Several HTC approaches, such as VCT, diagnostic testing and counseling, and now provider-initiated testing and counseling, have been in existence since 1998. As part of the strategies to expand access to and uptake of HIV testing services, Kenya has adopted a number of high-impact strategies including both community-based approaches (stand-alone HTC centers, outreach services and home-based testing and counseling) and facility-based ones (static sites integrated within hospitals and clinics) (Ng'ang'a et al. 2014). At the time of the current report, Kenya's MOH has committed to integrating HST into the national program, although the details of implementation have not yet been specified.

Our study results show that, in a large sample of ANC clients and their male partners, oral HIV self-test kits were acceptable and easy to use. In the range of 80–90% of both women and men considered that the instructions for the HIV self-test kits were very easy to understand, the test was very easy to conduct (swabbing the gums and placing the swab into the buffer), and the test results were very easy to read. These promising findings were similar across education levels and age groups, indicating that overall the acceptability and usability of the oral HIV self-test kit appears to be very high across different segments of the population.

Provision of HTC services in community-based settings is recommended by the MOH's community strategy as well as the National Health Sector Strategic Plan-III. Community-based HTC strategies have been classified on level one of the healthcare system in Kenya. As HST is done in the community, it fits within the strategic plans, and the initiative should be replicated in other settings with different cohorts in the general population.

It is already known that stigma against HIV hampers both the prevention and treatment of HIV in Kenya. An interview study in Kisumu found that many women using ANC clinics

for prenatal check-ups refused HIV testing in these clinics because of the stigma attached to being HIV positive in their communities (Turan et al. 2008). It can be seen that there is more to the low frequency of male partners of ANC service users taking the HIV test than purely access barriers such as income and distance from an ANC clinic. From the focus groups we can see that, although access does play a role in influencing the male partner's decision to test, there are other important factors in the decision-making process, including gender role, stigma in the society and fear of breaking of confidentiality. The HIV self-test kit for couples could be described as a driver for success, as it helps to overcome some of the privacy issues that the partners of ANC service users are concerned about, and it could also reduce the influence of community stigma by being discreet.

In conclusion, the findings from this study will advise HIV counseling and testing program implementers and policymakers on the likely impact on partner testing rates that may be achieved by providing HIV self-test kits for distribution by ANC clients to their male partners.

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The authors found that women were able to discuss HIV testing with their male partner, distribute the test and provide instructions on proper kit use. Additionally, partners of women who were given HIV self-test kits to take home were nearly twice as likely to test for HIV than their counterparts who were given a standard or improved invitation letter to come to the clinic.

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