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About this report

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Summary

The objective of the evaluation was to assess whether offering HIV testing choices to truck drivers in Kenya increased testing uptake. We conducted a randomized controlled trial among 305 truck drivers from two North Star Alliance roadside wellness clinics in Kenya.

Study participants were randomized to receive (1) a healthcare provider-administered, rapid blood (finger prick) HIV test (i.e. standard of care arm) or (2) a choice between the standard of care or an oral, rapid HIV self-test under the provider's supervision in the clinic (the choice arm). Participants in the choice arm who refused HIV testing in the clinic were offered a test kit for home use plus phone-based, post-test counseling. We compared HIV test uptake using the Mantel Haenszel odds ratio (OR), adjusting for clinic.

Truck drivers in the choice arm had higher odds of HIV testing uptake than those in the standard of care arm (OR = 1.5). The difference was not statistically significant (p = 0.189). When adding the option to take an HIV test kit for home use, the choice arm had significantly greater odds of testing uptake (OR = 2.8, p = 0.002). Of those in the choice arm who tested, 26.9% selected the standard of care test, 64.6% chose supervised self-testing in the clinic and 8.5% took a test kit for home use.

Participants varied in the HIV test they selected when given choices. Importantly, when participants who refused HIV testing in the clinic were offered a test kit for home use, an additional 8.5% tested. By offering truck drivers a variety of HIV testing choices, we may increase HIV testing uptake in this key population.

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Abbreviations and acronyms

ARV	Antiretrovirals
CI	Confidence interval
HTC	HIV testing and counseling
IQR	Interquartile range
KES	Kenyan shillings
NASCOP	National AIDS and STI Control Programme
OR	Odds ratio
SD	Standard deviation
SOC	Standard of care

1. Introduction

Truck drivers are at higher risk for HIV compared with people working in other settings (Ojo et al. 2011). HIV transmission has been associated with transportation routes (Ramjee et al. 1998) and in some areas, including Kenya, HIV rates remain high along border posts and major highways (IRIN 2013; Jurgensen et al. 2012).

High-risk behavior and HIV transmission were described in a study among truck drivers recruited from truck stops in KwaZulu-Natal, South Africa (Ramjee and Gouws 2002); 34% reported that they always stop for sex while traveling for work and 29% said they never used condoms with female sex workers. The majority of truck drivers in that study reported having a main partner (e.g. a wife or girlfriend) and, of those, only 13% reported using condoms with their main partner. HIV prevalence among that sample of truck drivers was similar to that of female sex workers, at 56%.

More recent studies among truck drivers in Africa have also found high HIV prevalence, including 23% among long-distance truck drivers in Nigeria (Azuonwu et al. 2011), 15.4% among truck drivers in Mozambique (Botão et al. 2016) and 26% among truck drivers in South Africa (Delany-Moretlwe et al. 2014. Because truck drivers often cross international borders for their work (Mills et al. 2012; North Star Alliance 2012; Mantell et al. 2014), high HIV prevalence among female sex workers and their truck driver clients in one country can lead to HIV transmission to truck drivers from other regions or countries, and to their wives and partners at home.

A study conducted in Kenya between 1993 and 1997 found that the prevalence of HIV among drivers at one company was 17.8% and that rates of HIV were much higher among truck drivers than stationary staff (e.g. administrators and mechanics). The truck drivers reported more time away from home, with an average of two weeks of travel per month, compared with stationary staff (Rakwar et al. 1999). This work-related separation may also make extramarital relationships more common among the wives and female partners who remain in the home community, further increasing HIV risk for both members of the couple (Lurie et al. 2003).

Gender disparities in HIV testing remain. Men are less likely to test for HIV than women in many African countries (Venkatesh et al. 2011; Ramkissoon et al. 2011; Shisana et al. 2009; Mills et al. 2012; Angotti et al. 2009). In Kenya in 2012, 35.8% of men versus 47.3% of women had been tested for HIV in the past year (UNAIDS 2014a). As truck driving is a male-dominated profession (Progressio 2013), we would expect truck drivers to have lower HIV testing rates than the general population.

Few studies have looked at HIV testing among truck drivers, but one study among 1,881 truck drivers in South Africa in 2003–2004 found that only 38.2% had ever been tested for HIV (Delany-Moretlwe et al. 2014). The North Star Alliance, the organization which implemented this study, which runs 35 roadside wellness clinics providing services to truck drivers on major transit routes in Africa, reported that in 2012 only about 21% of its 219,681 client visits included HIV testing, despite the fact that it is offered at every visit (North Star Alliance 2012). Trucking Wellness, which runs 22 roadside clinics for truck drivers in South Africa, reported that only about 10% of the more than 90,000 clients it

saw in 2012 were tested for HIV, of which 7% were found to be HIV positive (Trucking Wellness 2012).

Oral HIV self-testing, whereby a person collects an oral swab specimen, performs a test and interprets the test result themselves (UNAIDS 2014b), might be an effective tool for increasing rates of HIV testing among truck drivers. This form of testing can allow individuals to test themselves in private, e.g. at home or even in the cab of a truck during a work break, and to disclose the test results only when, and to whom, they choose. Oral HIV self-testing can also be performed in a clinic setting, with healthcare providers available to provide instructions and guidance, answer questions, and offer in-person counseling and referrals to healthcare if needed, while still allowing individuals to view test results in private and disclose them only if they choose.

We conducted a pilot program to introduce oral HIV self-testing as an option to truck driver clients of two North Star Alliance clinics in Kenya in two settings, either in the clinic or outside of it (i.e. a test kit to take for home use). We randomized 305 truck driver clients to be offered either the standard, provider-administered, blood-based (finger prick) HIV testing (standard of care [SOC] arm) or offered a choice between the SOC test or supervised oral HIV self-testing (choice arm). Self-testing in the choice arm involved using the OraQuick® in-home HIV test in the clinic, with professional staff available to answer questions during self-administration of the test and offer correction if the participant did something wrong. We offered a self-test kit to take for home use to participants in the choice arm who refused both testing options in the clinic.

All participants were told that they should test for HIV every three months. Those in the choice arm were also told that they could come to any North Star Alliance clinic in Kenya 3–6 months later and get a self-test kit to use at home or in the clinic with supervision. We interviewed participants after six months to ask about HIV testing during follow-up.

We hypothesized that offering a choice of testing methods would lead to more truck drivers accepting HIV testing in the clinic, both at baseline (including taking a test for home use) and during the six-month follow-up.

2. Background and context

2.1 Political and programmatic context

The Kenyan government has called for oral HIV self-testing to form part of the HIV testing and counseling policy (National AIDS and STI Control Programme [NASCOP] 2008). Other African governments are also considering making this type of test available (South African National AIDS Council 2011). Therefore, results from this intervention can help inform the development of policies around HIV self-testing.

This study was conducted in two North Star Alliance clinics in Kenya. The North Star Alliance is an international NGO that brings health services to hard-to-reach populations across Africa, including truck drivers and sex workers. It runs 35 clinics in Africa, eight of which are in Kenya. The clinics are open at hours that suit these target groups and offer a range of prevention and treatment services, including primary healthcare; sexually transmitted infection screening and treatment; tuberculosis screening and treatment; treatment of mobility-related illnesses; behavior change communication; laboratory

services; HIV counseling and testing; and, in some clinics, antiretroviral therapy for those who are HIV positive (North Star Alliance 2014).

In 2012, North Star Alliance served 219,681 clients throughout Africa, the majority of whom attended educational sessions (61.5%) or received primary healthcare services (31.7%) (North Star Alliance 2012). The two study clinics together serve about 400 clients weekly, about 30% of whom are truck drivers. Clients are offered HIV testing at every clinic visit. About 60% of truck driver clients accept testing, of whom about 1.5% test HIV positive (personal communication from Eva Mwai, East Africa director, North Star Alliance, July 3, 2014).

2.2 Theory of change

The theory of change guiding our hypothesis that HIV testing uptake among truck drivers will increase when they have more choices in testing strategies is Tversky and Kahneman's Prospect Theory (1981). Prospect theory is an expansion of behavioral economics that considers the certainty of various potential outcomes based on a cost-benefit analysis of the individual situation.

Thus, the barriers to HIV testing (time, financial and potential social costs associated with healthcare provider-administered, clinic-based testing) must be weighed against the benefits of knowing one's status to prevent HIV if one is HIV negative, preventing transmission to others if one is HIV positive, and of obtaining appropriate healthcare if one is HIV positive to improve or maintain health and reduce mortality risk. Any intervention that reduces barriers to HIV testing will have the effect of reducing the cost associated with HIV testing, and may increase the seeking or acceptance of testing.

Oral HIV self-testing as a choice may address some of the barriers preventing some individuals from testing under the current system, such as by increasing privacy (thus decreasing the potential social costs) and decreasing the time spent in the clinic for those taking test kits for home use. Furthermore, truck drivers have been described as having fatalistic views about their health (Progresio 2013; IRIN 2013). If it is possible to reduce the sense of fatalism among truck drivers by (1) making HIV testing more of an autonomous, empowering experience (Johnson et al. 2014) and (2) making the benefits of receiving care if they are HIV positive better understood and accessible, the probability of the desired outcome from HIV testing may improve in the probability assessment, leading more truck drivers to choose to test for HIV.

Thus, self-testing may decrease the barriers currently preventing some truck drivers from seeing the benefits of HIV testing. For some who are already accessing HIV testing under the current program (provider-administered blood test), it is possible that self-testing will have a more positive cost-benefit ratio, and those individuals may switch to the self-test when given a choice. For others, the cost-benefit ratio may be better for the provider-administered blood test. The cost-benefit ratio is affected by context and individual preferences. Offering choices in HIV testing should therefore be more likely to provide an acceptable option than offering only one HIV testing method.

2.3 Methods overview

Truck drivers from these two clinics were randomized 1:1, and selection was stratified by clinic into one of two groups: (1) SOC or (2) choice. Participants randomized to the SOC arm were offered the provider-administered, blood-based (finger prick) rapid HIV test used in all North Star Alliance clinics (Colloidal Gold test) (World Health Organization 2013). Participants randomized to the choice arm were offered the choice between (a) the SOC test described above or (b) supervised oral rapid HIV self-testing. Those who refused both in-clinic testing options were then offered (c) a test kit to use outside of the clinic (e.g. at home).

After the baseline data collection and HIV testing (or test refusal), those in the choice arm were also told that they could go to any North Star Alliance clinic in Kenya 3–6 months later to pick up a self-test kit for supervised use in the clinic or for unsupervised use outside of the clinic. After three months, we sent a text message reminder about availability of the self-test kit to participants in the choice arm. Those in the SOC arm were sent the standard North Star Alliance text reminding them to visit a North Star Alliance clinic for HIV testing. We then conducted a follow-up interview six months into the study, in which we collected information about HIV testing during the follow-up period.

As part of the baseline interview prior to randomization, we included a discrete choice experiment to investigate preferences regarding HIV testing modalities. This was designed to determine the feasibility, optimal methods and potential impact on test uptake of integrating HIV self-testing as an option within North Star Alliance clinics in Kenya and elsewhere. We also aimed to conduct in-depth interviews at baseline among 10 participants in each arm who refused HIV testing at baseline (n = 20) and another 10 participants in the choice arm who did not pick up a self-test kit during follow-up, in an effort to understand why some people refuse to test and if these reasons vary when offered testing choices.

Recruitment and testing at baseline occurred during a two-month period (October through December 2015) and follow-up interviews were completed six months later, in June 2016.

2.4 Outcomes examined

The primary outcome of interest for this study was uptake of HIV testing in the clinic. Specifically, we examined uptake of the initial HIV test in the clinic between those randomized to the SOC arm versus the choice arm (choice of either provider-administered or supervised self-test). We also looked at HIV test uptake at baseline, in which we included taking a test kit for home use for those in the choice arm. Secondary outcomes examined include: 1) the impact of the intervention on HIV testing uptake at six-month follow-up; 2) whether the uptake of follow-up HIV testing within six months differed depending on the HIV test outcome at baseline; 3) demographic and behavioral predictors of overall HIV testing, as well as predictors of selecting self-testing in the clinic among those in the choice arm; 4) preferences for HIV testing in a discrete choice experiment; and 5) reasons for choosing not to test from in-depth interviews.

2.5 Fieldworker training

In April 2015, we held four full days of fieldworker training in Nairobi, Kenya, attended by the study fieldworkers as well as North Star Alliance management. During this training, we reviewed the study protocol and read through all study data collection forms to ensure the questions were clear. The fieldworkers then practiced the study procedures through role-playing, and practiced the interviews. Questions were brought back to the group for consideration, and some edits were made to the questionnaires to ensure clarity.

In September 2015, we held a two-day refresher training for the fieldworkers in Nairobi. In October 2015, a study investigator visited each site the day before study recruitment started for a final review of preparations and fieldworkers' understanding of the study procedures. Because the in-depth interviews were postponed, a study investigator visited each clinic in March 2016 to conduct refresher training on the in-depth interview procedures right before the fieldworkers started recruitment for these interviews.

Study investigators and the project coordinator also conducted regular monitoring visits to the clinics to check that the fieldworkers were clear on the procedures, and the fieldworkers used WhatsApp to contact one of the Africa-based study investigators (in similar time zones) when they had questions or concerns.

2.6 Challenges encountered

Although the study was successfully implemented, there were some logistical issues that serve as lessons learned. We experienced significant delays in study start-up due to a large number of institutional review board and ethics committee queries. The requirement to submit to three different ethics committees meant that each time one committee requested a change, an amendment had to go to the other two committees, and they did not always agree on how best to implement the study. We also found that receiving the test kits for the study took more time than anticipated.

In addition, we had originally planned for fieldworkers to enter data from their interviews into an online database using computer tablets. To enter data, they would need an Internet connection to access the database that was housed on a secure server in New York City. Although internet connections were available at the clinics, the connections were too slow and unreliable to enter data into the database. We then sent hard copies of all of the study forms to North Star Alliance's central office in Nairobi, which has a reliable Internet connection, so staff members there could enter data.

Because data had to be transported to Nairobi and then entered in batches, investigators could not monitor data quality in real time. Periodically, we downloaded the data, identified missing data and illogical answers and sent these queries to staff at North Star Alliance's Nairobi office to compare with the hard copy files or clarify with fieldworkers. This delay in accessing data in the database and the quick study timeline (the baseline data was all collected in less than three months), we were not able to identify problems with the interviews early and retrain the fieldworkers to minimize problems going forward.

In addition, we found excessive data entry errors as the individuals entering the data were not as well trained and committed to the project as the fieldworkers, whom we

originally planned would enter the data. This led to our decision to do double data entry to minimize data entry errors. During this double data entry process, we found the files for five additional study participants that had not been entered into the database. We were targeting a sample of 300 participants for this study and closely monitored recruitment during the last few weeks to ensure we did not go over this target, but since these five participants had not been counted, we ended up with 305 participants, five more than our target.

In the future, we would recommend that fieldworkers in settings with unreliable Internet use portable wireless internet connections. Ideally, fieldworkers should enter the data they collect to ensure that it is accurate and that there are no errors on the hard copy forms. This would also allow faster access to the data by remote investigators to monitor data as it is being collected and quickly entered.

In-depth interviews were to be conducted in the clinics following the 1–1.5 hour long study interviews and HIV test offered at baseline. However, fieldworkers did not recruit participants for the in-depth baseline interviews as planned. This was due to time constraints (the truck drivers could not stay for an additional hour-long interview after having spent 1–1.5 hours on study interviews) and fieldworkers' lack of facility while learning the protocol for the baseline procedures. Therefore, we ended up conducting the baseline in-depth interviews during the follow-up period, which made it slightly harder to gain insight into the specific reasons why participants declined HIV testing at baseline.

This was not a problem with the follow-up interviews because they were scheduled for a separate phone interview following the final, phone-based follow-up quantitative interview, which was much shorter (15–20 minutes). Furthermore, upon receipt of the in-depth interview transcripts, we discovered that 5 of the 29 participants (4 of the 20 baseline and 1 of the follow-up interviews) were not actually eligible for the in-depth interviews as they had either tested for HIV at baseline or, in the case of the ineligible follow-up interview, the participant was in the SOC arm, not the choice arm. These interviews were therefore excluded from analysis. We suspect that this problem, at least for the baseline interviews, is related to the data entry error rates, as we used the entered data to identify those eligible for the in-depth interviews before the data was cleaned.

Another challenge was that, during follow-up, fieldworkers initially failed to contact study participants who picked up an oral self-test kit for home use. The protocol was for participants taking a test kit for home use to be told that they had to use the test within three days and should text the counselor for post-test counseling. After three days, if the participant had not sent this text, the counselor was to call the participant to inquire if he had used the test and, if so, to provide post-test counseling.

None of the participants during baseline or follow-up sent a text after using the test kit (all tests were negative according to the participants' reports when the counselor reached them). However, we found that the counselors neglected to contact the participants three days after taking a test kit during follow-up. We discovered this about 2 months into the 3–6 month period when participants were eligible to pick up test kits, and immediately instructed the counselors to contact those who took test kits for counseling, but by this point it was 1–2 months after testing.

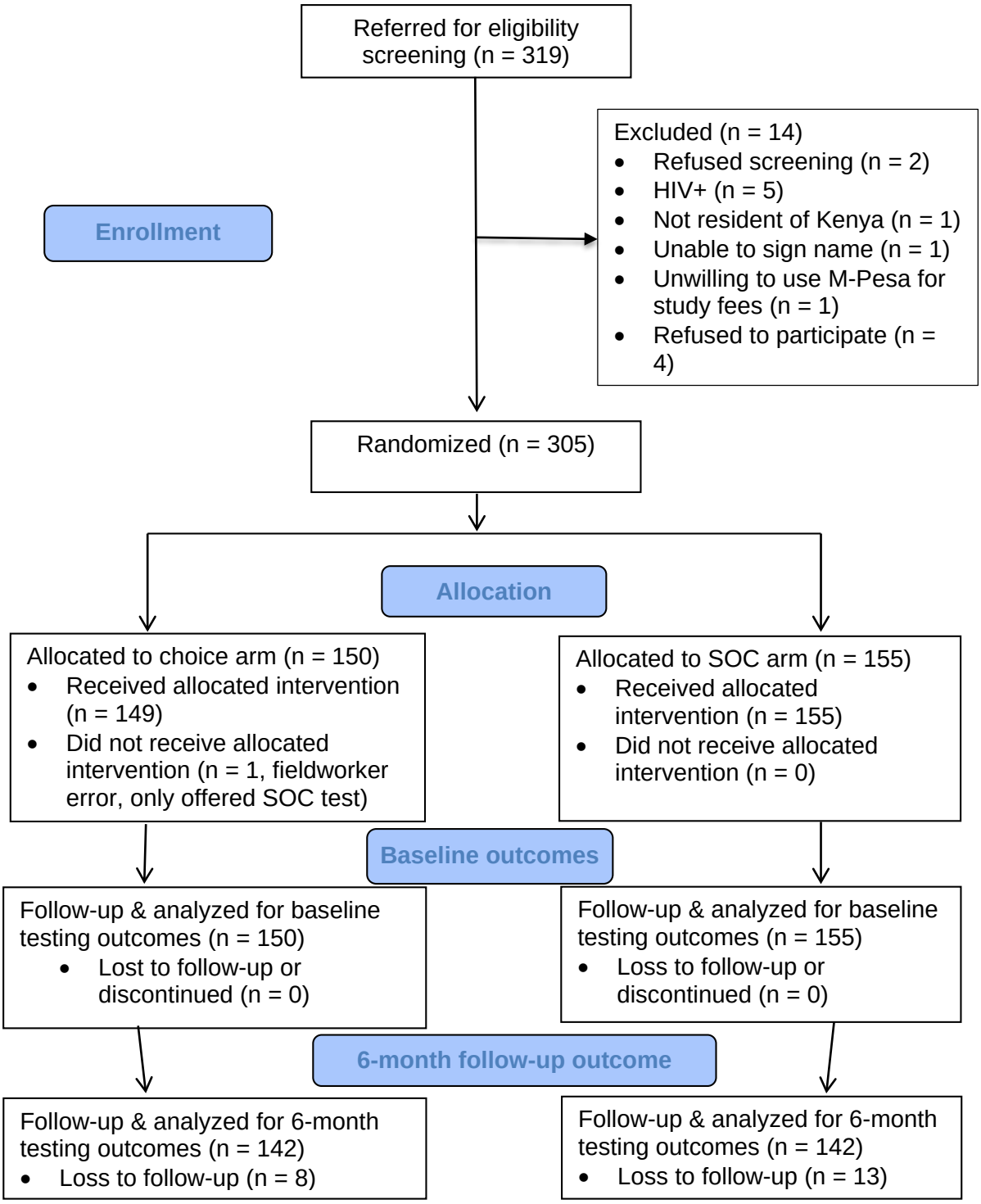
Fortunately, the counselors were able to reach all of the participants, and there were no adverse outcomes from this protocol violation, which was reported to the review board. Given the importance of post-test counseling in HIV testing in general, this highlights a possible problem if oral self-testing is implemented in Kenya. Protocols that implement HIV self-testing need to consider carefully how they will offer and deliver post-test counseling.

The fieldworkers were not used to administering such long questionnaires or following complex study protocols, which may have had an impact on the quality of the data. However, because the intervention was randomized, the impact of data quality issues should be non-differential by study arm and thus bias the results toward the null. While the fieldworkers were not blind after the randomization was revealed (following the baseline interview), the randomization process should ensure that about an equal proportion of the choice arm and SOC arm participants were recruited early in the study, when the fieldworkers were still learning the procedures. This would decrease our power to find a difference by study arm overall, but we can be fairly confident that any differences found are real or an underestimation of the true association.

3. Data and methods

Figure 1 depicts the study flow. The City University of New York Institutional Review Board, the Kenya Medical Research Institute Ethics Committee and the University of KwaZulu-Natal Biomedical Research Ethics Committee approved the study procedures.

Figure 1: Study flow diagram



3.1 Eligibility and recruitment

Any male truck driver who visited the two North Star Alliance clinics for reasons other than HIV care during the recruitment period was informed of the research study by the clinic receptionist. If interested, they were referred to a fieldworker for additional information and eligibility screening. The eligibility criteria were: (1) be at least 18 years old; (2) be male; (3) work as a truck driver; (4) reside in Kenya; (5) speak English or Kiswahili; (6) have a self-reported HIV-negative or unknown HIV status; (7) be able to sign the consent form; and (8) be willing to receive payment of participation fees via M-Pesa (a mobile phone-based money transfer system widely used in Kenya).

Participants were told that study participation involved completing two questionnaires on the day of recruitment (baseline visit) and a phone-based questionnaire six months later. The study was described to participants as being about HIV testing experiences and preferences. They were told that HIV testing would be offered, as it would be at any North Star Alliance clinic visit, but that their decision about testing would not impact their access to healthcare services or their study eligibility. Participants were not informed about the specific research question or the fact that they would be randomized to different HIV testing options in order to avoid bias.

3.2 First quantitative interview at baseline

Eligible men who were willing to participate in the study were asked to read and sign an informed consent or, if they preferred, the fieldworker would read the form to them before they signed their consent. Following the consent process, the fieldworker administered the first survey (baseline), which included questions about participants' demographic characteristics and sexual health behaviors and experiences, including HIV testing. We also administered a number of previously validated scales to quantify anticipated HIV stigma (Weiser et al. 2006), self-efficacy (Schwarzer and Jerusalem 1995), fatalism (Shen et al. 2009), self-esteem (Rosenberg 1965) and gender equity (Pulerwitz and Barker 2008).

We also asked participants about their HIV testing preferences, including (a) facility-based or home-based, (b) self-administered or provider-administered, and (c) blood-based or oral test (see Table 1 for a list of attributes).

We used discrete choice experimental methods to identify preferred HIV testing modalities. Discrete choice analysis is a stated preference method especially useful for assessing individuals' preferences for health and healthcare (Viney et al. 2002). The method forces individuals to make trade-offs between attributes by offering them a series of choices ("choice sets") between different scenarios ("options" or "alternatives") based on the attributes (e.g. type of test, who administers the test) and levels (e.g. blood or oral, provider or self) associated with the HIV testing options. Scenarios comprise combinations of different levels of each attribute and are presented to participants in sets of two, from which the participants pick which they would prefer.

Table 1: Discrete choice experiment attributes and levels

Attribute	Level 1 (baseline)	Level 2	Level 3	Level 4
Type of test	Finger prick blood test	Oral mouth swab test	–	–
Type of counseling	In-person counseling	Telephone-based counseling	–	–
Who administers the test	Nurse-administered	Self-administered	–	–
Location	At a roadside clinic	At a clinic near home	At the company office	At home
Time	90 minutes	20 minutes	40 minutes	3 hours
Cost	Free	You pay KES 250	You pay KES 300	We pay you KES 350

3.3 Randomization

Participants were assigned identity numbers consecutively that were pre-printed on the consent form and baseline survey. The last page of the baseline survey was attached to a sealed envelope with the randomization assignment, which was opened upon completion of the baseline survey. The randomization assignments were generated on a 1:1 ratio and stratified on clinic.

3.3.1 SOC arm

Following the baseline interview, participants randomized to the SOC arm were offered HIV testing using the standard clinic procedure by clinic HIV testing and counseling (HTC) staff. If the participant refused the HIV test, research staff administered a short second survey asking about reasons for the test refusal and plans for future HIV testing. Ten participants who refused HIV testing in each arm were invited to participate in an in-depth interview about their HIV risk perception, views about HIV testing and treatment, and reasons for refusing HIV testing. Participants were offered a choice of doing the in-depth interview at baseline or scheduling a phone interview for a later time (all were scheduled for a later time).

Participants in the SOC arm who accepted HIV testing received the standard pre-test counseling, provider-administered, blood-based (finger prick) HIV test and post-test counseling. Following the HIV testing procedures, the fieldworker administered a short survey about the participant's experience of the testing and counseling procedures and plans for future HIV testing. The research staff then collected the participant's contact information and made an appointment for a telephone follow-up interview six months later.

3.3.2 Choice arm

Following the baseline interview, participants randomized to the choice arm were given a brief demonstration of the HIV self-test kit and were told that if they chose to self-test, they would have the choice between viewing the test results with the counselor for help

with interpretation, or by themselves if they preferred to keep the test results private. Participants were then offered a choice of HIV testing methods, either self-testing supervised by the clinic HTC counselor or the SOC HIV test. If a participant refused both in-clinic HIV testing options, he was offered an HIV self-test kit to use outside of the clinic (e.g. at home). Those who refused all three testing options or who chose the SOC test underwent the same procedure as participants in the SOC arm (described above).

Participants in the choice arm who chose to undergo supervised oral HIV self-testing received the standard pre-test counseling. Then the healthcare provider gave the participant the HIV test kit with pictorial instructions plus written English and Kiswahili instructions under each picture, and instructed the participant to follow the instructions but to ask questions if anything was unclear. If the participant did something incorrectly, the counselor would intervene to ensure that the test was administered correctly.

During this process, the counselor completed a self-testing observation form, indicating at which steps the participant asked questions or required unsolicited correction, and if any steps were not completed correctly despite intervention by the counselor. After testing, the participant received post-test counseling. Participants who self-tested and chose to view their test result alone were encouraged to disclose the test results during post-test counseling, but were not required to do so.

If someone chose not to disclose their test results, they received post-test counseling and referrals for HIV-positive or HIV-negative results. They were told to use the appropriate information and referrals based on their test result. However, all participants in this study who self-tested either viewed the results with the counselor or disclosed their HIV test results during counseling (all tests were negative).

Participants who refused both in-clinic HIV testing options were offered an HIV self-test kit to take and use outside of the clinic. They were told to use the test within three days and to text the HTC counselor afterwards for a call back for post-test counseling and referrals if needed. Participants were also told that they could text or call the counselor while self-testing if they had questions or concerns. Those who took a test kit for use outside of the clinic received pre-test counseling before leaving the clinic. If they did not text the counselor after three days, the counselor called them to see if they had used the test, and to administer post-test counseling and provide referrals.

Following these HIV testing procedures, the fieldworker administered a short survey about the participant's experience of the self-testing and counseling procedures. For those who took a test kit for use outside of the clinic, this survey was administered over the phone following the post-test counseling.

All participants in the choice arm, no matter what their testing choices at baseline, were told that they could attend any of the 8 North Star Alliance clinics in Kenya within 3–6 months to pick up a second HIV test for use outside of the clinic and that their final follow-up interview would be done by phone after using that self-test or, for those who did not pick up a self-test kit, after six months (as for those in the SOC arm).

Before participants left the clinic, the research staff collected their contact information and made an appointment for a telephone follow-up interview in six months, which would be rescheduled for those in the choice arm who picked up a test kit before then. Ten

participants in the choice arm who did not pick up a test kit were invited to participate in an in-depth interview over the phone or in person, depending on the participant's preference. The interview included questions about reasons for not picking up a test kit and plans for HIV testing in the future.

3.4 Six-month follow-up interview

Participants in both study arms were called six months later for a follow-up telephone interview about whether they had been retested for HIV in the past six months and if they had received any other HIV-related services. If they had received services, we asked where they received them, what their experience was like and whether they needed any new referrals. Participants in the choice arm who picked up an oral HIV self-test from a clinic during follow-up completed the follow-up interview over the phone following post-test counseling. The interview explored the participant's experience with self-administered testing outside of the clinic and their plans for future testing.

3.5 In-depth interviews

We conducted in-depth interviews with 16 men who refused HIV testing at baseline (11 in the SOC arm and five in the choice arm) and eight men who in the choice arm who did not pick up a test kit during follow-up (one agreed to the interview but, despite multiple attempts, could not be reached for the interview). While the baseline in-depth interviews were originally planned to be conducted in person in the clinic directly following the second quantitative interview about refusal of HIV testing, we were concerned that some participants might not have time at baseline and allowed the option to schedule the in-depth interview for another time, over the phone or in person.

All of the baseline in-depth interviews were conducted 3–6 months after initial participation in the study due to scheduling challenges. The in-depth interviews with men who did not pick up an HIV self-test kit for use outside of the clinic were conducted 1–3 months following their quantitative follow-up interview, again due to scheduling difficulties.

All in-depth interviews were conducted in English, Kiswahili or a combination of these languages, according to participants' preference. The interviews were audio-recorded and then transcribed and translated into English for analysis. To ensure accurate translation, a bilingual Kiswahili and English member of the research team reviewed all in-depth interviews before they were submitted for coding and analysis. Because of some confusion with the eligibility criteria, we found that only 16 of the 20 baseline interviews and 8 of the 9 follow-up interviews were conducted with eligible study participants (i.e. participants who had refused HIV testing at the relevant time), as described in Section 2.6 above.

3.6 Data collection, management and cleaning

Quantitative data was collected by research staff using paper forms and stored in a locked file cabinet in the clinics. Forms with identifying information (the signed consent form and contact information form) were kept separate from those with study data and identified with a different study identification numbering system so that participants' names could not be linked to their study data through the paper forms. The forms with

study data were later transferred to the North Star Alliance Nairobi office for data entry and long-term storage while those with the participant contact information remained in the clinics.

Study data was entered by Nairobi research staff over a secure Internet connection into the password-protected, Internet-based database REDCap (Harris et al. 2009), which was housed on a secure server at Columbia University in New York City. After initial entry, double data entry was conducted for all baseline forms and half of the follow-up forms by study investigators to ensure accuracy. While the data entry error rates for the baseline data were fairly high, requiring double data entry, the error rate for the follow-up data was low and therefore we only double entered the first half of the forms.

We ran queries on the entered data to identify inconsistent responses and frequencies to explore missing data. In some cases, we asked fieldworkers to check responses on the baseline questionnaires with participants during the follow-up interview and make corrections when possible.

3.7 Participant compensation

At the end of each interview, participants were compensated for their time. The compensation was 270 Kenyan shillings (KES) for the baseline and discrete choice experiment interviews, which collected background information and information about testing preferences, KES 270 for the post-test interview, asking about the testing experience, KES 450 for the in-depth interviews asking for more details about testing decisions and assumptions, and KES 360 for the 6 month follow-up interview, also asking about the testing experience and decisions. Participant compensation was made via M-Pesa. At the time of the study, KES 1 was worth approximately USD 0.01.

3.8 Sample size and power

We estimated that if the testing rate in the SOC group was 60%, as expected based on the testing rates in the clinics before the study, we would have 80% power to detect an odds ratio of 1.7 at a 2-sided alpha of 0.05 with a sample of 150 in each arm.

3.9 Statistical analysis

3.9.1 Description of sample

We describe the participants overall and by randomization arm in terms of demographic characteristics, work history, HIV risk behavior and HIV testing history. We used the Pearson chi-square test (Fisher's exact if any expected cell counts were less than 5) to assess the significance of differences in categorical variables by randomization arm and the Mann Whitney U test for numeric variables.

3.9.2 HIV test uptake outcomes

We looked at the proportion of participants who accepted HIV testing in the clinic only, during baseline (including taking a test kit for home use), and at follow-up (overall and by randomization arm) in an intent-to-treat analysis. To assess the statistical significance of differences by randomization arm, we calculated Mantel Haenszel odds ratios, confidence intervals and p-values for HIV test uptake by study arm adjusted for clinic (strata used in the randomization scheme). We also compared each outcome by the HIV

test offered (SOC only versus choice) in a per protocol analysis, as one participant in the choice arm was only offered the SOC test.

3.9.3 Description of HIV test selected among those given a choice

Among participants in the choice arm who tested, we describe which test they chose (SOC test, supervised self-testing in the clinic, or test kit for home use) and the reason they gave for their choice. We also examine whether participants' testing choice at baseline was associated with picking up a test kit during follow-up.

3.9.4 Description of self-testing observations

For participants who self-tested for HIV at baseline in the clinic with supervision, we describe the steps in the testing process where the participant asked questions or required correction from the healthcare provider, based on the observation form completed by the counselor who supervised the testing process.

3.9.5 Predictors of HIV testing history and HIV test uptake at baseline and follow-up

We ran crude logistic regression models for four HIV testing outcomes (i.e. ever tested, tested in the past six months, test uptake at baseline and test uptake during follow-up) with a number of demographic variables as well as the attitude and belief scales (examined in the analyses as numeric variables).

We then ran separate multivariable logistic regression models for the HIV testing outcomes, which included all variables. All of these models were also adjusted for each clinic, and the models for HIV testing at baseline and follow-up were also adjusted for randomization arm as potential confounders. Finally, we ran four backward stepwise logistic regression models with a p-value of 0.2 as the criterion for retaining a variable in the model to determine if results from our full multivariable models changed due to a lack of statistical power when including so many covariates in the model.

3.9.6 Predictors of HIV test chosen in the clinic when given a choice

Similarly, we used logistic regression to identify predictors of choosing the oral HIV self-test over the provider-administered blood test in the clinic among participants who tested in the choice arm. We conducted a crude model looking at each demographic, attitudinal and belief scale, as well as HIV risk behavior variable individually, a multivariate model with all the predictors included, and backward stepwise regression using a p value of less than 0.2 as the cut-off for inclusion in the final model.

For these analyses, as well as looking at predictors of HIV testing history and HIV test uptake at baseline and follow-up, we looked at the various attitudinal and belief scales, the construction and reliability of which are described below.

3.9.7 Attitudinal and belief scales

We looked at six different attitudinal and belief scales, calculating a summary score and allowing up to 20% of the items to be left unanswered.

Anticipated HIV stigma

We used a nine-item anticipated HIV stigma scale that was adapted from the UNAIDS general population survey and the Department of Health Services AIDS module and had been previously used in Botswana (Weiser et al. 2006). The scale presents nine

statements about possible stigma-related scenarios if the participant was to test positive for HIV and others found out about their status (e.g. “Do you think you would be treated badly by health workers?”).

Each item elicited a yes/no response, and the number of yes responses was summed for a possible score of 0–9, with higher scores indicating more anticipated stigma. Seven out of 9 questions had to be answered for the scale to be calculated, and 6 participants missed responses to 1 or 2 items on the scale. The Cronbach’s alpha for this scale in our sample was 0.81, indicating good internal consistency.

General self-efficacy
We used a 10-item general self-efficacy scale (Schwarzer and Jerusalem 1995), which had previous multicultural validation in Europe and Asia (Luszczynska et al. 2005), and which presented statements related to participants’ belief in their ability to cope with a broad range of stressful or challenging demands (e.g. “I can always manage to solve difficult problems if I try hard enough”).

Response options were in a four-point Likert scale from “not at all true” to “exactly true.” Responses were summed for a possible score of 10–40, with higher scores indicating greater self-efficacy. We allowed up to one missing item in calculating the summary score, and three participants were missing responses to one item on the scale. Cronbach’s alpha for this scale in our sample was 0.89, indicating good to excellent internal consistency.

Fatalism
We used a 20-item fatalism scale (Shen et al. 2009) that elicited agreement to a series of fatalistic statements mostly related to health (e.g. “If someone is meant to get a serious disease, it doesn’t matter what kinds of food they eat, they will get that disease anyway”). Response options were in a five-point Likert scale, ranging from “strongly disagree” to “strongly agree.”

Responses were summed for a possible score of 20–100, with higher scores indicating more fatalistic views. We allowed for 2 missing responses in calculating the summary score, and 10 participants were missing responses to 1 or 2 items on the scale. The Cronbach’s alpha for this scale in our sample was 0.93, indicating excellent internal consistency.

Gender equity
We used a 24-item gender equity scale (the Gender Equitable Men scale) (Pulerwitz and Barker 2008) that has been widely used in Sub-Saharan Africa (World Health Organization 2012). It consisted of a series of statements related to relationships between men and women (e.g. “There are times when a woman deserves to be beaten”), with response options in a three-point Likert scale consisting of “agree,” “partially agree” and “do not agree.”

Responses were summed for a possible score of 24–72, with higher scores indicating more gender equitable attitudes. We allowed up to 2 items to be missing in calculating the summary score, and 19 participants were missing responses to 1–2 items on the scale. Cronbach’s alpha for this scale in our sample was 0.88, indicating good to excellent internal consistency.

Sensation seeking
We used a five-item sensation-seeking scale (Kalichman et al. 1994), previously adapted for use in South Africa (Kalichman et al. 2006, Kalichman et al. 2008), with statements about self-perceived propensity for risk and pleasure seeking (e.g. “I would enjoy the feeling of jumping off a high cliff into a river below”).

Responses were elicited on a four-point Likert scale, ranging from “not at all like me” to “very much like me,” with a possible score of 5–20 and a higher score indicating greater sensation seeking. We allowed for one missing item in the summary score calculation and one participant was missing a response to one item on the scale. Cronbach’s alpha for this scale in our sample was 0.74, indicating good internal consistency. To improve internal consistency, we dropped the first question from the scale.

Self-esteem
We used a 10-item self-esteem scale (Rosenberg 1965), which has been widely used globally, including in Sub-Saharan Africa (Schmitt and Allik 2005). The scale consisted of statements about perceived self-esteem (e.g. “I feel that I am a person of worth, at least on an equal plane with others”). Responses were elicited on a four-point Likert scale, ranging from “strongly agree” to “strongly disagree,” with reverse coding for five questions, with a possible score of 0–30 and a higher score indicating greater self-esteem.

We allowed for one missing item in the summary score calculation, and one participant was missing a response to one item on the scale. Because this scale was administered at follow-up, there were 21 participants from the original study population who did not have results for this scale, since they did not present for their follow-up interview. Cronbach’s alpha for this scale in our sample was 0.88, indicating good to excellent internal consistency.

3.9.8 Discrete choice experiment
Participants were presented with 9–10 choice sets, which contained two alternative HIV testing scenarios. The characteristics (or attributes) of testing in each alternative (shown in Table 1) included location (roadside wellness clinic, clinic near home, at home or at work), biological specimen (finger prick or oral swab), test administrator (nurse or self), counseling (in person or telephone-based), time (20 minutes, 40 minutes, 90 minutes or 3 hours) and cost (free, test costs KES 200, test costs KES 300, an incentive to test of KES 350), each of which varied between the two alternatives in each choice set.

Participants were asked to pick option A or B, depending on which combination of testing attributes they considered most preferable. The 32 statistically designed choice sets were divided into four different questionnaire versions, and participants were randomized to one of the four versions. One of the choice sets was consistent across all four versions of the questionnaire for a reliability check. The discrete choice data was modeled using logistic regression to determine which attributes predict whether a participant chose version A or B. In addition, we looked at interaction between each test attribute and marital status, as well as HIV testing history modeled two ways: as an indicator for ever having tested for HIV; and as an indicator for regular testing among those who had ever tested, defined as having ever tested more than once and the most recent test done in the past six months. When the interaction models were statistically

significant, we re-ran the models stratified on the effect modifier to describe the strength and direction of the effect modification.

3.9.9 Additional notes on quantitative analyses

All statistical tests were two-sided at alpha level of 0.05 and conducted using SPSS version 22 (Chicago, Illinois), SAS 9.4 (Cary, North Carolina: SAS Institute Inc.), or Stata Statistical Software: Release 14 (College Station, Texas: StataCorp LP).

3.9.10 Qualitative data analysis

Three researchers developed coding schemes independently after reviewing 4–5 interview transcripts. The codes were compared, combined and edited in an iterative process until a coding consensus was reached. The three researchers then independently coded four transcripts by hand and compared their coding to ensure that everyone was applying the codes in a similar way. The codes were edited as needed after this process.

The consensus codebook was then loaded into Dedoose version 6.2.21 (SocioCultural Research Consultants, Los Angeles, California) and the transcripts were analyzed by the three researchers by organizing the text within the codes. The coding scheme and the data analysis for this study were guided by the Social-Ecological Model (Bronfenbrenner 1994; Harper et al. 2014) in looking at the facilitators and barriers to HIV testing.

4. Results

4.1 Description of the sample

We screened 319 potential participants, of whom 305 were eligible and willing to participate (see Figure 1). All participants were male and of African race (data not shown). Their mean age was 37.0 years. Nearly two-thirds (64.3%) had not completed secondary school and 27.8% earned less than KES 24,000 per month. Participants had worked as truck drivers for a mean average of 8.7 years and 83.2% reported that the clinic where they were recruited was on their regular route. On average, the participants had spent 21.6 of the past 30 nights away from home due to work. The majority (56.7%) reported that they came to the clinic on the day they were recruited for the study for reasons other than HIV testing (see Table 2).

Table 2: Descriptive statistics for the sample, overall and by randomization arm

Variable	Total	SOC arm, n (%)	Choice arm, n (%)	p-value chi-square test, unless otherwise specified
Total	*305*	*155 (50.8%)*	*150 (49.2%)*	*NA*
Clinic from which recruited				0.787
Clinic 1	144 (47.2%)	72 (46.5%)	72 (48.0%)	
Clinic 2	161 (52.8%)	83 (53.5%)	78 (52.0%)	
Age in years				0.989*
Mean (SD)	37.0 (7.9)	36.9 (8.0)	37.2 (7.8)	
Median (range)	36.0 (21–62)	35.0 (21–60)	37.0 (24–62)	
Secondary school graduate				0.417
No	196 (64.3%)	103 (66.5%)	93 (62.0%)	
Yes	109 (35.7%)	52 (33.5%)	57 (38.0%)	
Mean trucking income per month (KES)				0.074
KES 8,000–15,999	15 (5.2%)	12 (8.1%)	3 (2.1%)	
KES 16,000–23,999	65 (22.6%)	33 (22.3%)	32 (22.9%)	
KES 24,000–55,000	208 (72.2%)	103 (69.6%)	105 (75.0%)	
Years worked as truck driver				0.650*
Mean (SD)	8.7 (7.1)	9.0 (7.8)	8.4 (6.3)	
Median (range)	6.7 (1.0–38.9)	6.7 (1.0–38.9)	6.7 (1.0–37.0)	
Clinic is on usual trucking route				0.573
No	51 (16.8%)	24 (15.6%)	27 (18.0%)	
Yes	253 (83.2%)	130 (84.4%)	123 (82.0%)	
Nights away from home in past 30 days				0.495*
Mean (SD)	21.6 (5.6)	21.3 (5.9)	21.8 (5.3)	
Median (range)	22.5 (0–30)	22.0 (0.0–30.0)	23 (2.0–30.0)	
Came to clinic specifically for HIV testing				0.365
No	173 (56.7%)	84 (54.2%)	89 (59.3%)	
Yes	132 (43.3%)	71 (45.8%)	61 (40.7%)	
Sexually active in the past 6 months				0.116**
No	6 (2.0%)	1 (0.7%)	5 (3.4%)	

Variable	Total	SOC arm, n (%)	Choice arm, n (%)	p-value chi-square test, unless otherwise specified
Yes	295 (98.0%)	152 (99.3%)	143 (96.6%)	
Married (legal or common law)				0.999
No	51 (16.9%)	26 (16.9%)	25 (16.9%)	
Yes	251 (83.1%)	128 (83.1%)	123 (83.1%)	
Other regular sexual partner(s) on trucking route				0.619
No	163 (53.4%)	85 (54.8%)	78 (52.0%)	
Yes	142 (46.6%)	70 (45.2%)	72 (48.0%)	
Paid for sex in past 6 months				0.7896
No	126 (44.1%)	65 (43.3%)	61 (44.9%)	
Yes	160 (55.9%)	85 (56.7%)	75 (55.1%)	
Always used condoms when had sex in the past 6 months (among those who had sex)				0.358
No	250 (85.9%)	127 (84.1%)	123 (87.9%)	
Yes	41 (14.1%)	24 (15.9%)	17 (12.1%)	
Ever HIV tested				0.259
No	25 (8.2%)	10 (6.5%)	15 (10.0%)	
Yes	280 (91.8%)	145 (93.5%)	135 (90.0%)	
Years since last HIV test (among those who had ever tested)				0.934*
Mean (SD)	1.1 (1.6)	1.0 (1.4)	1.1 (1.9)	
Median (range)	0.5 (0.1–12)	0.5 (0.1–7.4)	0.5 (0.1–12.0)	
Ever self-tested for HIV (among those who had ever tested)				0.499**
No	276 (99.3%)	142 (98.6%)	134 100.0%)	
Yes	2 (0.7%)	2 (1.4%)	0 (0.0%)	
Anticipated stigma				0.034
Mean (SD)	0.65 (1.41)	0.51 (1.27)	0.79 (1.53)	
Median (range)	0.0 (0.0–9.0)	0.00 (0.00–9.00)	0.00 (0.00–9.00)	
Self-efficacy				0.560
Mean (SD)	36.25 (4.89)	35.98 (5.20)	36.54 (4.54)	

Variable	Total	SOC arm, n (%)	Choice arm, n (%)	p-value chi-square test, unless otherwise specified
Median (range)	38.00 (22.00–40.00)	38.00 (22.00–40.00)	39.00 (22.00–40.00)	
Fatalism				0.982
Mean (SD)	46.85 (20.69)	46.97 (19.90)	46.73 (21.55)	
Median (range)	48.00 (20.00–97.00)	50.00 (20.00–96.00)	46.00 (20.00–97.00)	
Gender equity				0.119
Mean (SD)	59.38 (8.94)	60.36 (8.41)	58.37 (9.37)	
Median (range)	59.00 (32.00–72.00)	59.00 (32.00–72.00)	59.00 (34.00–72.00)	
Sensation seeking				0.228
Mean (SD)	5.72 (2.63)	5.90 (2.64)	5.55 (2,42)	
Median (range)	4.0 (3.00–15.00)	4.00 (3.00–15.00)	4.00 (4,00–12.00)	
Self-esteem				0.629
Mean (SD)	20.64 (5.54)	20.68 (5.23)	20.60 (5.84)	
Median (range)	19.00 (8.00–30.00)	19.00 (12.00–30.00)	18.00 (8.00–30.00)	

*Mann-Whitney U test.
**Fisher's exact test.

Almost all participants (98.0%) reported being sexually active in the past 6 months. Most (83.1%) were married (either legally or in common law), 46.6% reported that they had one or more other regular partners along their route in addition to a wife or girlfriend at home and 55.9% also reported having paid for sex in the past 6 months. Only 14.1% of participants who had been sexually active in the previous 6 months reported always using condoms during sex in that time.

Nearly all participants (91.8%) reported that they had previously tested for HIV and the mean time since last HIV test was 1.1 years. Only 2 participants (0.7%) reported that they had used an HIV self-test in the past. There were no significant differences in demographics or HIV-related behavior by randomization arm (see Table 2).

Descriptive statistics for the six attitudinal and belief scales (anticipated HIV stigma, self-efficacy, fatalism, gender equity, sensation seeking and self-esteem) are presented in Table 2. There was a significant difference in anticipated stigma score by randomization arm, such that the stigma score was higher among those in the choice arm (mean score 0.79 versus 0.51, p = 0.034) (see Table 2).

4.2 Impact of the intervention

Overall, 233 of the 305 participants (76.4%) accepted HIV testing in the clinic. In the intent-to-treat analysis, those in the choice arm had 1.5 times higher odds of accepting

HIV testing in the clinic compared to those in the SOC arm. However, this difference was not statistically significant (p = 0.189). One participant in the choice arm was erroneously only offered the SOC test. When the data was analyzed per protocol by moving this person into the SOC arm, these results did not change (OR = 1.5, p = 0.196) (see Table 3).

Table 3: HIV test uptake overall and by arm under intent-to-treat and per protocol status

	Total, n (%)	**SOC arm, n (%)**	**Choice arm, n (%)**	**Mantel Haenszel OR (95% CI) adjusting for strata**	**Mantel Haenszel p-value**
Total as randomized	*305 (100%)*	*155 (50.8%)*	*150 (49.2%)*	*NA*	*NA*
Total per protocol	*305 (100%)*	*156 (51.1%)*	*149 (48.9%)*	*NA*	*NA*
Tested in clinic (intent-to-treat analysis)					
Yes	233 (76.4%)	113 (72.9%)	120 (80.0%)	1.5 (0.9–2.7)	0.189
No	72 (23.5%)	42 (27.1%)	30 (20.0%)	NA	NA
Tested in clinic (per protocol analysis)*					
Yes	233 (76.4%)	114 (73.1%)	119 (79.9%)	1.5 (0.9–2.7)	0.196
No	72 (23.6%)	42 (26.9%)	30 (20.1%)	NA	NA
Tested either in clinic or took test kit for home use at baseline (intent-to-treat analysis)					
Yes	244 (80.0%)	113 (72.9%)	131 (87.3%)	2.8 (1.5–5.4)	0.002
No	61 (20.0%)	42 (27.1%)	19 (12.7%)		
Tested either in clinic or took test kit for home use at baseline (per protocol analysis)*					
Yes	244 (80.0%)	114 (73.1%)	130 (87.2%)	2.8 (1.5–5.4)	0.002
No	61 (20.0%)	42 (26.9%)	19 (12.8%)	NA	NA
Total with 6-month follow-up data	284 (100%)	142 (50.0%)	142 (50.0%)		
Tested at 6 month follow-up (intent-to-treat analysis)					
Yes	159 (56.0%)	79 (55.5%)	80 (56.3%)	1.0 (0.6–1.5)	0.972
No	125 (44.0%)	63 (44.4%)	62 (43.7%)	NA	NA
Tested at 6 month follow-up (per protocol analysis)*					
Yes	159 (56.0%)	79 (55.2%)	80 (56.7%)	0.9 (0.6–1.5)	0.872
No	125 (44.0%)	64 (44.8%)	61 (43.3%)	NA	NA

*One participant in the choice arm was only offered the SOC HIV test at baseline. Per protocol refers to what was actually offered so that individual is analyzed in the SOC arm in the per protocol analysis.

An additional 11 participants in the choice arm accepted HIV testing when offered a test kit for use outside of the clinic after refusing testing in the clinic, bringing the total number tested to 244 out of 305 (80.0%). When including self-testing outside of the clinic, those in the choice arm had 2.8 times the odds of accepting HIV testing at baseline compared to those in the SOC arm, and the difference was statistically significant (p = 0.002). In the per protocol analysis, these results did not change (OR = 2.8, p = 0.002). One participant who took a test kit for use outside of the clinic later returned to the clinic to take the test with supervision (see Table 3).

We also ran the analysis adjusting for anticipated stigma, the one participant characteristic that varied significantly by randomization arm. The results were similar (testing in the clinic OR = 1.6, p = 0.139; tested at baseline, including taking a test kit for home use, OR = 3.0, p = 0.001) (data not shown).

Twenty-five participants reported never having been tested. Among the 15 of these participants in the choice arm, 11 (73.3%) tested as part of this study compared to only 5 of the 10 (50.0%) in the SOC arm, with an OR = 4.2 (p = 0.280) after adjusting for clinic. Of the 15 in the choice arm who tested, 4 (35.3%) chose the SOC test, 6 (54.5%) chose supervised self-testing in the clinic and 1 (0.9%) took a test kit to use outside of the clinic (data not shown).

At the 6-month follow-up, 13 participants were lost to follow-up in the SOC arm and 8 were lost to follow-up in the choice arm. In the intent-to-treat analysis, there was no significant association between randomization arm and testing uptake (OR = 1.0, p = 0.972). The results were similar in the per protocol analysis (OR = 0.9, p = 0.872) (see Table 3), and when adjusting for anticipated HIV stigma and clinic (OR = 1.0, p = 0.889) (data not shown).

Among all participants, those who had not tested for HIV at baseline were more likely to test during the follow-up period (63.4% versus 54.2%), but the difference was not statistically significant (p = 0.236). Of the 80 participants in the choice arm who tested during follow-up, 18 (22.5%) did so using a self-test. Choice arm participants who had not tested at baseline were more likely to test during follow-up, although the difference was not significant (68.4% of non-testers versus 44.1% of those who were tested by the healthcare provider, 59.0% among those who self-tested in the clinic with supervision and 54.5% among those who took a test kit for home use at baseline tested during follow-up, p = 0.330).

Among participants who tested for HIV during follow-up, those who had self-tested at baseline were more likely to pick up a self-test kit during follow-up, but the difference was not significant (26.1% of those who self-tested in the clinic and 33.3% of those who took a self-test kit for home use at baseline versus 20.0% of those who were tested by the healthcare provider at baseline and 7.7% of those who did not test at baseline picked up a self-test kit during follow-up, p = 0.488) (see Table 4). Of these participants, 3 (16.7%) used the test at the clinic under supervision. One of the three had refused testing at baseline, one had undergone a supervised self-test at baseline and one had taken a test kit for home use at baseline (data not shown).

Table 4: Association between test selected at baseline and testing over six-month follow-up

Baseline testing		**Tested at follow-up**			**Picked up a self-test kit (among those who tested at follow-up)**		
	Total	**Yes**	**No**	**Fisher's exact p-value**	**Yes**	**No**	**Fisher's exact p-value**
Tested at baseline, total sample (n = 284)				0.236			
Yes	227 (79.9%)	123 (54.2%)	104 (45.8%)		NA	NA	NA
No	57 (20.1%)	36 (63.2%)	21 (36.8%)		NA	NA	
Tested at baseline, choice arm (n = 142)				0.324			0.278
Yes	123 (86.6%)	67 (54.5%)	56 (45.5%)		17 (25.4%)	50 (74.6%)	
No	19 (13.3%)	13 (68.4%)	6 (31.5%)		1 (7.7%)	12 (92.3%)	
Test used at baseline, choice arm participants with follow-up data							
No test	19	13 (68.4%)	6 (31.6%)	0.337	1 (7.7%)	12 (92.3%)	0.487
Provider-administered blood test	34	15 (44.1%)	19 (55.9%)		3 (20.0%)	12 (80.0%)	
Supervised oral self-test	78	46 (59.0%)	32 (41.0%)		12 (26.1%)	34 (73.9%)	
Oral self-test kit taken for home use	11	6 (54.5%)	5 (45.5%)		3 (33.3%)	4 (66.7%)	
Total	*142*	*80 (56.3%)*	*62 (43.7%)*		*18 (22.6%)*	*62 (77.5%)*	

Two participants tested positive for HIV at baseline and both were in the SOC arm. They both reported having gotten confirmatory testing at the follow-up interview but did not report having received any other HIV-related care. One of the two who tested positive at baseline requested new referrals at follow-up. None of the participants tested positive at

follow-up based on participant reports. All of the participants in the choice arm who self-tested at baseline or follow-up disclosed their test results to the counselor, and all of those test results were negative (based on the counselor's observation for those who self-tested in the clinic or participant self-reporting for those who tested outside of the clinic) (data not shown).

4.3 Reasons for HIV test selected at baseline by those in the choice arm

Of the 130 participants offered a choice in testing methods who tested at baseline, 35 (26.9%) chose the SOC test, 84 (64.6%) chose supervised self-testing in the clinic and another 11 (8.5%) took a test kit for use outside of the clinic. Participants who chose the SOC test most commonly reported doing so because they preferred a healthcare provider to administer or interpret the test for them (80.0%), they preferred a blood test over an oral test (60.0%), that they were not confident they could self-administer the test correctly (17.1%), or they trusted that the healthcare provider could administer the test correctly (14.3%).

Among participants who chose supervised self-testing in the clinic, the most commonly cited reasons for this choice were that they were curious to try the new test (89.3%), they felt confident that they could administer the test correctly themselves (25.0%), they preferred to administer the test themselves (15.5%) and that they preferred an oral test (15.5%).

Among participants who took a test kit for use outside of the clinic, the most common reasons mentioned for this choice were that they preferred to administer the test themselves (90.9%); felt confident that they could administer the test correctly themselves (45.5%); preferred to be with their partner, family or friends when testing (45.5%) or preferred to be alone when testing (36.4%); preferred an oral test (27.3%); or that they did not have time to test in the clinic (27.3%) (see Table 5).

Table 5: HIV test used at baseline and reason given for test choice (choice arm, of those who tested, n = 130)

Reason for test selected	SOC test, n (%)	Supervised rapid oral self-test in the clinic, n (%)	Rapid oral HIV self-test taken for home use, n (%)
Total	*35 (26.9%)*	*84 (64.6%)*	*11 (8.5%)*
Prefer provider to administer/interpret the test	28 (80.0%)	NA	NA
Prefer to administer/interpret the test myself	NA	13 (15.5%)	10 (0.9%)
Trust the provider can administer the test correctly	5 (14.3%)	NA	NA
Do not trust the provider to administer/interpret the test correctly	NA	1 (1.2%)	0 (0.0%)
Not confident that I could do the test correctly myself	6 (17.1%)	NA	NA

Reason for test selected	SOC test, n (%)	Supervised rapid oral self-test in the clinic, n (%)	Rapid oral HIV self-test taken for home use, n (%)
Feel confident that I can administer the test myself correctly	NA	21 (25.0%)	5 (45.5%)
Trust the provider to keep the results confidential	4 (11.4%)	NA	NA
Do not trust the provider to keep the results confidential	NA	1 (1.2%)	0 (0.0%)
Prefer to be the only one who knows my results	NA	1 (1.2%)	1 (9.1%)
Prefer to have someone with me when testing	1 (2.9%)	NA	NA
Prefer to be alone when testing	NA	1 (1.2%)	4 (36.4%)
Prefer to be with a partner or loved one when testing	NA	NA	5 (45.5%)
Feel uncomfortable in clinic settings	NA	NA	1 (9.1%)
Prefer a blood test	21 (60.0%)	NA	NA
Prefer an oral test	NA	13 (15.5%)	3 (27.3%)
Wanted to try the new test/curious about the new test	NA	75 (89.3%)	0 (0%)
Did not have time to stay at the clinic to test	NA	NA	3 (27.3%)

4.4 Self-test steps where participants had questions or needed correction

Based on the observation checklist completed by the HTC counselor supervising the 84 participants who chose the oral HIV self-test at baseline, more than half of participants (52.4%) completed the self-testing process without asking questions or needing correction, while 47.6% asked questions during the self-testing and 13.1% also needed the healthcare provider to intervene with correction when they were doing something wrong and did not ask for instruction (all those requiring correction also asked questions at other steps).

Steps where participants were more likely to need correction included waiting for the full 20 minutes before reading the test result (6.2%) and correctly interpreting the test result (5.0%). Note that all the tests were negative. At each step, about 20–30% of participants asked questions, most commonly about how to open the package and remove the materials (30.9%); how to locate and remove the testing swab without touching it (30.8%); the need to wait 20 minutes before viewing the test result (30.9%); and interpreting the test result (30.0%) (see Table 6).

Almost all of the participants (97.4%) asked the healthcare provider to stay and view their test results with them, while a few (2.6%) viewed the results themselves but then disclosed the result during post-test counseling (data not shown) (Kelvin et al. 2017).

Table 6: Self-test steps where participants had questions or needed correction*

	Tested correctly alone	Tested correctly but asked questions	Needed correction during test
Total (all participants who needed correction also asked questions so total = >84)	*44 (52.4%)*	*40 (47.6%)*	*11 (13.1%)*
Looked at instructions provided	60 (73.2%)	22 (26.8%)	0 (0.0%)
Opened package and removed materials (3 missing)	54 (66.7%)	25 (30.9%)	2 (2.5%)
Removed cap on test tube (3 missing)	56 (69.1%)	24 (29.6%)	1 (1.2%)
Placed test tub in holder (3 missing)	58 (71.8%)	22 (27.2%)	1 (1.2%)
Located and removed the testing swab without touching it (6 missing)	52 (66.7%)	24 (30.8%)	2 (2.6%)
Collected oral sample (3 missing)	55 (67.9%)	23 (28.4%)	3 (3.7%)
Inserted swab into test tube (3 missing)	55 (67.9%)	24 (29.6%)	2 (2.5%)
Waited 20 minutes before reviewing for results (3 missing)	51 (63.0%)	25 (30.9%)	5 (6.2%)
Interpreted test correctly (4 missing)	52 (65.0%)	24 (30.0)	4 (5.0%)

*n = 84. Multiple responses accepted so total is more than 84

4.5 Other predictors of HIV testing

Anticipated HIV stigma (OR 0.73; p = 0.002) was significantly associated with lower odds of participants ever testing for HIV in crude models. Self-esteem score (OR 1.11; p = 0.029), Catholic religion (OR 7.86; p = 0.047) and self-reporting as married (OR 2.56; p = 0.041) were significantly associated with greater odds of ever testing for HIV in crude models. In the multivariable model, anticipated HIV stigma remained significant (OR 0.70; p = 0.010), and “other” religion (OR 0.12; p = 0.029) and number of years worked as a truck driver (OR 0.89; p = 0.034) were significantly associated with lower odds of having ever tested for HIV.

In crude models, only sensation seeking (OR 0.89; p = 0.039) was significantly associated with lower odds of having tested for HIV in the previous 3 months. In the multivariable model, Catholic religion (OR 0.43; p = 0.048) was significantly associated with lower odds of HIV testing in the previous 3 months, and self-esteem (OR 1.09; p = 0.014) was associated with greater odds of having tested in the previous 3 months (see Table 7).

Table 7: Association between scales and demographic variables with HIV testing history

	Ever tested for HIV			Tested for HIV in past 3 months		
	Crude models	**Multi-variable model[a]**	**Stepwise multi-variable model**	**Crude models**	**Multivariable model[a]**	**Stepwise multivariable model**
	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value
		n = 258	n = 258		n = 258	n = 258
Anticipated HIV stigma	n = 305	—	—	n = 305	—	—
	0.73 (0.60, 0.89) p = 0.002	0.70 (0.54, 0.91) p = 0.008	0.66 (0.52, 0.85) p = 0.001	0.94 (0.78, 1.15) p = 0.560	0.84 (0.66, 1.06) p = 0.135	0.84 (0.67, 1.06) p = 0.139
Self-efficacy	n = 305	—	—	n = 305	—	—
	0.97 (0.89, 1.06) p = 0.504	0.96 (0.83, 1.12) p = 0.599	—	1.05 (0.99, 1.11) p = 0.129	0.99 (0.91, 1.08) p = 0.801	—
Fatalism	n = 305		—	n = 305	—	—
	0.98 (0.96, 1.00) p = 0.060	0.99 (0.96, 1.03) p = 0.694	—	1.0 (0.99, 1.01) p = 0.933	1.00 (0.98, 1.02) p = 0.953	—
Gender equity	n = 305	—	—	n = 305	—	—
	1.00 (0.95, 1.05) p = 0.972	0.99 (0.96, 1.03) p = 0.861	—	1.02 (0.99, 1.05) p = 0.175	1.01 (0.97, 1.06) p = 0.570	—
Sensation seeking	n = 305	—	—	n = 305	—	—
	1.08 (0.90, 1.30) p = 0.403	0.98 (0.74, 1.29) p = 0.870	—	0.89 (0.79, 0.99) p = 0.039	0.98 (0.84, 1.15) p = 0.824	—
Self-esteem	n = 284	—	—	n = 284	—	—
	1.11 (1.01, 1.23) p = 0.029	1.08 (0.93, 1.24) p = 0.297	—	0.99 (0.95, 1.04) p = 0.751	1.09 (1.02, 1.17) p = 0.014	1.09 (1.02, 1.16) p = 0.010

	Ever tested for HIV			Tested for HIV in past 3 months		
	Crude models	**Multi-variable model[a]**	**Stepwise multi-variable model**	**Crude models**	**Multivariable model[a]**	**Stepwise multivariable model**
	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value
Age	n = 305	—	—	n = 305	—	—
	1.05 (0.99, 1.11) p = 0.115	1.13 (1.00, 1.27) p = 0.053	—	0.99 (0.96, 1.02) p = 0.511	0.98 (0.93, 1.03) p = 0.485	—
Religion	n = 299	—	—	n = 299	—	—
Protestant (Ref)	—	—	—	—	—	—
Catholic	7.86 (1.03, 60.21) p = 0.047	4.44 (0.50, 39.66) p = 0.182	6.92 (0.81, 59.03) p = 0.077	0.62 (0.31, 1.21); p = 0.159	0.43 (0.19, 0.99) p = 0.048	0.45 (0.20, 1.02) p = 0.088
Muslim	1.53 (0.49, 4.76) p = 0.461	3.61 (0.72, 18.11) p = 0.118	3.61 (0.82, 15.92) p = 0.090	0.79 (0.39, 1.57) p = 0.496	0.51 (0.23, 1.14) p = 0.130	0.51 (0.24, 1.11) p = 0.159
Other[b]	0.23 (0.05, 1.01) p = 0.052	0.12, 0.02, 0.80) p = 0.029	0.21 (0.04, 1.05) p = 0.057	0.69 (0.14, 3.44) p = 0.652	0.26 (0.04, 1.50) p = 0.130	0.30 (0.06, 1.61) p = 0.159
Secondary school graduate	n = 305	—	—	n = 305	—	—
Yes	0.69 (0.30, 1.57) p = 0.370	0.76 (0.24, 2.40) p = 0.637	—	1.42 (0.84, 2.40) p = 0.195	1.18 (0.62, 2.27) p = 0.611	—
No (Ref)	—	—	—	—	—	—
Married	n = 302		—	n = 302	—	—
Yes	2.56 (1.04, 6.31) p=0.041	3.05 (0.83, 11.29); p = 0.095	3.66 (1.19, 11.22) p = 0.023	1.35 (0.66, 2.78) p = 0.415	1.79 (0.69, 4.65) p = 0.230	—
No (Ref)	—	—	—	—	—	—

	Ever tested for HIV			Tested for HIV in past 3 months		
	Crude models	**Multi-variable model[a]**	**Stepwise multi-variable model**	**Crude models**	**Multivariable model[a]**	**Stepwise multivariable model**
	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value
Mean trucking income per month	n = 288	—	—	n = 288	—	—
KES≤24,000 (Ref)	—	—	—	—	—	—
KES>24,000	1.52 (0.64, 3.60) p = 0.340	2.23 (0.68, 7.33) p = 0.185	—	1.62 (0.87, 3.03) p = 0.130	1.37 (0.65, 2.90) p = 0.409	—
Years worked as a truck driver	n = 305	—	—	n = 305	—	—
	0.98 (0.93, 1.04) p = 0.528	0.89 (0.80, 0.99) p = 0.034	—	1.01 (0.98, 1.05) p = 0.564	1.01 (0.95, 1.06) p = 0.840	—

[a]Models also adjusted for clinic location (data not shown).

[b]"Other" religion includes Hindu, traditional African and no religion.

In crude models, gender equity (OR 0.96; p = 0.032) was significantly associated with lower odds of accepting testing at baseline and sensation seeking was associated with greater odds of accepting testing at baseline (OR 1.14; p = 0.049). In the multivariable model, no variables were significant. In crude models, secondary school completion or higher (OR 1.78; p = 0.023) was significantly associated with greater odds of testing during follow-up. In the multivariable model, secondary school education (OR 2.37; p = 0.004) and self-esteem (OR 1.06; p = 0.045) were significantly associated with greater odds of testing during follow-up and Muslim religion (OR 0.4; p = 0.013) was associated with lower odds of testing during follow-up (see Table 8).

Table 8: Logistic regression models evaluating the association between scales and demographic variables with HIV testing at baseline and follow-up

	Accepted HIV testing at baseline			Tested for HIV during follow-up		
	Crude models	**Multi-variable model[a]**	**Stepwise multi-variable model[b]**	**Crude models**	**Multi-variable model[a]**	**Stepwise multi-variable model[c]**
	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value
		n = 258	n = 258		n = 258	n = 258
Anticipated HIV stigma	n = 305	—	—	n = 284	—	—
	0.86 (0.73, 1.03) p = 0.103	0.89 (0.71, 1.11) p = 0.291	—	1.03 (0.87, 1.21) p = 0.725	1.03 (0.85, 1.23) p = 0.786	—
Self-efficacy	n = 305	—	—	n = 284	—	—
	0.96 (0.90, 1.02) p = 0.204	1.03 (0.94, 1.14) p = 0.506	—	1.02 (0.97, 1.07) p = 0.567	0.99 (0.92, 1.06) p = 0.728	—
Fatalism	n = 305	—	—	n = 284	—	—
	1.00 (0.99, 1.01) p = 0.972	1.01 (0.99, 1.04) p = 0.400	1.02 (1.00, 1.04) p = 0.126	1.00 (0.99, 1.01) p = 0.546	1.00 (0.92, 1.02) p = 0.972	—
Gender equity	n = 305	—	—	n = 284	—	—
	0.96 (0.93, 1.00) p = 0.032	0.98 (0.93, 1.03) p = 0.403	—	1.00 (0.98, 1.03) p = 0.994	0.97 (0.94, 1.01) p = 0.164	0.97 (0.94, 1.00) p = 0.061
Sensation seeking	n = 305	—	—	n = 284	—	—
	1.14 (1.00, 1.30) p = 0.049	0.99 (0.82, 1.18) p = 0.884	—	0.95, 0.86, 1.04) p = 0.249	0.94 (0.92, 1.06) p = 0.354	0.92 (0.83, 1.03) p = 0.144
Self-esteem	n = 284	—	—	n = 284	—	—

	Accepted HIV testing at baseline			Tested for HIV during follow-up		
	Crude models	**Multi-variable model[a]**	**Stepwise multi-variable model[b]**	**Crude models**	**Multi-variable model[a]**	**Stepwise multi-variable model[c]**
	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value
	1.02 (0.97, 1.08) p = 0.430	0.95 (0.88, 1.03) p = 0.232	0.94 (0.87, 1.02) p = 0.144	1.03 (0.98, 1.07) p = 0.226	1.06 (1.00, 1.13) p = 0.045	1.05 (1.00, 1.10) p = 0.070
Age	n = 305	—	—	n = 284	—	—
	1.01 (0.97, 1.05) p = 0.676	0.97 (0.91, 1.04) p = 0.379	—	1.01 (0.98, 1.04) p = 0.401	1.01 (0.97, 1.06) p = 0.673	—
Religion	n = 299	—	—	n = 279	—	—
Protestant (Ref)	—	—	—	—	—	—
Catholic	1.20 (0.58, 2.48) p = 0.630	0.97 (0.37, 2.52) p = 0.952	—	1.04 (0.58, 1.88) p = 0.886	1.17 (0.60, 2.26) p = 0.642	1.08 (0.56, 2.06) p = 0.827
Muslim	1.05 (0.48, 2.25) p = 0.893	1.60 (0.61, 4.23) p = 0.341	—	0.54 (0.29, 1.02) p = 0.057	0.39 (0.19, 0.82) p = 0.013	0.41 (0.20, 0.82) p = 0.012
Other[d]	0.32 (0.08, 1.24) p = 0.098	0.71 (0.13, 3.86) p = 0.689	—	1.41 (0.34, 5.85) p = 0.637	1.15 (0.24, 5.40) p = 0.863	1.28 (0.30, 5.50) p = 0.744
Secondary school graduate	n = 305	—	—	n = 294	—	—
Yes	0.82 (0.46, 1.47) p = 0.511	1.05 (0.99, 1.14) p = 0.907	—	1.78 (1.08, 2.92) p = 0.023	2.37 (1.31, 4.27) p = 0.004	2.28 (1.31, 3.97) p = 0.004
No (Ref)	—	—	—	—	—	—
Married	n = 302	—	—	n = 282	—	—
Yes	1.01 (0.47, 2.15) p = 0.989	0.72 (0.24, 2.14) p = 0.550	—	0.99 (0.53, 1.85) p = 0.973	0.83 (0.38, 1.83) p = 0.650	—
No (Ref)	—	—	—	—	—	—

	Accepted HIV testing at baseline			Tested for HIV during follow-up		
	Crude models	**Multi-variable model[a]**	**Stepwise multi-variable model[b]**	**Crude models**	**Multi-variable model[a]**	**Stepwise multi-variable model[c]**
	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value	OR (95% CI) p-value
Mean trucking income per month	n = 288	—	—	n = 268	—	—
KES≤24,000 (Ref)	—	—	—	—	—	—
KES>24,000	0.59 (0.29, 1.18) p = 0.134	0.77 (0.32, 1.88) p = 0.567	—	1.06 (0.61, 1.83) p = 0.837	0.92 (0.48, 1.74) p = 0.789	—
Years worked as a truck driver	n = 302	—	—	n = 281	—	—
	1.02 (0.97, 1.06) p = 0.454	1.06 (0.99, .14) p = 0.124	1.04 (0.99, 1.09) p = 0.166	1.02 (0.99, 1.06) p = 0.212	1.02 (0.97, 1.07) p = 0.497	—

[a]Models also adjusted for the randomization group and randomization assignment (data not shown).

[b]Randomization group and clinic location were included in the final model.

[c]Randomization group and clinic location were not included in the final model.

[d]"Other" religion includes Hindu, traditional African and no religion.

In re-running our multivariable regression models using stepwise regression, our overall results remained consistent. For having ever tested for HIV, anticipated HIV stigma (OR 0.66 p = 0.001) remained significantly associated with lower odds of having ever tested, but unlike the main model, other religion (OR 0.21; p = 0.057) was no longer significant and self-reporting as married (OR 3.66; p = 0.023) was significantly associated with greater odds of having ever tested.

Self-esteem (OR 1.09; p = 0.010) remained significantly associated with greater odds of having tested for HIV in the past three months (see Table 7). No variables were significantly associated with accepting testing at baseline. For having tested during follow-up, self-esteem was no longer significantly associated (OR 1.05; p = 0.07) but Muslim religion (OR 0.41; p = 0.012) and secondary school education (OR 2.28; p = 0.004) remained significant (see Table 8).

4.6 Predictors of HIV test selected when given a choice

In the crude models, among choice arm participants who tested in the clinic, which test they selected was significantly associated with their alcohol consumption and fatalism scale score. Those who had consumed alcohol in the past year had 2.3 times the odds of choosing the self-test over the provider-administered test compared to those who had not consumed alcohol in the past year (p = 0.041). For each additional unit on the fatalism scale score, the odds of choosing the self-test was 0.98 times lower (p = 0.024).

Consistent condom use and higher general self-efficacy scale scores were both associated with participants having lower odds of selecting the self-test but the associations were only of borderline significance (OR = 0.4, p = 0.120 and OR = 0.9, p = 0.135). In the multivariate model, with all variables included, only scores on the fatalism scale were significantly associated with selecting the self-test over the healthcare provider-administered test (OR = 0.96, p = 0.030), although the association with self-efficacy (OR = 0.9, p = 0.077) and consistent condom use were at borderline significance (OR = 0.2, p = 0.100).

In the backwards-stepwise regression model, only participants' fatalism score, general self-efficacy score and consistent condom use remained in the final model (OR = 0.97, p = 0.003, OR = 0.8, p = 0.008 and OR = 0.3, p = 0.081, respectively) (see Table 9).(Kelvin et al. 2017)

Table 9: Demographics and risk behaviors as predictors of selecting the oral HIV self-test (versus the healthcare provider-administered blood test) among those who tested

	Crude models			**Adjusted model (n = 98)**		**Likelihood ratio backward stepwise regression with p = <0.2 for remaining in the model) (n = 98)**	
Variable	Number	OR (95% CI)	p-value	OR (95% CI)	p-value	OR (95% CI)	p-value
Age (years)	119	1.0 (1.0–1.07)	0.624	1.0 (0.9–1.1)	0.488		
Secondary school graduate	119	0.9 (0.4–2.0)	0.751	0.7 (0.2–2.3)	0.601		
Income from truck driving > KES 24,000 per month	109	1.0 (0.4–2.5)	0.969	1.2 (0.3–4.4)	0.748		
Married	118	1.8 (0.7–4.8)	0.270	0.5 (0.1–5.2)	0.551		
Have regular partner/s on trucking route in past 6 months (road wife)	117	1.5 (0.7–3.4)	0.322	1.7 (0.5–5.70	0.421		
Paid for sex in past 6 months	113	1.3 (0.6–3.0)	0.481	0.8 (0.2–3.0)	0.731		
Always use condoms	114	0.4 (0.2–1.2)	0.120	0.2 (0.02–1.4)	0.100	0.3 (0.1–1.1)	0.081
Drank alcohol in past year	119	2.3 (1.0–5.2)	0.041	1.4 (0.5–4.1)	0.523		
Ever tested for HIV	119	1.7 (0.4–6.4)	0.447	NA	NA		
Years since tested for HIV	116	1.0 (1.0–1.0)	0.531	1.0 (1.0–1.1)	0.322		
Anticipated HIV stigma	119	0.9 (0.7–1.1)	0.224	0.8 (0.5–1.2)	0.289		
Fatalism	119	0.98 (0.96–0.99)	0.024	0.96 (0.93–0.0.99)	0.030	0.97 (0.94–0.99)	0.003
General self-efficacy	119	0.9 (0.8–1.0)	0.135	0.9 (0.7–1.0)	0.077	0.8 (0.7–0.9)	0.008
Gender equity	119	1.0 (1.0–1.1)	0.214	0.98 (0.90–1.07)	0.692		
Sensation seeking	119	1.5 (0.8–3.0)	0.219	1.4 (0.5–4.1)	0.560		

4.7 Discrete choice experiment results

Preferences in the discrete choice experiment were analyzed in comparison to a baseline or reference scenario (HIV test that is blood-based, nurse administered, in a roadside wellness clinic, with in-person counseling, taking about 90 minutes total, free).

We found that participants had a significant preference for in-person counseling over telephone-based counseling (OR for telephone-based counseling = 0.9, p = 0.003), testing at a roadside clinic over testing at company office (OR for testing at the office = 0.8, p = 0.010), tests that take less time (20 minutes versus 90 minutes OR = 1.2, p = 0.034; 3 hours versus 90 minutes OR = 0.8, p = 0.001), and tests that are free versus those with any cost to the participant (KES 200 versus free OR = 0.6, p = <0.001; KES 300 versus free OR = 0.4, p = <0.001), and even over receiving payment, although this difference is only weakly significant (KES 350 payment versus free OR = 0.9, p = 0.056) (see Table 10).

Table 10: Discrete choice experiment results

		Main effects	
Attribute	**Level**	**OR (95% CI)**	**p-value**
Type of counseling Baseline: one-on-one	Telephone-based counseling	0.9 (0.81–0.96)	0.003
Who administers the test Baseline: nurse administered	Self-administered	1.0 (0.91–1.07)	0.726
Type of test Baseline: finger prick test	Oral mouth swab test	1.0 (0.90–1.06)	0.583
Location Baseline: roadside clinic	At home	0.9 (0.75–1.00)	0.051
	At a clinic near home	0.9 (0.77–1.07)	0.257
	At the company office	0.8 (0.71–0.95)	0.010
Time Baseline: 90 min	20 minutes	1.2 (1.01–1.36)	0.034
	40 minutes	1.0 (0.81–1.14)	0.637
	3 hours	0.8 (0.67–0.90)	0.001
Cost Baseline: free	You pay KES 200	0.6 (0.49–0.65)	< 0.001
	You pay KES 300	0.4 (0.30–0.42)	< 0.001
	We pay KES 350	0.9 (0.75–1.00)	0.056
Number of observations	4,828		
Log likelihood	–1,558.694		
Pseudo R-squared	0.068		

There was significant interaction between participants ever having tested and their preferred form of counseling (interaction p = <0.001) and biological specimen used (interaction p = 0.006).

Among participants who had never been tested for HIV, there was a strong preference for telephone-based counseling (OR for telephone-based versus in-person counseling = 2.0, p = < 0.001) while among those who had tested before there was a preference for

in-person counseling (OR for telephone-based versus in-person counseling = 0.8, p = < 0.001). Among those who had never previously tested for HIV, there was a preference for an oral swab test over a finger prick (OR = 1.6, p = 0.009) while among those who had tested before there was no preference regarding the biological specimen used (OR = 1.0, p = 0.400) (see Figure 2a).

There was also a significant divergence of preferences for participants who were regular (having tested in the past 6 months and more than once) and non-regular HIV testers regarding their preferred type of counseling (interaction p = 0.021), location of the test (home versus roadside wellness clinic interaction p = 0.019; clinic near home versus roadside wellness clinic interaction p = 0.071; workplace versus roadside wellness clinic interaction p = 0.004).

For non-regular HIV testers, all significant odds ratios favored the baseline or reference test, with in-person counseling preferred over telephone-based counseling (OR = 0.7, p = <0.001), a test at a roadside clinic preferred over testing at home (OR = 0. 7, p = 0.003), at a clinic near home (OR = 0.7, p = 0.031) or at the company office (OR = 0.6, p = <0.001), and a free test preferred over one they would have to pay for (KES 250 OR = 0.5, p = <0.001; KES 300 OR = 0.3, p = <0.001).

Regular HIV testers were indifferent between service delivery characteristics for every attribute except time and money, with the odds of choosing a test that would take three hours significantly lower than a 90-minute test (OR 0.7, p = <0.001), and a test that would cost even a small fee significantly less preferable than a free test (KES 250 OR = 0.6, p = <0.001; KES 300 OR = 0.4, p = <0.001) (see Figure 2b).

There was a significant interaction between participants' marital status and counseling preference (interaction p = 0.042), biological specimen used (interaction p = <0.001) and cost of the HIV test (interaction p-value for pay KES 250 versus free = 0.001, for pay KES 300 versus free p = <0.001) (data not shown).

Among married men, there was a preference for in-person counseling (OR phone versus in-person = 0.7, p = <0.001), while among unmarried men there was no preference (OR phone versus in-person = 1.0m p = 0.956). Among married participants, there was a preference for oral versus blood-based testing (OR = 1.2, p = 0.008), while among unmarried men the preference was reversed (OR = 0.8, p = 0.001). Finally, among married men, the preference for a free test was weaker (OR for paying KES 250 versus free = 0.7, p = 0.008, OR for paying KES 300 = 0.5. p = <0.001, OR for being paid KES 350 = 0.9, p = 0.548), while among those not married the preference for a free test was stronger (OR = 0.4, p = <0.001, OR = 0.2, p = <0.001, OR = 0.8, p = 0.036, respectively) (see Figure 2c).

Figure 2: Discrete choice experiment results – stratified models by HIV testing history and marital status

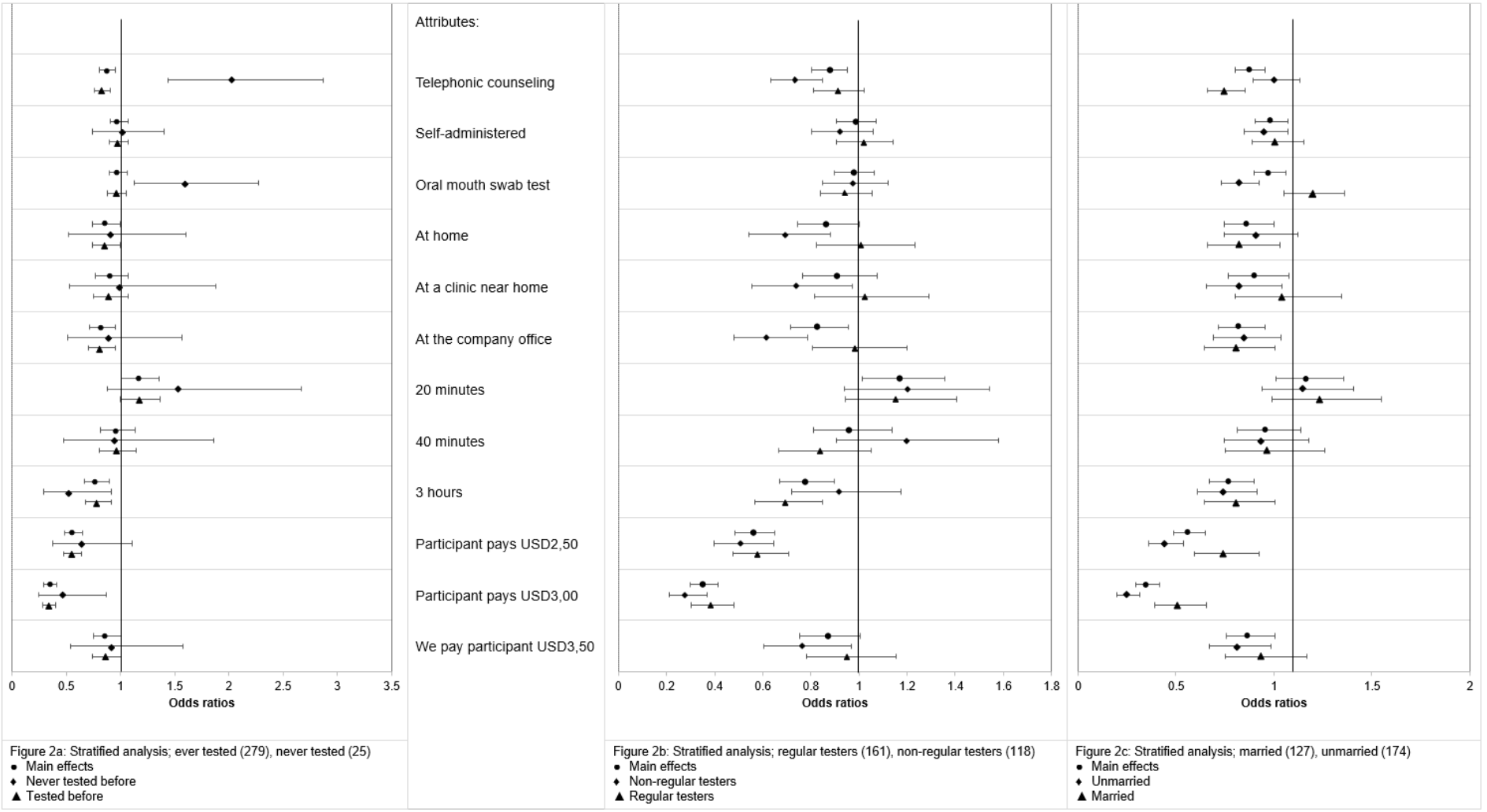


Figure 2a: Stratified analysis; ever tested (279), never tested (25)
- ● Main effects
- ♦ Never tested before
- ▲ Tested before

Figure 2b: Stratified analysis; regular testers (161), non-regular testers (118)
- ● Main effects
- ♦ Non-regular testers
- ▲ Regular testers

Figure 2c: Stratified analysis; married (127), unmarried (174)
- ● Main effects
- ♦ Unmarried
- ▲ Married

4.8 In-depth interview results

We conducted 16 in-depth interviews with participants who refused HIV testing at baseline, 11 participants in the SOC arm and five in the choice arm. As noted above, we conducted 20 in-depth interviews at baseline. After data cleaning, we found that four had tested for HIV, and were therefore ineligible for the in-depth interview and were excluded from this analysis. We also conducted in-depth interviews with eight participants in the choice arm, who were eligible to pick up a self-test kit for home use at any of the eight North Star Alliance clinics in Kenya during follow-up, but who did not test over the six-month follow-up period. A ninth participant interviewed for an in-depth interview at follow-up was later found to have been ineligible as he was in the SOC arm.

The mean age of the participants we interviewed in-depth was 37.3 years, and all reported that they had tested for HIV at some point before being recruited into the study. All of the eight participants in the choice arm interviewed at follow-up had tested at baseline (four had self-tested in the clinic with provider supervision and four had selected the provider-administered blood test). The mean time since last testing for HIV for those interviewed following baseline was 1.6 years, with a range of less than 1 month to more than 7 years since their last test.

We first present an overview of participants' beliefs and attitudes about HIV testing in general, their risk perception and beliefs regarding the benefits of antiretroviral (ARV) treatment for HIV and the impact that testing may have on their sense of masculinity or manhood. We then looked at recent barriers (in the previous three months) to clinic-based, provider-administered HIV testing reported by participants and we describe in greater detail the participants' perspectives on self-testing.

Although we attempted to explore differences in these domains by study arm, the small sample, uneven distribution of variables by study arm and the fact that the interviewers did not all address these issues in a standard manner precludes our ability to make any definitive conclusions about group differences, and thus their interpretation should be viewed with caution.

4.8.1 Importance of HIV testing

Interview participants generally felt that HIV testing was important for their health and their ability to protect and support their family:

> It [HIV testing] is very important because if I have a family, I have to think about my life and how my status is. — Participant 4154, choice arm

> It [HIV testing] is important so that you may be able to know how to live from that time henceforth so that you may not go ahead to be infected but take precautions. If you are married, then you have to make sure that your spouse is protected. Once you know your status, if you love your spouse and your family, then you would take necessary precautions to ensure that they are safe. — Participant 9012, choice arm follow-up

Most participants reported having had positive experiences when they tested in the past:

> Everything [during testing] was good actually. I mean, there is nothing I did not like, I liked everything there. There is nothing that displeased me. The whole environment was good. — Participant 5016, choice arm

> OK, up until now I think they are conducted [testing] well. Maybe the government could improve. They should improve a little bit. Make it a little easier and faster. If someone goes there, he is attended to faster. — Participant 4071, SOC arm

> I have always liked the testing services. — Participant 5119, SOC arm

However, lack of privacy was a complaint among a few interview participants:

> Interviewer: “What are some of the things you did not like when you went for testing, maybe the nurses?”

> Being given the results in public. I prefer someone being taken aside. — Participant 4016, SOC arm

> Many clinics that I know, you find maybe the place where the health provider is and where the patients are seated are so close to each other that when you speak, people can hear you out there. That also contributes to worrying. — Participant 4071, SOC arm

One interview participant complained about being given condoms that he did not want when testing:

> One experience was that I was forced to take the female and male condoms with me. Yet I am a religious man so I told the man that if I go with such things home, I will be asked questions. That irritated me because I had not gone there to request for condoms but to be tested. — (Participant 5021, SOC arm)

4.8.2 HIV risk perception on attitudes

Four of the SOC arm interview participants, two of the choice arm participants at baseline and seven of the choice arm participants at follow-up believed that they were not at risk of HIV. These participants explained that they did not engage in high-risk behavior (e.g. they used condoms with non-marital partners) or that they had tested for HIV recently. One participant qualified his risk, stating that he could only be at risk because of his wife’s behavior:

> No, I take care of myself. I don’t move around with other women. I only have my wife. — Participant 4106, choice arm

> I don’t think I am based on the knowledge I have. I used to be at risk of getting HIV when I hadn’t accepted to know my status. I had that risk. But when I accepted to know my status. You know in the earlier days, it was difficult to accept yourself. I mean getting to know your status. Then, I was at risk because I didn’t know if I had it or not until I went to [test]. In short, the person who has gone for a test to know his status is not so much at risk of getting HIV. But he

> who has not yet gone for a test, I feel he is at risk of getting it. — (Participant 4024, SOC arm)
>
> I take a lot of precaution. Because I have little children and I want them to get education. So if I was to deteriorate, health-wise, my children will suffer. I have no concerns unless my wife at home infects me. — (Participant 8018, choice arm follow-up)

4.8.3 Attitudes about antiretroviral therapy

All interview participants had positive views about ARVs, believing that this drug therapy could help to control HIV and prolong life:

> For me, I think that is the only solution and control to HIV. Without that and you decide to be misled by other people, you will die within a very short time. But if you use ARVs, you can even live for 10 years or even longer. — Participant 5145, choice arm
>
> We have some people who when they get so sick, you find out that they are infected but when they start using ARVs, you realize they become healthier and start recovering very well, and even start working and live their normal lives. So I think ARVs help in a big way. — Participant 5063, SOC arm

4.8.4 Effect on men's sense of power, manhood or virility

Only one interview participant suggested that HIV testing might have some impact on manhood or sense of masculinity:

> HIV testing sometimes brings us stress and depression. It lowers dignity in men and they feel stigmatized before even somebody else knows they are positive. They feel a lot of fear. You will see a man being so lonely, stressed and has very low confidence. At the end of the day, you see a man not being a man as usual. There are a lot of problems when you see a man being disturbed by a big thing or a small thing and you cannot tell what he is going through. So it can reduce their sense of power or manhood. — Participant 5021, SOC arm

However, 5 out of the 10 participants in the SOC arm, 1 out of 4 at baseline and 3 out of 4 at follow-up in the choice arm felt that testing HIV positive had serious implications for manhood. Being HIV positive meant that someone was sick and likely would be unable to support his family:

> You know when you go to get tested and it is a lady administering the test and let's say, for example, you find that you are positive, you feel like half of a man, half a man. So I feel it disturbs men a lot, especially if he is HIV positive. — Participant 9067, choice arm follow-up
>
> Obviously, when the HIV virus gets into you it kills is it the red blood cells or the white blood cells. The white blood cells so you become less energetic. I mean you become weak, you cannot work, you cannot fend for your families. You just sleep at home, helpless, you see. — Participant 9084, choice arm follow-up

However, some participants noted that if a man tested negative, it could actually increase his sense of power or manhood:

> Yes, after you test and find that you are HIV negative, usually one feels good, — Participant 5135, SOC arm

> Yes, if he gets tested and the result is negative, he will feel that he is a total man. — Participant 5044, SOC arm

> You know, after you have tested and found that you are HIV negative, you can even add another sexual partner. — Participant 5135, SOC arm

4.8.5 Barriers to clinic-based, provider-administered testing in the previous three months

Interview participants cited lack of time, concerns about confidentiality and stigma, already knowing their HIV status and it being less than three months since last tested as reasons for not being tested at a clinic. There were no differences in the responses of choice and SOC arm participants:

> Mostly it's time, time because of work. You know you can find free time, but there are those personal issues when you get time that's when you do your personal things. Before you finish, time is gone. — Participant 9012, choice arm follow-up

> Yes, the fear that I will be known I am here for HIV testing. — Participant 5145, choice arm

4.8.6 Attitudes about self-testing

The interview participants varied in their views about self-testing in general, and more specifically about the biological specimen used for a self-test. Those who saw a benefit in self-testing indicated that people could test on their own schedule and in privacy, and thus avoid being stigmatized or discriminated against as they might experience in a clinic. Self-testing was also seen as a way to help men plan their lives, and some participants believed that it would encourage men to test more frequently. Another perceived benefit of self-testing was the quick turnaround time for results:

> I think the main benefit is what I mentioned earlier on privacy, that you will be the only one who knows your status. — Participant 5135, SOC arm

One follow-up participant said that he did not like any type of self-testing, preferring provider-administered testing:

> If I was given the two options for self-testing [oral or blood self-test], I would say none because I want to be tested personally…. Because of my personality, I would prefer to be tested by a healthcare giver somewhere in a clinic. If not in a clinic, if you can come to my house, as long as you are a trained person, I have no problem. — Participant 9043, choice arm follow-up

Another participant was concerned about proper disposal of the test kits:

> Then he throws [the used HIV test kit] and then a child plays with the test kit and pricks him, you see it will hurt the child there. That's why I refuse this thing of

> people being given the test kit to go test themselves. — Participant 8037, choice arm follow-up

One participant complained that he would have trouble getting the privacy he needed to self-test at home:

> The issue of testing at home has no privacy. — Participant 5029, SOC arm

Other challenges to HIV self-testing included participants' concerns about the lack of in-person counseling, the potential for someone to perform the test incorrectly and accept false results, and also anxiety, fear and distrust around test results. However, regardless of their views about self-testing, participants agreed that people needed to have some type of counseling if they self-tested, and in-person counseling was generally preferred:

> I don't think [HIV counseling] through the phone helps, you know. Have you heard someone saying the telephone is for lying? Someone can lie to you that he is in Nairobi when he is not. Now you can speak to a person, but when he gets the results, he will say I didn't even see the person I was speaking to on the phone my case is bad. But if you have someone talking to face to face, he will remember that person…. As we are talking, I can just see you because we sat with you and saw each other you know. But if you will speak on the phone with someone to counsel him, you see that won't make sense. — Participant 8037, choice arm follow-up

> If you find that you are positive, you should get a professional counselor to counsel you and give you motivation and make you feel comfortable and know that even if you are positive, there is still life to live. So before someone is given that kit to test, he should be counseled and told, "If you are negative, then make sure you always are negative and if you are positive, please come and let us talk about the new way of life." People should be convinced and counseled that before they are given the kits. That's why I said before that the kits should be put in a health facility where a person who comes to pick or buy are counseled first before they are given the kits. So that whether they are positive, they will come back and give results and say, "I have found myself positive, which way should I go?" And that's when they will be guided, counseled to make them feel they are still part of the society and needs to go on with their lives….[adequacy of counseling over the phone] depends, because maybe where I will be when you are calling could be somewhere public and the people around may start saying, "This person is being counseled" because I will also have to give my views, opinions and we will discuss. So…phone is not good, I would prefer going to the facility and meeting the counselor one on one. — Participant 5021, SOC arm

One interview participant who voiced concern about self-testing believed that the test kits would be misused and lead to condomless sex:

> Of self-testing? To me I don't see any [advantages] because self-testing won't be beneficial, especially that again there will be misuse of the kit because you will want to self-test all the time you find a lady and I don't think that is a benefit because that can land you in a dangerous place. Then I was told these viruses are not detected within a short period. If you will test her, you will think she is

> negative and not use protection. To me, I don't think there is any benefit. — Participant 9067, choice arm, follow-up

Many participants believed that self-testing was a good option if they were trained properly and shown how to use the self-test kits. The biggest challenge would be learning how to use the kit, and the primary benefit would be to find out their results in private.

There were mixed opinions about the benefits of oral self-testing (as opposed to self-testing in general). Of the 20 interview participants who had an obvious position on oral self-testing, seven (2 out of 8 in the SOC arm, 2 out of 4 in the choice arm at baseline and 3 out of 8 in the choice arm at follow-up) were generally negative and 13 were positive. The reasons for the negative views varied. Participants who held positive attitudes about oral self-testing viewed it to be less painful than finger prick blood testing:

> I am usually afraid to get blood and the oral test kit does not have long processes because it is very easy to get saliva from the mouth. — Participant 5135, SOC arm

> The pricking one is painful, but the mouth one has no pain at all. — Participant 4153, SOC arm

The rapidity in return of results, endorsement of the test by trained healthcare providers and perceived efficacy of test results were seen as advantages of the oral self-test:

> Because you get to know your results in 20 minutes. You know, when one is testing, he gets very anxious to know the answer to know you have or you don't have that disease, so it will make your heart calm down because the results are fast. The positive is that you get the results instantly. The negative is that if you are testing for the first time you get very anxious and there is always that fear. But you get confident because you know it must be working correct because the healthcare workers already approved. — Participant 5145, choice arm

> Coz the provider is trained, I will be more confident. — Participant 5010, choice arm

> You will trust it because it is the doctors who invented it. — Participant 5135, SOC arm

Interview participants also reasoned that HIV is in body fluids like saliva and therefore the virus can be detected in saliva:

> You know, out of the education we have received, I know that HIV can be transmitted from bodily fluids which I think includes fluids that come out of the gums, then I think even the oral one can also be a good way of testing. — Participant 5021, SOC arm

However, other participants mistrusted the results of an oral test and believed that the virus cannot be detected in saliva, but only in blood:

> I cannot believe the results of this kind of test. Because, as per the information I have received, it is the one that uses blood that is used and gives correct results. I have never heard about the oral kit. — Participant 5119, SOC arm

> You mean the one to use in the gum? That one might not give results…Because many people say that saliva does not transfer any disease. — Participant 5029, SOC arm

One follow-up interview participant believed that oral self-testing was only for white people:

> That one I cannot do that one. You know, I was told the method that is known is the blood test. This oral one, you know, this are for white people. I cannot trust them. — Participant 9067, choice arm follow-up

Lack of familiarity with the oral swab self-test led some interview participants to report they could not comment on its advantages or feel they could say anything about it.

When asked about a hypothetical blood-based self-test, 2 of the 5 interview participants in the choice arm at baseline and 5 of the 8 at follow-up had positive views of a blood-based self-test, while 6 of the 11 participants in the SOC arm had positive views. Some participants indicated that such a test would have the benefit of high accuracy (based on the fact that it uses blood) in addition to the convenience of a self-test:

> Because it involves the direct use of blood… the positive is that the results is always accurate. — Participant 5063, SOC arm

> I think this is the best method because if you are pricked on the finger, the blood is taken and you see the results there immediately. That will be good because the blood has been tested as you see. — Participant 4071, SOC arm

> You know blood shows diseases from afar and it has confirmation, but this other oral one, that one no. — Participant 9067, choice arm follow-up

> Because we have grown up knowing about that blood test, whether it is malaria, whether it is anything. So our thoughts, our psychology still knows that is the best, although sometimes we fear pain, but that is the best. — Participant 9043, choice arm follow-up

> That is not bad…because you prick yourself and know your health. You have to get used [to it] because you have already been shown what to do. — Participant 8089, choice arm follow-up

Perceived challenges with using this blood-based self-test were pain, the fear of pricking oneself and contamination of the lancet:

> There is that pain of pricking yourself and then you get another pain if you find you are not OK. — Participant 5145, choice arm

> Negative is that sometimes I feel that the lancet used to prick may infect me of other diseases and then also that the same blood sample is used only to test HIV only whereas I feel it would have been better if used to test other diseases so that

> one leaves the hospital knowing their health status generally because one can be HIV negative, but positive with other diseases. — Participant 5021, SOC arm

> The one for pricking myself, that I can't [do]. Don't even talk about that one because I cannot see myself taking a needle and pricking myself. That is not possible. I am a coward… Maybe if someone holds my hand, that's when it will work. — Participant 8091, choice arm follow-up

When considering the results of a self-test, interview participants felt that people would view the test results as credible, but also preferred to have a healthcare provider perform a second test to confirm the results. If self-tests become available in Kenya, participants believed that truck drivers would be willing to pay KES 100–200 to purchase the kit.

4.8.7 Effect of self-testing on seeking HIV treatment

The majority of participants reported that they would seek HIV treatment if they tested HIV positive when self-testing:

> Yes, I would seek care and treatment. There are government clinics that have the drugs, and also clinics like North Star Alliance that educate people on HIV. It will be easy for them to get drugs faster because one will realize that since he is already infected with HIV, he has no other option other than to take the drugs. — Participant 5011, SOC arm

However, several participants in both study arms believed that if a person learned they were HIV positive via self-testing, this would have a negative effect on their linkage to HIV care, e.g. self-testing might encourage men not to share their results and therefore not to seek treatment:

> After that test, that man may take the results as his secret and may not share with anybody or be happy sharing. Maybe when he is negative, he can share but when he is positive, he may tend to hide. — Participant 5063, SOC arm

Reasons for not picking up self-test kit during follow-up Many of the participants who completed the follow-up interview noted that they did not have time to pick up the self-test kit due to their work schedules and not being close to a North Star Alliance clinic. A few reported that they were afraid to pick up the test kit due to stigma:

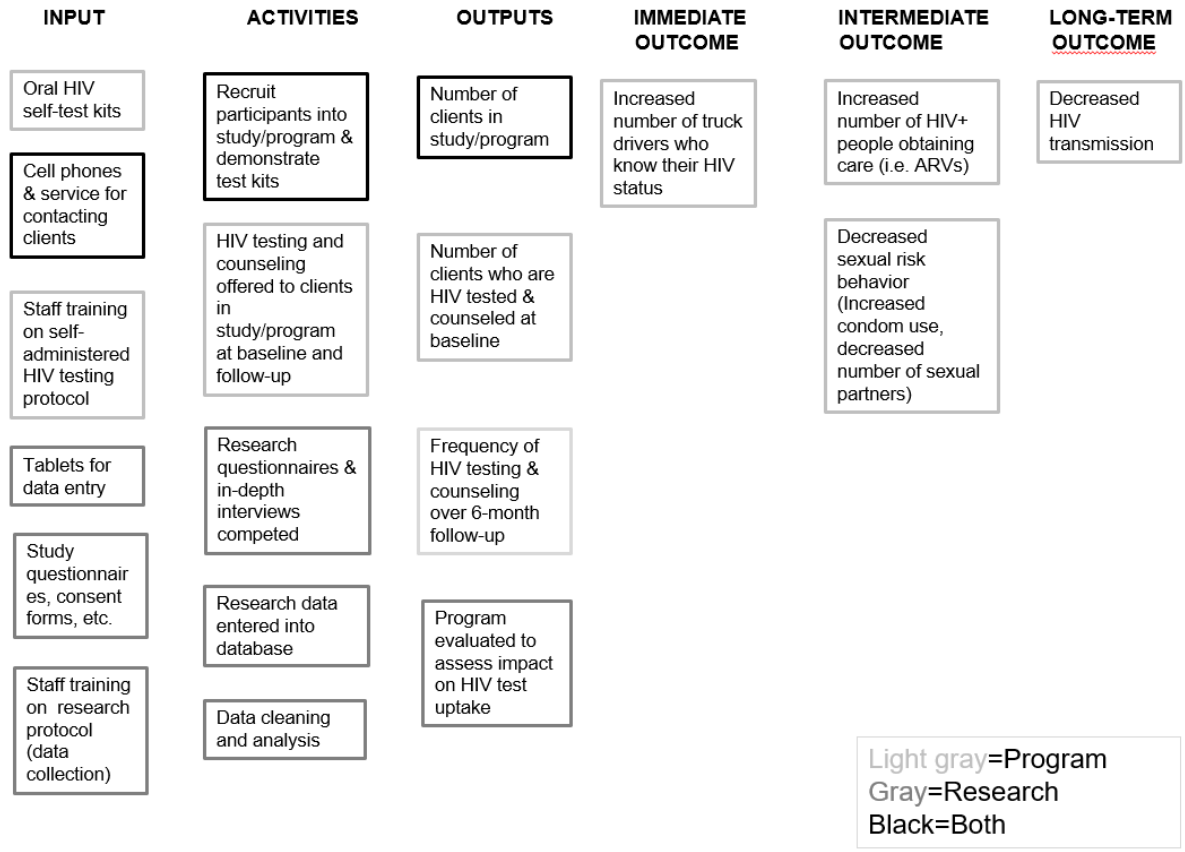
> Because some may think that you are coming to take medicine for curing HIV and AIDS. — Participant 5011, choice arm follow-up

In contrast, others stated that they already knew their HIV status (all participants in the follow-up interviews had tested at baseline). However, participants who reported that work schedule constraints hindered their picking up self-test kits indicated that if they had the kits at home, they would test themselves when they had time.

4.9 Estimation of the added cost of the choice program compared with SOC

We conducted an exercise after the program ended to estimate the cost of implementing the choice approach above the cost of the SOC approach by adding up the cost of the program-specific components included in our logic model (see Figure 3).

Figure 3: Logic model for study



Some of the costs are estimated as they were not collected formally during the study, and some cost differences were assumed negligible (e.g. the cost of clinic space), which may not be completely accurate and would need to be reassessed when implementing the choice program on a larger scale.

Thus, in estimating the cost of the choice program, we made a number of assumptions, which may not be entirely accurate:

1. The cost of time for pre- and post-test counseling per person was the same for both arms (SOC and choice), even though post-test counseling occurred over the telephone for those who took self-test kits for home use (n = 11 at baseline and n = 15 at follow-up), estimated as taking about 20 minutes in total.
2. The actual HIV testing process took 20 minutes, regardless of whether the self-test or the provider-administered test was used, and therefore the cost for the provider's time during the provider-administered test and the supervised self-test was the same.
3. The SOC HIV test kits had no cost as these kits were provided to the North Star Alliance by the Kenyan Ministry of Health for free (whereas there was a cost for the self-test kits as we had to purchase these).
4. The salary for a North Star Alliance provider (HTC counselor or other qualified provider) is roughly USD 1.50 per hour (USD 200 per month for a 35-hour workweek). There was no added cost for infrastructure for the choice program (e.g. clinic space and electricity).

Some of the costs estimated below are in part due to the fact that the choice program was being implemented within a research context rather than as a Ministry of Health-supported program. It is important to note, as described below, that two of the major drivers of the added cost of the program offered in the choice arm were the cost of the mobile phones and phone service and the cost of the self-test kits. We purchased high-end smartphones for this project and comprehensive service plans because the phones were being used for research purposes (e.g. phone-based interviews, including qualitative interviews that were recorded on the phone) as well as for phone-based, post-test counseling. Outside of a research context, it is possible that the phones and service available at the clinics would be sufficient.

Furthermore, if the Ministry of Health provides self-test kits to clinics at no cost, as it currently does with the SOC HIV test, this too would result in a large decrease in the cost of the choice program for the implementing organization. Therefore, we calculate the added cost per person in the choice arm and per additional person tested in the choice arm, both with and without the cost of the phones, phone service and test kits.

4.9.1 Additional cost for the choice arm at baseline compared with the SOC arm

a. Staff training on the self-test kits took about an hour to view the video, open and examine the test kits and discuss the best ways to demonstrate the test kits to clients. We trained four HTC counselors for this project, for an added cost of USD 6.00 (USD 1.50 per hour x 1 hour x 4 counselors), which is a total of USD 6.00 for training of counselors who served 150 people in the choice arm, or USD 0.04 per person in the choice arm.
b. We purchased four mobile phones for the telephone-based, post-test counseling so those self-testing at home could get questions answered. Each phone cost about USD 45.00. We purchased four for counseling purposes for a cost of USD 180, or USD 1.20 per person (USD 180 per 150 people) in the choice arm.
c. We paid for a mobile phone service estimated at USD 82.5 per month per phone. The baseline procedures were completed in 3 months, so this would cost USD 990 (USD 82.50 x 3 months x 4 phones), or USD 6.60 per person.
d. Each HIV self-test kit cost USD 7.54 (USD 6.50 per kit + 16% VAT). Ninety-five of the 150 people in the choice arm, or 63.33%, chose the self-test, for an average additional cost of USD 4.78 per person (7.54 x 0.6333).
e. Each participant in the choice arm was given a demonstration of the self-test kit before being asked which HIV test they would like to take. The additional cost per person to demonstrate the self-test kit was approximately USD 0.25 (calculated by assuming that it took 10 minutes of a healthcare provider's time, or 16.7% of an hour, on average, based on the duration of the OraQuick® demonstration video, which is about 6.5 minutes (see http://www.oraquick.com/Taking-the-Test/How-To-Video) plus a few minutes for questions (0.167 x 1.50).
f. In the choice arm, 131 of 150 clients (87.3%) tested for HIV, compared with 114 of 155 (72.9%) in the SOC arm, a 19.75% increase from 72.9%. If this increase is linear in relationship to the SOC rate, we expect that implementing the choice program would result in 19.75% more people in the program testing at baseline. This would result in an extra cost of pre- and post-test counseling of 20 minutes per person, or 33.3% of an hour (0.1975 x USD 1.50 x 0.333 hours) for an additional cost of USD 0.099 per person.

g. However, each HIV self-test that was used unsupervised (i.e. taken for home use) resulted in a saving of 20 minutes, or 33.3% of an hour, of the HTC counselor's time. Since 11 of the 150 participants (7.3%) took a test kit for home use, this resulted in an average saving of USD 0.04 per person (0.073 x 1.50 x 0.333).

Thus, the total additional cost of offering oral-HIV self-testing with supervision in the clinic or for unsupervised home use as choices in addition to the SOC test at baseline was USD 12.93 (0.04 + 1.20 + 6.60 + 4.78 + 0.25 + 0.099 – 0.04) per person in a 150-person program, on average. Cost would likely decrease with more participants, and increase if, over time, fewer people opted for self-testing and fewer people were inclined to test, as was observed in the follow-up period.

4.9.2 Assumptions on the added cost of self-testing in the choice arm over the 6-month follow-up compared to the SOC approach

a. We followed participants for an additional 6 months, which resulted in an additional cost of USD 1,980 (USD 82.5 x 6 months x 4 phones) or USD 13.20 (1,980 per 150 participants) per person
b. At follow-up, 18 of the 150 participants (12.0%) in the choice arm used self-test kits, which added a cost of USD 0.90 (USD 7.54 x 0.12) per person.
c. In the choice arm, 56.3% of clients tested for HIV during the 6-month follow-up compared with 55.2% in the SOC arm, a 2% increase over 55.2%. Thus, we assume that offering the choice program over a 6-month follow-up period would result in testing 2.0% more people over a 6-month period. This would result in the additional cost of the 20-minute pre- and post-test counseling of USD 0.01 (0.02 x 1.50 x 0.333) per person, on average.
d. Fifteen people in the choice arm, or 10% of the 150 participants, used the test kit outside of the clinic without supervision, for a cost saving of USD 0.05 (0.10 x 1.50 x 0.333) per person due to the lack of supervision required during the testing.
e. There was no additional cost to demonstrating the test kit since it had been demonstrated at baseline.

Thus, the total additional cost of offering the choice of oral HIV self-testing with supervision in the clinic or unsupervised home use over a 6-month follow-up period was USD 14.06 (13.20 + 0.90 + 0.01 – 0.05) per person on average.

4.9.3 Cost of implementing the choice approach at baseline and six-month follow-up compared with the SOC arm

The total additional cost of offering the choice of oral HIV self-testing with supervision in the clinic or for unsupervised home use in addition to the SOC test both at baseline and over a 6 month follow-up period was USD 26.99 (USD 12.93 + USD 14.06) per person on average.

4.9.4 Cost per additional person tested using the choice approach

The additional cost per person tested at baseline is USD 65.47 (USD 12.93 ÷ 0.1975), over six-month follow-up is USD 703 (14.06 ÷ 0.02), and at baseline and six-month follow-up combined is USD 124.09 (USD 26.99 ÷ (0.1975 + 0.02)).

If the choice program were being implemented outside of a research context on the same scale, it is likely that the phones and phone service the North Star Alliance currently has would suffice and there would be little additional cost. Further, if self-test kits were provided free by the Ministry of Health, the additional cost per person tested would be USD 1.77 at baseline (0.04 + ~~1.20 + 6.60~~ + 0.25 + ~~4.78 +~~ 0.099 – 0.04) ÷ 0.1975 = 0.349 ÷ 0.1975). There would be a saving of USD 2.00 during the 6-month follow-up per person tested (~~13.20 + 0.90~~ + 0.01 – 0.05) ÷ 0.02 = –0.04 ÷ 0.02), and a total additional cost for baseline and 6-month follow-up of USD 1.43 ((0.349 – .04) ÷ (0.1975 + 0.02)) per person tested.

Of course, if the choice program is implemented on a larger scale, there might be additional savings as well as additional costs to such scale-up related to the increased HIV testing rates, such as the need for larger clinic space, additional HTC counselors, additional phones and phone lines. These costs would depend on the level of scale-up and are beyond the scope of this costing exercise.

5. Discussion

5.1 Implications of study results

To our knowledge, this is the first study to look at offering oral HIV self-testing to truck drivers and also the first study comparing the offer of HIV testing choices to offering a single option in any population. We found that truck drivers who were offered a choice of HIV testing methods were more likely to test compared to those offered only the SOC test. This difference was not statistically significant when only looking at testing in the clinic (OR = 1.5, p = 0.189), but it was significant when including taking a test kit for use outside of the clinic (OR = 2.8, p = 0.002).

Importantly, the additional 11 participants who tested outside of the clinic had already refused both in-clinic HIV testing options and would not have tested at all if they had not been offered a test kit to take with them. The higher uptake of self-testing in the clinic (64.6%) and for use outside of the clinic (8.5%) compared to the SOC test (chosen by 26.9%) among those offered a choice suggests that truck drivers in Kenya are ready for self-testing, as has also been indicated by studies with other groups in Kenya (Heard and Brown 2016).

Furthermore, a higher proportion of the 25 participants who had never previously tested for HIV accepted HIV testing in the choice arm compared with the SOC arm (73.3% versus 50.0%). While the difference was not statistically significant, this suggests that offering oral HIV self-testing as a choice might be a way to get people to test who are not doing so under the current provider-administered, facility-based testing system. These findings are consistent with the results from the discrete choice experiment, which found that participants who had never tested for HIV had a significant preference for an oral swab test and for telephone-based counseling, two features not available with the SOC test. Those who had tested before preferred in-person counseling and had no preference regarding the biological specimen used for the test. However, larger studies are needed to determine if some of these suggestive but not statistically significant findings are real.

Study participants in the choice arm varied in which HIV test they picked, and a fair proportion (26.9%) picked the SOC test. This too is consistent with the discrete choice experiment, which found that preferences differed by HIV testing history as well as marital status. This is also consistent with the in-depth interviews, which found that participants who did not test at baseline or over follow-up had strong – but varied – preferences regarding the biological specimen used for the HIV test (oral fluid or blood). This variation in preference for blood versus oral HIV tests was also found in a qualitative study looking at views on oral self-testing among a sample of South African clinic attendees (Kelvin et al. 2016).

While this preference should not explain the failure to test for those in the choice group as they were offered both options, it could at least partially explain the failure to test for some of those in the SOC group. Therefore, oral HIV self-testing should not replace the current HIV testing options, which work for many and are preferred by some. Instead, by offering choices, people can select the HIV testing method that meets their needs and preferences.

The lack of a difference in uptake of HIV testing by study arm during follow-up was surprising. We might expect that the impact of offering testing choices during baseline would also be found during follow-up. However, it is important to note that we recruited study participants from the waiting room of the two participating clinics. While the majority of participants had not come to the clinic specifically for HIV testing, they were already at the clinic, so offering testing choices to them may have a different impact than offering choices but requiring people to go to a clinic to access those choices.

Many participants in the follow-up in-depth interviews specifically stated that the reason they did not test during follow-up was that they did not have time to go to a clinic to pick up a test kit. This has implications for making HIV self-test kits available to truck drivers, and perhaps others, in Kenya. The impact is likely to be stronger if those test kits are brought to the people than if they are made available but people need to travel to a clinic to access them.

It may also be the case that since such a high proportion of study participants tested at baseline, many who might have been motivated to test during follow-up when offered testing choices did not feel the need to do so since they had tested recently. In fact, one of the main reasons that in-depth interview participants gave for not testing during follow-up (all in the choice arm) was that they had tested recently and therefore felt confident that they knew their HIV status. Therefore, future studies should look into the impact of offering self-test kits over a longer follow-up period.

The steps in the self-testing process during which more participants asked questions or required unsolicited instruction included not contaminating the swab by touching it and waiting for the necessary amount of time before looking at the test result. These issues have been reported in another study in Kenya, where people were videotaped while self-administering the test (Kurth et al. 2016). Therefore, the instructions for these steps need to be clarified or better emphasized. This is particularly the case for the waiting time, as some people may not have access to a dependable clock and, as found in our study, even those who do may not monitor the time accurately.

However, when allowed to ask questions, we found that very few participants required actual correction during the testing process. This suggests that participants were well aware when they were unsure about what to do and asked questions to ensure that they did the testing correctly. Three of those who self-tested during follow-up chose to do so in the clinic with supervision, and that one person who took a test kit for home use at baseline later returned to the clinic to use the kit with supervision. This suggests that it is important to provide some mechanism by which people can ask questions and/or test with supervision if they prefer. Perhaps encouraging supervised self-testing the first time will allay some of people's concerns and ensure correct self-administration of future tests.

Almost all the participants who self-tested in the clinic chose to view their test results with the HTC counselor. Of the two who chose to view their results alone, both disclosed the test result to the counselor during post-test counseling. This is important, as one concern about self-testing is that people will not disclose their status and thus will not get appropriate counseling, referrals and linkages to care. In addition, it suggests that the possibility of confidentiality breaches by clinic staff is not a major concern among participants, which was supported by the generally positive experiences that in-depth interview participants reported having with HIV testing in the past.

However, all participants who self-tested in this study tested HIV negative. Whether those who test HIV positive who view their test results in private will also disclose that result during post-test counseling is unknown. Furthermore, the failure of those who self-tested outside of the clinic to contact the HTC counselor after self-testing is a concern as it suggests that some may not make the effort to obtain post-test counseling when self-testing outside of a clinic setting. Again, all of these participants reported that their tests were HIV negative. Therefore, they may not have felt the need for counseling and referrals since they had received pre-test counseling. Future research is needed to see if those testing HIV positive outside of a clinic setting will contact the clinic for counseling and referrals. While more evidence is gathered, we recommend that people who self-test outside of a clinic who do not contact clinic staff for post-test counseling should be contacted by clinic staff to ensure that they receive counseling and referrals as needed.

When looking at predictors of HIV testing, anticipated HIV stigma was significantly associated with lower odds of having ever tested for HIV in all models (crude, multivariable and when imputing missing data). This finding is consistent with another study among truck drivers in Brazil (Pulerwitz et al. 2008b) and other studies from Sub-Saharan Africa looking at non-truck driver populations (Weiser et al. 2006; Kalichman and Simbayi 2003; Mall et al. 2013; Kelly et al. 2016; Young et al. 2010). We were surprised to find that having more fatalistic views was not associated with lower HIV testing behavior. This could be because the fatalism scale we used was general and not specific to HIV. Future research could consider using the Powe Fatalism Inventory – HIV and AIDS to assess truck drivers' HIV and AIDS-related fatalism and if it influences testing uptake (Hess and McKinney 2007).

Other surprises were the lack of association of self-efficacy, gender equity and sensation seeking with HIV testing. However, keep in mind that participants in this study were all recruited from a healthcare clinic, which might have influenced these associations. We also found that participants' self-esteem score was significantly associated with greater

odds of having tested in the previous six months and testing during follow-up in the complete case multivariable model. Another study in Uganda also explored the relationship between self-esteem and having ever tested for HIV and found no significant association (OR 1.0; p = 0.819), although its population was restricted to adolescents (Hampanda et al. 2014). Certainly, future research is warranted to better understand if, and how, individual beliefs and attitudes influence HIV testing behavior.

We found that truck drivers who expressed more fatalistic views were less likely to choose the oral HIV self-test over the provider-administered blood test in all regression models (crude, multivariable and stepwise). Those with more fatalistic views might be more likely to choose the provider-administered test as fatalistic views may indicate a predilection for the more passive testing option, allowing the provider to administer the test rather than actively administering the test themselves.

We were also surprised to find that those with higher general self-efficacy were less likely to choose the HIV self-test among those who tested, although this only reached statistical significance in the stepwise model. We had expected that those with higher self-efficacy would be more likely to choose a self-test rather than having someone else administer the test. A previous study in Malawi found self-efficacy to be positively associated with HIV testing in general (Berendes and Rimal 2011), so again self-efficacy may have a different impact on test selection when given a choice, rather than on choosing to test in general. Also, since our participants were recruited from a general healthcare clinic, although they were not necessarily there for HIV testing, it is possible that the impact of self-efficacy on HIV testing may, in part, be related to getting to a clinic for testing as opposed to accepting testing when offered it after arrival at a clinic.

The results from the discrete choice analyses showed that preferences for various HIV test attributes vary by HIV testing history and marital status. Interestingly, there was no preference regarding who administered the HIV test (self or nurse) overall or in any of the subgroups examined. However, there were preferences regarding some other characteristics that may be related to self-testing, such as the use of oral fluid rather than blood, telephone-based rather than in-person counseling, and the testing location.

Participants' strong and varied preferences regarding the biological specimen used for the test and their preference for in-person counseling were echoed in the in-depth interviews. Thus, it is possible that the features of oral HIV self-testing that make it more acceptable to some groups, including some not testing under the current system, may not be self-testing itself. However, additional research is needed among truck drivers and other key populations before definitive conclusions can be drawn. It would be interesting to conduct a study in which people are offered various combinations of provider-administered oral testing, provider administered blood-testing, oral self-testing and blood self-testing, some with in-person counseling and some with telephone or Internet-based counseling, and see what people choose.

5.2 Limitations of the study

This study had a number of limitations. First, the HIV testing rate in the SOC arm at baseline (72.9%) was much higher than the 60% expected and higher than the 55% for all clients at the two clinics during the study period, and thus the study was

underpowered for some comparisons. In addition, our sample may not have been representative of all North Star Alliance clients. Specifically, only 8.2% of participants had never tested for HIV and, of those who had tested before, half had done so within the past 6 months. However, the higher testing rate we observed may also be related to offering HIV testing directly following a detailed interview about HIV testing and sexual risk behavior, which may have motivated some truck drivers to test who would not have tested otherwise.

Second, there may have been some errors in the data on self-reported measures, particularly around HIV testing history and past sexual behavior. However, our baseline HIV testing outcome was based on observation in all cases except for the 11 people who self-tested outside of the clinic, thus minimizing error. While interviewer error in the outcome (and other variables) is possible, we went through an extensive data cleaning process that included checking that the outcome was consistent with other data fields (e.g. if the outcome is a self-test in the clinic with supervision, we checked that there was a test observation form completed and that the correct version of the post-test questionnaire was administered and the answers made sense given the test used). However, some data collection errors are possible and, because of randomization, those errors would likely be non-differential by study arm and would result in bias towards the null. Finally, our results may not be generalizable to all truck drivers in Kenya or in other countries.

5.3 Policy implications

Despite these limitations, our findings suggest that offering oral HIV self-testing as a choice alongside the current testing options may have the potential to increase HIV testing rates among truck drivers in Kenya. Our results also have some important implications for policy development to deploy oral self-testing in Kenya among truck drivers, and possibly other populations. First and foremost, oral self-testing should be thought of as complementary to existing services rather than replacing them. Many of the participants in our study preferred the existing standard of care, but for others self-testing was an attractive alternative.

Implementing oral self-testing not only requires HTC counselor training and consideration with how self-testing fits into the current service model (e.g. costs and pricing, and dissemination venues), but it is critical to design appropriate information and counseling resources for clients. As we learned, questions about the self-testing process and interpretation of the results do come up during HIV testing, so clients need a way to have their questions answered. Some even need supporting through the instructions.

Similarly, mechanisms for pre- and post-test HIV counseling need to be established. Mandatory pre-test counseling might be combined with picking up self-test kits at a local clinic, but post-test counseling is more difficult to deliver because it depends on the client to seek out this service. In our study, none of the participants contacted the HTC counselor for post-test counseling. However, this may be because they all tested HIV negative and felt they did not need counseling and referrals.

An important question is whether those who test HIV-positive when self-testing outside of a healthcare venue will seek post-test counseling and referrals to care. Given the

challenge of linkage to care for those who test in a clinic setting, some consideration and program testing will be needed to ensure that those who self-test are not even less likely to link to care when required.

A possible solution to these issues might be to establish a 24-hour telephone hotline, as OraSure has done in the US (OraQuick 2016). Alternate approaches could include video-based counseling, perhaps using a QR code on the test package that links to the video when viewed using a smartphone or website. Of course, these options will only work for people with access to a landline, mobile or smartphone and/or the Internet. While such technology is increasing in Africa (Pew Research Center 2015), alternatives also need to be available for those without this access, such as via trained community health workers, pharmacists and clinic staff. Mandatory pre-test counseling might also serve to emphasize the availability of this resource to clients and the importance of seeking post-test counseling.

5.4 Conclusions

Oral HIV self-testing is acceptable and can be administered correctly by Kenyan truck drivers and other groups (Heard and Brown 2016), especially if the opportunity to ask questions is available. A number of questions remain about how best to incorporate self-administered oral HIV testing and HIV self-testing into national programs in Kenya and other African countries. If a considered approach to roll-out can be coupled with ongoing research and evaluation, and program modification when new evidence becomes available, this new technology may have the potential to reach the first 90 (that 90% of HIV-infected people know their status) in the 90-90-90 goal (UNAIDS 2014b) closer to reality.

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