Increasing HIV testing demand among Kenyan truck drivers and female sex workers

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Grantee Final Report

Accepted by 3ie: February 2019

Note to readers

Acknowledgements

Summary

The objective of this randomized controlled trial was to assess whether making HIV self-testing kits available as a testing option at North Star Alliance roadside wellness clinics in Kenya and advertising their availability via text message would increase HIV testing rates among truckers and sex workers who were irregular testers compared to sending text messages about HIV testing in general.

A sample of 2,262 male truckers and 2,196 female sex workers registered in the North Star Alliance electronic medical record system and who, based on these records, were irregular HIV testers were randomized to one of three study arms in which they were sent text messages about the HIV testing available to them at North Star Alliance Kenya clinics. Specifically, the different arms received a text, either (1) communicating the availability of HIV self-test kits at all North Star Alliance Kenya clinics which was sent three times (intervention), (2) about the availability of HIV testing in general at North Star Alliance clinics sent three times (enhanced standard of care (SOC)), or (3) about HIV testing at North Star Alliance clinics in general sent one time (SOC). When arriving at a North Star Alliance clinic in Kenya, those in the enhanced SOC and SOC groups were only offered one HIV test, the standard provider-administered rapid finger-prick blood HIV test. Those in the intervention group when arriving in a clinic were offered a choice among (1) the SOC HIV test, (2) a rapid oral HIV self-test for self-administration in the clinic with supervision or (3) the rapid oral HIV self-test kit to take for home use with phone-based post-test counselling. We followed each sample for two months and looked at differences in HIV testing using logistic regression.

Truckers and sex workers in the intervention arm were significantly more likely to test for HIV during follow-up compared to those in the enhanced SOC (OR=2.7, p=0.007 & OR=1.9, p=0.001 respectively). There was no difference in HIV testing between those in the enhanced SOC and the SOC arms for either sample. The intervention proved to be more cost effective than either the enhanced SOC or the SOC even though the HIV self-test kits cost much more than the standard provider-administered HIV test because of the higher HI testing rates in the intervention arm.

Offering HIV self-testing to high-risk populations such as truckers and sex workers and advertising their availability via text message may be a cost effect way to increase HIV testing rates in these important groups.

Contents

List of figures and tables

1. Introduction

In sub-Saharan Africa, truckers (drivers and assistants) as well as sex workers, who provide services at major transport hubs, are at higher risk for HIV compared to those working in other settings (Matama, 2013, Ojo et al., 2011). HIV transmission has been associated with migratory labour patterns and transportation routes (Ramjee et al., 1998, Abdool-Karim and Abdool-Karim, 2002), and in some areas, including East Africa, HIV rates remain high along border posts and major highways (Matama, 2013, FHY 360, 2013b, Tanser et al., 2000). A 1991 study among truck drivers in Kenya found 18% tested HIV-positive (Bwayo et al., 1991b). Sixty-one percent of the sample reported having visited female sex workers (FSW) and only 32% had ever used condoms (Bwayo et al., 1991a). A cross-sectional survey of 1896 long-distance truck drivers in South Africa between 2003-2004 found a 26% HIV prevalence with a modest dose-response relationship between time on road and HIV risk (Delany-Moretlwe et al., 2014). Other recent studies among truck drivers in Africa also found high HIV prevalence, including 23% among those age 31-40 in Nigeria (Azuonwu et al., 2011) and 15.4% among those in Mozambique (Frank et al., 2013). The work-related separation associated with truck driving may lead many to patronize commercial sex services or have multiple non-commercial partnerships along the trucking route. A recent study among 305 truckers in Kenya found that 55.9% had had paid for sex in the past 6 months and 46.6% had a regular partner along their trucking route in addition to a wife or girlfriend at home (Kelvin et al., 2017b, Kelvin et al., 2017a). HIV prevalence often is higher among FSW compared to the general population, making the use of commercial sex services a risk factor for infection. In Kenya, for example, about 30% of sex workers were HIV-positive in 2013, compared to 5.4% of the population as a whole (National AIDS Control Council of Kenya (NASCOP), 2014, Musyoki et al., 2015). Because of their complex sexual networks, truckers can be a conduit for the spread of HIV across partner types (commercial, regular partners on their trucking route, wives or girlfriends at home) as well as across national and international borders (2013a, International Labor Organization, 2005).

HIV testing among truck drivers and sex workers remains suboptimal. Few studies have looked at HIV testing among truck drivers, but one study among 1881 truck drivers in South Africa in 2003-2004 found that only 38.2% had ever been tested for HIV(Delany-Moretlwe et al., 2014). Testing among female sex workers is higher, but given their risk it is also lower than ideal. In Kenya in 2013, 68.0% of female sex workers had had an HIV test in the past 12 months (National AIDS Control Council of Kenya (NASCOP), 2014).

HIV self-testing may increase HIV-testing rates among key populations such as truckers and sex workers. A number of studies have found that offering HIV self-testing as an option increases HIV test uptake over the standard of care. A study in Kenya gave pregnant women recruited form antenatal care clinics self-testing kits to take home and give to their partners. The proportion of male partners who tested was 1.6 times higher among those in the intervention compared to those partners in the standard of care arm in which they were given an invitation card to come to the clinic for HIV testing (Masters et al., 2016). A study among female sex workers in Zambia found higher testing rates when self-tests were distributed via community health workers versus the standard care

(health workers give information about where to access clinic-based testing), but the difference was of borderline significance (84.1% versus 75.1% testing, p=0.11) (Chanda et al., 2017). A similar study in Uganda however found a significant difference (9% tested in the SOC arm versus 59.5% in the intervention arm, P=0.04) (Ortblad et al., 2017).

We conducted a randomized controlled trial in 2015 among 305 truckers looking at whether offering HIV oral self-testing as a choice to truck drivers (versus the standard of care (SOC) to offer only the blood-based provider administered test) would increase HIV testing. Truckers were recruited from the waiting rooms of two roadside wellness clinics in Kenya, randomized to the intervention or SOC and offered HIV testing as indicated by their study arm before they left the clinic (first offer of testing). In addition, those in the intervention arm were informed that they could pick-up self-test kits 3-6 months later and testing during follow-up was examined (second offer of testing). HIV testing rates were significantly higher in the Intervention group at the first offer of testing (OR=2.8, p=0.002 ,(Kelvin et al., 2017a, Kelvin et al., 2017b), but there was no difference during the 6 month follow-up (OR=1.0, p=0.972) (Kelvin et al., 2017a). There are a number of possible explanations for these findings, including: (1) the self-test may increase testing once someone is in the clinic where they can obtain a test kit (as was the case at the first offer of testing) but it is not sufficient motivation to bring people to the clinic to get a test kit (as was the case for the second offer of testing during follow-up), or (2) since HIV testing rates and frequency were high in this sample (92% had ever HIV tested before and the median time since last test was 6 months) and a high proportion tested at the first offer of testing (72.9% in SOC and 87.3% in intervention groups), few participants may have felt they needed another test by 6 month follow-up, thus maybe self-testing would have a greater impact among non-regular or infrequent testers. In fact, only 57 participants who completed follow-up had not tested at first HIV test offer and while they were more likely to test over follow-up (63.4% versus 54,2% of those who had tested, p=0.236),, the difference was not statistically significant, likely due to the small number(Kelvin et al., 2017a).

In an attempt to address some of these questions, we conducted a randomized controlled trial among samples of truckers and sex workers who were irregular HIV testers. We aimed to assess whether advertising the availability of HIV self-testing kits at clinics via text message would bring more people to the participating clinics for HIV testing compared to the standard of care text message reminder to test for HIV in general.

2. Background and Context

2.1 Political and programmatic context

The Kenyan government called for oral HIV self-testing to form part of the HIV testing and counselling policy in 2008 (NASCOP, 2008) and, in fact, since our study was completed the country has approved self-testing kits for sale in pharmacies in the country.*(WHO, 2017). R*esults from this study can help inform the expansion of HIV self-testing in the country, especially clinic-based self-testing programs.

This study was conducted in eight 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 38 clinics in eleven countries 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; behaviour change communication; HIV counselling and testing; and, in some clinics, antiretroviral therapy for those who are HIV positive and laboratory services (North Star Alliance, 2014). In 2016, the North Star Alliance served 207,038 client visits throughout Africa (North Star Alliance, 2014). In 2015, 18% of client visits at North Star clinic included HIV testing, while 33% were for primary healthcare,46% for educational sessions and behavioural change counselling. The North Star Alliance clinic system is cited as one of the most successful health interventions in the transport sector (Regondi et al., 2013).

2.2 Theory of change

Our hypothesis that HIV testing rates among truck drivers and sex workers would increase when they are informed, via text message in this case, that they have a new HIV testing option, specifically HIV self-testing, is based on Prospect theory (Tversky and Kahneman, 1981). Prospect theory is an expansion of behavioural economics that considers the certainty of various potential outcomes based on a cost-benefit analysis of the individual situation. However, this theory posits that losses hurt more than gains. Thus this theory suggests that the barriers to HIV testing that can lead to losses (time, financial and potential social costs associated with the healthcare provider-administered, clinic-based testing available) must be weighed against the benefits of knowing one's status to prevent HIV if one is HIV negative, prevent 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. Further, those potential losses may prevent accessing HIV testing even if their probability of occurrence is lower than the probability of the benefits because many people put more weight on the potential negative outcomes in their decision making process. Thus, interventions that reduce the probability of the potential costs associated with HIV testing should increase the seeking or acceptance of testing.

Oral HIV self-testing as a choice may address some of the risks associated with testing that prevent 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. Thus, self-testing may decrease the barriers currently preventing some truck drivers and sex workers 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 as it addresses the probability of risk which may be weighed more strongly in decision making than the benefits, 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 if the perception risk associated with the self-test is greater than that associated with the standard test (e.g. if they are more concerned that privacy will be breeched because someone will see them with the test kit

rather than a breech due to being seen or overheard at the clinic). The cost-benefit ratio is affected by context and individual preferences and concerns. Offering choices in HIV testing, including a self-testing option, should therefore be more likely to provide an acceptable option than offering only one HIV testing method.

2.3 Study implementation

The study was conducted in the 8 North Star Alliance clinics in Kenya among two different samples, one with male truckers and one with female sex workers. When a person comes to any North Star Alliance clinic, his/her information is entered into the electronic medical record system, including a mobile phone number if the client has one and is willing to share it. Once registered, information about any additional contacts the client has with the North Star Alliance clinic system is entered into the medical record system.

2.3.1 HIV testing standard of care:
At every client encounter in a North Star Alliance clinic, HIV testing is offered and the test used is a blood-based (finger-prick) provider-administered test. HIV testing by clients at North Star clinics is tracked in the electronic medical record system and a few times a year a text message reminder is sent to those clients who do not have a record of HIV testing in the past 3 months. The message for East Africa clients reads "North Star Alliance East Africa would wish to kindly remind you to visit any of our Roadside wellness centres for HIV testing. Your health, our priority." Other health-related text messages are also sent to individuals if they have an appointment or are due for some other test or treatment and this is client specific (so sent occasionally when appropriate); and messages are sent when there is a public health situation that people should know about (e.g. a disease outbreak).

2.3.2 The intervention
Those randomized to the enhanced SOC arm received the SOC message reminding clients to come to a clinic for HIV testing (described above in section 2.3.1), sent three times a week apart first in Kiswahili, then in English and then again in Kiswahili.

The intervention consisted of a text message informing participants that HIV self-test kits were available at all North Star Alliance clinics in Kenya. The message was sent three times a week apart, first in Kiswahili, then in English and then again in Kiswahili, and read:

"You can now self-test at home or in the clinic for HIV using a new test kit available from all North Star Alliance clinics in Kenya. Your health, our priority."

2.3.3 The HIV self-testing choice
Those in the Intervention arm who came to a North Star Alliance clinic in Kenya were given a brief demonstration of the self-testing kit and then offered a choice among (1) the standard provider-administered blood-based HIV test; (2) the self-administered oral HIV test for use in the clinic with provider supervision; or (3) a self-administered oral HIV test kit for home use. Study arm was identified by the clinic receptionist by looking-up the client's mobile phone number on an excel spreadsheet listing the numbers of those in the Intervention group. The counsellor was informed when an Intervention client came in so s/he would be given a demonstration of the self-test kit and then offered the testing

choices. Those in the Intervention arm who visited a North Star Alliance clinic outside of Kenya would be offered the SOC test only as those clinics did not have self-test kits. In addition, if someone not in the intervention arm came to a Kenyan clinic and specifically requested a self-testing kit, presumably having heard about them from someone in the intervention group, they were given the self-test so as not to lose an HIV testing opportunity. The HIV testing procedures were as follows:

Those who accepted the standard provider-administered blood-based test underwent the standard pre- and post-testing counselling and testing process.

Those who chose the self-test for supervised use in the clinic were given the OraQuick HIV self-test kit (OraSure Technologies, 2017) with written (English and Kiswahili) and pictorial instructions in a private room. An HTC counsellor sat in the room with the study participant while s/he used the HIV test (supervised self-administration) in order to answer any questions that arose during the test administration and offer correction if needed. Upon the availability of the HIV test results 20 minutes later, the client was given the option to view the results in private or with the counsellor. After viewing the HIV test results, the client received the standard post-test counselling and any needed referrals. If the client chose to view the test results in private, s/he was encouraged to disclose the test results during post-test counselling, but the final decision whether or not to disclose was the client's. If s/he did not disclose the results, the counsellor was to give the post-test counselling information for both scenarios (if the HIV test was positive and if it was negative), including information about accessing HIV care should the test have been positive.

Those who chose to take a test kit for use outside of the clinic were given pre-test counselling in the clinic and then instructed to use their test within 3 days of picking it up and to call or send a text message after using the test to receive a call-back for post-test counselling and any necessary referrals. Participants who failed to contact the clinic staff within 3 days after obtaining a test-kit were called to inquire about the use of the test and provide counselling and referrals if needed. Clients were also told that they could call or send a text at any time while self-testing should they have any questions or concerns. As with in-clinic self-testing, clients were encouraged to disclose their test results during post-test counselling, but whether or not they did so was the client's choice and if s/he did not disclose, the counsellor was to provide the information for both HIV test outcome scenarios.

2.3.4 Follow-up
Both samples were followed for 2 months to assess whether they accessed HIV testing services within that timeframe. A two month follow-up period was used based on historical data suggesting that reminder messages provide an increase in testing for approximately two weeks after which testing volume returns to normal. Two months allows for two weeks after the last message is sent plus a few more weeks to capture a few remaining that might trickle in later.

2.4 Implementation Challenges

For this study, we relied on the electronic medical record system used by the North Star Alliance clinic system for data on study participants and outcomes. Medical record data

is notorious for being messy (Kopytoff 2014). The system is dynamic and changes over time as patient information is updated. Entry of data into the system at each clinic may have a time-lag, some data may be entered incorrectly, entered into the wrong field or file, or never entered at all. What this means is that someone who met eligibility criteria at one point in time may have data added to the system at a later date which indicates he/she is ineligible. Outcome data may not be entirely accurate at the time it was pulled from the system if some data entry is pending, and phone numbers, which were used for the consent and intervention and also reconfigured to create unique ID numbers for merging data in this study, might be updated over the course of the study, making it impossible to link baseline data for outcome data for some participants. However, the large sample size available through the use of medical record data may provide sufficient power to overcome some of this messiness. In addition, the data errors are unlikely to be differential by study arm, especially in a randomized trial, and so we would expect that the direction of the bias due to data misclassification should be towards the null, making interpretation of the results easier. As described later in this report, we did find that some participants for whom we had administrative data from the clinic indicating that they had tested for HIV (our outcome of interest), did not have this indication in the electronic medical record system. While we were able to clean the data based on the clinic records, that cleaning could only be done for those in the intervention group, for whom such records were available, and thus would lead to differential misclassification, with greater error rates in the standard of care groups than in the intervention group. Therefore, for our primary analysis we used the electronic medical record data without correction, but we also ran the analysis with the corrections we were able to make to compare the impact under the two analytic methods.

3. Data and Methods

For this study (registered at RIDIE-STUDY-ID-582a2462ae2ab), we took advantage of the electronic record system and selected two separate samples of clients, one of male truckers and one of female sex workers registered in the North Star Alliance electronic medical record system.

3.1 Sample, eligibility criteria and consent

Eligibility criteria for each sample were: (1) no indication that they were HIV-positive, (2) reside in Kenya, (3) have a valid mobile phone number listed, (4) had had fewer than 4 HIV tests in the past 12 months (indicating that they were not following the recommendation to test every 3 months for 4 tests per year), (5) had not had an HIV test in the past 3 months, (6) had not participated in our previous study on self-administered HIV testing (Kelvin et al., 2017b, Kelvin et al., 2017a), (7) had an indication of male sex and trucker (driver or assistant) or female sex and sex worker.

Once the sample of eligible participants was selected from the electronic record system, we cleaned the data to remove duplicate entries with the same phone number so we would not send them study-related text messages multiple times. We kept the entry with the most recent HIV test date for the sample. The North Star Alliance then sent the following passive consent text message twice, once in Kiswahili and once in English, a week apart.

"North Star Alliance is evaluating our programs for their improvement using client information from our system. The information we use for this evaluation will not be linked to your name and you will not be contacted or have any expenses related to your inclusion. If you have questions about the use of your data, call [phone number of clinic where they had last been seen]. To have your data excluded, reply "NO" to this text."

After each consent message, any clients who contacted us indicating they wanted to opt out of having their data included were removed from the sample prior to randomization. Any further requests to opt out after randomization were considered study drop-outs and their data was excluded from analysis.

3.2 Randomization

We conducted the study first with the trucker sample which was randomized on Dec 20, 2016, and then randomized the female sex worker sample on March 2, 2017, a few months later so as not to overwhelm the clinics with the new procedures The eligible individuals in our samples who did not communicate their desire to opt out of the evaluation were randomized in a 1:1:1 ratio to one of the three study arms.

3.3 Sample size and power

Our primary outcome of interest was the comparison of HIV testing rates over a 2 month period following the first text message between the intervention and enhanced SOC arms. Current HIV testing rates among clients who have not tested in the past 3 months at the North Star clinics in Kenya is 50-58% for truck drivers and 38-48% among sex workers, depending on the month. We calculated sample size assuming the enhanced SOC will achieve the current highest rate (i.e. 58% among truck drivers and 48% among sex workers), and found that in order to find a 20% increase in the probability of testing in the intervention arm compared to the enhanced SOC arm (Risk ratio=1.2, odds ratio=1.4) at 80% power and 95% confidence level, we would need sample size of 1,100-1,500 truck drivers and a similar number of sex workers. Therefore, we set our target sample size to 750 truck drivers and 750 sex workers in each of the two study arms of primary interest, the intervention and enhanced SOC. All remaining eligible clients were allocated to the SOC arm. Thus the probability of being randomized into each of the 3 arms was determined by the number of eligible participants in order to ensured 750 in the intervention and 750 in the enhanced SOC arms.

3.4 Data collection methods

For this study, we relied on data from two sources: (1) the North Star Alliance electronic medical record system which documented HIV testing and which test was used (provider-administered test or self-test), and (2) administrative data collected at the clinics in a password protected excel spreadsheet for tracking the number of self-test kits used to order resupplies when needed and for documenting that post-test counselling was provided to at-home self-testers.

The study procedures were approved by 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.

3.5 Data Analysis

We described each sample in terms of the basic demographic characteristics (those available in the medical record system) overall and by study arm and assessed the statistical significance of any differences by study arm using a chi-square test for categorical variables and a Kruskal Wallis test for numeric variables. We then conducted logistic regression analysis to compare HIV testing during the 2 month follow-up period among clients in the intervention arm versus those in the enhanced SOC arm (primary comparison) as well as among those in the enhanced SOC versus those in the SOC (secondary comparison) to look at the impact of the content of the text message (i.e. about self-testing kits or about HIV testing in general) and of the number of text messages (1 versus 3) on HIV testing, respectively. We also used logistic regression to look at differences in clinic contact for any reason (i.e. for HIV testing or some other reason) between the groups to see if the text message brought more clients to the clinic even if some then chose not to test. Finally, we looked at whether the differences by study arm in HIV testing were modified by HIV testing history (whether the client had had an HIV test at a North Star Alliance clinic in the past year or not) and, for those in the intervention arm, we describe the HIV testing choices made.

We found some discrepancies between the electronic medical record data and the clinic administrative records that were kept on self-testers in number of people who self-tested for HIV in the intervention group. Specifically, there were 5 truckers and 38 sex workers whose data in the electronic medical record system did not indicate an HIV test but the clinics had them listed as having self-tested. This might happen for a number of reasons, such as the counsellor forgot to enter the data in the online system, or entered it but the internet connection was cut while it was being sent to the server, or the data was entered after we took our data download for these analyses. The data was downloaded from the medical record system 5 months after follow-up had ended for the truckers and 2 months after completing follow-up for the sex workers, which might explain the larger number of sex workers missing an HIV test indication in the system if some data gets entered after a significant time lag. Because of this discrepancy, we analysed the data first including these 5 truckers and 38 sex workers as not having tested (as indicated in the electronic medical records) because we did not have similar administrative data on HIV testing from the clinics for those in the SOC arms. Differential data cleaning could bias the results and incorrectly elevate the association between the intervention and HIV testing and we felt it best to err on the conservative side knowing that we might have bias towards the null. However, we also ran the analysis coding those 5 truckers and 38 sex workers as having tested, as indicated in the administrative clinic records, to see if it changed our results substantively, and while the strength of the effect increased, as would be expected, the conclusions regarding the significance of the associations remained unchanged in all comparisons.

3.6 Cost Effectiveness Analysis

3.6.1 Costing perspective and approach
Costs were estimated from the provider perspective using 2016 prices. Costs incurred prior to this period were adjusted for inflation using the annual average Kenyan inflation rate of 5.53% and 7.78% for 2015 and 2016, respectively(UNAIDS, 2000, KNBS, 2016). Costs were estimated in Kenyan Shillings (KES), and in cases where costs were

obtained in other international currencies, they were converted into the local currency. Once the analysis was complete, the results were converted to US dollars (USD) for international comparative purposes. The study used an average annual exchange rate for the base year (2016) of 101.51 KES/ 1 USD (UNAIDS, 2000). The unit of analysis identified by this study is the HTC client; hence, this costing analysis quantified the cost per client tested.

A mixed-methods approach was used to identify, measure and value costs (Hendriks et al., 2014). Costs were identified and valued using a bottom-up micro-costing approach where data were available, with the remainder estimated using a top-down gross-costing approach (Hendriks et al., 2014). Resources were allocated in line with an activity-based approach (Creese and Parker, 1994, UNAIDS, 2000), according to their economic classification, as per the activities identified:
  A. Sending text messages
  B. Pre-counselling
  C. HIV Testing
  D. Post-test counselling
  E. Call-back counselling

A secondary classification between direct and indirect costs was then implemented (Hendriks et al., 2014). In the context of this study, direct costs arose solely from the provision of the HTC service and were allocated as such. Direct costs emanating from this study included staff directly involved in HTC, as well as consumables used during the HTC process. All costs related to the text message service were also considered to be direct to that particular activity. All indirect costs identified (those not specifically borne by the HTC service) were allocated proportionally based on the amount of time healthcare providers spent per activity, such as buildings and overhead costs. All resources identified to have a lifespan greater than a year were treated as capital items and costed as such (UNAIDS, 2000). In addition to infrastructure and equipment, this included non-recurrent training and recruitment costs.

3.6.2 Data collection and analysis
The cost of providing HIV testing to clients within the different study arms depended on a number of key economic inputs including staff, consumables and medical supplies, equipment and infrastructure, training, and facility management and supervision. The approach to the collection and analysis of the data is described in the following sections:
  1. Measurement and valuation of cost items
  2. Cost allocation
  3. Cost-effectiveness analysis
  4. Outcomes
  5. Uncertainty Analysis

The measurement and valuation of cost items
Per client costs were estimated by activity for each resource identified. Primary cost data were collected. For certain resources, unit costs were available at the client level, which were multiplied by the patient utilisation of that resource to obtain a cost per client estimate (Hendriks et al., 2014). In the absence of client level data, average monthly costs per clinic were divided by the average number of HTC clients per month utilising the clinic, in order to arrive at a cost per client estimate (Hendriks et al., 2014).

Patient utilisation data were collected using questionnaires designed to first identify the exhaustive list of resources used within each of the activities, and second, to estimate the patient utilisation of each resource – the cost identification process for each activity (Hendriks et al., 2014, UNAIDS, 2000).

The questionnaire in Table 1 was distributed to clinic staff involved with HTC-related functions, as well as relevant head office staff who were directly involved with the randomized controlled trial (RCT), in order to determine the volumes of patient utilisation. All data were verified by interviews and discussions held with the relevant staff member or facility manager. The questionnaires became more specific and detailed with each round of data collection until the integrity and level of detail of the patient utilisation data was satisfactory. Additional information was obtained via email from the clinic and head office staff to clarify any remaining data uncertainties.

Table 1: Patient Utilisation Questionnaire

Resource	Data Requirement
Staff	To obtain patient utilization of staff*;* 1) If directly with patient, how many minutes per patient? 2) If indirectly with patients, what percentage of day spent on activity?
Equipment	To obtain patient utilization of equipment*;* 1) For total, for all activities that use this equipment, how many patients use it in a day? 2) For specific, for activity only, how many patients use it in a day? 3) What percentage of equipment is dedicated to activity per day?
Consumables & Running Costs	To obtain patient utilization; 1) For consumables, how many of each item are used per patient? 2) For running costs, how many patients benefit from this per month?
Infrastructure	To obtain patient utilization of infrastructure*;* 1) For total, for all activities that use this infrastructure, how many patients use it in a day? 2) For specific, for activity only, how many patients use it in a day? 3) What percentage of infrastructure is dedicated to activity per day?
Overheads	To obtain all indirect-cost items; 1) List all indirect items used in facility such as information technology, communications, water, electricity, fuel etc. 2) How many activities take place in this facility such as STI screening and treatment, TB screening etc.

To value each resource used, multiple interviews and discussions were held with relevant head office staff involved with the RCT, as well as facility managers to obtain the necessary cost information outlined in Table 2 (Hendriks et al., 2014, UNAIDS, 2000). As with the patient utilisation data collection process, the questionnaires became more specific and detailed with each round of data collection until the integrity and detail of unit cost data was satisfactory.

Table 2: Unit Cost Questionnaire

Resource	Data Requirement
Staff	1) What are their salary & benefits? 2) How many days do they work per year?
Equipment	1) What was the cost of this equipment? 2) How many years will this equipment last, before it needs to be replaced? 3) What is the cost to maintain this equipment per month?
Consumables & Running Costs	1) What is the cost of each consumable? 2) What are the running costs to provide this service per month?
Infrastructure	1) What was the cost of the facility? 2) How long will this facility last, before it needs to be replaced? 3) What does it cost to maintain facility?
Overheads	1) What do all of the indirect cost items cost per month? 2) Overall, how many patients attend facility per month?

Additional information was obtained via email from the clinic and head office staff. Where costs and costing information could not be ascertained, assumptions were made and rationalised.

Capital costs incurred by all three study arms such as infrastructure, furniture and equipment, were annuitized and apportioned for the HTC's share of usage (Hendriks et al., 2014, UNAIDS, 2000). The annuity calculation was performed in Microsoft Excel 2016 using the PMT function and required inputs such as interest rate, lifespan of the item, and purchase price. These inputs were converted to monthly values in order to estimate the monthly replacement value for each of the capital items. This study used an interest rate of 10.67 percent, the average 2016 central bank interest rate for Kenya (KNBS, 2016), in line with the costing guide (Hendriks et al., 2014). Where possible, estimates of useful life were used that were specific to the resource (Hendriks et al., 2014, UNAIDS, 2000), instead of annuitizing all capital inputs over a general three- to five-year period like other costing studies (Grabbe et al., 2010, Maheswaran et al., 2016, Sweat et al., 2000). This was considered to be a more contextually relevant approach.

Cost allocation
Indirect costs and those shared across multiple North Star health care services were allocated to the HTC function according to the proportion of HTC clients treated by the facility, which was estimated at 44.41% (Grabbe et al., 2010, Hendriks et al., 2014, Maheswaran et al., 2016). This was verified by the facility managers who estimated that the HTC function accounts for almost half of the clinic's resources, and staff time.

The counsellors reported spending 30 minutes per client on average, for HTC. More specifically, for the average HTC client (in the SOC or Enhanced SOC arms), the 30-minute period was utilised as follows: 5 minutes was spent on pre-test counselling, 20 minutes conducting the HIV test, and 5 minutes on post-test counselling. Thus the HTC share of indirect or shared costs was apportioned to each activity within the HTC function (Creese and Parker, 1994) accordingly: Activities B (5/30), C (20/30) and D (5/30), based on the fraction of time spent by the counsellors on each activity (Hendriks et al., 2014).

For the HIV self-test function (offered to participants in the Intervention arm), the cost allocation followed the same rationale used for HTC, but with different proportions. The HTC counsellors were trained to provide a five-minute demonstration of how to use the self-testing kit for clients who required guidance. Thus, for those who self-tested in the clinic with provider supervision, the total time spent by the counsellor was 35 minutes: (Activities B (5/35), C (25/35) which includes the self-test demonstration, and D (5/35). For those who self-tested at home, the total time was 15 minutes, but the activities comprising home-based HIV self-testing were still costed out of 35 minutes for methodological consistency: (Activities B (5/35) for the pre-test counselling, C (5/35) for the self-test demonstration, and E (5/35) for the call-back counselling (Hendriks et al., 2014).

Cost-effectiveness analysis
This study took an incremental approach to analysing the costs and effects of the RCT programs, using incremental cost-effectiveness ratios (ICERs) (Drummond et al., 2015).

$$ICER = (C_1 - C_0) / (E_1 - E_0),$$

where $(C_1 - C_0)$ is the magnitude of the increase in the cost of moving from one intervention to another, and $(E_1 - E_0)$ is the magnitude of the increase in outcomes resulting from that change in intervention.

C_0: Cost per client tested associated with the existing intervention
C_1: Cost per client tested associated with the intervention under analysis
E_0: The number of clients tested as a result of the existing intervention
E_1: The number of clients tested as a result of the intervention under analysis

The above equation was used to calculate the incremental cost of moving from the SOC to the Enhanced SOC arm (ICERESOC), and similarly to calculate the incremental cost of moving from the Enhanced SOC to the Intervention (ICERINT). More specifically, the difference in cost between the Enhanced SOC and the SOC was divided by the associated change in outcome between the two study arms, in order to calculate the ICERESOC. Similarly, the difference in cost of moving from the Enhanced SOC to the Intervention was divided by the associated change in outcome between the two study arms, to calculate ICERINT (Drummond et al., 2015).

The study arms were then ranked according to their respective ICERs into a league table, and the study arm associated with the lowest cost per unit of effect was deemed to be the most cost-effective (Drummond et al., 2015). In general, the lower the ICER, the more cost effective the intervention. A negative ICER could either mean that the new intervention is less effective and more costly than the existing intervention, or, that the new intervention is more effective and less costly than the existing intervention (Drummond et al., 2015).

Outcomes
The HIV testing outcome data for each of the three study arms in the RCT based solely on the data in the electronic medical record (i.e. excluding those additional 5 truckers and 38 sex workers who had an indication of self-testing in the clinic administrative records but not in the electronic medical record system) were used in our analysis.

The percentage of male truck drivers who tested was low across the RCT with 3.47% testing in the intervention arm and 1.34% and 1.31% testing in the enhanced SOC and SOC arms respectively. Of the 26 male truck drivers in the Intervention arm that tested, 15 (57.7%) opted for a self-test with 6 opting for the Provider-administered blood HIV test in the clinic. The percentage of female sex workers who tested during the RCT was higher with 10.80% testing in the intervention arm and 6.13% and 6.17% testing in the enhanced SOC and SOC arms respectively. Of the 81 female sex workers in the Intervention arm that tested, 34 (50.0%) opted for a self-test with the remaining 29 opting for the provider-administered HIV test.

Uncertainty Analysis

The study addressed uncertainty by performing a series of univariate sensitivity analyses on the major cost drivers and key parameters identified. This determined the robustness of the cost analysis and the impact on the resulting average cost per client and the ICERs estimated.

Finally, a scenario analysis was conducted that estimated optimal response rates for the SMS and HIV self-test interventions, and a cost for HIV self-test kits of $3 (a figure likely to be closer to the actual cost that kits will be procured at in Kenya).

4. Results

4.1 Trucker sample results

4.1.1 Description of the sample

On December 13, 2016, we selected the sample of 4,132 trucker clients from the medical record system who met eligibility criteria. We deleted duplicate phone numbers from the sample, leaving only the case of the phone number with the most recent HIV test date. These duplicates were cases in which the same phone number was associated with different client names in the system likely because the client was registered multiple times in the system due to the entry of variations in name either on purpose by the client (i.e. he did not want a particular clinic visit to be associated with his real name) or due to data entry errors. This left us with a sample of 2,324 truckers with unique phone numbers to whom we sent the first consent text message, after which 35 truckers contacted us to opt, and a week later we sent the second consent text message, after which an additional 6 truckers contacted us to opt out. On Dec 20, 2016 we randomized the remaining 2,262 truckers to the intervention arm (n=750), enhanced SOC arm (n=750) or SOC arm (n=762) and sent the first text message according to their study arm. The text messages were sent two more times a week apart for those in the intervention and enhanced SOC arms. During the follow-up period, two additional truckers contacted us to opt out and were excluded from analysis as study drop-outs. (Figure 1)

The mean age of the remaining truckers included in the final sample was 35.3 years and the majority (76.3%) were married or living with a partner. Most truckers worked as drivers (84.9%) and only 15.1% were trucking assistants. Overall, 73.1% had not had an HIV test in the past year, and among those who had tested in the past year, the mean time since testing was 5.9 months. The percent of participants in the sample varied by clinic in which they last received services from 0.2% in Maai Mahui to 27.7% in Salgaa.

Three truckers had last received services in clinics outside of Kenya (one in Tanzania and two in Uganda). There were no significant differences in these characteristics by study arm. (Table 3) We also compared the characteristics of those in the intervention arm to only those in the enhanced SOC arm (excluding those in the traditional SOC arm), as this was our primary comparison of interest, and found no significant differences. (Data not shown)

Figure 1: Flow of male truck driver participants (Consort Flowchart)
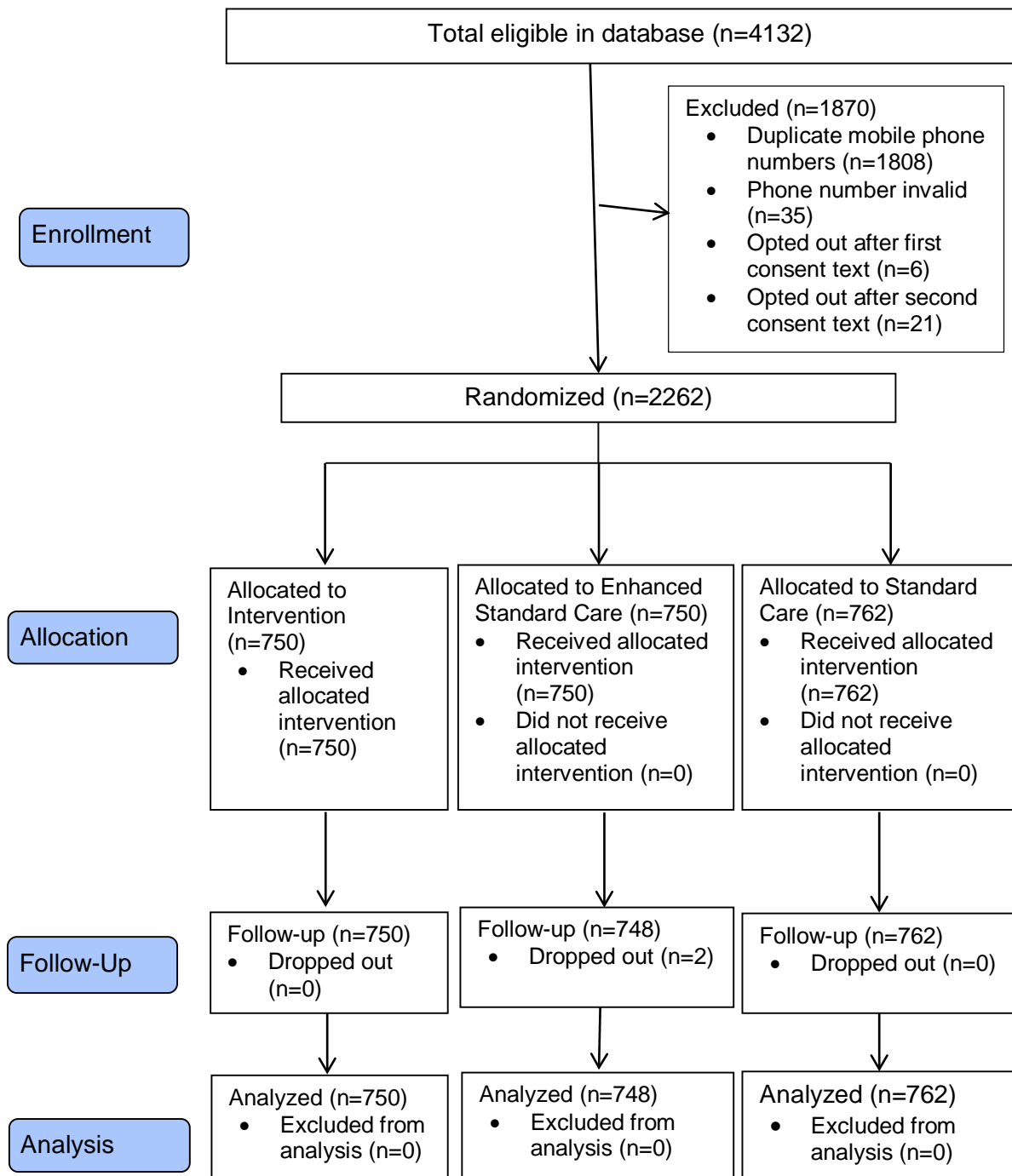
Table 3: Descriptive statistics for the sample overall and by the three study arms

	Total	Intervention	Enhanced SOC	SOC	P-value
Total, n (%)	2260 (100.0%)	750 (33.2%)	748 (33.1%)	762 (33.7%)	NA
Male, n (%)	2260 (100.0%)	750 (33.2%)	748 (33.1%)	762 (33.7%)	NA
Age					0.590[1]
Mean (SD)	35.3 (8.7)	35.2 (8.9)	35.5 (8.6)	35.2 (8.5)	
Median (Range)	34.0 (18.0-76.0)	34.0 (18.0-75.0)	34.5 (18.0-76.0)	34.0 (18.0-68.0)	
Marital status, n (%)					0.561
Married/Cohabitating	1725 (76.3%)	569 (75.9)	581 (77.7%)	575 (75.5%)	
Unmarried (single, divorced/separated)	535 (23.7%)	181 (24.1%)	167 (22.3%)	187 (24.5%)	
Trucker Job, n (%)					0.859
Driver	1917 (84.9%)	633 (84.4%)	634 (84.9%)	650 (85.4%)	
Assistant (Turnboy)	341 (15.1%)	117 (15.6%)	113 (15.1%)	111 (14.6%)	
Missing	2	0	1	1	
Test in past year, n (%)					0.254
Yes	607 (26.9%)	199 (26.5%)	188 (25.1%)	220 (28.9%)	
No	1653 (73.1%)	551 (73.5%)	560 (74.9%)	542 (71.1%)	
Months since last test among those tested in past year (among those who tested in past year)					0.301
Mean (SD)	5.9 (2.6)	5,8 (2.5)	6.1 (2.7)	5.8 (2.6)	
Median (Range)	4.0 (3.0-11.0)	4.0 (3.0-11.0)	5.0 (3.0-11.0)	4.0 (3.0-11.0)	
North Star Alliance Clinic where last seen, n (%)					0.582[2]
Burnt Forest, Kenya	17 (0.8%)	7 (0.9%)	5 (0.7%)	5 (0.8)	
Emali, Kenya	176 (7.8%)	53 (7.1%)	57 (7.6%)	66 (8.7%)	
Jomvu, Kenya	1094 (48.4%)	363 (48.4%)	370 (49.5%)	361 (47.4%)	
Maai Mahiu, Kenya	5 (0.2)	3 (0.4%)	1 (0.1%)	1 (0.1%)	
Mlolongo, Kenya	20 (0.9%)	4 (0.5%)	9 (1.2%)	7 (0.9%)	
Mombasa, Kenya	146 (6.5%)	45 (6.0%)	57 (7.6%)	44 (5.8%)	
Namanga, Kenya	174 (7.7%)	54 (7.2%)	51 (6.8%)	69 (9.1%)	
Salgaa, Kenya	625 (27.7%)	220 (29.3%)	197 (26.3%)	208 (27.3%)	
Malaba, Uganda	1 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	
Katuna, Uganda	1 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	
Tunduma, Tanzania	1 (0.0%)	1 (0.1%)	0 (0.0%)	0 (0.0%)	

[1] P-value from Kruskal Wallis Test

[2] P-value from Chi-square test

4.1.2 Logistic regression models comparing those in the intervention arm to those in the enhanced SOC arm

Overall 10 (1.3%) truckers in the enhanced SOC group and 26 (3.5%) in the intervention group tested for HIV during the 2-month follow-up. Those in the intervention group had 2.7 times greater odds of HIV testing compared to those in the enhanced SOC group which was statistically significant (p=0.009). If we include the additional 5 truckers who had an indication of HIV self-testing in the administrative clinic records as having tested, the odds ratio increases to 3.2 (p=0.002). (Table 4) The difference by study arm in HIV testing were not modified by having tested in the past year (interaction p-value=0.669). (Data not shown)

One hundred sixty nine clients in our sample had some form of contact with the North Star Alliance clinics during the follow-up period, 80 (10.7%) in the enhanced SOC arm and 89 (11.9%) in the intervention arm. Those in the intervention arm had 1.1 times greater odds of clinic contact compared to those in the enhanced SOC arm, but the difference was not statistically significant (p=0.474). If we include the additional 5 truckers who had an indication of HIV self-testing in the administrative records as having had clinic contact, the odds ratio increases to 1.2 (p=0.267). (Table 4)

Table 4: Logistic regression model results for HIV testing and clinic contact comparing the intervention to the enhanced SOC arms

	Total, n (%)	Enhanced SOC arm, n (%)	Intervention arm, n (%)	OR (95% CI)	Chi-Square p-value
Total	1498 (100.0%)	748 (49.9%)	750 (50.1%)	NA	NA
HIV Tested (according to electronic medical record system)					
Yes	36 (2.4%)	10 (1.3%)	26 (3.5%)	2.7 (1.3-5.5)	0.009
No	1462 (97.6%)	738 (98.7%)	724 (96.5%)		
HIV Tested (including the 5 participants with an indication of HIV testing in the clinic records as having tested)[1]					
Yes	41 (2.7%)	10 (1.3%)	31 (4.1%)	3.2 (1.6-6.5)	0.002
No	1457 (97.3%)	738 (98.7%)	719 (95.9%)		
Received any clinic services (according to electronic medical record system)					
Yes	169 (11.3%)	80 (10.7%)	89 (11.9%)	1.1 (0.8-1.6)	0.474
No	1329 (88.7%)	668 (89.3%)	661 (88.1%)		
Received any clinic services (including the 5 participants with an indication of HIV testing in the clinic records as having received clinic services)[1]					
Yes	174 (11.6%)	80 (10.7%)	94 (12.5%)	1.2 (0.9-1.6)	0.267
No	1324 (88.4%)	668 (89.3%)	656 (87.5%)		

[1]5 clients were noted as having HIV tested in the clinic administrative records used for tracking self-test kits and post-test counselling but their test was not indicated in the electronic medical record system. Here these 5 are recoded (data cleaned based on additional information) as having HIV-tested and the analysis rerun.

4.1.3 Logistic regression models comparing those in the enhanced SOC arm to those in the SOC arm

Overall 10 (1.3%) clients in the SOC arm and 10 (1.3%) in the enhanced SOC arm tested for HIV over the 2 month follow-up period (OR=1.0, p=0.967). There was also no difference in clinic contact between the two groups (10.6% in the SOC arm, 10.7% in the enhanced SOC arm, OR=1.0, p=0.987). (Table 5)

Table 5: Logistic regression model results for HIV testing and clinic contact comparing the enhanced SOC to the SOC arms

	Total, n (%)	SOC arm, n (%)	Enhanced SOC arm, n (%)	OR (95% CI)	Chi-Square p-value
Total with HIV Tested	1510 (100.0%)	762 (50.5%)	748 (49.5%)	NA	NA
Yes	20 (1.3%)	10 (1.3%)	10 (1.3%)	1.0 (0.4-2.5)	0.967
No	1490 (98.7%)	752 (98.7%)	738 (98.7%)		
Received any clinic services					
Yes	161 (10.7%)	81 (10.6%)	80 (10.7%)	1.0 (0.7-1.4)	0.967
No	1349 (89.3%)	681 (89.4%)	668 (89.3%)		

4.1.4 HIV testing choices made among those in the intervention arm

Of the 31 truckers who tested in the intervention arm (including the 5 identified in the administrative clinic records only), 20 (64.5%) chose a self-test. Of those, 14 (70.0%) chose to self-test in the clinic with supervision, 5 (25.0%) chose to take a test kit for home use, and one (5.0%) trucker initially took a test kit for home use but then changed his mind and returned to the clinic to test with supervision. (Table 6)

Table 6: description of HIV testing choices made for those in the intervention arm who tested[1]

	Study Sample
Total testers in the intervention group	31 (100,0%)
Chose a self-test	
Yes	20 (64.5%)
No	11 (35.5%)
Self-testing method chosen among those who self-tested	
In the clinic with counsellor supervision	14 (70.0%)
Took test kit for home use	5 (25.0%)
Took test kit for home use but returned to the clinic to use it with supervision	1 (5.0%)
Contacted clinic during or after self-testing at home	
Called while testing with questions	2 (33.3%)[2]
Called after testing for post-test counselling	1 (16.7%)
Called both during and after testing	2 (33,3%)
Did not call	1 (16.7%)
Number of contact attempts made by counsellor to reach the client who took self-test kit but did not call	2

[1] Includes the 5 clients who were listed as self-testers in the administrative records but not in the electronic medical record system.

[2] Includes the one client who decided to return to the clinic to self-test after initially taking the test-kit for home use.

Of the 6 who took a test kit for home use (including the one who changed his mind), 3 (50.0%) called while testing with questions, including the client who returned to the clinic to test with supervision, and 3 (50.0%) called after testing for post-test counselling (two called both during the testing and after for counselling). One client did not call the counsellor at all and it took two attempts for the counsellor to reach him to learn that he had used the test and provide post-test counselling. (Table 6) Five participants tested HIV+ during the study, all of whom were in the intervention group. (Data not shown)

An additional 6 clients not in the study asked for a self-test kit during the study. They were given a test kit and followed according to the study protocol to ensure they received appropriate counselling and support. (Data not shown)

4.2 Sex worker sample results

4.2.1 Description of the sample

On February 13, 2017, we selected the sample of 2,364 female sex worker clients from the medical record system who met eligibility criteria. We deleted duplicate phone numbers from the sample, leaving only the one case of the number with the most recent HIV test date. Duplicate numbers were cases in which the same phone number was associated with different client names in the system. This left us with a sample of 2,349 sex workers to whom we sent the first consent text message, after which 116 sex workers contacted us to opt out and 15 phone numbers were returned as invalid, and a week later we sent the second consent text message, after which an additional 22 sex workers contacted us to opt out. On March 2, 2017, the remaining 2,196 sex workers were randomized to the intervention (n=750), enhanced SOC (n=750) or SOC (n=696) arms and the first study text messages were sent according to their study arm. The text messages were sent two more times a week apart for those in the intervention and enhanced SOC arms. (Figure 2)

The mean age of the sex workers was 28.6 years and only a few were married or living with a partner (8.8%). Overall, 64.7% of the sex worker sample had not had an HIV test in the past year, and among those who had tested in the past year, the mean time since testing was 6.3 months. The percent of participants in the sample varied by clinic in which they last received services from 2.6% in Burnt Forest to 32.3% in Salgaa. There were no significant differences in these characteristics by study arm. (Table 7) We also compared the characteristics of those in the intervention arm to only those in the enhanced SOC arm (excluding those in the traditional SOC arm), as this was our primary comparison of interest, and found no significant differences. (Data not shown)

Figure 2: Flow of female sex workers participants (Consort Flowchart)

Total eligible in database (n=2364)

Excluded (n=168)
- Duplicate mobile phone numbers (n=15)
- Phone number invalid (not Kenyan numbers) (n=15)
- Opted out after first consent text (n-116)
- Opted out after second consent text (n=22)

Enrollment

Randomized (n=2196)

Allocation

Allocated to Intervention (n=750)
- Received allocated intervention (n=750)

Allocated to Enhanced Standard Care (n=750)
- Received allocated intervention (n=750)
- Did not receive allocated intervention (n=0)

Allocated to Standard Care (n=696)
- Received allocated intervention (n=696)

Follow-Up

Follow-up (n=750)
- Dropped out (n=0)

Follow-up (n=750)
- Dropped out (n=0)

Follow-up (n=696)
- Dropped out (n=0)

Analysis

Analyzed (n=750)
- Excluded from analysis (n=0)
- Note 2 were found to be HIV+ after randomization but are included in analysis to maintain randomization

Analyzed (n=750)
- Excluded from analysis (n=0)

Analyzed (n=696)
- Excluded from analysis (n=0)

Table 7: Descriptive Statistics for Female Sex Worker Sample Overall and by Study Arm

	Total	Intervention	Enhanced SOC	SOC	P-value
Total, n (%)	2196 (100.0%)	750 (34.2%)	750 (34.2%)	696 (31.7%)	NA
Female , n (%)	2196 (100.0%)	750 (34.2%)	750 (34.2%)	697 (31.7%)	NA
Age					0.408[1]
Mean (SD)	28.6 (5.9)	28.3 (5.9)	28.7 (6.0)	28.6 (5.9)	
Median (Range)	28.0 (18.0-61.0)	28.0 (18.0-61.0)	28.0 (18.0-52.0)	28.0 (18.0-53.0)	
Marital status, n (%)					0.356
Married/Cohabitating	176 (8.8%)	69 (9.9%)	52 (7.7%)	55 (8.8%)	
Unmarried (single, divorced/separated)	1818 (91.2%)	625 (90.1%)	620 (92.3%)	573 (91.2%)	
Test in past year, n (%)					0.862[2]
Yes	776 (35.3%)	270 (36.0%)	265 (35.3%)	241 (34.6%)	
No	1420(64.7%)	470 (64.0%)	485 (64.7%)	455 (65.4%)	
Months since last test among those tested in past year					0.144[1]
Mean (SD)	6.3 (2.6)	6.6 (2.6)	6.2 (2.6)	6.3 (2.6)	
Median (Range)	5.5 (3.0-12.0)	6.3 (3.0-12.0)	5.5 (3.0-12.0)	5.5 (3.0-12.0)	
North Star Alliance Clinic where last seen, n (%)					0.160[2]
Burnt Forest, Kenya	58 (2.6%)	19 (2.5%)	22 (2.9%)	17 (2.4%)	
Emali, Kenya	267 (12.2%)	90 (12.0%)	86 (11.5%)	91 (13.1%)	
Jomvu, Kenya	364 (16.6%)	121 (16.1%)	121 (16.1%)	122 (17.5%)	
Maai Mahiu, Kenya	265 (12.1%)	79 (10.5%)	105 (14.0%)	81 (11.6%)	
Mlolongo, Kenya	245 (11.2%)	71 (9.5%)	85 (11.3%)	89 (12.8%)	
Mombasa, Kenya	103 (4.7%)	43 (5.7%)	38 (5.1%)	38 (5.1%)	
Namanga, Kenya	185 (8.4%)	63 (8.4%)	69 (9.2%)	53 (7.6%)	
Salgaa, Kenya	709 (32.3%)	264 (35.2%)	224 (29.9%)	221 (31.8%)	

[1] P-value from Kruskal Wallis Test

[2] P-value from Chi-square test

4.2.2 Logistic regression models comparing those in the intervention arm to those in the enhanced SOC arm

Overall 106 (6.1%) sex workers in the enhanced SOC group and 81 (10.8%) in the intervention group tested for HIV during the 2-month follow-up. Those in the intervention group had 1.9 times greater odds of HIV testing compared to those in the enhanced SOC group which was statistically significant (p=0.001). If we include the additional 38 sex workers who had an indication of HIV self-testing in the administrative clinic records but not in the electronic medical record system as having HIV tested, the odds ratio increases to 2.9 (p<0.001). (Table 8) The difference by study arm in HIV testing was not modified by having tested in the past year (interaction p-value=0.851). (Data not shown)

A total of 70 (9.3%) sex workers in the enhanced SOC arm and 105 (14.0%) in the intervention arm had some form of clinic contact or service during the 2-month follow-up. Those in the intervention arm had 1.6 times greater odds of clinic contact compared to those in the enhanced SOC arm, which was statistically significant (p=0.005). If we include the additional 38 sex workers who had an indication of HIV self-testing in the administrative clinic records but not in the electronic medical record system as having had clinic contact, the odds ratio increases to 2.0 (p<0.001). (Table 8)

Table 8: Looking at differences in HIV testing and in receiving clinic services in general comparing intervention to the enhanced SOC among female sex workers

	Total, n (%)	Enhanced SOC arm, n (%)	Intervention arm, n (%)	OR (95% CI)	Chi-Square p-value
Total	1500 (100.0%)	750 (50.0%)	750 (50.0%)	NA	NA
HIV Tested (according to electronic medical record system)*					
Yes	127 (8.5%)	46 (6.1%)	81 (10.8%)	1.9 (1.3-2.7)	0.001
No	1373 (91.5%)	704 (93.9%)	669 (89.2%)		
HIV Tested ((including the 38 participants with an indication of HIV testing in the clinic records as having tested)					
Yes	165 (11.0%)	46 (6.1%)	119 (15.9%)	2.9 (2.0-4.1)	<0.001
No	1335 (89.0%)	704 (93.3%)	631 (84.1%)		
Received any clinic services (according to electronic medical record system)*					
Yes	175 (11.7%)	70 (9.3%)	105 (14.0%)	1.6 (1.2-2.2)	0.005
No	1325 (88.3%)	680 (90.7%)	645 (86.0%)		
Received any clinic services ((including the 38 participants with an indication of HIV testing in the clinic records as having received clinic services)					
Yes	199 (13.3%)	70 (9.3%)	129 (17.2%)	2.0 (1.5-2.8)	<0.001
No	1301. (86.7%)	680 (90.7%)	621 (82.8%)		

*38 clients were noted as having HIV tested in the clinic administrative records used for tracking test kits and post-test counselling but their test was not indicated in the electronic medical record system.

4.2.3 Logistic regression models comparing those in the enhanced SOC arm to those in the SOC arm

Overall 43 (6.2%) of clients in the SOC arm compared to 46 (6.1%) in the enhanced SOC arm tested for HIV over the 2 month follow-up period, giving an odds ratio of 1.0 (p=0.972). There was also no difference in clinic contact between the two groups (10.1% in the SOC arm, 9.3% in the enhanced SOC arm, OR=0.9, p=642). (Table 9)

Table 9: Looking at differences in HIV testing and in receiving clinic services in general comparing the enhanced SOC to the traditional SOC

	Total, n (%)	SOC arm, n (%)	Enhanced SOC arm, n (%)	OR (95% CI)	Chi-Square p-value
Total	1446	750 (52.0%)	696 (48.0%)	NA	NA
HIV Tested (According to the electronic medical record system)					
Yes	89 (6.2%)	43 (6.2%)	46 (6.1%)	1.0 (7.0-1.5)	0.972
No	1357 (93.8%)	653 (93.8%)	704 (93.9%)		
Received any clinic services (According to the electronic medical record system)					
Yes	140 (9.7%)	70 (10.1%)	70 (9.3%)	0.9 (0.7-1.3)	0.642
No	1306 (90.3%)	626 (89.9%)	680 (90.7%)		

4.2.4 HIV testing choices made among those in the intervention arm

Of the 119 sex workers who tested in the intervention arm (including the 38 identified in the administrative clinic records only), 71 (59.7%) chose a self-test. One participant took two HIV self-test kits from two different clinics for home use, for a total of 72 test kits used. Of those, 52 (72.2%) were used in the clinic with supervision and 20 (27.8%) taken for home use. (Table 10)

Of the 20 test kits used at home, in 5 (25.0%) cases the participant called while testing with questions, in 3 (15.0%) cases they called after testing for post-test counselling, and in 7 (35.0%) cases they called both while testing with questions and after for counselling. Five (25.0%) sex workers did not call at all, and the counsellor had to call them for post-test counselling. It took one attempt to reach three of these participants who did not call, two attempts for one participant and five attempts for one participant. (Table 10) Five sex workers tested HIV+ during the study, all of whom were in the intervention group. (Data not shown)

An additional 22 sex workers not in the study asked for a self-test kit during the study. They were given a test kit and followed according to the study protocol to ensure they received appropriate counselling and support. (Data not shown)

Table 10: description of self-testing among female sex workers in the Intervention group and 6 not in the sample who requested a self-test

	Study Sample
Total testers in the intervention group	119 (100,0%)
Chose a self-test	
Yes	71 (59.2%)
No	48 (40.3%)
Self-testing method (n=72 test kits used*)	
In the clinic with counsellor supervision	52 (72.2%)
Took test kit for home use	20 (27.8%)*
Took test kit for home use but returned to the clinic to use it with supervision	0 (0.0%)
Contacted clinic when self-testing at home	
Yes, while testing with questions	5 (25.0%)*
Yes, after testing for post-test counselling	3 (15.0%)*
Yes, both during and after testing	7 (35.0%)
No	5 (25.0%)
Number of attempts made by counsellor to reach client who took self-test kit but did not call (n=5)	
One	3 (60.0%)
Two	1 (20.0%)
Three	0
Four	0
Five	1 (20.0%)

*One person took a self-test kit twice from two difference clinics. The first time she called with questions while testing and the second time she called after testing for post-test counselling.

4.3 Costing results

4.3.1 Costs

The total cost of the trucker sample was 21% higher for the Intervention and Enhanced SOC arms, at $258.07 US and $257.88 US, respectively, compared to $212.48 US for the SOC arm. This is because fewer text messages were sent to participants in the SOC arm than the other two arms. The cost per client tested calculated for the Intervention arm was $8.32 US, while the cost per client for the Enhanced SOC and SOC arms was substantially higher at $25.79 US and $21.25 US, respectively. Although the total cost was highest for the Intervention arm, the cost per client tested was significantly lower due to the higher number of clients who tested in that arm. This trend continued for the sex worker sample with the Intervention and Enhanced SOC arms costing more that the SOC arm, however cost per client tested was lower in the intervention arm, driven primarily, by the greater number of sex workers who tested. Table 11 illustrates the SMS-related costs of the trial, costed as Activity A.

Table 11: Total SMS Costs and Average SMS Cost per Client (Activity A)

	Truckers			Sex Workers		
	Intervention	Enhanced SOC	SOC	Intervention	Enhanced SOC	SOC
Number of Text Messages Sent	8 406	8 400	6 921	8 384	8 384	6 831
Total Cost per Text Message (USD)	3.12	3.12	3.12	3.13	3.13	3.13
Total Cost per Study Arm (USD)	258.07	257.88	212.48	258.34	258.34	210.49
Number of HTC Clients per Arm	26	10	10	81	46	43
Cost per Client (USD)	9.93	25.79	21.25	3.19	5.62	4.90

The average cost per client tested attributed to the provider-administered HIV test and HIV self-test is broken down by economic classification in Table 12. The total costs of the counselling and testing component of the interventions were significantly different, depending on whether the client opted to self-test or for the conventional provider clinic-based test. A further difference in cost was dependent on whether the client chose the in-clinic self-testing option, or the home-based self-testing option. The cost per provider-administered HIV test was calculated at USD 5.01, while for HIV self-test, this cost was more than double, at USD 14.13 and USD 12.08 for the two self-testing options. This was mostly driven by the cost of the test kit itself (USD 7.95 +16%VAT), included in Table 12 under consumables/medical supplies/running costs. For conventional HTC, the bulk of the cost was attributed to staff costs (USD 1.15) and general clinic overheads (USD 2.05). For HIV self-testing, all costs other than the consumables/medical supplies/running costs and staff costs were lower than those calculated for HTC, with the vast majority of the total cost driven by the cost of the test kits.

Table 12: Average cost per HTC and HIV self-test client (activities B, C, D and E)

	Resource	HTC Cost per Client (USD)	HIV self-test Cost per Client (USD)	
			In clinic	Home-based
Staff	HTC counsellors	1.15	1.35	0.58
Consumables/medical supplies/running costs	Various	0.43	9.37	9.42
Equipment	Cell phones	-	-	0.62
Infrastructure	Clinic site	0.83	0.83	0.36
Training/recruitment	Once-off Training	0.03	0.03	0.01
	Once-off recruitment	0.00	0.00	0.00
Overheads and supervision	Site co-ordinator	0.51	0.51	0.22
	General overheads	2.05	2.05	0.88
Total: HIV self-test COST per client		5.01	14.13	12.08

Table 13 illustrates the total cost of the HIV testing activities, amounting to USD 1129.07 for the truckers and USD 2194.81 for the FSWs. The cost for the FSWs was almost double that of the truck drivers due to the larger number of FSWs that returned for testing. However, the cost per FSW client tested was substantially lower than that of the trucker across all study arms. The cost per client tested for the truckers ranged between USD 21.48 and USD 30.80 and from USD 9.90 to USD 15.80 for the FSWs, with the lowest cost per client tested for each group attributed to the Intervention, followed by the SOC arm, with the enhanced SOC having the highest cost per client tested.

Table 13: Total Cost and Cost per Client by study arm, truck drivers (Activities A – E)

	Number of HTC Clients	Total Cost per Activity (USD)					Total Cost per Study Arm (USD)	Cost per Client (USD)
		Activity A	Activity B	Activity C	Activity D	Activity E		
Truckers								
Intervention	26	258.06	18.20	259.14	14.11	9.00	558.51	21.48
Enhanced SOC	10	257.88	7.63	34.84	7.63	-	307.98	30.80
SOC	10	212.48	7.63	34.84	7.63	-	262.57	26.26
Total: Study costs	46	728.42	33.45	328.83	29.36	9.00	1,129.07	
% of total costs		64.52%	2.96%	29.12%	2.60%	0.80%	100.00%	
Female Sex Workers								
Intervention	81	258.34	55.90	893.60	42.28	30.00	1,280.12	15.80
Enhanced SOC	46	258.34	35.08	160.29	35.08	-	488.79	10.63
SOC	43	210.49	32.79	149.83	32.79	-	425.90	9.90
Total: Study costs	170	727.17	123.77	1,203.72	110.15	30.00	2,194.81	
% of Total Costs		33.13%	5.64%	54.84%	5.02%	1.37%	100.00%	

4.3.2 Cost-effectiveness results

For the trucker sample, the Enhanced SOC was not an effective or cost-effective alternative to the SOC arm. The Intervention arm was the most cost-effective for the trucker's sample, driven primarily by the increased number of testers. The ICER of the Intervention and Enhanced SOC arms was USD -0.58/1. Similarly, the Intervention arm was the most cost-effective option for FSWs, with an ICER of USD 0.15 per additional client tested. The Intervention arm is the most cost-effective option across the three

study arms for both population samples; however, it is far more cost-effective for the FSW sample due to the greater number who tested.

The CEA framework was determined to be robust to changes in the majority of significant cost drivers and parameters, with the exception of changes to outcomes, the cost of HIV self-test kits, and the supporting costs of sending SMSs.

Table 14: The ICERs across Study Arms, Truck Drivers

		Cost per Client (USD)	Outcomes	Change in Cost (USD)	Change in Outcome	ICER (USD)
Truck Drivers	SOC	26.26	10	-	-	-
	Enhanced SOC	30.80	10	4.54	0	-
	Intervention	21.48	26	-9.32	16	-0.58
Female Sex Workers	SOC	9.90	43	-	-	-
	Enhanced SOC	10.63	46	0.72	3	0.24
	Intervention	15.80	81	5.18	35	0.15

4.3.3 Sensitivity analysis

The sensitivity analysis revealed that a lower average monthly salary (by 43.98%) reduced the cost per client across all study arms by approximately USD 0.5, while the ICER for the Enhanced SOC and Intervention remained the same. The same effect was observed in reverse when implementing a 40.07% increase in salaries.

Spending an extended period of time with clients (45 minutes) increased the cost per client by USD 0.58 across the SOC and Enhanced SOC study arms, compared to a USD 0.13 increase in the Intervention arm. The ICER for the Intervention became more cost-effective by USD 0.03. Doubling the average HTC timeframe to 60 minutes increased the cost per client by USD 0.58, across the SOC and Enhanced SOC, and by USD 0.34 for the Intervention arm. The ICER decreased by a further USD 0.01 for the Intervention arm.

Because the cost of an HIV self-test kit was a key driver in the costs of the intervention, sensitivity analysis on this parameter had a large effect on the cost-effectiveness of the intervention. Changing the cost to USD 5 decreased the cost per client tested and the ICER for the Intervention arm by USD 3.25 and USD 0.20, respectively. Further decreasing the cost to USD 2.00 resulted in a USD 5.56 decrease in the cost per client as well as a USD 0.35 decrease in the ICER for the Intervention arm.

Sensitivity analysis on whether self-testing is supervised or not, revealed a difference in cost. Removing the supervisory costs resulted in a decrease of USD 2.07 and USD 0.13 in the cost per client and ICER of the Intervention arm respectively.

Assuming a discount rate of 3% decreased the cost per client by USD 0.35 across the SOC and Enhanced SOC, and by USD 0.30 in the Intervention arm, but has no effect on the ICERs.

Removing the supporting costs (staff time) associated with effecting Activity A (SMS intervention) resulted in a decrease of USD 8.68, USD 10.54 and USD 4.06 in the cost per client in the SOC, Enhanced SOC and Intervention arms, respectively. The ICERINT increases by USD 0.41 due to the decreased cost per client of the Enhanced SOC relative to the Intervention.

Table 15: Sensitivity analysis of ICER determinants

		Average Salary		Minimum Salary		Maximum Salary	
		Cost per Client (USD)	ICER (USD)	Cost per Client (USD)	ICER (USD)	Cost per Client (USD)	ICER (USD)
Salary	SOC	26.26	-	25.75	-	26.72	-
	Enhanced SOC	30.80	-	30.29	-	1.26	-
	Intervention	21.48	-0.58	20.99	-0.58	21.93	-0.58
		30 Minutes		45 Minutes		60 Minutes	
Time taken for testing	SOC	26.26	-	26.83	-	26.83	-
	Enhanced SOC	30.80	-	31.37	-	31.37	-
	Intervention	21.48	-0.58	21.61	-0.61	21.82	-0.60
		Test Kit = USD 9.22		Test Kit = USD 5.00		Test Kit = USD 2.00	
Price of HIV self-test kit	SOC	26.26	-	26.26	-	26.26	-
	Enhanced SOC	30.80	-	30.80	-	30.80	-
	Intervention	21.48	-0.58	18.23	-0.79	15.93	-0.93
		Supervised		Unsupervised			
Supervised vs unsupervised testing	SOC	26.26	-	6.26	-		
	Enhanced SOC	30.80	-	30.80	-		
	Intervention	21.48	-0.58	19.41	-0.71		
		Discount Rate = 10.67%		Discount Rate = 3.00%			
Discount rate	SOC	26.26	-	25.90	-		
	Enhanced SOC	30.80	-	30.44	-		
	Intervention	21.48	-0.58	21.18	-0.58		
		With Supporting Costs		Without Supporting Costs			
Supporting costs	SOC	26.26	-	17.58	-		
	Enhanced SOC	30.80	-	20.26	-		
	Intervention	21.48	-0.58	17.43	-0.18		

4.3.4 Scenario Analysis

From the sensitivity analysis, this study postulated a scenario in which the cost per client tested of and the resulting ICERs were considerably lower, using realistic assumptions drawn from the literature reviewed. The results of this scenario analysis are depicted in Table 16.

An HIV self-test kit price of USD 2 was assumed (Cambiano et al., 2015, WHO, 2017), along with an 80% preference for HIV self-testing in the intervention arms (Choko et al., 2011, Jamil et al., 2017). The Enhanced SOC response rate is increased to 55% (De Tolly et al., 2012), while that of the Intervention arm increased first to 55%, and then 60% (De Tolly et al., 2012). The ratio of in-clinic to home-based self-tests was maintained from the actual outcomes of the RCT (7:3). From the results above, the cost-effectiveness threshold of the Intervention, for the assumed values lies somewhere between a response rate of 65% and 70% in the intervention arm if the SOC is at 55%.

Table 16: Scenario Analysis of ICER determinants

	Actual Outcomes		65% Intervention Response		70% Intervention Response	
	Cost per Client (USD)	ICER (USD)	Cost per Client (USD)	ICER (USD)	Cost per Client (USD)	ICER (USD)
SOC	26.26	-	5.54		5.54	
Enhanced SOC	30.80	-	5.64	0.01	5.64	0.0145
Intervention	21.48	-0.58	7.21	0.04	6.53	0.0075

5. Discussion

HIV testing in these samples at baseline was very low, with only 26.9% of truckers and 35.3% of sex workers having had an HIV test in the past year. Testing rates overall during study follow-up were also low, at about 1% of truckers and 6% of sex workers in both the enhanced and traditional SOC arms. Advertising self-test kits increased HIV testing rates to 3.5% among truckers and 10.8% among sex workers, and thus increase was statistically significant. This is not very different from the increase in HIV testing at first offer of testing following randomization that we found when recruiting truckers from the waiting room of two North Star Alliance clinics in Kenya. In that study, most had HIV tested recently (median time since last test < 6 months) and only 8.2% had never tested before. Those in the intervention arm in which self-testing was offered as a choice had 2.8 times higher odds of testing compared to those in the SOC arm (Kelvin et al., 2017b, Kelvin et al., 2017a). Thus the relative increase in testing rate is fairly consistent across the two studies that differed in terms of how the self-test was initially introduced (by the counsellor when the client was already in the clinic versus via text message) and in terms of HIV testing history of the participants. It is interesting that this size of effect was similar among our sample of infrequent HIV testers and among the sample in our previous study who had tested more recently. However, the absolute difference in testing rates differed widely between the two groups (2.2 per 100 more truckers and 4.7 per 100 more sex workers testing in this study versus 14.9 per 100 people in the previous study) because in this study the baseline (or SOC) testing rate was very low. The higher baseline testing rate among the sex workers and the greater impact of the intervention in this group may be due to the fact that the sex workers work close to the clinics in local hotspots (the clinics are located near hotspots by design) as well as the possibility that sex workers have a higher perception of risk than truckers due to their profession.

Our use of text messaging in this study to advertise the availability of a new HIV testing option is also an important innovation which could be useful as countries roll out self-testing in various venues. HIV self-testing was initiated in Kenya in May 2017, a month after our study ended, with plans to make it available at public and private clinics and in pharmacies for a low cost of about $8 US (UNAIDS, 2017). Text messages could be used to inform the public as the test kits become available in new locations. Our text message was fairly simple, due to the character limits set for text messages, but now OraQuick has a video and package insert available online in multiple African languages, including Kiswahili (OraSure Technologies, 2017). With the increasing proliferation of smart phones in Kenya (Pew Research Center, 2015), the link could be sent to people so they can see what the self-test is and how it works. Providing more information about the self-test might lead to a further increase in test uptake over what we achieved with such a simple message.

Despite the success of our intervention, the percent testing even under the intervention remained alarmingly low (3.5% of truckers and 10.8% of sex workers in the intervention arm). Clearly offering self-testing at North Star Alliance clinics is only a partial solution to the low HIV testing rates among some truckers and sex workers, and other mechanisms will also be needed to increase testing rates in these important populations. One possible barrier may be the distribution mechanism. Distributing test-kits through clinics may not reach those who are unable to access or do not feel comfortable going to clinics. Although everyone in our study had received services from the North Star Alliance clinic system at least once in the past as indicated by their registration in the medical record system, some may have gotten those services via outreach instead of visiting a clinic. Other studies have looked at secondary distribution mechanisms for getting self-test kits to people. One study in Kenya compared HIV testing rates among male partners of women recruited in antenatal care clinics when the women were given self-test kits to give their partners for home use versus the standard of care in which women gave their partners a letter referring them to a clinic for standard HIV testing. In that study the HIV testing rate among the male partners was 1.76 times higher in the intervention group, 51.7% among the SOC arm versus 90.8% in the intervention arm (Masters et al., 2016). A study in Uganda which also distributed self-test kits to male partners via women recruited form antenatal clinics found an increase in HIV testing among those male partners of 2.1 times (risk difference of 38 per 100 men) (Pebody, 2017a). Another study conducted door-to-door HIV testing in Zambia and found that offering a choice between the standard provider-administered blood-based HIV test and an oral self-test kit increased testing rates from 55.1% to 60.4% (1.1 relative risk and 5.3 per 100 absolute risk difference) (Pebody, 2017a). Two studies conducted in Uganda and Zambia compared HIV test uptake among female sex workers when they were offered HIV self-test kits distributed via peer educators or given a coupon which could be redeemed for a self-test kit at a clinic, compared to the SOC in which the peer educator provides information about how provider-administered HIV testing can be accessed. In those studies the testing rates were 100%. 97% and 87% in Uganda and 95%, 84% and 89% in Zambia for each of the 3 groups respectively. Thus direct distribution had a greater impact than a coupon-based clinic distribution system (Pebody, 2017b). This suggests that different distribution methods among truckers and sex workers who are infrequent HIV testers should be explored. The North Star Alliance does outreach at truck stops and this might be a mechanism to conveniently distribute self-testing kits.

Because a goal of our study was to see if advertising the self-test kits would bring more truckers to the clinics to test, we did not take the test kits during outreach events. Demand creation may also be needed to reach some North Star Alliance clients with HIV testing, as well as those who are not accessing care in North Star or other clinic systems,

Among those in the intervention arm who were offered HIV testing choices, there was a range in which test participants selected. While the majority chose to self-test (64.5% and 60.5% for truckers and sex workers respectively), the SOC test was chosen by over a third of participants, and of those who chose to self-test, about two thirds chose to do so in the clinic with supervision while one third chose to take a test kit for home use. This suggests that people vary in their preferences around HIV testing and by offering choices we may increase the chance that one of the options is acceptable. Our previous self-testing study among truckers in Kenya found similarly varied choices (Kelvin et al., 2017c), as did the Zambian study in which home-based HIV testing choices were offered (home-based provider test only versus home-based testing choices including self-testing with and without supervision) was offered door-to-door (Pebody, 2017a). The fact that a sizeable proportion chose to self-test in the clinic with supervision both in our two studies and in the Zambian study warrants further exploration. It could be that some wanted guidance for their first time self-testing and going forward they would take a test kit to use at home, or it could also be that some people preferred an oral test over a blood test and preferred provider administration and supervised oral self-testing was the closest they could get to their ideal test in these studies. A discrete choice experiment we conducted in our previous study among truckers suggested that people have strong preferences regrading blood versus oral and form of counselling (in-person versus over the phone) and these differed by HIV testing history, but preferences regarding who administers the HIV test as well as the testing location were not strong (Strauss et al., 2017, Kelvin et al., 2017a). Thus future studies might explore different combinations of test choices, such as provider-administered oral tests and self-administered blood tests, to try to assess which tests are the most popular and what the array of testing choices should be in order to maximize test uptake.

The cost analysis found that the intervention was substantially more costly compared to the SOC and enhanced SOC, but the main driver of this additional cost was the test kit. The price of OraQuick HIV self-test kits in Kenya has since been reduced to $2, about a quarter of what we paid, with an agreement between the Gates Foundation and OraSure Technologies (WHO, 2017). This should bring the cost of the intervention much closer to that of the SOC. Furthermore, we found that the number of text messages sent (one versus three) made no difference in the comparison between the SOC and enhanced SOC, suggesting that we might get similar increased test uptake form the intervention if we sent only one text message announcing the availability of self-test kits, which would further reduce costs. Importantly, despite the higher cost of the intervention, it was found to be the most cost effective of the three programs due to the higher uptake of HIV testing.

There are a number of limitations to this study that should be considered in its interpretation. First, as mentioned before, our text message was not very detailed and we were unable to pilot test the intervention due to time constraints. Therefore, many receiving it may not have understood what it meant or not know what the self-test was.

This may have limited the number of participants who came to the clinics for the self-test and weakened the potential impact offering self-testing as a choice might have on testing rates. Second, our method of selection of eligible participants via the North Star Alliance medical record system might have led us to include some who were not really eligible and to exclude some who were eligible due to data errors in the system. The large number of duplicate phone numbers in the system as well as the missing HIV-testing data on five truckers and 38 sex workers who self-tested indicates a fairly high level of delayed data entry or error in the system. It is also possible that some included in our sample had recently tested or been diagnosed with HIV in a non-North Star clinic or tested for HIV during follow-up at a non-North Star clinic and were thus misclassified in our data. Importantly, the proportion who used the SOC test in the intervention arm was similar to that in the SOC arms (11/750=1.5% versus 10/748=1.3% and 10/762=1.3% among truckers and 47/750=6.3% versus 46/750=6.1% and 43/696=6.2% among sex workers in the intervention, enhanced SOC and SOC arms respectively). This suggests that the preference for and willingness to test with the SOC test at a North Star clinic is similar among all groups, which likely also indicates that willingness or preference to use this same test at a non-North Star clinic is also similar. Therefore, the error in misclassifying the outcome due to testing at other clinics is likely non-differential by study arm and would bias our results towards the null. Even if more participants in the SOC arms tested at other clinics than in the intervention arm, that difference would have to be large to wipe out the difference in HIV test uptake that we found, which seems unlikely. In addition, the HIV testing rate following a text message we used to estimate our sample size needs (58% among truck drivers and 48% among sex workers) was substantially higher than what we found in our study. This is likely due to differences in the eligibility criteria. North Star Alliance sends text messages to those who have no documentation of an HIV test in the past 3 months. In our study, we selected those who not only had not tested in the past 3 months but who also were not regular HIV testers (as measured by their not having tested 4 times in the past 12 months). This may explain why the testing rate in our SOC groups was much lower than that used in the sample size estimates. Fortunately, we still had sufficient statistical power to find the difference between the intervention and enhanced SOC groups to be statistically significant. Furthermore, it is possible that the increased testing rate among those in the intervention is partly due to curiosity about a new HIV test and over time the differences in testing rates may decline after self-testing becomes available. Longer follow-up studies are needed to assess the long-term impact of self-testing on testing rates and test frequency. And, finally, our results cannot be generalized to all truckers and sex workers in Kenya, let alone outside of Kenya, as we selected a sample meeting specific criteria and from a clinic-based medical record system. Those who do not access healthcare at all may differ in important ways that impact HIV testing.

6. Specific findings for policy and practice

We found that sending text messages announcing the availability of HIV self-testing kits at North Star Alliance clinics in Kenya increased HIV testing rates among male truckers and female sex workers who were inconsistent HIV testers. While the cost of this intervention was much higher than that of the SOC, it was found to be the most cost effective of the three programs included in the study. With the reduction of the cost of HIV self-test kits and the need to send fewer test messages, the widespread roll out of HIV self-testing in North Star Alliance and other clinics systems seems feasible and highly cost effective.

However, a number of considerations need to be made in designing a clinic-based program that includes self-testing. 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 chose the existing standard of care HIV test when given a choice, but for others self-testing was an attractive alternative, enough so that more people came to the clinic to test when learning about the availability of self-test kits. Thus testing choices may be the key to maximizing HIV testing rates.

Implementing oral self-testing not only requires HTC counsellor training and consideration of how self-testing fits into the current service model (e.g. costs and pricing, dissemination venues), but it is critical to design appropriate information and counselling resources for clients. As we learned in this and our other study, questions do come up during the testing process, so clients need to have some way to have their questions answered. For those with smart phones, the online video may help (OraSure Technologies, 2017). Offering or even requiring supervision the first time someone self-tests might be another option to ensure that people get their questions answered and feel confident in their ability to self-test in the future. Most of those who self-tested in our study chose to do so in the clinic with supervision even though it was not required, suggesting this is an acceptable option for many as they learn to self-test. Similarly, mechanisms for pre- and post-test counselling need to be established. Mandatory pre-test counselling might be combined with picking up self-test kits at a local clinic or pharmacy, but post-test counselling is more difficult to deliver because it depends on the client to seek out this service. In our study, about a quarter of participants who self-tested at home did not contact the HTC counsellor for post-test counselling. Given the challenge of linkage to care for those who test in a clinic setting, some thought about program development and evaluation will be needed to ensure that those who self-test are not even less likely to link to care when they need it.

However, another concern policy makers may have regarding self-testing is that without some mandatory post-test counselling mechanism through which providers can gather data on the test result, the quality of national data on HIV testing and prevalence may deteriorate or at the very least be less verifiable and thus questioned. If self-testing becomes wide-spread, as we hope it will, but national statistics only receive test-result data from those who take the initiative to contact HIV care providers upon a positive self-test result, there will have to be some effort made to validate HIV testing and prevalence estimates which could be costly. One option might be for self-testers to be required to contact the provider from whom they received the self-test kit after testing, as we did in our study, coupled with phone-based follow-up for those who fail to do so. This process

would require sufficient staff to take phone-calls from self-testers and conduct follow-up. However, an automated system could also be set-up in which the caller indicates their test result, which is recorded, and then the caller receives a recorded post-test counselling message with the option to speak with a counsellor at any time if they desire. But follow-up calls and possibly other contact methods will still be needed to reach those who fail to call-in, as we saw in our study.

Thus policy makers have a number of considerations to make before self-testing is rolled-out in clinic systems such as the North Star Alliance, and that roll-out should be done in a considered manner coupled with evaluation of the various policy and programmatic options in an effort to design policies and programs that can have the greatest impact on HIV testing rates while maintaining or improving linkage to care rates and the quality of the data on HIV testing and HIV incidence and prevalence. However, results from our study and the growing body of empirical evidence on self-testing suggests that it is time to start designing these programs and incorporating self-testing into clinic services.

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