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About this formative study

The 3ie HIV self-testing Thematic Window included feasibility studies, and pilot interventions and their impact evaluations in Zambia and Kenya. This study aimed to answer specific questions about the acceptability of HIV self-testing, about desirable distribution points, about the efficacy of kit instructions, and about the best ways to promote linkage to care. Any errors and omissions are the sole responsibility of the authors. All affiliations of the authors listed in the title page are those that were in effect at the time the study was accepted. Any comments or queries should be directed to the corresponding author, Arianna Zanolini, at azanolini@air.org.

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Investigating the feasibility of HIV self-testing in Zambia

Arianna Zanolini

Centre for Infectious Disease Research in Zambia (CIDRZ) and American Institutes for Research

Jenala Chipungu

CIDRZ

Stephanie Topp

University of Alabama at Birmingham

Charles Holmes

CIDRZ and Johns Hopkins University

Mazuba Mafwenko

CIDRZ

Harsha Thirumurthy

University of North Carolina at Chapel Hill

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Impact Evaluation**

Summary

Zambia is considering the use of HIV self-testing (HIVST) to increase awareness of HIV status in the population. We assessed acceptability and preferences for HIVST and multiple delivery models among adults in Lusaka province, Zambia using a mixed-methods design. Households in Lusaka Province were randomly selected to participate in a household survey and one member aged ≥ 16 years randomly selected as a respondent, for a total of 1,617 participants. A subset of them participated into a qualitative, in-depth analysis. We conducted focus group discussions with the key populations of truck drivers and sex workers, as well as with a special population of disabled people. No use of self-testing was done.

HIV self-testing was highly acceptable across all strata, with 74 per cent reported feeling “very comfortable” with HIVST and 76 per cent of those who have not tested in the past year reported they would definitely test if given a self-test. Only two per cent reported having concerns serious enough to not recommend HIVST in Zambia.

Qualitative work also revealed high acceptance amongst truck drivers and sex workers. However, all participants highly valued in-person counseling, which was found to be the main factor determining the preferred distribution model for self-testing. There was a general trust in the health facility and in its counselors.

Perhaps because of stigma, respondents did not like the idea of picking up the HIV self-tests at the HIV department of the health facility, the location where regular fingerpick testing is currently routinely done, and preferred the pharmacy at the outpatient department instead. Sex workers lamented the judgmental attitude of staff at the facility and would prefer picking up the test elsewhere. Truck drivers would also prefer picking up the test at their workplace rather than at the facility.

Overall, the test’s cost was important, especially for lower income and less educated groups, and for those who are already testing regularly.

To assess effectiveness of instructions, we tested understanding of the Oraquick® instruction sheet. The instructions were clear enough for 73 per cent of participants that they would feel confident in being able to do an HIV self-test by themselves. While the instructions were able to generate a good overall understanding of how the test is done, only 65 per cent of participants were able to correctly recognize all positive, negative and invalid results when shown a picture of them.

On the supply side, we did not identify challenges that are specifically associated with HIV self-testing. Their distribution can be compared to the distribution of other drugs. However, pharmacists expressed the need for being trained and to have guidelines on how to address counseling. We also interviewed two big companies to inquire about distribution at the workplace. We found general support for the idea, although they expressed a need for better data on the comparative advantage of self-testing.

However, under current regulations, only locations with a license from the Zambia Medicines Regulatory Authority are allowed to distribute self-tests. The overall results support the need for piloting distribution of self-tests. However, counseling was thought to be essential, and is likely to affect uptake as well as linkage to care. Any pilot should carefully plan for access to

in-person counseling services, fully describe the components of counseling provided, and how they were received.

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Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
CHAZ	Church Health Association of Zambia
CIDRZ	Centre for Infectious Disease Research in Zambia
CSA	Census Statistical Area
DCE	Discrete Choice Experiment
DMO	District Medical Officer
DHS	Demographic and Health Surveys
ERES	Excellence in Research Ethics and Science
FDA	Food and Drug Administration
FGD	Focus Group Discussion
FSW	Female Sex Workers
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counseling
HR	Human Resources
IQR	Interquartile Range
IRB	Institutional Review Board
KII	Key Informant Interviews
MCDMCH	Ministry of Community Development, Mother and Child Health
MOH	Ministry of Health
MSL	Medical Stores Limited
OPD	Outpatient Department, Department within a public health facility
PPS	Probability Proportional to Size
SAT	Southern African AIDS Trust
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	Voluntary Counseling and Testing
ZAFOD	Zambia Federation for the Disabled
ZAMTEL	Zambia Telecommunications Company Limited

ZESCO Zambia Electricity Supply Corporation

1. Overview

In 2014, UNAIDS released the 90%-90%-90% target for 2020 to stop the HIV epidemic: 90% of all people living with HIV should know their status; 90% of all people diagnosed should receive antiretroviral therapy; 90% of all those receiving antiretroviral therapy should have viral suppression. This is an ambitious goal, driven by the realization that bringing HIV treatment to all who need it is the only way to end the epidemic.

In Zambia, despite high awareness of HIV/AIDS among adult men and women, coverage of HIV Testing and Counseling (HTC) among adults remains low, with only 46% of women and 37% of men having tested in the past year, and with 80% of women and 64% of men 15-49 having tested for HIV ever in their lifetime (DHS 2014). Uptake of HTC among men is especially low and even among those who are HIV-infected, HTC remains far from universal (WHO 2011).

At this point, blood testing is the only form of HIV testing in Zambia and is predominantly performed using a rapid point-of-care fingerprick test for HIV-1/2 antibodies. The voluntary counseling and testing (VCT) department at the public clinics is the most common location to obtain an HIV test, and all of the public health facilities are providing it, for free. Recognizing the importance of extending VCT to patients visiting the health facility for other reasons, HIV testing is increasingly being integrated across all departments at the health facility, and in particular in VMMC and outpatient sites and, according to the guidelines, it should be done at all service delivery points within the facility. In addition, mobile outreach for testing, community-based and door-to-door HTC initiatives have been shown to be highly acceptable and rapidly expanding, encouraged also by the latest 2014 guidelines for HIV treatment and prevention. For women, a major entry point is still the antenatal clinic, where opt-out HIV testing has been part of the guidelines for more than a decade.

The expansion of availability and models for HIV testing have brought about a remarkable increase in testing, which grew 25 percentage points between 2007 and 2014 according to DHS (from 19% to 46% for women, and from 12% to 37% for men). However, in order to achieve the 90% goal and reach those difficult-to-reach through traditional testing models, Zambia is now considering adopting the use of HIV self-testing to increase knowledge of HIV status awareness. HIV self-testing is an alternative strategy whereby a person who wants to know his or her HIV status “collects a specimen, performs a test and interprets the test result in private” (WHO and HIV/AIDS 2014). The test can be either oral fluid-based or blood-based and can provide the results in less than 30 minutes. It is a screening test only, and any positive results will have to be confirmed by a trained health care worker. In this report we focus on oral fluid-based HIV self-testing. In terms of accuracy of self-testing, US emergency room patients achieved 100% accuracy, and in a study in Malawi accuracy was >99% (Choko *et al.* 2011). The FDA-approved Oraquick® In-home HIV test achieved 92% sensitivity in premarket self-testing in the US (Morgan 2012). A recent study in Kenya found 92.9% sensitivity and 97.8% specificity (Kurth and Siika 2014), and one specifically for Zambia achieved 98.7 sensitivity and 99.8 specificity for the OraQuick® when compared to HIV positive serostatus (Zachary *et al.* 2012).

Oral fluid-based HIV self-testing has the potential to overcome many barriers to HIV testing. With self-testing, individuals collect their own sample and perform a simple, rapid HIV antibody test in the absence of a provider. It offers increased convenience, privacy, and autonomy, and has the potential to increase normalization of regular testing. As highlighted in the 1st International Symposium on self-testing for HIV in 2013, self-testing can increase testing prevalence by improving access, autonomy, convenience and confidentiality.

Existing research in several countries shows a high level of acceptability and demand for self-testing. In studies from the US, Europe and Africa, 73% to 89% of people have reported interest in, preference for, or belief that self-testing should be made available (Corbett *et al.* 2007; Kalibala *et al.* 2010; NASCOP 2006; Carballo-Diequez *et al.* 2012; Lee *et al.* 2007; Gaydos *et al.* 2009; Spielberg and Foundation. 2010). Interest is typically highest among high-risk groups and those who have never tested for HIV (NASCOP 2006; Lee *et al.* 2007; Carballo-Diequez *et al.* 2012), although in a formative study in Kenya (Ochako, Vu & Peterson 2014) participants who had never tested for HIV displayed less willingness to use the oral self-test kit. In a community-based study in Malawi, 92% of participants opted for supervised oral fluid-based self-testing over provider-delivered HTC, including a high proportion of first-time testers (Choko *et al.* 2011) and, in a different study, 94.4% of the participants reported that they were happy with HIV self-testing (Choko *et al.* 2015). Data from six European countries indicated that 67% of self-testers would not have tested through provider-delivered HTC (MiraTes Europe BV 2008). These data suggest that HIV self-testing has the potential to reach new populations who are not comfortable accessing existing HTC services. Respondents from a range of studies report that self-testing would reduce or eliminate stigma around HIV testing, a formidable barrier, as well as increase convenience and confidentiality (Corbett *et al.* 2007; Carballo-Diequez *et al.* 2012; Lee *et al.* 2007; Sharma, Sullivan & Khosropour 2011; Gaydos *et al.* 2011). Linkage to care associated with HIV self-testing is hard to assess, but in Malawi, in a study offering both pre and post-counseling, 56.3% of participants enrolled in HIV care after one year and more than three-quarters revealing their status to the counselors and half of the participants being on HIV care after one year (Choko *et al.* 2015).

While the studies cited above have shown that self-testing can be implemented with few adverse consequences and with good rates of linkage to care, there is a need to better understand the potential risks of these issues in Zambia prior to widespread implementation. CIDRZ, in collaboration with the Ministry of Community Development, Mother and Child Health (MCDMCH) and the Ministry of Health (MOH), conducted a formative, mixed methods study to investigate factors influencing acceptability of the HIV self-test, potential methods to ensure linkage to care and feasibility of implementing an HIV self-testing program specific to the population and health system of Zambia.

2. Research Objectives

The objective of this study is to explore acceptability, distribution models, effectiveness of instructions, and linkage to care for HIV self-testing oral fluid-based kits in Zambia

There were 6 specific questions underlying the themes above: 1) What are likely to be the most effective, efficient, and ethical ways of distributing self-test kits to potential

users? 2) What methods are likely to be effective for ensuring and promoting linkage to care for counseling, confirmatory testing and treatment for those using self-tests? 3) What kinds of health providers and other service providers would be effective and acceptable in the distribution of self-test kits and the linkage to care? 4) What legal or social concerns might be associated with different distribution methods? 5) What tools, instructions and demonstrations are most likely to ensure users correctly perform and read the test? 6) Are there special considerations for any key populations?

As formative study research, the ultimate goal is to elicit information on the questions above in order to inform policy and a possible roll-out of HIV self-testing in Zambia. In this study we only studied the oral fluid based HIV self-testing kits.

3. Methods

We assessed the questions above with a mixed methods approach that includes exploring both the demand and supply sides. On the demand side, we included a representative survey of Lusaka province on a sample of 1,600 participants older than 16 years old, focus group discussions for general population and focus group discussions with special and key populations. On the supply and distribution side, we included key informant interviews with policymakers and informants. More details of the specific methods are found below.

We sought ethical approval from the ERES Converge IRB, Zambia. We received permission from the Ministry of Health and Ministry of Community Development, Mother and Child Health for both quantitative and qualitative components of the study. We translated the entire survey into the 4 languages spoken in the sampled areas: English, Nyanja, Bemba and Tonga.

3.1 Demand Side

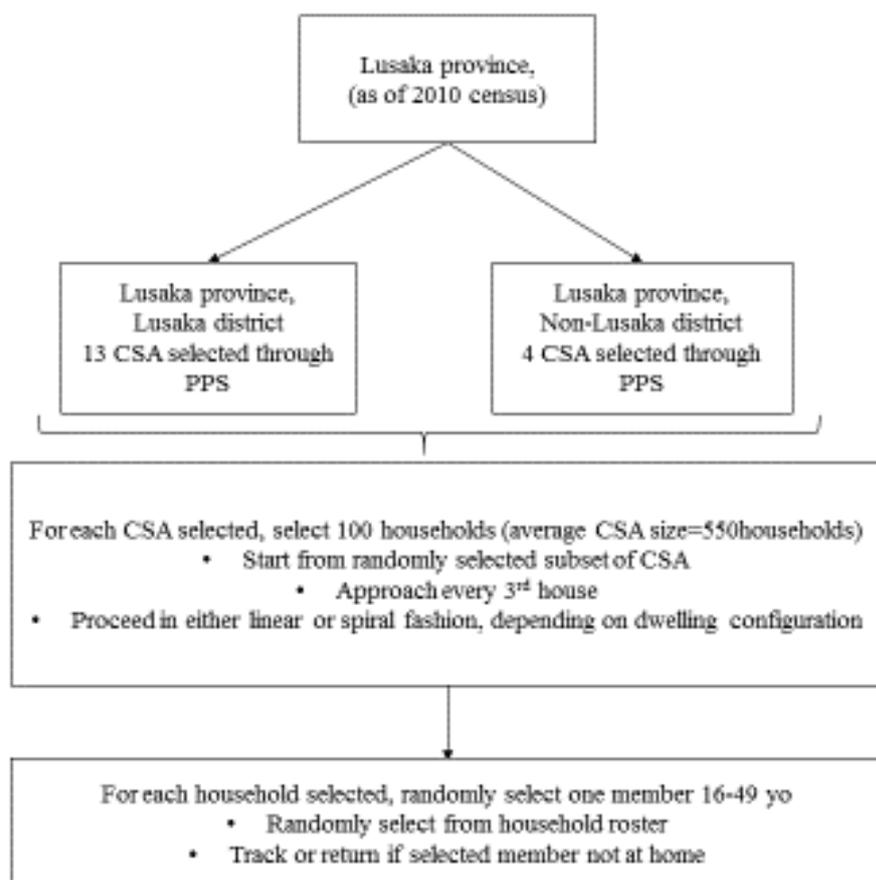
3.1.1 Survey

Study participants

We approached a representative sample of individuals 16-49 from Lusaka province. Lusaka province is marked as a priority province for HIV prevention and care given its high prevalence rate at 16.3% of the population (DHS 2014), and it is also the largest province in Zambia, with a total population of more than 2.1m people. We stratified our sample into Lusaka district and not-Lusaka district and selected through probability proportional to size (PPS) 13 CSA in Lusaka district and 4 CSA outside. We used the Census 2010 for our sampling scheme and definition of the boundaries of the province. We weighted the observations to guarantee representativeness. In each selected CSA we approached approximately 100 household, and found and interviewed an average of 95 participants. Surveyors utilized either the linear or the spiral approach depending on the geographical distribution of the household and approached every 3rd house starting from a place in a randomly selected subdivision of the CSA. Once a house was approached, a random person of the household was selected from the household listing to be interviewed. Participants not at home were called on the phone when possible to make an appointment, then revisited for a maximum of 3 other times; they were also met in their workplace whenever the participant agreed. To be eligible, participants had to be

between 16 and 49 years old, able and willing to give informed consent. Figure 1 below synthesizes the sample selection strategy.

Figure 1: sampling



Data collection procedures

Once a participant was selected, eligibility confirmed, and informed consent obtained, a survey composed of 5 sections started. The first section included questions about demographic variables, HIV testing history, knowledge and practices around VCT, and a few questions to assess HIV risk. Then, the surveyors showed a 2-minute video locally produced for this study, to introduce participants to what an oral-fluid based HIV self-test is (we used OraQuick ADVANCE HIV I/II kit OraSure Technologies), and how does it works. At this formative stage, no use of HIV self-testing was allowed if not for demonstration purposes, and virtually no participant knew what HIV self-testing was. We opted for a video in order to standardize the message around the test and to not create differences in the way surveyors were framing the introduction. Interviewers then moved to a second section with questions on acceptability, willingness to test, and concerns specifically around HIV self-testing as shown in the video. A third section covered questions about preferences around location for picking up a self-test kit like the one shown in the video, price and preferences around counseling. A fourth section investigated how comprehensible and clear were the Oraquick® instructions that had been developed specifically for resource-limited settings, and how well could respondents grasp the main steps needed to take and interpret the test after looking at the instructions. We also compared the understanding from Oraquick® instructions to the understanding from Oraquick® instructions plus an information video by randomizing participants into either instructions only or instruction and videos. Finally, a last section

inquired about self-reported and hypothetical linkage to care after a positive test using an oral fluid-based test. All data were collected through tablets.

There are several methods to elicit preferences around various topics, and in surveys the most common one uses Likert-scales. However, Likert scales are unidimensional, can only consider one attribute of a choice at a time, and do not allow us to understand how participants trade off different attributes. A different way to elicit preferences is based on revealed preferences, the concept that, if participants choose their preferred option when given the choice, we can infer their preferences using their choices. In a setting like a survey where we simply don't have access to how people would choose across different HIV self-testing models, we can use Discrete Choice Experiments (DCEs) (Ryan, Gerard & Amaya-Amaya 2007, de Bekker-Grob *et al.*, 2012, Mangham, Hanson & McPake 2009) to elicit preferences from participants' choices and understand how participants rank and trade-off characteristics of an HIV self-testing model. Discrete Choice Experiments stem from Lancaster's theory of consumer choice: consumers' utility is defined by the characteristics that define that product, so that the utility of different HIV self-testing models depends entirely on the characteristics that define each of the models. In accordance to revealed preferences, participants conducting a DCE are presented with 2 or more products or models that differ by one or more attributes, and then asked to choose between them. The rationale is that a participant will choose the option that gives him (or her) the higher overall utility. As participants choose the preferred model they reveal something by the way they rank and weight the various attributes; after enough questions, their choices allow us to identify each individual attribute's contribution to respondents' choices. DCEs have been successfully used in similar settings for health economics questions (Choko *et al.* 2015, MiraTes Europe 2008, Sharma, Sullivan & Khosropour 2011). The data from the DCEs is analyzed following the random utility model. In DCEs, the characteristics are called "attributes" (e.g. attributes for a drink could be color or sweetness) and the various ways in which these characteristics can manifest (e.g. orange or blue, sweet or sour) are called "levels".

In the survey, both Section 3 and Section 5 use DCEs to elicit preferences around, respectively, different HIV self-testing models for distribution and for linkage to care. In both sections, we only focused on 3 attributes to describe the models, because initial piloting indicated that adding more than 3 attributes would have reduced understanding and attention. Out of the 3 attributes, 2 had 3 levels and 1 had 2 levels, therefore generating a total of $3 \times 3 \times 2 = 18$ possible combinations. We used the entire full factorial design and just divided into 2 blocks, so that each respondent was responding to a block of 9 questions per section. Following Street *et al.* (2002), we used modulo addition to pick the alternative choice to each of the options. In Section 3, there were nine questions, each presenting two options for how HIV self-testing could be obtained. In our simple representation, there were 3 main attributes defining each option: where the test was distributed, how much the test cost, and whether obtaining the test involved having to go through a pre-counseling session or not. The possible distribution outlets were the VCT department in the public clinic, outpatient pharmacy (OPD) at the public clinic (typically where patients pick-up drugs as outpatient clients), or a private drugstore, as these are 3 of the main possible ways in which HIV self-testing can be distributed at scale. Cost could take 3 values (5 Kwacha—about 0.8 US\$ at the time-, 10 Kwacha, or 25 Kwacha). We chose the levels of these attributes after consulting with the Ministry

and with HIV experts, as well as with community representatives. After piloting, we decided to use pictures to help participants tease out the difference in attributes between the two models presented in each choice. In each question, we asked participants to imagine that both options were available, and that a third “none of the two” option was also available, which implied either regular rapid testing with fingerprick (for regular testers) or no testing at all (for non-regular testers). We then asked participants whether they would choose one of the 2 HIV testing options in the next 6 months, and if yes which one. In Section 5, we inquired about factors entering the decision to link to care after a reactive HIV self-test. We assumed that the utility of linking to care was a function of both facility-level pull attributes, such as niceness of staff (nice or rude) and waiting time (short, medium, long wait) at the facility, as well as push factors such as a call, visit, or text message from the health facility staff to check on the self-testing result. We asked participants under which option would they be more likely to visit the clinic after a positive result. The Section 5 DCE followed the same design as Section 3.

Section 4 investigated how comprehensible and clear were the Oraquick® instructions developed specifically for resource-limited settings, and how well could respondents grasp the main steps needed to take and interpret the test after looking at the instructions. This was done by administering a 10-items quiz (see Appendix A) asking about concepts that were covered in the instructions: e.g. how many minutes to leave the test into the vial, how to read the results correctly, what to do if the liquid spills. We also investigated if there was any additional value in complementing the instructions with an instructional video. We did this by randomizing participants into an instructions only arm and into an instructions and video arm. The video was produced as part of the study and featured a woman demonstrating the use of HIV self-testing. Participants in the instructions only arm were given a copy of the instructions and asked to study it for one minute. Participants in the instructions and video arm were shown the video, then given the instructions to study for the same amount of time. We then asked participants how confident they were that they had understood how to do the test. After that, we administered the quiz. During the quiz participants were allowed to refer to the instructions in both arms, in order to simulate a more realistic scenario. The randomization allows to compare the additional effectiveness, if at all, of having an additional video demonstrating the use. We kept the instructions in both arms because of external validity concerns.

Data analysis

We described responses to Section 1 and 2 through means and standard deviations, and we also compared means across different strata to tease out the presence of any clear sub-group with distinct preferences around self-testing. We weighted data using probability weighting to restore representativeness. Weights were calculated as $1/(p1*p2)$, where $p1=CSA\ population*number\ clusters\ in\ strata/total\ population\ in\ the\ strata$ and $p2=targeted\ population\ per\ CSA/total\ CSA\ population$.

Section 3 and Section 5 were analyzed using a mixed logit, clustering the standard errors to account for the fact that each individual gave multiple responses. Mixed logits are recommended when data are clustered or there are both fixed and random effects, but we also verified robustness using conditional logits.

Section 4 reports means for each of the items in the quiz, as well as overall scores. It also compares means and standard deviations across the instructions only group and the instructions and video group using p-values.

All data were analyzed using STATA®.

3.1.2 Focus Group Discussions to general population and to key and special populations

Study participants

The focus groups were aimed at giving us richer and more in-depth information around the same themes touched in the survey. We targeted general population females and males aged 16-49 years in Lusaka, Chongwe and Kafue Districts. We also conducted FGDs among key populations: female sex workers and truck drivers. Sampling for the general population of females and males aged 16-49 years was done within the survey sampling: every fourth survey participant surveyed by selected surveyors was invited to participate to a focus group. Sampling for female sex workers followed a snowball technique: we contacted an organization involved in identifying and rehabilitating female sex workers as our initial lead. Truck drivers were purposively sampled by contacting trucking companies and asking for permission to contact their employees. We also managed to interview 4 physically disabled and 2 physically disabled and blind. .

Data Collection

We used pictorial representations and the same videos used during the survey to introduce the topics. For eliciting the effectiveness of instructions, we showed both the video and the Oraquick® instructions, just like in the survey, and asked participants questions around their understanding. We also asked in a broader fashion about distribution methods preferences, and preferences related to linkage to care, as well as preferences for receiving counseling at the point of collecting the self-test kit.

Data Analysis

We used thematic content analysis to analyse the data. We voice recorded and transcribed all data and managed and coded it using NVivo®. The main themes were guided by the 4 research questions of acceptability, distribution models, effectiveness of instructions, and linkage to care, and these constituted the parent codes.

3.2 Supply side

3.2.1 Key Informant Interviews

We also interviewed key-informants on the supply side and especially investigated the themes of distribution and guidelines, but also acceptability and willingness to include HIV self-testing into Zambian guidelines. Below we summarize the key informant interviews (KII) done as part of the study. We interviewed Ministry representatives identified by the Ministry to be key players, purposively selected district pharmacists employed by the District Medical Office of Kafue, Chongwe and Lusaka, and randomly selected in-charge nurses from the facilities in the catchment areas covered by our survey. We also interviewed key informants in local NGOs. We finally identified representatives of the main distribution channels: Medical Store Limited (the national drug distributor for drugs in the public system) and randomly selected private drug-store owners. In addition, we included 2 government owned companies operating as private

companies (Zambia Telecommunications –ZAMTEL, and Zambia Electricity Supply Companies -ZESCO) which were selected as representatives of the business sector and sampled to understand possible ways to distribute HST through employment places. While other large privately owned companies in the country exist, it was easier and faster to consent quasi-government companies than privately owned companies.

Text box 1: Key Informant Interviews

Public Sector/ Social Sector	Description
Ministry of Community Development, Mother and Child Health – HIV Department	A government ministry at the national level that oversees and provides basic health services to the entire population.
District Medical Officers (DMOs)	The Head of an administrative health office at the district level. The DMO is responsible for ensuring the provision of health services at the district level through public health clinics.
District Pharmacists	A pharmacist that is in charge of the management and distribution of drugs and medical equipment to public health clinics.
Public Health Clinic Nurse In-Charges	A qualified nurse in charge of running a public health clinic.
Zambia Federation for the Disabled (ZAFOD)	An umbrella organization representing over 10 other organisations representing persons with disabilities. Their main aim is to support and promote the welfare of persons with disabilities. (Visit: http://www.zafod.org.zm)
Private Sector and Quasi Government Institutions	Description
Medical Stores Limited (National Drug Distributor) Representative	Medical Stores Limited is an autonomous national government agency responsible for the supply and distribution of drugs and medical equipment to public health centers across the country. (Visit: http://www.medstore.co.zm)
Registered Private drug-store owners	Privately owned drug stores selling drugs to the community.
Zambia Telecommunications Company Limited (Zamtel) Representative	Zamtel is company that is owned by the government and is responsible for providing communication services to the public. The company has approximately 750 employees and promotes good health as part of it social corporate responsibility. (visit: http://www.zamtel.zm)
Zambia Electricity Supply Corporation (ZESCO) Representative	ZESCO is a government owned institution that is responsible for generating, transmitting and distributing electricity to the whole nation. It has a large employee base (approximately 3,600). (Visit: http://www.zesco.co.zm)

4. Results

4.1 Recruitment and Study Population Characteristics

We approached a total of 1,912 houses during our interviews. Of these, 229 houses were empty and in 49 selected households we could not locate the person selected from the household listing despite several attempts. In addition, 17 selected persons did not consent to the study. This leads to the final sample of 1,617 participants (85% of the total households approached).

In each CSA, we interviewed an average of 95 participants [IQR: 92-99; min: 81; max: 105]. Amongst the total 1,617 participants, 970 (60%) were females and 647 (40%) were males. The gender imbalance is partly due to a sex ratio of around 90% in Zambia for those age 16-49 years (DHS 2014), but some tracing bias due to the higher employment rate of men has also likely contributed. Table 1 summarizes characteristics of study participants: on average, participants were 29 years old [IQR: 22-35, with 10% being 19 years old or younger], 50% were married, and 47% of them had completed senior secondary school or above. 52% reported being employed or self-employed as opposed to unemployed, and those employed reported working an average of 44 hours per week, with a mode monthly earning range of 500-1,000 Kwacha (approximately 75-130 US\$). Only 7% of the sample earned more than 5,000 Kwacha/month (750 US\$). 12% self-reported that they were HIV-positive (the Lusaka-province prevalence is 16% in the DHS 2013-2014) and 42% perceived their chances of contracting HIV to be moderate or high (Table 1).

In addition, we conducted 8 focus group discussions with females and males aged 16-49 years (n=8 in each group) and 1 focus group discussion each with female sex workers (n=6) and truck drivers (n=8). Key informant interviews were conducted with 3 DMOs, 3 district pharmacists, 6 public health facility in-charges and 4 private drug store owners. Interviews were also held with a representative from Zamtel, ZESCO, MSL and MCDMCH HIV Department.

Table 1: descriptive statistics

	Total		Female		Male	
	N	Mean/ proportion	N	Mean/ proportion	N	Mean/ proportion
Age	1,617	28.88	970	28.5	647	29.48
(SD)		(8.26)		(8.14)		-8.45
Education Level						
No secondary school	1,616	0.2	970	0.24	646	0.16
Jr. secondary school		0.32		0.11		0.29
Sr. secondary school		0.33		0.34		0.34
More than sec school		0.14		0.1		0.21
Marital Status						
Married or cohabiting	1,614	0.5	969	0.53	645	0.43
Single		0.38		0.32	645	0.47
Divorced, separated or widowed		0.12		0.14	645	0.09
Employment Status:						
Employed for wages	1,617	0.23	970	0.14	647	0.37
Self-employed with a business or farm		0.28		0.28		0.29
Unemployed, looking for work		0.23		0.27		0.16
Unemployed, not looking for work		0.26		0.32		0.17
Total hours worked	798	43.81	379	42.38	419	45.14
		-20.87		-21.54		-20.15
Individual Income Level						
500K or less	805	0.21	384	0.28	421	0.14
Between 500 and 1000k		0.28		0.33		0.23
Between 1000 and 2000k		0.21		0.18		0.25
Between 2000 and 5000K		0.23		0.16		0.3
More than 5000K		0.07		0.05		0.08
Number of children	1,599	1.76	970	1.95	647	1.47
		-1.84		-1.84		-1.81
Self-reported positive HIV Status:						
Perceived HIV risk	1,363		804		559	
High		0.14		0.15		0.13
Moderate		0.27		0.27		0.28
Low		0.31		0.3		0.32
No risk at all		0.28		0.28		0.27

*Note: standard deviations in parenthesis. All data weighted using probability weighting to restore representativeness. Weights were calculated as $1/(p1*p2)$, where $p1=CSA\ population*number\ clusters\ in\ strata/total\ population\ in\ the\ strata$ and $p2=targeted\ population\ per\ CSA/total\ CSA\ population$. Household income level was not collected.*

4.2 HIV Testing History

When asked about their HIV testing history (Table 2), 85% of participants reported that they had ever tested for HIV, but only 52% of women and 38% of men reported that they had tested in the past 12 months. This is very consistent with the results from DHS collected 2 years ago, which found that 47% women and 33% men had tested in the past year, considering that testing behavior is on an increasing trend every year.

The most common location for testing was a VCT Centre in the public clinic.¹ Among those who had tested, 56% reported that they had tested at a VCT Centre nearest to their home, 24% at a different VCT Centre in another public clinic, 11% in the community through a counselor or at an event, and 8% at a mobile clinic. 25% of participants reported they had tested together with their spouse. Only 62% of participants declared to know their partner's status (60% for women and 66% for men). The 2 main reasons for not testing, when asking unprompted, were no perceived need ("I know I am negative") and perceived time burden to do the test ("too time consuming"). Amongst other motivations, procrastination ("I lack self-motivation") emerged in 10% of participants. Participants seemed to trust the health care providers and counselors in maintaining confidentiality, with 86% believing that their result would stay confidential, but there was a general stigma associated with going to test: 60% of participants said that if people see them at the VCT Centre they will think that they have HIV (35%) or that they have been sleeping around too much (25%). With the exception of ever testing and testing in the past 12 months, where women have significantly higher proportions than men, there were no other striking gender imbalances in these responses (Table 2).

In the qualitative component another reason for not testing was highlighted: fear. Fear had two faces: the fear of having HIV and living with it, and the fear of others knowing that you have HIV. Stigma related to HIV was still very strong, and was discussed at length in the focus groups. Others mentioned that a lack of knowledge on what the virus is and how it can be handled prevented others from testing for HIV.

"Those that don't go to test are scared because they don't trust themselves and believe that they are already positive. They are not ready to receive a positive result and so they refuse. This happens for both male and female." – FGD Male Chazanga

"People are scared to go and test because they don't want to be laughed at, saying that they are positive," FGD Male Chongwe

While participants highlighted barriers to HIV testing, they were in general agreement that HIV testing is important because knowing your status can contribute to one knowing how to take care of yourself regardless of whether HIV positive or negative. Participants also felt that knowing your status translates into living longer on earth.

"If you're found positive you can begin medication and save your life," – FGD Female Chongwe

"There's no bad thing about testing because it's your own life and it helps to know where your life is going and you know how to keep yourself. A lot of people have died because of not testing for HIV," – FGD Male Chongwe

¹ Zambia has none or very few stand-alone or private VCT centres. The typical VCT centre is within the premise of the public health facility.

Table 2: HIV testing history

	Total		Female		Male	
	N	mean	N	mean	N	mean
Ever tested for HIV	1,617	0.85	970	0.9	647	0.77
Tested for HIV test less than 1 year ago	1,617	0.47	970	0.53	647	0.38
Where did you get tested?						
At VCT closer to home	1,375	0.56	875	0.59	500	0.51
At VCT away from home		0.24		0.23		0.26
With counselor at home		0.04		0.04		0.04
At public event		0.06		0.06		0.08
At mobile clinic		0.08		0.07		0.09
Other		0.01		0		0.02
If have not tested, why not?						
I know I am negative	242	0.37	95	0.35	147	0.39
Too time consuming		0.18		0.15		0.2
Other reasons		0.45		0.51		0.41
I know the HIV status of my partner	1,328	0.62	807	0.6	521	0.66
Last time I tested, I tested with my spouse	1,375	0.25	875	0.22	500	0.29
It takes 1 hour or less to test for HIV	1,463	0.79	900	0.78	563	0.79
I believe that the counselors will keep my HIV results private	1,415	0.86	864	0.88	551	0.82
If they see me at VCT, people will think that:						
I have HIV	1,586	0.35	953	0.36	633	0.32
I am sleeping around		0.25		0.23		0.29
I am at a routine check		0.34		0.35		0.33
Will think nothing		0.06		0.05		0.06

All percentages are weighted.

4.3 Acceptability of HIV Self-Testing

HIV self-testing was a concept that few participants had heard of before.² However, acceptability of HIV self-testing was almost universal: 96% of participants declared that they would feel neutral, somewhat comfortable or very comfortable with using an HIV self-testing, 86% that their friends would feel the same. 93% of participants also said that their partner would not feel uncomfortable (would feel neutral, somehow comfortable or very comfortable) taking the test if given by the participant, and 86% responded that they

² 6 people in our sample declared that they knew the product and that they had already used it in the past.

would not feel uncomfortable with giving it to friends or acquaintances. When we restrict answers to these questions to “very comfortable” only, we still find 74% of the sample very comfortable using it themselves, 52% think that their friends would feel very comfortable, 68% that their partner would feel very comfortable with doing a self-test if given by the participant, and 61% felt very comfortable giving it to friends and acquaintances. Given the almost universal acceptability, we displayed stratified results only for the “very comfortable” answers (Table 3). Respondents with higher education were more likely to feel “very comfortable” using it or giving it than those with low education; those with low perceived HIV risk more likely than those with high perceived HIV risk; and, interestingly, rural participants were also more likely to feel “very comfortable” than participants in the urban areas.

87% of participants thought that HIV self-testing would make them more likely to test for HIV than the current test, and only 4% thought that it would make them less likely. Similar responses were given when asked whether their friends would be more or less likely to test, with 85% declaring that their friends would be more likely to test for HIV if self-test was available. Women has slightly higher percentage of responses indicating that HIV self-test makes them more likely to test (88% vs 86%), and so did participants with higher education compared with the ones with lower education (89% vs 85%). Notably 76% of key subsample of non-testers (those who have not been testing in the past 12 months) declared that they would use the HIV Self-test “for sure” if it was available for free.

The high acceptability was confirmed through qualitative research, where participants had strong positive sentiments of enthusiasm for self-testing. During focus groups, the key themes that were raised were privacy, convenience, oral fluid instead of blood, as well as no need for lines at the clinic, or to wait for the tests:

*“It’s better to test yourself because a lot of time there are a lot of cues at the clinic,”
– FGD Male Chongwe*

“I like it very much, you can lock yourself in the bedroom and you can take the test properly and know your status,” – FGD Female Chongwe

“This test has made us feel nice because most people are concerned about being seen going to take an HIV test. But with this one you can do it in the privacy of your home and it’s your secret. They should hurry up in introducing it,” – FGD Female Chazanga

Table 3a: Acceptability of HIV self-testing

	Acceptability: Felt "very comfortable":				Would self-testing make you:			Would self-testing make your friends:			Would self-test "for sure"
	Using a self-test?	Your friends would feel	Your partner if you gave it to him/ her?	Giving it to your friends or acquaintances ?	More likely to test	Equally likely to test	Less likely to test	More likely to test	Equally likely to test	Less likely to test	Of those who have not tested
Female	75%	49%	69%	63%	88%	8%	4%	86%	9%	5%	79%
Male	73%	51%	66%	58%	86%	11%	3%	83%	11%	9%	73%
				*	**						
Non-tester	73%	51%	65%	60%	86%	10%	3%	85%	10%	5%	76%
Tester	76%	53%	71%	62%	88%	7%	4%	85%	9%	6%	
			**		*						
Low educ.	72%	47%	65%	60%	85%	10%	5%	83%	11%	6%	74%
High educ.	77%	56%	71%	62%	89%	8%	3%	87%	8%	4%	79%
	**	***	**		**						
Lower income	74%	50%	64%	61%	85%	10%	5%	82%	11%	7%	74%
Higher income	74%	54%	70%	57%	85%	10%	4%	87%	9%	4%	79%
HIV risk high	70%	45%	59%	56%	90%	7%	3%	84%	9%	6%	76%
HIV risk low	78%	57%	74%	63%	88%	9%	3%	85%	10%	5%	80%
											*
Rural	81%	56%	73%	66%	87%	9%	4%	86%	9%	5%	71%
Urban	73%	50%	67%	59%	87%	9%	4%	85%	10%	5%	77%
	***	**	**	**							
Total N	1605	1439	1430	1589	1600	1600	1600	1386	1386	1386	626
Total Mean	74%	52%	68%	61%	87%	9%	4%	85%	10%	5%	76%

All percentages are weighted; *: p-value for difference from chi2 test for difference amongst the two groups <0.10; **: p-value<0.05; ***: p-value<0.0. Non-testers are those who have not tested in the past 12 months. High income is considered >2000Kwacha per month; HIV high-risk is self-reported high or moderate perceived risk of contracting HIV. In the acceptability block, percentages represent proportion of respondents who answered "very comfortable" to

the questions. The last column indicates the percentage of respondents who have not tested in the past 12 months who responded that they would test “for sure” if HIV self-testing were available and for free.

Table 3b: Acceptability of HIV self-testing, continued

	Percentage	Percentage of overall sample
Do you have any concern at all with HIV Self-test?		35%
If yes, which one?		
Partners violence	8%	2.8%
Forcing people to test	5%	1.8%
Suicide	23%	8.1%
Lack of linkage to care	12%	4.2%
Validity of the test	12%	4.2%
Lack of behavioral post counseling advice	11%	3.9%
Lack of post counseling and mental health	18%	6.3%
Cost	3%	1.1%
Other (specify)	8%	2.8%
How severe is this concern?		
Very severe. No Self-testing in Zambia	6%	2.1%
Important but can be addressed	71%	24.9%
Relatively minor	24%	8.4%
No concerns		65.0%

All percentages are weighted. Responses were unprompted.

The second column indicates percentages as a fraction of the overall sample

Both the survey and the qualitative research also asked about concerns around self-testing. 35% of the sample responded that they had at least some concern around self-testing. We asked those participants what was the main concern, and the main concern that respondents brought up was the possibility of suicide for clients (25% of those with concerns, 8% of total sample), followed by the fear that the lack of post-counseling would lead to depression (18% of those with concerns, 6% of the sample). Concerns about validity of the test (4% of sample), lack of linkage to care (4% of sample), and lack of post-test behavioral counseling (4% of sample) were also brought up, as well as partner violence following couple self-test (3% of sample). Amongst other answers, there was some concern that the HIV test itself could transmit the virus through saliva. Only 2% of the total sample thought that the concerns were too severe to allow HIV Self-test in Zambia. 25% thought that their concerns could be addressed by counseling or careful policy, and 8% clarified that their concern was relatively minor.

Concerns linked to lack of post-counseling were also the main theme around concerns raised during focus groups. Both suicide and depression was brought up, others worried that the lack of behavioral post-counseling would not allow clients to deal with the disease. The main theme around lack of counseling was the inability of self-test to empower people with dealing with the result, and hence get treated:

“The one who did not receive counseling before testing and found out that they are positive can die of shock, but the one who receives counseling is told what to do and is strengthened,” - FGD Female Chazanga

“If one has been educated or taught on HIV, if they find out they are positive they will go to the clinic,” – FGD Male Chongwe

4.4 Models of HIV self-testing: distribution point, price, counseling.

The strong value that respondents gave to counseling was confirmed when assessing preferences for different distribution models. Tables 4-4d show the results of the Discrete Choice Experiment for distribution methods. The tables represent coefficients from a mixed logit model. While the level of the coefficients do not translate into any cardinal meaning, they still have an ordinal meaning: positive coefficients mean that individuals are more likely to choose a model with that characteristic. Attributes with higher coefficients carry more weight in the decision of choosing a specific model than others with lower coefficients. In the main model, the attribute with the highest coefficient is counselling: the coefficient is positive and significant. Next, we find location: participants had a negative and strong preference against picking up the tests at the VCT department at the facility. They instead preferred the outpatient department at the facility, or a private clinic. The cost was not as important of a factor as presence of counseling and location. A cost of 10 Kwacha did not change the probability that one model was chosen over another one, and it even had a very low but positive coefficient, which could be explained by the economic literature suggesting that a positive price can stimulate product use (Ashraf, Berry & Shapiro 2010). A cost of 25 Kwacha was instead associated with a negative and significant coefficient, suggesting that a 25 Kwacha price was decreasing the probability of choosing that model. However, cost seemed overall to have less importance than presence of counseling or location.

The results remain fairly constant across urban/rural and gender strata (4a to 4b)

Table 4: Results of a mixed logit of discrete choice experiment for models of HIV self-testing

Attribute	Non-testers		Testers	
	Mean	SE	Mean	SE
<i>Location for picking up test</i>				
Location: VCT	-1.45	0.07**	-1.03	0.08**
Location: OPD	0.132	0.05*	0.22	0.05**
Location: Chemist	<i>ref</i>	-	<i>ref</i>	-
<i>Counseling</i>				
Counseling not present	<i>ref</i>	-	<i>ref</i>	-
Counseling present	2.31	0.15**	3.08	0.15**
<i>Cost</i>				
Cost: free	<i>ref</i>	-	<i>ref</i>	-
Cost: 10 Kwacha	0.14	0.05**	-0.26	0.04**
Cost: 25 Kwacha	-0.86	0.05**	-1.07	0.05**
Model diagnostics				
Number of observations	17712		25920	
Log Likelihood	1424.37		2595.91	
Likelihood ratio chi2	<0.001		<0.001	

Table 4a: Results of a mixed logit of discrete choice experiment for models of HIV self-testing, all non-testers: education and gender strata

Attribute	Education				Gender			
	High Educ		Low Educ		Females		Males	
	Mean	SE	Mean	SE	Mean	SE	Mean	SE
<i>Distribution location</i>								
VCT	-1.64	0.11**	-1.36	0.10**	-1.62	0.11**	-1.30	0.094**
OPD	0.16	0.08*	0.12	0.07	0.11	0.08	0.15	0.075*
Chemist	<i>ref</i>	-	<i>ref</i>	<i>ref</i>	<i>ref</i>	-	<i>ref</i>	<i>ref</i>
<i>Counseling</i>								
Not present	<i>ref</i>	-	<i>ref</i>	<i>ref</i>	<i>ref</i>	-	<i>ref</i>	<i>ref</i>
Present	3.36	0.28**	1.60	0.16**	2.75	0.23**	1.85	0.18**
<i>Cost</i>								
Free	<i>ref</i>	-	<i>ref</i>	<i>ref</i>	<i>ref</i>	-	<i>ref</i>	<i>ref</i>
10 Kwacha	0.54	0.72**	-0.22	0.07**	0.25	0.07**	0.043	0.06
25 Kwacha	-0.5	0.076**	-1.25	0.08**	-0.83	0.079**	-0.902	0.07**
Model diagnostics								
Observations	9153		8559		8829		8883	
Log Likelihood	970		496.2		751.4		749	

Table 4b: Results of a mixed logit of discrete choice experiment for models of HIV self-testing, all non-testers: Income and Urban Strata

Attribute	Income				Urban Status			
	High		Low		Urban		Rural	
	Mean	SE	Mean	SE	Mean	SE	Mean	SE
<i>Distribution location</i>								
VCT	-1.78	0.22**	-1.36	0.1**	-1.53	0.08**	-1.31	0.16**
OPD	0.08	0.16	0.02	0.09	0.12	0.06*	0.184	0.12
Chemist	<i>ref</i>	-	<i>ref</i>	<i>ref</i>	<i>ref</i>	-	<i>ref</i>	<i>ref</i>
<i>Counseling</i>								
Not present	<i>ref</i>	-	<i>ref</i>	<i>ref</i>	<i>ref</i>	-	<i>ref</i>	<i>ref</i>
Present	3.87	3.87**	1.72	0.19**	2.61	0.18**	1.387	0.27**
<i>Cost</i>								
Free	<i>ref</i>	-	<i>ref</i>	<i>ref</i>	<i>ref</i>	-	<i>ref</i>	<i>ref</i>
10 Kwacha	0.69	0.14**	-0.15	0.07*	0.22	0.05**	-0.193	0.11*
25 Kwacha	-0.388	0.14**	-1.14	0.09**	-0.78	0.06**	-1.276	0.13**
Model diagnostics								
Observations	2862		6399		14256		3456	
Log Likelihood	416.4		395.4		1143		273.4	

Table 4c: Results of a mixed logit of discrete choice experiment for models of HIV self-testing, all testers: Education and gender strata

Attribute	Education				Gender			
	High Educ		Low Educ		Females		Males	
	Mean	SE	Mean	SE	Mean	SE	Mean	SE
<i>Distribution location</i>								
VCT	-1.32	0.14**	-0.87	0.09**	-0.91	0.10**	-1.22	0.13**
OPD	0.2	0.08*	0.23	0.06**	0.25	0.06**	0.1459	0.09
Chemist	ref	-	ref	ref	ref	-	ref	ref
<i>Counseling</i>								
Not present	ref	-	ref	ref	ref	-	ref	ref
Present	4.47	0.32**	2.13	0.15**	2.98	0.17**	3.026	0.27**
<i>Cost</i>								
Free	ref	-	ref	ref	ref	-	ref	ref
10 Kwacha	0.02	0.07	-0.47	0.06**	-0.28	0.05**	-0.227	0.07**
25 Kwacha	-0.73	0.07**	-1.32	0.06**	-1.06	0.06**	-1.074	0.08**
Model diagnostics								
Observations	11610		1530		17334		8586	
Log Likelihood	1530.9		1088.8		1664.2		917.74	

Table 4d: Results of a mixed logit of discrete choice experiment for models of HIV self-testing, all testers: Income and urban status strata

Attribute	Income				Urban Status			
	High		Low		Urban		Rural	
	Mean	SE	Mean	SE	Mean	SE	Mean	SE
<i>Distribution location</i>								
VCT	-1.31	0.298**	-0.817	0.11**	-1.07	0.09**	-0.92	0.14**
OPD	0.13	0.17	0.28	0.08**	0.24	0.06**	0.17	0.09
Chemist	ref	-	ref	ref	ref	-	ref	ref
<i>Counseling</i>								
Not present	ref	-	ref	ref	ref	-	ref	ref
Present	6.33	0.76**	2.28	0.19**	3.56	0.19**	1.96	0.21**
<i>Cost</i>								
Free	ref	-	ref	ref	ref	-	ref	ref
10 Kwacha	0.23	0.13*	-0.4	0.07**	-0.09	0.05	-0.74	0.08**
25 Kwacha	-0.53	0.14**	-1.25	0.08**	-0.85	0.05**	-1.71	0.10**
Model diagnostics								
Observations	3429		9018		19332		6588	
Log Likelihood	539.8		657.2		2109.8		501.8	

While the possible alternatives of picking up the test were limited by feasibility concerns in the DCEs, the qualitative component could explore more in detail the entire range of possibilities. Still, the OPD department at the public health facility was a place where most participants would feel comfortable collecting the self-test. The health facility was preferred mainly because of its association with counseling: participants believe that they will receive counseling when given the self-test and they thought they were free. Distribution of tests in the community was also suggested. In the community, participants would be comfortable getting the self-test from a community health worker distributing the tests from a central point or distributing them from door to door. This was better for those who cannot go to the health facility to get the self-test.

“The clinic is better because they won't just give it to you like at the drug store, there they will sit you down and give you information”- FGD Female Chazanga

“It's better if they distribute them door to door like the way they distribute medication for bilharzia. If they say collect from the clinic not everyone will go and collect,” – FGD Male Chongwe

When asked whether the church would be a comfortable point of access for the test, there were mixed reactions. While others thought it was a good location to reach the masses, others only agreed if there was someone from the health facility doing the distribution. On the other hand, others would not be comfortable at all because they would be embarrassed to collect it while others are looking.

“At church may not be good unless there is a health worker available. And it's not everyone that will be free to take it, but at the clinic people are more free,” – FGD Female Chazanga

“Not the church, it's embarrassing that others can see that you are going to test. I can feel embarrassed to stand on the line to get the test in public, unless they give it in private,” – Female Sex Worker

We further inquired about whether they would feel comfortable to collect it from the drug store if it was being distributed for free. During qualitative work, it was difficult to disentangle the drug store model from its lack of counseling and the cost. Even though the test would be free participants said they would get it from the health facility because at the drug store they will not receive any form of education or counseling. Others said they would rather collect it from the drug store on condition that the distributor was trained in counseling or education.

“Registered drug stores can also distribute the tests if the person knows the test well and can advise the client to go to the clinic after they have received the results,” – Female Sex Worker

“Even if it would be given free at the chemist, it's better to get it from the clinic because they will educate you,”- FGD Female Chongwe

“I wouldn't get the test from the drug store even if it were for free because they will not counsel me at the drug store. So I would still get it from the clinic because they will pass me through counseling,” – FGD Female Chazanga

4.5 Distribution: the supply

On the supply side, we inquired about the potential distribution channels for the self-test through key informant interviews with private drug store owners and a representative from Medical Stores Limited. Medical Stores Limited (MSL) is the institution responsible for the existing national drug distribution system for the public health facilities. MSL would therefore be the distribution channel for HIV self-tests in the health facility, as explained by the MSL representative. The test would be stored at MSL and distributed to the public health facilities through the District Health Offices. The quantities for distribution would be determined by the health facilities, who would use the existing system to put in orders for the self-test kits. A concern of the representative was the ability of the facilities to effectively and timely order new tests, as well as a lack of transport at the district level to distribute the self-test to the health facilities - a concern not specific to HIV self-testing

The private drug store owners expressed their willingness to sell the self-test. However, they also saw it important that the potential user is counseled and educated on how to use the test. When asked whether they would be able to provide these services, drug store owners felt they would be able to do it only if there was a training they could attend.

We finally inquired about distribution methods also amongst the two public companies. A study conducted in Zimbabwe showed that HIV testing offered at in-house clinics within companies has more potential to increase uptake than HIV testing offered at a health facility. (Corbett *et al.* 2006) This is a clear indication that employees need health care services provided within their reach at a time convenient to them. Our interviews with Zamtel and ZESCO were done with this perspective in mind.

ZESCO has in-house health facilities that are run by themselves. The representative had no reluctance in distributing the test through their clinic. However there was some concern expressed on linkage to care, where the representative thought employees would not return to the company clinic if they found out they were positive because everyone knows one another in the organization. Finally when asked whether they would be willing to procure the self-test kit for employees the representative said,

“We may have to understand what we are trying to achieve before we spend money. If we think that it is going to increase the uptake then we may decide to buy, but if we think that it may not have an impact, we do not want to spend our money,” – ZESCO

While ZAMTEL does not have in-house health facilities, one of their HR values is to promote employee health. Therefore every quarter they allow for a visit by health organizations to either disseminate information on health issues or conduct health checks including HIV. The representative was open to the idea of distributing the test through their organization.

A review by the Southern African AIDS Trust (SAT) titled *“Legal Issues Surrounding the Distribution of HIV Self-Testing Kits”* (SAT 2014) finds that the distribution of the self-test kit is governed by the Medicine and Allied Substance Act No. 3 of 2013, which implies that a pharmaceutical license is required for the distribution or manufacture of medicine or allied substance, under which the self-test falls. Therefore anyone dealing in the distribution of self-test kits should have obtained a license from the Zambia Medicines

Regulatory Authority and distribution through non-licensed outlet is currently not possible.

4.6 Effectiveness of Instruction Sheet and Video

Overall, instructions seem to perform well and to be well understood. After receiving the Oraquick® instructions (see Annex B), 73% of participants thought that the instructions were clear enough that they would feel confident in being able to do an HIV Self-test by themselves (Table 5). Lower education status was associated with lower understanding of the test: amongst the low educated, only 64% declared to be confident vs 83% for the higher educated (those who completed secondary school or above). The percentage dropped to 52% for those who did not complete primary school, and in qualitative research, respondents also emphasized the need for special consideration for the illiterate as they did not think that the instructions alone could be enough for low-educated people to fully understand. Accompanying a video to the instructions made participants more confident, with 79% declaring confidence in ability to do the HIV self-test. This result was upheld in the qualitative research, as people seemed to feel more confident about the overall process of how it works after visualizing it through the video.

“The steps are easy to understand especially when you see it with the video,” – FGD Male Chongwe

We then administered a 10-questions quiz mentioned in the methods section above, and reported in Appendix A. The quiz was intended to test understanding of the steps needed to take the test and understanding of how to interpret the results. Overall, the results indicated a good understanding of the instructions. During analysis we excluded the last question (“Is it OK to drink water right before taking the test?”) because information needed to respond to the question was not mentioned in the instructions. Out of the remaining 9 questions, participants responded correctly to around 8 of them on average [min: 2, max: 9, median 8]. However, most of the mistakes came from interpreting the results. When we showed an image of, respectively, an invalid, positive and negative test, only 65% of those who had been given instructions only was able to identify all 3 of them. This is a cause of concern. There was also a strong education gradient: the percentage was 44% for low education and 70% for higher education. On the positive side, 94% of respondents understood the requirement of leaving the test in the vial for 20 minutes (Table 5). There were no significant gender differences.

The video did not appear to improve understanding of how the test is done in its details. It was useful for making participants *feel* more confident, but it actually worsened their performance in the quiz. Participants who were given both video and instructions responded correctly on average to 0.2 less questions than those who had received only instructions (p-value<0.001). Only 61% of them (vs 65% of instructions only, p-value 0.02) were able to interpret correctly the images of the invalid, positive and negative test. In addition, only 90% of them (vs 94% of instructions only, p-value 0.01) understood the requirement of waiting 20 minutes.

Misinterpretation of key aspects of the test from those who were shown the video was also evident in the qualitative part;

“You put the stick in the liquid and wait for 15minutes,” – FGD Female Chazanga

“Once you have tested, when you see a minus sign then you are negative and when you see a plus sign then you are positive,”- FGD Female Chazanga.

Qualitative research gives us insights on why this might have happened. The video shifted attention away from the details, and made participants focus only on the big picture. It was said that the video was too fast, without stopping or having the possibility of going back to check again, and that it was really focusing on the process rather than the details.

“The instruction sheet is much more clear than the video, the video its not easily to follow because its fast,” – Female FGD Chazanga

In addition, surveyors also noticed that participants in the video arm were not likely to consult the instructions before responding to the questions, and were just relying on their memory from the video. This is not something likely to happen in a real-life scenario given the much higher stakes of wrongly interpreting a real HIV self-test result rather than an image in a survey.

Some participants in the qualitative groups highlighted complementarity: both videos and instructions were needed because they complemented each other. Some participants who only had the written instructions felt unsure about the identification of each of the components in the kit and expressed a desire to be educated more.

Table 5: Effectiveness of instructions

	Instructions			Video			Pvalue	All
	Total	High Ed	Low Ed	Total	High Ed	Low Ed		
Confident I can do an HIV Self-test								
Not confident	0.05	0.03	0.07	0.05	0.03	0.05		0.05
Somewhat confident	0.22	0.14	0.28	0.17	0.11	0.22		0.19
Confident	0.73	0.83	0.64	0.79	0.87	0.72	0.01	0.76
Quiz								
Knows to wait 20-40 minutes to read result	0.94	0.96	0.91	0.9	0.95	0.8	<0.01	0.91
Knows how to interpret results	0.65	0.7	0.44	0.61	0.67	0.35	0.02	0.59
Correct answers out of 9	8.1	8.3	7.9	7.9	8.2	7.6	<0.01	8
SE	(1.17)	(1.01)	(1.26)	(1.32)	(1.14)	(1.41)		(1.25)
Ok to drink water?	0.73	0.72	0.73	0.71	0.67	0.77	0.51	0.72

4.7 Linkage to Care

We first asked respondents to imagine that they had taken a self-test, and that the self-test was showing a positive/reactive status. We inquired when, if at all, would they go to the facility, and gave 3 options: within the same week, not within the same week, but before feeling sick, or would wait until feeling sick. 85% responded that they would go within the same week, 13% that they would not go in the same week, but would still go before feeling sick, and only 2% responded that they would wait until feeling sick. We

noticed differences in gender, with women more likely to go within the same week than men (Table 6a): only 82% of men (compared to 86% of women) would visit the facility in the same week. No differences by urban/rural status were detected.

We also inquired which type of follow-up would make participants more likely to return to the clinic in case of a positive result given a choice of a phone call from a counselor, an SMS, or an in-person visit. Both the qualitative and the quantitative analysis suggested that the in-person visit is the most effective method. However, for women, those with high education, and urban residence there did not really seem to be a difference between phone calls and in-person visits. Those with high income have a negative (non-significant) effect for in person visit (Table 6b).

In the survey, we approached this question again as a discrete choice experiment, asking participants to trade-off the follow-up options with more traditional pull factors to visit the health facility: waiting time and staff attitude. Results from the DCEs suggest a negative preference for a brochure compared to call or in-person follow-up, which were instead not significantly different from each other. The most important determinant of linkage to care, however, was not how the follow-up was made but the attitude of the staff. This is documented by the absolute level of the coefficient for attitude, much higher than the levels for the remaining attributes explored. Waiting time also had a more important effect on visiting the facility than follow-up method, with moving from 1 to 3 hours and from 3 to 5 hours both reducing the probability of linkage to care, independently of the other aspects (Table 6b). The results were consistent for different education, gender and urban/rural strata. In simulations based on this DCE results, having rude staff led to a 33% decrease in the probability of having that model chosen.

These results were upheld in the qualitative research. In that case, we assessed which had more value between i) a brochure/leaflet ii) an SMS iii) a phone call and iv) a visit from a health care worker. Just like in the DCE, participants placed more value on the more interactive forms of follow-up, and preferred a health care worker visit after they take the test. The main reason attributed to this choice is the possibility of creating a relationship with the community health worker, a relationship that cannot be established through an anonymous, possibly bad-connection phone call. Secondly, there was a feeling of being cared for when the community health care worker visits, who they generally recognize as someone trustable and knowledgeable. Thirdly, they valued the in-person contact because of the possibility of asking clarification questions. On the phone they did not think that they could get the same responses or be understood as well. Lastly, on the phone or SMS the user can easily give an excuse, but at a visit this is more unlikely.

“The person who is visited is more likely to return because the nurse has made more effort and is more serious. Even if you're busy, the nurse can encourage you to go. But if it's a phone call one can easily say I am busy,” – FGD Male Chongwe

“The one who is visited is better because they have the opportunity to sit, greet each other and have conversation before going on with the topic. But on the phone it's just about the result, there is no conversation,” – FGD Male Chazanga

Table 6a: Linkage to Care

	Total		Female		Male	
	N	%	N	%	N	%
If a reactive test, when would you go to the facility?						
Within the same week	1,617	84.7%	970	86.4	647	82.4%
Not the same week, but before I feel sick		13.5%		12.4%		15.1%
Would wait until feeling sick		1.7%		1.2%		2.5%

All percentages are weighted.

Table 6b: Mixed logit results on preferences around linkage to care through a discrete choice experiment

	All sample	by gender		by educ		by urban		by income	
		Males	Females	Low Educ	High Educ	Urban	Rural	Low income	High income
A counselor contacted you...									
Through an SMS	<i>ref</i>								
Through a call	0.24 [0.04]***	0.17 [0.07]**	0.30 [0.06]***	0.27 [0.07]***	0.17 [0.07]**	0.29 [0.05]***	0.10 [0.10]	0.27 [0.07]***	0.10 [0.13]
Through visit	0.29 [0.04]***	0.29 [0.07]***	0.29 [0.06]***	0.48 [0.07]***	0.18 [0.07]**	0.24 [0.05]***	0.46 [0.10]***	0.48 [0.07]***	-0.19 [0.14]
Waiting Time at the clinic									
1 hour	1.96 [0.07]***	2.12 [0.12]***	1.86 [0.10]***	2.10 [0.12]***	1.84 [0.11]***	1.97 [0.08]***	1.97 [0.16]***	2.10 [0.12]***	1.90 [0.23]***
3 hours	0.97 [0.05]***	1.08 [0.07]***	0.89 [0.06]***	1.01 [0.08]***	1.00 [0.07]***	0.99 [0.05]***	0.93 [0.10]***	1.01 [0.08]***	1.05 [0.14]***
5 hours	<i>ref</i>								
Attitude of health care staff									
Staff is rude	<i>ref</i>								
Staff is nice	3.74 [0.12]***	3.40 [0.18]	3.97 [0.16]***	3.22 [0.18]***	4.04 [0.19]***	3.74 [0.13]***	3.83 [0.27]***	3.22 [0.18]***	4.09 [0.34]***
Model Diagnostics									
Observations	27630	10,924	16,706	9,672	13,110	21,388	6,242	9,672	3,914
Log likelihood	2566.14	1087.92	1444.57	897.81	1176.16	1959.62	613.65	897.81	336.66

The value of pre-counseling returned as a theme in linkage to care as well. When asked what would motivate users to return to the clinic to confirm their results, participants felt that counseling at the point of receiving the test would make one return. If the user found him/herself positive s/he would be encouraged to return to the public health facility because s/he would have been prepared to handle his/her result better.

4.8 Considerations for special populations

We targeted the key populations of truck drivers and female sex workers, as well as disabled as a special population. Both truck drivers and female sex workers are more likely to be infected with HIV and more likely to transmit the virus to others than the general population - a 2012 study estimated that 7-11% of all new HIV infections were generated by encounters with sex workers (Gouws and Cuchi 2012). Having access to the self-test and using it is the first step to preventing the spread of the HIV virus. The physically challenged are a marginalized group in society whose ability to use the test should be considered. Therefore to guide policy and guideline development around self-testing, an understanding of the challenges the physically challenged will potentially face is needed.

Through focus group discussions, female sex workers (FSW) and truck drivers were asked whether they face challenges in accessing HIV testing through the current model. While some FSWs faced no serious problems, many individuals cited the negative attitude of health care workers towards their group as a major barrier in them accessing the clinic for an HIV test.

“The reason we do not go to the clinic because the health workers are not friendly. Everyone goes to the clinic to find out their status whether they are sex workers or not, but if we go there it’s possible we can even get insults,” – FGD Female Sex Worker

“I don’t manage to go to the clinic to test because I’m scared of what we will be told, I would rather test from those who test in the community,”- FGD Female Sex Worker

Truck drivers faced no discrimination, but they felt that the lack of time accompanied with long waiting times were the main barriers to accessing HIV testing.

“At times they are long lines. And the first test I took the test where they took a lot of blood, the process was too long...” – FGD Truck Driver

“Us men are very busy doing various things, so the its difficult just to get up and go to the clinic...” -FGD Truck Driver

Both FSW and truck-drivers showed high levels of acceptability, and were all in general agreement that it should be introduced in Zambia. The main reasons given for the acceptance of the self-test by FSWs and truck drivers were similar to the ones of the general population, and also centered on privacy, convenience and the fact that it uses oral fluid and not blood in comparison to the current model of HIV testing.

The FSWs and the truck drivers raised issues pertaining to linkage to care. As already mentioned earlier, the attitude of the health workers played a key role in their decision to return to the clinic to confirm results and receive further care. Interestingly, one health

facility in-charge admitted that good customer service is important in helping clients return to the clinic after taking the self-test.

“For clients to come back we need to improve on our customer service. If we attend to them, they get the confidence and they can come back. But if you don't speak to them very well because the counselor is burnt out, the attendance will not be so good,” – Health Facility In-charge

For the disabled and the physically challenged, one main point of discussion was around their ability to use the test. The major concern was that some types of disabilities could not allow the person to conduct the test. The interview with the blind showed acceptability, and acceptability of having someone do and interpret the test in his/her place, conditional only on being someone that he/she trusts in reading the instructions and sharing the result with. Those, whose disability did not allow them to conduct the test, also expressed the need to have someone present who they could trust to help them.

“I would want my young sibling to be there to help me test. Not my friend because you cannot trust a friend completely,” – Physically Disabled

“Yes I would want someone from my family who will keep my secret to help me use the self- test and read the results,”- Physically Disabled and Blind

5. Discussion

The results above allow us to respond to and discuss the initial questions that had guided this formative research. For each question, we will discuss briefly the key results, limitations, interpretation, and generalizability.

1. What are likely to be the most effective, efficient, and ethical ways of distributing self-test kits to potential users?

We found a strong, negative preference for models based on distribution at VCT department of the facility, possibly due to stigma. Models in which the tests are distributed in a department not specifically associated with HIV, such as the outpatient department, as well as private outlets such as chemists were instead equally valued. A small cost did not appear to be a major determinant of demand, and even a cost of 25 Kwacha reduced the probability of preferring a model by only around 20%. Cost was more of a concern for lower income and lower educated respondents, suggesting a double system where self-tests are given for free at the clinic, but available for a cost at the private pharmacies.

Another distribution method worth considering is at the community level, through community health workers employed by the clinics. For those dwelling in hard to reach areas, this method can be especially effective and was suggested during qualitative research. Participants trust counselors and value in-person interaction. Of course, a known bottleneck for community outreach activities is the shortage of human resource at the clinic and a lack of funds to support community workers. While community outreach may be expensive, it may have significant benefits in reaching those who do not have access to the health facility. In this context, HIV self-testing could integrate current

community efforts, for example counselors could leave behind tests for those who were not found during traditional HIV testing door-to-door.

For the effective distribution of the self-test kits through public health care facilities by MSL, human resource and transportation bottlenecks need to be addressed. These bottlenecks are not specific to HIV self-test but rather intrinsic in the current supply chain issues. There seemed to be a general trust of counselors and peer workers at the facility. Improving the lack of transport in the distribution process is a bigger challenge within the health system. Often, health care workers use personal transportation or NGO project vehicles to help in the distribution of HIV test kits. Long-term solutions still need to be sought to mitigate the challenges faced in the drug and supplies system. Private pharmacists indicated the need and the desire to be trained if they were to distribute the test. If private pharmacies provided self-tests, pharmacists could be a means to encourage and facilitate linking to counseling.

Companies with a structure like ZESCO, which has an in-house clinic, should be considered in the distribution process in an effort to reach those that are in full time employment, as lack of time and waiting times were mentioned as deterrents to visiting the health facility. HIV testing at the workplace is convenient as it brings the test closer to employees. Employees at ZESCO access health care services including HIV counseling, testing and treatment through the company's in-house clinic. However the interviewee identified stigma as a hindrance to HIV testing and treatment as employees know each other well and therefore would not want to be identified as HIV positive. In such cases, the HIV self-test has the potential to increase the number of people testing and knowing their status as the test can be done privately at a place convenient to them. Workplaces like ZAMTEL and ZESCO should be targeted for the distribution of the HIV self-test.

The DCE are best fit to disentangle factors such as cost from distribution outlet. Nonetheless, there is still the risk that individuals just naturally associate drugstores as a place where things are expensive. In Zambia, there is also a strong tradition of all HIV testing and care being free. However, distribution of HIV self-testing through drug stores seems accepted, so our recommendation is distributing the HIV self-test through drug stores may potentially be targeted primarily to those in higher income brackets.

2. What methods are likely to be effective for ensuring and promoting linkage to care for counseling, confirmatory testing and treatment for those using self-tests?

We looked at four ways of communication that would be most effective for promoting linkage to care, namely; brochure, SMS, phone call and a home visit. Participants seemed to value in-person contact and to appreciate the home visits. However, the results did not seem to indicate a significant difference between in-person contact and a phone call for a number of different subgroups. The home visit provided an opportunity for the user to build a relationship with the community health worker and to open up on issues that may be bothering him/her. While this is ideal, it is also an expensive strategy and a cost-effectiveness study should be conducted. We also asked participants to trade-off specific HIV Self-test follow-up strategies with the importance of health care facility characteristics for linkage of care. There, participants considered more important staff attitude and waiting times at the clinic than a specific attempt of following up for linkage to care. This result is consistent with the generally low rates of linkage to care

even when doing door-to-door fingerprick testing in the communities found in CIDRZ programmatic data.

This section is most susceptible to the limitations intrinsic in a survey, where self-report cannot be validated by real life behavior. Different methods will have to be assessed in their feasibility and then tested for effectiveness in a pilot.

3. What kinds of health providers and other service providers would be effective and acceptable in the distribution of self-test kits and the linkage to care?

There was general trust in the health facility staff, including counselors for the provision of the HIV self-test and linkage to care because they were considered knowledgeable on general health issues. Considering that the self-test is new in Zambia, myths and misconceptions may arise with the introduction of the HIV self-test. One of the misconceptions that arose during the study was that HIV could be transmitted through the saliva as the test depends on saliva to detect HIV. This is not true as the self-test detects the antibodies in the saliva and not the virus itself. However, this information should be given by a trusted source like community health workers (CHWs) that can further explain the means of HIV transmission. CHWs are widely used in the provision of health care services within the communities in Zambia. They usually serve the communities in which they reside and are generally trained in various health problems. They carry many different titles depending on the project they work under (Zulu *et al.* 2013). These CHWs are identified and trusted by members of the communities as shown in our study findings. Therefore they should be utilized in both the distribution of self-test kits and in initiatives promoting linkage to care. Programmes introducing the self-test in Zambia should ensure that CHWs are adequately trained in post-test counseling as they will be dealing with clients who have just taken the test.

4. What legal or social concerns might be associated with different distribution methods?

In the case of distribution through a public outlet, Medical Store Limited--the institution responsible for the supply chain of medical commodities in the public system--did not highlight any specific bottlenecks or challenges that are not already currently present with the distribution system of the fingerprick point of care method. The supply side for the private sector is more complicated, as a report on legal issues surrounding HIV self-testing prepared by Southern African AIDS Trust (SAT) highlights that the law limits distribution to licensed outlets, which would significantly limit potential distributors and capillarity of the availability of self-tests. Pharmacies, other potential private distributors, and regulators need to be brought in early in the scale-up process to insure that the model of distribution is feasible.

The results show a very high rate of acceptability of HIV self-testing, and enthusiasm for it. However, the results also indicate strong preference for counseling, and concern that the lack of counseling might lead to people falling into depression and not linking to care. These results are comparable to the ones of the Kenya formative studies. This is a finding that needs more investigation, as a limitation of this study is that all of these results are based on self-reporting and we don't have any real-life behavior to verify or support them. In addition, it is unclear whether counseling was sought for a purely information need around self-testing, or if there was a psychological need as well. By

definition, self-testing is something that is done in private and linking it to counseling would invalidate many of the advantages of HIV self-testing. The question of practicality is also an important one, due to limitations of human resources and the difficulty of disentangling the counseling component from the health facility as a distribution outlet. There seems to be a disconnection between the desire to not go to the facility and the desire to have counseling and personal relationship with the tester. More research is needed on whether alternative modalities of counseling are possible, especially when it comes to information needs of participants around self-testing. However, community distribution where a peer counselor residing in the community is available for questions, follow-up or psychological support could be a potential solution.

5. What tools, instructions and demonstrations are most likely to ensure users correctly perform and read the test?

Overall, instructions seem to perform well and to be well understood. Lower education status was associated with a lower understanding of the test, and respondents also emphasized the need for special consideration for the illiterate. The quiz questions were a start in assessing the understanding, but validation with real-life behavior is critical, as hypothetical questions and a low-stake quiz are significant limitations of this study section. In Kenya, 15% of HIV Self-test done by real patients as part of a formative studies were invalid (Kurth and Siika 2014) and this represents a red flag that deserves an investigation in Zambia with real patients. However, a dedicated counselor has demonstrated notable effectiveness: in Malawi, where a counselor demonstrated use and then asked the patient to demonstrate it back using a cotton swab, the test was conducted in a more accurate way with sensitivity at 93.6% and specificity 99.9% (Choko *et al.* 2011).

When we explored whether a video could increase understanding, we found that while it improves the perception of understanding and confidence, it actually decreases understanding of the specific steps and details. This result could be specific to our video, and we recommend any future video to be slowly focusing on each step, repeating instructions for each step twice and clearly emphasize how to read the results. The qualitative feedback received was that although our video was useful to see and understand more about the overall process, it was too fast and did not spend enough time on the details. A slow and comprehensive video might be a potential complementary tool to inform and boost understanding. Another recommendation is to use the video as an instrument to stimulate demand for HIV self-test by increasing the percentage of people who know about HIV self-tests, understand the overall process, and are confident that it is something that they could do, rather than as part of the instruction process.

6. Are there special considerations for any key populations?

The attitude of health care workers surfaced as an important determinant of clinic utilization for all, but it was most pronounced for key populations. Female sex workers in particular were concerned about disrespectful and judgemental attitude of health care workers and indicated it as the main barrier to their linkage to care behavior. Truck drivers also mentioned staff attitude as a possible barrier, but they were mostly concerned about access to self-tests. Being always on the road and not stationed in one

place, they highlighted that distribution at the clinic is not ideal. Distribution at the work place emerged as a possible recommendation.

Special considerations should be made towards persons with disabilities and the use of the HIV self-test. This population has been defined as those having long-term physical, mental, intellectual or sensory impairments hindering full and effective participation in society (UNAIDS 2009). The issue of privacy and confidentiality is compromised when the test is done in the presence of another person, but some subgroups of disabled (ex. the blind) would need another person's help in doing and/or interpreting the results. Both groups expressed the need for having someone with them to help them conduct the test, who should be someone trusted and able to keep the outcome of the test results confidential. Therefore considerable efforts should be made by authorities to ensure that those disabled have access to HIV self-tests. Authorities will have to address this issue in the future guidelines specifically stating that the disabled should not be prevented from accessing HIV self-tests and giving special considerations for disabled. This could include effective communications strategies to help the disabled identify a trusted person, and/or provide a clear discussion of disabled-specific pros and cons of utilizing the HIV Self-test kit rather than standard HIV testing done by a counselor.

A significant limitation of this study is that we did not oversample the niche of the very affluent, nor other important populations such as adolescents. In Choko *et al.* (Choko *et al.* 2011), adolescents had the highest uptake rates for HIV self-testing compared to other age groups. In this study, quantitative results from adolescents did not show any distinctively different dynamic from the general results, but qualitative inquiry for adolescents is missing.

6. Conclusion and recommendations

The results overall support the need for piloting distribution of self-tests in Zambia. There has been high acceptability, low concerns, and good signals that non-regular testers are interested in testing for HIV through self-testing. However, counseling was thought to be essential, and is likely to affect uptake as well as linkage to care. Participants seemed to prefer in-person methods, although whether for informational or psychological reasons still needs to be assessed. Any pilot should carefully plan for access to in-person counseling services, fully describe the components of counseling provided, and how were they received. As for distribution channels, there was a general dislike of the VCT department at the facility, probably due to stigma, but a general trust in the facility as well. OPD department and private drugstores seemed to be equally desirable. Pilot studies might initially distribute through these departments, through community workers, or pharmacy if counseling is feasible, but there is a need to understand how to operationalize counseling within a private pharmacy distribution model. Community models also seem very promising since they can allow individuals to receive counseling without the need of going to the facility. Oraquick® instructions developed for resource limited settings seemed adequate, but limitations intrinsic to this study limit the generalizability of the findings and there are concerns in terms of interpretability, and participants expressed the need for some more complementary information in order to feel more confident. This study attempted to complement instructions with a video, which gave some signals of boosting confidence and helping to understand the big picture, but that needs to be significantly improved in order to communicate details more effectively.

Appendix A: Quiz Questions on Correct use of Self-Testing

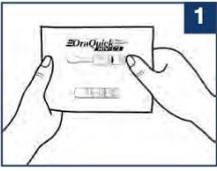
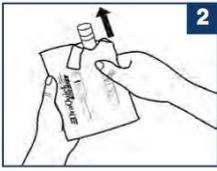
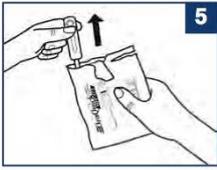
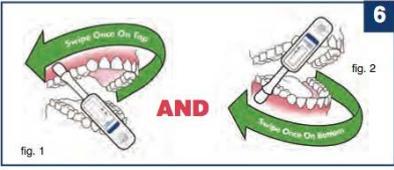
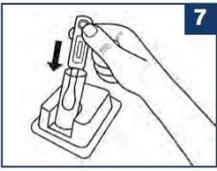
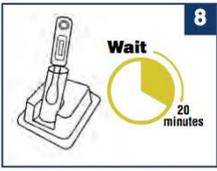
How many minutes do you need to leave the test in the solution in order to obtain a valid result?	Enter -98 for "Don't know"	
	Response constrained to: .>0	
What is this for? (show the picture of the bottle to the respondent)	1	It is the swab
	2	It is the stand where I need to put the bottle in
	3	It is just the package - no use for it
	-98	Don't know
How do you interpret this result? (show pic of valid positive test)	1	That the test is invalid and I need to do it again
	2	That the test is valid and indicating a HIV+ result
	3	That the test is valid and indicating a HIV- result
	-98	Don't know
How do you interpret this result? (show pic of invalid test)	1	That the test is invalid and I need to do it again
	2	That the test is valid and indicating a HIV+ result
	3	That the test is valid and indicating a HIV- result
	-98	Don't know
How do you interpret this result? (show pic of valid negative test)	1	That the test is invalid and I need to do it again
	2	That the test is valid and indicating a HIV+ result
	3	That the test is valid and indicating a HIV- result
	-98	Don't know
What gum do you need to swab to take the test correctly?	1	The top only
	2	The bottom only
	3	Both
	-98	Don't know
Should you swab your tongue as well?	1	Yes
	2	No
	-98	Don't know
Where do you put the test right after swabbing your gums?	1	In the bottle
	2	On a table
	3	I keep it in my hand until I see the results
	-98	Don't Know
What if the liquid from the bottle spills, can you still do the test?	1	Yes
	2	No
	-98	Don't know
Mrs. Phiri drank some water right before taking the test, because she was nervous. Is this a problem for the validity of the test?	1	Yes
	2	No
	-98	Don't know

Appendix B

Oraquick® instructions used for this study

You must follow the test directions carefully to get an accurate result.

Do not eat, drink or use oral care products (mouthwash, toothpaste) 15 minutes before you start the test.

This Kit Contains:	Performing the Test		
 <p>Test Device Stick</p>  <p>Developer Vial</p>  <p>Tube Holder</p>  <p>Preservative (not needed for the test)</p>	 <p>1</p>	 <p>2</p>	 <p>3</p>
	 <p>4</p>	 <p>5</p>	 <p>6</p>
	 <p>7</p>	 <p>8</p>	
	<p>Place test stick into tube.</p>	<p>Wait 20 minutes. Do not read the result before 20 minutes or for more than 40 minutes or you could get the wrong results.</p>	

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