HIV Self-Testing AfRica Zambia

Self-testing for HIV (HIVST) amongst urban, peri-urban and rural communities in Zambia, including a cluster-randomised trial of community-based HIVST distribution

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Abbreviations

3ie	International Initiative for Impact Evaluation
ANC	Antenatal Care
ART	Antiretroviral Therapy
CBDAs	Community-Based Distribution Agents
CBO	Community Based Organization
CSO	Central Statistics Office
CeSSHAR	Centre for Sexual Health, HIV, and AIDS Research
CIDRZ	Centre for Infectious Diseases Research in Zambia
CITAM	Community Initiative for Tuberculosis, HIV/AIDS and Malaria
CPP	Community Partners Platform
CRT	Cluster Randomised Trial
DALYs	Disability-Adjusted Life Years
DCE	Discrete Choice Experiments
DHO	District Health Office
DMO	District Medical Office
DHS	Demographic and Health Surveys
EQA	External Quality Assurance
FBO	Faith-Based Organisation
FGD	Focus Group Discussion
GBV	Gender-Based Violence
GPS	Global Positioning System
HIV	Human Immunodeficiency Virus
HIVOFT	HIV Oral Fluid Tests
HIVST	HIV Self-Testing
HTC	HIV Testing and Counselling
HIVRDT	HIV Rapid Diagnostic Test
IDI	In-Depth biographical Interview
ICW	International Community of Women Living with HIV
IFU	Instructions for Use
KII	Key Informant Interview
LSHTM	London School of Hygiene and Tropical Medicine
LSTM	Liverpool School of Tropical Medicine
MoH	Ministry of Health
NGO	Non-Governmental Organization
NAC	National Aids Council
NHC	Neighbourhood Health Committee
NZP+	Zambia Network of People Living with HIV
PQ	Pre-Qualification
PSI	Population Services International
SCQ	Self-Completed Questionnaire
SEA	Standard Enumeration Area
SFH	Society for Family Health
SOC	Standard of Care
SOP	Standard Operating Procedures

STAR	Self-Testing Africa
TALC	Treatment Advocacy and Literacy Campaign
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNZA	University of Zambia
UTH	University Teaching Hospital
VCT	Voluntary Counselling and Testing
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization
VSU	Zambia Police Victim Support Unit
ZAMBART	Zambia AIDS Related Tuberculosis (Project)
ZABS	Zambia Bureau of Standards
ZAMRA	Zambia Medicines Regulatory Authority
ZNARVs	Zambia National ARV Support Programme

1.0 Executive summary

Zambia has made substantial progress in providing access to HIV testing services. The availability of HIV testing services has expanded across the country. By 2012, Zambia had an estimated 1800 HIV testing and counselling sites available, up from 56 in 2001. The number of health facilities dispensing anti-retroviral treatment (ART) (564) was higher than the target of 500 set for 2015. As such, the country has made significant improvements in increasing access to lifesaving ART.

Despite advancements in providing access to HIV testing services, approximately 40% of Zambians have never tested for HIV. As a consequence, a high proportion of individuals are unaware of their HIV positive status and many people living with HIV access treatment at later stages of infection. There remain a number of barriers to accessing currently available HIV testing services, including structural barriers, such as the direct and opportunity costs associated with seeking HIV testing services at a health facility, and individual-level barriers, including fear of confidentiality of testing and a low perceived risk of HIV infection.

Self-testing for HIV (HIVST) has the potential to address these barriers and therefore reach HIV-positive individuals who remain undiagnosed, link these individuals into treatment and care services at earlier stages of infection, and reduce the risk of onward transmission of HIV infection. In light of this potential, Zambia is considering adopting HIVST as a strategy to deliver HIV testing services, alongside existing methods, to reach individuals underserved by currently available strategies.

Despite the potential of HIV self-testing, there is a lack of evidence on the acceptability, feasibility, accuracy and effective delivery strategies for Zambia. Furthermore, there is limited knowledge of the potential market for HIV self-testing. Evidence is therefore needed to support the roll-out of HIV self-testing across Zambia.

Through a combination of qualitative and quantitative research, this study aims to add to this evidence base by conducting a cluster randomised trial (CRT) of community-based HIVST distribution.

This evidence aims to support the Zambian Ministry of Health in their decision on how best to distribute HIV self-testing in Zambia.

2.0 Background: Country Context and Study Rationale

2.1 HIV/AIDS in Zambia

In 2013, Zambia had an estimated adult HIV prevalence of 13%[1].By 2015, an estimated 82% of people living with HIV (PLHIV) were on ART[2]. The 2013/14 Demographic and Health Survey (DHS) highlighted that approximately 20% of females and 36% of males aged 15-49 years had never tested for HIV. Among women who tested for HIV at ANC and received the result of an HIV test within two years preceding the survey, 69% disclosed their result to their male partner. The DHS also revealed pronounced inequity in access to HIV testing in the general population, with

adolescents, rural Zambians, and individuals with less education and no employment having the lowest levels of ever-testing for HIV and testing within the previous 12 months[1].

Major drivers of new HIV infections in Zambia include sero-discordancy among cohabiting/married couples and lack of knowledge of partner HIV status, multiple concurrent partnerships, including unprotected casual and transactional sex, low levels of condom use, and low uptake of male circumcision[2].Among cohabiting couples tested for HIV in the 2013/14 DHS, approximately 11% were sero-discordant. In over half of these couples, the male partner was the HIV-positive individual[1]. In the 2013/14 DHS, 5% of male participants reported having paid for sex in the previous 12 months. Of this figure, 40% reported not using a condom the last time they paid for sex [1].An estimated 22% of males aged 15-49 years reported being circumcised in 2013/14 compared to 13% in the 2007 Zambia DHS[1,3].

2.2 HIV Testing Services in Zambia

Over the last decade, levels of HIV-testing have increased markedly across Zambia [1,3]. In 2007, 19% of women and 12% of men aged 15-49 years had ever-tested and received the result of an HIV test in the previous 12 months [3]. By 2013, these figures were 46% and 37%, respectively [1]. This progress has been facilitated by delivering a combination of facility- and community-based services.

Across Zambia, HIV-testing services are predominantly health facility-based. Between 2005 and 2008, the number of voluntary testing and counselling sites increased from 500 to 1102 [4]. Provider-initiated HIV-testing and counselling (PITC) was implemented in health facilities in 2006/7. PITC was initially implemented in antenatal care settings and has facilitated near universal uptake of HIV testing services among pregnant women [5]. In 2010, community-based HIV-testing services, including home- and the mobile-based services, had been scaled-up [4]. In 2013, Zambia adopted Option B+ for pregnant women living with HIV and a policy of universal access to treatment for key sub-populations, including sero-discordant couples and individuals co-infected with TB/HIV.

Despite the availability of facility- and community-based HIV testing services, there remain a number of barriers to access, including concerns associated with confidentiality and privacy. As a consequence, a high proportion of individuals are unaware of their HIV positive status and many people living with HIV access treatment at later stages of infection when experiencing symptoms of illness.

2.3 Rationale for HIV Self-testing

The introduction of HIVST kits has the potential to reach individuals who are not being served by currently available HIV testing services. Through increased autonomy and choice regarding when and where to test for HIV, HIVST could address barriers to accessing existing HIV testing services. Further, HIVST is becoming an increasingly plausible option for the delivery of HIV testing services with the development of simple oral test-kits that have proved highly accurate when used by lay clients in Malawi [6,7].

Interest in and willingness to self-test for HIV also appears to be high in a range of settings[8]. Formative research conducted by the Centre for Infectious Diseases Research in Zambia (CIDRZ) with support from the International Initiative for Impact Evaluation (3ie) found that self-testing for

HIV was acceptable and feasible and has the potential to reach individuals with no history of ever-testing for HIV. A recent study in Zambia also found that HIVST could lead to higher linkage to HIV treatment services, with 75% of clients retained on ART after 1 year [11].

Data arising from HIVST studies conducted in Blantyre, Malawi highlight that HIVST is feasible, acceptable and the preferred choice for future repeat HIV testing among individuals with a history of ever-testing for HIV [7]. Among couples in Malawi, qualitative research found that HIVST encouraged partner testing and disclosure [9]. Estimates of confirmatory testing and linkage into HIV care within 12 months of a positive self-test were in the range of 42-73%, as assessed through a dedicated reception clinic service[7].

Through the distribution of HIVST in Zambia, there is potential to provide more equitable access to HIV testing and retesting services, thereby contributing to targets set by the Joint United Nations Programme on AIDS (UNAIDS) to ensure that 90% of PLHIV are aware of their status. However, the availability of quality-assured HIVST products will remain limited in resource-poor settings until the purchase of HIVST kits using donor funds is possible and national HIV programmes have adapted policy and programme documents, including algorithms and training materials, to fully accommodate HIVST.

To be put on approved donor purchase lists, HIVST products need to be suitably low cost and be supported by product approval by WHO and the development of WHO guidelines to support the use of HIVST in defined populations. WHO and UNAIDS have already issued Technical Updates that are supportive of HIVST, but the development of full guidelines requires results from implementation research to evaluate the public health risks and benefits from introducing HIVST into a range of settings.

There is need to further evaluate the feasibility and acceptability of HIVST, understanding of intended instructions-for-use (IFU), accuracy of self-testing, and optimal delivery channels to reach individuals who remain undiagnosed in Zambia. This study aims to provide this evidence through qualitative and quantitative studies.

2.3 UNITAID/PSI HIV STAR PROJECT

2.3.1 Project Activities

Project partners in Zambia include Zambart, Society for Family Health (SFH), Population Services International (PSI), London School of Hygiene and Tropical Medicine (LSHTM), and Liverpool School of Tropical Medicine (LSTM).

2.3.2 Project Aim

The UNITAID/PSIHIV Self-Testing Africa (HIV STAR) study aims to catalyse the HIVST market in Malawi, Zambia and Zimbabwe by testing innovative market interventions and strengthening the evidence base around the effective use of HIV rapid diagnostic tests (HIVRDT) through formative and evaluative research.

The study will proceed in ***two phases***, each lasting two years. In Phase 1 (Years 1 and 2), STAR will answer key questions required by policy- and decision-makers before HIVST scale-up. This phase will pilot and evaluate the acceptability and feasibility of HIVST among different target populations and generate evidence on how HIVST can be distributed most effectively to reach these populations. In Phase 2 (Years 3 and 4), STAR will move from formative research to impact evaluation of the models of HIVST distribution piloted in Phase 1.

Evidence gained through this study will be combined with information from Malawi and Zimbabwe STAR sites to provide answers to more global policy questions:

1. What is the estimated market size for HIVST?
2. What are users' preferences for HIVST and how can demand for HIVST and post-test services be maximised?
3. What level of accuracy can be achieved by users in community-based distribution models of HIVST?
4. Does HIVST increase HIV Testing and Counselling (HTC) frequency/coverage compared to current strategies? Is uptake equitable? Is ART initiation increased?
5. How effectively do individuals link into HIV care and Voluntary Medical Male Circumcision (VMMC) after HIVST?
6. How best can social harms from introducing HIVST to individuals and key populations be anticipated and reported?
7. What are the delivery costs of adding HIVST?
8. Are interventions to improve linkage into post-test services effective and cost-effective?
9. What is the population-level cost-effectiveness of introducing HIVST?

2.3.3 Project Objectives

The primary objective is to *increase the uptake of quality-assured HIVST among general and key populations in Malawi, Zambia and Zimbabwe.*

The secondary objectives are to:

1. *Increase access to quality-assured HIVST among target populations:* This includes directly addressing the availability, adaptability and affordability of HIVST and developing context-specific distribution models to more effectively reach target consumers.
2. *Increase informed demand for quality-assured HIVST:* The project will conduct formative market research to increase product responsiveness to client needs and preferences for HIVST, as well as improve package inserts and other IEC products so that clients are provided with the information they need to effectively use the tests and access relevant post-test services.
3. *Reduce policy barriers to market entry for quality-assured HIVST products:* This means using evidence around preferences and demand for HIVST to estimate the market size and to

inform global and national policy and guidelines, thereby helping to create a supportive policy and regulatory environment in which quality products can be introduced.

2.3.4 Project Activities

Given the need to increase the evidence base around effective models for the distribution of HIVST and subsequent linkages to care, HIVST will be launched using multiple distribution channels, already in existence supported either by SFH or Zambart. Specifically, HIVST will be delivered by existing community-based distribution systems intended to reach poor and marginalized groups currently underserved by HTC services as well as through peer-educators, and commercial and social marketing franchises. Developing this diverse range of service delivery models and fully evaluating their equity and public-health effects offers the advantage of adapting distribution approaches to specific contexts and populations to maximize uptake while providing evidence of consumers' ability to successfully link to post-test services. Cost effectiveness models and market research will also allow stakeholders to compare cost effectiveness and desirability of HIVST to existing HTC models.

The World Health Organization (WHO) will play a key role in informing global policy on HIVST and facilitating the prequalification (PQ) process for manufacturers of HIVRDTs for HIVST. This includes developing guidance and implementation tools, and leading dissemination of this guidance for inclusion in national HTC policies and algorithms, as well as procurement and post-market surveillance guidance.

3.0 Research Question and Objectives

3.1 Research Question

The study will conduct a combination of quantitative and qualitative research in order to address the following research questions:

1. What is the impact of HIV self-testing on HIV prevention and care in Zambia?
2. Can self-testing for HIV be provided in a way that is acceptable and feasible in Zambia?

Further, the findings from this study will complement the findings from the STAR clinical performance study.

3.2 Study Objectives

- To measure the impact of HIVST on the uptake of HIV testing within the previous 12 months
- To measure the impact of HIVST on linkage to HIV prevention and care services
- To measure demand for HIVST kits from the population
- To understand community perspectives on the best distribution methods for HIVST kits

- To measure and understand social harms that may arise as a result of HIVST
- To estimate the costs, both from a provider and societal perspective of HIVST and the cost-effectiveness of HIVST in this context

4.0 Study Design

This study consists of a CRT of community and facility-based HIVST distribution by SFH in multiple rural and peri-urban settings. Under Phase 1, we will conduct a baseline survey prior to the beginning of the intervention, an outcome evaluation using routine data collected by CBDAs and in health facilities, and health economics sub-studies. An end line survey will be conducted in Phase 2 contingent on continuation of funding by UNITAID.

The study will take place in Ndola, Kapiri Mposhi, Lusaka and Choma Districts. Within these districts, 6 matched pairs of health facilities and their catchment areas have been selected for study inclusion in collaboration with the district medical office (DMO). These pairs were matched based on distance to the DMO, catchment population, and availability of HTC and ART services.

One clinic catchment area from each pair will be randomly allocated to the HIVST arm (intervention) and the other to the standard of care (SOC) arm (Control). In the HIVST arm, community-based distribution agents (CBDA), including VMMC mobilisers, will deliver HIVST kits. The kits will also be available at the health facility. In the SOC arm, all HTC services will be conducted as currently.

4.1 Primary and Secondary Outcomes

Primary outcome

The primary outcome is: comparison between randomisation arms in coverage of recent (within the last 12 months) HIV testing among older adolescents and adults (age $\geq$ 16 years) in the clinic catchment areas 12 months after the start of the intervention.

A related pre-specified analysis is to compare the coverage of ever HIV testing among older adolescents and adults between randomisation arms. These analyses will be based on household surveys carried out in the pre-defined evaluation communities in each randomisation arm.

Secondary outcome

To track the number of referrals, HIV diagnoses and ART initiations, the study will extract self-referral forms and routine facility records on a quarterly basis from ART clinics serving the intervention and control zones. The self-referral forms will contain spaces for ART clinic staff to log confirmatory results, the national ART number for clients entering HIV care, and any other relevant referrals (e.g., VMMC). Clinic staff will also be requested to maintain a log of all clients seeking confirmatory testing following HIVST.

Additionally, in collaboration with MoH, VCT and ART registers will be adjusted to allow HIVST episodes to be documented in the “Comments” column. Clinic staff will be trained to ensure that all clients are asked if they are attending to confirm HIVST results and to ensure that area of residence is clearly recorded in the register.

Retention in HIV care

Retention in HIV care will be assessed through cohort analysis of HIVST participants starting ART at 3 months and 6 months. Data on accessed HIV care services will be extracted using the national ART number system.

The secondary outcome is: comparison between randomisation arms of ART initiation rates for older adolescent and adult (age ≥ 16 years) cluster residents, during months 1 to 12 of the intervention.

This analysis will be based on data extraction from routine ART clinic records. Residential address will be used to identify all new initiations among adults and adolescents (age ≥ 16 years) living within the wider clinic catchment area.

The impact of this study will be assessed by re-sampling a randomly selected group of participants after 2 years of intervention to assess whether the uptake of HIV testing within the last 12 months has increased. From previous experience new innovations take time to be taken up in communities and therefore a 2 year period is needed in order to assess full impact. This measurement will be covered in the Phase 2 of the UNITAID study and so is not as yet funded.

4.2 Formative Sub-studies

A number of formative sub-studies will also be conducted in complement with the CRT. This includes key informant interviews (KII), community mapping activities, and focus group discussions (FGD) and in-depth interviews (IDI). Findings from the FGDs and IDIs will help to inform the development of the Discrete Choice Experiments (DCE). The DCEs are designed to estimate user preferences for optimal HIVST delivery configuration and strategies for stimulating linkage to care.

5.0 Study Location, Population and Timeframe

5.1 Study Location

This study will take place in Ndola, Kapiri Mposhi, Lusaka and Choma Districts, each with at least one matched pair of clinic catchment areas. Specific clinics within each district may change as requested by the implementing organization (SFH).

- Ndola– Lubuto and Twapia clinics
- Kapiri Mposhi – Chankomo and Nkole clinics; St. Paul's and Mpunde clinics
- Lusaka – Ng'ombe and Kaunda Square Stage One Clinics. (Kaunda Sq. clinic may change depending on SFH requirements.)
- Choma – Mbabala and Mapanza clinics; Batoka and Sikalongo clinics

5.2 Study Population

The study population is defined as all adults (≥ 18 years old) and adolescents (16 and 17 years old) living in the clinic catchment areas.

Additional populations will be targeted for the formative studies, including stakeholders involved in HIV policy or regulation in Zambia (e.g., government officials engaged in HIV control, Medical Regulatory Authorities, National Reference Laboratories for HIV, donors, academics, and major implementing organisations) and representatives from HIV community-based organisations (CBO), non-governmental organisations (NGO) and faith-based organisations (FBO) operating in the study communities.

5.3 Study Timeline

All activities will be conducted in February 2016 until at least August 2017 (pending approval of continued funding).

6.0 Sampling Method and Sample Size Calculation

6.1 Sampling Method

A random sample will be selected from each community for the baseline household survey based on sampling standard enumeration areas (SEA) defined by the central statistics office (CSO). All individuals living in the sampled SEA will be invited to take part in the survey. A randomly selected subset of household members who give informed consent will also be asked to complete a longer questionnaire and DCE module.

Formative sub-studies

For the KIIs, we will use snowball sampling techniques to identify individuals affiliated with institutions or government entities in HIV policy and regulation who are willing to give informed consent.

Other qualitative research, including KIIs with community-based stakeholders, community mapping activities, and the formative DCE research, will be carried out across the study districts. Following the randomisation of the communities to either the control or intervention arm, two control communities and four intervention communities will be purposively selected for qualitative research activities. The communities will be selected based on socio-economic diversity, community organisation, history of HIV testing, and geographical location.

Community-based stakeholders will be identified through snowball sampling methods. Participants for the FGDs will be selected from community peer groups, including PLHIV, adolescents and youths, and men and women. Further disaggregation of participant groups will be done depending on context. For DCE formative IDIs, participants will be purposive selected based on socio-economic diversity and geographical location. Formative IDIs will also be conducted with HIV testing providers who will be purposely selected from lay workers, healthcare workers and policy makers to concretise the relevant decision-making context in which patient preferences can be of interest.

6.2 Sample size calculations

Baseline enumeration will include approximately 2400 participants in the intervention communities (400 per community) and 2,400 participants in the control communities (n=~4,800). Within this sample, 20% of participants (~1,000) will be randomly selected for the extended baseline survey. The sample size justification for the extended questionnaire is detailed below.

The sample size was calculated to ensure 80% power to detect a 50% change in the proportion of individual tested for HIV over the last twelve months, with 95% confidence. Using 2013-2014 DHS data, baseline rates for individuals tested in the last 12 months are estimated to be between 28.6-57.1% (lower in men than women); for this sample calculation, we have assumed a baseline testing rate of 50%. For a two-sample comparison of matched proportions across 6 pairs of matched communities, we estimate that it will be necessary to recruit around 400 respondents per community, or 4,800 respondents in total.

6.3. Inclusion criteria

- Adults (≥ 18 years old)
- Adolescents (16 and 17 years old)
- Able and willing to provide informed consent
- Residing within catchment area of a designated local health unit
- Residing in a randomly selected household

6.4. Exclusion criteria.

- Unable and unwilling to provide informed consent
- Residing outside the catchment area.
- Anything that, in the opinion of the investigator, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

7.0 Study Methods

The study has four main phases:

1. Formative sub-studies
2. Cluster enumeration
3. Intervention assignment
4. Outcome evaluation and health economics

7.1 Formative Sub-studies

Qualitative data will be collected through KIIs, community mapping activities, FGDs, and IDIs.

Key informant interviews with policy and regulation stakeholders

KIIs will be conducted with policy and regulatory stakeholders to determine barriers and enablers to HIVST scale-up and actions needed to develop supportive policy and regulatory pathways for HIVST in Zambia. Interview guides will be informed by a document review process in order to assess which areas within HIVST regulation and policy require further investigation.

Documents will be reviewed for the following:

1. The clarity of objectives and rationale
2. The institutions that the guidelines/laws/regulations are directed towards
3. How effective the guidelines are in terms of providing guidance to actors
4. Clarity regarding the identity of implementers and the process of implementation
5. Inclusiveness of stakeholders in the guidelines

Figure 2: Available Documents for Policy and Regulation Review

S/N	STAKE HOLDER	DOCUMENT	MAIN AREA OF FOCUS
01	Ministry of Health (MoH)	Guidelines	Policy and regulation
02	Ministry of Community Development	Guidelines	Policy and regulation
03	Ministry of Justice	Laws	Legal
04	Zambia Medicines and Allied Substances Regulatory Authority (ZAMRA)	Laws and regulations	Regulatory
05	Human Rights Commission	Laws	Legal
06	National Aids Council (NAC)	Guidelines	Policy
07	Zambia Bureau of Standards (ZABS)	Regulations	Regulatory
08	Zambia Police Victim Support Unit (VSU).	Laws	Legal
09	University of Zambia (UNZA)	Guidelines	Policy
10	University Teaching Hospital (UTH)	Guidelines	Policy
11	Zambia Enviromental Management Authority (ZEMA)	Regulations	Regulatory

The topic guides for the interviews were developed based on the Walt and Gilson policy analysis triangle (actors, content, context, process). In this case, context will include legal and regulatory issues, content will include perceptions of policy issues in place or to be developed, actors will be key players who can influence HIVST scale- up in each context, and process will determine potential next steps and how they would work in each setting.

Key informant interview guide with community-based stakeholders

KIIs will be conducted with community leaders and representatives from local peer groups, CBOs, FBOs, and NGOs. The interviews will seek to establish the history of HIV testing in the community, predicted responses to HIVST, predicted social arms and reactions to the actual HIVST kits when seen for the first time. KIIs will also aim to understand HIV services available and routes of referral

for HIV care, VMMC, and gender-based violence (GBV) as well as investigate systems for reporting social harms, such as coercive testing or GBV following HIVST.

Mapping exercise and transect walk

Mapping exercises and transect walks in selected communities will be conducted to better understand the local options for managing HIV and develop an overview of the conditions, social activities and groups, and health and general facilities in each community. Special focus will be given to assessing the representativeness of geographical versus social group clusters; identifying appropriate and effective mechanisms for sharing information; identifying where pharmaceutical drugs and items are sold, including informal trading centres; and direct and indirect mechanisms for referral to HIV testing and care services.

For DCE formative study, observational fieldwork with HIVST distributors will be conducted in selected sites to get a better understanding of HIVST process in selected sites across districts. The clients' questions and thoughts with regards to choosing HIVST will also be observed. Furthermore, the providers' part in the decision-making process will be observed.

The study will also explore best practices for HTC provision in order to contribute to the design of an accessible and supportive community-based HIVST system and to ultimately increase uptake of HTC. A social harms reporting system will also be established that will consist of CBDAs, local health clinics, and traditional leaders.

Focus group discussions

FGDs will be conducted with different community groups to obtain a broad perspective on the acceptability of HIVST. The FGD will aim to elicit background preferences for service delivery and linkage to care approaches and identify the most salient service attributes that drive decision-making. Participants will be asked about their knowledge of HIV testing opportunities available in their community, their perception of risk related to HIV testing, the potential for self-testing and the chances that self-test kits will be accepted in the community. The results from FGD interviews will be used to develop a list of HIVST delivery and linkage to care attributes that will be tested in the DCE module.

In-depth interviews

IDIs will also be conducted to inform the design of the DCE survey, ensuring that pictorial representations of salient attributes for the DCE scenarios are well understood by participants. Participants will be presented with images and asked what they think the images represent. If the pictures are not immediately clear, the concepts will be explained and the images shown again at the end of the IDI to check for recognition. Over the sequence of the IDIs, the tool will be iteratively adapted until it is suitable as a survey tool.

7.2 Cluster Enumeration

As part of the baseline survey, field staff will capture basic household information by surveying the head of each household, or if unavailable, an adult household representative. Data of interest includes household size, age and gender composition, household assets, and the demographic profile of the household head. Each adult household member will then be asked to participate in an

individual-level survey that will include demographic questions and a brief section on HIV testing and care history. The study intends to conduct a follow-up survey after two years.

A randomly selected subset of household members will also be asked to complete a longer questionnaire, which includes sections on sexual behaviour, HIV-related stigma, HIV testing and prevention, and costs related to accessing services. A DCE module exploring preferences around HIVST distribution models and linkage to HIV care and VMMC will also be included.

7.3 Intervention Procedures and Process Evaluation

The study will use the OraQuick® HIV Self-Test (Orasure Technologies, Thailand). The kits contain the HIV Oral Fluid Test (HIVOFT) test kit, stand, buffer solution, locally-translated IFUs, materials on counselling and linkage to care, and primary and secondary packaging. The kits will be distributed for free by CBDAs. Leaflets will be provided in lieu of patient information sheets, but no other consent will be required for HIVST implementation.

Randomisation and investigator blinding

Following baseline enumeration, clinic pairs will be randomly allocated to either the intervention or control arm at a public ceremony. An opaque bag containing 2 balls – one for HIVST and one for SOC – will be used to allocate the HIVST arm.

It will not be possible to blind participants, CBDAs, or their supervisors to the cluster intervention allocation, but all forms will be managed without reference to the intervention arm. Outcome data will not be analysed until completion of the trial, with the exception of data analysis by an independent statistician for presentation to the Trial Advisory Group.

Intervention procedures

CBDAs linked to intervention clinics will be provided with training in HIVST and Information, Education and Communication (IEC) materials including flipcharts, used kits to show clients how to interpret positive, negative and inconclusive results, a cotton bud and vial of water to demonstrate the mouth swabbing and development process, leaflets and a buffer stock of OraQuick® HIV Self-Test to be stored in a locked container in their own home. VMMC mobilisers will also be trained to deliver HIVST kits and will receive a stock of kits to distribute. The kits will also be available at the health facility.

Older adolescent and adult participants (age 16 - 17years or older) wishing to know their status will be provided with information on where to obtain further counselling and care together with the kit, and an envelope for return of the used kit, a self-completed questionnaire (SCQ), a self-referral slip for the nearest clinic in case of a positive result, and information on how to access VMMC for HIV-negative men.

Clients will be encouraged to return their used kits confidentially to the CBDA, either in person or by posting in the sealed envelope into an opaque locked “ballot box” container kept in/at the CBDA’s/counsellor’s house. Clients will also be encouraged to seek post-test advice from the CBDA, which can be “generic” or results-based.

Kits will be replaced by the clinic supervisors on presentation of used kits and following inspection of an HIV test logbook to confirm recording of names and addresses, but not results, of clients. Numbers of used kits, and re-read results, will be recorded by the CBDA/clinic supervisor. HIVST logbooks will be kept at the CBDA's home in a locked container.

Couple's testing will be encouraged. In the case of couples wanting to self-test together, both partners will be asked to attend the IEC session. Clients will be allowed to take up to 2 kits home if the partner cannot attend. Testing of children (aged 15 years or less) will not be permitted as part of this trial, but can be arranged through special arrangement with SFH supervisors.

There are no sharps or hazardous materials that will be used in this study.

Process evaluation

IDIs will be conducted with 1) couples who make a decision to test or not to test together 2) individual household members who make a decision to test or not to test individually. Among couples, the study will explore factors that impact on decision making vis-à-vis relationship dynamics and their perception of self-testing. Individual participants will also be asked about their relationship with their current partner and the HIST decision-making pathway they undertook.

7.4 Outcome Evaluation

Four data collection channels will be employed for the CRT:

1. Pre- and post-intervention household surveys
2. CBDA registers and forms
3. ART clinic registers and forms
4. VCT and VMMC Registers
5. Harms monitoring records.

Further, all other quantitative outcome data will be extracted from registers and clinic records using specifically designed data extraction forms. Data will be collected quarterly and then entered in databases at the Zambart head office.

Pre- and post-intervention household surveys

Prior to the initiation of the HIVST intervention, we will field a baseline survey asking questions about socio-demographics, prior testing history, stigmatizing attitudes about HIV, and other information related to HIV risk behaviours and care received by HIV positive respondents. The end line survey evaluating changes in prevalence of recent testing following the intervention will be fielded in phase II.

CBDA registers and forms

Process data on HIVST distribution by CBDAs will be captured using HIVST logbooks (date, name, village/community and number of HIVST kits taken), returned kits, SCQs and self-referral cards for ART clinics.

The SCQ will include questions about the self-read HIVST result, satisfaction, coercion, and HIV testing and ART history. The returned kits will be collected and read against the SCQ by field supervisors before disposal. This will allow the study team to conduct confirmatory readings of HIVST results and provide an ongoing measure of accuracy. CBDAs will also use registers to track the age, sex and HIV and ART history of participants and the nature of support received for HIVST.

ART clinic registers and forms

To monitor the number of referrals, HIV diagnoses and ART initiations, the study will extract routine facility records and, if applicable, self-referral cards from ART clinics serving the evaluation communities.

Social harms monitoring

Registers will be designed for use by community leaders to record incidents happening in the community during the study implementation period. Identified community leaders will provide weekly reports of episodes of intimate partner violence, coercive testing and deaths. They will be given the contact number of study staff nearest to them to report any serious incident immediately.

7.5 Health Economics

Two health economics sub-studies are included in the CRT – the Discrete Choice Experiments (DCE) and costing studies.

A DCE module will be embedded in the extended baseline questionnaire, with participants presented with a sequence of 6 to 9 DCE scenarios each relating to oral HIVST distribution, linkage to HIV care, and linkage to VMMC services. Linkage to care and VMMC scenarios will accordingly be tailored for those self-reporting as HIV negative or HIV positive. The results of the DCE survey will be used to better design HTC around client needs, with the aim of increasing uptake rates.

Costing tools will be used in conjunction with service-related financial and activity reports in order to determine the unit costs of providing HTC and subsequent HIV care. Obtaining costs from MoH will require permission from MoH and District Health Officers (DHO). Zambart will also carry out detailed micro-costing, including time and motion studies, at the evaluation clinics. This is important in order to identify instances of reduced crowding in facilities due to HIVST decentralisation. Additionally, full SFH costs for HIVST distribution will be derived from programme expenditure reports, while user costs will be collected through questions asked on service utilisation costs in the extended baseline questionnaire.

7.6 Data Analysis

Overall numbers of ART initiations per 1,000 total adult population will be calculated for each clinic during months 1 to 12, and will be compared between intervention and control arms after adjusting for any major imbalance between the trial arms in factors such as pre-intervention ART initiation rates.

The proportion of residents tested for HIV at baseline will be estimated both overall and within sex, age and village strata, using data from the baseline survey. After the end line survey is complete, participant characteristics during different time periods of the study will also be compared using design-based F-tests calculated by applying the second-order Rao and Scott correction to the usual Pearson chi-squared test statistic for two-way tables to allow for the clustered sampling design.

Estimates of linkage into newly accessed care will be assessed using the referral completion rate. This will compare the number of participants who disclosed positive results to CBDAs during a specific period of time to the number of participants accessing confirmatory testing following HIVST over the same time period. The number of new HIV-positive cases will be ascertained through re-reading of returned kits and participants sharing results with CBDAs.

For the DCE survey, the relative strength of HIVST preferences can be quantified using regression analysis. Drivers of uptake and variation between target populations can also be examined. Decision-analytic modelling will be used to compare the costs of the different HIVST models to current MoH HTC models. Key outcomes include the incremental cost per Disability Adjusted Life-Year (DALY) averted, which will allow the cost-effectiveness of HIVST and linkage to care models to be determined.

8.0 Data Management

8.1 Quantitative data

Quantitative data will be captured using electronic devices (tablets). Incoming electronic data will be checked on a daily basis for errors, with supplemental training provided to field staff if required. In the case of external manual data, Zambart will assess quality and accuracy through quarterly (initially monthly) supervisory visits.

All data will be cleaned and analysed using Stata software (Stata Corporation, College Station, Texas, USA). A study ID number will be used to link qualitative and quantitative data.

8.2 Qualitative data

Qualitative data will be recorded in three forms – 1) Notes from observations, 2) digital audio recordings and 3) video recordings. The audio files will be transcribed and translated into English. The recordings will be destroyed after transcription. All data will then be transferred to a qualitative data analysis software package, either NVIVO 10 (QSR, Melbourne, Australia) or Atlas-ti and filed according to document type. Coded data will be transferred to a Microsoft Excel spreadsheet for broader thematic analysis.

8.3 Data security

All data will be stored in locked cabinets at Zambart or in password protected computer data files. Only individuals authorised to access the data will be provided with codes for this.

9.0 Community and Civil Society Engagement

A process of community consultation will be initiated followed by sustained engagement for the duration of the study with the Neighbourhood Health Committee (NHC) in all the intervention communities. Community leaders and NHC members will be met to solicit permission for entry into the community. Following permission for entry, the study team will work with the NHC as its community advisory and representative body. NHC members will receive training in what is research, research ethics and the general design of the study. A study representative will attend NHC meetings to get feedback from the community as well as give study progress updates.

Additionally, Zambart has already an established civil society group called the Community Partners Platform (CPP). Membership of the CPP is drawn from organisations that represent PLHIV such as the Network of ARV Users, Zambia National ARV Support Programme (ZNARVs) Treatment Advocacy and Literacy Campaign (TALC), Zambia Network of People Living with HIV (NZP+), Community Initiative for Tuberculosis, HIV/AIDS and Malaria (CITAM), AfroCAB, and International Community of Women Living with HIV (ICW). CPP members will discuss the STAR study in their first meeting of 2016 (in January).

10. 0 Dissemination of findings

10.1 Policy for sharing data

A report on the study will be produced and disseminated to the Zambian MoH Results of the study will also be disseminated to the communities participating in the research, regionally, to the District Health Offices, and internationally through conference presentations and publications.

10.2 Strategy for public engagement

An initial stakeholder meeting with the MoH will be held around the time of the study initiation and at the midpoint of the study to discuss progress and any barriers or facilitators to progress, and at the end of the study to share and discuss the study findings. In addition, we would involve the Ministry of Community Development Mother and Child Health, the National AIDS Council, PEPFAR, UNAIDS, WHO, CDC, USAID, Community, and civil society. We would aim to meet with this group of stakeholders annually.

Core to Zambart's operational approach is the engagement of communities involved in research activities, and with civil society and national government. Zambart developed strong relationships with communities and key stakeholders, including the relevant ministries, during the ZAMSTAR trial and these relationships have been sustained throughout PopART and other studies and trials led by Zambart. This study will benefit from and build on these existing relationships.

11.0 Ethical considerations and confidentiality

11.1 Confidentiality

Hard copies of questionnaires and transcripts will be kept in locked cupboards in a secure location in Zambart and electronic transcripts will be password protected on a computer accessible only to authorised staff members.

11.2 Informed consent

Informed consent will be taken for participation in certain parts of the study. Where the study requires that participants give written consent, the investigator will first provide the potential participants with an explanation of the study as well as an information sheet with study details. The investigator will answer any questions raised by the potential participant and allow them sufficient time to come to a decision. Participants will then be required to give consent. In cases where written consent is required and the participant is illiterate, they will be asked to give verbal consent plus a thumb print; a witness has to append their signature in such a case. Parental consent will be required if participants are below the consenting age (16 or 17 years old).

11.3 HTC and HIVST

Pre- and post-test information

All individuals selecting to self-test will be offered pre- and post-test information and referral to the most convenient clinic offering ART services. Participants will also be given the opportunity to discuss any fears about the results or the process prior to testing and to disclose their status and receive advice and support in accessing ongoing services.

HIV disclosure

Participants are not required to disclose the results of HIVST to the distribution agent, but such will be encouraged so that they can receive results-based, post-test information.
All disclosed HIV status results will remain confidential.

11.4 Compensation for Participation

Study participants will not be compensated. Participants invited to focus group discussions may be compensated in the form of refreshments and refund of any transport costs incurred.

11.5 Adverse Event Reporting and Management

HTC, including HIVST, is well established, and known to have a high level of safety and favourable risk: benefit ratio. However, harmful reactions can occur. For the purposes of this trial, we will focus on capture of the following Serious Adverse Events (SAE). This includes:

- Death or hospitalisation due to self-inflicted injuries within 30 days of a positive HIVST results

- Death or hospitalisation resulting from violent assault by others (intimate partner violence, assault by family members, assault by community members) within 30 days of a positive HIVST result

For reporting of SAEs, SFH will be carrying out a mapping exercise, before the start of distribution. The mapping exercise will look to identify existing structures and channels for identification, reporting, and management of SAEs in general, including intimate partner violence in the project areas (from community level to provincial level); this is with the understanding that these areas already have existing structures such as Victim Support Units and some communities and facilities have undergone sensitization and training in Gender Based Training. This will be followed by stakeholder meetings to discuss possible SAEs related to HIV self-testing and best means of addressing the matter and thereafter development of the SAE strategy.

CDBAs will also be trained in how to identify, categorise and refer SAEs. The CBDAs will determine if the incident is related to the study. Serious and study-related incidents will be reported immediately to the study leadership. The study leadership will then report directly to relevant authorities including the ethics committees. Non-serious but study-related incidents will be documented and reported at the end of the month. They will be reviewed by a designated employee. If it is deemed that a particular incident was misclassified, the CBDAs and their supervisors will be asked to review/ investigate the incident again and use appropriate documentation for serious incidents related to the study.

Some serious incidents, including intimate partner violence, may not be study related. However, the study will work with established community systems to report and resolve these issues. Every community has an established CBO called the Neighbourhood Health Committee (NHC). A subcommittee within the NHC will be established as a Community Advisory Board (CAB) for the study. This CAB will recommend how to deal with such issues. Members of the CAB will include government employees from the Victim Support Unit and the Community Social Welfare Department as well as key opinion leaders in the community. They will be trained in Good Participatory Practice (GPP) and Good Clinical Practice (GCP) to ensure privacy, confidentiality and anonymity. GBV incidents will be presented to the CAB in an anonymised manner to ensure confidentiality. Specific members of the CAB may be appointed to deal with particular cases. To this end, members of the CAB will be asked to sign confidentiality statements. The study will also engage other established CBOs. The community mapping activities, done at the beginning of the study, will help identify relevant stakeholders for this purpose.

Institutional responsibilities

SAEs will be reported immediately to Zambart. All other adverse events will be logged and reported through regular follow-up reports.

As this is a public-health scale-up evaluation, following an intervention trial in Malawi that showed low risk of harm from HIVST (no suicides from 27,000 HIVST episodes), expected SAEs will be reported through 6-monthly progress reports that will report on safety as well as other important

process indicators and will be sent to the Technical Advisory Group (TAG) members and local and international collaborators.

12 monthly reports with full listings of SAEs will be submitted to Ethics Review Boards at the time of annual reporting.

Reporting procedures

SAE forms will be completed by the Zambart project coordinator and responsible SFH supervisor. The PI will check the form, make changes as necessary.

SAEs will be evaluated for seriousness, and likely relatedness by the PI.

12.0 Constraints and limitations

12.1 Risk mitigation

Social harms monitoring will be conducted by Zambart throughout the HIVST distribution period to respond to incidences of coercion, GBV, and other potential unintended consequences from self-testing. Systems for tracking social harms include a community-based reporting network using community stakeholders and leaders and hotline for HIVST participants to call and report adverse events. Tracking of social harms will then enable Zambart to assess and mitigate adverse events arising from HIVST.

12.2 Data quality

Zambart has considerable expertise in supporting all aspects of quality data management in Zambia. Standard Operating Procedures (SOP) will be used on study design, data collection instruments and data analysis procedures, with routine data quality audits conducted for quality assurance purposes. Zambart have also invested in electronic data collection, using open source software and computer tablets. This approach improves data collection efficiency and reduces traditional weaknesses associated with data collection such as completeness, consistency, and timeliness.

12.3 Governance

STAR will form a Technical Advisory Group to monitor and supervise progress of data collection, provide independent review of data collected during all CRTs conducted under the STAR project, and assist investigators in disseminating results.

Although Zambia has not included HIVST in its National HIV/AIDS Strategy, there is growing interest in the role of HIVST as part of a comprehensive HIV response. Zambia is considering adopting HIVST to support increasing the proportion of individuals aware of their HIV positive status and reaching individuals not being served by currently available HIV testing services. Additionally, the MoH has collaborated with 3ie to launch a request for proposals for the rapid evaluation of pilot HIVST interventions to provide evidence of accuracy, effective distribution strategies and linkage to care.

The trial will be conducted in accordance with GCP, and all staff will receive GCP training. The Ethics Committees to approve this study will be the Biomedical Ethics Committee of the University of Zambia and the ethics committee of the London School of Hygiene and Tropical Medicine. The study may be subject to audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to GCP

13.0 Budget

14.0 References

1. Zambia Demographic and Health Survey 2013-14. Rockville, Maryland, USA: Central Statistical Office (CSO) [Zambia], Ministry of Health (MOH) [Zambia], and ICF International, 2014.
2. National AIDS Council RoZ (2014) Zambia Country Report: Monitoring the Declaration of Committment on HIV and AIDS and the Universal Access.
3. Zambia Demographic and Health Survey 2013-14. Rockville, Maryland, USA: Central Statistical Office (CSO) [Zambia], Ministry of Health (MOH) [Zambia], and ICF International, 2014.
4. National AIDS Strategic Framework 2011-2015. Lusaka, Zambia: Ministry of Health, 2010.
5. Hensen B, Baggaley R, Wong VJ, Grabbe KL et al Universal voluntary HIV Testing in antenatal care settings: a review of the contribution of provider-initiated testing & counselling. Tropical Medicine and International Health 2011;17 (1) 59-70 doi: 10.1111/j.1365-3156.2011.028
6. Choko AT, Desmond N, Webb EL, Chavula K, Napierala-Mavedzenge S, et al. (2011) The uptake and accuracy of oral kits for HIV self-testing in high HIV prevalence setting: a cross-sectional feasibility study in Blantyre, Malawi. PLoS Med 8: e1001102.
7. Choko AT, MacPherson P, Webb EL, Willey BA, Feasy H, et al. (2015) Uptake, Accuracy, Safety, and Linkage into Care over Two Years of Promoting Annual Self-Testing for HIV in Blantyre, Malawi: A Community-Based Prospective Study. PLoS Med 12: e1001873.
8. Pant Pai N, Sharma J, Shivkumar S, Pillay S, Vadnais C, et al. (2013) Supervised and Unsupervised Self-Testing for HIV in High- and Low-Risk Populations: A Systematic Review. PLoS Med 10: e1001414.
9. Kumwenda M, Munthali A, Phiri M, Mwale D, Gutteberg T, et al. (2014) Factors Shaping Initial Decision-Making to Self-test Amongst Cohabiting Couples in Urban Blantyre, Malawi. AIDS and Behavior 18: 396-404.
10. MacPherson P, Choko AT, Webb EL, Thindwa D, Squire SB, et al. (2013) Development and validation of a global positioning system-based "map book" system for categorizing cluster residency status of community members living in high-density urban slums in Blantyre, Malawi. Am J Epidemiol 177: 1143-1147.
11. Scott CA, Iyer HS, McCoy K, Moyo C et al Retention in care, resource utilization, and costs for adults receiving antiretroviral therapy in Zambia: a retrospective cohort study*BMC Public Health* 2014, **14**:296 doi:10.1186/1471-2458-14-296 http://www.biomedcentral.com/1471-2458/14/296
12. Blood Products Advisory Committe USF (2012) Final Advisory Committee Briefing Materials: OraQuick In-Home HIV Test.

14.0 Appendices

Appendix 1:

Instruction sheet for HIVST

DIRECTIONS FOR USE

You must follow the test directions carefully to get an accurate result. Do not eat or drink for at least 15 minutes before you start the test or use mouth cleaning products 30 minutes before you start the test.

WARNING: If you are HIV-positive and on HIV treatment (ARVs) you may get a false negative result.

For QUESTIONS call the following TOLL-FREE number: 8080117

HOW TO USE THE OraQuick® HIV SELF-TEST KIT

1 YOU WILL NEED A WAY TO TIME THE TEST

2 Your test kit contains two pouches.

3 Tear open the pouch containing the **tube**.

4 Remove the cap.

5 **DO NOT** drink the liquid. **DO NOT** pour out the liquid.

6 Slide the tube into the **stand**.

7 Tear open pouch containing the **test device** and remove. **DO NOT** touch the flat pad with your fingers.

8 Press the **Flat Pad** firmly against your gum and swab it along your **upper gum once** (fig. 1) and **your lower gum once** (fig. 2).

9 Put the **flat pad** all the way into the tube until it touches the bottom.

10 **LEAVE IT THERE for 20 MINUTES before reading the results. DO NOT read the result after 40 minutes.**

Wait · Read · Expiration

FOR INVESTIGATIONAL USE ONLY • NOT FOR PATIENT CARE

OraQuick® HIV SELF-TEST

ENGLISH

INTERPRETING RESULTS

HIV POSITIVE RESULT

TWO LINES, even if the line is faint, means you may be HIV POSITIVE and you need to seek additional testing.

As soon as possible . . .

Call TOLL-FREE **08080117**

or

Visit your nearest HIV Testing Centre or Health Facility

HIV NEGATIVE RESULT

IF READ BEFORE 20 MINUTES, RESULT MAY NOT BE CORRECT

ONE LINE next to the "C" and NO line next to the "T", your result is HIV NEGATIVE.

Seek regular testing. If you may have been exposed to HIV, test again in 3 months. Call the toll free number for information about safe health practices.

Call TOLL-FREE **08080117** for more information

INVALID RESULT

No line next to the "C" (even when there is a line next to the "T"), or a red background makes it impossible to read the test, the test is not working and should be repeated.

You will need to obtain another test.

The test did not work properly.
Call TOLL-FREE **08080117**

or

Visit your nearest HIV Testing Centre or Health Facility to test again.

DISPOSE

Remove the test stick, put the cap on the test tube and throw away all contents in the normal trash.

Manufactured in Thailand for: OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015
01-610-882-1820
www.OraSure.com

Appendix 2: Tools for Qualitative studies.

Situational analysis of community organisations and community mapping

The purpose of this activity is twofold. The project will identify and establish contact with HIV/TB community-level organisations in the pilot communities to document the extent, nature and quality of direct and referral services provided at local level through community-based organisations (CBO) and faith based organisations (FBO) and the linkages between these and the District Medical Office (DMO) and the Ministry of Health (MoH).

The secondary purpose is to explore best practice approaches to communities in Lusaka and through this to contribute to the design of an accessible and supportive self-testing system for HIV located at community level. To contribute to this secondary purpose, visits to national and international NGOs working in Lusaka and further afield will also be conducted to learn from their experiences of providing HCT at community level.

We will also explore the extent, nature and quality of direct and referral services currently available at community level through community-based organisations (CBO) and how linkages between these and government health services function in practice, aiming to assess their potential to contribute to accessible and supportive self-testing strategies at community level.

The aim will be to inform the design of subsequent strategies for establishing effective community dialogue that represents all sectors of the community.

An evidence-based definition of community, described by MacQueen et al as 'a group of people with diverse characteristics who are linked by social ties, share common perspectives and engage in joint action in geographical locations or settings' (44) will be adopted to establish the foundation for effective community dialogue surrounding self-testing for HIV both to optimise testing uptake and to address the consequences of increased knowledge of HIV status and participation in HIV/TB interventions in study communities.

Activities

a) Identification and contact with CBOs, FBOs, NGOs and INGOs working within the evaluation communities and in the wider district regions.
b) Key informant interviews conducted with representatives from each of the HIV/TB related CBOs/FBOs operating in the intervention communities and districts.
c) Project visits and key informant interviews with representatives from NGOs and INGOs working in HIV/TB service provision in Zambia.
d) Mapping exercise and transect walk in Evaluation communities to identify local options for managing HIV and develop an overview of conditions, social activities and groups, health and general facilities in each local system. Specific focus will be given to the representativeness of geographical versus social group clusters; the identification of appropriate and effective mechanisms for sharing information; and identifying where pharmaceutical drugs and items are sold including informal trading centres.
e) Further analysis of identified "Current Best Practice" examples, using participatory techniques

Resource mapping (45 minutes)

a) Stick the big flipchart on the wall, or place on a table or floor so that everyone can stand around it.

b) Explain that you would like the group to make a map of the community. It does not have to be accurate, but it needs to show some of the main features and places that people go.

   Ask if anyone can draw in some key roads or rivers or other key features.
   Ask if they can show the entry and exit points- where people *come int*o the community and where they *go out?*
   Leave the group to build their map- allow at least 15 minutes for this.

c) Start with the 'Clinic' card and ask someone to put it on the map. Lay out all the other cards- including the blank cards and hand out markers and sticky stuff. Ask the group to now stick the cards to show where the places are. They can write or draw new cards for other places, or draw directly on to the map.

d) Now explain that you will be doing a walk around the community tomorrow. The focus of your research is HIV. Ask - *What are some of the key places we should see on the walk?* Ask participants to mark them on the map and find out why they have been identified. Refer to the transect walk observation checklist below [Stress the places could be linked to HIV testing, treatment and prevention)

e) Check if there are any other additions from the group about what they think the researchers should know about the community. Thank the participants.

Transect Walk Observation Checklist

Places
1 Health facility
1.1 Formal
1.2 Informal
2 Other places linked to HIV testing and treatment
2.1 Pharmacies
2.2 Drug stores
2.3 Trading places/ stores that sell drugs, syringes etc
3 Place of worship (what denomination?)
4 Recreational spaces
4.1 Library/ schools
4.2 Sports venue/ open ground
4.3 Disco
4.4 Community hall
4.5 Video club
4.6 Other
5 Alcohol outlet
5.1 Bar
5.2 Night club
5.3 Shebeen (informal)
5.4 Lodge
5.5 Other

6 Commercial Premises
6.1 Market area
6.2 Shop
6.3 Beauty salon
6.4 Shop selling pharmaceuticals
6.5 Stall selling pharmaceuticals

6.6 Other
7 Stations / bus stops
7.1 Bus
7.2 Mini Bus
7.3 Railway
7.4 Taxi rank
7 NGO
9 School
10 Residential housing (what type?)
11 Boundary landmark
12 Police Post
13 Other (AS SUGGESTED BY LOCAL EXPERTS)

Notes:

- TIME
- TYPE OF PLACE (see list of places above)
- STRUCTURE OF BUILDING – large / small (estimate in metres); new / old; cramped / spacious; well ventilated / not well ventilated (explain why); temporary / permanent; building materials – brick, concrete, grass, mud; etc.
- PEOPLE - busy / quiet; estimate number of men / women / children; estimate average age of children / youth / adults / elderly present
- ACTIVITY - what is happening? (e.g. playing football, watching a video, waiting, drinking etc.). Also if there is an event (e.g. football match, fight, outreach education etc), note this.
- RELEVANCE TO HIV – note or sketch briefly of particular relevance and write up in more detail later. Note areas where HIV testing is done, where people go for treatment, where people access drugs etc.
- Record all the words for HIV or ARVs or HIV testing (vernacular, English, slang, street language) that you have heard during this observation

Transect Walk Guide

Objectives:

- Observations of the range of HIV services.
- Observe activities and movement of different social, age and gender groups.
- Observe interactions between people and between people and activities
- Gain a rapid understanding of places of significance to the management of HIV, including any areas where HIV mobile testing is held.
- Identify places that pharmaceutical drugs and items are sold.

RA Roles: One RA to take GPS reading whilst other writes a description of the place. Both RAs to chat to local people during the transect walk.

Materials: Transect Walk Guide, map of community with transect walk plotted on (drawn by neighbourhood health committee), GPS, GPS Data Capture Sheet (see tools), Transect Walk Observation Guide, few sheets of A4 paper, notebook, pens.

Time of Activity: Afternoon and Morning.

Length of Activity: One afternoon and one morning.

Venue: No venue; rather going in concentric circles from the 'centre' of community and also following the lead from social and resource maps earlier drawn by participants of FGDs

Flow:

At the start:

- Set off from health centre and move from there from place to place using the administrative divisions of the community such as zones and or sections as a guide.
- The GPS receiver is to be switched on and left on during the entire walk so as to be able to view the route walked on the device's display screen. This is a "breadcrumb trail" called a Track Log.

During the walk:

- Observe the places passed, noting conditions in different sub-areas and housing clusters, activities and movements of people and livelihood options.
- Ask others who they pass probing questions about the different housing clusters and important places in the area with regard to managing HIV in this place, including testing options and specifically if they have heard about HIVST. Make rough notes or sketches in the notebook.
- Look out for the types of places suggested by the Transect Walk List of Places i.e. health facilities, commercial premises, places of worship, recreational spaces, boundary landmarks, graveyard, etc (see TRANSECT WALK OBSERVATION CHECKLIST). Stop at each such place.

- Look out for places where mobile HIV testing is held and where HIV testing is more frequently available.

- Note any stalls, shops and market areas where pharmaceutical products are sold.

- For each place (called a waypoint in GPS terms):

    - Take an accurate GPS reading to verify in an unobstructed position. The waypoint number and coordinates are recorded on the GPS DATA CAPTURE SHEET.
    - The type of place (selected from the TRANSECT WALK OBSERVATION CHECKLIST) and the name of this particular place (if applicable) are indicated for the waypoint.
    - A description is given of: time (use time of GPS waypoint reading); type of gathering place; size of building; what people are doing; the approximate number of people; the age mix of people there.
    - Assess whether the place is a possible observation point to return to on the following days.
    - If people ask, explain that the team are doing this for the purposes of understanding the community before a new HIV project begins. Engage in brief informal conversation, making field notes afterwards.

Data Collected and Stored:

- Make a rough sketch of the transect walk on blank A4 paper, indicating all the places plotted and observed during the walk.

- Complete the Transect Walk Activity Report Form on the same days as carrying out the walks, describing the process and the findings (from notes made in the note book) as they relate to activities and mobility of people and perceptions of HIV transmission and prevention.

- Record all the words for HIV or ARVs (vernacular, English, slang, street language) that you have heard during this observation.

- Record any discussions specific to HIV testing.

- Complete the GPS data capture sheet (tidy up, fill out).

- Store GPS and data collected.

Transect Spiral Walk ACTIVITY REPORT FORM

Date and place conducted:
Time taken and rough estimate of distance:

Observation of Place not captured in the Data Capture Sheets including: what people are there (ages, gender, local/not local); relevant IEC material/other visuals; activities during the day; movement of people; interactions between people; activities; gossip; entry/exit points: (use an extra pieces of paper to sketch any maps if helpful and attach)

Any observations of places/activities of significance to HIV transmission:

Any observations of places/activities of significance to HIV testing, drug marketing and distribution

Any information specifically on range, type of health services related to HIV:

Any information specifically on HIV testing:

Any information on HIV counselling:

Any information social harms related to HIV testing:

Record any words/phrases you have heard people use to talk about HIV, HIV testing, ART, counselling, and social harms (English, slang, vernacular, street etc…):

Any additional observations of relevance:

Key Informant Interview Guide for HIV Policy and Regulation

A. General information

1. What is your professional designation?
2. What is your role in HIV services and/or management?
3. How long have you been working in HIV services and/or management?

B. Current policy for HIV self-testing

4. What do you know about the current polices and guidelines in place for HIV self-testing?

   Probes: Is there a specific policy addressing HIV self-testing? Does it distinguish between different samples used of self-testing (i.e. blood and saliva)? Is self-testing mentioned in the national HIV guidelines or strategic plans? If current policy is absent or does not have much detail, why do you think that is? What do you think would need to be changed to allow HIV self-testing in policy?

5. What are the main aspects of current policy that support HIV self-testing?
6. What are the main policy gaps for HIV self-testing?

   Probes: probe to explore if they cover areas such as HIV self- testing algorithms, protocols for confirmatory testing, linkage to care, procurement and distribution of kits? Do they restrict who is allowed to perform HIV testing?

C. HIV self-testing counselling, consent and confidentiality in policy

7. Should counselling accompany HIV self-testing?
8. Is there any policy or guidance on consent for HIV self-testing?

   Probes: What are the main issues of consent in HIV self-testing in your opinion? Do you think consent has been given adequate consideration? Are there any groups who would be difficult to manage with regards consent (e.g. adolescents)? Are there mechanisms in place to allow testing of these groups (e.g. consent from guardian)? Are there any groups in which legal consent is not required for HIV self-testing (e.g. prisoners)?

9. Are there debates or concerns that HIV self-testing has potential for coercion? Might it be used for coercive testing?
10. Do you think there are situations in which HIV self-testing could be used to discriminate against those with HIV (e.g. industry, domestic workers)?
11. Do you think confidentiality is an issue when applied to HIV self-testing? If yes how?

D. Linkage to care from HIV self-testing in policy

12. How can HIV self-testing be most effectively linked to care?

E. Actors in HIV self-testing

13. Who are the key stakeholders HIV self-testing? What are their roles?

    Probes: These can be individuals or organisations. Why are these people/organisations important? Who supports HIV self-testing? Who has concerns over HIV self-testing?

14. Have you seen any changes in attitudes toward HIV self-testing in the last year?

    Probes: If so, who has been mainly responsible for these changes?

F. Actors in HIV self-testing regulation

15. What official institutions in Zambia would be responsible for the regulation of self-testing and self-testing kits for HIV?

    Probes: Which of these bodies are the most critical? Within those bodies, who would be the most involved?

16. What regional and international regulatory groups are you aware of? What, if any, is their role in the implementation of HIV self-testing in Zambia?

17. How do you think regulatory bodies and professional laboratory groups would react to the introduction of HIV self-testing?

G. Actors in HIV self-testing monitoring

18. Which different interest groups should be included in monitoring HIV self-testing?

    Probes: Can you think if any groups in the following sectors: legal, human rights, PLHIV, laboratory, Government Ministries, NGOs, donors, universities, regulatory authorities.

19. Is there a taskforce for HIV testing and counseling?

    Probes: Is there a group tasked with looking at HIV self-testing issues in specific?

20. Can you provide the names of the people who best represent these interest groups so we can include them in the discussion and possibly interview them?

H. Context of HIV self-testing

21. Are HIV self-tests and self-testing currently regulated in Zambia?

    Probes: Please explain what you know about their current legal and regulation status. Does it distinguish between different sample types (i.e. blood and saliva)?

22. If HIV self-tests or HIV self-testing are not currently regulated do you know of any plans to subject them to regulation?

23. Is there any policy or guidance on who can import, sell or distribute HIV tests?

    Probes: Do you think these guidelines are also appropriate for HIV self-tests? Do you think distribution and selling of HIV self-tests require any special considerations?

24. Are there registration and certification requirements for vendors, distributors and manufacturers for the legal purchase and use of HIV self-tests by consumers?

25. Are there any barriers to selling HIV self-tests or distributing them for free?

26. Is it possible that manufacturers and distributors could be legally liable for HIV self-testing (e.g. test causes harm)? How?

    Probes: What legal and regulatory protections are in place to address potential harms associated with incorrect results? Do you think these are sufficient? If not what else would be required to be put in place?

I. Process of HIV self-testing

27. How has HIV self-testing happened in Zambia to date? What have been the steps so far?

    Probes: What have been the main barriers to HIV self-testing? How could these barriers best be overcome?

28. How ready to you think Malawi now is for scale-up of HIV self-testing?

J. Monitoring of HIV self-testing

29. How can the accuracy and safety of HIV self-testing be monitored?

    Probes: This includes the type of sample used, monitoring the quality of the tests and the ability of users to obtain an accurate result. (FOR LAB PEOPLE: How would you go about designing an EQA system for HIV self-testing for both blood and saliva?)

30. What are the challenges with monitoring HIV self-testing?

    Probes: Can you see any solutions to overcome these challenges?

31. Are any other devices used for self- or home-testing (e.g. pregnancy tests, malaria RDTs)?

    Probes: What lessons can be learned from monitoring these?

32. How do you think the link between testing and seeking care could be monitored?

K. Concerns about HIV self-testing

33. Do you have any concerns about HIV self-testing?

    Probes: Misuse by certain groups e.g. young people, sex workers, husbands? Careless disposal of kits? Selling on of kits? Inability to link to services after testing HIV-positive?

K. Next steps

34. What next steps are needed to scale-up of HIV self-testing?

    Probes: What are the mechanisms for changing policy in relation to HIV testing and counseling? What else is required in terms of regulation? Logistics? Capacity strengthening to scale up HIV self-testing?

35. What would your role be in the scale-up of HIV self-testing?

    Probes: How would you interact with other involved in this process to fulfill your role?

36. Do you have any other comments?

Key Informant Interview Guide with Community-Based Stakeholders

A. General information

1. *(collect general demographic information: sex, age and how long participant has been living in the community)*
2. *What is your professional designation?*
3. *What is your role in HIV services and/or management?*
4. *How long have you been working in HIV services and/or management?*

B. History of HIV testing Timeline

5. Introduce the exercise: *We want you to help us learn about the history of HIV testing in this community.*
6. *Could you tell us about the history of HIV testing in this community?* Use these prompts to ensure you get a full picture:
    - *When and where did HIV testing first start in this community?*
    - *What other developments related to HIV testing have occurred ever since?*
    - *Why would people not test for HIV – in the past and now?*
    - *Where is the best place to get a test?*
    - *Is it better to test on your own, or with someone else?*
    - *What have you heard about HIV counselling here?*
    - *Does anyone offer household testing in this community?*
    - *Have you heard of the term 'Universal Testing and Treatment'? What does it mean to you?*
    - *What do you know about testing through Antenatal Care services?*
    - *Have you ever heard about self-testing for HIV?*

    Interviewer should transfer any information linked to time onto a timeline drawn on an A4 paper.
7. *Can we list all the places that people in this community go to get tested for HIV? Could you let us know of all the places within this community as well as places that people go to outside the community?*

    Free-list all HIV testing options on a paper. Identify places within and outside community. Probe again about preferences.

8. *Would you share with us your own experiences of testing for HIV?* Probe for when, why, where, initial reactions (of self, family, community), support.

C. Predicted response to HIV self-testing.

9. *Have you heard about self-testing in relation to testing for other diseases? By self-testing, we mean that individuals can conduct their own test to find whether they have an illness or not. For example, diabetes or malaria. Could you tell us about this in some detail including how and where self-test kits are obtained and how useful this is?*
10. *There is now a reliable test that can be used to test for HIV using a swab in your mouth. This particular form of testing is being considered as a way for people to self-test for HIV. Have you had any direct experience of self-testing for HIV? If so, could you kindly share this with me?*
11. *If self-testing were to be provided widely*

a. *Would people be supportive of it or not and why?*
b. *Would communities be supportive of it or not and why?*

12. What are the advantages of HIV self-testing to different groups of people? (Urban vs. rural dwellers, Young woman, Older woman, Young man, Older man, FSW *) ?*

Thinking first about the advantages, could we list them together?

Thinking now about the disadvantages, could we list them together?

Probes:

- *Convenience*
- *Counselling*
- *Response if HIV+/Response if HIV-negative*
- *Linkage to care*
- *Impact on HIV stigma*
- *Concerns about use of self-testing by particular groups (e.g. adolescents, husbands)*
- *Concerns about HIV being transmitted through saliva?*
-

D. Possible links between HIV self-testing and social harms

(It is possible that self-testing could result in social harms such as forced testing and gender based violence. If this were to happen, it would likely happen in secret and would be difficult to detect)

13. *What could be the harmful outcomes of self-testing?*
Probes: gender based violence, coercion, risk-taking, stigma and discrimination, suicide

14. How could we detect episodes of forced testing in communities?

i. How could we detect forced testing in the following types of relationship
   - Forced testing between couples
   - Forced testing in families e.g. parent forcing child or brother forcing sister
   - Forced testing in employer/employee relationships
   - Forced testing in other types of relationship that were discussed earlier

ii. How would we detect episodes of gender based violence in each of the types of relationship that we have discussed?

iii. How would we detect episodes of other harms *(discuss other harms aside from forced testing and GBV that participants mentioned)*

15. How could we prevent these harms from occurring in our communities?

a. Forced testing
b. Gender based violence
c. Other harms

16. *Thinking about these harmful outcomes one by one, what referral mechanisms could be used to address them?*

17. *Would your own organization have a role to play in this? Please explain what role you could play? Probe re community outreach, counselling support, policies.*

E. Reaction to the actual HIV self-test kit.

18. *This is a HIV self-test kit. Have you seen this before? Let's look at it together. Explain the test-kit – demonstrate how it is used. Then ask:*

    -Is this your first time to see this test kit?
    - Do you think you could use this test kit?
    - If you had this test kit, where would you most like to do the test? (at home, elsewhere?)
    - Would you show the test kit result to anyone? Who?
    - How would you dispose of the kit?
    - Where would you recommend people accessed kits like this?

19. *If someone is on ART and their viral load is very low – if they use this test kit, their result is hard to read or interpret. In other words it is not appropriate for people living with HIV and on treatment for some time to use the self-test kits. How do you think this should be communicated?*

F. **Self-testing and counselling**

20. What do you understand by the term counselling?

    Probe:

    a. What is it?
    b. What is the main purpose of counselling?
    c. Who should provide it/ do the counselling?
    d. How long should it take?
    e. What should be discussed?
    f. What does the term 'doing proper counselling' mean to you?'
    g. Is counselling the same as information giving?
    h. How do people want to be supported during and after the counselling session? (probe about venue, privacy, confidentiality)

21. What types of counselling do you know

    Probes:

    a. Telephone counselling
    b. Individual counselling,
    c. Couple counselling,
    d. Family counselling
    e. Traditional counselling

22. What kind of counselling do you think might be possible in the context of self-testing?

    Probe

    a. Telephone counselling
    b. Referral for counselling
    c. No counselling
    d. Locally available community-based counselling with neighbours/strangers

23. What do you think would be the counselling preferences for different groups of people?

    Probe:

    a. Urban vs. rural
    b. Young woman

c. Older woman

Thank you so much for your time today. Is there anything else you would like to discuss with me or do you think we should know about?

Focus Group Discussion Guide with Community Peer Groups (baseline)

Opening statements:

Thank you for agreeing to take part in this discussion group today. The discussion will probably take about one and a half hours and we will be exploring the practice and potential for self-testing for HIV in the context of Zambia.

A. Current HIV testing opportunities in the community

1. What current options for HIV testing in your community are you aware of?

   Action: Ask a member of the group to list options on a sheet of paper

2. How are these HIV testing options viewed in the community?

   Probes: Review each listed option & briefly discuss views on the advantages and disadvantages of the service [focus on access – location, transportation, quality of staff & treatment of clients, cost of services, ability to influence service provision through complaints system/feedback]

3. In general what do you think are the main reasons why people choose to go for HIV testing in your community?

   Probes: What about the main reasons why women and girls go for HIV testing? What about men and boys?

4. In general what do you think are the main reasons why people don't go for HIV testing in your community?
   Probes: Mean to but just don't get round to it? Time and opportunity costs? Reluctance of individuals to acknowledge risk? Not knowing how to include their partner in the decision to test? Fear of stigma, discrimination & violence? Confidentiality & trust in service providers? Provider-client interactions (how users are treated)? Personal relationships between providers and clients?

   Probes: What about the main reasons why women and girls don't go for HIV testing? What about men and boys?

5. Should HIV testing in general be targeted at couples or individuals? What do you see as the benefits and problems with individual and couple based strategies for HIV testing?
   Probes: If HIV testing is targeted at couples, how easy is it for couples to raise the issue of HIV testing? Does the ability to raise the issue of HIV testing vary by the length of time people are in relationships [when is it easiest & when is it harder]? Is it more or less difficult for women or men to raise the issue of HIV testing as a couple? Overall, is it more or less difficult to test as a couple or as an individual? Why?

B. Perceptions of risk

6. How often, in your opinion, should Zambians in general be testing for HIV? Why?

7. Under what circumstances, if any, should this level of frequency of testing be different? Why?

   Probes: Relationship circumstances (e.g. new vs. established relationships)? Environment circumstances (e.g. high risk locations)? Occupational circumstances? Gender or age (e.g. male vs. female)?

8. I will now present some examples which I would like you to discuss as a group. In considering your response to each of these, you should take into account the fact that anti-

retroviral therapy is available free for everyone who finds they are HIV positive once they need them.

8.1 Jonas has cough and fever and is admitted to clinic/hospital. He is told he has pneumonia and that he should go and have an HIV test. He decides to take his antibiotics but leaves the hospital without waiting for his test, and then decides that he is feeling OK. What is Jonas' risk of dying in the next year if he doesn't change his mind?

8.2 Jonas is married with children. He would like to continue having a sexual relationship with his partner, but doesn't want to test. He comes to you for advice. What would you advise Jonas to do?

8.3 Dorcas is diagnosed with tuberculosis and at the same time finds out she is HIV positive. She is also told that she is ready to go on ART. She receives treatment for TB and at the same time is provided with a free, daily drug regimen for HIV which she must take and attends a regular ART clinic to monitor her progress. What is Dorcas' risk of dying if she takes up ART, and if she doesn't take ART?

8.4 Dorcas is married with children. She would like to continue having a sexual relationship with her husband but she is concerned about her likelihood of infecting him. She comes to you for advice. What would you advise Dorcas to do?

C. Gender and health-seeking

1. What do you think it means to be a man in this community?
   Probes: What do you think are the most important roles and responsibilities of a man in the household? What roles or responsibilities does he often have when it comes to taking care of his own health or the family's health?
2. How can the distribution of self-test kits best reach men in this community? How can men best be supported to link to care if they get a positive self-result?
3. What do you think it means to be a woman in this community?
   Probes: What do you think are the most important roles and responsibilities of a woman in the household? What roles or responsibilities does she often have when it comes to taking care of her own health or the family's health?

C. How can the distribution of self-test kits best reach women in this community? How can women best be supported to link to care if they get a positive self-result?

D. The potential for self-testing in the community

9. If you could choose to design a new service for HIV testing in your community, what are the components that you feel would be important to include?

Probes: Level of supervision? Role of counsellors? Type of testing? Control of testing environment? Issues surrounding confidentiality? Issues surrounding accessibility?

10. What specific conditions do you think would need to be in place in order to introduce self-testing in your community?
11. If self-testing becomes available in your community, how do you think people should be able to access the self-test kits?

    Probes: Who should distribute self- test kits in the community? What role/linkages should there be with formal health services (health centres/HSAs/counsellors/VCT centres/referral services)?

    Probes: Should this be the same for everybody or should this differ to target different groups of people? (e.g., male vs female, old or young)? How?
12. When self-testing becomes available in your community, what are your views on the level of supervision that would be required to ensure it was conducted properly?

Probes: Should this be the same for everybody or should this differ to target different groups of people? (e.g., male vs female, old or young)? How?

13. Do you think that the level of supervision should be the same for everybody choosing to self-test or should this differ according to different types of people? How?
14. Probes: Information provided with the test kit on where to go? A help line number to call and ask where to go? A telephone call from a counsellor to help them to understand where to go? A home visit from a clinician to provide post-test services in the home? Post-test services made available locally in the community?

Probes: Should this be the same for everybody or should this differ to target different groups of people? (e.g., male vs female, old or young)? How?

15. When self-testing becomes available in your community, should this be targeted at individuals or couples? Why?
16. What are the advantages of HIV self-testing to different groups of people?

Probes: Is this the same for everybody or does this differ based on different groups of people? (e.g., male vs female, old or young)? How?

E Self-testing and counselling

17. What do you understand by the term counselling?

Probe: What is it? What is the main purpose of counselling? Who should provide it/ do the counselling? How long should it take? What should be discussed? What does the term 'doing proper counselling' mean to you? Is counselling the same as information giving? How do people want to be supported during and after the counselling session? (Probe about venue, privacy, confidentiality)

18. How important do you feel counselling is in currently available HIV testing services?

19. When self-testing becomes available in your community, what kind of role do you think there would need to be for counselling?
20. What kind of counselling do you think might be possible in the context of self-testing?

Probes: Telephone counselling? Individual counselling? Couple counselling? Family counselling? Traditional counselling (Locally available community-based counselling with neighbours/strangers?), Referral for counselling? No counselling?

21. What, if any, differences should there be for counselling strategies amongst different types of people in the community? Probes: Urban vs. rural dwellers, Young woman, Older woman, Young man, Older man, FSW

F Social harms

(It is possible that self-testing could result in social harms such as forced testing and gender based violence. If this were to happen, it would likely happen in secret and would be difficult to detect)

1. *What could be the harmful outcomes of self-testing? (Probes: gender based violence, coercion, risk-taking, stigma and discrimination, suicide)*
2. How could we detect episodes of forced testing in communities? (Forced testing between couples, Forced testing in families e.g. parent forcing child or brother forcing sister)
3. How would we detect episodes of gender based violence in each of the types of relationship that we have discussed?
4. How could we prevent these harms from occurring in our communities? (Forced testing, Gender based violence, Other harms)

E. The self-testing kit

I would now like to show you the self-testing kit that we want to use in Zambia. It is already the most common test that is used in America. It is designed to be used under supervision and detects HIV. It is as accurate as all other testing options. Here is one test that we have already run. It is very simple.

19. What do you think of this test kit in general?
    Probes: Clarity of instructions? Clarity of reading results? Packaging? Presentation and user friendliness in general?
20. What in your opinion are the potential advantages and disadvantages of self-testing using this test kit if it was introduced into the community? (Action: List these on a flipchart)
21. If the Government was not providing it for free, how much would you be prepared to pay for such a self-test kit?
22. Please indicate how many of you would be willing to test using this self-test kit if you could take it home with you with a show of hands [record the number of individuals who indicate their willingness to self-test (hypothetically at this stage)].

    Action: Record the number of individuals who indicate their willingness to self-test (hypothetically at this stage).

22.1 And if we ask you to test with us here now and have the results confirmed by blood?

22.2 How many of you prefer the idea of testing here with us to taking a kit home with you?

22.3 One last show of hands --- can I ask how many of you would be willing to have an HIV test through the routine Ministry of Health services?

23. What are the most important differences between self-testing and having ordinary VCT at the facility?
24. How much does knowing the VCT provider/counsellor matter?
25. Is it easier or harder to test at home compared to testing with us here?
26. Do you have any questions you would like to ask regarding the possibility of self-testing or the self-test kit itself?

Thank you for your time and participation. We have learnt a lot from our discussion here today and we hope the time has also been useful to you.

Focus Group Discussion Guide with Community Peer Groups (process evaluation)

Opening statements:

Thank you for agreeing to take part in this discussion group today. The discussion will probably take about one and a half hours and we will be exploring the practice and potential for self-testing for HIV in the context of Zambia.

1. In the past few weeks, community based distributors have been in your community distributing HIV self-test kits in households. What are your views on community-based distribution of self-test kits?
    a. Probe: Individual and community feelings about community-based distribution
        i. What are the advantages of community-based distribution of kits?
        ii. What are the disadvantages of community-based distribution of kits?
    b. Do you think people who were offered self-test kits accepted them?
        1. i What were the reasons why people self-tested? Were certain groups of people more likely to self-test (e.g., women vs men, young vs old, etc.)? What were the reasons why people did not self-test? Were certain groups of people less likely to self-test (e.g., women vs men, young vs old, etc.)?
    c. Do you feel that the distribution of self-test kits in your community equitably reached all community members?
        i Did certain groups of people have a greater advantage in accessing the kits (e.g., women vs men, young vs old, etc.) Did certain groups of people have a greater disadvantage in accessing the self-testing kits (e.g., women vs men, young vs old, etc.)ii Do you think there are people who wanted self-test kits but did not get them? Please explain
    d. Do you think there are people who were given test kits yet they did not want them? Please explain.
        i. What may have caused someone to take a test kit if they did not want it?
        ii. What sorts of people were more likely to take kits that they did not want?
    e. What are your views on whether people who got self-test kits used them?
        i. ***If there is view that some people did not use the kits****:*
        ii. What sorts of people used their kits? What sorts of people did not?
        iii. What happened to the kits that were not used?
    f. Who should distribute HIV self-test kits?
        i. Existing community health workers *(vanaMbuya/sekuru utsanana*)?
        ii. Kit distributors who were specifically appointed for the study – CBDs
        iii. Others?
    g. What are the preferred characteristics of a person who distributes self-test kits in the community?
        i. Is age important? Why?
        ii. Is gender important? Why?
        iii. Is there preference on where he/she lives?
            1. Within your community
            2. From outside your community
    h. Should distributors leave a kit for every member of the household (even those who are not home at the time of distribution) or should distribution be made only to a person who is physically present and expresses willingness to test? Please explain.

i. Are there precautions that a CBD must take when they are approaching a household to offer test kits?
    i. Who to speak to
    ii. Anything they should avoid saying or doing?
j. What are your views on what sorts of people should be offered self-test kits?
    i. Any age restrictions?
k. How do you suggest that self-test kits be distributed?
    i. The same system of using community-based distributors
        1. Should they come to people's homes or should those who want kits go to theirs?
    ii. Collection from clinics
    iii. Buying from pharmacies or other establishments
        1. How much would people be willing to pay?

2. Before one begins the self-testing process, what are your suggestions about how he/she should be educated about the process?

3. What sort of support do you think is important before and after self-testing?

4. What do you think it means to be a man in this community?
    a. What do you think are the most important roles and responsibilities of a man in the household? What roles or responsibilities does he often have when it comes to taking care of his own health or the family's health?

5. How can the distribution of self-test kits best reach men in this community? How can men best be supported to link to care if they get a positive self-test result?

6. What do you think it means to be a woman in this community?
    a. What do you think are the most important roles and responsibilities of a woman in the household? What roles or responsibilities does she often have when it comes to taking care of her own health or the family's health?

7. How can the distribution of self-test kits best reach women in this community? How can women best be supported to link to care if they get a positive self-result?

8. If self-testing were to be provided widely,
    a. Would you be supportive of it? Why?
    b. Would communities be supportive of it?
        i. What can be done to maximise support/acceptance from the community?
9. It is possible that self-testing could result in social harms such as forced testing and gender based violence. If this were to happen, it would likely happen in secret and would be difficult to detect.
    a. How could we detect episodes of forced testing in communities?
        i. How could we detect forced testing in the following types of relationship
            1. Forced testing between couples
            2. Forced testing in families e.g. parent forcing child or brother forcing sister
            3. Forced testing in employer/employee relationships

4. Forced testing in other types of relationship that were discussed earlier

ii. How would we detect episodes of gender based violence in each of the types of relationship that we have discussed?

iii. How would we detect episodes of other harms *(discuss other harms aside from forced testing and GBV that participants mentioned)*

10. How could we prevent these harms from occurring in our communities
    a. Forced testing
    b. Gender based violence
    c. Other harms

11. The self-test kits that were distributed in your community make use of oral fluids for testing. It is also possible to do self-testing using blood, where one can do a finger prick, collect their own small sample of blood and test themselves for HIV. Which one do you think is better, using oral fluids or a blood based test?
    a. Advantages of using oral fluids
    b. Disadvantages of using oral fluids
    c. Advantages of using a blood-based test
    d. Disadvantages of using a blood based test

We have reached the end of the discussion. Do you have any questions that you would like to ask me?

Thank you very much for the time you have spent in answering my questions today. Please remember that this information is all confidential. I have learnt a lot from our discussion here today and hope that the time has also been useful to you both.

In-Depth Interviews with Community Household Members (Couple)

Opening statements:

Thank you to both of you for agreeing to spend time to answer some more detailed questions about yourselves and your views of self-testing for HIV. This interview will probably take about two hours and we will be discussing your daily life and the factors that influenced your decision regarding self-testing.

A. Personal & couple characteristics

1. **W**hat year were you both born?
2. You made your decision to test or not to test for HIV together, why did you decide together?
3. Can you describe your relationship to me?

   Probes: Length of time together? Type of marriage? Whether they have children together – ages and where these children live? Whether they have other children (not together) and where these children live? Whether they live together (full-time, some of the time)?
4. What ethnic group are you both from?
5. What would you both describe your religion as? How often do you both attend church/mosque and is either of you a member of any groups associated with your religion?

B. Socio-economic and social status

6. Can you please describe the house in which you live (construction/roofing/facilities)?
7. Who would you say earns the majority of the money in your relationship?
8. What activities do you or both of you carry out to earn money?
9. Where does your household get food from (purchasing/agriculture own land/extended family land/ close by/ in village)?
10. Can you describe a typical meal in your household (time, meal composition, eating practices)?

C. Relationship dynamics and household relations

11. Who is the person who makes the majority of decisions in your household? Why? Does this differ according to the types of decisions (financial/education/health)?
12. How many other people live in your household and what are their relations to each of you?

Please could you both consider the following scenarios together, discussing together what you would do when faced with this scenario...

13.1 Your 15 year old son has begun to come home later after school recently. When confronted he says that it is because he is doing his homework at school with his friends. You then receive a report from a teacher that he has been skipping classes...

13. 2 You currently have no regular income coming into the household. It is difficult to provide food for everyone. Your 17 year old daughter, who is still in secondary school begins to contribute without explaining how she is able to this…

D. Perceptions of risks (HIV and testing-related)

13. What kind of things do both of you worry about most in life? Why?

14. What, if any, concerns do you have about HIV?
15. What, if any, concerns do you have about HIV for your partner?

I am going to provide you with 10 beans each. I would like to ask you a few questions and in answer you each need to pick the number of beans that reflects how likely it is that:

15.1 You will eat nsima tomorrow.

15.2 You are already infected with HIV.

15.3 You will become infected with HIV.

Please do this individually and then compare your responses and explore together why you have selected the particular number of beans in each case.

E. General health status & experience of health services

16. How healthy do you feel you both are in general?
17. Has either of you or anyone else in your household experienced an illness in the past six months? Can you describe this experience?

    Probes: Was this a one off illness or part of a longer term illness episode? Who was the sufferer and who was the carer? Treatment seeking pursued?
18. From the experience recounted or from other experiences, what is your opinion of your local health service?

    Probes: Accessibility & cost (convenience/transport/time taken from other activities)? Quality & trust (patient-provider relations & communication/power issues & perceptions of control)? Type of facility & differences by facility? Type of staff & differences by type of staff?

F. Previous experience of HIV testing

For couples who tested as a couple:

19. Have you ever had an HIV test before as a couple? You do not need to tell me the result.
20. **(If yes)** Can you please explain why you decided to test as a couple again or (if you have tested more than once as a couple) what your reasons for repeat testing were?
21. **(If yes)** Whose idea was it to test as a couple initially and how did you persuade your partner to agree?
22. **(If yes)** What was the whole experience like?

    Probes: Confidentiality? Trust in results & provider? Location and convenience?
23. **(If no)** Why did you not decide to test as a couple when offered the opportunity the other day?

For couples who did not test:

24. Have you ever had an HIV test before as a couple? You do not need to tell me the result.
25. **(If no)** Can you please explain why you decided not to test?

    Probes: Related to risk perceptions? Related to service perceptions? Related to family dynamics? Related to fears and concerns regarding stigma, disclosure or status?

G. Self-testing

26. Can you please describe briefly why you made your particular decision regarding self-testing as a couple when you were offered it the other day

    Probes: Factors related to individual/couple? Factors related to testing in general? Factors related to self-testing?

27. What do you think are the most important differences between self-testing and HTC?
28. What do you think are the most important differences between testing at home and testing at a facility?
29. If self-testing becomes available in the community, would you recommend it to your friends and family? Why?

H. Linkage to care

30. (If received a positive result) Can you please describe briefly why you made your particular decision regarding getting a confirmatory test or initiating ART after the self-test?

I. Gender

31. What do you think it means to be a man in this community?
    a. What do you think are the most important roles and responsibilities of a man in the household? What roles or responsibilities does he often have when it comes to taking care of his own health or the family's health?
32. How can the distribution of self-test kits best reach men in this community? How can men best be supported to link to care if they get a positive self-test result?
33. What do you think it means to be a woman in this community?
    a. What do you think are the most important roles and responsibilities of a woman in the household? What roles or responsibilities does she often have when it comes to taking care of her own health or the family's health?
34. How can the distribution of self-test kits best reach women in this community? How can women best be supported to link to care if they get a positive self-result?

J. Future of testing

35. In your opinion, what are the most important factors in HIV testing i.e. what factors would persuade you to test?
    a. Probes: Community or facility-based, integrated or stand-alone venues, home-based outreach services (accessibility)? Level of counselling? Provider-client relations/control of testing (self-testing)? Confidentiality? Confidence & trust in results and test? Accessible referral mechanisms to ART?
36. In your opinions is individually targeted or couple targeted HIV testing a better option? Why?
37. If you plan to test (again) in the future, what kind of testing would you prefer?
38. If we offered you the opportunity to self-test (again) today, would you opt to test or not to test?

I. **Oral versus blood based testing**

32. The self-test kits that were distributed in your community make use of oral fluids for testing. It is also possible to do self-testing using blood, where one can do a finger prick, collect their own small sample of blood and test themselves for HIV. Which one do you think is better, using oral fluids or a blood based test?
    a. Advantages of using oral fluids
    b. Disadvantages of using oral fluids
    c. Advantages of using a blood-based test
    d. Disadvantages of using a blood based test
    e. What do you think would be your community's preference?

J. **Self-testing and counselling**

23. What do you understand by the term counselling?
Probe: What is it? What is the main purpose of counselling? Who should provide it/ do the counselling? How long should it take? What should be discussed? What does the term 'doing proper counselling' mean to you? Is counselling the same as information giving? How do people want to be supported during and after the counselling session? (probe about venue, privacy, confidentiality)

24. What types of counselling do you know
Probes: Telephone counselling, Individual counselling, Couple counselling, Family counselling, Traditional counselling

25. Bases on your experience from the HIV self-testing you went through, what kind of counselling do you think might be possible in the context of self-testing?

Probe: Telephone counselling, Individual counselling, Couple counselling, Family counselling, Traditional counselling (locally available community-based counselling with neighbours/strangers) Referral for counselling, No counselling,

We have reached the end of the interview. Do you have any questions that you would like to ask me?

Thank you very much for the time you have spent in answering my questions today. Please remember that this information is all confidential. I have learnt a lot from our discussion here today and hope that the time has also been useful to you both.

In-Depth Interviews with Community Household Members (Individual)

Opening statements:

Thank you for agreeing to spend time to answer some more detailed questions about yourself and your views of self-testing for HIV. This interview will probably take about two hours and we will be discussing your daily life and the factors that influenced your decision regarding self-testing.

A. Personal characteristics

1. What year were you born?
2. What would you say is your main occupation?
3. What other activities do you perform which contribute to your monthly income?
4. What ethnic group are you from?
5. What would you describe your religion as?

5.1 How often do you attend church/mosque and are you a member of any groups associated with your religion?

B. Socio-economic & social status

6. Can you please describe the house in which you live (construction/roofing/facilities)?
7. Where does your household get food from (purchasing/agriculture/own land,/extended family land/close by/in village)?
8. Can you describe a typical meal in your household (time, meal composition, eating practices)?

C. Relationship status & household relations

9. What is your position/role in this household? (decision-making/carer/provider/central vs. peripheral)
10. How many people live in your household and what are their relations to you?
11. How many children do you have and what are their ages? Where do they live & with whom?
12. For how long have you been with your current partner and what kind of relationship do you have with him/her? (marital status/trust/decision-making)

D. Perceptions of risks (HIV and testing-related)

13. What kind of things do you worry about most in life? Why?
14. What, if any, concerns do you have about HIV for yourself?
15. What, if any, concerns do you have about HIV for your partner?
16. What, if any, concerns do you have about HIV for others in your household?
17. Can you describe to me what aspects in your current life you consider to be likely to increase your risk of HIV?
18. Can you describe to me what aspects in your current life you consider to contribute to your avoidance of HIV?

I am going to provide you with 10 beans. I would like to ask you a few questions and in answer you need to pick the number of beans that reflects how likely it is that:

19.1 You will eat nshima tomorrow?

19.2 If currently positive, you will infect others with HIV

19.3 If currently negative, you will become infected with HIV?

19.4 Please explain why you have selected the particular number of beans in each case.

E. General health status & experience of health services

20. How healthy do you feel you are?
21. Have you experienced illness yourself or has someone else in your family experienced illness in the past six months? Can you describe this experience?

    Probes: Was this a one off illness or part of a longer term illness episode? Who was the sufferer and who was the carer? Treatment seeking pursued?
22. From the experience recounted or from other experiences, what is your opinion of your local health service?

    Probes: Accessibility & cost (convenience/transport/time taken from other activities); quality & trust (patient-provider relations & communication/power issues & perceptions of control); type of facility & differences by facility; type of staff & differences by type of staff.

F. Previous experience of HIV testing

23. Have you ever had an HIV test before? You do not need to tell me the result.
24. (If yes) can you please explain why you decided to test or if you have tested more than once, what your reasons for repeat testing were?

    Probes: Fears? Own sexual behavior? Partner change? Voluntary versus coercive?
25. (If yes) what was the whole experience like?

    Probes: Couple or individual testing? Confidentiality? Trust in results and provider? Location and convenience?
26. (If no) can you please explain why you decided not to test?

    Probes: Related to risk perceptions? Related to service perceptions? Related to family dynamics? Related to fears and concerns regarding stigma, disclosure or status?

G. Self-testing

I would now like to show you the self-testing kit that we want to use in Zambia. It is already the most common test that is used in America. It is designed to be used under supervision and detects HIV. It is as accurate as all other testing options. Here is one test that we have already run. It is very simple.

27. What do you think of this test kit in general?
    Probes: Clarity of instructions? Clarity of reading results? Packaging? Presentation and user friendliness in general?
28. What in your opinion are the potential advantages and disadvantages of self testing using this test kit if it was introduced into the community? (Action: List these on a flipchart)
29. If the Government was not providing it for free, how much would you be prepared to pay for such a self-test kit?
30.
31. What are the most important differences between self-testing and having ordinary VCT at the facility?
32. How much does knowing the VCT provider/counsellor matter?

33. If self-testing became available in the community, would you recommend it to your friends and family? Why?

H. Future of testing

34. In your opinion and whether or not you have tested up to now, what are the most important factors in HIV testing i.e. what factors would persuade you to test?

    Probes: Community or facility-based, integrated or stand-alone venues, home-based outreach services (accessibility)? Level of counselling? Provider-client relations/control of testing (self-testing)? Confidentiality? Confidence & trust in results & test? Accessible referral mechanisms to ART?

35. In your opinion is individually targeted or couple targeted HIV testing a better option?
36. If you plan to test in the future, what kind of testing would you prefer?
37. If we offered you the opportunity to self-test (again) today, would you opt to test or not to test? If self-testing became available in the community, would you recommend it to family and friends? Why?
38. We have reached the end of the interview. Do you have any questions that you would like to ask me?

Thank you very much for the time you have spent in answering my questions today. Please remember that this information is all confidential. I have learnt a lot from our discussion here today and hope that the time has also been useful to you.

In-Depth Interviews with Community Household Members (Individual Post test kit distribution IDI)

Opening statements:

Thank you for agreeing to spend time to answer some more detailed questions about yourself and your views of self-testing for HIV. This interview will probably take about two hours and we will be discussing your daily life and the factors that influenced your decision regarding self-testing.

B. Personal characteristics

1. What year were you born?
2. What would you say is your main occupation?
3. What other activities do you perform which contribute to your monthly income?
4. What ethnic group are you from?
5. What would you describe your religion as?

5.1 How often do you attend church/mosque and are you a member of any groups associated with your religion?

C. Socio-economic & social status

6. Can you please describe the house in which you live (construction/roofing/facilities)?
7. Where does your household get food from (purchasing/agriculture/own land/extended family land/close by/in village)?
8. Can you describe a typical meal in your household (time, meal composition, eating practices)?

D. Relationship status & household relations

9. What is your position/role in this household? (decision-making/carer/provider/central vs. peripheral)
10. How many people live in your household and what are their relations to you?
11. How many children do you have and what are their ages? Where do they live & with whom?
12. For how long have you been with your current partner and what kind of relationship do you have with him/her? (marital status/trust/decision-making)

E. Perceptions of risks (HIV and testing-related)

13. What kind of things do you worry about most in life? Why?
14. What, if any, concerns do you have about HIV for yourself?
15. What, if any, concerns do you have about HIV for your partner?
16. What, if any, concerns do you have about HIV for others in your household?
17. Can you describe to me what aspects in your current life you consider to be likely to increase your risk of HIV?
18. Can you describe to me what aspects in your current life you consider to contribute to your avoidance of HIV?

I am going to provide you with 10 beans. I would like to ask you a few questions and in answer you need to pick the number of beans that reflects how likely it is that:

19.1 You will eat nshima tomorrow?

19.2 If currently positive, you will infect others with HIV

19.3 If currently negative, you will become infected with HIV?

19.4 Please explain why you have selected the particular number of beans in each case.

F. General health status & experience of health services

19. How healthy do you feel you are?
20. Have you experienced illness yourself or has someone else in your family experienced illness in the past six months? Can you describe this experience?

    Probes: Was this a one off illness or part of a longer term illness episode? Who was the sufferer and who was the carer? Treatment seeking pursued?
21. From the experience recounted or from other experiences, what is your opinion of your local health service?

    Probes: Accessibility & cost (convenience/transport/time taken from other activities); quality & trust (patient-provider relations & communication/power issues & perceptions of control); type of facility & differences by facility; type of staff & differences by type of staff.

I. Previous experience of HIV testing

22. Have you ever had an HIV test before? You do not need to tell me the result.
23. (If yes) can you please explain why you decided to test or if you have tested more than once, what your reasons for repeat testing were?

    Probes: Fears? Own sexual behavior? Partner change? Voluntary versus coercive?
24. (If yes) what was the whole experience like?

    Probes: Couple or individual testing? Confidentiality? Trust in results and provider? Location and convenience?
25. (If no) can you please explain why you decided not to test?

    Probes: Related to risk perceptions? Related to service perceptions? Related to family dynamics? Related to fears and concerns regarding stigma, disclosure or status?

J. Self-testing

26. Can you please describe briefly why you made your particular decision regarding self-testing when you were offered it the other day?

Probes: Factors related to relationship dynamics? Factors related to testing in general? Factors related to self-testing?

27. What do you think are the most important differences between self-testing and HTC?
28. What do you think are the most important differences between testing at home and testing at a facility?
29. If self-testing became available in the community, would you recommend it to your friends and family? Why?

K. Linkage to care

30. (If received a positive result) Can you please describe briefly why you made your particular decision regarding getting a confirmatory test or initiating ART after the self-test?

L. Gender

31. What do you think it means to be a [MAN OR WOMAN] in this community?
    a. What do you think are the most important roles and responsibilities of a [MAN OR WOMAN] in the household? What roles or responsibilities does [HE OR SHE] often have when it comes to taking care of [HIS OR HER] own health or the family's health?
32. How can the distribution of self-test kits best reach other [MEN OR WOMEN] in this community? How can [MEN OR WOMEN] best be supported to link to care if they get a positive self-test result?

M. Future of testing

33. In your opinion and whether or not you have tested up to now, what are the most important factors in HIV testing i.e. what factors would persuade you to test?

    Probes: Community or facility-based, integrated or stand-alone venues, home-based outreach services (accessibility)? Level of counselling? Provider-client relations/control of testing (self-testing)? Confidentiality? Confidence & trust in results & test? Accessible referral mechanisms to ART?
34. In your opinion is individually targeted or couple targeted HIV testing a better option?
35. If you plan to test in the future, what kind of testing would you prefer?
36. If we offered you the opportunity to self-test (again) today, would you opt to test or not to test? If self-testing became available in the community, would you recommend it to family and friends? Why?
37. We have reached the end of the interview. Do you have any questions that you would like to ask me?

I. Oral versus blood based testing

33The self-test kits that were distributed in your community make use of oral fluids for testing. It is also possible to do self-testing using blood, where one can do a finger prick, collect their own small sample of blood and test themselves for HIV. Which one do you think is better, using oral fluids or a blood based test?

    f. Advantages of using oral fluids
    g. Disadvantages of using oral fluids
    h. Advantages of using a blood-based test
    i. Disadvantages of using a blood based test
    j. What do you think would be your community's preference?

J. **Self-testing and counselling**

34. What do you understand by the term counselling?

    Probe: What is it? What is the main purpose of counselling? Who should provide it/ do the counselling? How long should it take? What should be discussed? What does the term 'doing proper counselling' mean to you? Is counselling the same as information giving? How do people want to be supported during and after the counselling session? (probe about venue, privacy, confidentiality)

35. What types of counselling do you know

Probes: Telephone counselling, Individual counselling, Couple counselling, Family counselling, Traditional counselling

36. Bases on your experience from the HIV self-testing you went through, what kind of counselling do you think might be possible in the context of self-testing?

Probe: Telephone counselling, Individual counselling, Couple counselling, Family counselling, Traditional counselling (locally available community-based counselling with neighbours/strangers) Referral for counselling, No counselling,

K. Social harms

(It is possible that self-testing could result in social harms such as forced testing and gender based violence. If this were to happen, it would likely happen in secret and would be difficult to detect)

37. *What could be the harmful outcomes of self-testing? (Probes: gender based violence, coercion, risk-taking, stigma and discrimination, suicide)*
38. How could we detect episodes of forced testing in communities? (Forced testing between couples, Forced testing in families e.g. parent forcing child or brother forcing sister)
39. How would we detect episodes of gender based violence in each of the types of relationship that we have discussed?
40. How could we prevent these harms from occurring in our communities? (Forced testing, Gender based violence, Other harms)

Thank you very much for the time you have spent in answering my questions today. Please remember that this information is all confidential. I have learnt a lot from our discussion here today and hope that the time has also been useful to you.

STAR project: Self-Testing Africa

Information sheet form for FGD and KII

Why are we doing this study?
This research is designed to find out what people in Zambia think about being able to test themselves for HIV ("self-testing"). We know that many people use HIV testing services, but we also know that many people have not yet gone for a test or had their last test a long time ago. So we are interested in finding out what people think about testing themselves, and how easy they find it to use their own HIV test kit.

Why are we asking you to take part in this study?
Regular HIV testing is very important in Zambia and worldwide because it helps people with HIV get treatment when they are still healthy and it may also help to cut down the spread of HIV. But it is important for people to get the right results, and we do not yet know how easy it will be for people in Zambia to do and read their own tests.

What will happen if you decide to take part in this study?
We will ask you to participate in a group discussion about HIV self testing which will be recorded using an audio recorder, so that we can make sure we capture everything that is said. We will also show you an HIV self test kit and its instructions and ask you whether you feel they are easy to understand or if they could be improved. We will give you an opportunity at the end to self-test with the support of a trained counsellor. And we will ask you to answer a few questions on an individual basis as you leave this discussion.
This discussion will take approximately 2 hours of your time.

Who are we asking to participate?
We are including people from this community to help us understand how to improve the instructions and make best use of the test. We have not chosen you for any specific reason only that you stay in this community

Where do we come from?
We work at Zambart, which is based in Lusaka on the University of Zambia Ridgeway Campus. We conduct research on diseases of local importance to Zambia and the region. Dr Helen Ayles is the principal Investigator with Dr Alywn Mwinga as co-investigator.

What are the risks and benefits of this study?
This is a research project that we hope will help us to understand if HIV self-testing is practical in Zambia and to decide how to provide it. There are no direct individual benefits to taking part in this study.

Do I have to participate?
Your participation is voluntary. You may withdraw from the study at any time and without giving a reason and without any penalty.

Confidentiality
All information obtained during the study will be held securely and stored on a voice-recorder and on paper and computer files. We will keep your information confidential.
Costs
Taking part in the study will not cost you anything except your time.

The Ethics Committees that have approved the study are:
University of Zambia Biomedical Research Ethics committee (UNZABREC), University of Zambia, Ridgeway Campus, Nationalist Road, Lusaka
and London School of Hygiene and Tropical Medicine ethics committee, ethics@lshtm.ac.uk

What if I have any questions?
If you have any questions about the disease or about this study please feel free to ask them. If you think of any questions after we have gone please feel free to contact us by calling the following number and asking for Dr Helen Ayles or Dr Alywn Mwinga Tel: 0211257215

FGD and KII Consent Form (adult)

Statement	Please initial or thumbprint* each box
I have received and read/had read to me the information sheet provided by the researchers that explains in detail the reasons for the study. I have read, discussed and understood the purpose of the research. I have asked all the questions that I have about the purpose of the research and feel happy that I have enough information about it. OR I have had the information explained to me by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand the reasons for this group discussion or interview and am willing and happy to participate in it.	
I know that I have the right to leave the discussion at any time or to refuse to answer any questions.	
I agree ☐ disagree ☐ to be quoted anonymously in this study	
If I do not agree to take part in this discussion I understand that I will not be penalised for doing so by the researchers nor by any medical service personnel in the future.	

I agree to take part in this focus group discussion or interview.

---------- -----/--------/------- ----------
Name of participant (BLOCK CAPITALS) Date Signature or thumb print

I attest that I have explained the study information accurately, and was understood to the best of my knowledge by, the participant and that he/she has freely given their consent to participate* in the presence of the below named impartial witness (where applicable).

---------- -----/--------/------- ----------
Name of Witness (BLOCK CAPITALS) Date Signature or thumb print

---------- -----/--------/------- ----------
Name of facilitator (BLOCK CAPITALS) Date Signature

[*Only required if the participant is unable to read or write.]

FGD and KII Consent Form (young adult)

Statement	Please initial or thumbprint* each box
1. I confirm that I am the parent or legal guardian of this young adult	
2. I have received and read/had read to me the information sheet provided by the researchers that explains in detail the reasons for the study. I have read, discussed and understood the purpose of the research. I have asked all the questions that I have about the purpose of the research and feel happy that I have enough information about it. OR I have had the information explained to me by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
3. I understand the reasons for this group discussion or interview and am willing and happy for my son/daughter to participate for it.	
4. I know that my son/daughter has the right to leave the discussion at any time or to refuse to answer any questions.	
5. I agree ☐ disagree ☐ for my son/daughter to be quoted anonymously in this study	
6. If I do not agree for my son/daughter to take part in this discussion I understand that I will not be penalised for doing so by the researchers nor by any medical service personnel in the future.	

I permit his/her participation in the study.

Young adult's Name: _____

Parent /Guardian's name: _____ (please print)
(Delete whichever is not applicable)

Parent/Guardian's signature/fingerprint: _____ Date _____

Signature of witness (if parent/guardian unable to write)

Signature of witness: _____Date_____

Witnessed by (print name): _____

Signature of young adult

Statement	Initial or thumbprint
1. I have received and read/had read to me the information sheet provided by the Researcher that explains the study in detail.	
2. I have discussed and understood the purpose of the study	
3. I have asked all the questions that I have about the study and feel happy that I have enough information about it.	
4. I agree ☐ disagree ☐ to be quoted anonymously in this study	

I agree to take part in this study.

Young adult's Signature or thumbprint: _____

Young adult's age (years): _____

The person who obtains the informed consent discussion must also sign and date this form.

Signature: _____Date _____

Name: _____ (please print)

STAR project: Self-Testing Africa

Information Sheet for IDIs

Why are we doing this study?

This research is designed to find out what people in Zambia think about being able to test themselves for HIV ("self-testing"). We know that many people use HIV testing services, but we also know that many people have not yet gone for a test or had their last test a long time ago. So we are interested in finding out what people think about testing themselves, and how easy they find it to use their own HIV test kit.

Why are we asking you to take part in this study?

Regular HIV testing is very important in Zambia and worldwide because it helps people with HIV get treatment when they are still healthy and it may also help to cut down the spread of HIV. But it is important for people to get the right results, and we do not yet know how easy it will be for people in Zambia to do and read their own tests.

What will happen if you decide to take part in this study?

We will ask you as an individual to participate in an in-depth interview about HIV self-testing which will be audio recorded so that we can make sure we capture everything that is said. We want to explore your understanding of the testing process or about your own feelings about HIV testing and self-testing as a particular option. This will take approximately one and half hours of your time.

Who are we asking to participate?

We are including people from this community to help us understand how to improve the instructions and make best use of the test. We have not chosen you for any specific reason only that you stay in this community

Where do we come from?

We work at Zambart, which is based in Lusaka on the University of Zambia Ridgeway Campus. We conduct research on diseases of local importance to Zambia and the region. Dr Helen Ayles is the principal Investigator with Dr Alywn Mwinga as co-investigator.

What are the risks and benefits of this study?

This is a research project that we hope will help us to understand if HIV self-testing is practical in Zambia and to decide how to provide it. There are no direct individual benefits to taking part in this study.

Do I have to participate?

Your participation is voluntary. You may withdraw from the study at any time and without giving a reason and without any penalty.

Confidentiality

All information obtained during the study will be held securely and stored on a voice-recorder and on paper and computer files. We will keep your information confidential.

Costs

Taking part in the study will not cost you anything except your time.

The Ethics Committees that have approved the study are:

University of Zambia Biomedical Research Ethics committee (UNZABREC), University of Zambia, Ridgeway Campus, Nationalist Road, Lusaka and London School of Hygiene and Tropical Medicine ethics committee, ethics@lshtm.ac.uk

What if I have any questions?

If you have any questions about the disease or about this study please feel free to ask them. If you think of any questions after we have gone please feel free to contact us by calling the following number and asking for Dr Helen Ayles or Dr Alywn Mwinga Tel: 0211257215

IDI Consent Form (adult)

Statement	Please initial or thumbprint* each box
1. I have received and read/had read to me the information sheet provided by the researchers that explains in detail the reasons for the study. OR I have had the information explained to me by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2. I have read, discussed and understood the purpose of the research.	
3. I know that I have the right to leave the discussion at any time or to refuse to answer any questions.	
4. I agree ☐ disagree ☐ to be quoted anonymously in this study	
5. I have asked all the questions that I have about the purpose of the research and feel happy that I have enough information about it.	

I agree to take part in this Interview

---------- -----/--------/------- ----------
Name of participant (BLOCK CAPITALS) Date Signature or thumb print

I attest that I have explained the study information accurately, and was understood to the best of my knowledge by, the participant and that he/she has freely given their consent to participate* in the presence of the below named impartial witness (where applicable).

---------- -----/--------/------- ----------
Name of Witness (BLOCK CAPITALS) Date Signature or thumb print

---------- -----/--------/------- ----------
Name of facilitator (BLOCK CAPITALS) Date Signature

[*Only required if the participant is unable to read or write.]

IDI Consent Form (young adult)

Statement	Please initial or thumbprint* each box
1. I have received and read/had read to me the information sheet provided by the researchers that explains in detail the reasons for the study. OR I have had the information explained to me by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2. I have read, discussed and understood the purpose of the research.	
3. I know that my son/daughter has the right to leave the discussion at any time or to refuse to answer any questions.	
4. I agree ☐ disagree ☐ for my son/daughter to be quoted anonymously in this study	
5. I have asked all the questions that I have about the purpose of the research and feel happy that I have enough information about it.	

I permit his/her participation in the study.

Young adult's Name: _____

Parent /Guardian's name: _____ (please print)
(Delete whichever is not applicable)

Parent/Guardian's signature/fingerprint: _____ Date _____

Signature of witness (if parent/guardian unable to write)

Signature of witness: _____Date_____

Witnessed by (print name): _____

Signature of young adult

Statement	**Initial or thumbprint**
1. I have received and read/had read to me the information sheet provided by the Researcher that explains the study in detail.	
2. I have discussed and understood the purpose of the study	
3. I agree ☐ disagree ☐ to be quoted anonymously in this study	
4. I have asked all the questions that I have about the study and feel happy that I have enough information about it.	

I agree to take part in this study.

Young adult's Signature or thumbprint: _____

Young adult's age (years): _____

The person who obtains the informed consent discussion must also sign and date this form.

Signature: _____Date _____

Name: _____ (please print)

Appendix 3: Impact Assessment

STAR project: Self-Testing Africa

Information Sheet for Household Survey

1. Why are we doing this study?

We are doing researcher on a new approach to HIV testing (self-testing), and so we would like to collect some information on people's preferences for different types of HIV testing services, and on other HIV-related issues, including sexual and reproductive health practices. We are interested in making it easy for people to get tested for HIV, and then get treatment if HIV-positive, or better protection if HIV-negative.

2. Why are we asking you to take part in this study?

Regular HIV testing helps people with HIV get treatment when they are still healthy, and can help to cut down the spread of HIV. This survey will be repeated in about two years' time so that we can understand what changes there have been in communities provided with HIV self-testing compared to villages without these services.

3. What will happen if you decide to take part in this study?

You will be asked questions about the following:

1. Details about you and your family who live here as well as information about your work and your household
2. Your past experience of HIV testing

Some people will be asked additional questions that include

3. Their preferences relating to HIV testing services
4. More detail on their past use of HIV services, including testing, treatment and actions that they may have taken to protect themselves from HIV, like cutting down on sex, using condoms, or circumcision for men.
5. Their sex life
6. Their views about people living with HIV, and how they are regarded by others

People chosen to answer additional questions will be chosen by chance, like a lottery.
This will take approximately 1 hour of your time.

4. Who are we asking to participate?

Members of all households in this community who are 16 years of age or older. We are conducting this study across 12 communities where we will be offering different HIV testing options. These options will be determined by chance ("random selection").

5. Where do we come from?

We work at Zambart and conduct research and implement projects on diseases of local importance to Zambia and the region.

6. What are the risks and benefits of the study?

This is a research project that we hope will help us to understand if self-testing is practical in Zambia and to decide how best to provide it.
There are no direct benefits to you in relation to this study, but future generations will benefit in that the country will make policies to the benefit of the population following the conclusion of such studies. There are no risks in taking part in this study except for the anxiety that you may experience if you accept to take the self test.

7. Do I have to participate in this study?

Your participation is voluntary. You may withdraw from the study at any time and without giving a reason. You can also decide to answer some questions, and not to answer others. If you take part in the discussion, we will not be offering HIV tests at this time.

8. Confidentiality

All information obtained from the study will be stored securely on paper and in pass word protected computer files and only researchers in this study will have access to them. Confidentiality will be maintained throughout all data handling and storage processes.

We will use a study number, and not your name, to identify you and your household. We will link the information that you give us to the information that was collected in the last household visit about the wealth and size of your household, but will not use your name or anything else to identify you personally.

9. Costs

Taking part in the study will not cost you anything. We will interview you at home.

10. The Ethics Committees that have approved the study are:

University of Zambia Biomedical Research Ethics Committee (UNZABREC) and London School of Hygiene and Tropical Medicine.

11. What if I have any questions?

If you have any questions about the disease or about this study please feel free to ask them. If you think of any questions after we have gone please feel free to contact us by calling the following number and ask for Dr Helen Ayles or Dr Alywn Mwinga.
Tel: 0211 254710

Household Survey Consent Form (adult)

Statement	Please initial or thumbprint* each box
1. I have received and read/had read the information sheet provided by the researchers that explains in detail the reasons for the study. I have read, discussed and understood the purpose of the research. I have asked all the questions that I have about the purpose of the research and feel happy that I have enough information about it. OR I have had the information explained to by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2. I understand the reasons for the survey and am willing and happy to participate in it.	
3. If I agree to participate in the survey I understand what I will be required to do.	
4. I know that I have the right to leave the interview at any time or to refuse to answer any questions.	
5. If I do not agree to take part in this interview I understand that I will not be penalised for doing so by the researchers nor by any medical service personnel in the future.	

I agree to take part in the baseline survey.

---------- -----/--------/------- ----------

Name of participant (BLOCK CAPITALS) Date Signature or thumb print

I attest that I have explained the study information accurately, and was understood to the best of my knowledge by, the participant and that he/she has freely given their consent to participate* in the presence of the above named impartial witness (where applicable).

---------- -----/--------/------- ----------

Name of Witness (BLOCK CAPITALS) Date Signature or thumb print

---------- -----/--------/------- ----------

Name of facilitator (BLOCK CAPITALS) Date Signature

[*Only required if the participant is unable to read or write.]

Household Survey Consent Form (young adult)

Statement	Please initial or thumbprint* each box
1. I confirm that I am the parent or legal guardian of this young adult	
2. I have received and read/had read the information sheet provided by the researchers that explains in detail the reasons for the study. I have read, discussed and understood the purpose of the research. I have asked all the questions that I have about the purpose of the research and feel happy that I have enough information about it. OR I have had the information explained to by study personnel in a language that I understand. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
3. I understand the reasons for the survey and am willing and happy for my son/daughter to participate in it.	
4. If I permit my son/daughter to participate in the survey I understand what s/he will be required to do.	
5. I know that my son/daughter has the right to leave the interview at any time or to refuse to answer any questions.	
6. If my son/daughter doesn't not agree to take part in this interview I understand that we will not be penalised for doing so by the researchers nor by any medical service personnel in the future.	

I permit his/her participation in the study.

Young adult's Name: _____

Parent /Guardian's name: _____ (please print)
(Delete whichever is not applicable)

Parent/Guardian's signature/fingerprint: _____ Date _____

Signature of witness (if parent/guardian unable to write)

Signature of witness: _____Date_____

Witnessed by (print name): _____

Signature of young adult

Statement	**Initial or thumbprint**
5. I have received and read/had read to me the information sheet provided by the Researcher that explains the study in detail.	
6. I have discussed and understood the purpose of the study	
7. I have asked all the questions that I have about the study and feel happy that I have enough information about it.	

I agree to take part in this study.

Young adult's Signature or thumbprint: _____

Young adult's age (years): _____

The person who obtains the informed consent discussion must also sign and date this form.

Signature: _____Date _____

Name: _____ (please print)

Appendix 4: In-Depth Interviews with Community Household Members (Individual Formative DISCRETE CHOICE EXPERIMENT IDI)

Opening statements:

Thank you for agreeing to spend time to answer some more detailed questions about yourself and your views of self-testing for HIV. This interview will probably take about two hours and we will be discussing your daily life and the factors that influenced your decision regarding self-testing.

A. Personal characteristics

1. What year were you born?
2. What would you say is your main occupation?
3. What other activities do you perform which contribute to your monthly income?
4. What ethnic group are you from?
5. What would you describe your religion as?

5.1 How often do you attend church/mosque and are you a member of any groups associated with your religion?

C. Socio-economic & social status

6. Can you please describe the house in which you live (construction/roofing/facilities)?
7. Where does your household get food from (purchasing/agriculture/own land/extended family land/close by/in village)?
8. Can you describe a typical meal in your household (time, meal composition, eating practices)?

E. Relationship status & household relations

9. What is your position/role in this household? (decision-making/carer/provider/central vs. peripheral)
10. How many people live in your household and what are their relations to you?
11. How many children do you have and what are their ages? Where do they live & with whom?
12. For how long have you been with your current partner and what kind of relationship do you have with him/her? (marital status/trust/decision-making)

F. Perceptions of risks (HIV and testing-related)

13. What kind of things do you worry about most in life? Why?
14. What, if any, concerns do you have about HIV for yourself?
15. What, if any, concerns do you have about HIV for your partner?
16. What, if any, concerns do you have about HIV for others in your household?
17. Can you describe to me what aspects in your current life you consider to be likely to increase your risk of HIV?

18. Can you describe to me what aspects in your current life you consider to contribute to your avoidance of HIV?

I am going to provide you with 10 beans. I would like to ask you a few questions and in answer you need to pick the number of beans that reflects how likely it is that:

19.1 You will eat nshima tomorrow?

19.2 If currently positive, you will infect others with HIV

19.3 If currently negative, you will become infected with HIV?

19.4 Please explain why you have selected the particular number of beans in each case.

G. General health status & experience of health services

39. How healthy do you feel you are?
40. Have you experienced illness yourself or has someone else in your family experienced illness in the past six months? Can you describe this experience?

    Probes: Was this a one off illness or part of a longer term illness episode? Who was the sufferer and who was the carer? Treatment seeking pursued?

41. From the experience recounted or from other experiences, what is your opinion of your local health service?

    Probes: Accessibility & cost (convenience/transport/time taken from other activities); quality & trust (patient-provider relations & communication/power issues & perceptions of control); type of facility & differences by facility; type of staff & differences by type of staff.

N. Previous experience of HIV testing

42. Have you ever had an HIV test before? You do not need to tell me the result.
43. (If yes) can you please explain why you decided to test or if you have tested more than once, what your reasons for repeat testing were?

    Probes: Fears? Own sexual behavior? Partner change? Voluntary versus coercive?

44. (If yes) what was the whole experience like?

    Probes: Couple or individual testing? Confidentiality? Trust in results and provider? Location and convenience?

45. (If no) can you please explain why you decided not to test?

    Probes: Related to risk perceptions? Related to service perceptions? Related to family dynamics? Related to fears and concerns regarding stigma, disclosure or status?

O. HIV Self-testing

46. Can you please describe briefly why you made your particular decision regarding self-testing when you were offered it the other day?

    Probes: Factors related to testing in general? Factors related to self-testing?

Now I'm going to present you with the diagrammatic/pictorial representations of HIVST scenarios and asked you about what you think the images represent. If the images are not clear, I'm going to explain the details/concepts of each diagram, and we will look at the images again at the end of the discussion to see if you will understand them.

Probe for each scenario:

47. What do you think of this HIVST strategy in general?
    Probes: Clarity, Presentation and user friendliness in general?
48. What in your opinion are the potential advantages and disadvantages of HIV self-testing using this strategy if it was introduced into the community? (Action: Note these in your notebook)
49. If this strategy was to be used, how much would you be prepared to pay to access it
50. If this HIVST became available in the community, would you recommend it to your friends and family? Why?

P. Future of testing

51. In your opinion and whether or not you have tested up to now, what are the most important factors in HIV testing i.e. what factors would persuade you to test?

    Probes: Community or facility-based, integrated or stand-alone venues, home-based outreach services (accessibility)? Level of counselling? Provider-client relations/control of testing (self-testing)? Confidentiality? Confidence & trust in results & test? Accessible referral mechanisms to ART?
52. In your opinion is individually targeted or couple targeted HIV testing a better option?
53. If you plan to test in the future, what kind of testing would you prefer?
54. If we offered you the opportunity to self-test (again) today, would you opt to test or not to test? If self-testing became available in the community, would you recommend it to family and friends? Why?
55. Now I'm going present you with the images we saw earlier in section G (HIV self-testing) to see if you will understand them now.

Probe for each scenario:

56. What do you think of this HIVST strategy in general?
    Probes: Clarity, Presentation and user friendliness in general?
57. What in your opinion are the potential advantages and disadvantages of HIV self-testing using this strategy if it was introduced into the community? (Action: Note these in your notebook)
58. If this strategy was to be used, how much would you be prepared to pay to access it
59. If this HIVST became available in the community, would you recommend it to your friends and family? Why?

We have reached the end of the interview. Do you have any questions that you would like to ask me?

Thank you very much for the time you have spent in answering my questions today. Please remember that this information is all confidential. I have learnt a lot from our discussion here today and hope that the time has also been useful to you.

Appendix 5: Observational fieldwork Guide for DISCRETE CHOICE EXPERIMENT (DCE) formation

Objectives:

- Observations of HIVST distribution process.
- Observe how clients make decision about accessing HIVST.

RA Roles: RA to take non-participatory observational walk with HIVST providers as they distribute HIVST products.

Materials: Observation Guide, notebook and a pen.

Time of Activity: working hours.

Length of Activity: 2 days per community (1 at the clinic and 1 in the community).

Venue: health facility (At least 2 observation) and community (at least 2 observations).

Flow:

At the start:

- Set off from health centre and walk with HIVST distributors as they distribute the product from place to place following their daily activity plans.

During fieldwork:

- Look for where and how HIVST product are distributed, noting conditions in different areas.
- Observe the clients' decision process, noting clients' questions and thoughts and providers' role in decision making, with regards to accepting HIVST products.

Data Collected and Stored:

- Make a rough sketch of the HIVST distribution points on blank A4 paper, indicating location and surrounding places observed during the walk.
- Complete the Transect Walk Activity Report Form on the same days as carrying out the walks, describing the process and the findings (from notes made in the note book) as they relate to activities and perceptions of HIVST.
- Record any discussions specific to HIV testing, especially HIVST.
- Store data collected safely.

Self-Completed Questionnaire

Please completed the following questionnaire. Your HIV result will not be linked to your name and no one including the distributor will know your result unless you disclose it yourself. Your answers will remain confidential, so please be honest.

Question No.	Construct	Variable name	Wording of question (English)	Data type
SC1	Age	age	My age is	Number
SC2	Sex	sex	I am	1 Male 2 Female
SC3	Result	hivresult	My HIV self-test result is:	1 Not sure/invalid 2 Positive 3 Negative
SC4	ART	art	If positive, are you already on ART?	1 Yes 2 No
SC5	Source of HIVST kit	source	Who did you receive the test from?	1 Community distributor 2 Husband / wife or partner 3 Parent or guardian 4 Other family member 5 Friend or neighbor 6 Employer
SC6	Testing coercion	coercion	Were you forced to test? If forced to test, who forced you?	1 I was not forced 2 Husband / wife or partner 3 Parent or guardian 4 Other family member 5 Friend or neighbor 6 Employer
SC7	Recommend self-tesitng	recommend	Would you recommend this HIV test kit for self-testing to friends and family?	1 Definitely yes 2 Not sure 3 Definitely no
SC8	Clinic ID	clinicid		Number
SC9	CBDA ID	cbdaid		Number
SC10	Kit seen	kitseen	Kit seen?	1 Yes 2 No
SC11	Rereading of result	reread	Result?	1 Negative 2 Faint positive 3 Clear positive 4 Invalid

Appendix 7: CVs