# HIV Self-Testing AfRica Zambia

A clinical performance study of self-testing using self-collected oral fluid transudate and the OraQuick® HIV Self-Test


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## Abbreviations

| | |
|---|---|
| 3ie | International Initiative for Impact Evaluation |
| ANC | Antenatal Care |
| ART | Antiretroviral Therapy |
| CAP | College of American Pathologists |
| 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 |
| DHS | Demographic and Health Surveys |
| EQA | External Quality Assurance |
| HIV | Human Immunodeficiency Virus |
| HIVRDT | HIV Rapid Diagnostic Test |
| HIVST | HIV Self-Testing |
| HPTN | HIV Prevention Trials Network (HPTN) |
| HTC | HIV Testing and Counselling |
| ICW | International Community of Women Living with HIV |
| IEC | Information, Education and Communication |
| IFU | Instructions for Use |
| IVD | In Vitro Diagnostics |
| LSHTM | London School of Hygiene and Tropical Medicine |
| LSTM | Liverpool School of Tropical Medicine |
| MoH | Ministry of Health |
| NHC | Neighbourhood Health Committee |
| NZP+ | Zambia Network of People Living with HIV |
| PICT | Provider-Initiated Counselling and Testing |
| PLHIV | People Living with HIV |
| PQ | Pre-Qualification |
| PSI | Population Services International |
| SEA | Sample Enumeration Area |
| SFH | Society for Family Health |
| SOP | Standard Operating Procedures |
| STAR | Self-Testing Africa |
| TALC | Treatment Advocacy and Literacy Campaign |
| TWG | Technical Working Groups |
| UNAIDS | The Joint United Nations Programme on HIV/AIDS |
| VCT | Voluntary Counselling and Testing |
| VMMC | Voluntary Medical Male Circumcision |
| WHO | World Health Organization |
| ZAMBART | Zambia AIDS Related Tuberculosis |
| 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 clinical performance study of self-testing using self-collected oral fluid transudate and the OraQuick® HIV Self Test.

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

## 2.0 Background: Research Questions, 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/PSI HIV 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, Aims, and Objectives

### 3.1 Research Question

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

Can HIV self-testing be performed to a high level of accuracy by different populations in Zambia?

Further, the findings from this study will complement the findings from the STAR cluster randomised trial.

### 3.3 Study Aims

This study aims to evaluate the clinical performance characteristics of OraQuick® HIV Self-Test (Orasure Technologies, Thailand) when used under direct observation.

### 3.3 Study Objectives

- To determine the sensitivity and specificity of the OraQuick® HIV Self Test as carried out by the intended user using manufacturer's IFUs, compared to a laboratory-based testing algorithm for HIV diagnosis.
- To estimate the sensitivity and specificity of OraQuick® HIV Self Test as carried out by the intended user compared to the Zambian national HIV testing algorithm of fingerprick rapid testing by a health worker.
- To estimate the relative performance of the recommended algorithm of OraQuick® HIV Self-Test, as carried out by intended user, followed by confirmatory fingerprick rapid testing, compared to a laboratory-based testing algorithm for HIV diagnosis.
- To assess user competency in performing the test using written and pictorial instructions only.
- To estimate levels of user competency in use and interpretation of the OraQuick® HIV Self Test result when compared to an OraQuick® HIV Self Test performed and interpreted by professional.
- To determine the stability of OraQuick® HIV Self Test results with delayed visual re-reading for up to 12 months.

## 4.0 Study Design

Before HIVST can be rolled out widely, the accuracy of HIVST in the study communities and the ability of the population to correctly perform the tests needs to be established. This study will assess the performance of self-testing using self-collected oral fluid transudate and the OraQuick® HIV Self-Test.

For the purposes of this study, clinical performance is defined as the performance of the test kit in the hands of the intended users – the target population for HIVST programmes. The target population resides in a high HIV prevalence setting (>1%) and consists of adults and adolescents 15 years of age or older. This includes rural and urban populations, first time testers and individuals who have previously tested and are not on antiretroviral therapy (ART).

The clinical performance study will incorporate assessments of the correct use of the test kits, the users' ability to interpret test results correctly, and the accuracy of testing, using laboratory-based reference standard. We will also assess quality assurance by evaluating the reliability of repeated reading of the OraQuick® HIV Self-Test after a prolonged period of time. Users will be provided with written and pictorial IFUs only. The manufacturer has provided the IFUs, which will be translated into relevant local languages before the start of the clinical performance study.

This study will provide information to WHO pre-qualification (PQ ) of in-vitro diagnostics (IVDs) programme to contribute to the pre-qualification of HIVRDTs self-testing (indicator O2.4 in project log frame). It will also provide information for the manufacturer's dossier submission for WHO prequalification for the intended use of HIV self-testing. This study will be conducted in accordance with WHO PQ IVD programme standards defined in the "Instructions for completion of a product dossier."[1]

### 4.1 Primary and Secondary Outcomes

The study will use sensitivity and specificity as the primary measurements of test performance, and will also assess invalid test results, user errors, understanding of written instructions for use (IFU) and interpretation of test results.

### 4.2 Formative Sub-study

Prior to the clinic performance study, Zambart will first assess how well testers understand the instruction materials provided by the manufacturer through cognitive interviewing. The findings will contribute to the understanding of how easy or difficult it is for community members to understand and use the prototype written and pictorial user instructions, Information, Education and Communication (IEC) materials for HIVST. Once we verify that the instructions are understood, we will use these materials to assess clinical performance.

[1] http://www.who.int/diagnostics_laboratory/evaluations/141015_pqdx_018_dossier_instructions_v4.pdf?ua=1 .

## 5.0 Study Location, Population and Timeframe

### 5.1 Study Location

The clinical performance study will be conducted in 2 communities in Zambia: one in urban Lusaka district (M'tendere) and one in rural Chongwe district (Kanakantapa). These sites were chosen to provide access to intended user populations and also to be in close proximity to the laboratory, so blood samples can be processed in a timely manner. In Kanakantapa, the study will be conducted only in the community, while in M'tendere, the study will be in both the community and the health facility.

Additional locations will be included for the cognitive interviews. This includes purposively-selected communities in the four study districts: Ndola, Kapiri Mposhi, Lusaka and Choma Districts. The communities will be selected based on socio-economic diversity, community organisation, history of HIV testing, geographical location, and trial intervention assignment.

### 5.2 Study Population

The study population will be comprised of individuals aged 15 and over living in the study communities who are able to give informed consent to be part of the study. Individuals who are on ART may be included in the study but they will not be included in the primary analysis as they are explicitly advised in the IFU not to use the test. However, it will be useful to collect data from these individuals for the clinical performance study to be able to report on the reduction in sensitivity that may be expected if they choose to self-test.

### 5.3 Study Timeline

This study will commence as soon as we have all ethical and regulatory approvals. We anticipate that the cognitive interviews will start in February 2016 and the clinical performance study will start in March 2016 and take 12 months to complete.

An interim analysis of data will be done 3 months after study initiation to provide a provisional estimate of accuracy of self-testing, and to alert the research team to any major issues with the testing procedure before wide-scale piloting of the HIVST in Zambia.

## 6.0 Sampling Method and Sample Size Calculation

### 6.1 Sampling Method

Maps of the 2 study communities will be generated using existing Zambart data sources and Google Maps. We will also use the census maps from the central statistics office with the sample enumeration areas (SEA). We will randomly select SEAs and visit every household within each area.

All members in a household (age $\geq$ 15 years) will be enumerated. For those aged 18 years or older, we will request their consent to participant in the study. For those aged 15 to 17 years, we will obtain their assent and parental/guardian consent. Each participant will be given a study number using a programme written into the electronic data collection device used for the study.

For the cognitive interviews, convenience sampling will be used to recruit clients from Voluntary Counselling and Testing (VCT) clinics. Four to 12 participants will be recruited for each iteration, with a maximum of 12 iterations of adaptation and trial of the intended instructions-for-use (maximum n = 144). Cognitive interviewing and iterative adaptation will continue until saturation occurs,

### 6.2 Sample size calculations

To reach a sample size of 3,250 testers, we will need to randomly select 14 SEAs. Assuming the true HIV prevalence in the tested population is 12.5%, and the true sensitivity and specificity of the test are 93.0% and 99.9%, respectively [2], a testing sample of 3,209 allows us to detect sensitivity with 95% confidence intervals of 90.1-95.1%, and specificity with 95% confidence intervals of 99.6-99.9%.

## 7.0 Data Collection and Analysis

The study has two main data collection phases: 1) cognitive interviews to test user understanding of HIVST IFUs, and 2) the clinical performance study.

### 7.1 Cognitive interviews

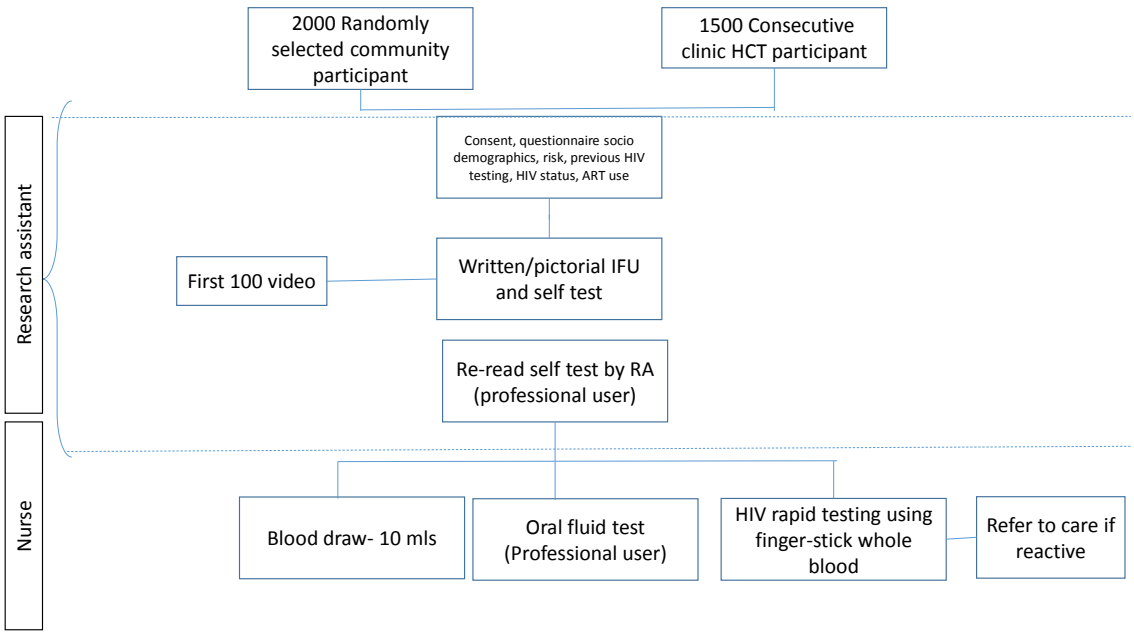
Cognitive interviewing and invited HIVST under observation will be used to evaluate and refine prototype written and pictorial instructions and IEC materials. The cognitive interview process will include a self-test supervised by the investigator and a discussion with participants describing how they interpret the instructions, test results, and next steps for accessing onward HIV services. Based on the findings, suggestions will be made on IFU modifications to optimise the ability of users to safely and accurately self-test.

### 7.2 Data Collection for Clinical Performance Study

Following informed consent, participants will complete demographic, HIV test history, and risk assessment questionnaires by trained research assistants. All participants will then be provided with a HIVST kit containing manufacturer IFUs. The lot number and expiration date of the OraQuick® HIVST kit will be recorded on the questionnaire given to the participant. The participant will be asked to choose a private space in which to do the test.

The entire procedure will be video recorded for 50-100 participants each in the rural community, the urban community, and the urban health facility. At all times, the video will attempt to protect the identity of the participant by not showing the full face (while recording the swabbing of the gums) and will focus more on the hands and testing procedures. Videos will be identified by the participant study number only.

**Figure 1: Clinical Performance Data Collection Methods**



Participants will then self-collect oral mucosa transudate, be asked to read their own result in private, and check the appropriate results box on a self-completed questionnaire, which includes symbols for those with lower literacy levels. The participant will be asked to place this form and the used test kit in an opaque envelope and seal the envelope. The research assistant will then re-read the participants test strip within 40 minutes of the test being performed and record the result. In addition, the research assistant will conduct a second oral fluid test using the OraQuick® HIV Self-Test and record the results.

A nurse/counsellor blinded to the oral test results will then proceed to draw up to 10 ml of venous blood into EDTA tube, which will be processed within 8 hours to prepare plasma aliquots that will be used for all laboratory-based reference testing. The nurse will also perform whole blood HIV rapid testing according to the Zambian national algorithm i.e. Determine™ HIV1/2 (Alere). If this fingerstick test is reactive, the nurse/counsellor will perform a Unigold™HIV1/2 (Trinity Biotech) test. These results will be provided to the participant. Any participants with reactive test results will be referred for HIV care at the associated health facility.

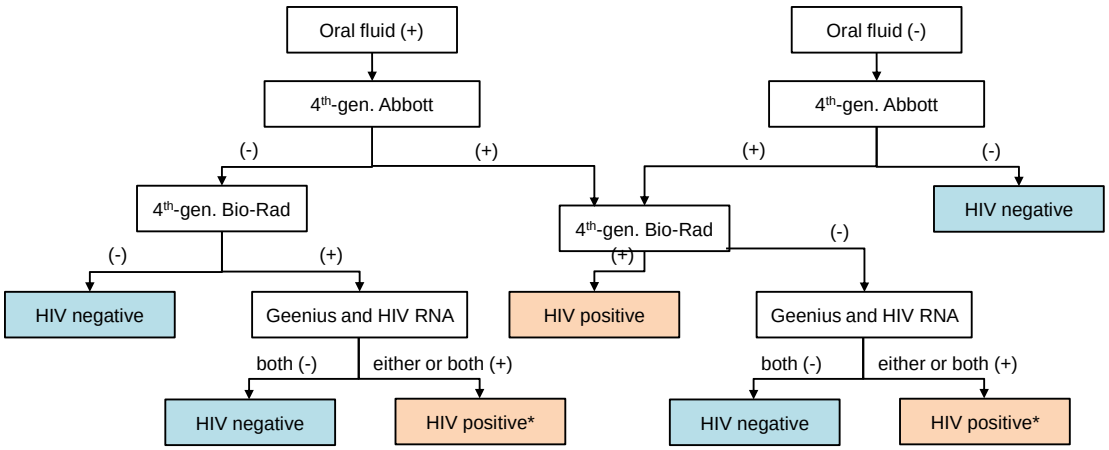
*Laboratory testing*

All laboratory testing will be conducted at the Zambart central laboratory which is currently registered under the College of American Pathologists (CAP) External Quality Assurance (EQA) programme for the Abbott Architect assay and is a certified laboratory by the National Institutes of Health HIV Prevention Trials Network (HPTN).

Venous whole blood specimens collected into EDTA will be processed within 8 hours. The whole blood will be centrifuged at 800gm for 10 minutes and plasma stored at -80$^{o}$C. All plasma samples will be tested according to a composite reference standard algorithm as shown in Figure 2.

**Figure 2:**

**Reference testing algorithm**




Assays: Oral fluid: OraQuick HIV test; 4th-gen. Abbott: Architect HIV Ag/Ab Combo assay; 4th-gen. Bio-Rad: GS HIV Combo Ag/Ab EIA assay; Geenius: Geenius HIV 1/2 Supplemental Assay; HIV RNA: Abbott Real Time HIV assay.
(+) indicates reactive/positive; (-) indicates non-reactive/negative.
*If HIV RNA is undetectable, samples may be tested for the presence of antiretroviral drugs.

All samples will be tested using the Abbott Architect HIV1 Ag/Ab combo assay. Any tests which are reactive on this assay will be confirmed using a second 4th generation assay, BioRad GS HIV combo Ag/Ab assay. Any discrepant results, either between the HIVST result or between laboratory results will lead to additional testing as per the algorithm. For individuals with results that lead to suspicion of ART usage e.g. negative HIVST, positive Ag/Ab tests but undetectable viral load will further be subjected to testing for common antiretroviral drugs.

## 7.2 Data Analysis for Clinical Performance Study

*Clinical performance compared to the composite reference standard:*

Clinical performance of OraQuick® HIV Self-Test will be assessed by analysing the self-tester recorded test result against results from the reference testing algorithm described above. This will provide the primary outcome of specificity and sensitivity in the intended user population. Clinical performance will also be analysed according to different socio-demographic characteristics that may affect self-test performance (e.g., age, gender, educational level, literacy, urban/rural resident). The analysis of the results is shown in Figure 3.

**Figure 3: Analysis of Self-Tester Oral Fluid Result and Laboratory Reference Standard**

| OF | 4th-gen. Abbott | 4th-gen Bio-Rad | Geenius/HIV RNA | HIV status | OF status |
|---|---|---|---|---|---|
| (+) | (+) | (+) | n/d | HIV pos | TP |
| (+) | (-) | (-) | n/d | HIV neg | FP |
| (+) | (-) | (+) | either or both (+) | HIV pos | TP |

| | | | | | |
|---|---|---|---|---|---|
| (+) | (-) | (+) | both (-) | HIV neg | FP |
| (-) | (-) | n/d | n/d | HIV neg | TN |
| (-) | (+) | (+) | n/d | HIV pos | FN |
| (-) | (+) | (-) | either or both (+) | HIV pos | FN |
| (-) | (+) | (-) | both (-) | HIV neg | TN |

Assays: Oral fluid:OraQuick HIV test; 4th-gen. Abbott: Architect HIV Ag/Ab Combo assay; 4th-gen. Bio-Rad: GS HIV Combo Ag/Ab EIA assay; Geenius: Geenius HIV 1/2 Supplemental Assay; HIV RNA: Abbott Real Time HIV assay.
Abbreviations: OF: oral fluid; gen.: generation; n/d: not determined; pos: positive; neg: negative; TP: true positive; FP: false positive; TN: true negative; FN: false negative. (+) indicates reactive/positive; (-) indicates non-reactive/negative.

*Clinical performance compared to the currently in use national testing algorithm*

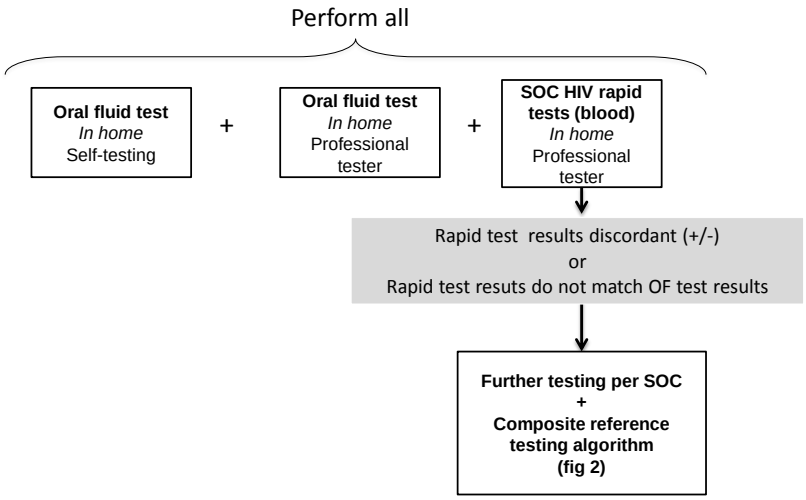
Clinical performance of OraQuick® HIV Self-Test will also be assessed by comparing the self-tester result to the result obtained using the standard national algorithm in place in Zambia at the current time: serial HIV rapid tests performed on whole blood obtained by finger stick (Figure 4). As above, clinical performance will also be analysed according to different socio-demographic characteristics that may affect self-test performance (e.g., age, gender, educational level, literacy, urban/rural resident).

*Understanding of test performance*

As we anticipate less than 100% sensitivity and specificity of OraQuick® HIV Self-Test, we plan to assess the proportion of incorrect test results that are due to differences in test performance (e.g., self tester vs. professional tester vs. laboratory-based testing), and how much is due to user factors in intended use settings. This will be a descriptive analysis.

**Figure 4:**

**Comparison of OF self-testing to skilled testing and to SOC HIV rapid testing**




SOC: local standard of care; QC: Quality control

*User competency:*

This will be assessed in several ways:

- Videos will be watched by a study team member and scored for correctness of each element of the procedure using a standardised data capture form. A score will be obtained for each participant and specific areas where the recommended procedure was not followed will be analysed
- The self-test reading will be compared to the re-read by the research assistant to assess ability of the self-tester to read the test correctly.
- The result of the OraQuick® HIV Self-Test repeated by the health worker will be compared to the participant OraQuick® HIV Self-Test result to provide a direct comparison of self vs. professional use results.
- The proportion of invalid tests will be recorded

These will be analysed according to different socio-demographic characteristics that may affect performance of the tester (e.g., age, gender, educational level, literacy, urban/rural resident). If the 3-month review reveals any major problems in competency requiring modification of the test instructions, the study may be stopped at that time so that the instructions can be revised.

## 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. Names will not be linked except through paper-based recruitment logs, which will be stored in locked cupboards and not entered into electronic form.

### 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 data files. Only individuals authorised to access the data will be provided with codes for this.

## 9.0 Dissemination of findings

### 9.1 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.

### 9.2 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.

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).
A process of community consultation will also 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.

## 10.0 Ethical considerations and confidentiality

### 10.1 Confidentiality

Participants will not have their names used during any stage of data collection and will be given a unique identifier. 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.

### 10.2 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 subject 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 (15-17 years old).

### 10.3 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.

### 10.4 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.

## 11.0 Constraints and limitations

### 11.1 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.

### 11.2 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.

### 11.3 Governance

STAR will form a Technical Advisory Group to review data and provide expert opinion to PQ on whether a product should be pre-qualified, and to support post-market surveillance reports and supervision when products enter the market place.

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.

## 12.0 Timeframe

# 9 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.1365-3156.2011.0289
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.

# 10 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 20 Read 20 Expiration 40

**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

# STAR project: Self-Testing Africa

## Participant Information Sheet – Clinical Performance

*1. Why are we doing this study?*

This study 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.

*2. 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.

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

We will ask you some questions about yourself and also about whether you have tested for HIV before.

We will then give you an HIV oral-fluid self-test kit with instructions and ask you to take this test into a private space and to test yourself following the instructions. We may video you doing the test. This is so that we can see how people understand the instructions. During the video we will attempt to avoid showing most of your face so that you cannot be identified. The video will only be shown to researchers who will assess how you did the test and it will then be erased.

We will then ask you to record the test result that you got on a results sheet. You will give this back to the researcher who will read your test strip as well. A trained research assistant will administer a second HIV test using oral fluid and record the results.

A nurse will then come and take approximately 10mls of blood from you (This is the same as 2 tea spoons of blood). This blood will be taken to our laboratory in Zambia where we will test it for HIV. In a few cases we may need to do some extra quality checking test that may require your blood to be transported to another laboratory outside of Zambia.

The nurse will then perform standard HIV testing as per Zambian guidelines. This involves having a finger prick and a drop of blood is used to test for HIV. If the first test is reactive we will ask you to have another fingerpick and to have a second test to make sure the result is correct. The nurse will provide you with counselling about the test and the results and will be able to answer any questions you may have at this time. The nurse will also refer you for any care that you may need

We will then ask you to fill in a small questionnaire, telling us how you found the experience. If you test HIV-positive then we will make arrangements for you to be seen at the nearest clinic that provides care and treatment for HIV.

This will take between 1½ to 2 hours of your time.

*4. Who are we asking to participate?*

We are asking adults who have attended the clinic for HIV testing as well as some adult members of households (and young adults aged 15-17 years) in this community. People in the community have been chosen by chance ("random selection"). There is no special reason for asking you and not your neighbour to participate.

*5. Where do we come from?*

We work at ZAMBART, a research project at University of Zambia, School of Medicine, Ridgeway, Lusaka. We 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 how best to provide it.

Having an HIV test can be stressful. We will ask you to take a swab from your gums for the first test with the oral fluid self-test kit, and a trained research assistant will also swab your gums. A nurse will take a finger-prick blood drop to be used to help confirm the result. Another 10ml (about 2 teaspoons) of blood from the vein, for further confirmatory HIV tests at the central laboratory. This can leave a small bruise. There are no other risks from this study.

The benefit of being in this study is knowing your HIV status.

*7. Do I have to participate in this study?*

Your participation is voluntary. You may stop the study at any time and without giving a reason and without any penalty. You will continue accessing regular health care services as before.

*8. Confidentiality*

All information obtained from the study will be stored securely. Hard copies of questionnaires will be kept in locked cupboards in a secure location in Zambart and electronic data will be password protected on a computer accessible only to authorised staff members.

We will use a number to identify you, and will only record your name on one enrolment form. Confidentiality will be maintained throughout all data handling and storage processes.

We will record if you had an HIV test, but not next to the result. If you have a self-test we will record the results next to the result that we got from your blood, but without any other information about you so that no one will be able to trace the result back to you.

*9. Costs*

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

*10. The Ethics Committees that have approved the study is:*

University of Zambia Biomedical Research Ethics Committee (UNZABREC), Lusaka Telephone: +260 211 256067.London School of Hygiene and Tropical Medicine Ethics Committee, **ethics@lshtm.ac.uk**

*11. The regulatory institution that has approved the study:*
Zambia Medicines Regulatory Authority (ZAMRA) Plot 6903 Tuleteka Road P.O. box 31890 Lusaka, pharmacy@zamra.co.zm. Tel 260 211 220 429

*12. What if I have any questions?*

If you have any questions about this study please feel free to ask them now. If you think of any questions after we have gone contact by calling:

1. Dr. Helen Ayles, ZAMBART Project PO Box 50697, Ridgeway Campus, School of Medicine Lusaka.
   Telephone: +260 211 255 715

2. Dr. Alwyn Mwinga, ZAMBART Project, P.O. Box 50697, Ridgeway Campus, School of Medicine. Lusaka. Telephone: +260 211 255 715

## Clinical Performance Consent Form (Adult)

| Statement | Initial or thumb print |
|---|---|
| 1. I confirm that I have read the information sheet, and that the information and procedures involved in my participation in this study have been explained to me. | |
| 2. I confirm that I have had the opportunity to ask questions about the study and that I am satisfied with the answers provided. | |
| 3. I have been given time and opportunity to read the information carefully and to decide whether or not to participate in this study. | |
| 4. I understand that I have been randomly selected and that my participation does not predict either a positive or negative HIV test result. | |
| 5. I also understand that the I will be required to perform a self-test for HIV as well as have a confirmatory blood testing. | |
| 6. I also understand that I will receive counseling before and after the HIV test. | |
| 7. I understand that the researchers will keep his/her information confidential. | |
| 8. I understand that the results for both the self –test and confirmatory HIV test will be recorded, but not with any identifying information about me. | |
| 9. I understand that not agreeing to participate in this study will not in any way disadvantage me from seeking medical services now and in future. | |
| 10. I understand that I have the right to withdraw from the study at any time without giving any reason and without worrying of being penalized thereafter. | |

**I agree to take part in this study.**

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

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

**If the participant gave verbal consent, please enter the name of person who witnessed the consent here, and their signature:**

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

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

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

Name of facilitator (BLOCK CAPITALS) Date Signature

.

## Clinical Performance Consent Form (Young Adult)

| Statement | Initial or thumb print |
|---|---|
| 1. I confirm that I am the parent or legal guardian of this young adult | |
| 2. I confirm that I have read the information sheet, and that the information and procedures involved in the participation of the said young adult in this study have been explained to me | |
| 3. I confirm that I have had the opportunity to ask questions about the study and that I am satisfied with the answers provided. | |
| 4. I have been given time and opportunity to read the information carefully and to decide whether or not to permit the participation of this young adult in this study. | |
| 5. I understand that the young adult has been randomly selected and that his or her participation does not predict either a positive or negative HIV test result. | |
| 6. I also understand that the young adult will be required to perform a self-test for HIV as well as have a confirmatory blood testing. | |
| 7. I also understand that Counseling will be given to the young adult before and after the HIV test. | |
| 8. I understand that the researchers will keep his/her information confidential. | |
| 9. I understand that the results for both the self –test and confirmatory HIV test will be recorded, but not with any identifying information about the young adult. | |
| 10. I understand that not agreeing to permit the young adult to participate in this study will not in any way disadvantage the young adult as he/she seeks medical services now and in future. | |
| 11. I understand that the young adult has the right to withdraw from the study at any time without giving any reason and without worrying of being penalized thereafter. | |

**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. | |

**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)

## List of data collection instruments

(1) Household enumeration (paper-based)
(2) Socio-demographic module (electronic)
(3) Client-adminstered OFT module (electronic)
(4) Self-completed questionnaire (paper)_
(5) Researcher-administered OFT module (electronic)
(6) Rapid diagnostic test results module (electronic)
(7) Experiences of self-testing module (electronic)

## FORM 1 – Front side

(8)

| Visit Date: | | | | | | | | Visit Time: | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | : | | |

| Household Consent Y/N: | Address: | SEA: |
|---|---|---|

| SEQ.NO. | FIRST NAME | SURNAME | HOH (Y/N) | SEX (M/F) | AGE | MARRIED TO [1] | CONSENT [2] | INDIVIDUAL BARCODE | EDC-NO | TAKEN TO SN |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 2 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 3 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 4 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 5 | | | | | | | | Reason for exclusion (Ineligibility) | | |

## FORM 1 – Back side

| SEQ.NO. | FIRST NAME | SURNAME | HOH (Y/N) | SEX (M/F) | AGE | MARRIED TO [1] | CONSENT [2] | INDIVIDUAL BARCODE | EDC-NO | TAKEN TO SN |
|---|---|---|---|---|---|---|---|---|---|---|
| 6 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 7 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 8 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 9 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 10 | | | | | | | | Reason for exclusion (Ineligibility) | | |

## FORM 2 – Front side

| Visit Date: | | | | | | | | Visit Time: | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | : | | |

| Household Consent Y/N: | Address: | SEA: |
|---|---|---|

| SEQ.NO. | FIRST NAME | SURNAME | HOH (Y/N) | SEX (M/F) | AGE | MARRIED TO [1] | CONSENT [2] | INDIVIDUAL BARCODE | EDC-NO | TAKEN TO SN |
|---|---|---|---|---|---|---|---|---|---|---|
| 11 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 12 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 13 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 14 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 15 | | | | | | | | Reason for exclusion (Ineligibility) | | |

## FORM 2 – Back side

| SEQ.NO. | FIRST NAME | SURNAME | HOH (Y/N) | SEX (M/F) | AGE | MARRIED TO [1] | CONSENT [2] | INDIVIDUAL BARCODE | EDC-NO | TAKEN TO SN |
|---|---|---|---|---|---|---|---|---|---|---|
| 16 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 17 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 18 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 19 | | | | | | | | Reason for exclusion (Ineligibility) | | |
| 20 | | | | | | | | Reason for exclusion (Ineligibility) | | |

## SOCIO-DEMOGRAPHIC MODULE

### Opening statements:

**I would like to ask you a few questions. It will only take about 10 mins.**

| | | | |
|---|---|---|---|
| D01 | ID | **Participant ID** | ☐☐☐/☐ |
| D02 | INTRD | **Interview date** | ☐☐/☐☐/☐☐ |
| D03 | INTID | **Interviewer ID** | ☐☐☐☐ |
| D04 | INTRD | **Participant group** | 1 = M'tendere community<br>2 = Kanakantapa community<br>3 = M'tendere health facility ☐ |
| D05 | SEX | **Sex** | 1 = Male<br>2 = Female ☐ |
| D06 | AGE | How old are you? | ☐☐ |
| D07/D08 | OCC | What is your usual occupation?<br>**[PROBE: What kind of work do you do most of your time?]**<br><br>Record answer then code<br>……<br>…… | 1 = Health worker,<br>2 = Farmer, Fishing, Agriculture, forestry<br>3 = Soldier, policeman<br>4 = Driver<br>5 = Manual worker<br>6 = Sales, service workers, Clerical<br>7 = Professional, managerial<br>8 = No employment (housework, student, unemployed)<br>9 = Other ☐ |
| D09/D10 | NATEMP | Are you now…?<br>**[READ OUT]** | 1 = Regularly employed full-time<br>2 = Employed seasonally or day-to-day<br>3 = Self-employed<br>4 = Unemployed/looking for work<br>5 = Homemaker with part-time work outside<br>6 = A homemaker with no other work outside<br>7 = A student<br>8 = Retired or disabled<br>9 = Other ..... ☐ |
| D11 | MSTAT | What is your marital status? | 1 = Never married<br>➔**IF 1 GO TO D14**<br>2 = Married or living with partner<br>3 = Divorced<br>4 = Widowed ☐ |

| | | | |
|---|---|---|---|
| D12 | MSTAT | **Is this your first marriage?** | 1 = Yes first marriage<br>2 = No remarried after divorce/death<br>9 = N/A ☐ |
| D13 | POLY | **[IF MEN]:**<br>Do you have more than one wife?<br><br>**[IF WOMEN]:**<br>Does your husband have other wives? | 1 = Yes<br>2 = No ☐ |
| D14 | LIT | Can you read a newspaper or letter? | 1 = Yes<br>2 = No ☐ |
| D14a | LANG | Which language do you use most often at home? | 1 = Bemba<br>2 = Nyanja<br>3 = Tonga<br>4 = English<br>5 = Other language ☐ |
| D15 | EDUC | Have you ever attended school?<br>**[If YES]:**What was the highest level that you completed? | 1 = Primary<br>2 = Secondary<br>3 = Higher<br>4 = Primary not completed<br>5 = Never ☐ |
| D16 | FOOD | During the past month, how often have you had problems getting the food you need? | 1 = Never<br>2 = Sometimes<br>3 = Often<br>4 = Always ☐ |
| D17 | SKPML | In the last two weeks, has an adult in your house skipped a meal or eaten less in order for there to be enough food for the children? | 1 = Yes<br>2 = No ☐ |
| D18 | AST | Do you, or does anyone in your household have any of the following? | Bicycle ☐YES ☐NO<br>Piped water? ☐YES ☐NO<br>Flush toilet? ☐YES ☐NO<br>Electricity? ☐YES ☐NO<br>Television? ☐YES ☐NO<br>Radio? ☐YES ☐NO<br>Electric or gas kitchen stove? ☐YES ☐NO<br>Refrigerator ☐YES ☐NO<br>Telephone OR mobile phone? ☐YES ☐NO<br>Working car or truck? ☐YES ☐NO |

**Now I am going to ask you about HIV testing and your general health.**

| | | | |
|---|---|---|---|
| D28 | PTST | Have you ever been tested for HIV? | 1 = Yes<br>2 = No<br>➔ IF 2 GO TO D36 ☐ |
| D29 | TMES | How many times have you been tested for HIV? | Give number of times ☐☐ |

| | | | |
|---|---|---|---|
| D30 | RECT | How long ago was your [most recent] HIV test? | ☐☐D ☐☐W ☐☐M ☐☐Y |
| D31 | WHRT | Where were you last tested?<br><br>Record answer then code<br>……<br>…… | 1 = Health center / Hospital<br>2 = At a VCT centre (e.g. New start)<br>3 = In community: mobile / AIDS day etc.<br>4 = Home-based testing service<br>5 = Self / informal testing<br>6 = Other..... ☐ |
| D32 | PREVST | Were you tested on your own initiative, or because you were offered a test by a health worker or counselor (at clinic or at home)? | 1 = Own initiative<br>2 = Offered by health worker / counselor ☐ |
| D33 | ANC | **[IF MEN]**<br>Did you have the test because your partner was pregnant, or you were planning to have a child or you were planning to get married?<br><br>**[IF WOMEN]**<br>Did you have the test because of pregnancy or planning to have a child or you were planning to get married? | 1 = Yes: During pregnancy<br>2 = Because of planning to have a child<br>3 = Because of planning to get married<br>4 = No: other reason ☐ |
| D33a | TRUST | Did you trust the result of your most recent test? | 1 = Yes<br>2 = No ☐ |
| D34 | RES | Would you mind telling me the result of your most recent test? | 1= Positive<br>2= Negative<br>3= Don't know/not want to reveal<br>➔ IF 2or 3 GO TO D37 ☐ |
| D35 | ART | **(For those who disclosed HIV positive)**<br>Are you currently taking ART? | 1= Yes<br>2= No<br>3= Don't know/no answer ☐ |
| D36 | NOTST | **[IF NO HIV PREVIOUS TEST]**<br>Have you ever thought about having an HIV test before? | 1 = No, does not want to be tested<br>2 = Yes, but has not got round to it<br>9 = Not applicable (has tested before) ☐ |

*What in your view would be the <u>most successful of the following options</u> to stop so many people getting very sick with AIDS before they know they are HIV-positive? And the <u>next most successful</u>?*

**[READ LIST]**

1. *Counselor from an <u>outside community</u> to go <u>house-to-house</u> & offer <u>ordinary</u> VCT & advice on ART if they test HIV+ve*
2. *<u>Local person</u> to go <u>house-to-house</u> & offer <u>ordinary</u> VCT & help people get ART if they test HIV+ve.*

3. *Mobile clinic with tents to visit every local neighborhood & offer VCT & advice on ART if they test HIV+ve*
4. *Free self-test kits in grocery stores & pharmacies for private home self-testing, with help on ART by telephone & from the vendor.*
5. *Local person to go house-to-house & offer self-test kits for use in private, & help those who want to share results*

| | | | |
|---|---|---|---|
| D37 | STRMST | **Most successful** | 1 = Option 1<br>2 = Option 2<br>3 = Option 3<br>4 = Option 4<br>5 = Option 5<br>6 = *None of these (if alternative suggestion, please record)*<br>……<br>……<br>……<br>…… ☐ |
| D38 | STRMST | **Next most successful** | 1 = Option 1<br>2 = Option 2<br>3 = Option 3<br>4 = Option 4<br>5 = Option 5<br>6 = *None of these (if alternative suggestion, please record)*<br>……<br>……<br>……<br>…… ☐ |

*What in your view would be the most important advantage if self-test kits became available for people to use in private? And the next most?*

**[READ LIST]**

1. *More people would test if it was made that easy.*
2. *More people would test if it was made that confidential.*
3. *People would be the first to know their own result.*
4. *It would save people who wanted to test time & money.*
5. *More couples would test together if they could take 2 kits home.*
6. *We would all encourage each other to test.*
7. *People would feel more in control of their own health.*
8. *People could have a test any time they wanted to.*
9. *People would be less anxious about testing at home & in private.*

| | | | | |
|---|---|---|---|---|
| D39 | ADMST | **Most successful** | 1 = Option 1<br>2 = Option 2<br>3 = Option 3<br>4 = Option 4<br>5 = Option 5<br>6 = Option 6<br>7 = Option 7<br>8 = Option 8<br>9 = *None of these (if alternative suggestion, please record)* | ☐ |
| D40 | ADNXT | **Next most successful** | 1 = Option 1<br>2 = Option 2<br>3 = Option 3<br>4 = Option 4<br>5 = Option 5<br>6 = Option 6<br>7 = Option 7<br>8 = Option 8<br>9 = *None of these (if alternative suggestion, please record)* | ☐ |
| D41 | GHLTH | *How do you rate your general health?* | 1 = Excellent<br>2 = Good<br>3 = Fair<br>4 = Poor | ☐ |
| D42 | RSK1 | *Considering your current and past relationship circumstances, what do you think is the chance of your having HIV now?* | 1 = High chance<br>2 = Medium chance<br>3 = No chance at all<br>9 = Don't know | ☐ |
| D43 | RSK2 | *Considering your current relationship circumstances, what do you think is the chance of your getting HIV in the future?* | 1 = High chance<br>2 = Medium chance<br>3 = No chance at all<br>9 = Don't know | ☐ |
| D44 | WORY | *How worried are you about getting HIV/AIDS?* | 1 = Worried a lot<br>2 = Not worried at all<br>9 = Don't know | ☐ |
| D45 | DEATH | *Do you personally know someone who is sick or who has died of AIDS?* | 1 = Yes<br>2 = No | ☐ |
| D46 | INT | Interview result | 1= Completed<br>2= Not located in 3 visits<br>3= Refused to Answer<br>4 = Partially completed<br>5 = Away for duration of study | ☐ |

## CLIENT-ADMINISTERED TEST MODULE

| | | | | |
|---|---|---|---|---|
| ST1a | CLSTLN | Lot number for self-administered HIVOFT given to client | ☐☐☐☐☐☐☐☐☐☐ | |
| ST1b | CLSTDA | Date of expiry for self-administered HIVOFT given to client | ☐☐/☐☐☐☐ mm/yyyy | |
| ST2 | START | Time client given HIVOFT | ☐☐:☐☐ (hh:mm) | |
| ST3 | ENDTIME | Time client presented completed HIVOFT to RA | ☐☐:☐☐ (hh:mm) | |
| ST4 | CLIRES | Client-read result of OFT (copy from SCQ1) | 1 Positive<br>2 Negative<br>3 Don't know/Invalid result | ☐ |
| ST5 | CLIERR | Client report of errors during test (check all that apply, copying from SCQ2) | 1. No errors ☐YES ☐NO<br>2. Rubbed the wrong part of the mouth. ☐YES ☐NO<br>3. Spilt developer fluid. ☐YES ☐NO<br>4. Touched the flat pad. ☐YES ☐NO<br>5. Pad came out of developer while testing. ☐YES ☐NO<br>6. Read the results before time. ☐YES ☐NO<br>7. Failed to identify the test area or the control area. ☐YES ☐NO<br>8. Mistook the control area for the test area. ☐YES ☐NO<br>9. Other (specify) _____<br>_____ | |
| ST6 | RESRES | Researcher-read result of client-administered OFT | 1 = Positive<br>2 = Negative<br>3 = Invalid<br>4 = Incomplete processing | ☐ |

## Self-Completed Questionnaire

SCQ1 RES

**What is your HIV test result?**

☐ **1 -** *Positive* ☐ **2** *Not sure/ Invalid* ☐ **3 -** *Negative*

SCQ2 CLIERR

**Did you make any errors in taking the test? (Circle all that apply)**

1. *No errors*
2. *Rubbed the wrong part of the mouth.*
3. *Spilt developer fluid.*
4. *Touched the flat pad.*
5. *Pad came out of developer while testing.*
6. *Read the results before time.*
7. *Failed to identify the test area or the control area.*
8. *Mistook the control area for the test area.*
9. *Other (specify)*

   ……

## RESEARCHER-ADMINISTERED HIV OFT MODULE

| | | | | |
|---|---|---|---|---|
| RAT1 | RATLN | Lot number for researcher-administered HIVOFT | ☐☐☐☐☐☐☐☐☐☐ | |
| ST1b | CLSTDA | Date of expiry for researcher-administered HIVOFT | ☐☐/☐☐☐☐ mm/yyyy | |
| RAT2 | RATRES | Researcher-administered HIV OFT results | 1 = Positive<br>2 = Negative<br>3 = Invalid<br>4 = Incomplete processing | ☐ |
| RAT3 | RATNOT | Notes on problems during researcher-administered HIV OFT | _____<br>_____ | |

## RAPID DIAGNOSTIC TEST RESULTS MODULE

| | | | |
|---|---|---|---|
| RDT1 | RDTID | Nurse/counsellor ID code | ☐☐☐☐ |
| RDT2 | RDTDETE | Determine | 1 = Reactive<br>2 = Non-reactive<br>3 = Invalid ☐ |
| RDT3 | RDTUNI | Unigold | 1 = Reactive<br>2 = Non-reactive<br>3 = Invalid ☐ |
| RDT4 | RDTSTAT | HIV status based on RDT | 1 = Positive<br>2 = Negative<br>3 = Indeterminate ☐ |
| RDT5 | STCORR | Was the participant self-read OFT result correct? | 1 = Yes<br>2 = No ☐ |

## EXPERIENCE OF SELF-TESTING MODULE

Now I am going to ask you a few questions about your experience of HIV self-testing today

| | | | |
|---|---|---|---|
| X1 | EASE | *How easy was the self-test to do?* | 1 = Very easy<br>2 = Somewhat easy<br>3 = Somewhat difficult<br>4 = Very difficult ☐ |
| X2 | DFCTY | *Which part of the self-test did you find the most difficult to perform?* | 1= Collecting the mouth swab.<br>2 = Putting test device in the vial.<br>3 = Not touching the pad<br>4 = Reading the test.<br>5 = All the steps were easy.<br>6 = Other difficulty<br>…… ☐ |
| X3 | INSTR | *How easy was it to understand the instructions in general?* | 1 = Very easy<br>2 = Somewhat easy<br>3 = Somewhat difficult<br>4 = Very difficult ☐ |
| X4 | RESCOR R | *Do you believe that the result of the HIV test you conducted yourself was correct?* | 1 = Definitely correct<br>2 = Probably correct<br>3 = Probably not correct ☐ |
| X5 | CONT | *How much did doing the test yourself make you feel in control?* | 1 = Very much in control<br>2 = Somewhat in control<br>3 = Did not feel in control ☐ |
| X6 | BLOOD | *How much do you trust a mouth swab compared to blood?* | 1 = Trust it as much as blood<br>2 = Trust it somewhat less<br>3 = Trust it much less ☐ |
| X7 | FTPRF | *If you had the opportunity and decided to self-test again in the future, what would you prefer?* | 1 = To conduct the test in private.<br>2 = To conduct the test with little supervision.<br>3 = To conduct the test in the presence of a counsellor. ☐ |
| X8 | SATIS | *Overall, how satisfied were you with the self-testing process?* | 1 = Very satisfied<br>2 = Somewhat satisfied<br>3 = A little satisfied<br>4 = Not satisfied at all ☐ |
| X9 | RECOM | *What would you recommend to improve the experience of self-testing?* | ……<br>……<br>……<br>……<br>…… |

| | | | |
|---|---|---|---|
| | | | …… …… |
| X10 | RCKIT | *Would you recommend this HIV test kit for self-testing to friends and family?* | 1 = Yes<br>2 = No ☐ |
| X11 | STFT | *How likely would you be to self-test in the future if kits were made available for the general public?* | 1 = Very likely<br>2 = Somewhat likely<br>3 = Not likely at all<br>4 = Never again ☐ |

## Appendix 3: Tools for Cognitive Interviews

# STAR project: Self-Testing Africa

### Participant Information Sheet – Cognitive interviews

**Why are we doing this study?**

This study 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 options. 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 Alwyn 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

**The regulatory institution that has approved the study:**
Zambia Medicines Regulatory Authority (ZAMRA) Plot 6903 Tuleteka Road P.O. box 31890 Lusaka, pharmacy@zamra.co.zm. Tel 260 211 220 429

**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 Alwyn Mwinga Tel: 0211257215

## Cognitive Interview Consent Form (Adult)

| Statement | Initial or thumbprint |
|---|---|
| 1. I have received and read/had read the information sheet provided by the researchers that explains in detail the reasons for the study | |
| 2. I have read, discussed and understood the purpose of the research. | |
| 3. 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

**If the participant gave verbal consent, please enter the name of person who witnessed the consent here, and their signature:**

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

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

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

Name of facilitator (BLOCK CAPITALS) Date Signature

**Cognitive Interview Consent Form (Young Adult)**

**For parent or guardian**

| **Statement** | **Initial or thumbprint** |
|---|---|
| 4. I confirm that I am the parent or guardian of this young adult. | |
| 5. I have received and read/had read the information sheet provided by the researchers that explains in detail the reasons for the study and the procedures involved in participation of this young adult in this research. | |
| 6. I have read, discussed and understood the purpose of the research. | |
| 7. 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 _____

**For young adult**

| **Statement** | **Initial or thumbprint** |
|---|---|
| 8. I have received and read/had read the information sheet provided by the researchers that explains in detail the reasons for the study | |
| 9. I have read, discussed and understood the purpose of the research. | |
| 10. 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 young adult Date Signature or thumb print
(BLOCK CAPITALS)

**If the participant gave verbal consent, please enter the name of person who witnessed the consent here, and their signature:**

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

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

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

Name of facilitator Date Signature
(BLOCK CAPITALS)

**Cognitive Interview Guide**

**Opening statements:**

Thank you for taking time to talk with me. As you may remember, my name is _____. We have asked you to participate in this exercise because we want to study the feasibility of HIV self-testing. For individuals to accurately and safely self-test they should have clear instructions on how to do so. We aim to develop clear instructions that can be used for this purpose. As discussed during the consent discussion, we will ask you go through self-testing using some instructions that we have developed. As you go through the process we will ask you questions about the understandability of the instructions. This process is likely to take about one hour to complete. Feel free to let me know if you need a break at any time. You can also stop the interview if you do not want to continue the discussion. Before we begin do you have any questions?

Please open up your test kit and take a few minutes to review the instruction sheet.

**A. General**

1. What do you think of the layout of these instructions?
2. Do you understand where to start and the order to follow?
3. What information is contained on the first side of the page?
4. What information is contained on the back page?

Now we will go through the instructions in more detail.

**B. Heading information**

5. What did you understand regarding the instructions on the top of the page?
6. Did you understand the pictures at the top of the page?
7. Did you understand that you should not eat and drink before the study, and how long you should wait between eating and testing?
8. Did you understand that you should not use mouth cleaning products (such as toothpaste/mouthwash) before the study, and how long you should wait?
9. What did you understand regarding the information on the time it takes to test?
10. What did you understand about the warning about taking ARVs and using the self-test?

**C. Instruction number 1**

***11.*** Please tell me in your own words what instruction number 1 is telling you.
*Probe: do you understand why you need a watch (or other time piece)?*

**12.** When would you begin timing the test?

**13.** How easy would it be for you to find something to use to time the test? *Probe: What sort of things would you use to time the test?*

**D. Instruction number 2**

14. Please tell me in your own words what instruction number 2 is telling you to do.

    *Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer? Do you think another person would understand what is meant by "two pouches"?*

**E. Instruction number 3 – removal of tube from pouch**

15. Please tell me in your own words what instruction number 3 is telling you to do.

    *Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer?*

16. Please go ahead and carry out the instruction as you understand it. How clear is the image? How clear is the instruction? How easy was it to open the pouch? Did you understand what the tube was that the instructions referred to?

    *Probes: Do you think another person would understand what is meant by "pouch containing the tube"? If it was not easy, what can be done to make it easier?*

**F. Instruction number 4 – opening of the tube**

17. Please tell me in your own words what instruction number 4 is telling you to do.

    *Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer?*

18. Please go ahead and carry out the instruction as you understand it. How clear is the image? How clear is the instruction? How difficult was it to open the cap of the tube? Did any of the liquid spill as you opened it?

    *Probes: If there are any problems, how could these be resolved? Do you think it is necessary to inform people that there is liquid inside the tube?*

**G. Instruction number 5 – use of the tube**

10. Please tell me in your own words what instruction number 5 is telling you. *(Probe: is the image clear in telling you not to drink the liquid or pour it out?)*

**H. Instruction number 6 – slide the tube into the stand**

19. Please tell me in your own words what instruction number 6 is telling you to do.

    *Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer?*

20. Please go ahead and carry out the instruction as you understand it. How clear is the image? How clear is the instruction? Were there any problems identifying the stand? Were there any problems sliding the tube into the stand? Did any liquid spill as you placed the open tube into the stand?

    *Probes: If any problems, how could these be resolved?*

**I. Instruction number 7 – removal of test device from pouch**

21. Please tell me in your own words what instruction number 7 is telling you to do.

    *Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer?*

22. Please go ahead and carry out the instruction as you understand it. How clear is the image? How clear is the instruction? How easy was it to open the pouch without touching the flat pad? Did you understand which end was the flat pad and which part was the results window? Did you understand what to do with the preservative?

    *Probes: How likely is it that others will find this an easy step?*

**J. Instruction number 8 – collecting the specimen**

23. Please describe to me in your own words how you collect the specimen.

    *Probes: Do you think another person would be able to understand the instructions and do this correctly? How could we modify the image or reword it to make it clearer?*

24. Please go ahead and carry out the instruction as you understand it. Is any part of the instruction unclear? How easy was it to collect the specimen? *(Probe: how was it to swab around your mouth?)*

25. Do you think this would easy for another person to do?

**K. Instruction number 9 – placing the test device**

26. Please tell me in your own words what instruction number 9 is telling you to do.

    *Probes: Would another person understand what it is that should be done?*

27. Please go ahead and carry out the instruction as you understand it. Did you understand how to put the flat pad into the tube? Did you have any trouble putting the flat pad into the tube of fluid? Did any liquid spill?

**L. Instruction number 10 – timing of the test**

28. Is it clear what needs to be done?

29. How easy is this instruction? After putting the flat pad into the tube, the instructions say to leave it there. What is meant by this? How long must you wait before reading the test result?

**M. Interpreting results – HIV positive**

30. Please tell me in your own words what a positive result looks like.

    *Probes: Do you think another person would be able to understand the instructions and read their positive result correctly? How could we modify the image or reword it to make it clearer? Did you understand that either of the two lines could be faint for a positive test?*

31. Is it clear what needs to be done if one tests HIV positive?

32. Please describe in your own words what needs to be done if one tests HIV positive.

**N. Interpreting results – HIV negative**

11. Please tell me in your own words what a negative result looks like.

    *Probes: Do you think another person would be able to understand the instructions and read their negative result correctly? How could we modify the image or reword it to make it clearer?*

12. What may happen if you read your result early?
13. Is it clear what needs to be done if one tests HIV negative?
14. Please describe in your own words what needs to be done if one tests HIV negative.

**O. Interpreting results – invalid**

33. Please tell me in your own words what an invalid result looks like.

    *Probes: Do you think another person would be able to understand the instructions and read their invalid result correctly? How could we modify the image or reword it to make it clearer?*

34. Is it clear what needs to be done if one has an invalid result?
35. Please describe in your own words what needs to be done if one has an invalid result.

**P. Interpreting own results**

36. Please read your results. Are the instructions on how to interpret the results clear?

    *Probes: Do you think other people would be able to interpret the results easily?*

37. Were you able to relate the appearance of your test to any of the pictures in the instructions? What was your test result? Do you feel confident that this result is correct?

    *Probes: Do you think others will believe their result? Why? If no, what could be done so that people have confidence in the test result?*

38. Is there any other information that you would like to have about what to do after taking the HIV self-test?
39. Do you think you would feel comfortable talking to someone over the phone about taking a HIV self-test or about your test result?

    *Probes: What about other people? Why do you say so? If not, what could be done?*

40. What do you think about the idea of visiting the nearest clinic after self-testing?

    *Probes: Where else would you rather go?*

**Q. Test kit disposal**

41. Is it clear what you should do with the self-testing materials after use?
42. Please describe in your own words what to do with the test device?
43. Please describe in your own words what to do with the remaining contents of the test kit?

**R. General**

44. What would you do if you had questions about how to perform the self-test correctly?

    *Probes: Who would you talk to? Where would you find their contact details?*

45. What would you do if you needed post-test counseling?

    *Probes: Where would you go*?

46. What is your opinion of the whole process of self-testing?

47. Do you think that other people would be able to self-test accurately?

    Probes: *Why do you say so?*

48. What suggestions would you have around improving these self-testing instructions?

**CURRICULUM VITAE**