

# A cluster randomised trial of interventions to improve linkage to care following community-based distribution of HIV self-test kits in rural Zimbabwean communities

Sponsored by London School of Hygiene & Tropical Medicine  
(LSHTM)

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## **Chief Investigator**

Professor Elizabeth Corbett

London School of Hygiene & Tropical Medicine

## **Zimbabwe Principal Investigator: Professor Frances M. Cowan**

CeSHHAR Zimbabwe and Liverpool School of Tropical Medicine

### *Sponsor*

London School of Hygiene & Tropical Medicine is the research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:

London School of Hygiene & Tropical Medicine

Keppel Street

London WC1E 7HT

Tel: +44 207 927 2626

Email: [RGIO@lshtm.ac.uk](mailto:RGIO@lshtm.ac.uk)



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## **PROTOCOL TEAM ROSTER**

### **Professor Frances M Cowan**

CeSHHAR Zimbabwe &  
Liverpool School of Tropical Medicine  
Email: [Frances.Cowan@lstm.ac.uk](mailto:Frances.Cowan@lstm.ac.uk)

### **Professor Elizabeth Corbett**

London School of Hygiene &  
Tropical Medicine (LSHTM)  
London, UK  
Email: [lizcorbett04@gmail.com](mailto:lizcorbett04@gmail.com)

### **Dr Fern Terris-Prestholt**

London School of Hygiene &  
Tropical Medicine  
London, UK  
Email: [Fern.Terris-Prestholt@lshtm.ac.uk](mailto:Fern.Terris-Prestholt@lshtm.ac.uk)

### **Dr Miriam Taegtmeier**

Liverpool School of Tropical Medicine  
Liverpool, UK  
Email: [Miriam.Taegtmeier@lstm.ac.uk](mailto:Miriam.Taegtmeier@lstm.ac.uk)

### **Dr Valentina Cambiano**

University College London  
London, UK  
Email: [v.cambiano@ucl.ac.uk](mailto:v.cambiano@ucl.ac.uk)

### **Ms Getrude Ncube**

AIDS & TB Unit  
Ministry of Health & Child Care  
Harare  
Email: [getrudencube@yahoo.co.uk](mailto:getrudencube@yahoo.co.uk)

### **Dr Karin Hatzold**

Population Services International  
Harare, Zimbabwe  
Email: [khatzold@psi.org](mailto:khatzold@psi.org)

### **Professor Helen Weiss**

London School of Hygiene &  
Tropical Medicine (LSHTM)  
London, UK  
Email: [helen.weiss@lshtm.ac.uk](mailto:helen.weiss@lshtm.ac.uk)

### **Dr Euphemia Sibanda**

CeSHHAR Zimbabwe  
Harare, Zimbabwe  
Email: [euphemia@ceshhar.co.zw](mailto:euphemia@ceshhar.co.zw)

### **Dr Melissa Neuman**

London School of Hygiene &  
Tropical Medicine  
London, UK  
Email: [Melissa.Neuman@lshtm.ac.uk](mailto:Melissa.Neuman@lshtm.ac.uk)

### **Professor Andrew Phillips**

University College London  
London, UK  
Email: [andrew.phillips@ucl.ac.uk](mailto:andrew.phillips@ucl.ac.uk)

### **Dr Owen Mugurungi**

AIDS & TB Unit  
Ministry of Health & Child Care  
Harare  
Email: [atp.director@ymail.com](mailto:atp.director@ymail.com)

## **1 Background**

In 2014, 1.2 million lives were lost to HIV and AIDS, while 2.0 million people became newly infected[1]. The majority of the burden is in Sub-Saharan Africa, where 71% of the global total of people living with HIV reside[2]. Zimbabwe is one of the worst affected countries with an HIV prevalence of 15% and an estimated 54,994 AIDS related deaths in 2014[3]. Interventions to prevent and treat HIV remain important in efforts to contain the epidemic. Key to these efforts is HIV testing which is the gateway to accessing interventions for prevention and/or treatment of HIV. Recent evidence of effectiveness of early treatment of HIV [4, 5] and the subsequent 2015 WHO “treat all” recommendations make it critical to optimise methods of identifying HIV infected individuals. UNAIDS have set global treatment targets, 90-90-90, that require that by 2020, 90% of people living with HIV are diagnosed, of whom 90% are on treatment and that 90% of those on treatment are virally suppressed[6]. Many settings are still far from reaching the first HIV testing target: globally it is estimated that only 54% of people living with HIV are aware of their status[6]. In Zimbabwe, the 2010/11 Demographic and Health Survey found that among individuals who tested HIV positive, 63.7% had previously tested (71% for women and 51.5% for men)[7]. Of note this survey was done a long time ago so these figures are likely to be out of date. Rates of HIV testing are lowest among men, adolescents and marginalised groups such as sex workers.[7] Barriers to testing include concerns about stigma, fear of prognosis, lack of awareness of HIV risk, and the inconvenience, transportation and opportunity costs incurred.[8, 9] Innovative models of provision of HIV testing services are required to ensure that all those infected benefit from treatment, thereby reducing their risk of onward sexual or vertical transmission.

### **1.1 The potential for HIV Self-testing**

HIV self-testing is a process where an individual collects their own sample and conducts their HIV test privately without a provider present. It has potential to substantially scale up acceptability and access to testing both in the general population as well as in hard-to-reach populations such as sex workers, in a manner that is low-cost, confidential, and empowering for users. Rapid testing technologies include simple-to-use oral HIV tests that offer high sensitivity and specificity, ideal for self-testing strategies.[10, 11] Early research suggests that self-testing is acceptable, with high uptake and accuracy of results. For example, in a community-based study in Malawi, 92% of participants opted for supervised self-testing over standard provider-delivered HIV testing and counselling (PDHTC), including a high proportion of men and first time testers, key groups that are historically reluctant to test. In the same country, the performance characteristics of the oral fluid test (Oraquick Advance) were acceptable with estimated sensitivity from two studies of 97.9% and 93.6% and specificity of 100% and 99.9% respectively. [12, 13] Similarly good accuracy results were found among rural and urban participants in South Africa[14]. Preliminary research in Zimbabwe also found that urban and rural participants were able to produce accurate self-test results using both written and video instructions[15].

Key stakeholders in the HIV testing field including policy makers, health care workers, academics and activists have welcomed the idea of self-testing but caution on the need for research and policy guidance before scale up[16]. Globally the adoption of self-testing into policy is at varying stages. A

few countries have HIV testing policies which include self-testing, e.g. Australia, China, France, Kenya and United States while others such as Zimbabwe, Malawi and Zambia are still considering it[17]. WHO needs more research before they can issue normative guidance on self-testing, but they have recommended that countries go ahead with demonstration projects, which Zimbabwe Ministry of Health and Child Care is interested in. Important questions to be asked before scale-up of self-testing include: 1) how self-test kits can be regulated, marketed and distributed, 2) how to ensure protection from social harms such as forced testing and gender based violence, 3) how can linkage to post-test services after testing be optimised, and 4) what is the relative cost and cost effectiveness of different self-testing models.

## **1.2 Regulation, Marketing and Distribution of Self-tests**

Because results of an HIV test can have significant implications for mental health, health seeking, sexual behaviour and transmission, it is necessary that self-testing be well regulated. This includes regulation of the quality standards of the self-test kits, how and where kits are distributed and by whom, and the nature of marketing/advertising messages[18]. There is evidence that trained community health workers can be useful in distributing self-test kits and providing instructions and support to self-testers [13, 17]. In a study that is being conducted in rural Zimbabwe, community-based distribution of test kits by trained lay health workers is being piloted. This will enable us to refine our implementation strategies for community distribution of self-test kits.

## **1.3 Ethical Issues during implementation of self-testing**

Although concerns have been raised about the potential for social harms such as suicides and intimate partner violence following self-testing [19, 20], in practise there is little evidence that such harm happens [13, 20]. In the self-testing study in Malawi, neither intimate partner violence nor suicides were reported. The prevalence of forced testing, often by main partners, was found to be 3%, although forced testers generally did not regret having tested [13]. Despite this promising evidence it is important that procedures are set in place to prevent, monitor and detect any social harm that may result from self-testing. Importantly, such harms may be difficult to detect, underscoring the need for innovative surveillance methods. In this study we will have ongoing surveillance for social harms using methods developed from the pilot self-test distribution study mentioned above (the pilot study will be done in Mazowe district and has been approved by MRCZ, London School of Hygiene & Tropical Medicine and UCL ethics committees, refs MRCZ/A/2023, 10533 and 5367/001 respectively).

## **1.4 Linkage to care following self-testing and cost effectiveness**

Because the value of testing comes from ability to link to prevention and/or treatment services, it is important to determine how well self-testers link to post-test services and to implement interventions for optimising linkage. Previous research has shown that self-testers link as well as individuals who tested using other models [13]. Optimal linkage rates are not only important for the health of HIV positive individuals but also for the cost effectiveness of the self-testing intervention. A 2015 modelling study found that for a country like Zimbabwe self-testing may be cost-effective; however cost effectiveness can be negatively affected by poor rates of linkage to care after

testing[21]. It is therefore important to address barriers to linkage, which include fear of disclosure (and subsequent stigma), long waiting times at health facilities, distance to health facility, travel costs and user costs [22]. Social support, including from lay health workers, has been found to be effective in facilitating linkage to care. In this study we aim to determine whether incentivising community-based kit distributors according to number of clients who link to post-test services will improve linkage to post-test outreach services in rural communities. We will also investigate whether provision of transport reimbursements to HIV positive participants will improve their linkage to government ART services. In addition, we will determine the cost and cost effectiveness of self-testing interventions with various models of facilitating linkage to care.

## **2 AIM OF THE STUDY**

The study is being conducted under a consortium, HIV Testing Africa (STAR) that is investigating models of distributing HIV self-test kits in three countries, Zambia, Malawi and Zimbabwe. The aim of the study is to determine the acceptability and feasibility of community-based distribution of HIV self-test kits in rural Zimbabwean communities.

### **Primary Objectives**

- To determine whether incentivising community based distributors (CBDs) to support self-testers is effective in improving uptake of self-testing and linkage to post-test services
- To determine whether incentivising HIV positive clients to link to government ART services through provision of funds to reimburse transport costs for their first clinic attendance is effective in increasing linkage

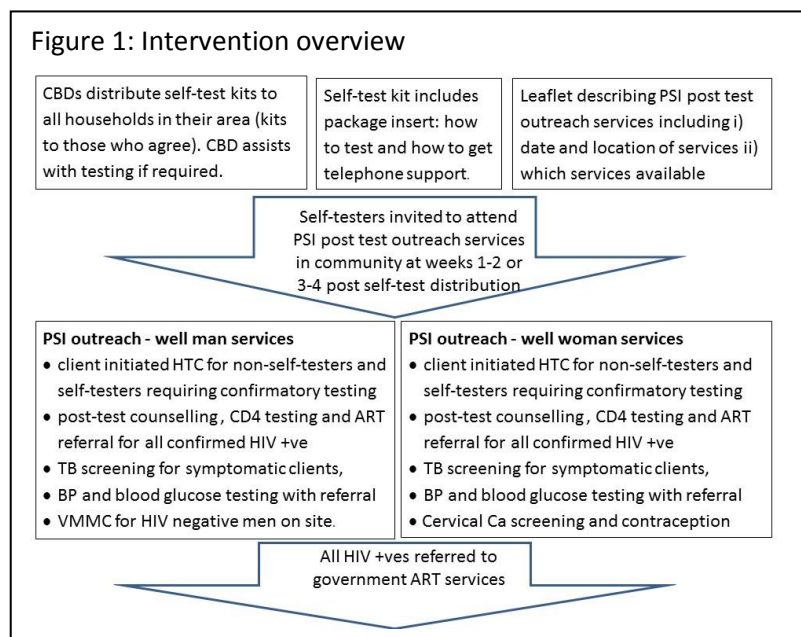
### **Secondary Objectives**

- To determine the effect of self-testing on HIV testing rates in rural Zimbabwean communities
- Using a discrete choice experiment, to explore client preferences for program characteristics that facilitate linkage to care after self-testing
- To determine incidence of gender-based violence in communities where self-test kits are distributed
- To pilot the distribution of HIV self-test kits at both static and mobile HIV testing centres and through voluntary medical male circumcision services
- To explore barriers and enablers to development of a national policy for the regulation, marketing and distribution of self-test kits among stakeholders providing/regulating HIV services in Zimbabwe
- To qualitatively explore feelings about self-testing and linkage to care among clients, health care workers and community-based kit distributors
- To determine the cost and cost effectiveness of community-based distribution of HIV self-test kits



### 3 OVERALL RESEARCH STRATEGY IN ZIMBABWE

We plan to deliver HIV self-test kits to households in rural communities using community-based distributors (CBDs). CBDs will be trained to provide assistance to help people self-test if requested /required. CBDs will encourage people who self-test to link to post-test services provided by PSI Zimbabwe in their communities at either 1-2 weeks or 3-4 weeks after self-test kit delivery (See figure 1). We propose to conduct a cluster-randomised trial in 44 rural outreach communities in order to



test whether: i) incentivising community based distributors (CBDs) according to number of clients who attend outreach services at weeks 1-2 and weeks 3-4 after self-test kit delivery increases testing uptake and linkage to post-test services; ii) incentivising HIV-positive clients to link to government ART services through provision of funds to reimburse transport costs for their first clinic attendance increases linkage to government ART services. A factorial design will be employed: sites will be randomised to incentives for community based distributors (CBDs) to link self-testers to post-self-test care, incentives for HIV positive individuals to link to care, both, or neither (See figure 2). Six weeks after the first PSI outreach visit, community-based surveys will be conducted in four randomly selected enumeration areas (EAs) in each outreach community. Survey participants will be asked about whether they were offered self-test kits, whether they used them and their linkage to post-test services. In addition, to verify self-reports dried blood blot (DBS) samples will be taken for testing for HIV, viral load, recent infection and ARV levels. Study outcomes will be assessed programmatically and through the survey.

Before randomisation, formative work with the following aims will be conducted:

- I. Understanding client/user preferences for HIV self-testing services
- II. Maximising detection of social harms as a result of HIV self-testing
- III. Refining procedures for facilitating and documenting linkage to prevention and care services after self-testing.

A detailed process evaluation will be conducted throughout the program implementation period.

#### Primary outcomes assessed in representative population based survey

- Proportion of individuals who have self-tested in each community
- Proportion of people who linked to PSI outreach services
- Proportion of men taking up VMMC in each community

- Proportion of HIV positives assessed for ART
- Proportion of HIV positives initiated on ART
- Proportion of women accessing contraception consultations in each community

### **Programmatic data outcomes collected by PSI outreach sites**

- Number of individuals who have self-tested in each community
- Number of people who linked to PSI outreach services (Primary outcome)
- Number of men taking up VMMC in each community
- Number assessed for ART
- Number initiated on ART
- Number taking up cervical cancer screening in each community
- Number of contraception consultations in each community

### **Data obtained from government ART services**

- Number of HIV positive individuals who have linked to care

Pilot distribution of HIV self-test kits will be done at New Start static and mobile HIV testing and counselling centres and through VMMC services. Clients who seek testing at these facilities will be offered a choice between HIVST and PDHTC and we will measure uptake of HIVST and linkage to post-test services among self-testers.

## **4 DETAILED PROCEDURES**

### **4.1 Formative Work**

Formative work that will inform the implementation of community-based kit distribution will be done according to the study protocols that have been approved by MRCZ and UCL, references MRCZ/A/1801 and MRCZ/A/2023 for MRCZ; and 5367/001 for UCL.

#### **4.1.2 Methods for detecting social harms during study implementation**

A mapping exercise will be conducted in the study communities to determine the means for detecting /monitoring GBV in communities as well as the levels of support available for victims through the District AIDS Action Committees (DAAC). The mapping exercise described below will also take into account findings of the FGDs investigating the issue of social harms.

The study team will investigate what kind of support services including counselling and legal support are available for the victims and what data these agencies collect. In communities where services are inadequate or not available, discussions will be held with organisations in nearby communities and a referral system will be established to ensure that support is extended and that all study communities have access to GBV support services. Organisations operating within the relevant districts will be alerted of the study. On a monthly basis the study team will consult with the organisations to determine the number of GBV reports and underlying causes.

Participants will be given a toll-free number that they can call to discuss any concerns or questions they may have before, during and after self-testing. Participants will also be told to use this number if they need any support in the event that they have any difficulties after testing. While this will be for general questions and/or support, staff manning the line will actively document all reports on social harms as a result of the study. PSI will develop standard operating procedures to deal with these reports and assist victims of domestic violence. Staff manning the hotline will take action according to the standard operating procedures.

### **REFINING STUDY PROCEDURES FOLLOWING FORMATIVE RESEARCH**

Based on findings from formative work, the study team will refine procedures for facilitating and documenting linkage to prevention and care services.

## **4.2 TRIAL PROCEDURES**

### **4.2.1 Site selection**

The cluster randomised trial will be conducted in eight districts in five provinces in Zimbabwe.

- Mashonaland Central Province – Mazowe
- Manicaland Province – Buhera
- Masvingo Province – Gutu, Masvingo, Chivi
- Midlands Province – Mberengwa, Gweru
- Matebelend South- Bulilima

Forty-four PSI outreach communities defined by local government as wards will be selected from across these eight districts. PSI outreach sites are located in rural communities, each serving a ward, and provide VMMC services (except for Mberengwa District) and outreach HTC. Outreach communities included in the trial will be separated from each other by at least 20km (i.e. the outer border of a community is at least 20 km from the nearest point of another community) to minimise risk of contamination between communities.

In addition to the trial, PSI will continue to implement provider delivered HTC through outreach in 10 districts. Programmatic data collected from these 10 districts will also be analysed to explore the effects of provision of self-testing on HTC uptake.

#### **4.2.2 Randomisation**

A factorial study design will be employed. The two interventions are i) provision of incentives for CBDs to link self-testers to post-test services and ii) provision of incentives for HIV positive self-testers to link to government ART services. Forty-four outreach communities in the eight study districts will be randomised in a 1:1:1:1 ratio to receive either one intervention, neither, or both. Randomisation will be performed by an independent statistician. Communities will be stratified by district and restricted randomisation will be used to minimise imbalance in key factors between arms (HIV prevalence and proximity to a health facility). A public randomisation ceremony will be held to select the final allocation from a randomly-generated list of acceptable allocations.

#### **4.2.3 Distribution of self-test kits and PSI programme activities**

HIV self-test kits will be distributed by CBDs to all households in the study communities. CBDs will ensure that each household receives a kit for each member of the household who is willing to test. At time of kit distribution, CBDs will give out appointment cards on which clients will document the intended date and time of performing the self-test. This will ensure that clients make a commitment to self-test (an intervention that previous research has proven effective in ensuring future uptake of health interventions [23, 24]). CBDs will inform clients of the date of the next PSI outreach visit, and encourage them to think about the time that they would like to attend the outreach clinic. The client will be asked to write this time on their card, which will help foster a commitment to attend post-test services. The card will have the CBD identity number, and clients will be asked to take it to the outreach clinic.

Once they have self-tested, clients/participants will be asked to complete a short results form and to return both the form and the used test kit in a sealed envelope to a drop-off point in the community. The used kits will be placed in locked boxes that will be kept at health facilities. In addition, CBDs will also keep locked drop-boxes where clients can deposit their used test kits. No client identifiers will be placed on the used test kits, although it will be possible to know which household the kit came from. On a weekly basis PSI will collect the sealed boxes. Only authorised PSI staff will have the keys to the drop boxes. A late read of results of the returned kits will be done to estimate HIV prevalence among the HIV self-testers.

One to two weeks after self-test kits have been distributed to households within a community, a PSI outreach team will visit the community to provide a comprehensive package of services packaged as ‘well woman’ and ‘well man’ services. These services will include client-initiated counselling and testing (for those who opted not to self-test); confirmatory tests, post-test counselling, CD4 testing services and clinical staging for those who self-tested HIV positive; referral to government treatment services for those confirmed HIV positive, , TB screening and TB laboratory testing for symptomatic clients, STI screening, blood pressure and blood glucose testing with onward referral to government services as required. HIV negative men will be referred to the nearest voluntary medical male circumcision (VMMC) outreach team. Women, regardless of HIV status, will be able to access cervical cancer screening using VIAC, contraceptive advice and provision including long acting reversible contraceptive methods (LARC).

This outreach team will revisit the community 3-4 weeks later to provide a second opportunity for those who did not attend at the first visit to access services.

Figure 3: Roles and responsibilities of CBDs and PSI/Z outreach

<b>Community based distributors (CBDs)</b>	<b>PSI/Z mobile outreach</b>
<p>House-hold level distribution of HIV self-test kits in 44 outreach communities</p> <ul style="list-style-type: none"> <li>• Distribute appointment cards with each client’s intended date and time of self-testing</li> <li>• Provide support to self-testers as necessary including with the testing process if requested</li> <li>• Inform clients of the date of the next PSI outreach visit</li> </ul>	<p>Provision of comprehensive package of services - well-man and well-woman - 1-2 and 3-4 weeks after distribution of kits by CBDs</p> <ul style="list-style-type: none"> <li>• Services include client-initiated HIV testing for both self-testers and non self-testers</li> <li>• Referral of all confirmed HIV positive clients to government treatment services for ART, OI treatment</li> </ul>

#### 4.2.4 Description of study interventions

##### *Incentives for CBDs*

During training, CBDs in communities that have been randomised to CBD incentives for linking self-testers to post-test services will be told that they will get a stipulated amount of money (20c) for each self-tester who attends the PSI outreach site after testing. Upon attendance at outreach sites, all clients who report having self-tested will be asked to show their self-completed appointment card (which bears the CBD identity number) to PSI staff. Staff will keep a log of clients that attend according to CBD in order to facilitate payment of the CBD. If a client has not brought their appointment card, they will be asked to provide the name of the CBD who supplied the self-test kit,

which will be verified with CBD kit distribution records in that area before the CBD is credited with the attendance.

#### *Incentives for linking HIV infected clients to treatment and care services*

Following confirmatory HIV testing and counselling at the outreach site, PSI will conduct point of care CD4 testing for HIV positive clients. HIV positive clients who are eligible for ART according to National ART Guidelines will be referred to local HIV treatment centres by using a paper referral slip as per existing PSI procedures. A carbon copy of the referral slip will be retained by PSI staff. HIV positive clients will be encouraged to take their referral slip to the referral treatment and care centre where staff will have been trained to keep all referral documentation from the referring organisation (in this case PSI) and mark the source of referral during patient registration, as per existing procedures.

#### *Incentives for HIV positive clients*

Clients who test HIV positive at the PSI outreach sites will be referred for ART initiation and HIV care at government health facilities of their choice. To facilitate linkage to HIV care, referred clients will be offered transport reimbursement of between \$1-2 for attending the HIV clinics. The exact amount given will depend on the distance travelled by the client to the health facility and standard transport fares charged per route. This reimbursement will be made as an electronic cash transfer once linkage has been confirmed by verifying the OI number provided by the client.

### **4.2.5 Qualitative study on linkage**

From three months after distribution of test kits, in-depth interviews will be conducted with

- 20-30 clients who have tested using an HIV self-test
- 20-30 PSI health care workers
- 20-30 CBDs
- 20-30 Public sector health care workers,

to explore the barriers and facilitators to linkage to HIV treatment and prevention services and VMMC services. Participants will be asked about barriers and facilitators to linkage, perceived effect of HIV self-testing on autonomy, responsibility, empowerment and abandonment in terms of linkage to prevention and care services.

These qualitative studies will be conducted in the 8 study communities (two from each arm) that will be designated for process evaluation (Section 4.2.9 below), except for IDI with PSI health care workers where attempts will be made to ensure representation of PSI teams from all provinces.

Key informants from Ministry of Health and Child Care and other providers of HIV testing and counselling services will also be interviewed about this.

#### *Recruitment of Clients*

HIV positive participants will be purposively selected from the eight study communities to ensure representation of those who did/did not link to PSI outreach sites and those who did/did not link to government ART services. The following sorts of clients will be eligible for the study

- At least 16 years old
- Having lived in the study community at the time kit distribution was done
- Self-tested HIV positive (based on self-reports at PSI outreach site or household survey)
- Willing and able to give written informed consent for participation (in addition parental consent will be required for individuals who are less than 18 years old)

#### *Recruitment of PSI health care workers*

PSI health care workers who provide outreach services in the study communities will be purposively selected to ensure representation of teams from all five provinces. Eligibility criteria for PSI health care workers:

- Having provided outreach services in the study communities during the study period
- Willing and able to provide written informed consent for study participation

#### *Recruitment of CBDs*

CBDs will be recruited from the eight process evaluation study communities. Purposive selection will be done to ensure inclusion of both low and high 'performing' CBDs (based on number of clients in respective catchment area who take up services at PSI outreach sites. Inclusion criteria for CBDs:

- Working as a CBD in any of the 8 communities mentioned above
- Willing and able to provide written informed consent for participation

#### *Recruitment of public sector health care workers*

Public sector health care workers who provide ART services in 8 communities mentioned above will be recruited. Purposive sampling will be done to ensure representation of all cadres who provide HIV services in the 8 communities. Eligibility criteria:

- Providing HIV services at health facilities
- Willing and able to provide written informed consent

The in-depth interviews described above will be conducted by trained study staff according to an interview guide. They will be audio-recorded, transcribed and analysed according to thematic analysis.

### **4.2.6 Population-based Survey**

A representative population-based survey will be conducted six weeks after the first PSI outreach visit in four randomly-selected enumeration areas (EAs) in each study community. Two survey teams of eight people will each survey one community per week. It is anticipated that one survey assistant will recruit 5 people per day, giving an anticipated total of 160 surveyed adults in each community.

Survey questionnaires will be self-administered using Audio Computer Assisted Self Interview (ACASI) on computer tablets, and will be piloted. Respondents will be asked whether they or other household members were offered, accepted, used self-test kits and if not why not; their experience

of self-testing, whether they chose to link to services, what factors influenced their decision to attend or not attend, what their experience was, whether they would opt to self-test again, recommend to a friend etc. In addition, information on previous testing history and ART experience of household members will be collected.

Furthermore, survey participants will be asked to give a finger-prick blood sample that is collected on dried blood spot filter paper according to standards set by the United States National Committee for Clinical Laboratory Standards (NCCLS) published in "Blood Collection on Filter Paper for Neonatal Screening Programs" (LA4-A; 1997). The samples will be air dried onto filter paper and stored at room temperature until they are transported to PSI Zimbabwe's laboratory in Harare for HIV-1 antibody testing using validated testing algorithms. The filter papers will be labeled with unique barcodes that are also entered into the tablet for the corresponding questionnaires to ensure that survey data can be linked to laboratory results. Identifying information will be collected on the consent form, which will not be linked with survey materials. DBS samples will be stored at -20°C and then tested in batches. They will be tested serially for HIV-1 antibody with discrepant results resolved by PCR. Testing for viral load will be carried out on all samples which are HIV antibody positive on DBS (as well as a sub-set of those HIV antibody negative) using the Abbot Real Time HIV-1 m2000 viral load assay. All samples that are confirmed HIV infected will be tested using a qualitative assay for the following antiretroviral drugs at a lab to be determined: Efavirenz, Nevirapine, Lopinavir and Atazanavir. Samples that are confirmed HIV positive will also be tested for recency of HIV test using the lag avidity assay.

After administering the questionnaire, participants will be strongly encouraged to get tested and know their HIV status if they did not test recently. In addition, they will be given the option to obtain their DBS HIV and viral load results (if applicable) at their local clinic. While minimum identifying data is collected during informed consent, if participants wish to receive their results they will be requested to provide additional identifying information (i.e., name, date of birth, national ID number, address), which will be linked with their blood samples using a numerical barcode label. However, if participants explicitly say that they do not want to receive their HIV test results, no additional identifying information will be collected and their HIV test results will not be sent to the local clinic. HIV test results will be available within two months of the survey date (to allow for specimen testing and transportation to and from the laboratory). The clinics will be asked to keep the HIV test results for 3 months, so participants are able to pick up their results in 2 to 5 months of the survey date. Participants will be able to collect their HIV test results at the local health facility with their national ID card (or some other form of identification if National ID card is not available), to allow identity verification. HIV test results will be sent to the clinics in sealed envelopes; nurses will only know the HIV test results of the participants that go to the clinic to receive their results.

#### *Inclusion criteria for survey participants*

- At least 16 years of age
- Willing and able to provide written informed consent
- Have resided in the community for the last three months

#### **4.2.7 Refining procedures for facilitating linkage to care**



### Discrete choice experiments

Discrete choice experiments will be conducted in study communities to determine client preferences for methods of facilitating linkage to prevention and care services. Because DCEs are typically used to test preferences of programme packages, the preference of other programme attributes that might stimulate linkage to prevention and care services as revealed in formative qualitative research will also be tested.

### Developing the DCE questionnaire

DCEs will be kept simple by investigating a small number of attributes. Hypothetical alternatives for each attribute will be developed and these will be combined into choice sets, which the questionnaire will be based on. An example of a choice set that might be given is shown in Fig 4 below. The computer programme NGENE will generate a series of choice sets to capture optimal variation in attribute levels across the choices, allowing for the most efficient design of the experiment (called a d-efficient design). As such we will be able to retrieve the most information from each choice without overburdening respondents with excessive numbers of repeated scenarios. Participants will be presented with a number of choice pairs (between 8 and 12) and will be asked to make a choice on which set of conditions might best motivate uptake of post-test prevention and care services. An opt-out choice will allow for respondents to state if neither of the linkages would induce them to seek follow-up care. In addition, for respondents who choose neither option, there will be a second question where participants will be constrained to take account of their own circumstances and indicate whether they would choose the first or second option. The questionnaire will be completed on paper and will be piloted before use.

**Fig 3: An example of a choice set that might be developed**

Attribute	Attribute level		Not seek care (Opt-Out)
	Programme 1	Programme 2	
Method of disbursing incentives for linkage	Airtime	Mobile money	
Form of referral letter	SMS referral	Referral letter	
Volume of people at outreach testing site	Very quiet site, few people at a time	Busy facility with lots of patients or attendees	
Attitude of health care centre staff	Friendly staff	Friendly staff	
User fees	No fees levied	No fees levied	
CHOICE			No Fees

### Recruitment and Sample sizes for the DCE

The first 500 participants who complete the household survey will also be asked to complete the DCE. As stated for the distribution DCE above this number is based on pragmatic considerations and is within the range of other DCE studies in the literature [25, 26].

### Data analysis for the DCE

Discrete Choice models will be used to estimate changes in the odds of linkage to prevention and treatment services associated with changes in attribute levels moving from one alternative to another. We will also look at preferences by user / client characteristics and how much variation in preferences there are.

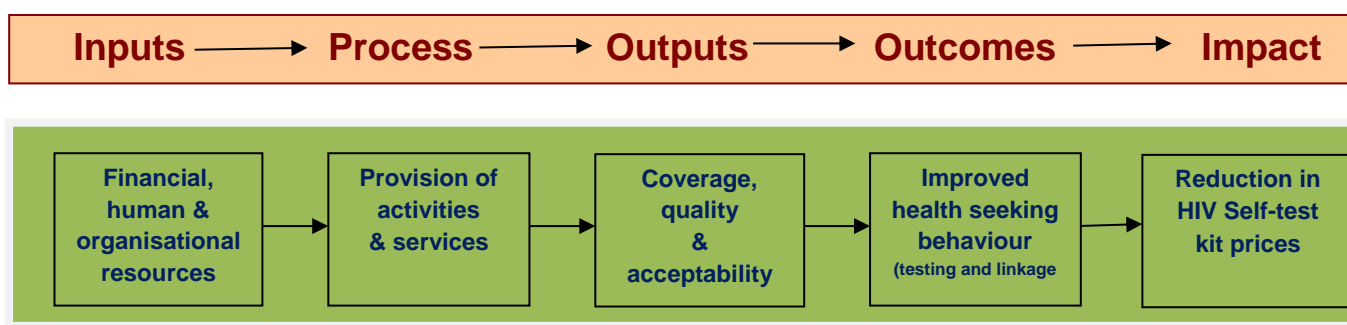
#### 4.2.8 HIV Self-Testing costing study

The costing study will adopt the provider’s perspective: detailed costing of all resources used in the provision of HIV self-testing services and in the support of linkage to HIV care and VMMC will be done. Cost data will be collated from project accounts as well as time and motion studies. An ingredients based approach will be used to collect costs based on actual expenses for capital items, and recurrent costs. University College London researchers will conduct cost effectiveness analysis and economic modelling using the cost data from Zimbabwe. An inter-country protocol will be written for this work.

#### 4.2.9 Process evaluation

The process evaluation will be used to provide information on how and why interventions resulted in improved linkage to prevention and care services (or why there was no observed effect). Throughout the study, data will be collected to capture progress and adherence to programme activities and timelines.

The process evaluation framework below provides a structure for measuring the progress.



For the process evaluation, we hypothesise that:

- If there are adequate project inputs (financial and human resources, partnerships and collaboration, established procedures and protocols, effective trainings),
- these will ensure a smooth process of implementation,
- producing well-functioning outputs (efficient and high quality clinic services, motivated and skilled staff, community uptake of HIV self-testing).

- Subsequently, if the intervention outputs have good coverage, are feasible to deliver, and considered acceptable to the communities,
- they will contribute to outcomes necessary for achieving the intervention’s ultimate goals or impact including improved uptake of HIV testing, including repeat testing and linkage to prevention and care services. By demonstrating the feasibility and acceptability of self-testing, plus the potential cost effectiveness it is anticipated this will ultimately result in an increase in the market for HIV self-test kits with a commensurate reduction in prices.

The intervention impacts will be assessed through overall analysis across all participating countries. The outcomes related to uptake of HIV testing and linkage to prevention and care will be measured in the trial, and are thus not included in the monitoring and process evaluation framework, which documents only the lower stages of the pathway. Although data collected through the framework cannot prove causal relationships between stages, they can build up a more comprehensive picture of what “actually happened” during implementation and how this may have affected observed outcomes. The research questions for each level of the framework are as follows:

- (1) Inputs: How many resources were required to deliver the intervention?  
 Were these adequate given the activities implemented?  
 Were resources well managed and appropriately allocated?
- (2) Process: Did activities occur according to the intervention design?  
 Were all intervention components delivered?  
 How did timing of implementation compare to plans?
- (3) Outputs: What was the coverage of each intervention activity?  
 Was implementation of the activities feasible (from the perspective of programme) and acceptable (from the perspective of clients/community)?  
 At what intensity was the intervention delivered (frequency of contact, number of different activities, length of events)?  
 What were the levels of quality achieved (assessed by external criteria according to standards set by the intervention, as well as from the perspectives of clients/community)?
- (4) Outcomes: Have programmatic messages been adopted?  
 Are behaviours that are known determinants of expected impacts being taken up?  
 Is there evidence of changing environmental factors?

Implementation of Intervention		Coverage & Intensity
<p><b>Inputs/ Preparation</b></p> <ul style="list-style-type: none"> <li>•Partnership with relevant partner agencies established (MoH, xxx)</li> <li>•New staff (including community based distributors) recruited, trained and deployed</li> <li>•PSI procedures and sites set-up for self-testing roll-out</li> <li>•Referral mechanisms put into place, including training of public sector health care workers</li> <li>•Community mobilisation activity protocols and tools introduced</li> </ul>	<p><b>Activities</b></p> <p><b><u>KIT DISTRIBUTION</u></b></p> <ul style="list-style-type: none"> <li>•Community education on programme and important dates</li> <li>•Kit distribution</li> </ul> <p><b><u>LINKAGE TO CARE</u></b></p> <ul style="list-style-type: none"> <li>•PSI outreach visits at each of the time points as per protocol</li> <li>• Distribution of incentives to both CBDs and clients for linkage, and to health care workers for linkage notification</li> <li>•Training public health care workers on communication of referral uptake by SMS</li> </ul>	<p><b>Programme Delivery</b></p> <ul style="list-style-type: none"> <li>•Number of community mobilisation/education meetings held</li> <li>•Number ST kits distributed</li> <li>•Number outreach visits in each ward</li> <li>•Number of CBDs, health care workers and clients receiving incentives</li> </ul> <p><b><u>Quality of Activities</u></b></p> <ul style="list-style-type: none"> <li>•Proportion of general population who have received ST kits</li> <li>•Timing of outreach visits (adherence to schedule)</li> <li>•Proportion of CBDs, clients and HCW receiving their incentives on time</li> <li>•All well woman/well man services provided as per protocol; all supplies in stock</li> <li>•Knowledge &amp; awareness of importance of testing &amp; linkage to prevention and care services increased</li> </ul> <p><b><u>Acceptability of Interventions</u></b></p> <p><i>PSI Staff (including CBDs) and public sector health care worker perceptions</i></p> <ul style="list-style-type: none"> <li>•Positive &amp; negative experiences</li> <li>•Programme strengths &amp; weaknesses</li> </ul> <p><i>Client perceptions</i></p> <ul style="list-style-type: none"> <li>•Positive &amp; negative experiences</li> <li>•Likes &amp; dislikes in delivery of services</li> </ul>
<b>Tools</b>		
<ul style="list-style-type: none"> <li>•<i>Checklist of planned activities, with dates</i></li> <li>•<i>Staff records: % of staff hired and still in place each year;</i></li> <li>•<i>Trainings: # conducted and % staff attending</i></li> <li>•<i>Programme records: # community mobilisation activities designed; # sensitisation/training meetings planned with public institution health care workers</i></li> </ul>	<ul style="list-style-type: none"> <li>•<i>Programme records: # of community education/mobilisation /outreach visits actually done</i></li> <li>•<i>Number and timing of kit distribution</i></li> <li>•<i>Distribution of incentives</i></li> </ul>	<ul style="list-style-type: none"> <li>•<i>Surveys: % received ST kits; knowledge and awareness of importance of testing and linkage to care</i></li> <li>•<i>Qualitative studies (in-depth interviews and FGDs)- PSI staff, public sector health care workers and client perspectives</i></li> <li>•<i>Programme records: number and frequency of outreach visits and adherence to schedule, adherence to schedules for giving client, CBD and public health care worker incentives; inventory records for critical supplies like ST kits and other products required for well woman/man clinics</i></li> </ul>

Monitoring and process evaluation data collection

### Checklists

A prospective record should be maintained of if/when planned activities (as per protocol) were implemented.

### Staff and training records

Routine programme documentation on start-up activities of the project, including the number of staff hired and deployed, and how many attended all relevant trainings. These will be reviewed annually and at the end of the project if staff retention/performance is considered to be an issue affecting the delivery of intervention components.

### CBD kit delivery and support documents

CBDs will be given forms on which to record all contact with households in their catchment area. These will be used to document the number of kits delivered per household, date of delivery, any help that clients may have asked for and the timing of this.

### Programme Records

Staff facilitating community mobilisation meetings will fill out forms to capture the following:

- (1) Location, duration & topics covered at each organised meeting/event
- (2) Number of health care workers, CBDs or clients attending the meeting/event

Programme records will also be maintained to ensure that the following data will be obtained about outreach visits and linkage to HIV prevention and care services:

- Dates and location of outreach visits to each community
- Uptake of various well-woman and well-man services at each outreach visit
- Log of uptake of various outreach services, by CBD
- Schedule of payment to CBDs
- Number of HIV positive clients initiated on ART and referred to public health care institutions
- Log of SMS attendance confirmation that has been sent in by health care workers
- Schedule of payment of health care workers for referral notification
- Schedule of payment of transport reimbursement for those clients who took up referral
- Stock cards for the various supplies and commodities that are necessary for the provision of well-man and well-woman services

## **SURVEYS**

Surveys will be conducted as part of the research. Some research outcomes in the survey will also be used as process outcomes, e.g. the proportion of individuals who received HIV self-test kits and knowledge of the importance of HIV testing and linkage to prevention and care services.

## **QUALITATIVE DATA**

Qualitative studies will be done soon after the start of program implementation, and at the end of each 12-month period.

### **Site selection for the qualitative studies**

Eight study communities (wards, two in each arm of the study) will be purposively selected for the process evaluation. PSI program data for the first month will be used to inform site selection in order to ensure representation of both areas with good and poorer uptake of 'well-woman' and 'well man' services.

### **Qualitative studies**

The in-depth interviews described in section 4.2.5 will also be used for process evaluation.

In-depth interviews will be conducted with CBDs to explore their views on the ST program. They will be asked about what is going well, what is going less well and recommendations for change.

Purposive sampling will be done to ensure inclusion of CBDs in all trial arms, and to include those associated with both good and poor uptake of outreach services after self-testing.

Interviews and FGDs will also be held with clients in all arms of the study. Clients will be asked about their view of the program and procedures for kit distribution, views about having the CBDs come into their homes, whether they feel able to seek help from CBDs, barriers and facilitators to self-testing and linkage to care, and views on incentives for linkage. Purposive sampling will be done to ensure inclusion of clients in all study arms, those who linked or did not link to outreach visits, and those who linked or did not link to HIV care and treatment services at public health care institutions.

Interviews will also be done with PSI and public sector health care workers to explore their views on the programme, what is working well and what is not, and recommendations for improvement.

All in-depth interviews and FGDs will be audio-recorded, transcribed and analysed according to thematic analysis.

### **Audio diaries**

Before the beginning of each implementation cycle, purposively selected CBDs in the 8 study communities will be given audio recorders where they will be asked to audio record their experiences of distribution of self-test kits and perceptions of the intervention. They will be given a written guide on what sort of experiences and impressions they are expected to record, and examples of when it might be useful to do this, e.g. in the evening after a day of kit distribution or mobilisation for uptake of 'well woman' and 'well man' activities. The audio diaries will be collected from the CBDs six weeks after kit distribution.

Audio-diaries will be transcribed verbatim, translated, and analysed according to thematic analysis.

### **Project diary**

A calendar or diary will be kept by a member of the research team to record any events (particularly external) that may affect ability of the intervention to be delivered as planned. Political events, local festivities, or other health promotion campaigns should be noted, with a description of their activities and effect. Internal events that have bearing on implementation (such as increased funding, or break-down of a project vehicle) will also be noted to help contextualise other information collected.

### **4.3 Pilot HIVST kit distribution at New Start HIV testing Centres**

Distribution will occur in six geographic areas where New Start HIV testing services are offered in the following cities: Harare, Bulawayo, Chitungwiza, Masvingo, Mutare and Gweru. Three channels of HIVST distribution will be employed: 1) distribution at static sites through the offer of a choice between PDHTC or HIVST; 2) distribution to partners of individuals who test HIV positive at the static sites, and 3) distribution during testing and counselling outreach in urban areas in Bulawayo and Harare. In this model we aim to:

1. Determine the acceptability of HIVST among individuals who seek HTS within New Start static and mobile sites in urban areas
2. Determine HIV yield among clients who are given HIV self-test kits compared to those who opt to test using PDHTC
3. Measure uptake of self-test kits for partners among clients who have tested HIV positive at New Start Static sites
4. Determine rates of linkage to HIV care, voluntary medical male circumcision (VMMC), and PrEP (offered to women aged 18-24) among individuals who are given HIV-self-test kits
5. Determine the cost and cost-effectiveness of providing HIVST through New Start HIV testing services

Detailed procedures are given in Appendix 1, Standard Operating Procedures (SOP) for the New Start Model.

#### **4.4 Pilot distribution in the VMMC model**

Two models of distribution will be employed for VMMC services . At static VMMC centres, distribution will occur as for New Start Centres: clients will be given the choice of PDHTC or HIVST. In the other model, distribution of kits will be done by community mobilisers to potential VMMC clients at community level. With VMMC distribution our aims are:

1. To determine the uptake of self-testing among men who visit PSI-managed VMMC centres in urban areas
2. To determine the acceptability of distributing self-test kits to potential VMMC clients during community-based mobilisation for VMMC
3. To determine the cost and cost effectiveness of distributing self-test kits through PSI 's VMMC services

Detailed procedures are given in Appendix 2, Standard Operating Procedures (SOP) for the VMMC Model.

#### **4.5 Costing of distribution of test kits in the PSI New Start and VMMC systems**

The costing study will adopt the provider's perspective: detailed costing of all resources used in the provision of HIVST and linkage services will be done. Cost data will be collated from project accounts as well as time and motion studies. An ingredients based approach will be used to collect costs based on actual expenses for capital items, and recurrent costs. The costing procedures will be done according to written standard operating procedures.

#### **4. 6 ENSURING DATA QUALITY**

CeSHHAR Zimbabwe has considerable expertise in supporting all aspects of quality data management. 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. CeSHHAR 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. CeSHHAR have an internal research monitoring committee who are tasked with ensuring data quality and adherence to GCP. In addition, LSHTM will work with the local team to support data quality.

## **5 ETHICAL CONSIDERATIONS**

Ethical approval of the research will be sought from the local institutional review board (IRB) in Zimbabwe, and the IRBs of relevant participating institutions: London School of Hygiene & Tropical Medicine and University College London. No research procedures will take place until approval from these ethical review boards has been granted. Procedures will be implemented in a way that upholds the confidentiality of client data. The trial will be conducted in accordance with GCP, and all staff will receive GCP training. The bulk of the data will be programmatic; and is anonymised. The database of client contact details will be kept separate from that which has client demographic and clinical information. Written informed consent for participation in the surveys, discrete choice experiments and qualitative studies will be obtained.

### **Governance**

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.

STAR will form a Technical Advisory Group (TAG) 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.

### **Adverse Event Reporting and Management**

HIV testing and counselling, 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

Ongoing surveillance for social harms and adverse events will be done according to methods described in section 4.1.5.

In addition, CBDAs 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.

### **Institutional responsibilities**

SAEs will be reported immediately to CeSHHAR. 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 CeSHHAR project coordinator and responsible PSI Program Manager. The PI will check the form and make changes as necessary.

SAEs will be evaluated for seriousness and likely relatedness to HIVST by the Zimbabwean principal investigator.

## **6 STATISTICAL CONSIDERATIONS**

### **Sample size calculations**

#### **1) Linkage to PSI outreach services**

Assume 1750 adults per PSI outreach site, based on the harmonic mean of communities (wards). With 22 communities per arm we have >90% power to detect at least a difference of 10% linkage to post-test services in the control arm versus 13.6% in the intervention communities, assuming a coefficient of variation (k) of 0.3.

#### **2) Linkage of HIV positive individuals to government services**

With 22 communities per arm we have >90% power to detect at least a difference of 2% linkage to government care services among the whole population in the control arm vs 2.8% in the intervention arm, assuming a coefficient of variation (k) of 0.3.

Similarly, we have 80% power to detect a difference of 27.8% vs 35.6% linkage to government care services among HIV positive people not on ART attending outreach services (i.e those randomised to an incentive to link).

<b>Primary Outcomes</b>	<b>Denominator</b>	<b>Control sites</b>	<b>Intervention sites</b>	<b>Power</b>
% who link to PSI outreach services	All (N=1900 per cluster)	10%	13.6%	96.3%
% who initiate ART at government services	All	2% (n=35)	2.8% (n=49)	96.2%
% who initiated ART at government services	HIV positive individuals attending PSI	27.8% (n=38)	35.6% (n=49)	80%

### **Data analysis**

#### *Cluster randomised trial*

The main statistical analyses for the cluster randomised trial will include (i) descriptive analyses of community characteristics by arm; and ii) outcome evaluation of the primary and secondary outcomes. Analyses will be intention-to-treat. A random effect will be included to account for clustering at site level. For binary outcomes, a random effects logistic regression model will be used. Intervention arm will be included as a covariate, and the model will adjust for cluster-level HIV prevalence and other key characteristics.

#### *Population-based survey*

The data from the population-based survey will be analysed using random effects logistic regression models to assess association between individual-level and community-level factors associated with accepting and using self-test kits, adjusted for clustered survey design using a random effects term for cluster.

#### *Analysis of New Start program data*

We will analyse of characteristics of clients testing through the New Start model descriptively. Factors associated with opting for self-testing will be investigated, with odds ratios and 95% confidence intervals computed using logistic regression. Rates of linkage to HIV care and VMMC for clients and partners of HIV positive clients will be investigated using appropriate models.

## **7 DISSEMINATION OF RESEARCH FINDINGS**

A report on the study will be produced and disseminated to the Zimbabwean Ministry of Health and Child Care. Results of the study will also be disseminated to the communities participating in the research, regionally and internationally through conference presentations and publications.

## 8 STUDY TIMELINES

Quarters (2016-2017)	Q1			Q2			Q3			Q4			Q5			Q6		
Month (2016-2017)	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
Ethical approval of the study	x	x	x															
Finalise model for kit distribution based on pilot study results				x														
Recruitment and training of community based distributors				x														
Community based kit distribution					x	x	x	x	x	x	x	x	x	x	x	x		
Household surveys						x	x	x	x	x	x	x	x	x	x	x	x	
DCE on linkage to care						x												
Process evaluation including qualitative studies						x	x	x	x	x	x	x	x	x	x	x	x	
Data analysis																	x	x

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## **Appendix 1: Standard Operating Procedures for the New Start Model**

### **Overview**

Distribution will occur at six PSI outreach New Start Centres in Harare, Bulawayo, Chitungwiza, Masvingo, Mutare and Gweru. Three channels of HIVST distribution will be employed: 1) distribution at static sites through the offer of a choice between PDHTC or HIVST; 2) distribution to partners of individuals who test HIV positive at the static sites, and 3) distribution during testing and counselling outreach in urban areas in Bulawayo and Harare

Clients who opt for HIVST can either test onsite, or, if they are able to provide the relevant contact information, take the kit for off-site testing at a time that is convenient to them.

Clients who are confirmed HIV positive through PDHTC will be offered the possibility of taking an HIVST away for their partners to use.

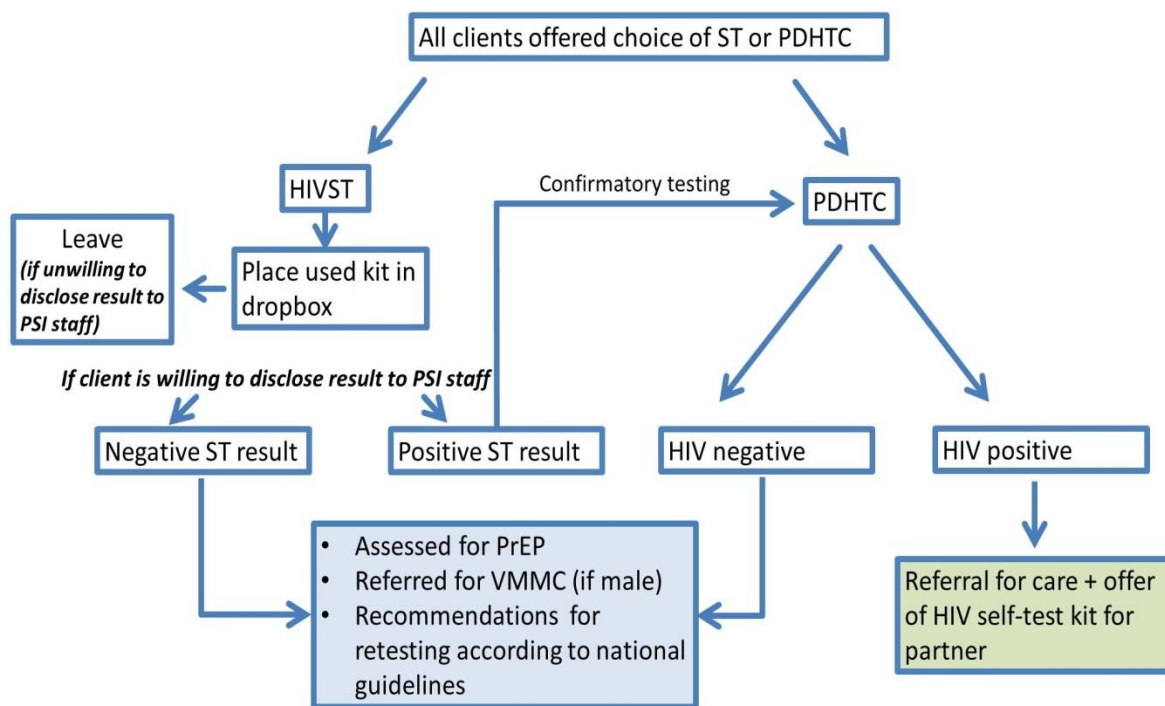
### **Outcomes from the pilot distribution at New Start facilities:**

1. Proportion of clients seeking HTS at static centres who opt for HIVST
2. Proportion of clients who opt for HIVST who choose to test-onsite
3. Among clients who choose to self-test on-site, the proportion who self-test positive and are confirmed positive through PDHTC
4. Among clients who choose to test off-site, proportion reporting testing within (i) two weeks, (ii) four weeks, (iii) three months
5. Among clients who choose to test off-site, proportion reporting linkage to appropriate prevention and care services, by three months, to (i) confirmatory testing, if self-test result was positive, and, (ii) voluntary medical male circumcision (VMMC), if male, uncircumcised and tested negative, (iii) PrEP among HIV negative at risk individuals
6. Among PDHTC clients who test HIV positive, proportion who accept HIVST kit for partner
7. Among PDHTC clients who accepted self-test kit for partner, proportion who report giving kit to the partner
8. Among PDHTC clients who accepted self-test kit for partner, proportion reporting testing of partner within (i) one week, (ii) two weeks, (iii) one month
9. Among PDHTC clients who accepted self-test kit for partner, proportion aware of partner's self-test result
10. Among clients who collect self-test kit for partner, proportion reporting linkage of partner, by three months, to (i) confirmatory testing, if partner obtained a positive self-test result; (ii) VMMC, if partner is male and obtained a negative self-test result

### **Detailed procedures:**

#### **Offer of HIVST at Static New Start Centres**

The offer of self-testing at static facilities will be done according to the figure below.



## Methods for distributing self-test kits at static sites

### Direct distribution to clients

At the six static sites, clients will be told about the option to self-test and invited to watch an instructional video about HIVST. They will be then be given a choice between PDHTC or HIVST. Those who opt for self-testing will have the choice of testing on site or taking the kits away for testing at their convenience.

#### Clients choosing to test on site

Clients who choose to self-test on-site will be given a self-test package and access to a cubicle or room where they can self-test in private. The self-test package will consist of the kit, validated testing instructions, and a result form where the client will write down the result of the HIV self-test. At the time of receiving the package participants will be shown an instructional video on a computer, tablet, smartphone or television screen. They will also provide information that New Start routinely collect from clients seeking HTS, including demographic information and history of HIV testing; these data are collected electronically. The results form and electronic form will only be identified by bar-coded identity numbers. In a separate database, the client's name, home address, mobile telephone number and bar-coded identity number will be recorded. Where possible, mobile phone numbers will be verified by ringing.

Clients will be asked to place their used test kits, together with the results form, in a dropbox that will be at the facility. They will be told that they do not have to disclose their self-test results to New Start staff. However it will be emphasized that should they obtain a positive self-test result, confirmatory HIV testing is necessary and will be available on-site on the same day. Confirmatory testing will be offered according to usual procedures for provider-delivered testing. In addition they

will be advised that if they are HIV negative there are HIV prevention interventions that they may wish to consider (VMMC or PrEP).

#### *Clients choosing to self-test off site*

Clients choosing to test off-site will be given the self-test package and will be shown the instructional video, as per those testing on site. In addition, they will be given detailed instructions on how to seek post-test support services, including confirmatory testing if needed. In order to restrict the use of self-test kits to the intended purpose, clients eligible for taking kits away must be:

- Willing to provide a telephone number that *must* be verified through ringing at time of kit distribution
- Willing to receive telephone calls from New Start staff. These calls will be to check whether the participant has self-tested, and if required, whether he/she has linked to care.

Participants will provide verbal consent to this effect.

Participants who cannot meet the above criteria will be asked to self-test on site or to take up provider-delivered testing.

At the time of collecting the self-test kit, participants will be asked to think about the date and time they are likely to self-test, and to write these down on an appointment card which they will keep (previous research has shown that this approach improves completion of health tasks or health-related appointments) [23, 24]. The 'appointment date' will also be recorded together with the participant's other electronic data.

Participants who take self-test kits away will be asked to drop off the used test kits with the results form at the nearest New Start Centre or nearest polyclinic (kits and results forms are only identified by bar codes with no client names). New Start Staff will regularly collect the used kits from the drop-off sites for late reads as described in section 4.2.3 of the protocol.

At two weeks after collection of the kit, a random selection of the clients who took kits away will be telephoned to ask if they self-tested, and the result of the self-test. 200 clients will be telephoned per month based on a sampling fraction that alters every month depending on number of clients who have opted to take self-test kits away. If the self-test was positive, they will be asked whether, when and where they sought confirmatory testing. Males whose self-test result was negative will be asked whether, when and where they went for VMMC. This information will be updated on the participant's electronic record. Women who have tested negative will be asked if have considered PrEP.

Participants who had not tested at two weeks, or had not linked to services as applicable, will be given another call at 4 weeks and at three months. To ensure that participants' confidentiality is maintained and that telephone interviews are conducted with the correct person, staff who do the telephone calls will verify the following information before proceeding:

- Name of participant
- Date of birth



- Correct response to a 'password' question that is completed at time of kit collection according to participant's preference, for example name of primary school that was attended, mother's maiden family name, etc

**NOTE:** there is a requirement by funders of this programme to determine rates of linkage which is independent of the research. PSI are routinely following clients to determine linkage as part of their programme activities

### ***Offer of kits for partners of HIV positive clients***

Individuals who test positive during PDHTC will be offered a self-test kit for their regular partner/s. Participants will be encouraged to check with their partner if they may want a self-test kit, and to check if the partner is happy to have their contact details passed on to study/program staff. In addition to the kit and instructional materials (a whatsapp version of the video will be shared with the participant if he/she has whatsapp) that are given as per clients taking the kits themselves, an information sheet that is addressed to partners will be enclosed. Only individuals who meet the following criteria will be eligible for taking kits to their partner:

- Willing to offer an HIV self-test kit to partner
- Willing to provide a telephone number that *must* be verified through ringing at time of kit distribution
- Willing to receive telephone calls from New Start staff. These calls will be to check whether the participant has given the kit to his/her partner, whether the partner tested, and whether, when or where the partner linked to confirmatory testing (if result of self-test was positive) male circumcision (if male and self-test result was negative), or PrEP, if at risk of HIV acquisition.
- Willing to give the partner's contact details for contact by the study team.

Clients will be told that a positive self-test result necessitates a confirmatory test, which must be provider-delivered. They will be told about possible places where confirmatory testing can be accessed if needed.

At two weeks after collection of kit, the client will be telephoned to ask if he/she gave the kit to the partner, whether the partner accepted it, whether the partner self-tested, and the result of the self-test if known. If the self-test was positive, they will be asked whether, when and where the partner sought confirmatory testing. Participants whose male partner's self-test result was negative will be asked whether, when and where the partners went for VMMC. Participants reporting that their partner obtained a negative self-test result will be asked if the partner linked to PrEP. This information will be updated on the participant's electronic record.

Participants who, at two weeks, had not yet given the kit to their partner (and report intention to do so), or those whose partner accepted the kit but had not tested at two weeks, or had not linked to services as applicable, will be given another call at 4 weeks and at three months. To ensure that participants' confidentiality is maintained and that telephone interviews are conducted with the correct person, staff who do the telephone calls will verify the following information before proceeding:

- Name of participant
- Date of birth
- Correct response to a 'password' question that is completed at time of kit collection according to participant's preference, for example name of primary school that was attended, mother's maiden family name, etc.

If the participant reports that the kit was given to her partner, at four weeks the partner will be telephoned to determine whether he/she self-tested, and the result of the self-test. If the self-test was positive, they will be asked whether, when and where they sought confirmatory testing. If the self-test result was negative and the partner is male, he will be asked whether, when and where he went for VMMC. Partners reporting a negative self-test result will be asked if, when where they linked to PrEP.

To ensure that the partner's confidentiality is maintained and that telephone interviews are conducted with the correct person, at time of collecting the kit from program staff, participants will be asked to share their 'password' information above with their partners. This information will be verified with the partner before the telephone interview can proceed.

#### ***Offer of self-testing during PSI New Start mobile outreach***

The New Start Centres also provide testing outreach. In Bulawayo and Harare, during outreach in urban areas, clients will be given information about HIVST and offered a choice between HIVST and PDHTC. Those who opt for self-testing will be given the test package, shown the instructional video, and given access to confidential on-site self-testing in a tent. At outreach facilities no option will be given for taking kits away for off-site testing. Clients will be asked to place their used test kits, together with the results form, in a dropbox that will be available at the outreach testing facility. Clients will be told that they do not need to share their self-test result with New Start staff. However it will be emphasized that should the self-test result be positive, confirmatory PDHTC is necessary and will be available at the outreach site on the same day. Such participants will be offered preferential access to PDHTC, as much as is feasible without breach of confidentiality of their HIVST result. To protect participant confidentiality and suspicion of HIV positive self-test from other people, outreach teams will also offer other services on site, including family planning, blood pressure and diabetes monitoring, VMMC and PrEP.

## **Appendix 2: Standard Operating Procedures for the VMMC Model**

### **Overview**

Two models of distribution will be employed at VMMC facilities in Bulawayo and Harare. At static VMMC centres, distribution will occur as for New Start Centres: clients will be given the choice of PDHTC or HIVST. In the other model, distribution of kits will be done by community mobilisers to potential VMMC clients in the community.

### **Outcomes from programmatic data at VMMC centres**

1. Proportion of males who do not have an HIV result at time of initial visit to the VMMC centre
2. Proportion of males who opt for HIVST
3. Proportion of self-testers who obtain reactive self-test results and are confirmed HIV positive with standard testing algorithm

### **Outcomes from programmatic data from community mobilisers**

- Proportion of potential VMMC clients accepting HIV self-test kit
- Proportion of potential VMMC clients who go on to self-test
- Proportion of individuals who are given HIVST kits who take up VMMC
- Proportion of individuals who are given kits who have a reactive self-test
- Proportion of individuals who have a reactive test who link for confirmatory testing

### **Methods for distributing self-test kits at VMMC centres**

The same methods that are employed for on-site testing at New Start Centres will be used for on-site self-testing at VMMC centres (described above). At static VMMC sites clients who opt for self-testing will be given access to a room/cubicle where they can self-test in private. Clients will not be given the option to take the self-test kit away. Clients will be told that should the self-test result be positive, confirmatory PDHTC is necessary and will be available on the same day. Clients who get a negative self-test result will show their test device to VMMC health care workers who will then proceed with provision of VMMC services. Programmatic data, mostly demographic information and history of previous tests, will be collected electronically, similar to the process at New Start Centres.

### **HIVST kit distribution by community mobilisers**

The PSI VMMC program is supported by a network of trained VMMC mobilisers who work in communities to mobilise men to take to up VMMC. When a mobiliser invites a man to a VMMC clinic, he gives him an appointment card which identifies the mobiliser who has made the referral. This allows the VMMC program to track how many clients each mobiliser has successfully referred.

For the VMMC sites in Harare and Bulawayo, as part of their standard mobilisation, the mobilisers will also offer HIV self-test kits to potential VMMC clients. They will electronically record details of clients who have taken up the self-test kits as for the New Start system for kits that are taken away, section, 4.3.1.1. Self-testers will be asked to bring the used self-test kits and appointment cards (which show which mobiliser gave the kit) when they take up services at VMMC centres.

On a monthly basis, VMMC centres will compile a list of clients who accessed VMMC after self-testing, by community mobilisers. Clients who received kits but did not come for VMMC will be followed up telephonically, as for section 4.3.1.1, to check if they self-tested and result of the HIV self-test. If they had a reactive self-test, they will be asked if they took up confirmatory testing. All VMMC clients who received kits and did not turn up for VMMC will be followed up telephonically.