

## **Secondary distribution of HIV self-tests through antenatal and HIV testing services: a pragmatic cluster-randomized trial (STAR-ANC)**

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## 1. Executive Summary

**Type of study:** This proposal is for a 3-arm pragmatic cluster randomised trial (CRT) using primary care clinics as the unit of randomisation. The three arms are: 1) Standard of care (SOC) with written invitation to the partner, and two intervention arms of 2) SOC + HIV self-test kits delivered by the partner; and 3) arm 2 plus \$10 for partners who participate in a linked-accuracy study.

**Problem:** Malawi's Ministry of Health (MoH) uses a highly decentralized approach for delivery of HIV services that delivers over 3 million HIV tests each year, and has taken the country close to the UNAIDS 90-90-90 targets. However, a testing gap remains among populations with barriers to accessing facility-based HTS, including men. We recently showed partner-delivered (secondary distribution) of HIV self-testing (HIVST) kits, via women attending antenatal clinics (ANC) in urban Blantyre, to be effective at increasing the uptake of HIV testing and subsequent HIV care and prevention services among male partners. However, unanswered questions that remain to be addressed include:

- the accuracy of HIVST when kits are provided by secondary distribution
- how effective secondary distribution is when fully devolved to MoH providers ("pragmatic")
- whether the high safety profile and acceptability of secondary distribution of HIVST from ANC clinics can be generalised to other clinic services.

**Role of MoH, implementers and researchers:** HIVST will be delivered by the HIV Department of MoH, Malawi, in partnership with Population Services International (PSI)-Malawi. MoH aims to routinely scale-up secondary distribution from ANC in high HIV prevalence districts, and HIV testing services (HTS) nationally if results are satisfactory.

**Research Question:** Can secondary distribution of HIV self-tests through antenatal and HIV testing services improve coverage of HIV testing in sexual partners of pregnant women and newly-diagnosed PLHIV, while maintaining low costs and acceptable linkage, safety and accuracy?

**Objectives:** The broad objective is to determine the feasibility, benefits, costs, safety and accuracy of secondary distribution of HIVST kits from routine antenatal and HTS clinics in Malawi. The specific aims are to conduct a pragmatic cluster randomized trial to:

1. Assess the feasibility of programmatic implementation of secondary distribution of HIVST kits from routine MoH clinics.
2. Establish the effectiveness of secondary distribution of HIVST kits on:
  - a. HIV testing among male partners of antenatal care (ANC) attendees
  - b. Initiation of ART and uptake of VMMC among male partners of ANC attendees
  - c. Disclosure and couple testing among male partners of ANC attendees
  - d. Identification of HIV-positive contacts among partners of newly diagnosed HIV-positive index clients through routine HTS
3. Investigate the impact of secondary distribution of HIVST kits on the frequency of social harms affecting distributors of HIVST kits
4. Estimate the costs and cost-effectiveness of adding secondary distribution of HIVST kits to the ANC and HTS.
5. Estimate the sensitivity and specificity of OraQuick HIVST kits under secondary distribution.

## **Methodology**

### *Participants and intervention*

Pregnant women registering for ANC in 27 primary health clinics and newly diagnosed HIV+ clients from the same 27 clinics in Blantyre, Chikwawa, Machinga and Zomba Districts. Restricted randomisation will be used to allocate clinics to the 3 arms (1:1:1). MoH Clinic staff in the HIVST arms will be trained in use of oral HIVST kits (OraQuick). HIVST kit supply will use MoH supply chains. Information and educational materials will include a tablet with a video clip demonstrating correct use of kits. Data capture tools and training materials will be developed with MoH.

A full-time research assistant will support research-data capture at each clinic. For the accuracy sub-study this will include a brief questionnaire, repeat HIV testing (2 finger-prick HIV rapid diagnostic tests plus repeat OraQuick) and dried blood spots (DBS) for ART drug and HIV viral load testing.

### *Primary and secondary outcomes:*

The **two** primary outcomes are comparison between SOC and HIVST arms of:

1. % of women reporting that their partner has tested for HIV within 28 days of ANC appointment.
2. Number of previously undiagnosed PLHIV identified among partners of HIV-positive index patients by Day 28

The **six** secondary outcomes are:

1. % of partners of ANC attendees who start ART, undergo VMMC, or attend discordant couples clinic within 28 days of enrolling the woman
2. % of partners of ANC attendees who attend the clinic for any HIV services within 28 days of enrolling the woman
3. % HIV+ index clients who self-report at least one partner tested for HIV as a result of their diagnosis, measured at Day 28
4. Number of partners of HTS index clients who start ART, or undergo VMMC, or attend discordant couples clinic within 28 days of index diagnosis
5. Number of partners of HIV+ Index clients who attend the clinic for any HIV services within 28 days of index diagnosis
6. Risk of adverse events (e.g. partnership breakdown, intimate partner violence, etc.) related to self-testing reported by ANC / HIV-positive index clients, measured at Day 28

### *Sample size:*

9 clinics per arm each recruiting 350 ANC clients and 135 newly diagnosed PLHIV will provide 90% power to detect a 12% absolute difference in the primary outcome, assuming 20% of SOC partners, and a coefficient of variation (k) of 0.25. Cluster-level summaries with a t-test applied to the mean of clinic proportions will be compared to the SOC for the primary outcome.

**Ethical considerations:** We request a waiver of informed consent for HIVST, as this is now international best practice, and delivery will be by MoH routine systems. Written informed consent (witnessed thumb-print if illiterate) will be taken from all participants in the accuracy sub-study.

**Dissemination:** The results will be used to inform MoH on HIVST scale-up plans, and will also be disseminated through College of Medicine in Blantyre including COMREC, and through conference presentations and publication in peer-reviewed journal.

## 2. Background

Malawi's Ministry of Health uses a highly decentralized approach for delivery of HIV testing, care and prevention services that has been globally applauded as effective and affordable.<sup>1</sup> Facility-based HIV testing services (HTS) deliver over 3 million tests each year, and have taken the country close to the 'First 90' of the UNAIDS 90-90-90 targets.<sup>2</sup> However, a gap remains among populations with barriers to accessing facility-based HTS, including men.<sup>2,3</sup> Programmes to improve testing in low-coverage populations, including Family Referral Slips (FRS) among partners of newly identified people living with HIV (PLHIV), have resulted in sub-optimal uptake.

There has also been relatively little focus on the link between HIV testing and prevention in routine service delivery. Effective HIV prevention approaches include: "treatment as prevention" (addressed by the UNAIDS 90-90-90 targets), routine identification and management of HIV serodiscordant couples, and voluntary medical male circumcision (VMMC) in HIV-negative men.<sup>2</sup>

Recently, HIV self-testing (HIVST) was fully endorsed, with supportive guidelines released by WHO and WHO-prequalified products now available for procurement.<sup>4</sup> HIVST, a private and out-of-clinic approach, can provide low-cost,<sup>5,6</sup> complementary coverage to facility-based HTS.<sup>7</sup> In Malawi, over 200,000 HIV self-tests, using the OraQuick oral fluid kit, have been evaluated under multiple delivery models since 2012.<sup>8-11</sup> These have shown that HIVST:

- Is simple enough for populations with low literacy or education levels to obtain accurate results when oral fluid-based self-tests are provided by trained lay distributors.<sup>8</sup>
- Can increase coverage of recent and lifetime testing in adolescents, men and facilitate shared knowledge of status in established couples.<sup>8</sup>
- Is highly acceptable, with high uptake of HIVST kits distributed by partners,<sup>7</sup> community members and peers,<sup>8</sup> reflecting the intrinsic privacy of HIVST.<sup>12</sup>
- Leads to acceptable linkage to care, provided that distributors promote the need for timely confirmatory testing through pre-defined referral routes.<sup>8</sup>
- Is cost-effective when provided to the general population in urban Blantyre, reflecting low costs per testing episode and increased demand for ART services.<sup>5,13</sup>

## 3. Study Rationale

This study builds on promising results concerning secondary distribution of HIV self-test kits to the male partners of ANC clients, in combination with educational messages on HIV care and prevention, and strategies for promoting linkage.<sup>3,7,14</sup> The results suggest that secondary distribution of HIVST kits could substantially increase the uptake of HIV testing, care and prevention in the sexual partners of ANC clients, potentially addressing an otherwise high ongoing risk of HIV.<sup>15</sup> Uptake of HIV testing among male partners of pregnant women remains unacceptably low,<sup>16</sup> despite concerted efforts by MoH, Malawi, to improve uptake.

We aim to design and evaluate a pragmatic cluster-randomized trial (CRT) with MoH and PSI as the main implementing partners to address the following unanswered questions that currently preclude scale-up of secondary distribution approaches under the Malawian MoH HIV programme:

- The accuracy of HIVST when kits are provided by secondary distribution
- How effective secondary distribution is when fully devolved to MoH providers ("pragmatic")

- Whether the high safety profile and acceptability of secondary distribution of HIVST from ANC clinics can be generalised to other clinic services.

## 4. Research Question, Objectives and Study Design

### 4.1 Research Question

Can secondary distribution of HIV self-tests through antenatal and HIV testing services improve coverage of HIV testing in sexual partners of pregnant women and newly-diagnosed PLHIV, while maintaining acceptable linkage, safety and accuracy?

### 4.2 Aims and objectives

The broad objective is to determine the feasibility, benefits, costs, safety and accuracy of secondary distribution of HIVST kits from routine antenatal and HTS clinics in Malawi.

The specific aims are to conduct a pragmatic cluster randomized trial to:

1. Assess the feasibility of programmatic implementation of secondary distribution of HIVST kits from routine MoH clinics.
2. Establish the effectiveness of secondary distribution of HIVST kits on:
  - a. HIV testing among male partners of antenatal care (ANC) attendees
  - b. Initiation of ART and uptake of VMMC among male partners of ANC attendees
  - c. Disclosure and couple testing among male partners of ANC attendees
  - d. Identification of HIV-positive contacts among partners of newly diagnosed HIV-positive index clients through routine HTS
3. Investigate the impact of secondary distribution of HIVST kits on the frequency of social harms among distributors of HIVST kits
4. Estimate the costs and cost-effectiveness of adding secondary distribution of HIVST kits to the ANC and HTS.
5. Estimate the sensitivity and specificity of OraQuick HIVST kits under secondary distribution.

## 5. Methods

### 5.1. Study Design and Setting

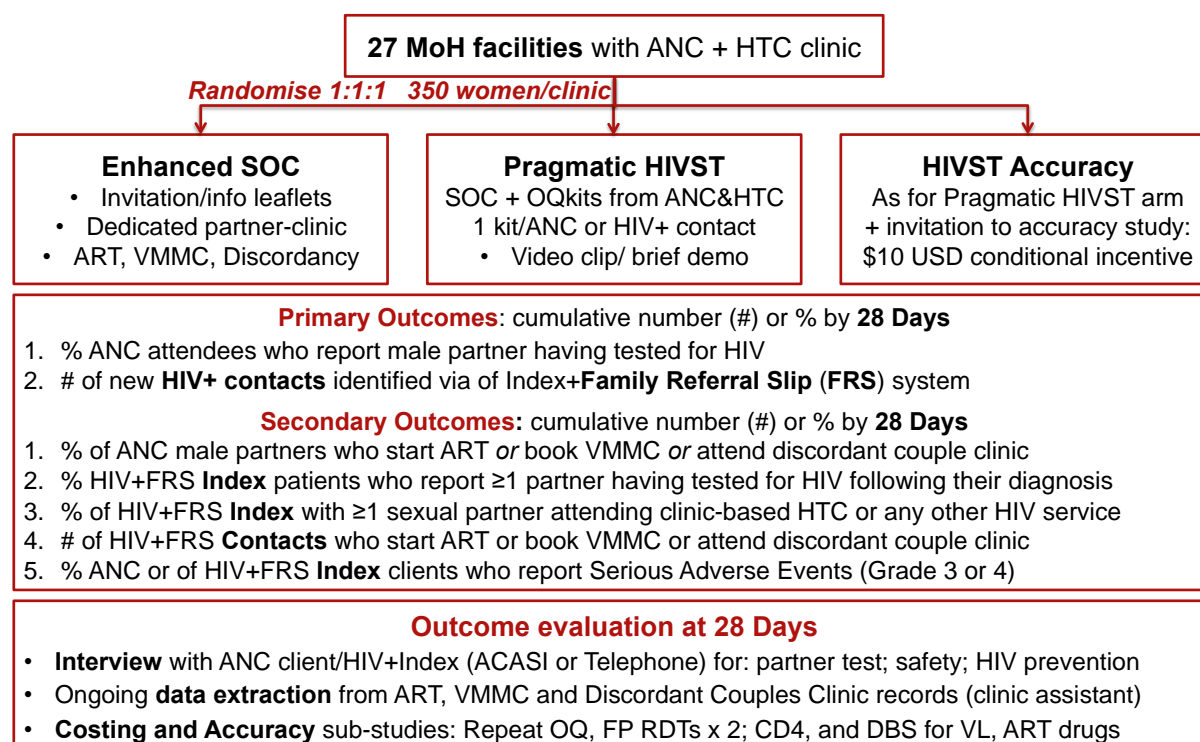
The main study consists of a three-arm pragmatic cluster randomized trial across 27 government primary health centres in Blantyre, Chikwawa, Machinga and Zomba (Figure 1). Clinics will be randomized 1:1:1 to one of three study arms:

1. *Enhanced standard of care (SOC) arm*: Clinics will establish best-practice services for partner testing among ANC or HIV-positive index patients. This includes provision of invitation letters or FRS for partner testing at protected time slots, and information leaflets promoting HIV prevention and follow-on HIV services (e.g. ART, VMMC, discordant couples' services).
2. *HIVST arm*: In addition to invitation letters or FRS and information leaflets provided in the enhanced SOC arm, clinics will offer HIVST kits to test partners of ANC or HIV-positive index patients, with one kit provided for each eligible (i) pregnant woman attending her first ANC

appointment, and (ii) each sexual partner reported by newly diagnosed or untreated HIV-positive index patients.

3. *HIVST + accuracy arm*: Secondary distribution of HIVST kits will be provided, as described in the HIVST arm, but with the addition of a conditional financial incentive. A US\$10 incentive will be given in cash to partners who return for confirmatory testing and consent to the intended-user intended-setting accuracy sub-study.

**Figure 1: Trial Schema**



## 5.2. Study Population

The study will be conducted in 27 health facilities in Blantyre, Chikwawa, Machinga and Zomba, which have been selected by MoH as priority high HIV-prevalence districts.<sup>17</sup>

Eligibility criteria for health facilities include:

- Government primary health clinic or centre
- Provides ANC, HTS and ART services

## 5.3. Randomisation and Blinding

### 5.3.1. Randomisation

Government health facilities (clinic) will be the unit of randomisation (Figure 1). Randomisation will be constrained to minimise imbalance around clinic-level variables such as District, geographic spread of clusters within Districts, HIV prevalence among ANC clients, number of newly diagnosed PLHIV in the 3 months before randomisation, and any other variable considered relevant. A random



selection of 999 acceptable allocations will be used for open randomisation at a public ceremony with representation from all partners and facilities.

### **5.3.2. Blinding**

It is not practical to blind either the participants or the investigator in this study because of the nature of the interventions which include collection of different study materials such as HIV self-test kits and receipt of financial incentives. However, all data will be managed without reference to the study arm until the final data analysis, thus providing masking to main investigators and collaborators.

### **5.4. Primary Outcomes**

The two primary outcomes are comparison between arms of:

1. Percentage of self-reported partner testing among ANC attendees measured at Day 28 of enrolling the woman.
2. Number of previously undiagnosed or untreated HIV-positive contacts identified among partners of HIV-positive index patients (adjusted for average number of newly-diagnosed PLHIV per clinic in the 3 months prior to implementation), measured at Day 28

### **5.5. Secondary Outcomes**

Six secondary outcomes are comparison between arms of:

1. Percentage of partners of ANC attendees who start ART, or undergo VMMC, or attend discordant couples clinic within 28 days of enrolling the woman
2. Percentage of partners of ANC attendees who attend the clinic for *any* HIV services including confirmatory testing, counselling, condoms, ART, discordant couple services, or VMMC within 28 days of enrolling the woman
3. Percentage HIV+FRS index cases who self-report at least one partner tested for HIV as a result of their diagnosis, measured at Day 28
4. Number of partners of (or % of Index patients with at least one) HTS index cases who attend the clinic for *any* HIV services including confirmatory testing, counselling, condoms, ART, discordant couple services, or VMMC within 28 days of index case diagnosis
5. Number of partners of HTS index cases who start ART, or undergo VMMC, or attend discordant couples clinic within 28 days of index case diagnosis
6. Percentage of adverse events (e.g. partnership breakdown, intimate partner violence, etc.) related to self-testing reported by ANC / HIV-positive index patients, measured at Day 28

### **5.6. Outcome measurement**

The primary outcome of partner testing, and frequency of adverse events will be measured through Audio Computer-Assisted Self-Interviews (ACASI) or phone interviews of ANC or HIV-positive index patients, conducted 28 days after the ANC appointment for pregnant women or 28 days after diagnosis for PLHIV (Appendix 1: form PQ06).

All other outcomes will be measured through interviews with partners who were identified as having attended the clinic within 28 days of enrolling the woman or index patient. Additional data will be recorded on recruitment, and care/prevention services logs to indicate final post HIV testing services provided to the client. All letters and FRSs will be enumerated for purposes of reconciling study outcomes.

As not all HIVST clients will want to identify their route into HIV care and prevention services, we will also monitor overall clinic-level time trends in new ART initiations, new referrals for VMMC and newly registering discordant couples, and will use time-trend analyses to relate the availability of HIVST to demand for these services.

## **5.7. Trial Procedures**

### **5.7.1. Standard of Care arm**

Prior to randomisation, staff in all clinics will be invited to plan and implement an enhanced standard of care, employing best-practice strategies for promoting partner testing. Eligible patients will be asked to provide their partners with (i) an invitation letter or family referral slip (FRS), with a time-protected slot to test partners at each clinic, (ii) an information leaflet explaining and promoting HIV prevention including serodiscordancy, treatment-as-prevention, and VMMC (Appendix 2: PQ25c and Appendix 3: PQ25d).

### **5.7.2. Intervention arms**

Clinic staff will attend an additional training on storage and provision of HIVST kits to ensure accurate and safe use. HIVST kits, IEC materials and data capture tools will be provided by the project. HIVST kits will be delivered through standard MoH supply chains to participating health facilities. Programme tools will be developed in partnership with MoH.

Ministry of Health staff will implement HIVST in their antenatal and HIV testing services as part of their routine care service delivery. Partner-delivery of HIVST kits will be integrated into the enhanced standard of care in routine ANC and HTS clinics, with the aim of aligning distribution as closely as possible with future MoH HIVST programmes.

The following principles have been agreed with the Malawi HIV Department:-

- Training of clinic staff will be carried out by MoH assisted by PSI and MLW partners
- One HIVST kit will be provided to all pregnant women attending their 1st ANC (booking) visit for the current pregnancy, unless already known to be HIV-positive and on ART.
- For newly diagnosed HIV+ve index clients, the existing patient-delivered Family Referral Slip (FRS) system will be supplemented with provision of one HIVST kit per named sexual partner
- Participation will be voluntary, and patients will be informed through posters, leaflets, and group counselling that this intervention is novel and being evaluated for safety and impact
- HIVST kits will be provided with a brief demonstration of use (in person demonstration or video clip) to supplement the Manufacturer's instructions for use (which are already translated into Chichewa)
- A brief information leaflet will be provided for the partner in lieu of informed consent, explaining the nature of the evaluation (and accuracy study if in that arm), and encouraging partners to access confirmatory HTS, VMMC, ART or discordant couple's services within 28 days.

A full-time assistant will be provided for each clinic to support research-related data capture.

### 5.7.3. Serious adverse events

All adverse events temporally related to participation in each trial arm particularly following delivery of HIV self-test kits will be captured according to a standard operating procedure for handling adverse events. The trial will only use the *grading* of adverse events: grade 1 (*mild*), grade 2 (*moderate*), grade 3 (*severe*), and grade 4 (*potentially life threatening*) or grade 5 (*death*) in order to classify all adverse events. Although all adverse events will be recorded, only grade 3-5 events, which are considered as serious adverse events (SAEs) will be reported to the institutional review boards (IRBs) as defined below:

#### Definition of serious adverse event

Any *grade 3, 4 or 5* events that occur within 30 days of delivering self-test kits to women or men enrolled in the trial.

#### Grade 3 events:

1. Intimate partner violence that leads to pain, bruising or marks within 24hrs.
2. Life-threatening violence (e.g. statement of intent to kill, strangulation, threatened with a knife or gun.
3. Physically coercive sex.
4. Reports fearing for her life.
5. Marriage break-up.

#### Grade 4 events:

1. Intimate partner violence leading to hospitalisation or death.
2. Suicide or attempted suicide.
3. Attack using potentially lethal force (e.g. knife, gun, hammer, and kicks to the head).

#### Grade 5:

1. Death

## 5.8. Sample Size Considerations

For secondary delivery through ANC, we assume that 20% of male partners will test in the standard of care arm. With nine clusters per arm and 350 pregnant women per cluster, we will have 90% power to detect a 12% increase in partner testing using a coefficient of variation (k) of 0.25.

## 6. Sub-studies

### 6.1. Economic evaluation

Economic and financial data will be collected to estimate the unit costs of HIV testing in all study arms. These data will be applied to determine the cost-effectiveness of secondary partner distribution and project scale-up costs.

### 6.2. Diagnostic accuracy study

An intended-user intended-setting diagnostic accuracy study will be included in the third arm of the study. Here, we aim to estimate the sensitivity and specificity of the OraQuick test kit in the context of secondary distribution.

This arm will adopt the same procedures as the HIVST arm, but with the addition of US\$10 financial incentive conditional on (i) use of the self-test and (ii) subsequent attendance at confirmatory HTS and referral to VMMC, ART or discordant couple's services (Appendix 4: consent form PQ25a and Appendix 5: PQ25b).

The conditional incentive is intended to provide >60% participation<sup>7</sup> within the accuracy sub-study, with the details described below. To conduct this sub-study, the project will provide an additional trained HTS counsellor for each clinic in this arm.

Participants will be asked to:

- Relate their self-test self-read result.
- Select from an illustrative set of OQ kits (e.g. weak and strong positives, invalids, negatives) to recount which most closely reflected their own self-test result.
- Repeat the OraQuick HIV Self-Test under observation and score using an error checklist.
- Receive confirmatory HIV testing using two finger-prick rapid diagnostic tests (RDT) administered and read by a trained HTS provider, regardless of self-reported HIV results. This will be used as the gold standard when computing accuracy estimates.
- Have finger-prick blood or 7 mls of venous blood (in EDTA) taken for:
  - CD4 counts using PIMA if HIV-positive on any test
  - Viral load if HIV-positive on any test
  - ART drug detection in all participants with discrepant, weak or inconclusive RDTsParticipants with inconclusive results will be seen for repeat HIV testing after three weeks.

Sample size for this sub-study was calculated based on precision. Assuming that each cluster will have 350 women, a total of 3150 women will be recruited in the nine clusters in the accuracy arm. We further assume that 60% of the male partners will attend the clinic in this arm,<sup>7</sup> at least 70% will finally participate in the accuracy study procedures, and that 6% will report a positive self-test result.<sup>7</sup> Under these key assumptions, 1323 participants will be required to demonstrate previously observed sensitivity to a precision of 0.8%.<sup>10</sup>

## 7. Study Period (Timelines)

The trial is set to take place for a period of 6 months between April to September 2018 followed potentially by scale up of findings nationwide in 2019 (Figure 4).

**Figure 4:** Project timeline

Activity	2017		2018				2019			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Preparatory meetings	■	■								
Prepare protocol		■	■							
Develop study tools			■	■						
Hire and train staff				■	■					
Seek ethics approval			■	■						
Pilot study procedures and data collection				■	■					
Data analysis of pilot data					■					
Dissemination meeting with Ministry					■					
Revise tools						■	■			
Scale up activities & implementation							■	■	■	■
Final data cleaning & analysis										■
Dissemination										■
Publication							■	■		■

## 8. Data Management and Statistical Analysis

### 8.1. Data Management

Data will be managed through infrastructure set up within Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW). Data collection and processing will be as detailed in the data management plan (DMP) developed for the project. Data will be collected using tablets running Open Data Kit (ODK) and will be downloaded onto a server running a MySQL Relational Database.

Data quality assurance will be implemented within the electronic form so that out of range values, inconsistent values and required variables will be checked at the time of data collection. All tablets will have full log-in details of the person collecting the data including a password. Access to the study database will be protected by a password known only to the PI (Augustine Choko) and the IT systems administrator in MLW. Data for study monitoring will be periodically exported into comma separated values (CSV) from the study database on the MLW server for analysis and to raise plus resolve data queries.

Protocols for managing data without breach of confidentiality are in place within MLW. Access to the final data set will be limited to the PI (Augustine Choko), co-principal investigators and colleagues at the HIV/AIDS Department and PSI listed as co-investigators. Sensitive information (including HIV results) will not be linked to personal identifiers in the final data set.

All devices and paper-based tools containing data will be kept in locked offices at MLW during data processing and in a locked data repository room for longer term storage. All data will be backed up daily by the MLW Data Office, with offsite back up once weekly. Backup data will be stored in a locked filing cabinet away from the office by the PI.

#### Data capture tools

Draft data tools are shown in Appendix 1: PQ06 form, although the final versions may have system generated fields from the tablet that are not included. At enrolment a baseline questionnaire will be administered, including eligibility screen.

At 28 days, or the date of next clinic appointment, a questionnaire will be administered to all ANC/Index Client participants using ACASI or phone call, aiming to capture adverse events (intimate partner violence), occurrence of testing and other secondary outcomes.

## 8.2. Statistical Analysis

Analyses will be done in R<sup>18</sup> and Stata 14.0 (Stata Corp, Texas, USA). Baseline characteristics will be computed as proportions or median (interquartile range [IQR]), as appropriate, by arm in each of the two stages. Any variables that show imbalances will be adjusted for when testing the null hypothesis of no difference in mean of proportions achieving the primary outcome (s) between the SOC and each of the intervention arms.

The main statistical analysis will be for the primary outcome of uptake of HIV testing among partners within 28 days of enrolling the woman as well as number of previously undiagnosed or untreated HIV-positive contacts. All analyses will be by intention-to-treat using the total number of eligible women or index clients at baseline taking into account the clustered design according to a plan of analysis which will be written. We will conduct a sensitivity analysis controlling for multiple comparisons using the Dunnett test<sup>19</sup> given that two hypotheses tests will be conducted using the same SOC arm.

Given the small number (nine) of clusters per arm, analysis will be by cluster-level summaries using mean of proportion of male partners per clinic who achieve the primary outcomes in each arm. A log transformation of the clinic proportions will be applied if a positive skew is observed<sup>20</sup>. If baseline imbalance is observed an adjusted analysis, using a two stage process<sup>20</sup> appropriate for a small number of clusters, will be conducted. The mean of clinic proportions in each of the two intervention arms will be compared to the SOC arm using unpaired t-test. An estimate of the risk ratio (RR) and a 95% CI will also be computed for each comparison.

## 9. Ethics, Conflict of Interest, Data Availability and Dissemination

### 9.1. Ethical Approval

Ethics approval will be sought from the College of Medicine Research Ethics Committee (COMREC), Malawi, the London School of Hygiene and Tropical Medicine Ethics Committee, and from the World Health Organization.

As the nature of the intervention is not compatible with written informed consent, we will request ethics committee waivers and will instead provide information through group counselling, leaflets, and directions to clinic-based services (Table 1).

**Table 1:** Consent requirements for research activities

Research activity	Research component	Consent requirements
HIVST kit provision for secondary distribution	Intervention	Request waiver of informed consent
HIVST kit recipient	Intervention	Request waiver of informed consent (leaflet provided in lieu)
ACASI or Phone interview with kit distributor	Outcome evaluation	Verbal consent

Accuracy sub-study	Accuracy of secondary distribution	Written (witnessed) informed consent
Routine programme data collection	Process evaluation	Not applicable
Routine clinic data extraction	Outcome evaluation	Not applicable
Direct observation	Health economics	Verbal
Informal interviews	Health economics	Verbal
Extraction of programme and government expenditure reports, databases and logs	Health economics	Verbal

Waiver of informed consent for individuals providing and accepting HIVST kits is requested on the following grounds:

- The intervention is being supported by MoH and delivered by routine clinic staff.
- HIVST is now recommended as international best practice by WHO <sup>4</sup>
- The OraQuick HIV Self-Test has been evaluated and approved by WHO Prequalification <sup>21</sup>.
- Secondary-distribution is becoming an established practices, with minimal risk of harms as demonstrated in Malawi and other sub-Saharan African countries <sup>22</sup>.
- The trial aims to assess a pragmatic, unrestricted intervention, with potential integration and scale-up by MoH. Formal consent procedures would by definition affect the nature of the intervention.
- Clinic staff, along with intervention materials, will aim to adhere to international best practice for HTS, stressing that all HIV testing is a voluntary process.
- MoH, PSI and MLW will continue to monitor any social harms or breach of voluntariness

## 9.2. Conflict of interest

Neither the PI nor any of the collaborators has any conflict of interest.

## 9.3. Compensation for participants

Participants in the accuracy sub-study will be compensated MK7,000 (US\$10) per participant for transport and their time away from income-earning activities.

Given the pragmatic nature of the HIVST intervention, and according to directions from MoH partners, participants in the main study will not have any monetary compensation for participation.

## 9.4. Data Availability

The final fully anonymised data from the study will be made publicly available through the LSHTM data repository (<http://datacompass.lshtm.ac.uk/>).

## 9.5. Dissemination

Findings from the trial will be primarily aimed to inform the Ministry of Health (MoH) through presentations and final copy of the report. Further local dissemination will be done at the National AIDS Commission (NAC) / College of Medicine (COM) annual dissemination conference. Findings will also be presented at peer-reviewed regional and international conferences. Copies of the final

report, published peer-reviewed paper (s) and abstracts will be made available to the COM Library, and to College of Medicine Research Ethics Committee (COMREC).

## **10. Possible Constraints**

A major anticipated concern is potential for intimate partner violence (IPV) although evidence from studies using other populations and other HTC models suggests this approach is unlikely to increase this problem<sup>7, 16, 23, 24</sup>. For example, there were no serious adverse events including IPV in the Phase II trial conducted in Blantyre on whose premise this Phase III trial is based.<sup>7</sup> Similarly, in large community-based HIV self-testing study in Blantyre, Malawi increased intimate partner violence was not reported despite an active community liaison system among 27,000 self-testing participants<sup>8</sup>. We will carefully monitor IPV in this trial.

The measurement of the primary and some secondary outcomes is by self-report through women and index clients. Although the use of ACASI has been shown to reduce the risk of social desirability bias, this may not be an accurate method of measuring these outcomes as there is potential for misclassification. We will estimate the magnitude of misclassification by assessing these outcomes in the subset of men or women in the HIVST + accuracy arm.

## **11. Training and Capacity Building**

This work is anticipated to part of my (Augustine Choko) Post-Doctoral training with LSHTM. Study personnel including government HIV counsellors will be trained on research ethics, maintaining confidentiality and data collection using tables among other essential skills. All study staff including the principal investigator (PI) will undergo Good Clinical Practice (GCP) training or refresher GCP training as appropriate.

## **12. Personnel, Materials and Consumables, Equipment, Space and Miscellaneous**

### **12.1. Personnel**

The implementation of trial procedures is intended to be by the Ministry of Health as this is meant to be a pilot project before national scale up. Therefore, government HIV counsellors will be responsible for participant recruitment and baseline data capture. Additional field staff will be provided by the STAR project via PSI to manage follow-up interviews. Field supervisor (s) will supervise the HIV counsellors and the field workers while the PI will provide overall leadership of the study.

### **12.2. Materials and Consumables**

The following materials and consumables will be required for the study

- a) OraQuick ADVANCE HIV I/II (OraSure Technologies, Bethlehem, USA) for oral tests
- b) Determine 1/2™ (Alere, Waltham, USA) and Uni-Gold™ Recombigen® HIV (Trinity Biotech, Bray, Ireland) for confirmatory HIV testing using finger prick blood --- but with additional collection of dried blood spots (DBS) to be available for Viral load testing and ART drugs in case of any inconsistencies in results of the HIV rapid diagnostic testing.



- c) Blood specimen bottles for the participants that will be tested for CD4 and viral loads
- d) Writing materials, study materials, visual aids and clip boards will be required during protocol training and other training activities.
- e) Printing
- f) Vehicle running costs

### **12.3. Equipment**

Tablets for electronic data capture, lockable filing cabinets for temporary storage of completed consent forms and study tools.

### **12.4. Space**

Space for storing study tools, equipment and consumables as well as private space for conducting study procedures will be required in all recruitment primary health centres.

### **12.5. Miscellaneous**

Airtime for mobile communication between study personnel will be required.

### 13. Budgetary Estimate

<b>1 Personnel and training</b>	<b>Qty</b>	<b>Unit</b>	<b>Amount</b>	<b>Total (MWK)</b>	<b>GBP</b>
Field worker	27	each/12 m	520000	14,040,000	14327
HIV testing & counselling refresher	1	total	1000000	1,000,000	1020
Good Clinical Practice refresher	5	each	220500	1,102,500	1125
Protocol training	1	total	100000	100,000	102
<b>2 Implementation costs</b>					
Participant compensation (\$10)	900	each	7000	6,300,000	6429
Vehicle hiring costs	12	month	120000	100,000	102
Mobile phone credit	5	each/12 m	50000	250,000	255
<b>3 Equipment &amp; consumables</b>					
Tablet	4	each	150000	600000	612
Office equipment	3	each	300000	900000	918
OraQuick test kits	300	each	1750	5250000	5357
	0				
Confirmatory test kits	120	each	918.75	1102500	1125
	0				
Stationary	1	lumpsum	1000000	1000000	1020
<b>Dissemination costs</b>					
<b>4 National dissemination</b>	<b>2</b>	<b>each</b>	<b>110250</b>	<b>220500</b>	<b>225</b>
<b>5 COMREC fee</b>	<b>1</b>	<b>each</b>	<b>110250</b>	<b>110250</b>	<b>113</b>
Budget total	1			32,075,750	32730
10% COM overhead fees	1			3207575	3273
<b>Grand total</b>				<b>35,283,325</b>	<b>36,003</b>

<b>1 Personnel and training</b>	<b>Qty</b>	<b>Unit</b>	<b>Amount</b>	<b>Total (MWK)</b>	<b>GBP</b>
Field worker	27	each/12m	520000	14,040,000	14327
HIV testing & counselling refresher	1	total	1000000	1,000,000	1020
Good Clinical Practice refresher	5	each	220500	1,102,500	1125
Protocol training	1	total	100000	100,000	102
<b>2 Implementation costs</b>					
Participant compensation (\$10)	900	each	7000	6,300,000	6429
Vehicle hiring costs	12	month	120000	100,000	102
Mobile phone credit	5	each/12m	50000	250,000	255
<b>3 Equipment &amp; consumables</b>					
Tablet	4	each	150000	600000	612
Office equipment	3	each	300000	900000	918
OraQuick test kits	3000	each	1750	5250000	5357
Confirmatory test kits	1200	each	918.75	1102500	1125
Stationary	1	lampsum	1000000	1000000	1020
<b>Dissemination costs</b>					
<b>4 National dissemination</b>	2	each	110250	220500	225
<b>5 COMREC fee</b>	1	each	110250	110250	113
Budget total	1			32,075,750	32730
10% COM overhead fees	1			3207575	3273
<b>Grand total</b>				<b>35,283,325</b>	<b>36,003</b>

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## 14. Appendices



### 14.1. Appendix 1: Form PQ06

#### PQ06: Follow-up Questionnaire for ANC or HTC index client (Audio Computer Assisted Self-Interview)

##### *Instructions to the field worker*

- a) Make sure that the participant is oriented in using both the tablet and the ACASI system before leaving them to answer the questions
- b) Stick around while maintaining confidentiality so that the participant can call you in case of issues
- c) Fieldworker to complete the four test questions below together with the participant

##### **Section A: Test questions**

- I. Did you eat when coming to the clinic? If you ate nsima, press thumbs up  or if you didn't eat nsima, press thumbs down  (back end capture as 1=yes; 0=no); if you want the question to repeat, press the white button to repeat the question

Kodi munadya pobwera kuchipatala?

*[Ngati munadya nsima lero, tobwanyani chala choloza m'mwamba*

*Ngati simunadye nsima lero, tobwanyani chala choloza pansi*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

To continue to the next question press the forward arrow button

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

- II. Is it raining now?  
Kodi panopa kukugwa mvula?

- III. Do you live in Malawi?  
Kodi m'makhala ku Malawi?

- IV. Is this Mulanje district?  
Kodi lino ndi boma la Mulanje?

V. Describe how you moved from home to the clinic.

Fotokozani momwe mwayendera pobwera ku chipatala lero.

Press record sound button, then another screen will come up

Kuti muyambe kufotokoza tobwanyani batani lalitali lomwe lili ndi malemba m'musimu, kenako pabwera ka sikirini kena.

Press the big circle button on this new screen to start talking

Tobwanyani batani lalikulu lozungulira lomwe liri pa ka sikirini kameneka nkuyamba kulankhula.

When done speaking press the square button

Mukamaliza kufotokozaku tobwanyani batani lalikulu lama kona anayi

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

To continue to the next question press the forward arrow button.

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

## Section B: Identifiers

### Instructions to the field worker

- a) Fill in this part before taking leave of the participant
  - b) Ensure that all identifiers are automatically filled before taking leave of the participant.
1. **a01idate** Date of interview [Date]
  2. **a02start** Start time [Time] → automatically filled by the tablet
  3. **a03pidw** Field worker to scan woman barcode [Numeric] → field worker to scan from the woman's health passport

## Section C: Questions related to the activities in the allocated arm, woman specific

Now I am going to ask you about activities in the allocated study arm.

*Panopa ndikufunsani zokhudzana ndi zochitika malingana ndi kafukufukuyu.*

4. **a04st** Did you receive self-test kits from anybody in the last 4 weeks? [Numeric, Y/N] → Ask to participants in the SOC arm only

Kodi munalandira zipangizo zoziyezera wekha kwa aliyense?

*[Ngati munalandira, tobwanyani chala choloza m'mwamba*

*Ngati simunalandire, tobwanyani chala choloza pansi]*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

5. **a05let** Did you deliver the letter given to you at enrolment to your male partner? [Numeric] → use thumbs up and thumbs down as in c) above all the questions unless stated otherwise

Kodi munapereka kalata yomwe munalandira mu kafukufukuyu kwa wachikondi wanu?

*[Ngati munapereka, tobwanyani chala choloza m'mwamba*

*Ngati simunapereke, tobwanyani chala choloza pansi]*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo



6. **a06kits** Did you deliver self-test kits to your male partner? [Numeric, Y/N] → *only to participants in the intervention arms*

Kodi munapereka zipangizo zoziyezera wekha kwa wachikondi wanu?

*[Ngati munapereka, tobwanyani chala choloza m'mwamba*

*Ngati simunapereke, tobwanyani chala choloza pansi]*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

7. **a07ipvl** Did you experience any social harm from your partner after bringing the letter to your partner? [Numeric] → Y/N

Kodi kupereka kalata kwa wachikondi wanu kunakubweretserani mavuto ena ali onse?

*[Ngati munakumana ndi mavuto ali onse, tobwanyani chala choloza m'mwamba*

*Ngati simunakumane ndi mavuto ali onse, tobwanyani chala choloza pansi]*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

8. **a08ipvk** Did you experience any social harm from your partner after delivering self-test kits to your partner? [Numeric, Y/N] → *Hide this question for participants in the standard of care arm*

Kodi kupereka zipangizo zoziyezera wekha kwa wachikondi wanu kunakubweretserani mavuto ena ali onse?

*[Ngati munakumana ndi mavuto ali onse, tobwanyani chala choloza m'mwamba*

*Ngati simunakumane ndi mavuto ali onse, tobwanyani chala choloza pansi]*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

9. **a09ipv** Please describe any kind of social harms you faced? For example: beaten, yelled at, denied sex, marriage break-up, not given money, being locked out, being neglected, or being threatened

Chonde fotokozani mwatsanetsatane mavuto a mtundu uliwonse omwe munakumana nawo kaya kumenyedwa, kukalipidwa, kukanizidwa za m’banja, kutha kwa banja, kumanidwa ndalama, kutsekeredwa panja, kusalidwa, kapena kuopsyzedwa.

Press record sound button, then another screen will come up

Kuti muyambe kufotokoza tobwanyani batani lalitali lomwe lili ndi malemba m’musimu, kenako pabwera ka sikirini kena.

Press the big circle button on this new screen to start talking

Tobwanyani batani lalikulu lozungulira lomwe liri pa ka sikirini kameneka nkuyamba kulankhula.

When done speaking press the square button

Mukamaliza kufotokozaku tobwanyani batani lalikulu lama kona anayi

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

To continue to the next question press the forward arrow button.

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

#### Section D: Questions related to male partner testing

Now I am going to ask you about HIV testing issues related to your male partner.

*Panopa ndikufunsani mafunso okhudzana ndi wachikondi wanu pa nkhani ya zoyezetsa HIV.*

10. **a10mtest** Did your partner test after you explained to him about the study? I mean any kind of HIV test [Numeric, Y’N]

Kodi wachikondi wanu anayezetsa kachilombo ka HIV mutamufotokozera? Ndikati kuyezetsa ndikutanthauza kuyezetsa kulikonse kaya ndi ku chipatala, ku malo ena oyezetsera, kapena kuziyeza wekha.

*[Ngati anayezetsa, tobwanyani chala choloza m’mwamba*

*[Ngati sanayezetse, tobwanyani chala choloza pansi]*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

11. **a11mself** Did your partner self-test? [Numeric] → depends on answer to did male partner test?; hide for participants in standard of care arm and NO to a06 above.

Kodi wachikondi wanu anaziyeza yekha mutamufotokozera?

*[Ngati anaziyeza yekha, tobwanyani chala choloza m’mwamba*

*[Ngati sanaziyeze yekha kapena simukudziwa, tobwanyani chala choloza pansi]*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

12. **a12self2** Did you self-test together? [Numeric] → depends on answer to did male partner test?; hide for participants in standard of care arm and NO to a06 above.

Kodi munaziyeza limodzi ndi wachikondi wanu mutamufotokozera?

*[Ngati munaziyeza limodzi, tobwanyani chala choloza m’mwamba*

*[Ngati simunaziyeze limodzi, tobwanyani chala choloza pansi]*

*[Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso]*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

13. **a13sharea** Did male partner disclose result if he tested alone [Numeric] → depends on answer to did male partner test? Ask for participants in standard of care arm only.

Kodi wachikondi wanu anakuwuzani zotsatira zake ngati anayezetsa payekha?

[Ngati anakuwuzani, tobwanyani chala choloza m'mwamba]

[Ngati sanakuwuzeni kapena simukudziwa, tobwanyani chala choloza pansi]

Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

14. **a14shareb** Did male partner disclose result if he self-tested alone [Numeric] → depends on answer to did male partner test? Hide for participants in standard of care arm.

Kodi wachikondi wanu anakuwuzani zotsatira zake ngati anaziyeza payekha?

[Ngati anakuwuzani, tobwanyani chala choloza m'mwamba]

[Ngati sanakuwuzeni kapena simukudziwa, tobwanyani chala choloza pansi]

Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

15. **a15result** What was his test result? [Numeric] → depends on answer to did male partner test?  
1=positive; 0=negative; 2=DK

Kodi zotsatira za wachikondi wanu zinali zotani?

[Ngati anati alibe kachilombo, tobwanyani chala choloza m'mwamba]

[Ngati anati alinako kachilombo, tobwanyani chala choloza pansi]

Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

16. **a16hard** Did you or your partner experience any difficulties in conducting self-testing? [Numeric]

Kodi inu kapena wachikondi wanu munakumana ndi vuto lililonse poziyeza nokha?

[Ngati panalibe vuto lililonse, tobwanyani chala choloza m'mwamba]

[Ngati munakumana ndi vuto lililonse, tobwanyani chala choloza pansi]

Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

17. **a17link** Did your partner come to the clinic after testing regardless of result? [Numeric] → Y/N,  
depends on testing questions above

Kodi wachikondi wanu anabwera kuno ku chipatala potsatira kuyezetsa mutamufotokozera posatengera zotsatira?

*[Ngati anabwera, tobwanyani chala choloza m'mwamba*

*Ngati sanabwere kapena simukudziwa, tobwanyani chala choloza pansij]*

*Ngati mukufuna kuti funso lifunsidwenso tobwanyani batani lobwerezera funso*

Kuti mumve funso lotsatira tobwanyani batani la muvi oloza kutsogolo

*This marks the end of the questions, thank you for your time.*

Pano ndi pa mathero pa mafunso athu, zikomo kwambiri chifukwa choyankha mafunsowa.

18. **a18end** End time

If you experienced any adverse events please inform the field worker who will be able to help you with the next steps.

## 14.2. Appendix 2: PQ25c Partner Invitation Letter, English

LONDON  
SCHOOL of  
HYGIENE  
& TROPICAL  
MEDICINE



Date: \_\_\_\_\_

25003

Clinic: \_\_\_\_\_

Arm: \_\_\_\_\_

### Partner Invitation Letter— ANC/FRS Trial

Dear \_\_\_\_\_

At \_\_\_\_\_ primary health clinic we are offering free HIV testing and follow on services including teaching men about maternal care in relation to their pregnant partner. We are running a separate clinic called the “male friendly clinic”, which is linked to antenatal clinic specifically to help men. Your partner got a self-test kit from her/his clinic visit today for you to use. You will get MWK7,000 as transport reimbursement and lost time compensation if you come to the male friendly clinic and undergo trial procedures.

You may come on any day from Monday to Saturday starting from 7:30am to 4:00pm. On arrival at the clinic, ask for antenatal clinic where they will direct you to the male friendly clinic.

If you have any questions or you want to book an appointment at a time of your convenience please call \_\_\_\_\_ on \_\_\_\_\_

**Bring this card along with used/unused self-test kits and you will be attended to right away.**

### 14.3. Appendix 3: PQ25d Partner Invitation Letter, Chichewa

LONDON  
SCHOOL of  
HYGIENE  
& TROPICAL  
MEDICINE



Tsiku: \_\_\_\_\_

Clinic: \_\_\_\_\_

Arm: \_\_\_\_\_

\*25003\*

**kalata yakuyitadwa kwa a  
bambo – ku kafukufuku wopereka zipangizo  
zoziyezera wekha**

Okondeka: \_\_\_\_\_

Kuno ku chipatala cha \_\_\_\_\_ tikuyeza magazi, kupereka chithandizo komanso kuphunzitsa abambo zokhudzana ndi kukonzekera pa uchembere. Takhazikitsa ka chipatala komwe kali mbali ya sikelo kotchedwa “chipatala chokomera abambo”. Cholinga cha ka chipatala kameneka ndikuthandiza makamaka abambo amene wachikondi wawo ali oyembekezera. Tamupatsa wachikondi wanu zipangizo zoziyezera wekha ziwiri pamene anabwera ku sikelo kuti muthe kuziyeza nokha. Tidzakupatsani MWK6,500 ya mayendedwe komanso kaamba ka nthawi yomwe mwawononga mukabwera ku chipatala chokomera abambo ndikulandira thandizo loyenelera.

Mukhoza kubwera tsiku lina lirilonse kuyambira lolemba mpaka loweruka nthawi ya 7 koloko m'mawa mpaka 4 koloko madzulo. Mukadzafika ku chipatalaku mudzafunse kumene kuli sikelo ndipo kumeneko adzakulondolerani ku chipatala chokomera abambo.

Ngati muli ndi mafunso kapena mukufuna kukonza nthawi ya padera yofuna kukumana nafe fulashani kapena tumizani “chonde ndiyimbileni” kwa \_\_\_\_\_ pa nambala iyi \_\_\_\_\_

**Chonde kumbukirani kubweretsa zipangizo zoziyezera wekha zogwiritsidwa ntchito limodzi ndi chi kalata chimenechi pobwera.**

#### 14.4. Appendix 4: Consent form PQ25a, English

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Malawi-Liverpool-Wellcome Trust  
Clinical Research Programme  
P.O Box 30096, Chichiri, Blantyre 3,  
Malawi.  
Tel. +265 1 876444 Fax +265 1 875774

### **Title: Secondary distribution of HIV self-tests through antenatal and HIV testing services: a pragmatic cluster-randomized trial (STAR-ANC)**

**Protocol lead:** Mr. Augustine Choko

**Participant barcode**

*[The following text must be read to the participant, who must have their own copy to take home]*

#### **Introduction**

How are you today? My name is ....., and I am working with Malawi Liverpool Wellcome Trust (MLW) on behalf of Mr. Augustine Choko and colleagues. We thank you for having accepted an offer of an HIV test from us through your partner. In this component of the study, we are interested in investigating the accuracy of the HIV self-test kit that you used for HIV testing. We also wish to assess if you obtained correct results by asking you to interpret some HIV test results after which we will take some blood samples in order to perform additional tests.

#### **Request for your Voluntary Participation**

I would like to ask you to voluntarily participate in this sub-study. You have been identified because you are attending this clinic following participation in the trial that we are conducting. Please note that you were not selected to participate in this sub-study because you are HIV positive or negative. We consider that your participation would help us understand the accuracy of HIV self-testing in the hands of lay people. This is very important because the Ministry of Health would like to roll-out secondary distribution which assumes that lay people can correctly perform an HIV self-test.

#### **Procedure**

Please note that we are carrying out these procedures on everyone who accepts participate in this sub-study regardless of their HIV results. I will ask you to relate your self-test self-read result to already performed self-test results. You will then be asked to select from an illustrative set of OQ kits (e.g. weak and strong positives, invalids, negatives) to recount which most closely reflects your own self-test result. I will give you a fresh OraQuick test to swab in the gums under observation, as per instruction and I note any errors that you may make. I will also note the results of this test. I will then perform two finger-prick rapid diagnostic tests to confirm your self-test results that you reported earlier. I will ask you to give 7 mls of venous blood by finger-prick blood so that we can measure your CD4 count and viral load if you are



HIV-positive on any test, and ART drug detection if your results are discrepant, weak or inconclusive. If your results are inconclusive I will have to see you again for repeat HIV testing after three weeks.

Your participation is entirely voluntary. If you decide to take part, you may withdraw from any procedure or interview in this sub-study any time. You also have a right not to answer any particular question or questions that will be asked. Declining to participate in this sub-study will not affect any health services that you or any person related to you may be currently receiving or may require in future.

### **Confidentiality**

All personal information collected in this study will be kept strictly confidential. I will not share the information you provide with anyone who is not part of this research. But it may be shared with fellow researchers and may also be published through meetings or journals in a manner that does not reveal your identity. Before sharing in this manner, the information from you will be combined with that from other research participants. Information which could identify you or anyone related to you will never be released. This also means that names of study participants, including your own will not be included when sharing the data. Data collection equipment and the data collected will be kept with identifiers, locked, and only accessible to people that have authorised access.

The blood samples that you provide as part of this sub-study will be used only for the purposes that have been stated in this document. Any blood samples that remain during tests or after completion of all tests will be destroyed.

### **Risks**

You may be uncomfortable with some of the questions that I will ask. You are perfectly entitled to refuse to discuss issues that you do not want to. You may also feel slight pain during the finger prick although this is a normal procedure in most diagnoses with rapid tests.

### **Benefits**

There are no direct benefits to you in your taking part in this study. However, what we learn from this study would help the Ministry of Health to make important decisions regarding scale up of secondary distribution. It is not yet known if lay users reached via secondary distribution would correctly interpret their HIV self-test results. Therefore, your participation would benefit many others in the future.

### **Compensation**

You will not receive payment for participating in the study. You will however, be compensated for your time and out of pocket costs associated with attending the clinic amounting to MWK7,000 (US\$10).

### **Contact details**

This research has been approved by the College of Medicine Research Ethics Committee (COMREC), the London School of Hygiene and Tropical Medicine Research Ethics Committee, and the World Health Organization. If you have any questions regarding your rights as a research participant, or concerns on how you have been treated in the study, please feel free to contact **Mr. Augustine Choko** [+265 (0) 999 577 452] or [augutcg@gmail.com].

If you have any questions regarding your rights as a research participant, or concerns on how you have been treated in the study, please feel free to contact COMREC Secretariat, College of Medicine, Private Bag 360, Chichiri, Blantyre 3 or call on 01871911 ext 334.

### **Consent Declaration**

If you agree to voluntarily participate in the study, please sign or write your initial or your thumb print below to show that you understand the information above and that your consent is given voluntarily.

- |   |            |           |
|---|------------|-----------|
| 1. I have received and read or had read to me the information sheet provided by the Researcher that explains in detail the reasons for the study                            | <b>Yes</b> | <b>No</b> |
| 2. I have understood the purpose of the research  | <b>Yes</b> | <b>No</b> |
| 3. I have asked all the questions that I have about the purpose of the research and feel that I have enough information about it  | <b>Yes</b> | <b>No</b> |
| 4. I understand the reasons for this study  | <b>Yes</b> | <b>No</b> |
| 5. I am willing to take part in the study   | <b>Yes</b> | <b>No</b> |
| 6. I understand what I will be required to do if I participate in the study   | <b>Yes</b> | <b>No</b> |
| 7. I know that I have the right to leave the study at any time or to refuse to answer any questions   | <b>Yes</b> | <b>No</b> |
| 8. If I do not agree to take part in this study I understand that I will not be penalized for doing so by the researcher nor by any medical service providers in the future | <b>Yes</b> | <b>No</b> |
| 9. <b>I voluntarily agree to take part in this study</b>  | <b>Yes</b> | <b>No</b> |

-----	-----	-----/-----/-----
Participant's full name	Signature/thumb print	Date

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Study staff full name	Signature & staff No.	Date

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

-----	-----	-----/-----/-----
Name of witness	Signature/thumb print	Date

## 14.5. Appendix 5: Consent form PQ25b, Chichewa

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Malawi-Liverpool-Wellcome Trust  
Clinical Research Programme  
P.O Box 30096, Chichiri, Blantyre 3, Malawi.  
Tel. +265 1 876444 Fax +265 1 875774

### Mutu: Kafukufuku wogawa zipangizo zoziyezera wekha ku sikelo ya amayi oyembekezera komanso malo oyezetsera HIV (STAR-ANC)

Woyang'anira kafukufuku: Mr. Augustine Choko

Participant barcode

*[Zalembedwa m'msimu zikuyenera kuti ziwerengedwe kwa wotenga nawo mbali, amene ayeneranso kukhala ndi chikalata chake choti atenge kunyumba]*

#### Mau Oyamba

Muli bwanji? Dzina langa ndine....., ndipo ndimagwira ntchito ndi bungwe la Malawi Liverpool Welcome Trust mmalo mwa bambo **Augustine Choko** ndi anzawo. Zikomo povomereza kuziyeza nokha kudzera kwa okondedwa wanu. Mu gawo lino tikufuna kudziwa ngati anthu monga inuyo angathe kugwiritsa ntchito zipangizo zoziyezera wekha molondola atapatsidwa ndi okondedwa wawo. Motero, tikufuna tiwone ngati munatanthauzira zotsatira zanu molondola. Kenako ndikutengani magazi pa chala kuti ndikuyezeninso ndi cholinga choti tisiyanitse zotsatira zomwe munapeza ndi zomwe ndingapeze ineyo pokuyezani.

#### Pempho loti mutenge nawo mbali mwakufuna kwanu.

Ndikufuna kukupemphani kuti mutenge nawo mbali pagawo limeneli lakafukufuku mwakufuna kwanu. Mwasankhidwa kuti mutenge nawo mbali mu gawo limeneli chifukwa choti munatenga nawo mbali poziyeza nokha potsatira kulandira zipangizo zoziyezera wekha kuchokera kwa okondedwa wanu. Chonde dziwani kuti simunasankhidwe potengera kuti munapezeka ndi kachilombo kapena ayi. Kutenga nawo mbali kwanu kuthandiza kuti tidziwe ngati anthu angamakwanitse kutanthawuzila zotsatira zawo ataziyeza wokha. Unduna wa za Umoyo ukufuna kumagawa zipangizo zoziyezera wekha mu zipatala koma sitingatero ngati sitikudziwa momwe anthu angamakwanitsire kuziyeza wokha.

#### Ndondomeko

Chonde dziwani kuti tikupanga ndondomeko yomwe ndifotokozeyi kwa aliyense yemwe akutenga nawo mbali mu gawo lino posatengera zotsatira zawo. Poyamba ndikufunsani kuti muyerekeze zotsatira zanu ndi zotsatira zomwe zinapangidwa kale. Mudafunsidwa kuti musankhe zotsatira mwa zotsatira zomwe ndanenazi zomwe zikufana ndi zanu. Kenako ndikupatsani chipangizo choziyezera wekha kuti muyendetse munkhama potsatira malangizo ndipo ndiyang'ana malo omwe angalakwike. Ndilemba zotsatira zomwe zitulukezo. Kenako ndikutengani magazi pa chala kuti ndikuyezeninso HIV. Ndikutenganinso magazi kuti tithe kuyeza chitetezo chamthupi mwanu komanso unyinjira wa kachilombo ngati zimodzi mwa zotsatira zawonetsa kuti muli nako kachilombo. Tidzayezanso ngati mthupi mwanu muli mankhwalu a ma ARV ngati zotsatira zikusiyana, kapena sizikuwoneka bwino bwino. Ngati sitingathe kukuwuzani zotsatira zanu kaamba kotu zikusiyana, ndidzakupemphani kuti mubwerenso pakatha masabata atatu kuti tidzakuyezeninso.

Dziwani kuti kutenga nawo mbali kwanu ndikodzipereka. Mukasankha kutenga nawo mbali, muthanso kusiya kutenga nawo mbali nthawi ina iliyonse ngati simukufuna kupitiriza. Mulinso ndi ufulu wosayankha funso kapena mafunso amene afunsidwe. Kusiya kutenga nawo mbali mu gawo limeneli la kafukufuku sikukubweretserani vuto lina lilironse mwanjira ina iliyonse ndiponso sikusokoneza chithandizo chomwe mukulandira ku chipatala panopa kapena mtsogolo muno.

### **Kusunga chinsinsi**

Chilichonse chomwe tatolera kapena kumva kuchokera kwa inu kudzera mu kafukufukuyu chidzasungidwa mwachininsi. Munthu wina aliyense amene sakukhuzidwa ndi kafukufuku ameneyu sadzamva nawo zokambiranazi. Koma titha kukambirana ndi anthu ena opanga kafukufuku kapena kutsindikiza zotsatira zomwe tapeza kudzera mukafukukuyu. Koma tisanatero, tidzaphatikiza zomwe inu mwanena ndi zomwe anzanu ena otenga nawo mbali mu kafukufukuyu anena. China chilichonse chimene chingathe kukuzindikiritsani inuyo kapena m'bale wanu sichidzawulutsidwa. Chimenechi chikutanthauzanso kuti mayina a anthu amene anatengapo mbali mu kafukufuku ameneyu, kuphatikizapo dzina lanu, adzachotsedwa pamene tikuwapatsa anthu ena zomwe tatolera kwa inu. Zipangizo komanso zomwe zalembedwa zidzapatsidwa zizindikiro ndikutsekeredwa ndi makiyi, ndipo ndi anthu okhawo amene ali ndi chilolezo ndi amene adzathe kufikira malo amenewa.

Magazi omwe tidzakutengeni adzagwiritsidwa ntchito poyeza zinthu zokhazo zomwe zalembedwa mu chikalatachi. Magazi omwe angatsale potsatira kuyezaku adzatayidwa potsatira ndondomeko.

### **Ziopsyezo**

Nthawi zina mutha kusamva bwino ndi mafunso ena omwe ndikufunsa. Inu muli ndi ufulu wonse wokana kukambirana nkhani zimene simukufuna. Panthawi yomwe tikutenga magazi pamakhala ka ululu pang'ono pa chala komanso pa msempha.

### **Phindu**

Palibe phindu lopezekera kwa inu chifukwa chotenga nawo mbali mu kafukufukuyu. Komabe zomwe tingapeze kudzera pa kafukufukuyu zidzathandiza Unduna wa za Umoyo kupanga chiganizo pankhani yogawa zipangizo zoziyezera wekha mu zipatala. Sitikudziwa ngati anthu angamakwanitse kuzeyeza wokha atapatsidwa zipangizo zoziyezera wokha. Choncho, kutenga nawo mbali kwanu mu gawoli kuthandiza kuti mtsogolo muno ena adzathe kugwiritsanso ntchito njirayi.

### **Malipiro**

Simudzalandira malipiro ena aliwonse chifukwa chotenga nawo mbali pa gawo limeneli la kafukufuku. Komabe mudzapatsidwa MWK7,000 malingana ndi nthawi yomwe mwawononga komanso ndalama zomwe mwagwiritsa ntchito pobwera kuno ku chipatala.

### **Mmene mungalumikizirane nafe**

Kafukufuku ameneyu anavomerezeka ndi makomiti oyang'ana za chikhalidwe ndi ufulu wa anthu pa ntchito za kafukufuku a College of Medicine Research Ethics Committee (COMREC)

komanso London School of Hygiene and Tropical Medicine. Ngati muli ndi mafunso ena alionse okhuzana ndi ufulu wanu ngati wotenga nawo mbali, kapena madandaulo okhuzana ndi mmene akulandirirani mkafukufukuyu, chonde khalani omasuka kuwadziwitsa abambo **Augustine Choko** pa nambala iyi: +265 (0) 999 577 452, kapena powalembe kalata pa adiresi iyi: [augutc@gmail.com](mailto:augutc@gmail.com).

Ngati muli ndi mafunso pa za ufulu wanu kapena muli ndi madandaulo monga munthu otenga nawo mbali mukafukufukuyu adziwitseni a bungwe loyang'anira ufulu wa otenga mbali mu kafukufufuku la COMREC polemba kalata ku COMREC Secretariat, College of Medicine, Private Bag 360, Chichiri, Blantyre 3 kapena imbani foni pa 01871911 ext 334.

### Kupereka chilolezo

Ngati mukuvomereza kutenga nawo mbali mu kafukufukuyu mwakufuna kwanu, chonde, sayinani kapena lembani dzina lanu kapena dindani chidindo cha chala m'msimu kusonyeza kuti mukumvetsa uthenga umene wafotokozedwa m'mtundamu komanso kuti mukupereka chilolezo mwakufuna kwanu.

- |   |            |            |
|---|------------|------------|
| 10. Ndalandira ndi kuwerenga kapena andiwerengera chikalata chokamba za kafukufukuyu chofotokoza mwachindunji cholinga cha kafukufuku   | <b>Eya</b> | <b>Ayi</b> |
| 11. Ndamvetsetsa cholinga cha kafukufuku  | <b>Eya</b> | <b>Ayi</b> |
| 12. Ndafunsa mafunso onse amene ndinali nawo okhudzana ndi cholinga cha kafukufukuyu ndipo ndili okhutira kuti ndalandira mfundo zokwanira  | <b>Eya</b> | <b>Ayi</b> |
| 13. Ndamvetsetsa cholinga cha zokambiranazi   | <b>Eya</b> | <b>Ayi</b> |
| 14. Ndikufuna kutenga nawo mbali pa zokambiranazi   | <b>Eya</b> | <b>Ayi</b> |
| 15. Ndamvetsetsa zimene ndiyenera kuchita ndikatenga nawo mbali pa zokambiranazi  | <b>Eya</b> | <b>Ayi</b> |
| 16. Ndikudziwa kuti ndili ndi ufulu kusiya kutenga nawo mbali pa zokambiranazi kapena kukana kuyankha funso lina lirilonse  | <b>Eya</b> | <b>Ayi</b> |
| 17. Ndikudziwa kuti sindilandira chilango china chilichonse kuchokera kwa wochititsa kafukufuku, kapena ogwira ntchito za chipatala mtsogolo muno, ndikakana kutenga nawo mbali muzokambiranazi | <b>Eya</b> | <b>Ayi</b> |
| 18. <b>Ndikuvomereza kutenga nawo mbali mu kafukufukuyu mwakufuna kwanga</b>  | <b>Eya</b> | <b>Ayi</b> |

-----	-----	-----/-----/-----
Dzina la wotenga mbali	Siginecha/Chidindo cha chala	Tsiku

-----	-----	-----/-----/-----
Dzina la wakafukufuku	Siginecha/Nambala	Tsiku

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

-----	-----	-----/-----/-----
Dzina la mboni	Siginecha/Chidindo cha chala	Tsiku