# HIV Self-Testing AfRica (STAR) Malawi: Key Populations

***Monitoring social harms following peer-led delivery of HIV self-testing to key populations in Malawi***


**Malawi Investigators**

Dr Nicola Desmond [1,3] (Principal Investigator)
Professor Liz Corbett (Chief Investigator)[1,2,3]
Sarah Gibson [7]
Pitchaya Indravudh [1]
Wezzie Lora [1]
Phillip Mkandawire [8]
Chiwawa Nkhoma [8]

**Global Investigators**

Dr Helen Ayles [6]
Dr Rachel Baggaley [9]
Dr Virginia Bond [6]
Professor Frances Cowan [4,5]
Dr Katherine Fielding [2]
Dr Karin Hatzhold [7]
Dr Rein Houben [2]
Cheryl Johnson [9]
Professor Graham Medley [2]
Dr Melissa Neuman [2]
Professor Rosanna Peeling [2]
Dr Miriam Taegtmeyer [3]
Dr Fern Terris-Prestholt [2]
Amy Power [7]
Professor Helen Weiss [2]
Dr Richard White [2]

**Collaborating Institutions**

[1] Malawi-Liverpool-Wellcome Trust Clinical Research Programme, Malawi
[2] London School of Hygiene & Tropical Medicine, United Kingdom
[3] Liverpool School of Tropical Medicine, United Kingdom
[4] University College London, United Kingdom
[5] CeSSHAR: Centre for Sexual Health and HIV/AIDS Research, Zimbabwe
[6] ZAMBART: Zambia AIDS Related Tuberculosis Project, Zambia
[7] PSI: Population Services International, United States
[8] PSI: Population Services International, Malawi
[9] World Health Organization, Switzerland


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# Abbreviations

| | |
|---|---|
| ACASI | Audio Computer Assisted Self-Interview |
| ART | Antiretroviral Therapy |
| CBO | Community Based Organisation |
| CEDEP | Centre for Education & Development of People |
| CeSSHAR | Centre for Sexual Health, HIV, and AIDS Research |
| CIN | Critical Incident Narrative |
| COMREC | College of Medicine Research Ethics Committee |
| CRT | Cluster Randomised Trial |
| DHS | Demographic and Health Surveys |
| FBO | Faith-Based Organisation |
| FGD | Focus Group Discussion |
| FSW | Female Sex Worker |
| GBV | Gender-Based Violence |
| HIV | Human Immunodeficiency Virus |
| HIVOFT | HIV Oral Fluid Tests |
| HIVRDT | HIV Rapid Diagnostic Tests |
| HIVST | HIV Self-Testing |
| HTC | HIV Testing and Counselling |
| ID | Identification |
| IDI | In-Depth Interview |
| IEC | Information, Education and Communication |
| LDS | Longitudinal Diary Study |
| LSHTM | London School of Hygiene and Tropical Medicine |
| LSTM | Liverpool School of Tropical Medicine |
| MLW | Malawi Wellcome Trust Clinical Research Programme |
| MSM | Men who have Sex with Men |
| NGO | Non-Governmental Organization |
| REA | Rapid Ethnographic Assessment |
| PLHIV | People Living with HIV |
| PSI | Population Services International |
| PSI-M | PSI Malawi |
| PSI-Zam | PSI Zambia |
| PSI-Zim | PSI Zimbabwe |
| SBI | Serial Biographical Interview |
| SCQ | Self-Completed Questionnaire |
| SOP | Standard Operating Procedures |
| STAR | Self-Testing Africa |
| TAG | Technical Advisory Group |
| TB | Tuberculosis |

| | |
|---|---|
| UCL | University College London |
| UNAIDS | Joint United Nations Programme on AIDS |
| VMMC | Voluntary Medical Male Circumcision |
| WHO | World Health Organisation |

# 1. Executive summary

## 1.1 Research problem

In Malawi, adult HIV prevalence remains high, with pronounced social and economic inequity in access to HIV prevention, testing and care services. Prevalence is even higher among key populations, specifically Female Sex Workers (FSW) and Men who have Sex with Men (MSM), due to their high risk of HIV infection and low uptake of HIV testing. Stigma among these groups act as an additional barrier to accessing facility-based HIV-related services.

Self-testing for HIV is becoming an increasingly plausible option with the recent development of simple and accurate oral test kits, which have proven to be highly accurate when used by lay clients. However, HIVST research to date has largely been limited to a single delivery model among general populations. More research is needed on the acceptability of HIVST among key populations and the social benefits and harms of introducing HIVST to particularly vulnerable groups, such as FSWs and MSM.

## 1.2 Research description

HIV STAR Malawi Key Populations is a longitudinal, mixed methods study monitoring social harms among FSWs as part of a pilot distribution of HIVST kits. Formative research among FSWs and MSM will also be conducted to inform development of peer-led HIVST distribution models.

Research under HIV STAR Malawi KP will be managed by the Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW), London School of Hygiene and Tropical Medicine (LSHTM), and London School of Tropical Medicine (LSTM). Population Services International (PSI) will oversee all HIVST implementation activities.

## 1.3 Research aims and objectives

### 1.3.1 Research objectives – broad

The aim of HIV STAR Malawi KP is to investigate appropriate HIVST delivery models among FSWs and MSM and monitor unintended social consequences and human rights impacts from introducing HIVST to FSWs and MSM in Malawi.

### 1.3.2 Research objectives – specific

1. To conduct a situation analysis that establishes current HIV testing services that are available to key populations and the outstanding HIV testing needs of FSWs and MSM.
2. Determine preferred HIVST delivery models among FSWs and MSM in Malawi.
3. Investigate the acceptability and feasibility of using peer distributors of HIVST among FSWs in Malawi.
4. To determine the impact of HIVST on social relations, structural support systems, and exposure to violence at the household and community level.
5. To investigate decision-making dynamics around HIVST and the nature and extent of coercive testing and disclosure among FSWs.

6. To estimate linkage into and retention in HIV care following a positive self-test result among FSWs in Malawi.

## 1.4 Methodology

Monitoring of social harms will take place alongside peer-led delivery of HIVST kits. The study will employ quantitative and qualitative methods to assess the social benefits and harms of introducing HIVST among FSWs. IDIs, FGDs, quantitative Audio Computer Assisted Interviews (ACASI) and longitudinal diary studies (LDS) with FSWs are aimed at understanding decision-making processes around HIVST and social benefits and harms from self-testing. MLW-LSHTM will then pilot peer-led delivery models, which will be assessed through participatory workshops and Focus Group Discussions (FGD) with FSWs. FGDs will also be conducted with peer distributors to understand their potential role in reducing unintended social consequences from HIVST.

Formative research will be conducted to examine the HIV testing needs of key populations and inform effective models for HIVST delivery by peer distributors through Key Informant Interviews (KIIs) and Rapid Ethnographic Assessments (REA) with FSWs and MSM. A prototype peer delivery model will be validated among FSWs and MSM through FGDs and participatory workshops.

## 1.5 Research findings and dissemination

Early evidence in Malawi points to substantial willingness to self-test and the potential of HIVST products to provide affordable community-based HTC and improve linkages to HIV services. The results of this research will be used to guide the introduction of self-testing into community-based HTC models and the formation of national and international policies around HIVST. Results will be disseminated to the Ministry of Health (MoH) HIV Unit, College of Medicine Research and Ethics Committee (COMREC) and UNITAID. Findings will also be distributed internationally to global health policy makers, nationally to the Malawian government, and regionally to District and Council Health Offices.

# 2. Background

Malawi has a high HIV prevalence, with an estimated 10.2% of adults living with HIV. Of those who are HIV positive, 46% are on Antiretroviral Therapy (ART) (UNAIDS, 2014). In key populations, HIV prevalence is substantially higher than in the general population, with estimated prevalence of 21.4% among Men who have Sex with Men (MSM) and 70.7% among Female Sex Workers (FSWs) (Wirtz, et al., 2014) (Baral, et al., 2009).

Major factors driving new HIV infections in Malawi include lack of knowledge on partner HIV status in serodiscordant relationships, high rates of transactional sex, and low uptake of HIV prevention services including consistent condom use and Voluntary Medical Male Circumcision (VMMC) (UNAIDS, 2014). According to the 2010 Demographic and Health Survey (DHS), 9.7% of male respondents had paid for sex at least once, with low condom use (60.7%) during transactional sex (National Statistical Office and ICF Macro, 2011). Uptake of VMMC in Malawi was estimated as 2% in December 2012 (UNAIDS, 2014).

Reaching the Joint United Nations Programme on AIDS (UNAIDS) 90-90-90 targets (90% of all HIV-positive individuals aware of their status, of whom 90% are retained in ART programmes, of whom 90% have viral load suppression) will require substantial scale-up of HIV testing services with new approaches that more effectively reach marginalised populations who are not well served by current approaches. Notable gaps in HIV Testing and Counselling (HTC) coverage exist for men, adolescents (age 16 to 19 years), rural Malawians and the poorest members of society (National Statistical Office and ICF Macro, 2011).

A further challenge is that linkage into HIV treatment and VMMC services following HTC remains suboptimal. In Blantyre, only 50.7% of newly diagnosed People Living with HIV (PLHIV) at routine facilities had successfully completed eligibility assessments and were retained into care 6 months after testing positive (MacPherson, et al., 2012).

Barriers to HTC and ART initiation include long distance and congestion of health facilities, concerns about lack of confidentiality and privacy, and high out-of-pocket costs (MacPherson, et al., 2012; Morin, et al., 2006; Angotti, et al., 2009). These barriers are particularly significant among certain demographics, including men, young people, impoverished rural residents (Weinreb & Stecklov, 2009) and key populations (i.e., SWs, MSM) (Govindasamy, Ford, & Kranzer, 2012). Therefore, current HTC strategies, which are predicated on clinic-based service delivery, need to be complemented by affordable community-based services that allow better coverage, particularly for key populations and rural populations in Malawi.

Based on previous work in Malawi, proactive and accountable distribution of HIV Self-Testing (HIVST) products offers the promise of providing a safe and accurate form of HIV testing and facilitating acceptable rates of linkage into HIV care.

## 2.1 HIV self-testing

The development of HIV Rapid Diagnostic Tests (HIVRDT) has enabled highly accurate results from HIVST when carried out by untrained lay clients (Choko, et al., 2015). On a societal level, HIVST requires lower human resource demands and could provide more cost-

effective community-based HTC in comparison to current community-based models (Cambiano, Mavedzenge, & Phillips, 2014).

HIVST kits are already available for purchase over-the-counter in several countries, including the United States, United Kingdom, and Kenya. However, the availability of quality-assured HIVST products will remain limited in resource-poor settings until the purchase of HIVST kits using donor funds is possible and national HIV programmes have adapted policy and programme documents, including algorithms and training materials, to fully accommodate HIVST (Ministry of Health Kenya, 2009).

To be put on approved donor purchase lists, HIVST products need to be suitably low cost and be supported by:

1. Product approval by the World Health Organisation (WHO) Prequalification Department. An application is currently underway for OraQuick ADVANCE Rapid HIV-1/2 Antibody Test – the HIVST product to be used under the HIV STAR Malawi study – and has already received approval from the United States Food and Drug Administration (FDA).
2. WHO guidelines to support the use of HIVST in defined populations, such as rural and urban adults living in high HIV prevalence settings, adolescents, and key populations.

WHO and UNAIDS have already issued Technical Updates that are supportive of HIVST, but the development of full guidelines requires results from implementation research to evaluate the public health risks and benefits from introducing HIVST into a range of settings. Key considerations include user ability to conduct HIVST and interpret results, user ability to cope with and act upon positive HIVST results in the absence of face-to-face counselling, the accuracy of test results particularly among low literacy populations, and the potential for unwanted social harms such as coercive testing and gender-based violence (GBV) (Napierala Mavedzenge & Corbett, 2009; Wright & Katz, 2006; Pant-Pai & Klein, 2008; Frith, 2007).

Though evidence to date has been reassuring, more data is needed from implementation studies in representative African populations (Napierala Mavedzenge & Corbett, 2009; Wright & Katz, 2006; Pant-Pai & Klein, 2008; Frith, 2007; Gaydos, et al., 2009; Project Masiluleke, 2010)

### 2.2 HIV self-testing in Malawi

Malawi has assumed a leadership position in HIVST research, with the only large-scale implementation project to date. From 2012-2015, a HIVST study was conducted in Blantyre in collaboration with the National HIV department (Choko, et al., 2015) and has produced results that have been highly influential in moving forward international policy regarding HIVST.

Choko, et al. demonstrated that there was high readiness for HIVST, with pronounced user preference for HIVST over facility-based services, and high accuracy of results. Acceptability was even high among men and adolescents, who have been difficult to reach with standard HTC services. Acceptable rates of linkage to confirmatory testing and HIV care services were also obtained through the promotion of HIVST by briefly trained local volunteers and provision of home-based ART eligibility assessments (MacPherson, et al.,

2014). This resulted in a significant increase in demand for ART services at population level.

Additionally, national HIV policies and strategic frameworks (e.g., 2016-25 National HIV and AIDS Strategic Plan, 2015-20 HIV Prevention Strategy), have started to mention HIVST, but have yet to include adapted HIV testing algorithms and HTC materials and standard operating procedures and guidelines for how HIVST should complement current HTC models.

## 2.3 UNITAID/PSI HIV STAR project

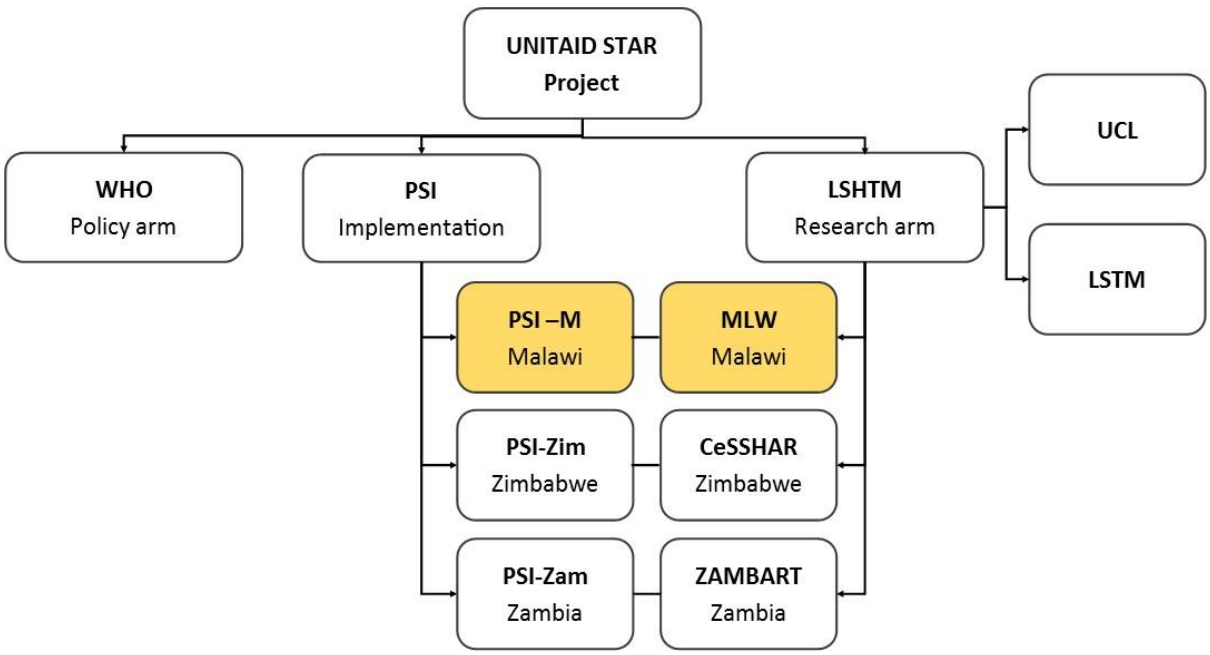
The UNITAID/PSI HIV STAR project will conduct HIVST implementation research to generate the evidence base required for WHO guidelines in Malawi, Zambia and Zimbabwe. The project has a dual focus on marginalised sections of the general population (defined by poor coverage of HTC under current strategies) and key populations (i.e., FSWs, MSM).

Collaborators include WHO, Population Services International (PSI), London School of Hygiene and Tropical Medicine (LSHTM), Liverpool School of Tropical Medicine (LSTM), and University College London (UCL).

PSI is responsible for HIVST implementation, while LSHTM, in conjunction with local partners (the Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW) in Malawi) is responsible for implementation research. WHO will lead the development of policy and regulatory guidelines around HIVST.

The funding body for the UNITAID/PSI HIV STAR project is UNITAID, a United Nations organisation housed within WHO that supports the development and optimisation of robust, high-quality and low-cost products specifically intended to meet the diagnostic and pharmaceutical needs of HIV, tuberculosis (TB) and malaria programmes in low-resource countries.

**Figure 1. HIV STAR Project Organogram**



### 2.3.1 Overall project goal

The UNITAID/PSI HIV STAR project aims to catalyse the HIVST market regionally by testing innovative interventions and strengthening the evidence base around the effective use of HIVST through formative research and impact evaluation.

### 2.3.2 Overall project objectives

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

The secondary objectives are:

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

**Figure 2. HIV STAR objectives and activities**

| Objectives | Implementation Activities | Research Activities | Policy Activities |
|---|---|---|---|
| **1. Increase access to quality-assured HIVST among target populations in intervention areas.** | • Distribute HIVST kits through CBDAs, social marketing franchises, peer educators, and VMMC mobilisers to target populations. | • Conduct formative research and preparatory work for HIV distribution models.<br>• Pilot and conduct interim evaluations of HIV distribution models. | • Partner with MoH on developing training curriculum and tools for CBDAs and defining acceptable CBDA cadres.<br>• Work with MoH to include HIVST in national algorithms. |
| **2. Increase informed consumer demand for quality-assured HIVST.** | • Develop marketing and communication strategy using marketing planning processes.<br>• Strategically design and test branded packaging and | • Conduct formative market research to better understand barriers and motivators to using HIVRDT for self-testing.<br>• Perform economic and mathematical modelling of HIVST | • Share findings on user preferences with MoH collaborators. |

| | | | |
|---|---|---|---|
| | inserts. | delivery. | |
| **3. Reduce policy barriers to market entry for quality-assured HIVST products.** | • Establish expert HIVST Advisory Board to provide scientific oversight on project implementation and to inform global quality standards and guidelines. | • Provide technical support and assistance for global and national-level policy makers and regulators.<br>• Disseminate findings at key intervals with local, national and international stakeholders. | • Develop normative guidance on HIVST. |

### 2.3.3 Summary of UNITAID/PSI HIV STAR activities in Malawi

In 2016 and 2017, PSI plans to provide a total of 171,054 HIVST kits to underserved general population adults and key populations in Malawi using multiple distribution channels. As part of HIVST implementation to key populations, MLW will pilot the delivery of HIVST kits to FSWs through peer distributors.

MLW-LSHTM will conduct a series of research studies, packaged as *HIV STAR Malawi*, to inform and evaluate PSI HIVST implementation. The HIV STAR Malawi study is then divided into two protocols based on the target population segment:

1. *HIV STAR Malawi General Population (HIV STAR Malawi GP)* – This protocol consists of a cluster randomised trial (CRT) to evaluate HIVST interventions among the general population. The study will also conduct formative research to inform the design of HIVST distribution models.
2. *HIV STAR Malawi Key Populations (HIV STAR Malawi KP)* – This protocol covers formative research to inform peer-led delivery models among FSWs and MSM and a pilot study of peer-based FSW delivery. The study will also carry out social harms research to monitor unintended consequences from accessing HIVST among a sub-cohort of participants within the pilot delivery model.

**Figure 3. Breakdown of target populations**

| Target Populations | Target Number of Self-Tests* Year 1 | Year 2 | Total | Districts | Distribution models |
|---|---|---|---|---|---|
| **1. General population** | | | | | |
| **Rural and peri-urban populations** | 25,000 | 96,000 | 121,000 | Blantyre, Mwanza, Machinga, Thyolo | CBDAs |
| **Tunza social franchise clients** | 3,600 | 27,000 | 30,600 | Mchinji, Lilongwe, Salima, Dedza, Nkhotakota, Kasungu | Tunza providers |
| **Potential VMMC clients** | 1,500 | 4,800 | 6,300 | Blantyre | VMMC mobilisers |
| **2. Key populations** | | | | | |
| **FSWs** | 1,728 | 8,294 | 10,022 | Blantyre | FSW peer educators |

| | | | |
|---|---|---|---|
| **Total** | **32,368** | **138,686** | **171,054** |

*Includes cases of repeat testing with the same individual.

# 3. Rationale and objectives

## 3.1 Rationale

In Malawi, adult HIV prevalence remains high, with pronounced social and economic inequity in access to HIV prevention, testing and care services. Prevalence is even higher among key populations, specifically Female Sex Workers (FSW) and Men who have Sex with Men (MSM), due to their high risk of HIV infection and low uptake of HIV testing. Stigma among these groups act as an additional barrier to accessing facility-based HIV-related services.

Self-testing for HIV is becoming an increasingly plausible option with the recent development of simple and accurate oral test kits, which have proven to be highly accurate when used by lay clients. Early evidence in Malawi points to substantial willingness to self-test and the potential for HIVST products to provide affordable community-based HTC and improve linkages to HIV services. However, HIVST research to date has largely been limited to a single delivery model among general populations. More research is needed on the acceptability of HIVST among FSWs and MSM and the social benefits and harms of introducing HIVST to particularly vulnerable groups.

## 3.2 Research question

What are the social benefits and harms of introducing HIVST to key population, specifically FSWs, in Malawi?

## 3.3 Research objectives

### 3.3.1 Research objectives – broad

The aim of HIV STAR Malawi KP is to investigate appropriate HIVST delivery models among FSWs and MSM and monitor unintended social consequences and human rights impacts from introducing HIVST to FSWs in Malawi.

### 3.3.2 Research objectives – specific

1. To conduct a situation analysis that establishes current HIV testing services that are available to key populations and the outstanding HIV testing needs of FSWs and MSM.
2. Determine preferred HIVST delivery models among FSWs and MSM in Malawi.
3. Investigate the acceptability and feasibility of using peer distributors of HIVST among FSWs in Malawi.
4. To determine the impact of HIVST on social relations, structural support systems, and exposure to violence at the household and community level.
5. To investigate decision-making dynamics around HIVST and the nature and extent of coercive testing and disclosure among FSWs.
6. To estimate linkage into and retention in HIV care following a positive self-test result among FSWs in Malawi.

# 4. Methodology

## 4.1 Study description

HIV STAR Malawi Key Populations is a longitudinal, mixed methods study monitoring social harms among FSWs as part of a pilot distribution of HIVST kits. Formative research among FSWs and MSM will also be conducted to inform development of peer-led HIVST distribution models. HIV STAR Malawi KP builds on a previous Blantyre-based study, which explored the social impacts of introducing HIVST to the general population (Desmond N. , The Social Impact of HIV Self-Testing: Reconstructing Knowledge and Re-framing Risks Associated with HIV Prevention).

Monitoring of social harms will take place alongside peer-led delivery of HIVST kits. The study will employ quantitative and qualitative methods to assess the social benefits and harms of introducing HIVST among FSWs. IDIs, FGDs, quantitative Audio Computer Assisted Interviews (ACASI) and longitudinal diary studies (LDS) with FSWs are aimed at understanding decision-making processes around HIVST and social benefits and harms from self-testing. MLW-LSHTM will then pilot peer-led delivery models, which will be assessed through participatory workshops and Focus Group Discussions (FGD) with FSWs. FGDs will also be conducted with peer distributors to understand their potential role in reducing unintended social consequences from HIVST.

Formative research will be conducted to examine the HIV testing needs of key populations and inform effective models for HIVST delivery by peer distributors through Key Informant Interviews (KIIs) and Rapid Ethnographic Assessments (REA) with FSWs and MSM. A prototype peer delivery model will be validated among FSWs and MSM through FGDs and participatory workshops. (Desmond, The Social Impact of HIV Self-Testing: Reconstructing Knowledge and Re-framing Risks Associated with HIV Prevention).

MLW will pilot HIVST kit distribution to key populations through two peer-led models, targeted respectively toward street-based FSWs and venue-based FSWs. All UNITAID/PSI HIV STAR activities, including the MLW-led pilot, will use the same HIV Oral Fluid Test (HIVOFT) for self-testing – OraQuick ADVANCE Rapid HIV-1/2 Antibody Test. The kits, which are manufactured by Orasure, contain the HIVOFT, stand for the buffer solution, IFUs, materials on counselling and linkage to care, and primary and secondary packaging. A toll-free telephone number will also be provided with the HIVST kit, which can be used to access verbal pre-test information, test instructions, and results-based post-test information. All kits are provided free of cost.

## 4.2 Study location

Formative research among FSWs and MSM and piloting of FSW-led HIVST delivery will take place in urban Blantyre.

## 4.3 Study population

The HIV STAR Malawi KP study population (age ≥ 16) for the formative research consists of the following groups:

1. *FSWs* – Female older adolescents or adults whose primary source of income comes from the sale of sex, though this does not necessarily mean that they identify as sex workers. Transgender women are not included as part of this sample. Further, FSWs can be divided into two groups: 1) street-based FSWs, who primarily solicit or conduct their business in public spaces, and 2) venue-based FSWs, who are employed by, associated with, or operate from venues such as hotels, bars, restaurants or brothels.
2. *MSM* – Male older adolescents or adults who engage in sexual activities with members of the same sex (regardless of their identified gender).
3. *Peer educators* – FSW peer educators who will distribute the HIVST kits as part of the pilot study.
4. *Venue owners* – Owners of hotels, bars, restaurants, brothels or other establishments that host FSWs or MSM.
5. *Stakeholders* – Community-based organisations (CBO), non-governmental organisations (NGO), or faith-based organisations (FBO) that target or serve FSWs or MSM.

Only FSWs and peer educators will make up the study population for the piloting of HIVST distribution and monitoring of social harms.

## 4.4 Study period

The formative study will take place in April and May 2016. The study will conduct KIIs and REAs in Blantyre, and provide recommendations on a pilot peer-led delivery model. These recommendations will be refined based on feedback from participatory workshops with FSWs and MSM.

In June, the study will then pilot peer-led distribution of HIVST kits among FSWs, with feedback from FSWs and peer distributors collected after the pilot through FGDs.

Social harms research will start the same time as the HIVST pilot. Staggered recruitment of ACASI (and LDS and SBI) participants will take place during the first three months of distribution. ACASIs and SBIs will be conducted following study enrolment, with follow-up ACASIs performed three months later. During this period, participants will also be asked to maintain a diary to record social harms.

Peer distributors will also monitor unintended consequences experienced by FSWs who have accessed HIVST through Critical Incident Narratives (CIN). Finally, in December 2016, MLW-LSHTM will conduct FGDs with peer distributors and FSWs.

Data transcription, translation, cleaning and analysis will happen during the data collection period, with a preliminary report on the results generated in January 2017.

## 4.5 Pilot delivery procedures

A peer-led delivery model appropriate for both street-based and facility-based FSWs will be developed for urban Blantyre. This model will be based on a combination of the WHO guidelines for delivering HIV services for sex workers (WHO, 2013), previous sexual and reproductive health delivery models for FSW employed by PSI in Malawi, and the

formative research and results from FGDs and participatory workshops under HIV STAR Malawi KP. An amendment outlining the details for the final selected peer-delivery model will be submitted following the formative research phase.

This workshop will confirm context-driven details for the local setting, including the type of peer-based delivery system for HIVST and appropriate linkage to care models following HIVST. Advice and materials will also be taken from an established Zimbabwe team providing comprehensive sexual and reproductive health services under Prof. Frances Cowan.

### 4.5.1 HIVST distribution

Peer distributors will be provided with training in HIVST, instructional leaflets and Information, Education and Communication (IEC) materials in Chichewa, used kits to show participants how to interpret positive, negative and inconclusive results, a cotton bud and vial of water to demonstrate the mouth swabbing and development process, and a buffer stock of OraQuick ADVANCE HIV I/II test kits to be stored in a locked container in their own home. There are no sharp or hazardous materials.

All participants will be offered pre- and post-test information, including how to access confirmatory testing and ART services. Participants will also be given the opportunity to discuss any fears about the process or results prior to testing and to disclose their status and receive advice and support for post-test services. A toll-free telephone number will also be provided with the HIVST kit, which can be used to access verbal pre-test information, test instructions, and results-based post-test information and also to report any adverse events arising as a consequence of HIVST.

Process data on HIVST delivery by peer distributors will be captured using HIVST logbooks (e.g., date, name, number of test-kits taken) but not results. If considered acceptable when discussed in the FGDs and participatory workshops, participants will be encouraged to return used kits with a self-completed questionnaire (SCQ) in an opaque envelope. The envelope will be posted in a locked opaque "ballot box" provided by the study team to each peer distributor.

Kits will be replaced by MLW following inspection of an HIVST logbook. HIVST logbooks will be kept at the peer distributor's home in a locked container.

### 4.5.2 Linkage to care following HIVST

Participants will not be required to disclose their HIVST results to the peer distributor. Peer distributors will receive training in providing post-test support, including providing 'generic' information as well as standard, results-based support. Peer-distributors will be trained on the importance of maintaining confidentiality.

Confirmatory testing and linkage to care for pilot study participants who self-test HIV positive will be supported through two approaches:

1. Information will be compiled on all clinics providing special services for sex workers within Blantyre and will be provided by peer-distributors along with a 'self-referral card' at the time of kit distribution.

2. The self-referral card will also provide details on how to directly access a STAR study clinical officer or nurse who will offer confirmatory testing and counselling and provide the first 2 weeks of HIV care medications and registration into routine ART clinic services for subsequent management.

## 4.6 Sampling method and sample size

### 4.6.1 Formative research

#### *4.6.1.1 Key informant Interviews (KII)*

Stakeholders engaged with FSWs and MSM will be recruited for KIIs through snowball sampling methods. The research team will capitalise on existing relationships between PSI and the National Female Sex Worker Alliance and identify structures and services that are associated with street-based and venue-based FSWs. Services that are associated with MSM will similarly be located through existing relationships between PSI and the Centre for Education and the Development of People (CEDEP). The study will use these relationships to link with other organisations conducting similar work.

Once stakeholders have been identified, they will be asked to provide written consent to participate in IDIs. Interviews will be conducted until the point of saturation when new links are no longer possible.

#### *4.6.1.2 Rapid Ethnographic Assessments (REAs)*

The MLW-LSHTM team will identify venue owners and FSWs and MSM for REAs through snowball sampling. Venue owners will be asked for written consent to offer their venue for participant observations. Verbal consent will be taken for informal REA interviews with FSWs and MSM.

The total number of REA participants will be determined once the study has reached saturation point.

#### *4.6.1.3 Participatory workshop and FGDs*

Participatory workshop and FGD participants will be randomly selected from the group of FSWs who accessed HIVST during the pilot of the REAs in Blantyre. There will be 2 FGD and 2 participatory workshops for FSWs with 8-12 participants, who will be asked to provide written consent.

### 4.6.2 Social harms research

#### *4.6.2.1 ACASI and Longitudinal Diary Studies (LDS)*

MLW-LSHTM will work with peer distributors to recruit study participants during the HIVST pilot period. Distributors will briefly discuss the aims of the social harms study and record if HIVST users are interested in participating in the study.

The study team will then visit all peer distributors to review the registers and follow up with eligible participants. Those who give informed written consent will be enrolled into the study.

Staggered recruitment will take place over a three-month period and aim to reach a total of 204 participants of the 1,728 target population in Year 1, including 102 street- and 102

venue-based FSWs. The sample size is calculated based on the assumption that there are at least 3614 FSWs (Chizimba & Malera, 2011) in Blantyre (Wright & Katz, 2006). An additional assumption is that there are at least 400 street-based SWs and 400 venue-based FSWs who will have accessed HIVST kits from peer distributors.

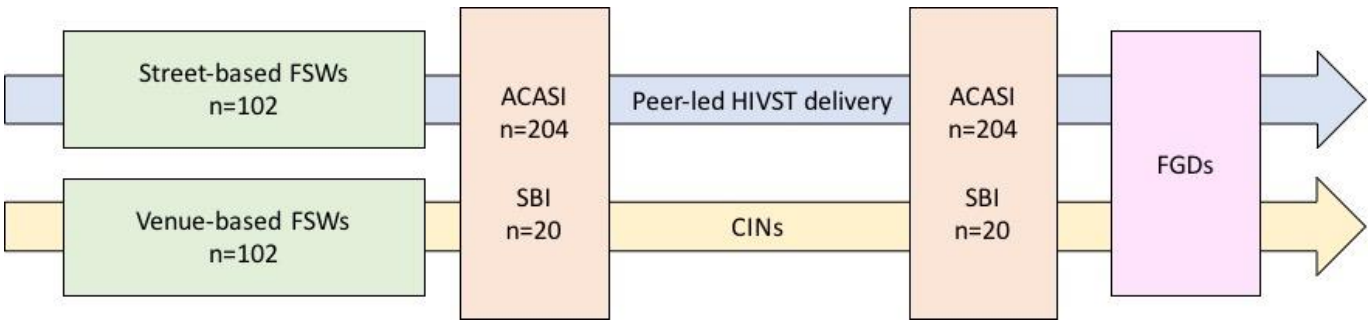
The sample size of 204 FSWs has been chosen to provide 3% precision around an estimated prevalence of social harms related to HIVST of no more than 5% (N=PQ/(E/1.96)^2).

#### *4.6.2.2 Serial Biographical Interviews (SBIs)*

From the random sample of ACASI participants, 20 FSWs will be purposively selected to participate in SBIs. FSWs will be selected to ensure that there is sufficient representation of participants who identify as sex workers and participants who do not identify sex workers but sell sex in exchange for material goods or money.

Eligible participants will then receive information about the SBIs and have the opportunity to provide informed, written consent. Participants will take part in two SBIs, each following the first and second ACASI.

**Figure 4. Social harms evaluation**




#### *4.6.2.3 Critical Incident Narratives (CINs)*

Peer distributors will be asked to report social harms that have occurred among FSWs who had access to HIVST during the project implementation period. FSWs who report critical incidents will be confidentially followed up by the MLW-LSHTM team and asked if they would like to participate in CINs. Following written, informed consent, the study team will conduct CINs with enrolled participants.

#### *4.6.2.4 FGDs*

Peer distributors will identify 2 hotspots (1 street-based FSW and 1 venue-based FSW) and recruit 8-12 participants from each hot spot for FGDs (n=24). FSWs who may or may not have accessed HIVST, will be approached about the study and asked to provide written consent.

Additionally, the study will respectively conduct two FGDs with peer distributors from each key population group (n=24). Peer distributors will be given information about the FGD and the opportunity to provide written consent.

## 4.7 Data collection

HIV STAR Malawi KP data collection will involve the use of paper-based forms and computer-based and digital audio recorders. Further, quantitative and qualitative data will be gathered using methods detailed in the rest of this section.

### 4.7.1 Formative research

#### *4.7.1.1 Document review*

MLW-LSHTM will perform a document review of organisations that are supporting or working with key populations. For the document review, personnel responsible for archiving documents at each organisation will be approached and asked to share documents that pertain to their work with FSWs or MSM. Data will then be gathered on the organisation's services, methods of delivery, and programmatic impact.

#### *4.7.1.2 Key Informant Interviews (KIIs)*

KIIs with stakeholders seek to understand the HIV testing needs of FSWs and the types of health services that are being provided for key populations. KIIs will be conducted with representatives from each identified organisation and will cover topics on organisational background, target population, and service delivery models.

#### *4.7.1.3 REAs – mapping exercises, staged participant observations, and informal interviews*

REA activities, which include mapping exercises, staged participant observations and informal interviews, will be implemented as part of the situation analysis.

The study team will conduct mapping exercises to identify establishments and locations that are associated with FSWs and MSM in urban Blantyre. Information will also be collected on the estimated number of FSWs and MSM and their locations of residence and work.

Researchers will also immerse themselves in identified key population hotspots, paying particular attention to the physical environment and social interactions by FSWs and MSM. Staged participant observations will be used to understand the behaviours, needs and practices of key populations and potential social and structural barriers and facilitators to HIVST. Power dynamics are also of interest, specifically between clients and FSWs, venue owners and FSWs, and among key population members themselves.

Additionally, informal interviews will be administered with venue owners, FSWs, and MSM. Notes will be taken after conducting the interviews.

#### *4.7.1.4 Participatory workshops*

Using participatory workshops, MLW-LSTHM will launch discussions with FSWs and MSM around the results of the REA and development of a peer-led delivery model for HIVST. During the workshop, participants will be asked to identify weaknesses of traditional delivery methods and potential barriers and facilitators to the adoption of HIVST. The workshops will confirm context-driven details for the local setting, including for example the type of peer-based delivery system and appropriate linkage to care strategies.

#### *4.7.1.5 FGDs*

A series of FGDs with FSWs and MSM will be undertaken to assess the acceptability and uptake of the prototype HIVST delivery model. Specific themes to be discussed will include what needs to be modified for each target group. In addition, the study is interested in understanding the quality of the HIVST process and identifying contextual factors associated with any variation in quality.

### 4.7.2 Social harms research

#### *4.7.2.1 ACASI*

FSWs will take part in ACASIs both at the point of enrolment and three months after enrolment in order to monitor the social impact of HIVST. The questionnaire will cover reported sexual behaviours, HIV testing practices and incidents of social harms in the three months prior to each ACASI.

Participants will be trained to complete the ACASI questionnaire, which is presented both orally and visually to address any literacy issues among participants. ACASIs will be piloted prior to the study to ensure that the user is able to operate the tool.

#### *4.7.2.2 Longitudinal Diary Studies (LDS)*

After the ACASI, FSW participants will be asked to complete a daily pictorial diary to measure the frequency and nature of sexual behaviours, HIV testing, and social harms in the three months following HIVST. The reported events for the second ACASI will be validated against the LDS data.

Pictorial representations of key variables will be developed and pre-tested in collaboration with local artists and community members. Prototype designs for pictures will be presented and discussed with FSWs to ensure cultural acceptability and optimise user understanding. Each of the key variables will be developed into pictures with tick boxes for marking occurrences and events on a daily basis.

The diary will be designed to cover two weeks, with collection on a biweekly basis by researchers. Instructions for completion and emergency contact numbers will be provided by the study team. MLW-LSHTM will establish a close rapport with the cohort of FSWs to address any ongoing issues and to ensure that the diaries are completed at regular intervals.

The diary will be formatted similarly to the diary used for a previous social harms study in Blantyre (Desmond, et al., 2016)

#### *4.7.2.3 Serial Biographical Interviews (SBIs)*

After each ACASI, SBIs will be conducted with FSWs and MSM to explore decision-making processes and social harms related to HIVST. The SBI will document the experiences of participants around HIV testing and compare power dynamics, risks, and social harms in the three-month period before and after HIVST.

Events reported in the SBI will be triangulated against the ACASI and LDS.

#### *4.7.2.4 Critical Incident Narratives (CINs)*

MLW-LSHTM will conduct CINs with FSWs who have reported experiencing social harms from self-testing. As part of the CIN, consenting participants will be asked to recount HIV testing practices and previous episodes of social harm.

#### *4.7.2.5 FGDs*

FGDs with FSWs will explore the impact of HIVST on the community level. Topics of discussion include perceptions of HIVST, sources of information on HIV testing, community relations and decision-making around HIV testing, and the impact of HIVST on the community.

The study team will also conduct FGDs with peer distributors to understand their influence on the overall HIVST process and experience. Issues to be explored include the experience of HIVST initiation, interpretation of HIV test results, and issues around confidentiality, willingness to test, and disclosure.

## 4.8 Data management

### 4.8.1 Quantitative data

Quantitative data from the ACASIs and LDS will be entered into a Filemaker Pro database. Diaries will be collected from participants on a biweekly basis and regularly checked for errors.

All data will be cleaned and analysed using Stata software (Stata Corporation, College Station, Texas, USA). All participants will be assigned a study ID number to link qualitative and quantitative data. Participant names will not be linked except through paper-based recruitment logs, which will be stored in locked cupboards and not entered into electronic form.

### 4.8.2 Qualitative data

Qualitative data will be collected through investigator notes, qualitative forms, and digital audio recorders. Following each day of data collection, the investigators will be responsible for expanding their notes and entering them into a text file. All files will be saved on REDCap, the MLW data management programme, as a backup copy on MLW-hosted servers in Malawi. REDCap is a secure and web-based application designed to support data capture and storage. Only researchers and transcription and translation team will be given individual log in details from the Data Manager in order to access REDCap. Qualitative forms will be captured using Optical Character Recognition technology.

For audio recorders, following each interview or focus group, the investigator will be responsible for saving the audio file on REDCap as a backup copy and transfer a copy to the transcription and translation team. The audio file will be transcribed verbatim into written chiChewa and translated to English within the same document. All data will then be transferred to a qualitative data analysis software package, NVIVO 10 (QSR, Melbourne, Australia) and filed according to document type.

## 4.9 Data analysis

Data from the REAs will be analysed to understand the HIV testing needs of FSWs and MSM used to develop prototypes of peer-led delivery models that are acceptable to key populations. Researchers will take findings from the FGDs to modify the prototype model before the pilot phase.

Quantitative and qualitative results from the ACASIs and LDS will be triangulated to understand the frequency and nature of reported social harms, including coercive testing and GBV, pre- and post-HIVST. Analysis of the SBIs, using longitudinal case study analysis, and CINs will help to derive whether incidences of social harm stem from the introduction of HIVST.

Linkage into care will then be estimated from the number of participants using self-referral cards to access services at collaborating sex-worker clinics or through the study's clinic service. If return of used HIVST kits with self-completed questionnaire is considered acceptable and is high, then an established method of rereading returned test kits against self-reported results and ART status on the self-completed questionnaire will be used to provide a denominator for estimated numbers of newly diagnosed HIV-positive participants (Choko, et al., 2015). To monitor retention in care, the study will extract routine facility attendance records for all participants who are referred into HIV care through the STAR study clinic, using the ART clinic number provided at the time of registration.

If found acceptable in discussions with FSWs, MLW-LSHTM is also interested in determining the accuracy of HIVST by comparing self-read HIVST results, as recorded into a self-completed questionnaire to reread results by field supervisors (Choko, et al., 2015). Data will also be used to inform economic and mathematical modelling studies to estimate the expected costs and benefits from introducing HIVST to key populations.

## 4.10 Results presentation and dissemination

Quantitative results will be presented through tables and histograms, line graphs and other figures, where relevant.

The results of this research will be used to guide the introduction of self-testing into community-based HTC models and the formation of national and international policies around HIVST. Results will be disseminated to the MoH HIV Unit, COMREC and UNITAID. A report on the study will be produced and disseminated to COMREC, the College of Medicine (COM) Library, the Health Sciences Research Committee and the University Research and Publication Committee. Findings will also be distributed internationally to global health policy makers, nationally to the Malawian government, and regionally to District and Council Health Offices. Presentations will be given at the COMREC research dissemination day and at MLW research-in-progress meetings. Copies of peer-reviewed publications from the research will be submitted to COM, MLW, and LSHTM.

In terms of public engagement, the MLW-LSHTM team will work with the MLW Science Communication team to disseminate the project results and raise the profile of HIVST in Malawi. MLW actively engages with both urban and rural communities, and has already hosted a range of programmes including science cafes, radio projects, and mobile exhibitions about HIVST. These mediums will be employed to educate the general public about the UNITAID project and the results.

# 5. Ethical considerations

## 5.1 Confidentiality and privacy

This project targets sensitive issues and behaviours related to HIV testing, sexual practices and social harms. An HIVST log will be maintained by peer distributors, and will include the name of kit recipients in order to promote accountability and enable purposive sampling of HIVST participants for the social harms evaluation studies. HIVST logs will be kept at the peer distributors house in a locked container provided by the project to each peer distributor, and will be collected and stored in a locked cabinet in MLW at the end of the study. Results will not be recorded on the named HIVST log, and names will not be recorded on any other data collection form or electronic record.

Peer distributors and field workers will be trained on confidentiality procedures. Participants will be given a unique identifier (Study ID number) used to allow linkage of qualitative and quantitative data without breaching confidentiality. Hard copies of participant screening logs and transcripts will be kept in locked cupboards in a secure location in MLW and electronic transcripts will be password protected on a computer accessible only to authorised staff members.

Findings from the formative research will help to determine preferred locations for HIVST distribution and linkage to care and ways that the study can best uphold privacy for participants.

All interviews requesting sensitive information (for which written informed consent will be requested) will also be held in private in community-based locations identified by the study team. Dr. Nic Desmond and Wezzie Lora have experience conducting qualitative research for social harms following HIVST with general population participants. Convenient community-based venues were hired for the purpose of ACASI, FGDs and IDIs and the study will ensure that these venues a remain suitable for key population participants before the field work starts.

## 5.2 Adverse events

The social harms monitoring study will be conducted to measure and explore social harms occurring both as a direct consequence of HIVST and during the period after HIVST has taken place. We acknowledge that participation in the study has the small potential to exacerbate pre-existing social and interpersonal tensions. Relationships will be assessed during the process of enrolment. FSWs will not be enrolled if investigators deem that study participation could expose them to excessive social harms given their personal and occupational circumstances.

Adverse events reported by participants during the project period will be followed up with interview by a study team member to establish whether the event was related to HIVST. The investigators will also aim to establish individual rapport with the cohort of participants by maintaining regular contact with participants and follow-up on their specific needs during the study.

The researchers have been trained in GBV response and critical incident reporting. Attention will be paid to all cases of reported social harms and appropriate and ethical responses will be assessed. Follow up visits and links made to health care facilities and local support organizations for GBV (e.g., Chikondano Women) will be provided in all cases, regardless of whether or not the participant experienced GBV as a result of exposure to HVIST.

## 5.3 Informed consent

Informed consent will be taken at different points in the study, as outlined in **Figure 5** below. For activities where participants are required to give written informed consent, interviews will take place in a private location (see **Section 5.1**) and the investigator will first provide the potential subject with an explanation of the study as well as an information sheet with study details. The investigator will answer any questions raised by the potential participant and allow them sufficient time to come to a decision.

Participants will then be asked to provide written informed consent, or witnessed verbal consent plus a thumb print for illiterate participants.

A breakdown of each of the activities and corresponding consent requirements are listed below.

**Figure 5. Consent requirements for each research activity**

| Study | Activities | Consent Requirements |
|---|---|---|
| **Formative research** | IDI | Written |
| | REA | Verbal |
| | Participatory workshops | Verbal |
| | FGD | Verbal |
| **Social harms research** | HIVST distribution | Request waiver of informed consent; leaflets provided in lieu of participant information sheets |
| | ACASI and LDS | Written |
| | SBI | Written |
| | CIN | Written |
| | FGD | Written |

## 5.4 HTC and HIVST

### 5.4.1 Pre- and post-test information

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

### 5.4.2 HIV disclosure

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

## 5.5 Compensation for participation

Study participants will be compensated for their time away from income-earning activities, but this will be packaged as compensation rather than payment. This will include refreshments and refund of any transport costs incurred. MWK 1000 will be given for IDI, FGD, ACASI, and CIN participants. Selected SBI participants will be given an extra MWK 500.

# 6. Constraints and limitations

## 6.1 Risk mitigation

As noted in Section 5.3, MLW-LSHTM will monitor social harms throughout the HIVST distribution period and respond to incidences of coercion, GBV, and other potential unintended consequences from self-testing. Investigators will individually provide follow-ups with each study participant in order to assess and mitigate adverse events arising from HIVST. Peer-distributors will be trained to include screening questions about intimate partner violence along with pre-test information, and to alert women to this potential risk.

## 6.2 Data quality

MLW-LSHTM has considerable expertise in supporting all aspects of quality data management in Malawi. 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.

The Research Governance unit in MLW will conduct periodic (usually annual) internal audits to ensure that all documentation and data capture is within acceptable international standards. Should the study be found to be not compliant with SOPs or fail a data quality audit, they will be required to revise their practices with close supervision from external technical staff, i.e., Regional Researchers and Health Area Research Advisors.

## 6.3 Partnerships

HIV STAR will form a Technical Advisory Group (TAG) to review data and provide expert opinion on how a product should be pre-qualified. They will also advise on post-market surveillance reports and supervision when products enter the market.

HIV STAR Malawi has the support of key officials in the Government of Malawi. The MoH has collaborated in a number of HIVST projects to date and supported publications and presentations from projects hosted by MLW. Dr Frank Chimbwandira, Director of the

Department of HIV and AIDS of the MoH, is a collaborator with MLW and PSI and has provided a letter of support for the HIV STAR Malawi project.

# 7. Capacity building and training

This research will contribute to qualitative and quantitative data capacity at the College of Medicine both in terms of establishing a resource base of qualified and trained researchers to conduct qualitative and quantitative fieldwork and a system for accurate and timely transcription and translation services and data management.

Data and field staff employed on the project will be trained in both qualitative and quantitative techniques, in Good Clinical Practice, and on the protocol, and will be uniquely placed to understand the complementarity of triangulation between quantitative and qualitative methods.

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# Addendum to COMREC submission

# Study requirements

| Requirements | Category | Item |
|---|---|---|
| **Personnel** | Core | Country research manager, admin offer/bookkeeper, administrator, driver* |
| | Data management | Data manager, data collector, data clerk |
| | Quantitative | Quantitative research assistant, |
| | Qualitative research | Social scientist, assistant social scientist, translator/transcriber assistant |
| | HIVST pilot distribution and linkage to care | Clinic-based clinical officer/nurse, peer distributors, peer distributor supervisor |
| **Training** | Good Clinical Practice training (by COM prior to research implementation) | Country research manager, data manager, data collector, data clerk, quantitative research assistant |
| | Data management (by research coordinator and data manager prior to data collection) | Data manager, data collector, data clerk, quantitative research assistant, social scientist, assistant social scientist, translator/transcriber assistant |
| | Protocol (by research coordinator and social scientist prior to study implementation) | Data manager, data collector, data clerk, assistant social scientist, translator/ transcriber assistant<br>PSI: PSI lead, peer distributors |
| **Data collection** | Formative and social harms research | Paper-based forms, audio recorder, ACASI device<br>HIVST kits |
| **Transport** | Transport to and from research sites | |

# HIV STAR Malawi Budget

# Budget justification

# STAR Malawi KP Work Plan

| Activities | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **FORMATIVE KEY POPULATION STUDIES** | | | | | | | | | | | | | | | | | | | | |
| **1. Study preparation - stakeholder interviews and REAs** | | | | | | | | | | | | | | | | | | | | |
| Meet with DHOs to ensure project buy-in | | | ■ | | | | | | | | | | | | | | | | | |
| Finalize and translate tools and SOPS | | | ■ | ■ | | | | | | | | | | | | | | | | |
| Identify key population stakeholders | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Identify FSW and MSM hotspots | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| **2. Data collection and analysis - stakeholder interviews and REAs** | | | | | | | | | | | | | | | | | | | | |
| Recruit and enroll key population stakeholders | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Conduct interviews with key population stakeholders | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Conduct document review | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Conduct REAs with key populations and establishment owners | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Transcribe audio-based qualitative data into electronic files | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Transcribe observation notes into electronic files | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Code qualitative data | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Conduct analysis of qualitative data | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Generate report on findings with recommendations on peer delivery model | | | | | ■ | ■ | | | | | | | | | | | | | | |
| **3. Study preparation - participatory workshop and FGDs** | | | | | | | | | | | | | | | | | | | | |
| Finalize and translate tools and SOPs | | | ■ | ■ | | | | | | | | | | | | | | | | |
| Develop peer delivery model based on REAs | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Recruit and enroll participants for participatory workshops | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Conduct participatory workshops | | | | | | ■ | | | | | | | | | | | | | | |
| Refine and finalize peer delivery model based on participatory workshops | | | | | | ■ | | | | | | | | | | | | | | |
| Recruit and enroll participants for FGDs | | | | | | ■ | | | | | | | | | | | | | | |
| Conduct post-pilot FGDs | | | | | | ■ | | | | | | | | | | | | | | |
| Conduct pre-ACASI/LDS FGDs | | | | | | ■ | | | | | | | | | | | | | | |
| Transcribe audio-based qualitative data into electronic files | | | | | | ■ | | | | | | | | | | | | | | |
| Code qualitative data | | | | | | ■ | | | | | | | | | | | | | | |
| Conduct analysis of qualitative data | | | | | | ■ | | | | | | | | | | | | | | |
| Generate report on findings with recommendations on final peer delivery model | | | | | | ■ | | | | | | | | | | | | | | |
| Develop training guide for peer educators | | | | ■ | ■ | ■ | | | | | | | | | | | | | | |
| Train peer educators on tools and SOPs for pilot distribution | | | | | | ■ | | | | | | | | | | | | | | |
| **SOCIAL HARMS EVALUATION** | | | | | | | | | | | | | | | | | | | | |
| **1. Study preparation** | | | | | | | | | | | | | | | | | | | | |

| Activities | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Finalize and translate tools and SOPs | | | | | | | | | | | | | | | | | | | | |
| Program ACASI tool into tablet | | | | | | | | | | | | | | | | | | | | |
| Develop database for entering quantitative data | | | | | | | | | | | | | | | | | | | | |
| Develop code for checking incoming data from tablets and manual records | | | | | | | | | | | | | | | | | | | | |
| Develop training guide for field (peer educators, RAs nurses) and data team | | | | | | | | | | | | | | | | | | | | |
| Finalize home-based ART initiation procedures | | | | | | | | | | | | | | | | | | | | |
| Train field (peer educators, RAs, nurses) and data team on tools and SOPs | | | | | | | | | | | | | | | | | | | | |
| **2. Data collection and analysis - ACASI, SBI, LDS and CII** | | | | | | | | | | | | | | | | | | | | |
| Identify and recruit eligible participants for ACASIs/IDIS | | | | | | | | | | | | | | | | | | | | |
| Check in with peer educators to monitor social harms and recruit for CIIs | | | | | | | | | | | | | | | | | | | | |
| Conduct first round of ACASIs with purposively selected participants | | | | | | | | | | | | | | | | | | | | |
| Conduct second round of ACASIs with purposively selected participants | | | | | | | | | | | | | | | | | | | | |
| Conduct SBIs with purposively selected participants | | | | | | | | | | | | | | | | | | | | |
| Monitor diary participants and collect records on a biweekly basis | | | | | | | | | | | | | | | | | | | | |
| Conduct CIIs with purposively selected participants | | | | | | | | | | | | | | | | | | | | |
| Enter audio and paper-based files into electronic files | | | | | | | | | | | | | | | | | | | | |
| Conduct quality and accuracy checks on incoming electronic data | | | | | | | | | | | | | | | | | | | | |
| Clean quantitative data | | | | | | | | | | | | | | | | | | | | |
| Transcribe and translate qualitative data | | | | | | | | | | | | | | | | | | | | |
| Code qualitative data | | | | | | | | | | | | | | | | | | | | |
| Conduct preliminary analysis of quantitative data | | | | | | | | | | | | | | | | | | | | |
| Conduct preliminary analysis of qualitative data | | | | | | | | | | | | | | | | | | | | |
| Generate preliminary report on social harms evaluation findings | | | | | | | | | | | | | | | | | | | | |
| Conduct in-depth analysis of quantitative data | | | | | | | | | | | | | | | | | | | | |
| Conduct in-depth analysis of qualitative data | | | | | | | | | | | | | | | | | | | | |
| Generate in-depth report on social harms evaluation findings | | | | | | | | | | | | | | | | | | | | |
| **3. Data collection and analysis for FGD** | | | | | | | | | | | | | | | | | | | | |
| Identify FSW and MSM hotspots for FGDs | | | | | | | | | | | | | | | | | | | | |
| Conduct FGDs with FSW and MSM | | | | | | | | | | | | | | | | | | | | |
| Randomly select peer educators for FGDs | | | | | | | | | | | | | | | | | | | | |
| Conduct FGDs with peer educators | | | | | | | | | | | | | | | | | | | | |
| Transcribe and translate qualitative data | | | | | | | | | | | | | | | | | | | | |
| Code qualitative data | | | | | | | | | | | | | | | | | | | | |
| Conduct analysis of qualitative data | | | | | | | | | | | | | | | | | | | | |
| Generate report on FGD findings | | | | | | | | | | | | | | | | | | | | |

# Forms and Tools Guide

| Form No. | Type | Form Name |
|---|---|---|
| PS08A | Information Sheet | Participant Information Sheet, IDI Stakeholders |
| PS08B | Consent Form | Consent Form, IDI Stakeholders |
| PS08C | Information Sheet | Participant Information Sheet, REA Venue Owners |
| PS08D | Consent Form | Consent Form, REA Venue Owners |
| PS08E | Information Sheet | Participant Information Sheet, FGD FSW MSM |
| PS08F | Consent Form | Consent Form, FGD FSW MSM |
| PS802 | Qualitative tool | IDI Guide Stakeholder |
| PS806 | Qualitative tool | FGD Guide FSW MSM |
| PS09A | Information Sheet | Participant Information Sheet, ACASI/LDS |
| PS09B | Consent Form | Consent Form, ACASI/LDS |
| PS09C | Information Sheet | Participant Information Sheet, SBI |
| PS09D | Consent Form | Consent Form, SBI |
| PS09E | Information Sheet | Participant Information Sheet, CII |
| PS09F | Consent Form | Consent Form, CII |
| PS09G | Information Sheet | Participant Information Sheet, FGD Distributors |
| PS09H | Consent Form | Consent Form, FGD Distributors |
| PS09I | Information Sheet | Participant Information Sheet, FGD FSW/MSM |
| PS09J | Consent Form | Consent Form, FGD FSW/MSM |
| PS901A | Quantitative | ACASI Questionnaire - FSW |
| PS901B | Quantitative | ACASI Questionnaire - MSM |
| PS903 | Qualitative | SBI Guide |
| PS904 | Qualitative | CIN Guide |
| PS905A | Qualitative | FGD Guide Peer Distributor |
| PS905B | Qualitative | FGD Guide FSW MSM |