Harnessing male peer networks to enhance engagement with HIV prevention: A large-scale cluster randomized trial to increase HIV self-testing and PrEP uptake among men in Eastern Zimbabwe

STUDY PROTOCOL

V2.2

7 November 2023

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1. Administrative Information

1.1. Title

Harnessing male peer networks to enhance engagement with HIV prevention: A large-scale cluster randomized trial to increase HIV self-testing and PrEP uptake among men in Eastern Zimbabwe.

1.2. Trial Registration

The trial will be registered with ClinicalTrials.gov and the Pan African Clinical Trials Registry.

1.3. Protocol Version

Version 2.2

1.4. Funding

The study will be funded through the United States National Institute of Health through National Institute of Mental Health.

1.5. Sponsor

The Stellenbosch University will be the sponsor for this study. Stellenbosch University has a Clinical trial insurance policy in place that provides cover in the event that a participant holds Stellenbosch University liable for any injuries or illnesses sustained during a trial.

1.6. Investigators

1.6.1. Principal Investigators

Dr Constance Nyamukapa - Imperial College London

Prof Frank Tanser - Centre for Epidemic Response and Innovation (CERI) at Stellenbosch University, South Africa

1.6.2. Co-Investigators

Prof Simon Gregson - Imperial College London, UK

Dr Louisa Moorhouse - Imperial College London, UK

Dr Paul Mee - University of Lincoln, UK

1.7. Roles and Responsibilities

The roles and responsibilities of the investigators are shown in the following table

Investigator	Role
Professor Frank Tanser	Project co-PI responsible for overall leadership of the project jointly with co-PI Nyamukapa. Responsible for supporting protocol development, oversight of safety and monitoring plan, coordination of international co-I's, responsible for analysis of data and dissemination of results through publication and oral presentations
Dr Constance Nyamukapa	Project co-PI responsible for overall leadership of the project jointly with co-PI Tanser. Responsible for day-to-day oversight of field operations, responsible for analysis of data and dissemination of results through publication and oral presentations
Professor Simon Gregson	Project co-I responsible for protocol development, participation in senior leadership team, responsible for analysis of data and dissemination of results through publication and oral presentations
Dr Louisa Moorhouse	Project co-I responsible for protocol development and delivery of training materials support for co-PI Nyamukapa in the day monitoring and operations of the fieldwork. Participates in senior leadership team. Provides support and supervision for the data team and overall responsibility for the development of data systems. Participation in the analysis of data and dissemination of results through publication and oral presentations
Dr Paul Mee	Project co-I responsible for protocol development, participation in senior leadership team and support for the day-to-day monitoring and operations of the fieldwork. Support and supervision for the data team, responsible for analysis of data and dissemination of results through publication and oral presentations

Table 1 – Role and Responsibilities of Project Investigators

2. Introduction

2.1. Background and Rationale

2.1.1. Summary

The objective of this project is to use an implementation science approach to establish the impact of HIVST distribution through male social networks, with phone-based support and improved risk perception, on PrEP uptake among men in Eastern Zimbabwe. The project will leverage infrastructure and data associated with 20-year programme of HIV surveillance and behavioural research in a well-characterized population cohort hosted by the Manicaland Centre for Public Health Research, Zimbabwe. The project is particularly opportune given the very recent adoption of PrEP as a key component of the Zimbabwean national AIDS response and the subsequent roll-out of PrEP in all local clinics.

The study will utilise a cluster randomised design. In intervention clusters we will identify initial distributors who will receive an HIVST kit for personal use and HIVST kits to distribute to local peers. These peers can subsequently become distributors, allowing the intervention to propagate through peer networks. A toll-free helpline will provide pre- and post-test support and an SMS-based risk assessment will expedite PrEP initiation at the clinic. We will conduct a process evaluation of the intervention to assess implementation fidelity and causal mechanisms underlying trial effectiveness including how characteristics of peer networks affect outcomes. We will use the results of the study to quantify the population level impacts

and cost-effectiveness of male peer to peer HIVST distribution strategies on the uptake of PrEP in HIV hyper-endemic settings using a fully calibrated individual-based mathematical model. The envisaged long-term impact of this research is the development of a generalizable, multicomponent male peer based HIVST and PrEP uptake model for settings where HIV incidence is high.

The study protocol follows the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT). [1–3]

2.1.2. Background

Effectively engaging men in HIV prevention remains one of the greatest challenges to driving the epidemic to low levels of endemicity in Sub Saharan Africa (SSA). [4–6] If HIV elimination strategies are to succeed in SSA, innovative solutions are needed to more effectively engage men in HIV testing, prevention and care.[7] Suboptimal engagement with HIV prevention by men increases their risk of HIV acquisition,[8] and is an important driver of new HIV infections in women.[9] Increased HIV testing is a prerequisite for meeting targets at subsequent stages in the HIV treatment and prevention cascades,[10, 11] but males face multiple gender-specific barriers to engagement with facility-based HIV testing and care services.[12] HIV self-testing (HIVST) addresses several key facility-based access barriers[13] and the distribution of HIVST through male peer networks to promote HIV prevention is feasible, acceptable and effective in SSA.[14, 15] Leveraging peer networks increases the penetration of health interventions to hard-to-reach individuals. [16] In hyperendemic settings in SSA the high HIV incidence in subgroups of the general population indicate that a population-wide scale-up of Pre Exposure Prophylaxis (PrEP) could substantially impact the HIV epidemic's trajectory.[17, 18] Demand for PrEP among men is high[19] and the use of HIVST in conjunction with PrEP increases adherence.[20] The positive impact of eHealth interventions on HIV care engagement has also been widely demonstrated.[21] Whilst support from male peers improves testing behaviour, no study yet has been able to measure the impact of such a strategy on the uptake of PrEP at scale.

This study will employ a combination of technologies and strategies that have been proven to work in isolation to overcome barriers to male engagement with care. [22–27] HIV Self testing (HIVST) which allows men to test privately and to retain autonomy in their engagement with healthcare have been shown to be acceptable to men. [14] HIVST has been adopted as part of the national HIV care strategy in many SSA settings including Zimbabwe. A meta-analysis of studies in Malawi, Zambia and Zimbabwe investigating the impact of community based HIVST distribution on ART initiation showed positive effects on levels of ART initiation and emphasised the importance of integrating initiation support with HIVST distribution.[23] Studies in Uganda showed that encouragement from a trusted peer increased the willingness of men to test.[24] Recent studies in both rural and urban SSA settings have shown that the peer distribution of HIVST to men is both feasible and acceptable. [22, 25] A recent review confirmed the advantages of peer distribution for males and emphasised the importance of combining distribution with linkage to existing provision for confirmatory testing, linkage to care and PrEP where it was available. A study conducted in KwaZulu Natal South Africa showed that HIVST distribution could reach to extended levels in a peer network and increase the take-up of HIV testing. [28] Research in Eswatini showed that demand for PrEP among men was high with a preference for PrEP delivery to be linked to testing or outpatient settings.[19] A systematic review has shown that use of mobile phone-based approaches can be effective in promoting behaviour change with trials showing improvement in adherence to ART and biological outcomes with results dependent on the precise strategy employed. [27]

HIV prevention cascades (HPCs) have been developed as a tool to track and increase availability, uptake and adherence to efficacious HIV prevention strategies.[29–31] This follows from the success of the HIV treatment cascade in articulating the multiple steps required to fully exploit the potential of ART. [30] These start by considering the fraction of the population who are at risk, and then apply filters that reflect the proportions for whom a service is available, that take up that service, that adhere to the use of the service, and that ultimately benefit from it. In this way, missed opportunities to maximize the impact of a particular 'prevention technology' are quantified. In this proposal, we consider the factors acting at individual, partner, community, and structural levels that influence and impede progression through HPCs for men with an ultimate focus on PrEP uptake. Using this overarching formulation, we have developed an intervention which targets multiple barriers to successful male engagement with HIV prevention. A prevention cascade (Fig 1) when applied in this setting to assess barriers to the adoption of PrEP amongst HIV negative men indicated low levels of knowledge and risk perception and extremely limited current access to the technology amongst this group (Fig 1). Whilst HIVST is a key component of the Zimbabwean Ministry of Health strategic response [32] our research indicates that whilst around 60% of men are aware of HIVST , less than 6% have actually used the kits.

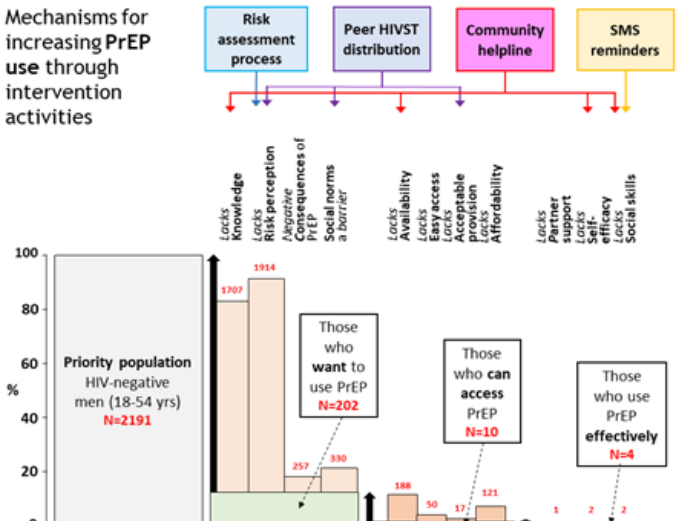

Figure 1 An HIV Prevention Cascade for PrEP use populated with data from the 2021 Manicaland HIV surveillance survey

Process evaluations are central to both understanding what did and did not work during implementation of complex interventions, and for adjusting implementation in real-time to maximize effectiveness. [33] Past evaluations of randomised control trials at this site have stressed the importance of involving community members in programme design and implementation to optimise intervention outcomes. [34, 35] Previous work in this setting has highlighted the role formal and informal social networks paly in affecting HIV risk acquisition[36, 37] and HIV care, [38, 39] suggesting that social networks are likely to affect the effectiveness of the proposed trial. A full understanding of the distribution networks within the trial is likely to provide vital insight into both where our trial did and did not work, and in what settings our model is likely to require additional adjustment. Exploration-phase work has shown that HIV prevention methods such as PrEP are wanted by men in this area, [40, 41] and that the various components proposed for our trial are feasible and likely to be of interest.

Our hypotheses are that: (i) pre-intervention context analysis will achieve a more acceptable implementation design that considers the array of distal and proximate determinants of

intervention outcomes; (ii) real-time feedback during implementation will facilitate adjustments to both the intervention and the evaluation; (iii) post-trial evaluation will identify "what works in which circumstances for whom" which is critical to assess fidelity and implementation quality; (iv) social networks, both in terms of individual position and community structure, will be important predictors of intervention effectiveness.

Our design for the process evaluation is guided by the updated Medical Research Council guidance for developing and evaluating complex interventions, [42] paying attention to broad context and stakeholder experiences before, during and after the intervention. It also fits within the Exploration Preparation Implementation Sustainment–(EPIS) framework,[43, 44] specifically focusing on the preparation and implementation phases, with an eye to building sustainment post-trial.

We have also scoped the complex context of PrEP delivery in Manicaland, identifying outer context components – including national and local government structures and existing NGOs supporting HIV prevention inner context components within our planned trial delivery system and the bridges between them. All of these will feed into our implementation plan.

Impact and cost-effectiveness are crucial considerations in deciding whether to adopt a new intervention. Mathematical modelling, combined with cost data collection, provides a widely used method to estimate population-level impact and cost-effectiveness, and to extrapolate estimates beyond the duration of the trial. The choice of mathematical model must include considerations of feasibility of approach (both in time to develop and calibrate the model, and availability of data to calibrate the model) and the ability to represent the epidemiology and proposed intervention as realistically as needed. Individual-based models (IBMs) offer a parsimonious and flexible way to characterize HIV prevention, where individuals have multiple prevention options and channels to use them. They also explicitly represent the sexual network, an advantage over other compartmental models. However until recently the computational intensive nature of IBMs, making systematic calibration challenging, [45] as well as the substantial data needs to parameterize the sexual network, means that IBMs have rarely been used in impact evaluation in practice.

2.2. Objectives

The aims of the research are:

1. To establish the impact of HIVST distribution through peer networks with improved access and enhanced community support structures on the uptake of PrEP in men.

2. To conduct a process evaluation of the intervention in this typical rural African population and characterize peer networks.

3. To quantify the population level impacts and cost-effectiveness of male peer to peer HIVST distribution strategies on the uptake of PrEP in HIV hyper-endemic settings

2.3 Trial Design

The study will use a cluster-randomised trial design with clusters based on existing village boundaries, which have been utilised as part of the ongoing population-based HIV surveillance. In some cases, neighbouring villages will be aggregated to give approximately equal numbers of adult men in each cluster. Feedback from the participatory 'theory-of-change' workshops involving key community stakeholders will be taken into account by the PI's and CoI's when considering further refinements that can support the successful implementation of the trial. Real-time feedback from the process evaluation will ensure the roll-out is as specified in the protocol thus maximising the fidelity of the intervention.

3. Methods, Participants, Interventions and Outcomes

3.1. Study Setting

The study cohort from which participants will be recruited is located in Manicaland province, east Zimbabwe. [46] The most recent round of surveillance in 2018/19 was conducted across 8 sites ranging from rural to urban. [47] These sites represent the 5 of the major socioeconomic strata in Manicaland; small towns, agricultural estates, roadside settlements, subsistence farming areas and urban areas (Figure 6). Local healthcare is provided through a network of public sector primary care clinics, with clinics operating as public-private partnerships in the two estates.

3.2 Eligibility Criteria

All males aged 18 and over will be eligible for recruitment to the study.

3.3 Interventions

3.3.1 Intervention – HIVST distribution through male peer networks

The intervention will proceed with the following steps: (see summary Fig 2)

i. Potential primary distributors will be identified by the research team following engagement with local key informants, these individuals will be contacted and screened for study enrolment. The desired characteristics of these individuals would be that they are respected members of their community with strong local networks of peers. If they choose to participate an informed consent procedure will be completed by the fieldworkers.

ii. If enrolled, the distributor will be given a pack containing four HIVST kits, one for their own use and three for distribution within the cluster. The study team will collect basic demographic data (name/age / cell number) for the distributor and the intended recipients. They will also record the unique ID of the pack of kits. Advice will be provided on the correct use and interpretation of the HIVST, the need for post-test confirmatory testing in a health facility and the availability of HIV prevention methods including PrEP.

iii. The distributor will be asked to give the test kits to the intended recipients within a seven-day period.

iv. After seven days the helpdesk will contact the distributor and the intended recipients to ascertain whether kits have been received and used, to collect behavioural HIV risk data for the recipients and encourage attendance at a healthcare facility for a confirmatory test. HIVST recipients will be invited to complete the informed consent over the telephone and be enrolled in the study. Follow-up calls will be made to these individuals if necessary. Recipients will be encouraged to consider becoming distributors and advised on the location of community facilities (shops, pharmacies, hairdressers etc.) from where they can obtain the HIVST packs for distribution. This method of HIVST distribution through community-based hubs has been proven to be successful in studies in other Sub-Saharan African settings. [48] A small renumeration of $1 per peer will be transferred electronically to the initial distributor for each kit successfully distributed. Successful distribution to peers is defined as the peer having received the HIVST and has been successfully contacted by the helpline to confirm receipt of the HIVST but does not have to use the HIVST or agree to enrol in the study as a distributor. Names and cell numbers will be collected for intended recipients by the study team and held confidentially.

v. If the recipient chooses to become a distributor they will go to the facility and the owner will check using a real-time database that they have not already received a pack of kits for distribution. If they pass this screening, they will be given a pack of three HIVST kits for within cluster distribution, again A small renumeration will be paid to the facility owner for each pack of kits given out.

vi. After seven days the helpdesk will contact the second level recipients and steps iv) and v) will be repeated until all kits allocated to a particular community have been distributed.

vii. When participants attend a clinic for confirmatory testing, they will return the HIV test kit packaging with the unique label and based on their self-reported HIVST result (unreactive/reactive) be screened for PrEP or ART. The outcome of the screening will be recorded in a tick-box on the label and the packaging deposited in a secure box at the clinic from where it will be collected by the study team.

viii. HIVST kits will be returned to the central data processing facility for data entry and an additional small renumeration of $1 paid to the initial distributor for each individual attending the clinic and participating in a confirmatory HIV test.

ix. All individuals initiating PrEP or ART will be contacted monthly for six months to provide support and to ascertain whether they are still adhering to/continuing with PrEP/ART.

x. Additionally, we will contact all men who report they are still taking PrEP/ART at the end of the follow-up period in order to obtain a dry blood spot to verify the self-report of adherence. This will be sent for analysis in order to assess the intracellular levels of tenofovir diphosphate (TFV-DP) in red blood cells . [49]

In a second phase of the intervention, we will return to the intervention clusters and invite the initial distributors to participate in a second phase of wider distribution. In this stage they will be able to distribute the packs of kits to individuals they contact over the next 14 days resident anywhere within the study site. The distribution process will proceed as previously for up to 2 months following the initial acceptance of the HIVST pack.

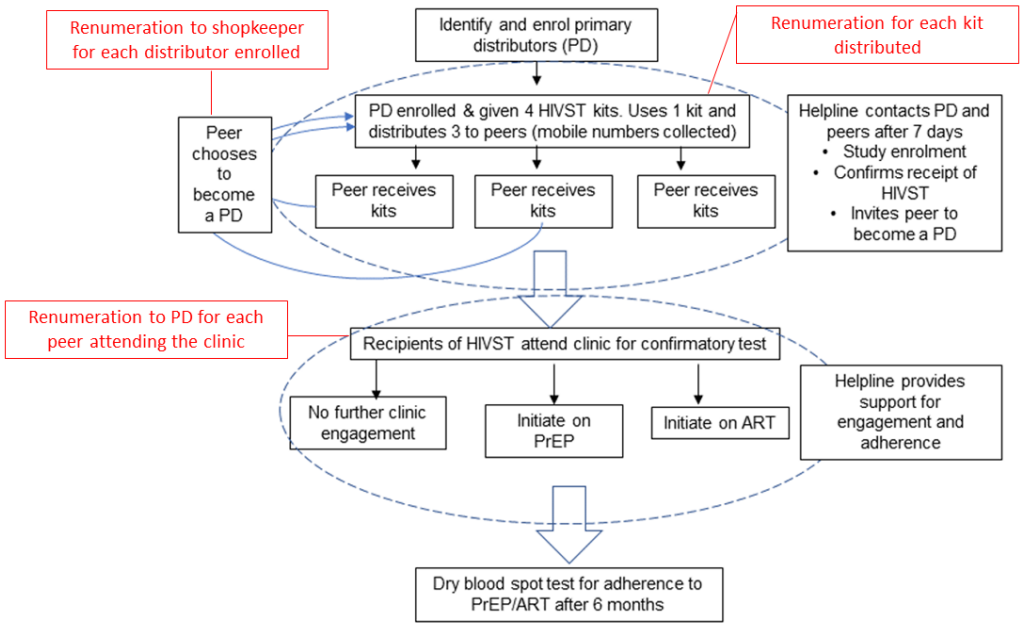

Figure 2 Schematic flowchart for the intervention as described in steps i) to x) above

3.3.2 Control – Standard of care

The existing Ministry of Health and Child Care programme of direct HIVST distribution in the community through community health workers (CHW) will be the standard of care in the study.

3.3.3 HIV risk self-assessment tool

Previous work has indicated that males in this community have a low level of perception of their risk of HIV infection. [41, 50] To address this, a tool will be developed that will allow study participants to make a self-assessment of their level of risk. Information on how to use the tool will be provided to all recipients of HIVST kits including the primary distributors as part of the kit insert. They can use this tool multiple times during the study period as their risk profile may change over this time. All SMS messages will be free, and no identifying data will be collected by the study team. After submission of an SMS users will be prompted by an automated interactive system to provide a numerical response to a series of behavioural risk questions. The questions will be the same as those used in the national PrEP screening tool. Based on the responses they will receive an automated message indicating whether they have a high level of risk and if so recommending that they consider PrEP initiation.

3.3.4 Study Helpline

A study helpline with a toll-free number will be established which will provide the key point of contact between the participants and the study team. In addition to the structured contact with the participants as outlined below all participants will be able to contact the helpline with any questions or concerns about the study, the interpretation of their results, for support and counselling related to HIVST or their engagement with the healthcare clinics or for any other reason. The helpline will be staffed within working hours with a messaging/call-back service available out of these times.

3.3.5 HIVST kits

In this study we will use the WHO approved OraQuick oral fluid test kits (OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, OraSure Technologies, Inc.)

3.3.6 HIVST packaging and kit inserts

Study specific packaging will be created for each HIVST kit into which the original kit with packaging from the manufacturer will be inserted. A sticker on each box will contain the following information:

- A unique 6-digit identifier for the kit
- A set of tick-boxes on which the clinic staff will record the outcome of the engagement with the clinic
- A kit insert sheet within each box will contain the following:
    - A copy of the informed consent form
    - Details of accessing SMS-based HIV risk self-assessment tool
    - Contact details for the study helpline
    - Details of the study procedures including the renumerations paid for successful kit distribution and engagement of recipients with the primary care clinics

- Detained instructions on the use and interpretation of the HIVST kit

Individual HIVST kits will be placed in a larger box with its own unique identifier. Four kits will be provided in these boxes for the primary distributors and three for the secondary distributors. The study team will keep a record of the unique identifiers of the kits packaged in each box to enable the kit distribution process to be tracked.

3.3.7 Strategies to improve adherence

Follow-up calls from the study helpline will be the main strategy to support participants through HIV self-testing and engagement with HIV care. These calls will be made at monthly intervals following the initiation of ART or commencement of PrEP.

3.3.8 Process Evaluation

The process evaluation will be primarily conducted in one urban and one rural site. A trained Shona-speaking qualitative researcher will lead the evaluation, alongside a team of trained research assistants and peer researchers (men from the target population acting as local community advisors and research assistants). Qualitative data will be thematically coded and analysed in NVivo 12. The performance evaluation consists of three stages, with all data collected informing the final evaluation stage. (Fig 3)

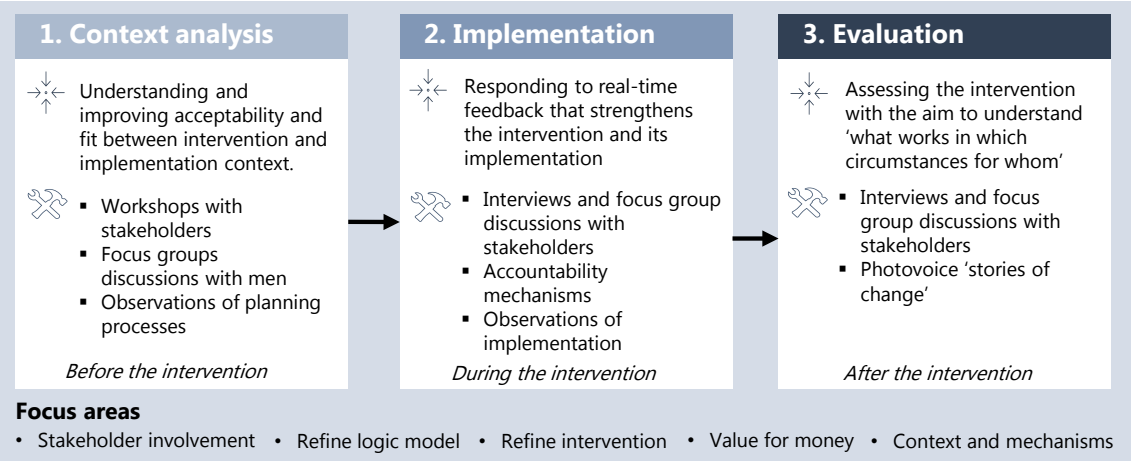

Figure 3 Framework for the Performance Evaluation

First, a **pre-intervention context analysis** will be conducted to understand the context within which the intervention will be implemented, and thus to improve the fit between context and approach (months 7-12). Workshops with men who represent the target group (n=2), healthcare providers (n=2) and project implementers (n=2) will provide feedback on and help refine the intervention, further develop the evaluation logic model, and identify local resources that can support the intervention. Focus group discussions with men (n=4) will explore the structures, attitudes and practices surrounding men's social networks, to inform intervention design to maximize its reach to PrEP-eligible individuals in terms of HIVST distribution, uptake and clinic attendance. Finally, participant observations will generate notes about all planning processes. All these inputs will be used to map, and design trial adaptations to account for, barriers and facilitators for implementation and sustainment.

Second, accountability mechanisms will generate **real-time feedback during implementation** to support the PI's in strengthening of intervention practices (months 13-42). Focus group discussions (n=4) and interviews (n=12) with implementers will capture barriers and

facilitators to implementation success, what is and is not working and any unintended consequences. A designated helpline and mailboxes for anonymous feedback will be available at all study sites to allow helpline and other staff provide qualitative insights into how the intervention is processing. Focusing on the two sites subject to qualitative investigation, participant observations of intervention implementation and home and community visits will help monitor progress, as well as interactions in peer networks and between men and shopkeepers distributing HIVSTs. All this will be triangulated with real-time quantitative data on enrolment and progress of men through the intervention.

Third, the **post-trial process evaluation** will examine "what works in which circumstances for whom" (months 43-48). Through interviews (n=24) and focus group discussions (n=8) with a mix of stakeholders, including men reached through the intervention (in combination with intra-trial data), we will explore contextual factors and social network mechanisms shaping experiences of, and engagement with, intervention activities along the HIV prevention cascade (see Figure 5). This will include examining the 'what' (social network structures and processes), the 'how' (implementation processes), 'where' (spatiality, location, community/cultural/ political/religious context), 'when' (timing, momentum, cyclicality, flow, speed, duration, frequency), and 'who' (people and organisations, interpersonal relations, social networks and norms) that influence HIVST distribution and PrEP uptake. Finally, 20 men will be invited to photographically capture 'stories of change' through the Photovoice method. [51]. The men will be invited to write captions to their photos, and to select photographs representing 'significant changes' (good or bad). These photographs will guide subsequent interviews, which will also seek to understand how the men's social networks affect the changes they report by visualizing their personal networks and using them as a tool for discussion.[52, 53]. Further details of the Photovoice procedures are given below.

As a token of appreciation for participating in process evaluation activities, workshop participants will be given USD$10 at the end of the activity, individual qualitative interview participants will be given 2 bars of laundry soap, focus group discussion participants will be given2 bars of laundry soap, and Photovoice participants will be given a t-shirt and USD$10.

Photovoice guidelines

Justification for Photovoice

Photovoice is a research method that qualitatively captures the lived experiences of participants in ways that words alone, produced through interview interactions, cannot capture. In this project it will be used as a participatory evaluation method. Photovoice provides participants with time to reflect on key barriers and facilitators to success of an intervention, and to photographically capture and articulate their perspectives. Although the photographs, and accompanying written reflections about their meanings, constitute important data in their own right, the reflection that takes place during the Photovoice exercise, can be explored further in interviews. Photovoice therefore both triangulates and strengthens interview methods.

Process (step-by-step)

1. 20 men aged 18 and above who have participated in the intervention will be invited to participate in this exercise. They will be recruited from two different intervention clusters. A key criterion for selection is their representativeness and interest to participate in Photovoice.

2. A three-hour photography workshop will be arranged at a central location (e.g., community hall, school classroom) of each cluster to cover the following:
    a. Aims and objectives of the exercise
    b. What we are interested in (theme: men's experiences of the peer network intervention). The men will be asked to focus their photography and reflections around the following three questions:
        i. 'How did the intervention affect you?'
        ii. 'What are the most significant accomplishments of the intervention?'
        iii. 'What aspects of the intervention were not particularly successful?'
    c. The practicalities of using a camera and take good pictures.
    d. Ethical dilemmas with photography in public areas – this will include an explanation and dialogue about the consent forms. The men will be encouraged to think of scenarios where taking a photograph may not be appropriate and could cause discomfort to those photographed. These scenarios will be discussed and the men will be told that if they want to share a story and they are unsure about whether it may be inappropriate to take the photo, or if they do not get an opportunity to take a representative photo, they can draw the scenario instead and describe their drawing(s). The men will be discouraged from taking photos of people who may be identifiable.
3. The men will be given two weeks to take photos answering the above questions. After the two weeks the cameras shall be collected for development of the photos with two copies being printed of each photo.
4. After development of the photographs, the men will be gathered in a second workshop and asked, echoing the aims and objectives of this exercise, to pick six of their favourite photos that depict one or more of the following:
    a. Two photos capturing the most significant accomplishments of the intervention.
    b. Two photos depicting something that helped make the intervention a success or failure.
    c. Two photos that depicts something that enabled or prevented men from engaging with the intervention.

    Again, if the men want to share a story and scenario they did not capture with the camera, they were encouraged to draw the scenario. The men will be invited to pick six photos they are happy to share with the research team, who might make the photos available in the public domain, and will be asked to sign the photograph release consent form.
5. The men will be encouraged to write short essays to each of the six photos with the following guidelines:
    i. 'I want to share this photo/drawing because…'
    ii. 'What's the real story this photo/drawing tells?'
    iii. 'How does this story relate to your life and/or the lives of other men in your community?'

<u>Training, facilitation, accountability and ethics oversight</u>

1. *Participant training* – Photovoice participants will be thoroughly trained on the purpose of the exercise, use of cameras, the ethics of taking pictures in public for research purposes,

and in the process for obtaining informed consent from the subjects in photographs. In terms of the ethics of picture taking, we will introduce the participants to a variety of strategies to overcome key ethical dilemmas. These include: i) draw a situation that cannot be captured photographically for ethical research; ii) use themselves, and each other, to stage a scenario that fictitiously depict a situation they would like to capture photographically; iii) think creatively about how they tell a story photographically without people appearing in the pictures; iv) refrain from taking pictures of people and places that can be recognized on the images.

2. *Facilitator training* – The person facilitating the Photovoice exercise has previous experience of implementing a Photovoice project, but will receive further training from the study investigators, who has written academic articles and book chapters on the use of Photovoice in health research.
3. *Community oversight* – Local community leadership will be involved in the selection of men, and consulted on the use of Photovoice in their communities. The advice we receive from the local community, and their inputs on what constitutes ethical and unethical picture-taking, will shape the trainings listed above. Village headmen/women will be included in parts of the training (as well as in the initial consultations) and requested to oversee the process. In practice, they may delegate day-to-day oversight and monitoring responsibility to VCHWs or other responsible community members. If/when significant problems arise, these can be referred to the headman/woman to resolve.
4. *Fieldwork team level oversight*: We will appoint one of the field supervisors to review the photographs and consent forms coming in on a weekly basis to make sure they conform to the ethical requirements; and to obtain details from the headmen/women of any cases referred to them to resolve. This person will then prepare monthly reports summarizing their findings.
5. *Investigator level oversight*: Photovoice participants will be given access to the project's 24-hour phone line so that they can report complaints immediately to one of the PIs (Nyamukapa) who will arrange to have such complaints investigated and acted upon as necessary. Nyamukapa will review the supervisor's monthly reports, provide instructions on any remedial action that might be necessary in the field, and make decisions on the ethical suitability (or not) of related photos/drawings for use in the research.

3.3.9 Modelling Study

PopART-IBM is an individual-based model originally developed and successfully used to generate long-term projections of impact that have been used in estimating the cost-effectiveness of the HPTN 071 (PopART) trial. [54] It is computationally efficient, capable of simulating 50 years of an HIV epidemic in a population of 100,000 individuals, using a weekly timestep, on a standard laptop in under a minute. [54] Thus, it can explore hundreds of thousands of parameter combinations on a standard computer cluster. Work comparing the calibrated output of PopART-IBM in Zambia with phylogenetic analysis from the same community provides validation of the simulated sexual transmission network in a sub-Saharan African setting. [55]

The model will be modified to explicitly include an HIV testing channel corresponding to self-testing and parameterize this using age-specific uptake rates over time in men collected as secondary outcome data. Initialisation of PrEP will be added as part of the self-testing process, as shown in the model schematic, with initialization additionally contingent on overcoming

the barriers associated with every step in the HIV Prevention Cascade. Using an inference framework,[54] multiple simulations consistent with the trajectory will be used to take parametric uncertainty into account; uncertainty resulting from stochasticity of the model can also be taken into account. Impact will be calculated relative to a simulated counterfactual in which the intervention was not introduced, and will also be calculated for the HIV self-testing component alone, using approaches to evaluation that we have previously successfully applied. [56, 57] The measures of impact will be HIV infections and deaths averted, as well as DALYs averted for the cost-effectiveness analysis, under the assumption that uptake of HIVST and PrEP are maintained over time. Using the multiple simulations, we can generate uncertainty bounds arising from stochastic and parametric uncertainty.

3.3.10 Cost Effectiveness analysis

The modelling framework will be used to undertake a formal cost-effectiveness analysis. This analysis will use the actual costs and observed outcomes and will project the stream of benefits that could accrue to the men and their partners and the indirect population-level benefits.

3.4 Outcomes

The primary outcome of the trial will be the proportion of men initiating PrEP out of all men aged 18 and over.

Secondary outcomes will include: i) the proportion of men self-testing for HIV over the period of the intervention out of all men aged 18 and over. and ii) the proportion of screened men adhering to PrEP or ART six months after initiation, measured by laboratory analysis of dry blood spots, out of all men initiating PrEP or ART after receiving an HIVST kit.

The qualitative performance evaluation will inform work to combine several quantitative data sources to evaluate how the intervention spread through social networks, and how network position and structure affected trial outcomes. We will combine information on intended and actual HIVST recipients with the existing Manicaland census data to measure what proportion of PrEP/ART eligible men were reached by our intervention. We will assess the level of network saturation achieved by the distribution process [16], and whether our approach reached individuals at higher risk of HIV acquisition as the recruitment process advanced – a key aim of the respondent driven sampling (RDS) methods on which our peer recruitment methods are based. Using entity resolution algorithms and hand-checking, we will identify linkages across distribution chains, and from this build network graphs of connections between men in the study areas. We will use these graphs to describe the structure of local male peer networks and statistically evaluate how characteristics of distributors and their social contacts influenced network distribution process and subsequent engagement with care. We will also evaluate whether intervention success differed across study clusters based on cluster-level network structures (e.g., density, clustering, age, and risk homophily) as well as by non-network characteristics (e.g., urbanicity, economy). Finally, once wider geographic distribution occurs in the second trial phase, we will evaluate whether distribution chains overlap and if greater geographical distribution affects study outcomes. We expect that our work will explain variation in outcomes and detail the contextual factors to consider when replicating or taking this intervention to scale. [33] We also expect to develop light-touch tools for use by implementors pre- and during implementation of such interventions, which can guide localization of this socially mediated design.

Through the modelling study we will generate population-level estimates of the incremental impact over three and ten years of: (i) the introduction of HIVST through male social networks and associated PrEP uptake; (ii) the introduction of HIVST alone.

From the Cost-effectiveness analysis, summary measures of benefit will include infections averted, reductions in lifetime-risk for men, deaths averted, and DALYs averted compared to the simulated counterfactual. Adjustments will be made to model the costs as they would be in a 'routine' application, removing any elements that are exclusively required by the evaluation. All uncertainties in the epidemiology, cost, outcome, and potential for future compensatory changes would be reflected in the model.

3.5 Participant timeline

The follow-up schedule for recipients of HIVST kits is shown in figure 4.

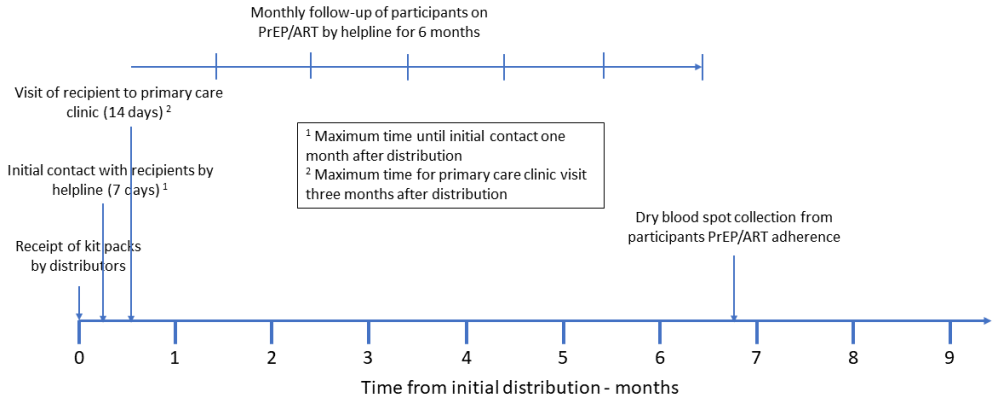

Figure 4 Timeline for engagement with participants after HIVST kit distribution

3.6 Sample size

Based on data on HIV risk collected in the 2020/21 surveillance round we estimate that 33% of men aged 18 and over, will fulfil the requirement for PrEP initiation. A comparable study indicated that 43% of those identified as at risk would take-up PrEP. [18] In the 2020/21 surveillance round 3/3591 (0.14%) men were currently using PrEP. With a continued roll-out of PrEP until the start of the study, we assume a baseline PrEP usage of 1% which will increase to 2% over the course of the trial in control communities. The study will use a cluster-randomised trial design. To have sufficient men in each cluster to explore multiple waves of network recruitment we will create 22 clusters in the intervention arm and 22 in the control, from a total population of 3591 men which equates to 81 men in each cluster. The clusters will be created from either a single village or groups of neighbouring villages. In each intervention cluster a maximum of 90 HIVST kits will be distributed, assuming that 70% of these kits reach men in the cluster, 80% of these men use the HIVST, 33% of these are eligible for PrEP and 43% of these initiate PrEP , we estimate we will have 7.15 men / cluster initiating PrEP a total of 157 men. This represents 8.8% of the study population in the intervention clusters. Using an Intra-Cluster correlation coefficient of 0.1, a conservative estimate based on data collected in similar settings [58] and with a total sample size in the intervention and control arms of 3591 we will have greater that 85 % power to detect a difference in the percentage of men initiating PrEP from 2% in the control arm versus 8.8% in the intervention arm.

3.7 Recruitment

The initial distributors will be identified by the research team as described above. We will have an initial target number of distributors e.g., 5 per intervention cluster. We will have target recruitment of 63 men in each cluster. If it becomes clear that the target recruitment for an individual cluster will not be reached, we will identify further initial distributors in the cluster and re-start the distribution process. We will provide telephone support for study participants to maximise adherence to PrEP/ART and maintain retention in the study.

3.8 Study timeline

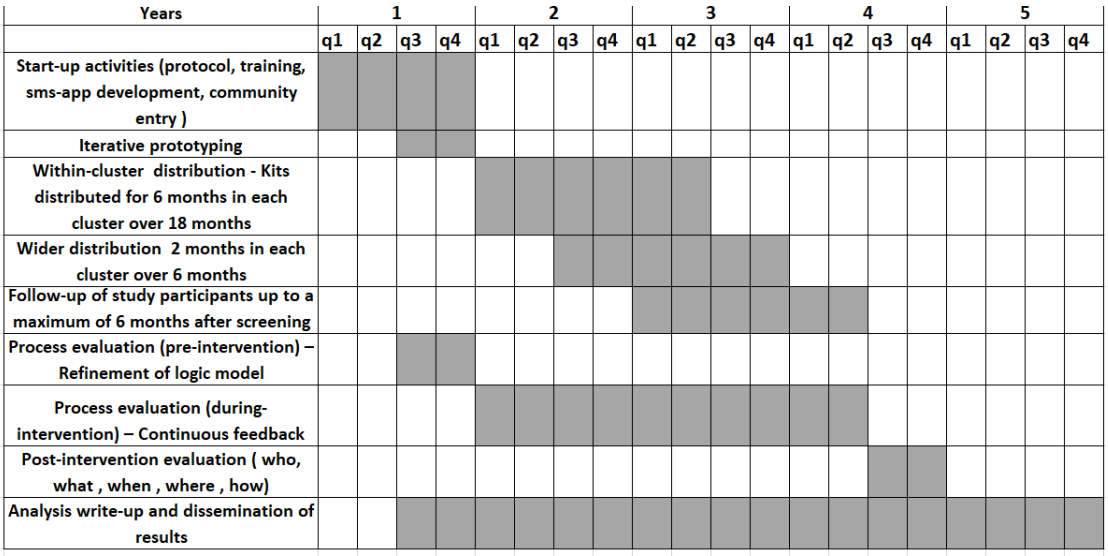

Figure 5 Planned timeline for the study

4 Methods: Assignment of interventions

4.1 Allocation

All participants will be assigned to clusters consisting of one or more distinct villages as described in the sample size section of this protocol. Clusters will be randomly assigned to either the intervention or the control arms of the study. Allocation will be stratified on the basis of the five major socioeconomic strata in Manicaland; small towns, agricultural estates, roadside settlements, subsistence farming areas and urban areas environments.

4.2 Blinding

Given the nature of the intervention, blinding of participants, study team or analysts is not feasible.

5 Methods: Data collection, management, and analysis

5.1 Data collection methods

There will be three modes of data collection used in this study

i) Direct data collection by fieldworkers for the recruitment of the primary distributors.

ii) Telephone-based data collection by the central helpline staff for all follow-up data and enrolment of peers
iii) Central data entry of information data on kit packaging labels

Data collection will be carried out by trained research assistants on password protected tablets and smartphones which are tracked via an asset register. These devices will be collected from the Data Management team at the start of the day and returned at the end of the day to be stored in a locked room. Data will be entered using Open Data Kit installed on tablets and smartphones and will be transferred to the electronic database on a daily basis. Following confirmation of successful data transfer, records will be deleted from the smartphones and tablets at the end of each day, in order to minimise the amount of data stored on these devices.

All data will be entered into a central database and used for study monitoring and analysis.

5.2 Data management

Survey data will be entered into and stored within an SQL relational database system. A system is being developed to run validation and internal consistency checks and to generate error reports for immediate follow-up in the field. A dashboard will be created to provide key statistics on recruitment and progress of the study to the investigative and fieldwork management team. Quantitative data will be analysed using standard statistical methods. Qualitative data will be collected in Shona (in the qualitative cohort), transcribed in English and analysed using NUD*IST.

Unique IDs will be used to identify each participant in the study. The consent audio files will be labelled with the unique ODK generated audio file ID to match with the interview. Audio files will be stored in a password protected standalone local server and encrypted drive and will also be backed up on a separate Imperial College drive. The database will be hosted on the server, owned by Imperial College and located at the field office, with SSL (secure socket layer) and password protected. There will be a local backup database server which is password protected and access rights activated which will not be online. Penetration tests will be contacted on the database servers monthly to ensure that the servers are still safe. Backup files will be hashed and stored in an external drive.

Access to the SQL server database will be limited to the Data Management team only. Requests for data access for analysis purposes will be made to the Data Management team and in such cases, the Data Management team will create pseudonymised datasets, removing any unnecessary personally identifiable for use in data analyses.

5.3 Statistical methods for analysing primary and secondary outcomes

For the test of the intervention effect on the primary and secondary outcomes will be conducted using the intent-to-treat (ITT) analysis for all men randomized at the community level. We will define our intent to treat population as those clusters who were randomized to intervention and control groups. We will use generalized linear models with Poisson distribution, log link function and robust error terms, adjusting for community-level clustering through random effects.

Analysis of baseline data will be carried out once recruitment has completed in all clusters. Final analyses will begin following field data and all associated data cleaning and quality control procedures. No interim analyses will be conducted.

6 Methods: Monitoring

6.1 Study Steering Committee

Whilst this is deemed to be a low-risk study, a steering committee will be appointed to provide trial oversight and meet once a year to review study progress, adherence to the protocol and safety of study participants. Any study related adverse events will be documented and reported to the Steering Committee. The Steering Committee members are investigators and experts in HIV program, epidemiology and statistics.

6.2 Data monitoring

Study progress and safety will be reviewed annually (and more frequently if needed) during the intervention. An annual report will be compiled and will include a list and summary of adverse events. In addition, the annual report will address (1) whether adverse events rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The institutional review boards and other applicable recipients will review progress of this study on an annual basis.

6.3 Ethical issues arising from the project and measures to address them

The study poses minimal risks to the participants. As with any research study there are possible associated risks.

Experience of stigma linked to participation - Distributors and recipients of HIVST kits may experience stigma from fellow community members if they are perceived to be individuals who are part of peer networks adopting high risk sexual behaviour. We will mitigate this in two ways, firstly in our community engagement process by reinforcing the message that all men aged 18 and over are eligible to participate in the study regardless of their behavioural risk profile or HIV status and secondly by ensuring any meetings or phone calls with the distributors remain private and confidential. When the study team contact participants by phone they will confirm their identity and ask if they are in a location where they can speak confidentially. If not, they will arrange a time for a follow-up call when the respondent is in a private setting.

Psychological harm associated with the HIV self-test result. There is a risk of psychological harm associated with an individual obtaining a positive/reactive HIV self-test without having support from trained counsellors. To mitigate this the study materials will confirm that the result is not definitive and should be confirmed through a facility test, a free toll helpline will be also implemented and will provide support and counselling through the testing process. There is no evidence of there being an increased risk of harm associated with HIV self-testing when compared to facility based testing. [13]

Provision of third-party information & identities. In providing contact information for peer's respondents are providing information on third parties. Such information may include the existence of a relationship hidden from many other people that would not typically be public information. Such information might cause social harm if passed to others in the community. Additionally, individuals outside the study are being included in the study prior to providing consent to be so involved. Revelation of third-party identities is common in research contexts such as this (e.g., when conducting proxy interviews about household members with household heads). Furthermore, it has been argued that the information provided by respondents about contacts is theirs to give, i.e. respondents are providing their view of relationships with others. [59] Specifically, this author argues that the network contacts of respondents are not

human subjects under the United States' Common Federal Rule "as no interaction occurs and name, address, and knowledge of participant-associate contact generally are not likely to be private information", and thus consent is not required. Nevertheless, this does not negate the potential harm that would be caused if study information were made public.

We have evaluated our collection of third-party information under an existing ethical framework on obtaining third-party identities for research proposed [60]. Here the authors suggested that such data collection should be conducted only when three criteria are met:

i. **No other method is available**. This is the case for any sociocentric analysis, since only by asking respondents to identify their social contacts can connections between responses be made.
ii. **Third-party identities are maximally protected.** This study will never collect third-party identities outside of an encrypted electronic environment. These identities will be held within datasets using project-specific identifiers, the linkage for which is held by key employees only. At no point will information provided by one participant be provided to another.
iii. **Benefits outweigh harms.** Stakeholders here include respondents, third parties and the broader public. Respondents' social connections are central to understanding social norms, which in turn are central to understanding HIV-related risk in a community with a generalized HIV epidemic. In this setting, these data therefore have a strong potential to benefit all community members. All proposed study instruments will be developed with the community advisory boards and community-based groups. The study will intentionally not focus primarily on sexual relationships with named contacts, asking only sufficient questions to identify peers and make contact prior to obtaining informed consent.

6.4 Harms/Adverse events

Adverse Events that are unanticipated, serious, and possibly related to the study intervention will be reported to the SMC, IRBs and NIH in accordance with requirements.

6.4.1 Adverse event definitions

Adverse event (AE): An AE is any unfavourable and unintended harm directly or indirectly incurred by participation in any aspect of the proposed study. This includes symptom and disease incidences due to medical procedures, as well as material, psychological or social harm as an indirect consequence of participation in the study.

Serious adverse event (SAE): SAE is any AE that results in death, life-threatening situation, hospitalisation, or persistent or significant disability or incapacity. All AEs and SAEs are graded according to their seriousness, causality, and expectedness.

Classification of AEs and SAEs

Severity: Non-serious AEs are graded according to their severity:

Mild: An experience that is transient, and requires no special treatment or intervention. The experience does not generally interfere with usual daily activities.

Moderate: An experience that is alleviated with simple therapeutic treatments. The experience may impact usual daily activities.

Severe: An experience that requires therapeutic intervention to prevent the AE from becoming a SAE, i.e., to prevent death, a life-threatening condition, hospitalisation, or persistent disability or incapacity.

Causality: All AEs and SAEs will be graded according to their causal relationship to the participation in the study.

Unrelated: There is no evidence of the adverse event being related to the study procedures (i.e., another cause of the event is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event).

Possible: There is some evidence to suggest a causal relationship between the adverse event and the study procedures as the event follows a reasonable temporal sequence from the initiation of study procedures, but that could readily have been produced by a number of other factors.

Probable: There is evidence to suggest a causal relationship between the adverse event and the study procedures and the influence of other factors is unlikely.

Definitely: There is clear evidence to suggest a causal relationship between the adverse event and the study procedures and other possible contributing factors can be ruled out.

Expectedness: All AEs and SAEs will be graded according to their expectedness:

Expected: The adverse event was expected under the risks anticipated for study participants of this study as outlined in the protocol.

Unexpected: The adverse event was not expected under the risks anticipated for study participants of this study as outlined in the protocol.

6.4.2 Protocol deviations and violations

Protocol deviation: Any process or action in relation to the study that is not in line with the study protocol that received ethics approval.

Any non-compliance with the study protocol may impact the integrity of the research. However, protocol deviations are those occurrences of non-compliance that are considered minor and do not affect participant safety or the integrity of the research, for example study visits outside of the defined visit schedule.

Protocol violation: A protocol deviation that may affect participant safety or the integrity of the research. Minor protocol deviations may become protocol violations if they occur consistently or affect multiple participants. Protocol changes without ethics approval or non-compliance with the inclusion and exclusion criteria are protocol violations.

Given the potentially significant impact of protocol violations, they are treated like SAEs in terms of reporting.

7. Ethics and dissemination

7.1. Research ethics approval

The Principal Investigator will obtain approval from the Stellenbosch University Medical Research Ethics Committee (MREC) and in Zimbabwe with the Biomedical Research and Training Institute (BRTI) MREC and the Medical Research Council of Zimbabwe MRCZ MREC. The IRB of the Medical

Research Council of Zimbabwe (MRCZ) will serve as the reference IRB for this study as MRCZ is the authority for conducting health research in the country where this study will be conducted. Additionally, approval will be obtained in the UK from the Imperial College Research Ethics Committee (ICREC) and other institutional review boards as required The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. [61]

7.2. Community Advisory Board

A 'Community Advisory Board' (CAB) will be established consisting of community members from each of the 8 study sites. The CAB will serve as an advisory group providing the perspectives of members of the local communities to the study and will support all stages of the study. CAB members will be selected to represent a range of different perspectives including different male/female and different age-groups. The CAB will meet every 3 months throughout the study. Any CAB members who are legal minors will be accompanied during travel to and from CAB meetings and at the meetings themselves by community elders from their home areas.

7.3. Informed Consent

For the recruitment of the primary distributors of HIVST kits research assistants, with Good Clinical Practice (GCP) certificates and trained on how to appropriately inform potential participants about the study and to request informed consent, will contact potential participants. Informed consent will be sought on a one-to-one basis after ensuring that the respondent is in a private space. Research assistants will read out the consent form to the potential participant in the local language (Shona) or in English depending on the respondent's preference. In so doing, they will describe the study, including potential risks for participants, potential benefits for participants and the local community, and participants' right to withdraw from the study at any time with no loss of healthcare entitlements. Then they will answer all questions about the study. Potential participants will receive the details of a person to contact in case of any problems. Research personnel collecting data will include qualified social workers and will be trained to ensure that assent from adolescents and consent from parents or guardians is appropriately sought before recruiting adolescents into the study.

For the recruitment and informed consent of the recipients of the HIVST kits and the invitation of these individuals to become HIVST kit distributors the same procedures will be completed by phone. This process of remote informed consent has been increasingly common in clinical trials in recent years. [62]. This approach has been successfully used in recent rounds of the Manicaland HIV surveillance survey and approved by all relevant IRBs. In this case eligible individuals' decisions on whether or not to consent to participate will be recorded on a separate mobile telephone to the one being used for interviews. Participants will be asked to say their name and acknowledge that the study was explained to them, that they understood everything, and are willing to take part in the study. These individuals will receive a printed copy of the Informed Consent form as a part of the HIVST kit insert. Evidence shows that this combination of a printed form and an explanation of the consent process from a study member leads to a higher level of comprehension of the informed consent information. [63]

The recorded consent files will be extracted from the mobile phones daily to make sure the phones are cleared. These consent audios will be stored on a local server and encrypted backup drive at the study field office in Manicaland, well-labelled with the participant study ID number, date, and time to generate the audio file ID to match with the ODK questionnaire form in the database. The form will be submitted as one entire form consisting of the data fields plus audio file ID and this

submission generates a unique submission identification. The audio file ID will be generated automatically in ODK and the research assistant will be forced to rename the audio consent file with the ODK generated audio file ID.

For the qualitative study written informed consent will be obtained from workshop and focus group participants.

7.4. Confidentiality

Unique IDs will be used to identify each participant in the study, the consent audio files will be labelled with the unique ODK generated audio file ID to match with the interview. Audio files will be stored in a password protected standalone local server and encrypted drive. The database will be hosted on the server, owned by Imperial College and located at the field office, with SSL (secure socket layer) and password protected. There will be the local backup database server password protected and access rights activated which will not be online. Penetration tests will be contacted on the database servers monthly to ensure that the servers are still safe. Backup files will be hashed and stored in an external drive.

7.5. Declaration of interests

The PI and Co-Investigators declare no conflicts in relation to this study.

7.6. Access to data

We will follow the University of Stellenbosch's IRB-approved Policies and Procedures. Study data are for sole use of the study team in the first instance and cannot be shared or transmitted to other investigators without a prior written approval from the Deputy Vice-Chancellor (Research, Innovation and Postgraduate Studies) at the University of Stellenbosch.

The project investigators have exclusive use of data and biological samples collected as part of an individual project for a 5-year period following the conclusion of an approved project, unless data sharing is approved by the process described above. During the 5-year period, the investigators reserve the right to use data items and biological samples to perform preliminary analyses to develop new proposals A signed data distribution agreement will be required for each interested researcher, as well as an IRB approval, in order to ensure proper procedures of protecting participants' confidentiality and privacy. However, this 5 year period may be reduced with permission of the PI's.

Further analyses of the study data may be carried out by the study investigators or by other scientists. The purpose of these will be to develop a better understanding of sociodemographic and other factors associated with the use of HIVST, engagement with health facilities, initiation of and adherence to PrEP and ART. Researchers may also investigate temporal patterns of engagement with and disengagement from HIV care. This may lead to the development of future interventions which aim to improve levels of HIV testing and care engagement.

A committee consisting of the two principal investigators of the proposed research and other senior persons will evaluate each proposal and may request that the proposal will be revised and resubmitted to the committee through a formal application process. Investigators are required to outline the use of the desired data and/or biological samples, for example, for a proposed paper on a specific topic, or to conduct preliminary analyses for grant applications. The PI's will review

the application for scientific value, feasibility, and bioethical considerations of the proposed project. Finally, prior to releasing data, researchers interested in using the data will be required to sign an agreement stipulating that under no circumstances may they share data with other researchers. Additionally, they will be required to sign a confidentiality agreement specifying that they will use the data only for their specified research purposes and they will not identify any individual participant. Investigators must also agree to use secure technology to safeguard the data. Data will be directly transferred to the investigators. Only de-identified data will be shared with the investigators.

7.7. Dissemination policy

7.7.1. Plans for communication of trial results

For a wider audience, our aim is to enable practitioners and policymakers to apply our findings and guidance in a robust and timely manner. Our dissemination strategy has been developed to support this process as follows:

Scientific community: The results will be published in peer-reviewed scientific journals and presented to the scientific community at conferences and other events as well as at national scientific and policy meetings. Finally, information sheets, reports, and other materials as well as ongoing news on the study and its results will be made available on the website of the Manicaland Centre (http://www.manicalandhivproject.org/).

Research participants: We will also disseminate our findings during community engagement meetings with local community leaders and community.

Local and national stakeholders: Results from the study will be shared and reviewed with the local and district authorities and with the national government in Zimbabwe (including the Zimbabwe Ministry of Health and Child Care's AIDS and TB unit, and the National AIDS Council) and in reports and presentations made at meetings and workshops. The findings will be disseminated within the local community in Manicaland, where the data have been collected, through district and local meetings, information sheets (translated into the local language) and other activities. The information provided at these meetings and in the information sheets will be adapted to the specific study sites to present locally relevant highlights of and details on the research results. Feedback from these local meetings may be incorporated in the feedback provided to district and national stakeholders. Results will also be disseminated to local, national, and international organisations working on the HIV prevention.

Key findings will be presented followed by a discussion with researchers and breakout groups to discuss the implications of the study findings. We will produce a summary position paper of the key issues raised during the workshops and share it with the wider community in line with the principles of 'Public Engagement in Science'. The strategy will leverage existing resources within the participating organizations, their academic infrastructure, professional relationships and community networks. These papers and all associated data will be made available in accordance with the NIH public access policy.

8. Appendix 1

8.1. Informed Consent Materials

Informed Consent forms for the Quantitative and Qualitative research are attached to this protocol.

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