Pilot study of secondary distribution of HIV self-screening tests by women with HIV: An innovative strategy to improve testing, identification, and linkage to treatment of men in South Africa

Study Investigators:

Principal Investigators:

1. Dr. Dvora Joseph Davey, Honorary Senior Lecturer, Epidemiology, School of Public Health and Family Medicine, University of Cape Town
2. Dr. Kristin Wall, Epidemiologist, Emory University, Atlanta, USA

Co-Investigators:

1. Dr. Kathryn Dovel, Behavioral Scientist, University of California, Los Angeles, USA
2. Todd Malone, Chief of Party, BroadReach, South Africa
3. Dhirisha Naidoo, Project Director, BroadReach, South Africa
4. Dr. Nireshni Naidoo, Epidemiologist, BroadReach, South Africa
5. Sila Chatikobo, BroadReach, South Africa
6. Jimmy Lebwada, BroadReach, South Africa
7. Gugu Xaba, BroadReach District Director, Nkangala District
8. Dr Cheryl Nelson, Mpumalanga Department of Health

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1. Background and Rationale:

Though access to and uptake of HIV testing in South Africa has improved, a recent study demonstrated that 55% of males and 48% of female adults over 15 years who were diagnosed with HIV in the last 12 months were previously unaware of their seropositivity (1), impeding efforts to bring the South African HIV epidemic under control. Despite the significant move towards community based HIV counselling and testing (HCT), many South Africans, especially men, remain unaware of their HIV status until HIV related illness forces presentation at clinic or health facility (2-4). A successful treatment cascade provides early and regular testing opportunities, linkage to HIV care for those who test HIV positive, and retention to achieve undetectable viral loads (5-7). Many South African men choose not to visit conventional HIV clinics due to multiple real and perceived barriers that prevent access. These barriers include a fragmented healthcare system, congested clinics, unfriendly staff, restricted clinic work hours, multiple visits, and stigma and privacy concerns (8, 9).

In Mpumalanga, Gert Sibande and Nkangala Districts have significant gaps to identifying people living with HIV (PLHIV) who are not on antiretroviral therapy (ART), and reaching their ART targets, especially in adult men. In line with prior research of HIV treatment, estimate that over 65% of PLHIV not on ART are men (1), which is a gap of ~39,000 men living with HIV needing to be tested and initiated on ART. To diagnose over 60,000 new PLHIV or PLHIV not on ART (38,000 in Gert Sibande and 30,000 in Nkangala) and initiate them on ART in the next year (PEPFAR, Implementing Partner data, August 2020), innovative testing strategies are required. Index partner testing, defined as testing partners of individuals living with HIV, has not been brought to scale in Mpumalanga, despite research demonstrating the positive impact of index testing.(10, 11) To improve case finding among men in these districts we propose to evaluate how best to reach partners of PLHIV (newly diagnosed or on ART) with index testing by using HIV self-screening (HIVSS) and linkage to ART start.

Secondary distribution of HIV self-screening kits (HIVSS), whereby clients bring HIVSS kits to their partners, addresses many important barriers by enabling sex partners to screen themselves at their convenience and in the privacy of their own homes (12). HIVSS is a particularly promising strategy to engage African men who are less likely to attend clinic services or receive clinic-based HIV testing (13). Male clients perceive HIVSS as a strategy that saves the time and cost spent going to a clinic for testing, reduces stigma, and prepares them for retesting or confirmatory testing in the clinic (14). Secondary HIVSS distribution dramatically increased male partner and couples testing in antenatal and postpartum care settings in Kenya (15), male partner testing in antenatal care settings Malawi (16), and male partner testing in Malawi among HIV-positive women accessing ART services (10). Few adverse events, including intimate partner violence (IPV), have been associated with secondary HIVSS distribution strategies in five randomized trials (12). However, several gaps remain.

- First, there is an urgent need to examine secondary distribution of HIVSS by women to male partners in **South Africa**. Few HIVSS studies have been conducted in South Africa which has very different epidemic and contextual factors (e.g., higher levels of IPV) versus Kenya and Malawi where most previous studies were conducted. In contrast to the higher acceptability of HIVSS reported by clients in Kenya and Malawi (17) some studies from South Africa indicate that acceptability may be low which could greatly limit HIVSS impact, while other studies indicate that acceptability may be high in South Africa (18). To our knowledge, no randomized controlled trials of the effectiveness of secondary HIVSS distribution have taken place among South Africa adults.
- Second, more research is needed to **validate partner HIVSS use and results** after distribution. A systematic review found that three strategies may be able to verify HIVSS results (supervision by a health provider, returning used kits, and electronic transmission of photographs), but evaluation and development of innovative strategies for verifying HIVSS use and results is urgently needed (19).

- Finally, prior trials of HIVSS have focused on primary outcomes of HIVSS uptake among partners. It is additionally and critically important to understand whether HIVSS strategies lead to **improved partner ART uptake** among newly diagnosed men.

COVID-19 and study implications. The Department of Health and PEPFAR partners, including BroadReach Healthcare, have continued to offer HIV testing, treatment and monitoring during the COVID-19 lockdown in South Africa as HIV services are essential health services. The team will continue to observe all Department of Health infection prevention and control methods. The proposed intervention is important during the COVID-19 lockdown as it is designed to promote HIV testing and case finding from home to improve linkage to treatment from the HIV+ partner.

3. **Study Objectives:**

We will partner with BroadReach Healthcare, a PEPFAR partner in South Africa, to pilot test an innovative index partner HIVSS strategy in one urban and one rural public health clinic in the Nkangala district of Mpumalanga Province to evaluate **acceptability**, **barriers**, and **preliminary efficacy** of secondary HIVSS distribution in a randomized control trial enrolling women newly diagnosed with HIV or on ART. In the intervention arm, women will receive counselling on how to use HIVSS, how to encourage their male partner to screen, and 2 HIVSSs with HIVSS instructions and invitation to return for confirmatory testing. In the standard of care arm, index women will receive counselling on the importance of disclosure to their family and partner(s) and referral for HIV testing (per SA national guidelines). We will evaluate the following aims:

1. Conduct a mixed-methods survey with N=100 HIV+ women to assess perceived **acceptability and barriers** (including perceived safety, IPV) to secondary HIVSS distribution by women to male partners.

2. Test the **feasibility** and **preliminary efficacy** of secondary HIVSS distribution through a 1:1 randomized control trial in n=100 HIV+ women to assess, comparing standard of care to intervention arm:
    a. % of index women who self-report that they gave the HIVSS or standard of care referral for testing to their male partner
    b. % of male partners who either screened or tested for HIV assessed at 3 months after randomization *(primary outcome*)
        i. Measured via options of: index or partner self-report, SMS/WhatsApp of a picture of the used HIVSS sent by partner or index, return of a used self-test to the facility by either the index or partner, and/or partner coming into facility for with an invitation for confirmatory testing or SOC counseling referral
    c. % of male partners with a positive HIV screening/test result
    d. % of newly diagnosed male partners who initiate ART within 3 months of diagnosis
    e. % of those on ART with viral suppression after 6 months on ART (index and partners)

3. <u>In the intervention arm</u>, we will assess **acceptability and barriers (including safety/IPV)** related to HIVSS distribution or use via surveys with all intervention participants who return for the study endline survey and a convenience samples of n=20 male partners (n=10 men who used HIVSS and n=10 men who did not use HIVSS)

We will publish these results to inform PEPFAR index and HIVSS implementation in South Africa. This study will inform a larger trial to apply for a large research grant to the US National Institute of Health (NIH) in late 2021.

3. Study design

Randomized control trial of n=100 WLHIV (50 in each arm) in two facilities in the Nkangala district. We selected high-density facilities, Kwamhlanga CHC and Sr Mashiteng Clinic facility from a rural and urban area, respectively, to ensure that the results are generalizable. These facilities use oral HIV test kits, which has been shown to be more acceptable in terms of ease of use (20, 21). WLHIV will be recruited in antenatal care or in HIV care services. Inclusion criteria are listed below.

Inclusion Criteria:

1. Adult female 18+ years old
2. confirmed HIV-positive or on ART
3. confirmed to currently have a male partner and are sexually active
4. male partner is of HIV- or unknown status
5. confirmed to have a cell phone that can read and respond to SMS/WhatsApp messages
6. confirmed to be able to consent to study participation (no language constraints or psychological issues that would make it difficult to consent to participate in the study)

Exclusion criteria: Failure to meet all of inclusion criteria

Procedures for the informed consent process are outlined below. Throughout, trained BroadReach staff will ensure that women are aware of their right to refuse and/or withdraw from the study at any time. In addition, study staff will emphasize that all study activities are entirely separate from routine HIV care services received and that refusal or withdrawal from the study will have no impact on their ability to access any services provided at any public-sector health facility.

Study procedures

The study will be integrated into Kwamhlanga CHC (rural facility) and Sr Mashiteng Clinic facility (urban facility) in Nkangala district. WLHIV will be recruited directly from the clinic HCT, antenatal care, or ART services. All trained staff are already working in the facility part of the ongoing current APACE (Accelerating Programme Achievements to Control the Epidemic) programme under USAID. The trained study recruiter will recruit eligible directly from women in the study, and if interested and eligible after the screening process, the women will go to a private room for the study consent and interview.

Baseline survey: After consent, a trained interviewer/counselor will administer a brief 10-15 minute survey to n=100 WLHIV about socio-demographics (age, education, relationship status), knowledge of partner's prior HIV testing and status, willingness to distribute HIVSS to their partner(s), facilitators/barriers to HIVSS (17). A trained study staff will ask the survey questions in the local dialect using RedCap. Participants will receive an option to participate in the interview on the phone instead of returning to the health facility.

Randomization: Following the baseline survey, women will be randomized to receive a HIVSS or referral in a 1:1 ratio to the intervention or standard of care arm. Randomization will be performed using a random number table by participant ID, who will be provided with sealed randomization envelopes. The participants will open the envelopes sequentially.

Male partner contact: For women allocated to the intervention arm, the participant will be given a HIVSS to take home to their partner(s). The counsellors will give the participant two options for contacting their partners:

- The participant will contact their partner (via a telephone call or SMS) while in the counselling session to confirm the partner's participation and obtain permission to provide his contact details.
- The participant will ask the partner to contact the counsellor to confirm participation and provide his contact details.

If the participant confirms that her partner consented to participate in the study, the counsellor will call him to request his consent over the phone and confirm that he is her partner (using his name and date of birth). The interviewer will read the consent form on the phone and send him a copy via SMS/WhatsApp or email.

Standard of care arm: In the standard of care arm, women will receive standard of care partner referrals for HIV testing, including counselling about disclosure and referral for her partner(s) to return to the facility for testing. They will complete an endline survey after ~3 months (or when they return for their next clinical visit, ART start, or drug pick up visit) to evaluate the uptake of partner testing, results, and safety, including IPV.

Female partner endline survey (intervention arm): Study staff in the facility will conduct a brief 10 minute endline survey in all participants who return at 3 months (or when they return for their next clinical visit, ART start, or drug pick up visit) to report on primary outcomes including partner HIV testing, results and confirmatory testing. If the women do not return in 3 months, UCT staff will conduct the survey telephonically.

Male partner endline survey (intervention arm): Following the survey and counselling, we will ask female participants to ask their partner if he consents (verbally or via SMS/WhatsApp) that we can follow them up. Study staff will contact women who agree in 24-48 hours following the survey to speak with her partner or ask her to give the study phone number to call us to consent to participate in a brief survey. We will attempt to recruit 20 male partners from the intervention arm (n=10 who used the test and n=10 who did not use the test) to provide informed consent to participate study survey to evaluate use of HIVSS, acceptability (including linking HIVSS to couples testing or disclosure), barriers and any reported harms or reactions over the phone. Male partners will be asked about what they liked about HIVSS, acceptability and ease of use.

Note: All surveys will be translated into isiZulu and back-translated into English to confirm accuracy prior to implementation.

Human Resources: We will train 1-2 BroadReach and DoH HTS counsellors to select the women, consent them and interview them (30-45 minutes) and then either allocate the HIVSS or counselling about importance of partner testing, depending on randomization. A BroadReach Manager will manage the quality of the study and ensure a timely reporting, and contact colleagues at UCT with problems/queries. A trained UCT research staff will conduct the follow up surveys telephonically with women who are unable to return to the facility. The research staff will also conduct interviews with men (n=20) for the endline survey.

Table 1. Pilot study timeline

	Nov	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**
Mpumalanga Province, District and UCT HREC proposal submission, review and approval	X						
Train HTS counsellors and BR manager in pilot study SOPs, survey and procedures	X						
Develop RedCap survey and pre-test with staff	X						
Recruit and enroll n=100 WLHIV in the study (n=50/month)			X	X			
Baseline survey and eligibility screening (n=100 WLHIV)			X	X			
Randomize n=100 WLHIV to intervention vs standard of care			X	X			
Deliver HIVSS and instructions to n=50 and referral counseling to n=50			X	X			
Follow up participants at ~3 months (to coincide with next clinical visit) to conduct endline survey and evaluate HIV testing uptake, results					X	X	X

(positivity) and linkage (telephonically and using health records)							
Study endline survey for n=20 partners in the intervention arm (telephonically)					X	X	X
Analysis and dissemination						X	X

Evaluation: We will evaluate the following outcomes in the study including:

1. % of index women who self-report that they gave the HIVSS or SOC counseling referral to their male partner
2. % of male partners who either screened or tested for HIV assessed at 3 months after randomization (primary outcome)
    i. Outcome measured via: index or partner self-report, SMS/WhatsApp of a picture of the used HIVSS sent by partner or index, return of a used self-test to the facility by either the index or partner, and/or partner coming into facility for with an invitation for confirmatory testing or SOC counseling referral
3. % of male partners with a positive HIV screening/test result (case finding)
4. % of newly diagnosed male partners who initiate ART within 3 months of diagnosis
5. % of those on ART with viral suppression after 6 months on ART (index and partners)

4. Ethical considerations

The study protocol, informed consent form, all data collection tools, and other requested documents will be reviewed and approved by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (UCT-HREC).

Informed consent

The study informed consent for the study and questionnaire are modelled after that used in previous studies and will be delivered in participants' home language by trained interviewers. The informed consent form (ICF) will be translated into isiZulu and back-translated into English to confirm accuracy. This study ICF details the purpose of the study, study procedures, and the risks and benefits to women that participants may encounter at the second study visit. We will ask women if they want to consent to give her partners' contact information (phone number), but this will not required be to join the study.

Here, study staff will emphasize to participants that:

- Participation is entirely voluntary, and their choice regarding participation will in no way influence the quality of routine medical care for mothers

- Women may exit the study at any time for any reason without compromising the quality of health care received.

Risks

The potential risks to participants in the study include:

- Risks associated with collection of self-reported behavioral and psychosocial information, related to psychosocial distress raised by questionnaire items involving social support, mental health, or disclosure of HIV status

- Risks due to loss of confidentiality due to study procedures—for instance, in the process of data collection

- Risk associated with asking participants to disclose their status, and potential for interpersonal violence by the partner resultant from the disclosure

All participants will be informed of these risks, and the strategies to minimize these, as part of the informed consent process. These strategies draw directly from prior experiences conducting research on HIV prevention and treatment in Mpumalanga.

Safeguards for adverse events: We will screen for IPV risk at baseline and inform women that they do not have to participate in the study if they feel that they are at risk of any violence or harm at home from their partner or anyone else at home. This is in line with prior studies of HIVSS in Malawi and Kenya. Referrals for support related to reported IPV will be given to local social services and NGOs who work with victims of IPV.

5. Benefits

Direct benefit: The primary direct benefit from participating in this pilot study is that women in the intervention arm will receive HIV self-tests for their partner and follow up counseling and support. The proposed intervention is designed to promote case finding, ART linkage and retention in couples living with HIV. We will refer women experiencing IPV to local organizations for counselling and support.

Indirect benefit: By identifying the optimal strategy for improving case finding and index partner testing, this study has the potential to lead to improved HIV treatment interventions to improve case finding interventions across South Africa. Further, if the pilot works and is implemented more widely, it will improve disclosure, ART linkage and potentially retention and viral suppression.

Confidentiality: The following steps will be taken to minimize the risk of any loss of confidentiality throughout study design and conduct.

- All personnel involved in data collection and management will undergo specific training for the study in confidentiality and related patient protection issues.
- Following standard practice, all patient- and study-related information will be kept in locked cabinets at either the BR office.
- Anonymous participant identification numbers will be used on all study documents. Collection of participant names and other identifiers will be restricted to informed consent documents, patient tracing materials, and a study identification key, all of which will be kept in a locked cabinet in the BR office separate from other study documentation and accessible only by the project coordinator and PI. No CRF will include participant name, including CRF that may reflect HIV status of women or their children.
- All electronic records will be kept in password-protected files. All electronic communications of study data will be through password-protected, encrypted files. All data storage at the University of Cape Town will be within a firewall-protected server.

While efforts will be made to minimize the loss of confidentiality, in the event that staff learn that the participant is a threat to themselves or to others or of possible abuse by partners, the proper authorities will be notified. This exception will be included in all study informed consent forms.

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INTRODUCTION

Good Morning/Afternoon. My name is _____. I work for BroadReach Healthcare. BroadReach, along with our partners at the University of Cape Town School of Public Health and Family Medicine, and the Mpumalanga Department of Health, are conducting a research study to evaluate the feasibility and acceptability of HIV self-testing for male partners. Before you decide if you want to take part, I will tell you more about the study participation including the benefits and risks to you and what would be expected of you. This information is described in the consent form, which I will give to you now. If you agree to participate, I will ask you to sign the form confirming your willingness to participate. I will give you a copy of the signed consent form to keep.

Why is this study being done?

Men who live with HIV are less likely to test and get on treatment compared to women. Our study seeks to understand how we can improve HIV testing and treatment in male partners of women living with HIV by offering HIV self-tests, or referral to the facility for testing.

Why are you being asked to take part?

Because you are seeking HIV testing and/or treatment in this clinic and are eligible to participate.

How many people will take part in the study?

100 women living with HIV.

How long will the study last?

The study lasts 3 months after you start.

What do we do to decide if you are eligible to take part?

You must be part of of the following group to be part of this study:

1. Adult female 18+ years old
2. confirmed HIV-positive or on ART
3. confirmed to currently have a male partner and are sexually active
4. male partner is of HIV- or unknown status
5. confirmed to have a cell phone that can read and respond to SMS/Whatsapp messages
6. confirmed to be able to consent to study participation (no language constraints)

What will happen if you decide to take part in the study?

Study procedures: After you consent to participate in this study, **we will tell you what group you are in.** You have a 50% chance of selecting the standard of care or intervention groups.

If you are in the **standard of care group**, we will:

1. provide you with counselling about partner testing
2. ask you a brief questionnaire (10-15 minutes) about yourself and your partner.
3. ask you to return in 3 months and ask you similar questions about your HIV testing experience
    a. Note: We will call you to interview you if you don't return to the clinic.
4. We will also access your medical records to see if you are on treatment and achieve viral suppression in the next 3 months.

If you are in the **intervention group,** we will:

1. Give you a HIV self-test and counselling on how to use this for your partner(s).
2. Ask you a brief questionnaire (10-15 minutes) about yourself and your partner.
3. Ask you to contact your partner to see if **he consents over the phone or text to be contacted by our research team** on the telephone for follow up in 1-2 days (total of 20 male partners will be interviewed).
4. Ask you to return in 3 months and ask you similar questions about your HIV testing experience.
    - Note: We will call you to interview you over the phone if you don't return to the clinic

5. We will also access your medical records to see if you are on treatment and achieve viral suppression in the next 3 months.

Are there any benefits to you for being in the study?

For women in the standard of care group, there is no direct benefit for participating in this study. For women in the intervention group, you will receive HIV self tests for your partner to use to encourage his HIV testing and linkage to treatment.

What are the risks and discomforts of this study?

The potential risks to participants in the study include:

- Risks associated with collection of information about your health, HIV status and partner related to stress in questions about your health, mental health, or disclosure of HIV status
- Risks due to someone putting your name down on a file or record and finding out your HIV status or that you are part of this study
- Risk associated with asking participants to disclose their status, and potential for interpersonal violence by the partner resultant from the disclosure

What other choices do you have?

Taking part in this study is voluntary. If you choose not to participate, your care at this clinic will NOT be affected today or in the future. If after you join the study, you decide that you no longer want to be involved, you can speak with one of the nurses or study staff, and we will take you off our list and you will not be contacted about the study again. You are free to withdraw from the study at any time and are not required to inform the study staff, although investigators prefer that you do, and that way they will no longer be contacted.

What will happen when the study is over?

When the study is over, you will continue to get clinical care as before in this clinic. We will store your data electronically in a password protected site (RedCap) that will not contain your name or any identifying information. This confidential data will be stored for five years, and then will be deleted and destroyed.

Who will see the information which is collected about you during the study?

All information that will be collected from your will be kept confidential. No one but the researchers will be able to see it. We will not tell anyone about your participation. Your name will not be linked to your information. Only the special study number we give you will be able to identify you, and only the researchers will know what your number is. We will lock this information up with a lock and key.

FOR ADDITIONAL INFORMATION:

The UCT's Faculty of Health Sciences Human Research Ethics Committee has approved this study in accordance with the Helsinki Declaration. UCT HREC can be contacted on 021 406 6338 in case you have any ethical concerns or questions about your rights or welfare as a participant on this research study.

If you have any questions or have any problems while taking part in this research study, you should contact:

Dr Dvora Joseph Davey
School of Public Health and Family Medicine
Faculty of Health Sciences, University of Cape Town
Tel: 0829430578
Email: dvora.josephdavey@uct.ac.za

CONSENT FOR STUDY PARTICIPATION

CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree to participate in the study, including regular data collection. I know that I may withdraw my consent at any time. My participation is voluntary. I understand that whether or not I take part will not affect my health care services received today, or at any time in the future.

Please indicate your consent with your signature.

Participant's name _____

_____

Signature of Participant Date (DD/MM/YYYY)

Please indicate if you consent to the study reviewing your medical files once in 3 months after today (X):

____Yes, you can access my medical file

____No, you cannot access my medical file

Please indicate if your partner consents to us contacting him for a survey on the phone **(intervention group only)**

____Yes, you can contact my partner. His name and phone number are:

_____

____No, you cannot contact my partner

Staff member's name_____

_____

Signature of study staff Date (DD/MM/YYYY)

If the participant is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

Fingerprint of participant:

Witness:

I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the participant

Name: _____

Signature: _____

Date (DD/MM/YYYY): _____

Thank you