

*Traditional healer-initiated HIV counseling and testing in rural South Africa*

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## 1. Introduction

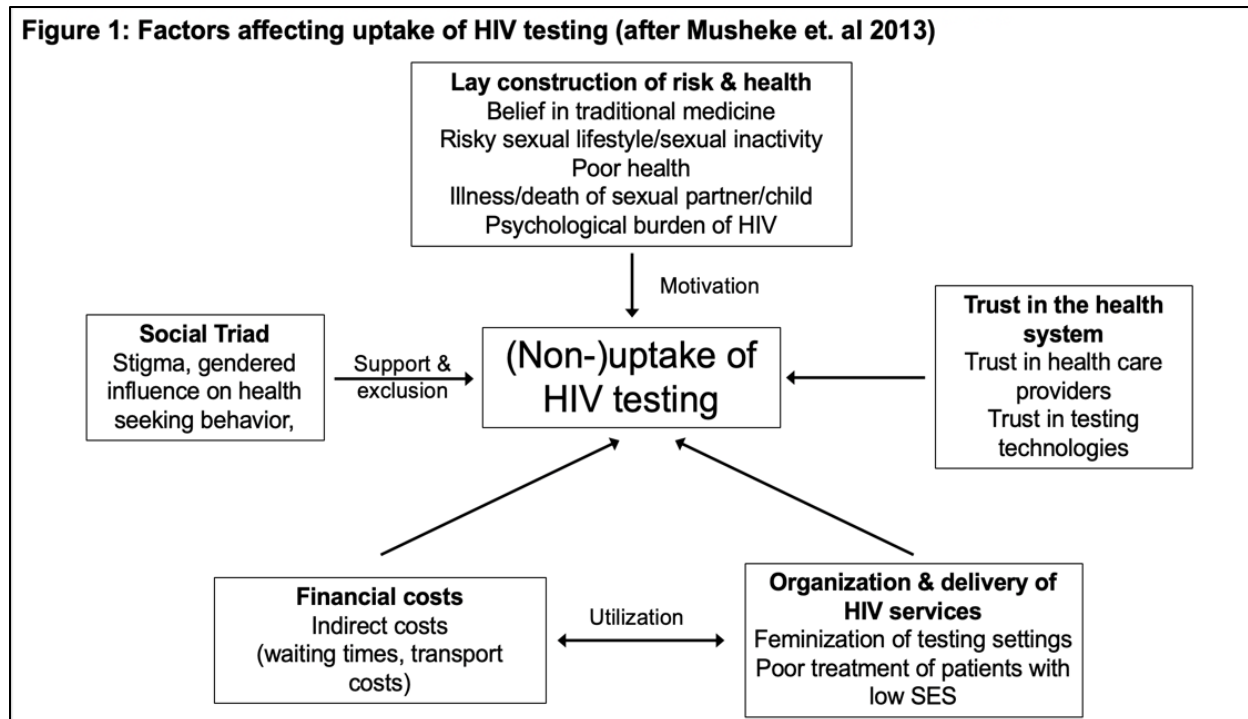
In 2019, 7.97 million South Africans (22.7% of adults) were living with HIV. Uptake of HIV testing has been undermined by a combination of factors, including HIV stigma, distrust in the health system, skepticism toward allopathic medicine, a preference for traditional medicine, and distance to the nearest health facility.<sup>1-9</sup> The unique sociocultural identities and generalized HIV epidemic in South Africa may require a focus on different socially stigmatized categories. Community members with low socioeconomic status (SES),<sup>10-12</sup> as well as those who are male,<sup>13,14</sup> younger,<sup>15,16</sup> immigrants,<sup>17</sup> harbor distrust toward allopathic medicine,<sup>18</sup> and those with higher anticipated HIV stigma<sup>14</sup> are more likely to seek care from a traditional healer and have lower odds of, or delayed, HIV testing.<sup>19-21</sup> Innovative campaigns aimed at testing individuals who are less likely to visit health facilities include: home-based testing,<sup>22</sup> testing in bars,<sup>23,24</sup> testing at sports events,<sup>25</sup> and distribution of self-testing kits.<sup>26</sup> All are available in many parts of rural South Africa. These interventions, while yielding successes, still miss 12-20% of the population.<sup>27-30</sup> South Africa has made progress towards their 90-90-90 targets, yet a substantial proportion of the population do not test regularly;<sup>31</sup> only 33.9% of adults in rural Agincourt, Mpumalanga province (our study population, and the province with the second highest HIV prevalence in the country<sup>32</sup>) received an HIV test in the past year.<sup>33</sup> Interventions that engage those with one or more of the above overlapping demographics/characteristics are needed to maximize HIV prevention.

Annual community-based HIV testing, mobile testing, self-testing and clinic-based testing opportunities are available to people living in Agincourt, South Africa. Despite these ongoing efforts, testing uptake remains low. People with low SES, high levels of HIV stigma, immigrants, men, and those who distrust the allopathic health system are less likely to receive regular HIV testing and more likely to visit a traditional healer. In 2019, 7.97 million South Africans (22.7% of adults) were living with HIV<sup>32</sup> with women bearing a disproportionate burden (26.6% among females vs. 14.8% among males).<sup>31</sup> Though women bear a larger HIV burden, rural South Africa's "hidden HIV population" comprises patients that the allopathic health system fails to reach. In Mpumalanga province, only 33.9% of adults aged 15-59 received an HIV test in the past year.<sup>33</sup> Undiagnosed HIV infection is highest among men, those with low SES, those with high perceived HIV stigma, and those who believe a traditional healer can cure HIV or deny the existence of the disease.<sup>1-3,11,14,34-37</sup> Fear of stigma and discrimination, harmful gender norms, confidentiality fears, and a lack of policies supporting these populations render them reluctant to utilize clinic-based testing.<sup>21,38-43</sup> We propose to create a new testing option to test those individuals for whom other testing mechanisms fail.

While extremely successful, community-based HIV testing is still refused by 12-20% of the population. In a rigorous systematic review of 117 community-based testing strategies in 16 African countries, index, self, mobile, and door-to-door testing achieved the highest uptake (88%, 87%, 87% and 80%, respectively).<sup>27</sup> While we have eliminated the need for people to travel for their test (e.g. mobile testing), ensured confidentiality (self-testing), and targeted those at high-risk (index testing), South Africa still has a testing and linkage to care gap among difficult to reach subpopulations.<sup>28-30</sup> People who perceive, experience or internalize stigma or other forms of marginalization are more likely to utilize traditional healers, less likely to seek care at a health facility, and less likely to undergo HIV testing.<sup>20,44-49</sup>

Stigma continues to impact HIV testing uptake but needs to be addressed in a broader context. A review by Musheke of qualitative factors impacting uptake of HIV testing in sub-Saharan Africa (SSA) found structural (health care organizations, delivery, and costs), social (HIV stigma), and individual belief (trust, health belief) factors all served as barriers to HIV testing (Figure 1).<sup>50</sup> It further concluded that HIV stigma is "inextricably linked" with gender, reproductive norms and economic support, suggesting that in SSA, where much of the HIV epidemic remains generalized, a broad assessment of HIV stigma in the context of gender norms and SES is needed. Individuals

**Figure 1: Factors affecting uptake of HIV testing (after Musheke et. al 2013)**



who are already marginalized from society or the health care system (low SES, immigrants, men) may be even more vulnerable to the negative impact of HIV stigma. Yet few studies have addressed this broader context of stigma.

In Nigeria, Babalola et al.<sup>51</sup> found that among women, individual-level HIV stigma was negatively associated with willingness to test for HIV, while among men, community-level HIV stigma was negatively associated with a willingness to test. More recently in South Africa, and in contrast to Babalola et al., Treves-Kagan et al.<sup>14</sup> found that community-level HIV stigma was negatively associated with HIV testing among women, while individual-level stigma was associated with low HIV testing among men. These studies highlight the complex nature of stigma and the large gap that exists in our understanding of its impact on testing. Given low levels of testing among some subgroups, interventions should simultaneously address this confluence of factors (stigma, gender, SES, health care system barriers, mistrust) to maximize HIV prevention interventions.

Traditional healers see patients who avoid allopathic health services, including those who refuse HIV testing. Patients report a general preference for traditional healers, given their fluency in local language, the length of time they spend with patients, the respect they show patients, the cultural congruity to their diagnosis, and their proximity to the patients.<sup>38,47,48,52-55</sup> Reports of poor treatment by health care providers are common in SSA, often resulting in patients refusing or delaying allopathic health services and/or seeking alternative health services.<sup>18,20,39</sup> Men, immigrants, and those with low SES most frequently report poor treatment at the health facility or report that the health system is not designed for their needs.<sup>14,15,56</sup> People who first visit a traditional healer for HIV-associated symptoms before seeking an HIV test are delayed 2.4 times longer in seeking health services than those who do not.<sup>21</sup> Among patients enrolled in HIV care and treatment, a preference for traditional medicine impacts their treatment decisions: patients who report use of both traditional and allopathic services are 45% less likely to enroll in antiretroviral therapy (ART) services.<sup>54</sup>

Healers are respected members of their communities, play an integral role as informal referral agents to the South African health system,<sup>47,48,57</sup> and act as supportive providers to patients living with chronic disease, if effectively engaged.<sup>58-61</sup> In rural South Africa, traditional healers provide

physical and psychological services to >80% of the population.<sup>62</sup> There are more than 200,000 traditional healers in South Africa, but only 46,000 registered physicians (> 20:1 ratio)<sup>63</sup> who provide services for a myriad of disease conditions, including HIV, TB, malaria, epilepsy, schizophrenia, and depression.<sup>48,52,53,57</sup> Given the level of trust in the community and the numbers of healers,<sup>64,65</sup> partnerships may facilitate diagnosis and linkage to care via the creation of unique testing locations.<sup>62,66-71</sup> It is up to researchers and health care providers to overcome our own biases and/or prejudices against this workforce to develop an effective strategy to increase testing uptake.

Traditional healers can bridge the testing gap between “non-testers” and the allopathic health system. Traditional healers have been successfully engaged in health systems to promote care linkage among people living with diabetes, TB, HIV, malaria, and mental illness- many of whom initially did not believe in their allopathic diagnosis until a healer convinced them that their condition was not caused by a curse.<sup>4,58,61,72-84</sup> Those who are hesitant to test need a trusted and culturally concordant<sup>85-87</sup> provider (traditional healer) to both vouch for and deliver the HIV test, and the same provider to create a bridge to the allopathic health facility, providing a metaphorical “safe space” for the patient while they transition to HIV care. Traditional healers are strongly motivated to play this role for two reasons: (1) Better patient health outcomes are strongly correlated with perceived quality of traditional healer care. Healers do not want to be associated with high levels of morbidity or mortality, as it is bad for business;<sup>88</sup> and (2) Healers are excited at expanding their public health services. As allopathic medical knowledge is disseminated, healer views on disease causation are expanding to include the germ theory of disease.<sup>89,90</sup> Patients are open to this partnership, given their inclination to ping-pong between the two systems depending on their needs.<sup>47,88</sup>

## **2. Objectives**

The objective of this proposal is to conduct a pilot test of a program aimed at training traditional healers to conduct HIV testing and implementing HIV testing among people living in Bushbuckridge, South Africa.

Pilot Healer-initiated HIV testing uptake and linkage to prevention services. Trust in allopathic health care and HIV stigma will be measured among participants at study enrollment and at month seven.

*Hypothesis:* HICT will increase trust in allopathic health care and reduce HIV stigma.

## **4. Study Population**

### **Population**

Traditional healers, people seeking care from traditional healers, and biomedical practitioners (including clinicians and nurses) providing patient care in the Bushbuckridge area.

### **Inclusion Criteria**

1. Traditional healers  $\geq$  18 years of age, who are registered as traditional healers with the government of South Africa, are currently practicing in the Bushbuckridge area, and are trained to provide HIV testing.
2. Biomedical practitioners  $\geq$  18 years of age, who are currently providing HIV-related health care services to patients at government or private health facilities in Bushbuckridge.
3. Community members  $\geq$  18 years of age, who have not received an HIV test result in the past year and who currently live in Bushbuckridge.

### Exclusion Criteria

1. Traditional healers who do not pass their HIV counseling and testing certification.
2. Biomedical practitioners who do not interact with patients seeking treatment for HIV.
3. Community members who are not out sound mind or body during the recruitment (inebriated, too sick to leave the house) and community members with a previous positive HIV test result.

### Calculation of Sample Size & Sampling Strategy

We anticipate approximately 5%, perhaps 10%, of study participants will test positive for HIV and not be eligible for the analysis of health facility HIV testing within 6 months among those testing **HIV negative or refusing testing**. We further estimate that 70% will complete the healer-initiated HIV test, 60% will participate in additional counseling sessions, and 50% will attend an open house. Because study participants had no history of HIV testing in the prior year, we anticipate the primary endpoint of uptake of HIV testing at the health facility will be low, approximately 30%. Finally, given the importance of identifying sub-groups which may benefit the most from the intervention components, we have powered our study to detect significant associations within strata of potential modifiers (e.g., gender). We utilized Stata psim command to conduct 500 simulations each for all combinations of the parameters described above to estimate power to detect a range of RRs.

Given our sample size of 600 study participants, with 5% testing HIV+, and for a modifying variable distributed 50%/50%, we have ~90% power to detect stratum-specific RRs of 2.0 for each intervention component (Table 1). We still retain >80% power to detect RRs of 2.25 even if uptake of HIV testing in control group is as low as 20%. Similarly, if the modifying variable is distributed 40%/60%, we retain ≥80% power to detect stratum-specific RRs of 2.0 (Table 2). Thus, the high power due to our sample size allows for robust assessment and identification of intervention associations within key subsets of participants (gender, stigma, etc.).

Given that we only anticipate 10-30 participants to test HIV+, we will be underpowered to detect a meaningful association for how the intervention components associate with uptake of ART services at the health facility within three months among those testing **HIV positive**. However, the proportion testing positive, the proportion linking to ART care, and the magnitude of the RR for the intervention components will provide important preliminary data for whether this intervention improves ART care and retention, and not just linkage to HIV prevention services (such as follow-up HIV testing in those who are negative).

**Table 1.**

Stratum specific sample size*	Baseline uptake of health facility HIV testing	Intervention component distribution	Power for relative increase in HIV testing uptake among those with the intervention component vs. those without		
			RR=1.75	RR=2.0	RR=2.25
135	20%	40%	0.484	0.702	0.856
		50%	0.458	0.724	0.868
		60%	0.432	0.622	0.824
		70%	0.346	0.576	0.762
135	25%	40%	0.628	0.852	0.954
		50%	0.596	0.832	0.952
		60%	0.604	0.814	0.964
		70%	0.501	0.708	0.874

135	30%	40%	0.772	0.924	0.994
		50%	0.738	0.928	0.996
		60%	0.726	0.924	0.998
		70%	0.592	0.850	0.976
135	35%	40%	0.868	0.990	1.000
		50%	0.832	0.974	1.000
		60%	0.830	0.980	1.000
		70%	0.744	0.952	0.996
135	40%	40%	0.922	1.000	1.000
		50%	0.924	1.000	1.000
		60%	0.932	1.000	1.000
		70%	0.852	0.990	1.000

\*N=135 assumes ~10% test HIV+ and are excluded and the remaining participants are divided equally into two strata of a modifier (e.g., 50% female)

**Table 2.**

Stratum specific sample size*	Baseline uptake of health facility HIV testing	Intervention component distribution	Power for relative increase in HIV testing uptake among those with the intervention component vs. those without		
			RR=1.75	RR=2.0	RR=2.25
115	20%	40%	0.464	0.660	0.814
		50%	0.412	0.596	0.802
		60%	0.346	0.536	0.770
		70%	0.298	0.468	0.654
115	25%	40%	0.574	0.780	0.928
		50%	0.546	0.782	0.932
		60%	0.536	0.746	0.898
		70%	0.412	0.624	0.820
115	30%	40%	0.646	0.896	0.974
		50%	0.676	0.902	0.986
		60%	0.638	0.852	0.958
		70%	0.516	0.796	0.934
115	35%	40%	0.796	0.972	0.998
		50%	0.802	0.972	0.998
		60%	0.716	0.958	0.998
		70%	0.638	0.910	0.994
115	40%	40%	0.908	0.992	1.000
		50%	0.914	0.996	1.000
		60%	0.858	0.990	1.000
		70%	0.794	0.986	1.000

\*N=115 assumes ~5% test HIV+ and are excluded and the remaining participants are divided unequally into two strata of a modifier (e.g., 40% female or other modifier)

## 5. Methods



## Measurement of Results

*Community member (those offered HIV testing) and healer outcomes:* Participants will complete both a baseline and 7-month post-enrollment questionnaire using the ACASI-system on a tablet. Data collection at 7 months will include the baseline survey and additional questions about uptake of HIV testing outside of the study and feedback about the acceptability and satisfaction with the study experience. These will be conducted by a study assistant based in the Agincourt area who is fluent in English and xi-Tsonga. The number of participants approached, the number who agree to testing and counseling (including testing outcome), and reports on the impact of performing HIV testing and counseling on healer income will be collected by the traditional healer. Health clinic research staff will collect uptake of testing during one of the “Open House” events and during non-open house days (if, for example a patient seeks testing during regular clinic hours). Clinical data will be accessed using “Clinic Link” which allows us to gain access to relevant clinical data, including ART uptake and retention in care. Data from clinical providers who participate in the stigma reduction intervention will complete surveys at study initiation and immediately after the study has concluded.

### **Table 3: Outcomes**

#### **Traditional Healer Outcomes**

**Acceptability Endpoints:** (1) Percent of eligible healers who enroll in the training program and (2) Acceptability of the intervention scale (as used in Aim 2).

**Feasibility Endpoints:** (1) Percent of healers who complete training, (2) Change in self-reported healer income, and (3) Feasibility of the intervention (as used in Aim 2).

#### **Patient Outcomes**

**Primary Continuum of Care Endpoints:** (1) Uptake of health facility HIV-test at 6-months (if previously negative or refused test), (2) Uptake of ART services, if positive.

**Secondary Endpoints:** (1) Mistrust towards the allopathic health system, (2) Change in levels of HIV-related stigma among those who test negative, (3) Change in levels of conspiracy beliefs

**Feasibility Outcome:** (1) Uptake of healer-based HIV testing

## *Clinician outcomes:*

We will assess baseline, midterm (after the first training) and end line (after the second training) stigma levels among providers using a Likert-style scale that will assess attitudes towards PLHIV, traditional healers (and healers providing HIV testing in the community), people who use traditional healers, sex workers, men who have sex with men, immigrants, young pregnant women who are not married, and sex workers. We will ask if health care workers: (1) would prefer to not provide services; (2) believe that sub-populations put clinicians at higher risk of acquiring HIV; (3) agree that specific populations engage in immoral behavior; and (4) agree that specific populations deserve their HIV diagnosis.

## Study Procedures

Participants will be recruited among those who present for health care services from one of our traditional healers trained in conducting HIV counseling and testing. Participants will be recruited after their healer consultation is completed to ensure we do not impact their services. Healers will screen potential participants for eligibility (no HIV test in past year, over 18 years of age, live in Agincourt) and if they are eligible, the healers will ask if they are willing to participate in a research study. Healers will state clearly that there is no obligation to participate and that choosing not to participate will in no way impact their health care from this traditional healer. Healers will consent participants via an online consent form via tablet, so all consent forms will be online and backed up to the secure Vanderbilt REDCap cloud.

## Training Activities

To enable traditional healers to acquire the skills necessary to undertake home-based HIV testing as well as HIV coping skills counseling, traditional healers selected to participate will enroll in a 2-week course used with HIV counselors that includes certification to conduct HIV counselling and testing and basic lay counseling to develop patient coping strategies. During the testing and counseling course, 9 topics will be covered including: 1) epidemiology and pathophysiology of HIV/AIDS and disease stages, 2) attitudes and social views of HIV, an introduction to HIV counselling and testing, legal and ethical issues of HIV and HIV testing, 3) pre- and post- test counselling, 4) performing an HIV rapid test and interpretation of the results, 5) psychological stress as a result of a positive test, 6) identifying depressive symptoms (and how to refer a patient to psychological services), 7) referral and management of HIV, 8) counseling patients on primary and secondary prevention methods (including condom use, Pre-Exposure Prophylaxis [PrEP] after HIV testing) and 9) safe disposal of HIV testing equipment. Counseling support will include the development of coping strategies to overcome the negative effects of HIV stigma, risk reduction, and linkage with appropriate community organizations.<sup>91</sup>

The course content will be delivered in an iterative fashion and trainees will have ample opportunity to ask questions with facilitated discussions. Traditional healers/trainees will be asked to orally respond to questions posed by the trainer throughout the training to gauge comprehension as new concepts are introduced. More formally, both a written and practical assessment will be administered. The trainee will be required to pass to be considered proficient to undertake HIV counselling and testing. Fidelity to the intervention, including the safety of the intervention for those tested by the healers, will be monitored via monthly observation using a checklist of procedural activities. This same mechanism is currently employed with community health workers who are providing home-based HIV counseling and testing, to which we have not experienced any difficulty implementing.

Health care providers will receive training in stigma reduction and structural changes to engage these previously stigmatized populations. We will focus on four essential elements identified by Nybalde<sup>92,93</sup> (1) Participatory learning via the provision of information about the impact of stigma on health care outcomes and; (2) Skill building activities (communication, openness) with health care providers to develop skills to work with stigmatized populations (3) Contact with the stigmatized group, including healers and their patients via testimonials and (4) group activities to develop empathy, humanize this stigmatized group, and break down stereotypes.

The stigma reduction training will be conducted by clinician-trainers based at the University of the Witwatersrand. The first part of the training will include an initial two-day training followed by a one-day training two months later that include the following components:

Title of exercise/session	Educational technique	Intended learning outcomes
1. Naming stigma through pictures	In this session, prepared pictures based on personal stories of stigma are viewed. Then, the participants discuss and analyze the forms, causes, and effects of stigma.	Participants discuss what similar stigma takes place in different contexts and start to share stories of what they have personally witnessed.
2. Our own experiences of stigma	This exercise asks participants to think about a time in their life when they felt stigmatized, share this with a partner, and discuss with the larger group	Gives participants a better understanding of the personal feeling and the long0term impacts of stigmatization
3. Key populations stigma problem tree	Using colored cards and markers, participants discuss and write forms of stigma faced by key populations at risk of HIV. The cards are posted on a wall with the causes of stigma representing "roots"	Helps participants to recognize the causes of stigma and how the resulting effects are manifested.



	of a tree at the bottom, actual forms of stigma as the “trunk” of the tree in the middle, and effects of stigma as the tree’s leaves and branches.	
4. Value clarification	Participants fill and individual questionnaire about their personal values and reflect and discuss how these values affect their judgement of others.	Recognition of how personal attitudes and beliefs influence stigmatizing behavior.
5. Things people say	Group brainstorming of what people say about different key populations at risk of HIV.	Understanding how language is used to stigmatize different population subgroups and how words may have harmful impacts.
6. Traditional healers and HIV	Small group discussions about different case studies based on health service experiences of traditional healers, and those who seek services from traditional healers.	Enhanced ability to identify stigma-related barriers for people who use traditional medicine and traditional healers to access and receive appropriate health services.
7. Be the change	Paired role playing to practice challenging stigma in the workplace and elsewhere.	Increased ability to personally challenge or change stigmatizing attitudes among peers and in other situations
8. Writing a charter for stigma-free service	Small group work discussing ideas to promote stigma-free health services. Ideas are promoted in a larger group, and ways forward are discussed.	Understanding of how to develop ideals for promoting stigma-free services when service providers return to their workplace.

Table 5: Stigma Training for providers

**Data Collection:** Participants will complete both a baseline and 7-month post-enrollment questionnaire using the ACASI-system on a tablet. Data collection at 7 months will include the baseline survey and additional questions about uptake of HIV testing outside of the study and feedback about the acceptability and satisfaction with the study experience. These will be conducted by a study assistant based in the Agincourt area who is fluent in English and xi-Tsonga. The number of participants approached, the number who agree to testing and counseling (including testing outcome), and reports on the impact of performing HIV testing and counseling on healer income will be collected by the traditional healer. Health clinic research staff will collect uptake of testing during one of the “Open House” events and during non-open house days (if, for example a patient seeks testing during regular clinic hours). Clinical data will be accessed using “Clinic Link” which allows us to gain access to relevant clinical data, including ART uptake and retention in care. Data from clinical providers who participate in the stigma reduction intervention will complete surveys at study initiation and immediately after the study has concluded.

Time point	Activity	Data Collection
Baseline	Enrollment	Demographics, HIV Stigma, Trust in allopathic provider, belief in HIV test, use of traditional medicine, perceived risk of HIV
Baseline	Healer-initiated C&T, including stigma reduction	Attendance, HIV status, enrollment in care and treatment if positive
Month 6	HIV re-test	Attendance, HIV status, enrollment in care and treatment if positive
Month 7	Follow-up survey & qualitative questions	HIV Stigma, Trust in allopathic provider, belief in HIV test, use of traditional medicine, perceived risk of HIV, experience with the healer-clinician collaborative

Table 6: Project Activities and Data Collection Points

## **6. Study Location**

### **6.1 Location**

The MRC/Wits Agincourt Research Unit oversees the maintenance and operation of the Agincourt Health and Demographic Surveillance Site (HDSS). Roughly 500km northeast of Johannesburg, the unit has been engaged in population-based health and demographic research since 1992. Strong ties with the local community ensure the continual functioning and sustainability of the research.

Constituting a sub-district of the Bushbuckridge district, the Agincourt study site consists of 420 km<sup>2</sup> of semi-arid scrubland with low rainfall, poorly-suited for subsistence farming though used for game farming and low- density cattle rearing. The study area contains six government run clinics, a private community health centre, and one larger area public health centre with patients being referred to three district hospitals, each located at 25- 55 kilometers from the site and relying on namely public means for transport.

### **6.2 Study Population**

The Agincourt HDSS population is comprised of roughly 120,000 individuals- mainly xiTsonga-speaking- spread throughout 20,000 households in 31 research villages. Roughly one-third of the permanent HDSS population is comprised of former Mozambican refugees, who immigrated to South Africa during the 1980s. Our population of focus will include traditional healers living in this region, their patients, and health care workers providing services at local health facilities.

## **7. Data Management and Analysis**

### **Data Management**

#### *Quantitative data:*

Questionnaires, observations of training, as well as HIV testing data will be collected and uploaded to a REDCap database which is housed at Vanderbilt University. REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields. It also provides additional security options, including the ability to restrict a user's ability to download data tagged as identifiers to further protect participant privacy.

Study participants will be assigned a unique, coded identification number at the time of study enrolment. In order to maintain participant confidentiality, all laboratory specimens, study case report forms, and reports will be identified using that coded number. Only research staff will have access to the coded number. Key study personnel, including Drs. Audet and Wagner, will store research data, including medical and laboratory records, in locked cabinets and all e-files will be password protected. Data will be stored in password-protected files within secure buildings at the MRC/Wits Agincourt Research Unit's rural field offices. We have additional measures to enhance security when data are housed at Vanderbilt. Access to all data will be ID and password-protected, including data warehouse software and computers managing and analyzing survey data. No data will be released with any information that may directly or indirectly identify participants, their clinical information, or laboratory results to outside agencies.

### **Data Analysis**

Given that participants may complete none, one, two, or all three of these intervention components, we will consider four different intervention component variables to the Healer-Clinician HIV Prevention Collaborative intervention: (1) Uptake of healer-initiated HIV counseling and testing (vs. those who did not), (2) Participation in additional counseling sessions (vs. those

who did not), (3) Attendance at  $\geq 1$  Open House event at the health facility (vs. those who did not), and (4) An index ranging from 0 to 3 indicating the number intervention components completed.

The primary outcome among those testing HIV negative or refusing testing is uptake of health facility HIV testing within 6 months. We will operationalize the outcomes in the positive (e.g., tested at health facility within 6 months) such that the risk ratios (RR) for the intervention components will be  $>1.0$  if effective. We will estimate the association of each intervention component individually (numbers 1-3 above) using separate regression models that are each further stratified by potential modifiers such as gender, age, sexuality, immigration status, and other baseline characteristics. We will use *modified Poisson regression* models for each intervention component to estimate risk ratios and 95% confidence intervals.

## **8. Ethical Considerations**

### Recruitment and Consent

Participants will be recruited among those who present for health care services from one of our traditional healers trained in conducting HIV counseling and testing. Participants will be recruited after their healer consultation is completed to ensure we do not impact their services. Healers will screen potential participants for eligibility (no HIV test in past year, over 18 years of age, live in Agincourt) and if they are eligible, the healers will ask if they are willing to participate in a research study. Healers will state clearly that there is no obligation to participate and that choosing not to participate will in no way impact their health care from this traditional healer. Healers will consent participants via an online consent form via tablet, so all consent forms will be online and backed up to the secure Vanderbilt REDCap cloud.

### Participant Confidentiality

The study will be conducted according to national and international standards of research ethics, to ensure that the rights of all participants will be respected. Ethical approval from the Wits Human Research Ethics Committee (Medical), the Mpumalanga Provincial Research Committee, and of the Faculty of Medicine at Vanderbilt University will be obtained before any data collection activity commences.

The involvement of individuals in the interviews will be strictly voluntary. After introducing him/herself, the interviewer will read the informed consent to the participant and answer any questions they may have. If he/she does not accept, the discussion with the interview will end. The participants will be assured of the utmost confidentiality on the part of the teams involved in the study.

Information regarding consent will not be logged anywhere and signed forms will be stored in a locked cabinet separate from transcripts and other potentially identifying information from the study. Only the principal investigators will have access signed consent forms. Transcripts will also be maintained to ensure confidentiality and access is restricted to authorized investigators. The confidentiality of the information collected will be strictly guarded.

### Adverse Events

The proposed research will establish the following data and safety monitoring procedures, in compliance with NIH requirements, to ensure participant safety and protect the validity and integrity of data. The study is low risk, with intervention content focusing on providing personal protective equipment to rural South African traditional healers. However, we acknowledge that the participant population is vulnerable and given that the focus of the research is on HIV, a stigmatized condition, the following safety plan will be implemented.

Dr. Audet will be primarily responsible for monitoring the proposed study. Together Drs. Audet and Wagner (Wits), will meet regularly with the site study coordinator and research team to discuss and resolve any situations arising that relate to ethics or human subjects protection. Together with MRC/Wits Agincourt Research Unit senior field staff, they will devise and implement an appropriate remedial course of action that sufficiently addresses any critical incident or adverse event that arises. Dr. Audet will promptly inform the VU IRB, while Dr. Wagner will inform the Wits HREC and Mpumalanga Province research ethics committee of any event that occurs.

Any time an adverse event occurs and at least once a year the investigators will conduct a data and safety review. During this review process, the investigators will evaluate any adverse events and determine whether the event changes the risk/benefit ratio of the study and whether modifications to the protocol or consent process are required. When necessary, they will seek recommendations from Vanderbilt University, Wits University and/or Mpumalanga Province research ethics committee.

The VU and South African (Wits and Mpumalanga Province) IRBs will also review the study proposal and annual reports will be submitted as part of the continuing review process. At this time, they will complete the following: (1) reassess the risks and benefits to participants, the informed consent process, and safeguards for human subjects; (2) review participant enrollment and retention; (3) consider any new scientific or therapeutic developments that might impact the safety of participants in the study; and (4) review any adverse events. Changes to the DSMP will be made as needed.

The investigators will adhere to the VU and South African IRBs' policies on unanticipated problems involving risks to participants or others. The following problems would require prompt reporting to the IRBs. This procedure outlines the process for reporting adverse events, serious adverse events, and unanticipated problems involving risk to participants or others.

#### Investigator Responsibilities

A. The Investigator submits any serious adverse event that requires reporting according to this policy and any other adverse event that may represent an unanticipated problem involving risk to participants or others as follows:

1. A "Report of Unanticipated Problem Involving Risk to Participants or Others" is submitted to the IRB as soon as possible, but no later than 7 calendar days after the Investigator first learns of the event or problem.

This form contains the Investigator's assessment of causality (related or not related to the study) and a description of the actual event;

2. The form also contains an evaluation of whether the event meets the following criteria:
  - a. An event that suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized;
  - b. Unanticipated (i.e., the event was not foreseeable); and
  - c. Related (i.e., likely to have been caused by the research procedures)
3. Finally, any associated materials such as medical record notations or reports with the name and medical record number of the individual redacted (removed) will be included with the report.



4. When applicable, a "Request for Amendment" indicating changes associated with the event or problem is submitted.

#### *Serious Adverse Event (SAE) Reporting*

The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table), Version 1.0, December, 2004, will be used to determine clinical and laboratory grades of any/all grade 2 or higher events (including signs and symptoms, laboratory abnormalities, and diagnoses).

In addition, any/all deaths, disabilities, malignancies, and/or any other conditions deemed serious and/or debilitating/incapacitating by the clinical team will be reported to all involved ethical review boards. The PI will submit SAE information as required by local regulatory or other local authorities, and the research team will adhere to these stringent requirements and submit full reports detailing any SAEs in a timely fashion (i.e. in accordance with existing standards). After the end of the protocol-defined SAE reporting period stated above, the site will report serious, unexpected, clinical suspected adverse drug reactions if the study site staff becomes aware of the event on a passive basis, i.e., from publicly

#### Benefits

Traditional healers in this study could potentially benefit from training on HIV testing protocols as this opens up a new avenue for paid employment in the future. For community members, it provides a new, less stigmatized avenue to access HIV counseling and testing.

#### **9. Limitations**

This pilot study is not a randomized controlled trial, thus we cannot compare uptake of healer-initiated testing with other modalities; however, we will capture uptake of healer-initiated testing, impact of uptake on key psychological outcomes, including HIV stigma and mistrust in the health system, and obtain data on linkage of participants to the health system - key elements to developing and powering a larger randomized controlled trial. We have framed the intervention and subsequent analysis in the cultural context and are collecting data to specifically identify/inform subgroup effects, including sex. While we may be underpowered to detect some of these effects in small subgroups, a low p-value on heterogeneity tests will provide us with a signal for further investigation in a sufficiently powered future RCT.

#### **10. Dissemination Plan**

Results of this study will be collected into a report and shared with the national, provincial and local Departments of Health, traditional healers and biomedical practitioners in the Bushbuckridge area, and researchers at the University of Witwatersrand and Vanderbilt University and the Agincourt research community. Results of this study will also be presented in peer-reviewed journals and at conferences.



## **Appendices**

### *Appendix 1: Surveys for health care providers*

As a health care worker...

I would prefer to not provide services to immigrants here illegally

I believe that illegal immigrants put clinicians at higher risk of acquiring HIV

I agree that illegal immigrants engage in immoral behavior

I agree that illegal immigrants deserve their HIV diagnosis.

I would prefer to not provide services to patients who prefer traditional medicine

I believe that people who use traditional medicine put clinicians at higher risk of acquiring HIV

I agree that people who use traditional medicine engage in immoral behavior

I agree that people who use traditional medicine deserve their HIV diagnosis.

I would prefer to not provide services to young unmarried, pregnant girls

I believe that young, unmarried pregnant girls put clinicians at higher risk of acquiring HIV

I agree that young, unmarried pregnant girls engage in immoral behavior

I agree that young, unmarried pregnant girls deserve their HIV diagnosis.

I would prefer to not provide services to men who have sex without a condom.

I believe that men who have sex without condoms put clinicians at higher risk of acquiring HIV

I agree that men who have sex without condoms engage in immoral behavior

I agree that men who have sex without condoms deserve their HIV diagnosis.

I would prefer to not provide services to sex workers.

I believe that sex workers put clinicians at higher risk of acquiring HIV

I agree that sex workers engage in immoral behavior

I agree that sex workers deserve their HIV diagnosis.

### *Appendix 2: Surveys for participants*

#### **A. Adapted items from the Group-Based Medical Mistrust Scale (GBMMS) Items**

People like me cannot trust doctors and health care workers.

People like me should be suspicious of modern medicine.

People like me should be suspicious of information from doctors and health care workers.

People like me should not confide in doctors and health care workers because it will be used against them.

Doctors and health care workers treat people like me like guinea pigs.

People like me receive the same medical care from doctors and health care workers as people from other groups.

People like me are treated the same as people of other groups by doctors and health care workers.

In most hospitals, people of different backgrounds receive the same kind of care.

Doctors have the best interests of people like me in mind.

Doctors and health care workers sometimes hide information from people like me.

I have personally been treated poorly or unfairly by doctors or health care workers because of who I am.

## **B. Items from the HIV Conspiracy Belief Scale**

HIV is a manmade virus.

AIDS was produced in a government laboratory.

There is a cure for AIDS, but it is being withheld from the poor.

AIDS is a form of genocide, or planned destruction, against Blacks.

AIDS was created by the government to control the Black population.

HIV was created and spread by the CIA.

People who take the new medications for HIV are human guinea pigs for the government.

The medicine that doctors prescribe to treat HIV is poison.

The medication used to treat HIV causes people to get AIDS.

## **C. Items from the Perceptions of HIV Seriousness, Risk, and Threat Survey**

How serious for you would it be if you contracted HIV?

How would you rate your risk for contracting HIV based on your current behavior?

How confident are you that you can stay HIV-negative in your lifetime?

**D. Items from the Internalized Stigma Scale**

*If you were to test positive for HIV and told others your status...*

you would experience a break-up of your marriage or relationship.

you would experience physical abuse by your spouse/partner(s).

you would lose your job/ livelihood.

you would be treated badly at work or school.

you would lose your friends.

you would be disowned from or neglected by your family.

you would be treated badly by health professionals.

your community(village) would treat you like a social outcast.

your family would not care for you if you became sick.

**E. Items from the HIV stigma and Discrimination Scale**

People living with HIV/AIDS should be ashamed

People with AIDS should be isolated from other people

People who have HIV/AIDS are cursed

A person with HIV/AIDS should be allowed to work with other people

People living with HIV/AIDS deserve to be punished

Families of people living with HIV/AIDS should be ashamed

It is reasonable for an employer to fire people who have HIV/AIDS

People with HIV/AIDS are disgusting

People who have HIV/AIDS deserve compassion

People with HIV should be allowed to participate fully in the social events in this community

People living with HIV/AIDS face neglect from their family

People living with HIV/AIDS face physical abuse

People want to be friends with someone who has HIV/AIDS

People living with HIV/AIDS face ejection from their homes by their families

Most people would not buy vegetables from a shopkeeper or food seller that they knew had AIDS

People who are suspected of having HIV/AIDS lose respect in the community

People who have HIV/AIDS face verbal abuse

People living with HIV/AIDS face rejection from their peers

People who have HIV/AIDS should be treated the same as everyone else

People with HIV/AIDS do not deserve any support

People with HIV/AIDS should not have the same freedoms as other people

People living with HIV/AIDS should be treated similarly by health care professionals as people with other illnesses

### *Appendix 3: Consent Forms*

See attached documents.

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