The Risk of HIV Acquisition among Traditional Healers in South Africa: Implementing Novel Strategies to Improve Protective Behaviors

Carolyn M. Audet, PhD, MSc
Assistant Professor
Department of Health Policy
Institute for Global Health
Vanderbilt University, Nashville USA

Ryan G. Wagner, PhD, MSc(Med)
Research Fellow & Trials Manager
MRC/Wits-Agincourt Research Unit
University of the Witwatersrand, Johannesburg

May 28, 2021
NCT Number: NCT04440813

1. Introduction

In rural South Africa, traditional healers provide physical and psychological services to >80% of the population.[1] There are more than 200,000 traditional healers in South Africa and 2 million in all of SSA.[2-6] A patient often first seeks a healer for their health needs, receiving herbal remedies ("injected" and ingested) to prevent and cure ailments. While substantial research efforts have been expended on understanding the positive[7-16] and negative[4,17,18] impact that healers can have on the health of their patients, occupational hazards associated with traditional healer practices in SSA have attracted scant attention.[18] Allopathic health care workers (HCWs) are recognized to be at risk for HIV, HBV, HCV, and other bloodborne infections through occupational exposure to blood and body fluids.[19-23] Similar to allopathic HCWs, healers are also exposed to patients' blood and body fluids. A widespread practice is the traditional "injection," in which the healer performs dozens of subcutaneous incisions in order to rub herbs directly into the bloodied skin.[24-26] In South Africa, 98% of healers report conducting "injections", resulting in an estimated 1,500 blood exposures over the course of their lifetime.[27] Despite pressure to eliminate the practice of "injections," these treatments have been used for centuries and are often the preferred treatment delivery method by patients.[28,29] Like clean needle exchange programs, the provision of personal protective equipment (PPE) does not enable traditional "injection" behavior. Instead it bridges the divide between these two systems and reduces healers' occupational hazard.

Traditional healers face a risk of acquiring bloodborne pathogens from contaminated blood and body fluids. While most exposures for unbroken skin do not result in infection, risk of infection varies by the pathogen involved, the type of exposure, the amount of blood involved, and the amount of virus in the patient's blood at the time of exposure.[30] The average risk of HIV infection after a needlestick or cut exposure to HIV-infected blood is 0.3%, and after exposure to eye, nose, or mouth is estimated to be 0.1%.[30] "Injections" result in substantial blood exposure- approximately 2 mL of blood per injection, which is in contact with a healer's bare skin (primarily hands and arms- we find blood under healer fingernails after treatments- but as people touch their faces 23 times per hour, exposure to the mucus membranes is possible).[31] Healers are often subsistence farmers (resulting in small cuts and abrasions on their hands from planting and harvesting, as well as from regular household activities, including preparing food and washing clothes). Furthermore, they have limiting access to potable water in their homes (thus, limited hand washing opportunities post-"injection") exacerbating their risk of acquisition. In the Agincourt area (Figure 1), healers have an overall HIV prevalence of 30% (CI: 23%-37%) vs. 19% in the general population;[32] in our previous study, healers who reported exposure to patient blood had 2.4-fold higher risk of being HIV-positive than those with no reported blood exposure (59% vs. 25%, respectively).[27]

Low rates of PPE training and use can place healers at risk. PPE is defined as equipment or instruments (gloves, safety glasses, facemasks, respirators, etc.[33]) worn to avoid and/or minimize exposure to hazards that could cause injuries or the spread of infection and illness. Use of PPE has been shown to be effective in reducing occupational exposures.[33-35] Healers living with HIV may be perpetuating the epidemic, given their high HIV prevalence and their reluctance to attend clinical services (including HIV counseling, testing, and treatment). Healers may represent a reservoir of HIV-infected individuals with limited health facility contact. After acquiring HIV through their injection practices or elsewhere, healers are at risk of spreading the virus not only to their partners and children but also to other patients through further blood exposure, thus amplifying the effect of limited PPE/poor occupational hygiene.

2. Objectives

The objective of this proposal is to adapt PPE training guidelines issued by the World Health Organization (WHO)[36] and the U.S. Occupational Safety and Health Administration (OSHA)[33] for use by healers and to fill the current evidence-to-practice gap by comparing effectiveness of two practical strategies for implementing evidence-based PPE guidelines.

Our proposal compares two implementation strategies to increase PPE use and proper disposal during procedures and decrease the number of risky injections performed (de-implementation of traditional injections): (1) Health care worker (HCW)-led education on blood exposure risk and PPE use through a week-long training, followed by three educational outreach visits at the healer's place of practice vs. (2) "Early adopter" healer[37-40] and HCW co-led training followed by three educational outreach visits. We hypothesize that "early adopter" healer messaging and delivery will have greater impact given their membership within the healer community.

Aim 1. Gather information about how healers and health care workers are learning about PPE use to develop an acceptable and appropriate PPE training program.

Aim 2: Compare fidelity to delivery of PPE training between the HCW-only and the healer plus HCW teams**.**

We will compare training fidelity of the two teams via three constructs: (1) content, (2) coverage, and (3) duration[41,42] to determine if there is a difference in fidelity between the two types of teams.

Hypothesis 1: Training fidelity will be greater among healer + HCW teams, as they will have greater motivation to comprehensively deliver education and skill building sessions to healers.

Aim 3: Compare the effects of the two implementation strategies on healer exposure to patient blood.

We will enroll traditional healers into each PPE strategy using a stratified random sampling. Healers will use containers to collect all used sharps and used gloves over a six-month period and complete a low literacy data collection form to document glove use to identify gaps in PPE use.

Hypothesis 1: Healers who are trained by the healer + HCW team will have a higher proportion of glove use during injections than those in the HCW-only trainer arm.

4. Study Population

Population

Traditional healers and biomedical practitioners (including clinicians and nurses) providing patient care in the Bushbuckridge area.

Inclusion Criteria

1. Traditional healers ≥ 18 years of age, who are registered as traditional healers with the government of South Africa, are currently practicing in the Bushbuckridge area, and conduct traditional vaccinations.
2. Biomedical practitioners ≥ 18 years of age, who are currently providing health care services to patients at government or private health facilities in Bushbuckridge.

3. Community members ≥ 18 years of age, who currently live in Bushbuckridge and sought health care services from a traditional healer in the past year.

Exclusion Criteria

1. Traditional healers <18 years of age, who are not registered as traditional healers with the government of South Africa, are not currently practicing, or do not conduct traditional vaccinations on their patients.
2. Biomedical practitioners < 18 years of age or who are not currently providing health services in the Bushbuckridge area.
3. Community members < 18 years of age or who do not seek health care services from traditional healers.

Calculation of Sample Size & Sampling Strategy

Aim 1: We anticipate recruiting 20 traditional healers and 10 health care workers to achieve data saturation.

Aim 2: With n=61 traditional healers per arm, we will have approximately 80% power to detect a difference between intervention arms for the fidelity scores of 0.5 standard deviations, and approximately 90% power to detect a difference of 0.6 standard deviations. These power calculations are based on a two-sample t-test and are likely conservative because the primary analyses will incorporate multiple (correlated) observations per healer. It should be noted that we do not have preliminary data for the fidelity scores; therefore, our power calculations are based on generic standard deviations. Finally, it should be noted that the sample size was primarily based on ensuring adequate power for Aim 3.

Aim 3: From preliminary data collected from healers in Agincourt in 2019, the median proportion of glove use during vaccinations was 0.44, mean 0.39, and standard deviation (SD) 0.39. Our sample size is calculated based on a two-sample t-test and incorporates these preliminary data. Assuming the SD=0.39, then we anticipate needing 61 healers per arm (total of 122) to have 80% power to detect at the (alpha=0.05-level) a difference of 0.2 in the proportion glove use between the HCW-only and the healer + HCW teams (e.g., 0.4 vs. 0.2). Included below is the variability in power given different deltas (differences in the mean proportion of blood exposure between the two arms) (Table 1). Note, that these power calculations are approximate as primary analyses will be performed using negative binomial regression. Power calculations using negative binomial regression would require assuming a distribution of the offset (number of procedures performed per healer), which substantially complicate the calculations. Therefore, we present power calculations based on two-sample t-tests, which should be fairly similar.

Table 1 Sample Size and Power

N	△	SD	α	P
61	0.17	0.39	0.05	66.57
61	0.18	0.39	0.05	71.52
61	0.19	0.39	0.05	76.08
61	**0.20**	**0.39**	**0.05**	**80.22**
61	0.21	0.39	0.05	83.89

61	0.22	0.39	0.05	87.08
61	0.23	0.39	0.05	89.81
61	0.24	0.39	0.05	92.09
61	0.25	0.39	0.05	93.96

N: number of healers per arm
△: Difference to detect (delta)
SD: Standard deviation
α: Significance level (alpha)
P: Power, %

Randomization strategy
To avoid concerns that, despite randomization, one intervention arm of healers will substantially differ from the other, we will conduct stratified randomization. Specifically, we will stratify based on healer sex and the number of patients seen in a given month (dichotomized into high/low based on the estimated median number of patients seen in the past month). This will result in 4 strata. At the time of randomization, each healer will be put in a strata and equal numbers of healers in each strata will be randomized to the two intervention arms.

5. Methods
Measurement of Results

Aim 1: We will use qualitative measures to understand the best strategies to delivery PPE training to traditional healers in Bushbuckridge.

Aim 2: We will rate training fidelity via two constructs: (1) content and (2) coverage[41,42] during the week-long training session and community-based outreach sessions (Appendix 2). Understanding the fidelity of training delivery is essential to interpreting the effect of the intervention on PPE behavior change. If HCW + healer teams can deliver training with greater or equal fidelity than HCWs alone, PPE training can be more quickly scaled up nationwide (given the large number of healers) and conducted at lower cost (healers charge considerably less per hour than HCWs). We believe that the healer + HCW teams may have more motivation to deliver the program with fidelity during community-based sessions than the team of HCWs alone because of healers' desire to protect their peers living in their own community. Three HCWs who volunteer to work on this project will be randomly assigned to the intervention team (along with the healers), with six volunteer HCWs assigned to the control arm.

Aim 3: Healers will complete an interviewer-assisted survey immediately post training (Appendix 3) using the Consolidated Framework for Implementation Research framework[43] (compatibility of PPE with current behavior, peer pressure to use PPE, perception of the inclusiveness of the training process, cost) and individual characteristics from the situated-IMB model (Figure 3)[44,45]. During the six months of the trial, healers in each arm will record data on our primary outcome: the proportion of injections conducted using PPE in two ways.

(1) Collect used sharps and PPE. Healers will be given containers to place all used gloves and razors/sharps to both ensure healer safety and allow us to count materials used (healers use gloves and a single razor once per patient and subsequently throw them into latrines or trash piles). We will use the *number of glove pairs as the numerator* (number of times they used gloves during procedures) and the *number of razor blades as the denominator* (number of injections given). While some may be concerned with social desirability bias, healers have been told for years to use gloves and were very open with us about their non-use. Healers have no reason to

under- or over-inflate their PPE use as it will not benefit them- in fact, they would have to buy the razor blades or travel to a health facility to obtain additional latex gloves, something that seems unlikely in this population. (2) Self-report. Healers will record behavior (injection and glove use) every time they conduct an injection.

Study Procedures

Aim 1:

Phase 1: Information Gathering: We will interview select traditional healers and health care workers who have received some training on the use and disposal of PPE. Among traditional healers we will probe into how we can improve the training they receive, their preferred method of receiving information, and perceived gaps in their knowledge. From health care workers, we will gather information about how they were trained in the donning and doffing of PPE, aspects of the training that they believe would be most useful to traditional healers, and strategies to deliver these messages in a way that would be accessible to those with low levels of literacy.

Phase 2: Production of Draft Program: After we gather information from healers and health care workers, we will produce a draft of our training program. Our team will ensure we are maintaining fidelity to core elements and the underlying theoretical framework of the original evidence-based intervention. If there are substantive changes, we will draft additional measures to assess impact of these changes on the intervention outcomes. We will also develop quality assurance metrics (e.g. to ensure healers are using and disposing of PPE safely) and process measures to track the program's success.

Phase 3: Topical Experts: With our advisory counselor, as well as local leaders (e.g. leader of the traditional healer association, head of HIV care and treatment in the Department of Health), we will elicit feedback on our draft protocol. These experts will be tasked to focus on "big picture" issues, specifically sustainability and integration into district, provincial, and national level systems.

Data Collection:

In-depth Interview Question Guide**:** All participants will provide feedback on the acceptability, feasibility, and appropriateness of PPE training via open-ended questions (e.g. What information was most useful?), as well as questions about perceived barriers and facilitators to PPE training (How difficult will it be to use the sharps containers?) (Appendix 1).

Aims 2 & 3: Traditional healers randomized to both the control and intervention arms will receive PPE education and training, general HIV prevention education and skill building (including condom use, positive prevention, and pre-/post-exposure prophylaxis services), and three educational outreach and coaching visits at the healer's place of practice to provide on-the-ground advice and support for PPE use. These training and educational outreach sessions are designed to allow healers to receive education about bloodborne disease transmission (information), accurately assess their risk of contracting bloodborne illness (motivation), and develop skills to effectively don, doff, and dispose of used PPE (behavior) (Appendices 2 and 3). Outreach visits will focus on delivering five key messages and troubleshoot any issues healers may have in following recommendations. We will assess the impact of our evidence-based PPE intervention on the knowledge, motivation, and behavioral skills developed by traditional healers using the Situated Information Motivation and Behavioral Skills (Situated-IMB) model.[44] The use of in-class

and educational outreach strategies have yielded improvements in clinical care delivery,[46-48] including use of PPE,[49] among physicians, nurses, and community health workers in low-resource settings. These strategies were selected in consultation with traditional healers in Agincourt who reported never having received training on how to protect themselves from exposures based on the strategies used around the world to train health care providers to avoid infection.[33,36,49-51] PPE use is feasible and acceptable to most healers and their patients already,[27] but they lack the knowledge and/or motivation to use gloves properly and regularly.

Our intervention arm will receive the same training and educational outreach as the control arm, but with training and outreach conducted by a clinical team that includes healers who adopted and use PPE on their own (early adopters).[37-40] Early adopters are people who identify a new behavior as innovative (i.e. use of latex gloves) and adopt this behavior before the majority of their colleagues. Used primarily in the Diffusion of Innovation Theory[52] to explain adoption of new behaviors, we hypothesize that the strategy of engaging early adopting healers as trainers in collaboration with HCWs will increase peer pressure, perceived tension for change, participant self-efficacy, and acceptability of PPE use among healers who do not use any barrier to blood exposure. Early adopters can achieve this by highlighting relative advantages, compatibility with their role of a traditional healer and leader in the community, simplicity, and ease of trialability of using gloves with patients.[52]

Participants will receive a baseline and end line (7 months post- training) HIV test (to detect any seroconversion events and to determine if those living with HIV are as motivated to use PPE as those who are HIV-negative). Participants will also complete baseline and end line surveys to assess their knowledge, motivation, and behavioral skills to determine the impact of training on the healer. Once a month, a study assistant will visit each healer to collect all used sharps and PPE; three times during the study the study assistant will also conduct observations of healers using PPE to determine if they are using it correctly post-training.

Healers and healer care workers who are selected, consent and contribute to the training of healers will be reimbursed for their transportation to the training venue and provided with a small token of appreciation (a voucher to a local store for R150) at the conclusion of the workshops.

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^2 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 facilitates.

7. Data Management and Analysis

Data Management

Qualitative Data: Data from interviews will be transcribed in the original language and subsequently translated into English (if necessary). We will randomly select 10% of the original interviews to be re-translated to check for accuracy. The English transcriptions will be imported into Atlas Ti © to be coded by Prof. Carolyn Audet. All data will be password protected to ensure confidentiality. Data will be stored in restricted access folders (protected by an additional password) that sits on the Agincourt and Vanderbilt servers. Both servers have daily backups scheduled; therefore, all data will be backed up on a day-to-day basis.

The original recordings, which will not include participant names or other identifiable information, will be locked in a file cabinet at the Agincourt field site until they have been entered into the database and the data has been checked for errors. After this point they will be erased to ensure voices cannot be linked back to the transcripts. All paper copies of transcripts will be destroyed once they have been typed up, verified, and electronic versions sent to Vanderbilt. All electronic copies of transcripts will be kept in a password-protected folder on a secure server at Agincourt and Vanderbilt for a period of 7 years, after which time they will be destroyed by the study investigators.

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

Aim 1: Audio files will be transcribed by a research assistant. The PI will code and analyze the interviews using Atlas-Ti software. Framework analysis will be used to identify responses to our questions about the drivers, core facilitators, and barriers to intervention acceptability and success.[53] Two code maps will be developed to categorize data: (1) To understand the social, structural, and informational drivers, facilitators, and barriers to acceptability of education and PPE skill building, and (2) To understand participant concepts of "best practice" for healer PPE

use (including best practice for communicating this use to patients). Data will be coded by two independent coders to ensure that Cohen's Kappa is >85%. For quantitative surveys, results will be summed to generate three scores (acceptability, appropriateness, and feasibility). Descriptive analyses will be done with survey results from each permutation of the intervention to determine if changes made have resulted in improvements. We will triangulate qualitative and quantitative data to ensure understanding; inconsistencies in findings will be investigated to ensure understanding.

Aim 2: Analysis plan for content: A numeric scale will be used to assess the fidelity of the delivery of *each* topic in the training session. Topics include: (1) Delivered information about the definition of PPE, (2) Provided information about when to use PPE, (3) Provided information about what types of PPE to use in different circumstances, (4) Provided information about the appropriate fit of PPE, (5) Provided do's and don'ts of glove use, (6) Provided information about don PPE, (7) Provided information about how and where to remove PPE, (8) Provided information about how to safely store used PPE, (9) Provided information about hand hygiene, (10) Provided instruction and feedback during PPE practice session. Each of the ten training items will be scored (each with a score of 0-10; 10 represents the greatest fidelity to the training guide, 0 not covering the material at all) for a total of 100 points. The summation of all scores across topics will be used to measure fidelity to content for that training session. Each participant will participate in three training sessions. The mean difference between the two interventions in the total fidelity scores will be estimated using mixed effects linear regression models with 95% confidence intervals (CIs). These models will include random effects for the participant (to account for correlation across multiple sessions) and the trainer (to account for one trainer instructing multiple participants) and a 95% CI will be constructed. The outcome will be transformed as necessary to meet modeling assumptions. Covariates will include patient volume, sex, and baseline age. Any missing data will be imputed using chained equations with 20 imputation replications. Based on prior experience working with healers, we anticipate very low rates of loss to follow-up (LTFU). Healers who are LTFU will be censored at the time of their last recorded data collection, and inverse-probability of censoring weights based on healer characteristics randomization will be used, if necessary, to account for differences between healers who are LTFU and those who remain in the study.

Analysis plan for coverage: We will calculate the percentage of sessions completed as the actual number of sessions completed for a participant divided by the total number of planned sessions. The percentage of sessions completed between the two intervention arms will be compared using mixed effects Poisson regression with the number of planned sessions (in most cases 3) as an offset. 95% confidence intervals will be constructed. The models will include random effects for the trainers. Covariates will include patient volume, sex, and baseline age. Missing data and LTFU will be handled as described above.

Aim 3: The analysis will follow intent-to-treat protocol. Our primary outcome is the proportion of a healer's procedures that were conducted using latex gloves (numerator = number of procedures with blood exposure, denominator = number of procedures). We will compare the blood exposure proportions between the two study arms using a negative binomial regression model. In the negative binomial regression, the outcome will be the number of times gloves were used and the number of procedures performed by the healer (number of razor blades) will be included as an offset. Such an analysis is appropriate because it properly accounts for heterogeneity between healers in the number of procedures performed, and the resulting estimates from the model can be interpreted as relative proportions (proportion of procedures with blood exposure in Arm 1 vs. proportion of procedures with blood exposure in Arm 2). In addition to our primary intervention

exposure variable, we will include healer sex and baseline age as covariates in our model. Sensitivity analyses will compare blood exposure proportions between the two intervention arms using a two-sample t-test; a Wilcoxon rank sum test will be fit as needed to avoid normality assumptions.

Based on prior experience working with healers, we anticipate very low rates of loss to follow-up (LTFU). Healers who are LTFU will be censored at the time of their last recorded data collection, and inverse-probability of censoring weights based on healer characteristics randomization will be used, if necessary, to account for differences between healers who are LTFU and those who remain in the study. Missing data will be imputed using chained equations and 20 imputation replications.

The secondary outcome, proportion of injection events, will be analyzed in a manner identical to that of our primary outcome except the outcome will be the total number of skin-cutting events performed by the healer, regardless of the use of PPE. A negative binomial regression model will be fit using the number of overall procedures as an offset. While we will not specifically look at HIV seroconversion as a study outcome, we will assess healers' baseline and end line HIV status for ethical reasons. Historical data show that the one-year incidence rate of HIV seroconversion is 1.7%. Since the incidence rate is low, we will likely not have adequate power to see a difference between intervention arms, but this information will allow us to appropriately power our subsequent R01 trial.

A separate analysis will assess each strategies' effect on PPE self-efficacy, PPE knowledge/ skills, and accurate risk assessment post-training. We will explore whether the intervention effects on these measures differ by a) trainer fidelity to the intervention and/or trainer identity (healer vs. clinician), respectively. These analyses will provide quantitative data to revise and refine, as needed, the intervention for evaluation in a large RCT effectiveness study as a means of improving prevention engagement while reducing stigma.

8. Ethical Considerations

Recruitment and Consent

Aim 1: *Traditional healers* from the target community will be recruited via two strategies: (1) Healers in target catchment area are currently being mapped by two students (one from Vanderbilt and one from University of Witwatersrand). The healers are providing their address/location and contact information (phone numbers, contact for other family members) for use in future activities (including research endeavors). The healers will be contacted and given general information about the proposed study. All healers will be invited to community meetings where more information about the study procedures and aims will be provided. (2) The Kukula Traditional Healers association- the primary healer organization in the region- will hold 3 meetings to recruit healers interested in participating. Healers who express interest will be given the option for dates/locations where we will conduct recruitment fairs or the option to have a study assistant visit them at home. All recruitment will be conducted in a private room or at the home of the healer (as per the participants preference).

Health care workers from the target community will be recruited if they provide primary care or HIV/TB services in the primary health care facility. A list of eligible providers will be elicited from the facility manager; three meetings to discuss the study will be held in the clinic. If the health

care worker is interested in participating, they will be consented by a study assistant at the health facility or in a location of their preference.

Aims 2 and 3: *Traditional healers (participants)* from the target community will be recruited via two strategies: (1) Healers in target catchment area are currently being mapped by two students. The healers are providing their address and contact information (phone numbers, contact for other family members) for use in future activities (including research endeavors). The healers will be contacted and given general information about the proposed study. All healers will be invited to community meetings where more information about the study procedures and aims will be provided. (2) The Kukula Traditional Healers association will hold 3 meetings to recruit healers interested in participating. Healers who express interest will be given the option for dates/locations where we will conduct recruitment fairs.

Traditional healers (trainers) from the target community will be recruited based on results of a previous PPE use study among 200 healers. These healers have given us permission to contact them again for subsequent studies so we will visit their place of work to gauge their interest in acting as PPE trainers. We plan to recruit up to 10 healers who report using PPE effectively at every vaccination event.

Health care workers from the target community will be recruited if they provide primary care or HIV/TB services in the primary health care facility. A list of eligible providers will be elicited from the facility chief; one meeting to discuss the study will be held in the clinic. If the health care worker is interested in participating, they will be consented by a study assistant at the health facility or in a location of their preference. A letter of support for this study from the Provincial Department of Health is attached.

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 PPE education and skill building and increased engagement with the health system which will likely highlight the importance of protecting themselves from blood exposures. Health care workers in this study could potentially benefit from their additional PPE education and skill building, which could help protect themselves from blood exposure.

9. Limitations

This study will not be powered to assess seroconversion among traditional healers exposed to HIV but will give us proxy outcomes (blood exposure) and implementation outcomes (acceptability, fidelity to PPE use) to predict the success if we developed a larger trial.

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 are, 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.

References

1. King R. Collaboration with traditional healers in HIV/AIDS prevention and care in sub-Saharan Africa: a literature review. *UNAIDS Best Practices Collection* 2000. http://data.unaids.org/Publications/IRC-pub01/jc299-tradheal_en.pdf. Accessed August 19, 2013.
2. Audet CM, Ngobeni S, Graves E, Wagner RG. Mixed methods inquiry into traditional healers' treatment of mental, neurological and substance abuse disorders in rural South Africa. *PloS one.* 2017;12(12):e0188433.
3. Audet CM, Ngobeni S, Wagner RG. Traditional healer treatment of HIV persists in the era of ART: a mixed methods study from rural South Africa. *BMC complementary and alternative medicine.* 2017;17(1):434.
4. Moshabela M, Bukenya D, Darong G, et al. Traditional healers, faith healers and medical practitioners: the contribution of medical pluralism to bottlenecks along the cascade of care for HIV/AIDS in Eastern and Southern Africa. *Sexually transmitted infections.* 2017;93(Suppl 3).
5. Moshabela M, Pronyk P, Williams N, Schneider H, Lurie M. Patterns and implications of medical pluralism among HIV/AIDS patients in rural South Africa. *AIDS and behavior.* 2011;15(4):842-852.
6. Government Gazette. Traditional Health Practitioners Act, 2007. In. Vol 511. Cape Town2008.
7. Oswald IH. Are traditional healers the solution to the failures of primary health care in rural Nepal? *Social science & medicine (1982).* 1983;17(5):255-257.
8. Green EC. Engaging Indigenous African Healers in the Prevention of AIDS and STDs. In: Hahn R, ed. *Anthropology in Public Health.* Oxford: Oxford University press; 1999:63-83.
9. Lin J, Puckree T, Mvelase TP. Anti-diarrhoeal evaluation of some medicinal plants used by Zulu traditional healers. *Journal of ethnopharmacology.* 2002;79(1):53-56.
10. Louw CA, Regnier TJ, Korsten L. Medicinal bulbous plants of South Africa and their traditional relevance in the control of infectious diseases. *Journal of ethnopharmacology.* 2002;82(2-3):147-154.
11. Ssali A, Butler LM, Kabatesi D, et al. Traditional healers for HIV/AIDS prevention and family planning, Kiboga District, Uganda: evaluation of a program to improve practices. *AIDS and behavior.* 2005;9(4):485-493.
12. Mills E, Cooper C, Seely D, Kanfer I. African herbal medicines in the treatment of HIV: Hypoxis and Sutherlandia. An overview of evidence and pharmacology. *Nutr J.* 2005;4:19.
13. Madamombe I. Traditional healers boost primary helath care: Reaching patients missed by modern medicine. *African Renewal.* 2006;19(4):10.
14. Rudolph MJ, Ogunbodede EO, Mistry M. Management of the oral manifestations of HIV/AIDS by traditional healers and care givers. *Curationis.* 2007;30(1):56-61.
15. Furin J. The role of traditional healers in community-based HIV care in rural Lesotho. *J Community Health.* 2011;36(5):849-856.
16. Zuma T, Wight D, Rochat T, Moshabela M. The role of traditional health practitioners in Rural KwaZulu-Natal, South Africa: generic or mode specific? *BMC complementary and alternative medicine.* 2016;16(1):304.
17. Smyth A, Martin M, Cairns J. South Africa's health. Traditional healers may cause dangerous delays. *BMJ (Clinical research ed).* 1995;311(7010):948.

18. Audet CM, Blevins M, Rosenberg C, et al. Symptomatic HIV-positive persons in rural Mozambique who first consult a traditional healer have delays in HIV testing: a cross-sectional study. *Journal of acquired immune deficiency syndromes (1999).* 2014;66(4):e80-86.
19. Kumakech E, Achora S, Berggren V, Bajunirwe F. Occupational exposure to HIV: a conflict situation for health workers. *Int Nurs Rev.* 2011;58(4):454-462.
20. Joyce M, Kuhar D, Brooks J. *Notes from the Field: Occupationally Acquired HIV Infection Among Health Care Workers — United States, 1985–2013.* Atlanta, GA: Centers for Disease Control and Prevention;2015.
21. Mbaisi EM, Ng'ang'a Z, Wanzala P, Omolo J. Prevalence and factors associated with percutaneous injuries and splash exposures among health-care workers in a provincial hospital, Kenya, 2010. *Pan Afr Med J.* 2013;14:10.
22. Anagaw B, Shiferaw Y, Anagaw B, et al. Seroprevalence of hepatitis B and C viruses among medical waste handlers at Gondar town Health institutions, Northwest Ethiopia. *BMC Res Notes.* 2012;5:55.
23. Rossouw TM, van Rooyen M, Louw JM, Richter KL. Blood-borne infections in healthcare workers in South Africa. *South African medical journal = Suid-Afrikaanse tydskrif vir geneeskunde.* 2014;104(11):732-735.
24. Audet CM, Blevins M, Moon TD, et al. HIV/AIDS-Related Attitudes and Practices Among Traditional Healers in Zambezia Province, Mozambique. *Journal of Alternative and Complementary Medince.* 2012;18(12):1-9.
25. Peters EJ, Immananagha KK, Essien OE, Ekott JU. Traditional healers' practices and the spread of HIV/AIDS in south eastern Nigeria. *Trop Doct.* 2004;34(2):79-82.
26. Wojcicki JM, Kankasa C, Mitchell C, Wood C. Traditional practices and exposure to bodily fluids in Lusaka, Zambia. *Tropical medicine & international health : TM & IH.* 2007;12(1):150-155.
27. Audet CM, Ngobeni S, Mkansi M, et al. Occupational hazards of traditional healers in rural South Africa: Bloodborne pathogen exposures and risk of HIV transmission. Late Breaker Poster Presentation presented at 22nd International AIDS Conference July 23-27, 2018, 2018; Amsterdam, Netherlands.
28. Scorgie F, Beksinska M, Chersich M, Kunene B, Hilber AM, Smit J. “Cutting for love”: genital incisions to enhance sexual desirability and commitment in KwaZulu-Natal, South Africa. *Reproductive Health Matters.* 2010;18(35):64-73.
29. Jolles F, Jolles S. Zulu Ritual Immunisation in Perspective. *Africa.* 2011;70(2):229-248.
30. Centers for Disease Control and Prevention. Exposure to Blood: What Healthcare Personnel Need to Know. In: National Center for Infectious Diseases DoHQPaDoVH, ed. Atlanta, USA: CDC; 2003.
31. Kwok YL, Gralton J, McLaws ML. Face touching: a frequent habit that has implications for hand hygiene. *Am J Infect Control.* 2015;43(2):112-114.
32. Gomez-Olive FX, Angotti N, Houle B, et al. Prevalence of HIV among those 15 and older in rural South Africa. *AIDS care.* 2013;25(9):1122-1128.
33. Occupational Safety and Health Administration. Personal Protective Equipment 2004; https://www.osha.gov/Publications/osha3151.pdf. Accessed 25 June 2018, 2018.
34. Leow JJ, Groen RS, Bae JY, Adisa CA, Kingham TP, Kushner AL. Scarcity of healthcare worker protection in eight low- and middle-income countries: surgery and the risk of HIV and other bloodborne pathogens. *Tropical medicine & international health : TM & IH.* 2012;17(3):397-401.
35. Federal Drug Administration. Personal Protective Equipment for Infection Control, 2018. 2018; https://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/personalprotectiveequipment/default.htm. Accessed June 29, 2018.

36. World Health Organization. Personal protective equipement in the context of filovirus disease outbreak response. In. Vol WHO/EVD/Guidance/PPE/14.1. Geneva: WHO; 2014.
37. Wilson T, Berwick DM, Cleary PD. What Do Collaborative Improvement Projects Do? Experience from Seven Countries. *The Joint Commission Journal on Quality and Safety.* 2004;30:25-33.
38. Spallek H, Song M, Polk DE, Bekhuis T, Frantsve-Hawley J, Aravamudhan K. Barriers to Implementing Evidence-Based Clinical Guidelines: A Survey of Early Adopters. *Journal of Evidence Based Dental Practice.* 2010;10(4):195-206.
39. R. BK, Bita N, Ilana S, et al. Next-Generation Testing for Cancer Risk: Perceptions, Experiences, and Needs Among Early Adopters in Community Healthcare Settings. *Genetic Testing and Molecular Biomarkers.* 2015;19(12):657-665.
40. Huynh TM. Innovators and early adopters of population health in healthcare: real and present opportunities for healthcare-public health collaboration. *HealthcarePapers.* 2013;13(3):53-57; discussion 85-59.
41. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. *Implementation science : IS.* 2007;2:40.
42. von Thiele Schwarz U, Hasson H, Lindfors P. Applying a fidelity framework to understand adaptations in an occupational health intervention. *Work (Reading, Mass).* 2015;51(2):195-203.
43. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science : IS.* 2009;4:50.
44. Amico KR. A situated-Information Motivation Behavioral Skills Model of Care Initiation and Maintenance (sIMB-CIM): an IMB model based approach to understanding and intervening in engagement in care for chronic medical conditions. *J Health Psychol.* 2011;16(7):1071-1081.
45. Williams CK, Carnahan H. Development and validation of tools for assessing use of personal protective equipment in health care. *American Journal of Infection Control.* 2013;41(1):28-32.
46. Zwarenstein M, Bheekie A, Lombard C, et al. Educational outreach to general practitioners reduces children's asthma symptoms: a cluster randomised controlled trial. *Implementation Science.* 2007;2(1):30.
47. Pinto D, Heleno B, Rodrigues DS, Papoila AL, Santos I, Caetano PA. Effectiveness of educational outreach visits compared with usual guideline dissemination to improve family physician prescribing—an 18-month open cluster-randomized trial. *Implementation Science.* 2018;13(1):120.
48. Bazos DA, LaFave LRA, Suresh G, Shannon KC, Nuwaha F, Splaine ME. The gas cylinder, the motorcycle and the village health team member: a proof-of-concept study for the use of the Microsystems Quality Improvement Approach to strengthen the routine immunization system in Uganda. *Implementation Science.* 2015;10(1):30.
49. Hennessy KA, Dynan J. Improving compliance with personal protective equipment use through the model for improvement and staff champions. *Clinical journal of oncology nursing.* 2014;18(5):497-500.
50. CDC. Personal Protective Equipment (PPE) in Healthcare Settings. 2010; https://www.cdc.gov/hai/prevent/ppe_train.html. Accessed March 27, 2019.
51. Honda H, Iwata K. Personal protective equipment and improving compliance among healthcare workers in high-risk settings. *Current opinion in infectious diseases.* 2016;29(4):400-406.
52. Rogers EM. *Diffusion of Innovations.* New York: The Free Press; 1962.
53. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ (Clinical research ed).* 2000;320(7227):114-116.

Appendix 1: Interview Questions for Aim 1

Trainers/Higher level creators of PPE training programs

Demographics:

Age (years)

Gender (M/F/Trans/Non-binary)

Race (Black, White, Indian, Coloured)

Name of hospital/university/clinic where you work?

Position

Number of years practicing as a health care worker?

Main Questions

1. Tell me about how you train future health care workers on infection prevention and control. (Probes: How do you tailor this to the type of student you are teaching? how much time (days and hours) do you allocate? What topics do you focus on? How do you introduce the topic? Is the training formal (i.e. they all attend at the same time or does it occur informally in the clinic, ward or operating theatre?)

2. Thinking about the training material, how much time is spent on theory (i.e. germ theory and droplet versus aerosolized contagions) versus practice (donning, doffing and disposal)? In your view, is the balance between theory and practice adequate? Is there anything missing in the training that you feel is missing in the training that you provide?

3. How do you train them in the donning, doffing and disposal of personal protective equipment? What type of PPE do you train on (e.g. gloves, masks, surgical gowns, hair nets, foot coverings, visors)? (Probes: How do you tailor this to the type of student you are teaching? what kinds of difficulty do trainee's experience? How to you help them overcome those challenges?)

4. How has the training changed since COVID-19? Have you noticed a change in the use of PPE during COVID (probes: do you think health care workers are using PPE more appropriately during COVID)?

5. Once students have their basic training how frequently do you think they need refresher training? What are common mistakes health care workers make once they get accustomed to using PPE. How do they let their guards down?

6. What role does peer pressure from other providers (or more senior staff [e.g. consultant or head matron]) have in the proper use or misuse of PPE? How do you create a positive culture? How do you overcome one that is problematic?

7. We are planning to train traditional healers to properly use PPE in an effort to protect them from infectious disease. If you were to train a lay person, thinking specifically about traditional healers, how would you approach it? What topics would you focus on? What challenges do you imagine encountering?

8. What types of reinforcement or retraining would you imagine they would need?

Front Line Health Care Providers

Demographics:

Age (years)

Gender (M/F/Trans/Non-binary)

Race (Black, White, Indian, Coloured)

Name of hospital/university/clinic where you work?

Position

Number of years practicing as a health care worker?

Main Questions

1. Tell me about the PPE training you have received during your training? (Probe: what did they teach you?) Who provided the training? (Probe: where did you receive it [hospital, offsite, part of orientation?]; who gave the training [scrub nurse, ID physician, microbiologist?]). What strategies did they suggest employing to use it correctly? Did you have any difficulties using and disposing of PPE?

2. Think back to your first clinical rotation after graduation. How well were other health care providers using PPE? What were people doing correctly? How were they using PPE incorrectly?

3. Did your PPE use change after you began working? What role does peer pressure from other providers (or your seniors) have on your use of PPE?

4. Can you describe any issues accessing or disposing of PPE at your health facility? Probe: is this infrequent? What steps are being taken to fix the issue?)

5. Did you have any refresher training on the use or disposal of PPE before COVID hit South Africa? (What did the training include? If you had a previous training, did it change your use of PPE?)

5. During COVID-19, has your health facility provided additional PPE training and resources? What did the training include? How effective was it at changing PPE behavior in your facility? Changing your behavior?

6. Have you ever tried to train a lay person to use PPE? Can you tell me about that experience? What were the challenges?

7. We are planning to train traditional healers to properly use PPE in an effort to protect them from infectious disease. If you were to train a lay person, thinking specifically about traditional healers, how would you approach it? What topics would you focus on? What challenges do you imagine encountering?

8. What types of reinforcement or retraining would you imagine they would need?

9. Is there anything else about PPE use that you think we should know about before we start this study?

10. With regards to PPE, what have you found to be the most effective way at conveying both the theory and practical aspects of PPE during training? If you have been involved in multiple PPE trainings or refresher trainings, which one did you feel was the most effective and why? (Probe: Did the person giving the training affect the effectiveness of the training? If so, what type of person gave the training [e.g. ID physician, scrub nurse, etc.) Was the training organized better? If so, describe.)

Traditional Healers

Demographics:

1. Sex of respondent. 0= Male 1= Female

These are some general questions about you and your life.

2. How old are you today (age in years)?

_____

3 What is the highest grade of education that you have completed?

_____

4. What languages do you speak fluently? (check those English that apply)
    - Shangaan
    - Afrikaans
    - Portuguese
    - Zulu
    - Xhosa
    - Other

5. What community do you live in?

_____

6. What is your marital status?
    - 1= Single
    - 2= Married
    - 3= Living with partner
    - 4= Widowed
    - 5= Divorced
    - 6= Separated

7. What religion are you? (list options)
8. Are you in a polygamous relationship (do you/ does your partner have multiple wives)? Yes No
9. How many years have you been practicing as a traditional healer? _____
10. What type of traditional healer do you MOST identify as?
    - 1= traditional healer
    - 2= Religious healer (Muslim)
    - 3= Religious healer (Christian)
    - 4= Herbalist
    - 5= Prophet
    - 8= Other
    - 8a. If other, please specify:

11. Have you ever received an HIV test? Yes No
12. If you are willing to share the results, what were they?
    - 0= Refused to share
    - 1= Negative
    - 2= Positive

3= Don't know/ didn't return for results
4= Indeterminate

13. HIV Rapid Test Results (baseline and end line, only used if negative or no results from prior test, we don't re-test positives)

1= Negative
2= Positive
4= Indeterminate
5= Refused Test

Demographics for health care providers

1. Sex of respondent. 0= Male 1= Female
2. How old are you today (age in years)?

_____

3 What is the highest grade of education that you have completed?

_____

4. What languages do you speak fluently? (check those English that apply)

Shangaan
Afrikaans
Portuguese
Zulu
Xhosa
Other

5. What community do you live in?

_____

6. What is your marital status?

1= Single
2= Married
3= Living with partner
4= Widowed
5= Divorced
6= Separated

7. What is your current clinical position?
8. Health care facility where you are employed?

Main Questions:

1. Can you tell me about any training you have received to use gloves and/or a mask or face shield when you are treating a patient? Who provided this training? What are the skills you have learned?

2. Can you tell me if you use gloves during each procedure where you could be exposed to blood? If you don't use gloves, do you use something else, like a plastic bag?

3. If you do not always use gloves, can you tell us why? Probe: cost, access, don't believe in germ theory of disease, God will save me) Are there specific patients where you ensure that you always where gloves? (e.g., someone you suspect has HIV?)

4. Now that COVID is widespread, do you use a mask when you have patients in your hospital or home? If you don't use a mask, can you tell me why not? Are there specific patients where you always use a mask? (e.g., someone you suspect has COVID-19 or TB?). If you use a mask, what type of mask do you use (e.g. cloth, surgical [the blue looking ones], N95)? Where did you get the mask? If you had to pay for the mask, how much did you pay?

5. How has COVID affected your physical interaction with patients? Do you see patients in person (more or less than before)? Do you talk to patients over the phone (more or less than before)? If you see patients in in-person have you changed the way that you do anything (length of consultant, change in traditional vaccinations or other procedures?

6. What effect has COVID had on you as a traditional healer?

5. Have you ever had a patient ask you about your gloves/mask use? If so, did this happen during the current COVID situation? What did the patient ask and what was your response?

5. We want to provide training to you and your colleagues to ensure traditional healers are protected from infectious diseases. Would you prefer to learn these lessons from another traditional healer or from a health care provider? Why? What do you think are the most important lessons for you to learn?

6. Lets talk about disposal of gloves for a moment. When you decide that you need to protect your hands, do you put gloves/bags on both hands or only one? Do you reuse them or dispose of them? If you reuse them, how do you clean them? If you dispose of them, where do you put them?

7. Lets talk about disposal of masks for a moment. What kind of masks are you using, one that can be washed or one that needs to be disposed of? If you use one that can be washed, how often do you wash it? If you use a disposable one, where are you getting them? How long do you use it before putting it in the trash?

8. We will be providing sharps containers and containers for used gloves/bags and razor blades for those healers who enroll in the study. We will come by every week to collect these materials. Do you think anyone would have difficulty using it?

9. Our aim in providing this training and material is to ensure traditional healers are protected from infectious disease. Besides the training, masks, gloves and sharps containers. As a traditional healer, is there anything else that you think we should be discussing or considering? If so, what?

9. Is there anything else about glove or mask use that you think we should know about?

Appendix 2: PPE Training Content Fidelity Evaluation

Directions: Score each measure with a value between 0-10 (0 is assigned if the topic is not discussed, 10 for discussed fully); total score is out of 100

1. Delivered information about the definition of PPE.

Score _____

2. Provided information about when to use PPE.

Score _____

3. Provided information about what types of PPE to use in different circumstances.

Score _____

4. Provide information about the appropriate fit of PPE.

Score _____

5. Provide do's and don'ts of glove use.

Score _____

6. Provided information about don PPE.

Score _____

7. Provided information about how and where to remove PPE.

Score _____

8. Provided information about how to safely store used PPE.

Score _____

9. Provided information about hand hygiene.

Score _____

10. Provided instruction and feedback during PPE practice session.

Score _____

TOTAL SCORE FOR TRAINING SESSION _____ / 10

Appendix 3: Combined CFIR and IMB Model Predicting PPE use

Part A. Example CFIR questions

Intervention Characteristics

1. Did you find the PPE training strategy acceptable?
2. How feasible do you think it will be to implement PPE use?
3. How do you think cost will impact your ability to implement PPE?

Inner Setting

1. How important to do think it is for healers to start using PPE during every injection?
2. Does the use of PPE clash with your current practices?

Outer Setting

1. How has your perception of the use of PPE been influenced by other healers in the from the Kukula Organization
2. How have your patients influenced your use of PPE during treatments?

Process

1. Tell us about your experience being recruited and engaged in the PPE training?
2. How has your perception of the use of PPE been influenced by the leaders in the Kukula Organization.
3.

Part B. Questions from the Situated-Information Motivation Behavior Questions

Information (from the HIV Knowledge Scale, Ciampa et al. 2012) True/False/Do Not Know

1. A person can get HIV by getting an injection with a needle that was already used on someone else.
2. A person can get HIV by sharing blades.
3. A person can get HIV from mosquito bites.
4. A person can get HIV by sharing forks, spoons or cups with a person who has HIV.
5. A person can get HIV from a curse
6. Using gloves during injections will prevent HIV transmission.

Motivation (5-point Likert scale, strongly disagree to strong agree)

1. I believe I can use PPE every time I conduct an injection
2. I believe I am at high risk of HIV infection.
3. I believe PPE will prevent me from contracting HIV from my patients during treatments.

Appendix 4: Behavior Assessment of PPE Skills at the completion of the training sessions

Hand Hygiene Checklist

Score each method of hand hygiene based on the tasks indicated: done - 1; not done or done incorrectly - 0; not applicable or not assessed - N/A.

Method	Task	Status	Notes
Alcohol-Based Hand Rub	ABHR is appropriate choice of hand hygiene for the situation		
	Remove inappropriate jewelry		
	Use enough alcohol rub to thoroughly wet both hands		
	Spread product over all surfaces of hands (palms, between fingers, fingertips, back of hands and wrists)		
	Rub hands for at least 15s or until product is dry		
Alcohol-Based Hand Rub Subtotal			
Soap and Water	Remove inappropriate jewelry		
	Wet hands and apply soap		
	Lather all surfaces of hands for 15s (palms, between fingers, fingertips, back of hands and wrists)		
	Rinse all sides of hands under running water		
	Dry hands with paper towels		
	Turn off taps with paper towels		
Soap and Water Subtotal			
TOTAL SCORE			

Donning Checklist

Indicate the personal protective equipment (PPE) required for the scenario then number them in the table as the user dons each item. Score the use of each item based on the tasks indicated: done - 1; not done or done incorrectly - 0; not applicable or not assessed - N/A.

PPE Required: _____

User's PPE sequence↓	Task	Status	Notes
Hand Hygiene #____	Hand Hygiene was performed		
	The choice of Hand Hygiene was appropriate		
Gown #____	Choose correct type of gown (if available)		
	Put gown on with the opening at the back		
	Tie neck and waist ties		
Mask #____	Chosen mask is appropriate face protection for the situation		
	Place mask over the nose and mouth		
	Mold metal strip to nose		
	Secure elastics or ties		
Eye Protection #____	Put on		
	Adjust to fit (e.g. face shield should fit over brow)		

Gloves #____	Remove inappropriate jewellery		
	Choose correct type of gloves (if available)		
	Choose well-fitting gloves		
	Put on gloves (if gown is worn, place gloves over gown cuffs)		
	Subtotal		
	PPE Selection Score (Add 5 points for each required item that was selected and subtract 5 points for each necessary item that was **not** selected.)		
	PPE Donning Sequence Score (No points if any sequence errors. Award 5 points for each required item/step in a perfect sequence - as listed in table.)		
	TOTAL SCORE		

Doffing Checklist

Score the use of each item based on the tasks indicated: done - 1; not done or done incorrectly - 0; not applicable or not assessed - N/A.

Number of ***items*** to be doffed: _____
Number of hand hygiene ***steps*** required: _____

User's PPE sequence↓	Task	Status	Notes
Gloves #____	Remove the first glove using glove-to-glove technique		
	Remove the second glove using skin-to-skin technique, turning gloves inside out		
	Drop into garbage without touching bin		
Gown #____	Unfasten the ties or Velcro and peel gown away from the neck		
	Remove the gown slowly, pulling away from the body, without touching the outside or contaminating clothing		
	Roll the gown into a bundle inside-out or fold dirty-to-dirty		
	Discard the gown in appropriate receptacle		
Hand Hygiene #____	Hand Hygiene was performed		
	The choice of Hand Hygiene was appropriate		
Eye Protection #____	Remove goggles/visor using the earpiece/band		
	Lift away from the face without touching the face/eyes/nose		
	Discard in the garbage/If reusable, clean and disinfect		
Mask #____	Undo the ties or elastics without touching the front of the mask		
	Holding the ties or elastics, lift mask away from the face		
	Discard mask in the garbage		
Hand Hygiene #____	Hand Hygiene was performed		
	The choice of Hand Hygiene was appropriate		
	Subtotal		

Doffing Sequence Score (No points if any sequence errors. Award 5 points for each required item/step in a perfect sequence - as listed in table.)	
TOTAL SCORE	

PPE Handling (Correct and careful use of PPE)					
N/A	1 Incorrect donning/doffing of PPE with critical errors	2	3 Mostly correct donning/doffing of PPE with few non-critical errors and/or correction of critical errors	4	5 Perfectly correct donning/doffing of PPE with no errors
Flow of Operation (Forward planning and continuity of procedure)					
N/A	1 Demonstrated no forward planning and appeared unsure of next steps with irregular progression of actions	2	3 Demonstrated some forward planning and anticipation of the situation with steady progression of actions	4	5 Demonstrated obvious forward planning and anticipation of the situation with effortless progression of actions
Self-Contamination (Avoidable/unnecessary contamination of PPE user during or after care activities)					
N/A	1 Indiscriminately contaminated self during and/or after client/patient care activities	2	3 Made appropriate corrections for self-contamination during and/or after client/patient care activities	4	5 Perfect technique employed to prevent self-contamination both during and after client/patient care activities
Contamination of Environment (Contamination of environmental surfaces during or after care activities)					
N/A	1 Touched environmental surfaces inappropriately putting others at risk of transmission of microorganisms through contaminated surfaces	2	3 Touched environmental surfaces inappropriately but corrected errors to prevent transmission of microorganisms through contaminated surfaces	4	5 Did not touch environmental surfaces inappropriately, preventing risk of transmission of microorganisms through contaminated surfaces
Cross-Contamination (Contamination of client/patient due to contaminated PPE used between care activities and procedures)					
N/A	1 Indiscriminately caused cross-contamination of PPE and/or client/patient between care activities	2	3 Made appropriate corrections for cross-contamination of PPE and/or client/patient between care activities	4	5 Appropriate technique used throughout the procedure to prevent cross-contamination of PPE and/or client/patient between care activities
TOTAL SCORE|					