MRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt)
School of Public Health, University of the Witwatersrand, 27 St Andrew's Road, Parktown, Johannesburg, South Africa, 2193
Tintswalo Hospital, Main Road, Acornhoek, Mpumalanga, South Africa, 1360
Telephone: +27 11 717 2085 (Johannesburg) | +27 13 795 5076 (Acornhoek) | www.agincourt.co.za | twitter@weallcount2

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

Institution: Vanderbilt University Medical Center & University of the Witwatersrand

KEY ELEMENTS OF THE STUDY

1. This consent form contains information about a new study to provide training on personal protective equipment (PPE) use to traditional healers.

2. Some healers will be randomized to a receive an in-person training program from a combination of healers + health care workers, others will be randomized to receive training from only health care workers.

3. Participants will be asked to complete baseline and repeat HIV testing 7 months post-training. The baseline test will be conducted today.

4. Participants will also be asked to complete baseline and repeat surveys to assess changes in knowledge and motivation to use PPE. The baseline survey will be conducted today.

5. You can stop participating in the study at any time without penalty.

6. A risk of participating in this study is that you may have difficultly dealing with a positive HIV test result. We will provide referral to the health facility for treatment and ongoing support to anyone who request additional assistance during the study.

This informed consent document applies to adults 18 years or older. This document is to be read aloud to the participants in the intervention arm.

Age of participant: _____

Introduction

Good Day.

My name is _____ and I work for the MRC/Wits Agincourt Research Unit. I am part of a a new study that aims to provide training on the use of personal protective equipment to traditional healers in Bushbuckridge, South Africa. We will do this by offering training to traditional healers on both glove use and the proper disposal of used gloves and razor blades.

You have been selected because you are a registered traditional who conducts traditional vaccinations on your patients. You do not have to be in this research study. You may choose not to be in this study. You can stop being in this study at any time. If we learn something

new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

This form describes your rights as a participant. It is meant to answer your questions. We will read this form to you. Please feel free to ask any questions you may have about this.

If you both agree to participate in this program, I will ask you to sign the form or make your thumbprint mark. Even if you agree to participate, you can stop participating at any time. I will give you a copy of this form. Please ask me to explain anything you do not understand.

Purpose of this study

This study is being done by staff from Vanderbilt University Medical Center (VUMC) and the University of Witwatersrand (Wits). We are concerned that traditional healers are being exposed to HIV and other bloodborne diseases when they conduct different treatments with their patients. We want to be sure that healers are protected – primarily by using latex gloves- and are disposing of contaminated materials safely. Traditional healers who are in this study will receive training on how they can protect themselves from patient blood and how to safely dispose of this material.

Procedures to be followed and approximate duration of the study

This study will begin today and last for the next seven months. If you agree to be part of this study, we will conduct a baseline survey and HIV test with you today. You will be assigned to one of two training groups. In one group, you will receive training by health care workers only. The second you will receive training by a group of health care workers and traditional healers. In both cases, this training will be for two days. After the training, someone will visit you at your home three times to observe how you are protecting yourself when conducting treatments with your patients.

After 6 months, a study staff person will contact you to complete a second survey and a repeat HIV test (if your baseline test is negative). You do not need to answer all the questions in the surveys if you do not want to. If a question makes you feel uncomfortable or you do not know the answer, it is ok to tell the interviewer that you do not want to answer the question. You can also stop the surveys at any time without any penalty. If you do not wish to complete the follow up HIV test, that is also okay. Just let the counselor know at the time of his or her visit.

Alternative Treatments Available

Our study is only studying the impact of our PPE training program. We are not providing treatment for any condition.

Expected Costs:

None.

Possible Risks

We know that talking about your personal experiences with patient treatment and HIV can be uncomfortable. We will try to have a comfortable, honest, and relaxed discussion. Still we know that some of the questions we ask might make you feel uncomfortable. We will try to limit

uncomfortable questions as much as possible. No study staff will tell anyone else your responses to the survey questions.

Possible Benefits

The information we gather from this study may change the way to provide training to traditional healers across South Africa. If it is effective, we plan to scale up this project to help protect healers across the country. However, the program may not be successful. There is no guarantee you will benefit from participating in this study.

Unforeseeable Risks

In any research study there are the possibility of unforeseeable risks. We try to minimize these by employing trained study assistants to conduct our surveys to make you comfortable and to identify any potential problems. We are also partnering with a local health facility to ensure everyone has access to the free health services they need. If your HIV test is positive, we will provide you with details on how to access HIV treatment (available at all local government health facilities).

What happens if you choose to withdraw from study participation?

Nothing. You are free to stop participating at any point without problem. You only need to say that you would like to stop being in the study. You can tell this to us at any time.

Confidentiality

We will make every effort to keep your personal information confidential. However, it is not possible to guarantee total confidentiality. The information obtained during this study will be stored securely at the MRC/Wits Agincourt Research Unit's field offices and on a protected database. Only trained study staff will have to access this clinical information.

Privacy Information

Your information may only be shared if you or someone else is in danger, or if we are required to do so by law. If this occurs, your information may be shared with VUMC, or the U.S. and/or South Africa government. This includes, for example, the VUMC IRB board, U.S. Federal Government Office for Human Research Protections, or the South African Department of Health.

Study Results

We will gather former participants and community members once the study ends to tell you the results. You are welcome to attend this meeting to learn if our training program was effective.

Clinical Trials Registry

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Contact Information for Questions

If you should have any questions about study or wish to have additional counseling related to your care, please feel free to contact the study manager, TBC, at the MRC/Wits Agincourt Research Unit at TBC.

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

You may also contact the Vanderbilt University Medical Center Institutional Review Board (IRB) office in the U.S. at +001-615-322-2918 or toll free at +001-866-224-8273.

Do you have any questions?

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Informed Consent (IC4): Traditional healers Participation in Personal Protective Equipment (PPE) Trial

This form has been read and explained to me. I have been given an opportunity to ask questions I have about the study. I understand that I may decide at any time that I do not want to continue participating in the study. I understand that I will receive a copy of this consent form.

By saying yes, you agree to participate in the study for 7 months, including undertaking an HIV test today and (if negative today) again at the end of the study. By saying no, you decline to participate in all parts of the study.

I give my consent participate in the study. [ ] Yes [ ] No

_____ _____

Printed Name of Participant Date

Thumbprint of Participant

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness (if thumbprint used) Date

_____ _____

Signature of Person Who Explained This Form Date

I have explained to the participant the study purpose and procedures and we have discussed all the risks that are involved. I have answered questions to the best of my ability.