Official Title: Community and Physician Perceptions of Barriers to Care for Acute Coronary Syndrome Among HIV-infected and -Uninfected Patients in Moshi, Tanzania_1

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DUKE UNIVERSITY HEALTH SYSTEM
K.C.M.C Kilimanjaro Christian Medical Centre
TUMAINI UNIVERSITY KILIMANJARO
CHRISTIAN MEDICAL COLLEGE

Hypertension Study (Majengo/Pasua) Informed Consent, English

INTRODUCTION

You are being asked to take part in this research study because you are a patient at Majengo Health Center or Pasua Health Center. This study is being conducted by Dr. Sakita and Dr. Mmbaga of Kilimanjaro Christian Medical Center with Dr. Hertz of the Department of Emergency Medicine at Duke University. The sponsor of the study, the U.S. National Institutes of Health, will pay for the research. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study staff member discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign and date this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to start a new program to improve treatment of high blood pressure for people living with HIV. This study will help us evaluate if this program is possible, if people like this program, and if the program improves hypertension care.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

If you are eligible to enter the study, we will then ask you another series of questions that will focus on your medical history, and your use of any medications. We will draw up to 1 tablespoon of blood and will use this blood to perform a test for blood sugar. We will look in your medical chart to get information about your medicines and other test results. If the results of some tests are not available in your chart, we may draw up to 2 tablespoons of blood for a CD4 count and HIV viral load test. We will let your doctor know about the results of all these tests. If your blood pressure is elevated, a community health worker will speak with you to provide education for you about hypertension, measure your blood pressure, and refer you to a doctor for medications if you have high blood pressure. The community health worker will speak to you approximately every month during your appointments for the next six months. With your permission, the community health worker may call you in between your clinic appoinments to check on you and answer additional questions about hypertension. In six months, when you come for your return appointment with your doctor, we will ask you some more questions. If you do not return for your appointment, we call you on the phone or visit you at your home to check on you.

HOW LONG WILL I BE IN THIS STUDY?

Our questionnaire and tests will take about 20 minutes of your time. Each community-health worker session, completed approximately every month for a total of sevene times, will take between 30-60 minutes. When you return to the doctor in six months, our questionnaire will take about 15 minutes of your time.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 150 people will participate in this study.

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?

The study could be ended early by the Ministry of Health in Tanzania or by the Ethics Committee of KCMC. Ethics Committees and Institutional Review Boards watch over the safety and rights of research subjects. Also, the study could be ended early by the following groups in the United States, the Duke University Health System Institutional Review Board and the Office of Human Research Protections.

WHAT ARE THE RISKS AND BENEFITS OF THE STUDY?

There is benefit to you for participating in this study. You will have access to health information on preventing heart disease and hypertension. If we discover that you have a health problem this may be useful information to your doctor and we will share it with them. If you have high blood pressure and are referred to see a doctor, we will subsidize the cost of your travel and medications. There are minimal physical risks associated with this study. Risks associated with drawing blood from your arm include minimal discomfort or bruising. There is a small risk of blood clot or minor skin infection where the needle enters the body. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

CONFIDENTIALITY

Study records will be kept confidential as required by law. Your records will be assigned a unique study number. Information that links your name to the study number will be kept in a locked cabinet that can only be accessed by members of the research team. The study results will be retained in your research record for at least 20 years, according to Tanzanian regulations. No personal identifiers will be sent to or used at Duke. If information from this study is presented at scientific meetings or in scientific journals, your identity will not be revealed. A description of this clinical trial will be available on *www.ClinicalTrials.gov*. 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 website at any time."

WHAT ARE THE COSTS TO ME?

There is no additional cost to you for taking part in this research study.

WILL I RECEIVE ANY PAYMENTS?

There will be no financial compensation for participating in this study. You will receive transportation money (tsh 5000) if you return for your appointments with your doctor for the next six months. You will also receive travel and medication subsidies if you are referred to a doctor for medication for a high blood pressure.

WHAT ABOUT RESEARCH RELATED INJURIES?

No injuries are expected through your participation in this study. Immediate necessary care and support is available if an individual is injured because of participation in this research project, however, there is no provision for free medical care or for monetary compensation for such an injury. For questions about the study or research-related injury, contact Dr. Sakita from KCMC at (255) 767 865 441

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you agree to participate, you may refuse to answer any question or stop the interview at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits, and will not affect your access to health care. If you do decide to withdraw, we ask that you contact Dr. Sakita in writing and let her know that you are withdrawing from the study. His mailing address is KCMC-Duke Collaboration, Box 3010, Sokoine Road, Moshi. We will tell you about new information from this or other studies that may affect your health, welfare or willingness to stay in this study. If you want the results of the study, let the study staffs know. We plan to present the results to the healthcare providers at Majengo and Pasua Health Centers. We will also present these results to the leaders of KCMC. If possible, we plan to distribute the results of our study more widely through presentations at medical conferences and journal articles.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Dr. Sakita from KCMC at (255) 767 865 441. For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Kilimanjaro Christian Medical Centre (KCMC) Ethics Committee at telephone number (255) 27 27-53909, the Duke University Health Systems Institutional Review Board at +1-919-668-5111 or the chair of the Medical Research Coordinating Committee (MRCC) Prof. Said Aboud at 255-22-2410394.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____ _____ _____

Signature of Subject Date Time

_____ _____

Signature of Witness (if required for subjects who are illiterate or blind) Date Time

_____

Printed Name of Witness

_____ _____

Signature of Person Obtaining Consent Date Time