Title: Partners-based HIV Treatment for Sero-concordant Couples Attending Antenatal Care

Identifier: NCT03149237

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Informed Consent Form for HoPS+ Study

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

Age of patient: _____

Introduction

This consent form contains information about a new study to provide couples-based HIV care and treatment to pregnant couples. 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 and your partner 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. This form might contain some words that are unfamiliar to you. 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 Friends in Global Health (FGH). We want to try a new way to offer HIV care and treatment to HIV positive couples who are expecting a child. Right now, couples can receive HIV testing together but cannot enroll together in HIV treatment services. Pregnant women are enrolled in antenatal clinics (ANC) and men in adult HIV services.

Couples who are in the intervention group of this study will be able to get HIV services with their partner. This will happen first in ANC and then in the Child at-Risk (CCR) clinic after delivery. Couples in the intervention group will also receive additional couples counseling and community based support from peer educators. We want to see if couples who get these services together are better at staying on HIV treatment compared to couples in regular care.

Procedures to be followed and approximate duration of the study

This study will begin today and last for the next three years. If you and your partner agree to be part of this study, we will enroll you both into HIV care and treatment. All future clinical visits, counseling sessions, and drugs will be given to you at the ANC or CCR clinics. After you are enrolled in HIV treatment, you and your partner will be brought to meet with a couples' counselor.

We will also provide you both with a list of peer educators who successfully completed the steps of the prevention of mother-to-child treatment cascade. You will be able to choose the couple you wish to work with. Once you have made your choice, our study coordinator will arrange a meeting with you and your peer support couple in the next two weeks. Your peer supporters will meet with you every month for the first seven months of your care. These meetings may be at your home or in another safe place you choose.

We will access your medical records to see what medications you are taking, medical data about your health (CD4 cell count and viral load), and the dates you pick up your medications.

A study staff person will also conduct three surveys at the beginning of your treatment, at six months, and 18 months after you start treatment. 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.

Some couples enrolled in the study will be asked to participate in an interview to describe their experience with the program and costs related to your and your family's health care. This interview will occur once between 12 and 18 months after starting in the study. You do not need to answer the questions 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 interview at any time without penalty.

Expected Costs:

None.

Possible Risks

The idea of providing HIV care and treatment together for couples expecting a baby is new and untested. While we will provide extra counseling for this, there is a chance that you and your partner will not agree on ways to take medication or talk together. This could make more problems in your relationship. If you feel any discomfort or have relationship problems please contact us as soon as possible so we can work to resolve it together.

We know that talking about your personal experiences with HIV with your partner or health care workers 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 embarrassment as much as possible. No study staff will tell anyone else your responses to the survey questions.

Possible Benefits

The information you share may help us to offer better services for couples living with HIV who come for ANC services. This could benefit Mozambican society by improving health programs for people living with HIV. If the project is successful, you may have better communication and trust with your partner after our counseling sessions.

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 clinical information obtained during this study will be kept with

your medical record and stored securely at the health facility in locked areas and on a protected database. Only trained medical and study staff will have to access this clinical information.

The information related to the study activities will be kept at the health facility and at FGH offices in locked secure areas. Only trained study staff will have access to this study 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 Mozambican government. This includes, for example, the VUMC IRB, U.S. Federal Government Office for Human Research Protections, or the Mozambican Ministry of Health.

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 HoPS+ study manager, Ezequiel Barreto, at the FGH office in Quelimane at +258 24217593.

For more information about giving consent or your rights, please feel free to contact the National Committee for Bioethics of Health in Mozambique at +258 824066350. You may also contact the VUMC 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?

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 Partner-based HIV care and treatment for the next 18 months. You are agreeing to participate in our interviewer-administered surveys and that we can look at your medical records, and that of your unborn child. By saying no, you decline to participate in all parts of the study.

Moderator: Answer the participant's questions before proceeding to the next question.

I give my consent to participate in the study.

_____ _____

Printed Name of Patient Date

Informed Consent Form for HoPS+ Study

Thumbprint of Participant

Signature of Patient 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.