IPrEP: A Combination HIV Prevention Strategy for Young Women at Risk for HIV in Kisumu, Kenya

STUDY #2

Evaluating the effectiveness, feasibility and acceptability of enhanced Pre-exposure Prophylaxis (PrEP) packages for young female sex workers in Kisumu, Kenya

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TITLE OF STUDY: **IPrEP: A Combination HIV Prevention Strategy for Young Women at Risk for HIV in Kisumu, Kenya**

We invite you to take part in a research study conducted by Impact Research and Development Organization (IMPACT-RDO) and ICAP at Columbia University.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to find ways to help young women who are at risk of getting HIV take a daily pill that has been shown to reduce their chance of getting HIV. In this study, we will compare two different ways of helping women take this pill, to see which way works better. The pill is called Truvada. It contains two medicines that have been used for HIV: emtricitabine and tenofovir.

Truvada has been shown to reduce the chances of HIV-negative people getting HIV if taken regularly every day. This HIV prevention approach is called PrEP or pre-exposure prophylaxis.

You are being asked to take part in this study because you are at risk of getting HIV. The purpose of this form is to give you information about the study and to help you decide if you want to take part in this study.Today's visit will take up to 2 hours.

This form might use some words that are not familiar to you. Please ask us to explain anything that you do not understand.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?

If you agree to be in the study, you will take part in a baseline interview. In this interview, we will ask you about your background, sexual partnerships, HIV testing, condom use and sexual practices, social support, stigma, mental health, gender-based violence, beliefs and attitudes about preventing HIV, like condom use.

After completing this interview, you will be tested for HIV. If you are found to be HIV-positive, you will be counseled and we will help you to link with an HIV clinic so you can learn more about HIV care and medications. We will not ask you to return to the study site again after today if your test result is positive.

If you are found to be HIV-negative, you will receive information about PrEP, including talking to you about how to take PrEP, side effects of PrEP as well as safer sex practices and family planning while on PrEP.

If after this discussion you agree to start PrEP as part of the study, you will be counseled on how to take PrEP, what possible side effects you might feel, and how to contact us if needed.You will then be given a 1-month supply of PrEP pills.

- We will collect a sample of blood (equivalent of 2 teaspoons) and urine
    - The blood will be used to check if your kidneys and liver are healthy.
    - The urine will be used for pregnancy testing.
- You will be screened for sexually transmitted infections.

- You will receive counselling and services for family planning.

After the initial interview and collection of blood and urine samples, you will also be randomly assigned to one of two groups to help you take your PrEP pill every day. "Randomly assigned" means that you have an equal chance of being assigned to either group. In the first group, study participants will receive support to help them take PrEP from a peer supporter. In the second group, participants will receive SMS reminders to take their PrEP pill and a small gift for responding to these text messages and confirming you have taken the pill.The decision regarding the group a participant will be assigned to is made by a computer. The staff does not know the group to which particpants are assigned until particpants open their assignment envelopes.

- We will ask for your help to find more people like you to join the study. We will give you some coupons to give to other people like yourself that you want to refer to the study and explain to you how to use them. We will also talk to you about how to explain the study to the women that you refer. You may refuse to take the coupons or refer others to the study.

Follow-up visits

You will be asked to come back at 1 and 3 months and then every 3 months until Month 24 after study enrollment. Each visit will take about 60-90 minutes.

At the Month 1 visit:

- You will be asked questions about how you are taking the PrEP pill and if you are experiencing any side effects. We will also ask you about your health, sexual behaviour, family planning use and if you have experienced any problems as a result of your taking part in the study.
- You will have an HIV test.
    - If you are found to be HIV-positive, we will not prescribe you PrEP again and you will not complete any additional study procedures. You will be counseled and we will help you to link with an HIV clinic so you can learn more about HIV care and medications. We will not ask you to return to the study site again if your test result is positive.
- We will collect a sample of blood (equivalent of 2 teaspoons) and urine
    - The blood drawn will be stored to check for the amount of medicine that is in your blood at a later time. Currently, no laboratory in Kenya can do this test. We will therefore send your sample to South Africa where the test will be done. We will remove your name from the sample so no-one can link your sample with you. However, if by the time we want to do the test there is a laboratory in Kenya that can do it, then we will do the test in Kenya.
    - The urine will be used for pregnancy testing.
- You will be screened for sexually transmitted infections.
- You will receive counselling and services for family planning.
- You will be provided with results of the blood test of your kidney health from today's visit.
    - If your blood test suggests that you may have a problem related to your kidneys, we will not continue to prescribe you PrEP. We will refer you to medical care to assess your kidney health. We will not ask you to return to the study site again after this visit.
- You will be given a 1-month supply of PrEP pills.

At the Month 3, 6, 9, 12, 15, 18, 21, and 24 visits:

- You will be asked questions about how you are taking the PrEP pill and if you are experiencing any side effects. We will also ask you about your health, sexual behaviour, family planning use and if you have experienced any problems as a result of your taking part in the study.
- You will have an HIV test.
    - If you are found to be HIV-positive, we will not prescribe you PrEP again. You will be counseled and we will help you to link with an HIV clinic so you can learn more about HIV care and medications. We will not ask you to return to the study site again if your test result is positive.
- We will collect a sample of blood (equivalent of 2 teaspoons) and urine
    - The blood drawn will be stored to check for the amount of medicine that is in your blood at a later time as explained above under month 1 visit.
    - The urine will be used for pregnancy testing.
- You will be screened for sexually transmitted infections.
- You will receive counselling and services for family planning.
- You will be given a 3-month supply of PrEP pills (PrEP pills will not be dispensed at Month 24 visit).
- At Month 12 and Month 24, we will collect an additional sample of blood (equivalent of 2 teaspoons).
    - The blood will be used to check if your kidneys are healthy.
- At Month 15, you will receive the results of your Month 12 blood test. If the Month 12 blood test suggests that you may have a problem related to your kidneys, we will not continue to prescribe you PrEP. We will refer you to medical care to assess your kidney health. We will not ask you to return to the study site again after this visit.
- If your Month 24 blood test suggests that you may have a problem related to your kidneys, we will contact you and refer you to medical care to assess your kidney health. We will recommend that you should discontinue PrEP if you have been prescribed it by another prescriber.

You will continue taking the PrEP pill for a total of 24 months. We will provide you with the PrEP pills and follow-up visits free of charge. At the end of the study, we will provide you with information about where you can access PrEP if you would like to continue taking it.
You will receive support to take your PrEP pills for 12 months of the study, after which you will continue to take PrEP pills for another 12 months.

Follow-up of missed visits
You will be asked to provide information so that we may get in touch with you during the study. Study staff will talk with you about the best way to contact you. This information will be used to remind you of study visits. In addition, in the event that you miss one of the scheduled study visits, a member of the study staff will contact you in order to find out how you are doing and to reschedule your visit. This may include phone contact, and if needed, a home visit. All contact information will be kept confidential.

WHAT ARE THE POTENTIAL RISKS?

Drug side effects
Most people who take PrEP do not experience any side effects. However, for the minority who develop side effects, the most common are nausea, abdominal cramping and headache. These side effects are typically mild and occur early after starting the medicine and go away on their own after a few weeks.

The medicine can rarely cause kidney problems. We will check the health of your kidneys before you join the study. This will reduce the chances of having any side-effects.

A small number of people in this study may have these side effects. It is important that if you develop any side effects or any evidence of illness, you return to see the study staff as soon as possible.

Blood draw
Some people feel discomfort when blood is drawn and may feel dizzy or even faint at the sight of blood. You may have a bruise or swelling where the needle goes into your arm. Some people may develop an infection where the needle goes in, but this is very rare. Trained staff will draw blood under sterile conditions in order to protect you against these risks.

Sensitive topics
Some of the questions asked during the study may make you uncomfortable. You do not have to answer any questions that may make you uncomfortable.

Loss of confidentiality
We have taken a number of steps to ensure your privacy and confidentiality. However, there is always a very small chance of loss of confidentiality. To avoid this, all staff working on this study have been trained on how to respect participant confidentiality. Other procedures for protecting your confidentiality are described below.

Other possible risks
There may also be some social risks to taking part in this study. You may experience stigma or discrimination as a result of being involved in a study about HIV. To assist with this, study staff can offer counselling and assistance with disclosure of study participation, if requested.

WHAT ARE THE POTENTIAL BENEFITS?
PrEP works for HIV prevention when it is used correctly, and you may benefit from the protection against HIV that it provides. In addition, you will be provided with condoms and lubricant at all study visits. Condoms should be used when taking PrEP because PrEP does not protect against other sexually transmitted infections and pregnancy.

The counselling that you get during this study may help you avoid HIV and other sexually transmitted infections. At all study visits we will check to see if you have HIV infection. If you become infected, we will refer you for HIV care and treatment.

You may not receive any other personal benefit from taking part in this study. The information gained in this study may help to develop future HIV-related programs for other young women like you.

WHAT ABOUT CONFIDENTIALITY?
This study has been approved by the Maseno University Ethics Review Committee (MUERC) and the Columbia University Medical Center Institutional Review Board (CUMC IRB). An IRB or ERC is a committee organized to protect the rights and welfare of people involved in research.

If you agree to take part, all information collected during the study will be kept strictly confidential. Your name will not be included on the tablet computer or written on any of the study forms and will not be used in connection with any information that is collected as part of the study. All study records will be kept securely at our offices, and they will be destroyed after 3 years. Any information from this study that is published or presented will not include your name or other personal information

During the study, study staff from IMPACT-RDO and ICAP at Columbia University will have access to this information. All such staff have received training in the importance of confidentiality. Additionally, members of the MUERC, the CUMC IRB, and other additional local and U.S. regulatory agencies like the US Office for Human Research Protections (OHRP) and US Food and Drug Administration (FDA), as well as the study sponsor may look at the research records.

All study staff will be trained on confidentiality and data security issues and will be required to sign confidentiality agreements. All efforts will be made to protect your confidentiality.

Use of information in future studies
Sometimes researchers share information they learn from people enrolled in studies like this one. If you agree to take part in this study, your information will be combined with information we collect from other people in the study and shared. The information that is shared will not have anything in it that can identify you like names or birthdays. Any researcher who wants to see the information that was collected must request access to it and be approved. If a researcher is approved, they may be able to use your information, along with that from many other people. They will not be able to tell that it is your information. They will only know that it is information from someone enrolled in this study. You will not receive direct benefits from any future use of your information. If you decide to stop taking part in this study, you can withdraw permission for your information to be used in the future.

WILL I BE GIVEN ANYTHING FOR TAKING PART?
At the end of each study visit, you will be given 1,000 Ksh for transport reimbursement and compensation for time. During the 1-month visit, you will also receive 200 Ksh for each woman you give a coupon to who participates in the study (up to three women). This means you could receive an additional 600 Ksh during the 1-month visit.

ARE THERE ANY COSTS?
There is no cost for take part in this study.

CAN I LEAVE THE STUDY?
Your participation in this study is voluntary. You are free to leave the study at any time. If you choose not to take part or complete the study, it will not affect you in any way or impact any services that you receive from IMPACT-RDO or any health facility in your community. If you decide to leave the study, no more information will be collected from you. However, we will not be able to take back the information that has already been collected. If you would like to continue taking PrEP, we will provide you with information about where you can access it. If you decide to leave the study, we will ask you some questions about your experience in the study. You may chose not to answer these questions.

QUESTIONS/POINTS OF CONTACT

If you have any questions, please ask, and we will do our best to answer them. Do you have any questions?

If you have questions about the study or any problems with the study, you may contact Dr. Kawango Agot at 0736505046.

If you have any questions about your rights as a participant in this study, please contact the Maseno University Ethics Review Committee at +25457351622 EXT 3050, the Columbia University Medical Center Institutional Review Board at +1 212-305-5883 or visit the website at http://www.cumc.columbia.edu/dept/irb/info.html.

PARTICIPANT STATEMENT

Any questions that I had were answered satisfactorily. I agree to be in this study. I have been offered a copy of this consent form. I am not giving up any of my legal rights by signing this consent form.

Participant signature or thumprint_____ Date: ___/___/___

Printed name of participant_____

Participant study ID number _____

Signature of person obtaining permission_____ Date: ___/___/___

Printed name of person obtaining permission_____

Survey staff ID number _____

[For illiterate participants]*

Witness signature or fingerprint_____ Date: ___/___/___

Printed name of witness_____

* Witness is only required if participant is illiterate