INFORMED CONSENT FORMS: KISUMU

Pharmacy delivery to expand the reach of PrEP in Kenya:

Pilot study

NCT04558554

January 19, 2022

Informed Consent Form – Aim 1a: CLIENTS (Kisumu)
TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Dr. Elizabeth Bukusi	Site Principal Investigator	Kenya Medical Research Institute	0733617503
Dr. Zachary Kwena	Co-Investigator	Kenya Medical Research Institute	0722386714
Josephine Odoyo	Co-Investigator	Kenya Medical Research Institute	0733276275
Dr Peter Mugo	Co-Investigator	Kenya Medical Research Institute	0738141494
Kevin Oware	Coordinator	Kenya Medical Research Institute	0723873505
International investigators			
Dr. Jared Baeten	Principal Investigator	University of Washington	+1-2065203817

Emergency number: 0723873505

Study location: Kisumu, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to joint or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The purpose of this study therefore is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya.
- **Duration.** Your initial visit will be no more than 2 hours, and you will be invited to refill PrEP at a retail pharmacy over the next 7 months (=4 visits in total).
- **Procedures and activities.** At each study visit, you will be asked questions about your sexual behavior, fertility intentions, drug adherence, HIV stigma, and COVID-19 risk. If you are interested in initiating PrEP, we will provide PrEP screening and counseling, sexually transmitted infection (STI) testing (optional), HIV testing to confirm HIV-negative status prior to dispensing PrEP, PrEP (daily oral TDF/FTC, 300mg/200mg), and dried blood spot testing.
- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about sexual behaviors with the research assistant or that you may learn you are living with HIV from HIV testing. There are some potential health risks associated with PrEP, which range from upset stomach (mild, rare) to kidney damage (severe, very rare).
- **Benefits**. We expect some benefits from this study, as well. You will get access to PrEP at your local retail pharmacy for seven months. Also, you will contribute to developing new models for the delivery of PrEP for HIV prevention in Africa, which will help others in the future.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities at each study visit (<1 hour):

- Enrollment: At this ~2 hour study visit you will complete a survey and if you are interested in starting PrEP, we will provide: 1) *PrEP screening* and *counseling*, 2) *testing,* including optional STI testing and HIV testing to confirm HIV-negative status prior to dispensing PrEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 1-month supply), and 4) *dried blood spot testing*. You will be charged a small fee to start PrEP at the pharmacy and scheduled for a follow-up pharmacy visit in 1 month.
- Follow-up: At these ~1 hour study visits, you will complete a survey and if you are interested in continuing PrEP, we will provide: 1) *PrEP counseling*, 2) *testing,* including optional STI testing and HIV testing to confirm HIV-negative status prior to dispensing PrEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 3-month supply), and 4) *dried blood spot testing*. You will be charged a small fee to refill PrEP at the pharmacy and scheduled for a follow-up pharmacy visit in 3 months. At your last follow-up visits (7 months following enrollment), you will receive a 3-month PrEP supply and be referred to a public HIV clinic to continue PrEP care.
- Surveys: At each study visit, you will complete a face-to-face survey with a research assistant that includes information on where you live, your sexual practices (e.g., number of recent sexual partners and condom use), how well you take your medications, and your thoughts on the COVID-19 outbreak. You do not have to answer any questions you do not want to answer.
- Dried blood spot collection: A research assistant will collect a dried blood spot from you. This sample may be tested at a later time to measure the amount of PrEP drug in it as an indicator of PrEP use.
- Urine sample collection: If you are interested in free STI testing (for *C. trachomatis* and *N. gonorrhoeae*) at your PrEP visit, you will be asked to self-collect a urine sample in a private backroom of the pharmacy. These samples will be delivered same-day to a health facility for processing. You will only receive a call from study staff if you test positive for an STI.
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- In-depth interviews: At the end of the study (month 7), you may be randomly selected to participate in a face-to-face interview (~1 additional hour). This interview is voluntary, and you may choose not to participate in it. In this interview, a research assistant will ask you about your experience with and attitudes towards pharmacy-based PrEP delivery and how the COVID-19 outbreak has affected your health seeking behaviors.
- Data: All survey data will be captured electronically and stored in a secure database. All interviews will be audio recorded, transcribed, translated, and stored in a secure online folder. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.

IF YOU BECOME HIV INFECTED

During the course of the study we will provide you with PrEP and counseling on HIV prevention. However, it is possible you may become HIV infected. If you have a positive HIV test during the study:

- The study staff will talk with you about this test result and what this means for you.
- You will stop taking the PrEP medication.
- You will be referred to a nearby HIV clinic for further HIV testing and linkage to HIV treatment, provided for free by the Kenyan Ministry of Health.

IF YOU TEST POSITIVE FOR AN STI

If you choose to test for STIs (either *C. trachomatis* or *N. gonorrhoeae*) at your study visit, you will only learn your tests results if you test positive for an STI. If you test positive for an STI, a study staff member will call you to talk about what this test result means for you and will send a prescription for STI treatment (available for free pick up) to the pilot pharmacy where you STI tested.

IMPORTANCE OF NOT SHARING THE STUDY MEDICATION

It is very important that you do not share your PrEP medication with anyone else. Although the PrEP medication is used to treat HIV infection, it is only effective for treating people who already have HIV infection if they are used in combination with other medications. Thus, PrEP by itself is only for HIV uninfected people.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when talking about your sexual practices, ways to protect against HIV, and your HIV test results. You may become worried or anxious while waiting for your HIV test results. If you become infected with HIV, knowing this could make you worried or anxious. Talking about HIV or PrEP and finding out your test results could cause problems between you and your sexual partners, including the potential for intimate partner violence (e.g., any physical, verbal, sexual, or economic harm). Trained study staff will help you deal with any feelings or questions you may have.

Risks and side effects related to PrEP include gastrointestinal intolerance and rarely more serious side effects; these are detailed on the package insert. This project is not testing PrEP itself but its delivery. The medical risks of HIV testing using blood collection are small.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff are wearing face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Screening you for COVID-19 symptoms at each pharmacy visit and screening research and pharmacy staff daily for COVID-19 symptoms. We will only allow people who are free of COVID-19 symptom to enter a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You will get access to PrEP at your local retail pharmacy. PrEP is not regularly available in other retail pharmacies in Kenya. You may not benefit directly from answering the survey questions; however, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

COSTS TO YOU

There may be nominal costs associated with PrEP initiation and refills at pharmacies. These costs are necessary to cover pharmacy staffing and space needs. There are no other costs to you for being in this study.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent if the study is stopped or cancelled or if staying in the study would be harmful to you. Specifically, you may be removed if you become pregnant or if the pharmacy provider determines your PrEP care is outside of their expertise and refers you to an HIV clinic.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. However, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. The link between your name and code will be kept in a secure location at the clinic only. Any publication of this study will not use your name or identify you personally.

RESEARCH-RELATED INJURY

We do not anticipate any research related injury. However, if you feel you are injured from participating in this study, you will be offered care at a nearby clinic free of charge. There is not a program of monetary compensation through this institution. You do not give up any legal rights by signing this consent form.

REIMBURSEMENT

You will receive Kshs 500 at every study visit (including survey completion) for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you think you have been harmed by research participation, you should contact Kevin Oware on 0723873505.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form I do not give up any rights that I have as a research participant.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date
_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Copies to: 1. Investigators
2. Study participant

SPECIMEN STORAGE AND USE OF YOUR DATA AND SAMPLES FOR FUTURE STUDIES:

Please initial and date one option:

_____ I DO agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____ I DO NOT agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

SPECIMEN SHIPMENT TO UNIVERSITY OF WASHINGTON

Please initial and date one option:

_____ I DO agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests.

_____ I DO NOT agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Informed Consent Form – Aim 1a pilot: PROVIDERS & CLINICANS (Kisumu)

TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Dr. Elizabeth Bukusi	Site Principal Investigator	Kenya Medical Research Institute	0733617503
Dr. Zachary Kwena	Co-Investigator	Kenya Medical Research Institute	0722386714
Josephine Odoyo	Co-Investigator	Kenya Medical Research Institute	0733276275
Dr Peter Mugo	Co-Investigator	Kenya Medical Research Institute	0738141494
Kevin Oware	Coordinator	Kenya Medical Research Institute	0723873505
International investigators			
Dr. Jared Baeten	Principal Investigator	University of Washington	+1-2065203817

Emergency number: 0723873505

Study location: Kisumu, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to joint or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya.
- **Procedures and activities.** You will be trained on the delivery of PrEP in pharmacies. If you are a pharmacy provider, you will provide PrEP screening and counseling, STI testing (optional, urine self-sample) HIV testing to confirm HIV-negative status prior to dispensing PrEP, and PrEP (daily oral TDF/FTC, 300mg/200mg) to interested clients. Over the course of the study, patient actors will visit you clinic to assess how well you deliver PrEP and follow the checklist; they will not reveal to you that they are actors. If you are a remote clinician, you will oversee pharmacy-based PrEP delivery remotely by making yourself available for consultation via phone or WhatsApp (remote clinicians). You may be asked to complete an in-depth qualitative interview at the end of the study where you discuss your experiences with and attitudes towards pharmacy-based PrEP delivery with a research assistant.
- **Duration.** The patient actor visits will be the same duration as a normal client visit (~30 minutes). If you are selected to participate in an interview, it will last no longer than 2 hours.
- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about experiences with pharmacy-based PrEP delivery to the study staff.
- **Benefits**. You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Africa, which will help others in the future.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities:

- Pharmacy PrEP training: Prior to delivering PrEP in pharmacies, pharmacy providers will complete a training based on the Kenya Ministry of Health PrEP guidelines. This will include training on HIV risk assessment, counseling for sensitive subjects (e.g., number of sexual partners, condom use), provider assisted HIV self-testing, the prescribing checklist, remote clinician consultation, clinical safety and side effect assessment, drug dispensing, and the importance of maintaining client confidentiality. Remote clinicians will be trained on pharmacy PrEP study procedures, including the prescribing checklist and how to provide consultation to pharmacy providers via phone or WhatsApp.
- PrEP prescribing and refilling: Trained pharmacy providers will deliver PrEP at pharmacies using a prescribing checklist that will guide procedures that need to be completed prior to PrEP dispensing – e.g., risk assessment, counseling, clinical safety assessment, testing for STIs (optiona0 for participants) and HIV. If clients does not meet criteria outlined on the checklist, the provider will either consult with a remote study clinician via phone or a WhatsApp group, or they will refer the client to the nearest public HIV clinic for care. If the client does meet the criteria outlined on the checklist, the pharmacy provider will dispense PrEP (daily oral TDF/FTC, 300mg/200mg, 1-month or 3-month supply).
- In-depth interviews: At the end of the study, you may be randomly selected to participate in a face-to-face interview. This interview is voluntary, and you may choose not to participate in it. In this interview, a research assistant will ask you about your experience with and attitudes towards pharmacy-based PrEP delivery (e.g., any challenges you may have had, your thoughts on the price at which pharmacy-based PrEP should be delivered) and the impact of COVID-19 on the provision of care; the interviews will be audio recorded.
- Data: All interviews will be audio recorded, transcribed, translated, and stored in a secure online folder. All WhatsApp messages between pharmacy providers and remote clinicians will be securely stored in an online database and used as research data. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.
- Patient actor visits (providers only): Over the duration of the study, four patient actors will visit each pharmacy once for PrEP initiation, and again for PrEP refills. The purpose of these visits is to evaluate how well you are delivering PrEP to clients, including how well you are following the prescribing checklist. The actors will not reveal themselves to you and will present like any normal pharmacy client. You are expected to provide the patient actors with standard pharmacy PrEP services. Following their visit to your pharmacy, the actors will complete checklists to assess your performance.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. Your information will be assigned a unique ID code and any identifying information linking you to this code will be stored in a secure location at the research site. If we use the information you give us or if we give it to another investigator for future research studies we will not get additional permissions from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when having conversations about HIV risk-related behaviors and other sensitive topics with pharmacy clients, who will likely be members of the local community. Additionally, sharing your experience with and attitudes towards pharmacy-based PrEP delivery with study staff may be uncomfortable.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff are wearing face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Screening you for COVID-19 symptoms at each pharmacy visit and screening research and pharmacy staff daily for COVID-19 symptoms. We will only allow people who are free of COVID-19 symptom to enter a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

OTHER INFORMATION

Your information will be kept private and any publication of this study will not use your name or identify you personally.

REIMBURSEMENT

If you complete an in-depth qualitative interview, you will receive Kshs 500 for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions to your job.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you think you have been harmed by research participation, you should contact Kevin Oware on 0723873505.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
Witness Name (print)	Witness Signature	Date

Informed Consent Form – Aim 1c with STI testing: CLIENTS
TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Dr. Elizabeth Bukusi	Site Principal Investigator	Kenya Medical Research Institute	0733617503
Dr. Zachary Kwena	Co-Investigator	Kenya Medical Research Institute	0722386714
Josephine Odoyo	Co-Investigator	Kenya Medical Research Institute	0733276275
Dr. Peter Mugo	Co-Investigator	Kenya Medical Research Institute	0738141494
Kevin Oware	Coordinator	Kenya Medical Research Institute	0723873505
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: 0723873505

Study location: Kisumu, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The primary purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya. Studies have also shown that the medications used to treat HIV infection can also be used to reduce the chance of transmission of HIV in an HIV-negative person who has recently been exposed to HIV; this concept is called post-exposure prophylaxis, or PEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PEP can only obtain PEP at clinics. This study will investigate whether if, upon completing PEP, individuals who initiated PEP at retail pharmacies will go on to initiate PrEP. Lastly, studies have shown that sexually transmitted infections (STIs), such as chlamydia and gonorrhea, are common among individuals with high HIV risk. Some individuals with high HIV risk may be good candidates for PrEP; therefore, this study will investigate whether offering STI testing alongside PrEP screening to individuals who are not currently using PrEP leads to them initiating PrEP.
- **Duration.** This study will run for 6 months from January 2022 until the end of July 2022. Depending on when you enroll in the study, you may have up to 3 study visits in total. Your initial (enrollment) visit will last no longer than 2 hours.If you undergo STI testing, you will be invited to also screen for PrEP. If you initiate PrEP, you will be invited to refill PrEP at a retail pharmacy one month later and quarterly thereafter until the study ends. Each follow-up visit will last no longer than 1 hour. If you initiate PEP, you will be invited to screen for PrEP one month later.

- **Procedures and activities.** At each study visit, you will be asked questions about your sexual behavior, fertility intentions, and drug adherence. If you are interested in initiating PrEP, we will provide PrEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP, PrEP (daily oral TDF/FTC, 300mg/200mg), and dried blood spot testing. If you are interested in initiating PEP, we will provide PEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PEP, PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg), and dried blood spot testing. If you are interested in STI testing, we will provide STI screening and counseling, supplies for you to collect your own urine sample, notification via phone call if you test positive for chlamydia and/or gonorrhea, and, if eligible, treatment for the aforementioned STIs.
- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about sexual behaviors with the research assistant or that you may learn you are living with HIV from HIV testing. There are some potential health risks associated with PrEP and PEP, which range from upset stomach (mild, rare) to kidney damage (severe, very rare).
- **Benefits**. We expect some benefits from this study, as well. You will get access to PrEP at your local retail pharmacy for seven months. Also, you will contribute to developing new models for the delivery of PrEP for HIV prevention in Africa, which will help others in the future.
- **Costs**. While enrolled in this study, you will receive free HIV testing and, if eligible, free PrEP, PEP, and/or STI testing and treatment. You will not be charged anything for these services.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The primary purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities at each study visit:

- Enrollment visit: At this ~2 hour study visit, you will complete a survey, and if you are interested in STI testing, we will provide: 1) *supplies* to collect your own urine sample, which we will transport via courier to a nearby clinic for STI testing, 2) *notification* via phone call of any positive test result, 3) *STI treatment* if you test positive and have no contraindications for treatment, and 4) *dried blood spot collection*. If you are interested in starting PrEP or PEP, we will provide: 1) *PrEP* and/or PEP *screening* and *counseling*, 2) *HIV testing* to confirm HIV-negative status prior to dispensing PrEP or PEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 1-month supply) or *PEP* (daily oral, TDF/3TC/DTG, 300mg/300mg/50mg, 1-month PEP supply or TDF/3TC/ATV/r, 300mg/300mg/400mg, 1-month PEP supply), and 5) *dried blood spot collection*. You will be not be charged anything for PrEP, PEP, or STI testing services at the pharmacy, and you will be scheduled for a follow-up pharmacy visit in 1 month if you initiated PrEP or PEP (with remote follow-up visits via phone at 7 days and 14 days after starting PEP to assess for and manage any side effects due to PEP).

- Follow-up visit: During this study, if you initiate PrEP and/or PEP, you will have a maximum of two follow-up visits, depending on when you enrolled. Each follow-up visit will last approximately 1 hour. At each follow-up visit, you will complete a survey. If you previously started PEP and/or underwent STI testing and were not given PrEP, we will invite you to be screened for PrEP. If you previously started PrEP and are interested in continuing, we will provide: 1) *PrEP counseling*, 2) *HIV testing t*o confirm HIV-negative status prior to dispensing PrEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 3-month supply), and 4) *dried blood spot testing*. You will not be charged to refill PrEP at the pharmacy. After your first PrEP follow-up visit, you may be scheduled for a second follow-up pharmacy visit in 3 months. At your last PrEP follow-up visit (1-4 months following enrollment, depending on

when you initiated PrEP), you will receive a 3-month PrEP supply and be referred to a public HIV clinic to continue PrEP care.

- Surveys: At each study visit, you will complete a face-to-face survey with a research assistant that includes information on where you live, your sexual practices (e.g., number of recent sexual partners and condom use), how well you take your medications, and your experience of receiving services at the pharmacy. You do not have to answer any questions you do not want to answer.
- Dried blood spot collection: At each study visit, a research assistant will collect a dried blood spot from you. This sample may be tested at a later time to measure HIV viral load (if any) and/or the amount of PrEP drug in it as an indicator of PrEP use.
- Urine sample collection: If you undergo STI testing at your enrollment visit, you will be asked to self-collect a urine sample in a private backroom of the pharmacy. These samples will be delivered same-day to a nearby health facility for processing. After the urine sample is tested, it will be discarded. It will not be stored for any future use.
- Data: All survey data will be captured electronically and stored in a secure database. Some answers to survey questions will be audio recorded, transcribed, translated, and stored in a secure online folder. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.
- Optional initial at-home HIV self-testing: If you are interested in initiating PrEP at a pilot pharmacy, you will have the option to take home an HIV self-testing kit (blood-based or oral fluid-based) and complete the self-test at home before undergoing blood-based, assisted HIV self-testing with a pharmacy provider as required for PrEP initiation. The purpose of giving you this option is so you have the opportunity, if you wish, to learn of your HIV status in the privacy of your home. If you opt to complete an initial HIV self-test at home, you will receive the testing kit free of charge.

IF YOU BECOME HIV INFECTED

During the course of the study, if you are found eligible, we will provide you with PrEP or PEP and counseling on HIV prevention. However, it is possible you may become HIV infected. If you have a positive HIV test during the study:

- The study staff will talk with you about this test result and what this means for you.
- You will stop taking the PrEP or PEP medication.
- You will be referred to a nearby HIV clinic for further HIV testing and linkage to HIV treatment, provided for free by the Kenyan Ministry of Health.

IF YOU TEST POSITIVE FOR AN STI

If you choose to test for STIs (*C. trachomatis* or *N. gonorrhoeae*) at your enrollment visit, you will only learn your tests results if you test positive. If you test positive for an STI, a study staff member will call you to talk about what this test result means for you and will send a prescription for STI treatment (available for free pick up) to the pharmacy where you STI tested.

IMPORTANCE OF NOT SHARING THE STUDY MEDICATION

It is very important that you do not share your PrEP or PEP medication with anyone else. Although the PrEP and PEP medications are also used to treat HIV infection, they are only effective for treating people who already have HIV infection if they are used in combination with other medications. Thus, PrEP and PEP by themselves are only for HIV-uninfected people.

USING YOUR DATA FOR FUTURE RESEARCH

The information and/or dried blood spot samples that we obtain from you for this study might be used for future studies. For example, the dried blood spot samples we collect from you may be stored and tested at a later time to measure HIV viral load (if any) and/or the amount of PrEP drug in it as an indicator of PrEP use. We may remove anything that might identify you from the information and/or dried blood spot samples. If we do so, that information and/or dried blood spot samples may then be used for future research studies on HIV, HIV-related diseases, and other sexually transmitted diseases or given to another investigator working on one of these topics without getting additional permission from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when talking about your sexual practices, ways to protect against HIV, and your HIV test results. You may become worried or anxious while waiting for your HIV test results. If you become infected with HIV, knowing this could make you worried or anxious. Talking about HIV, PrEP, PEP, and/or STI testing and finding out your test results could cause problems between you and your sexual partners, including the potential for intimate partner violence (e.g., any physical, verbal, sexual, or economic harm). Trained study staff will help you deal with any feelings or questions you may have.

Risks and side effects related to PrEP and PEP include gastrointestinal intolerance and rarely more serious side effects; these are detailed on the package inserts. This project is not testing PrEP or PEP itself but its delivery. The medical risks of HIV testing using blood collection are small.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff are wearing face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You will get access to PrEP and PEP at your local retail pharmacy during this study. PrEP is not regularly available in other retail pharmacies in Kenya. You may not benefit directly from answering the survey

questions; however, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

COSTS TO YOU

There are no costs to you for being in this study. If eligible, you will receive PrEP, PEP, and/or STI testing for free.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent if the study is stopped or cancelled or if staying in the study would be harmful to you. Specifically, you may be removed if the pharmacy provider determines your care is outside of their expertise and refers you to an HIV clinic.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. However, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Any publication of this study will not use your name or identify you personally. A description of this clinical trial will be available on http://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 website at any time.

RESEARCH-RELATED INJURY

We do not anticipate any research related injury. However, if you feel you are injured from participating in this study, you will be offered care at a nearby clinic free of charge. There is not a program of monetary compensation through this institution. You do not give up any legal rights by signing this consent form.

REIMBURSEMENT

You will receive Kshs 500 at every study visit (including survey completion) for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the United States National Institute of Mental Health and the Bill & Melinda Gates Foundation.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you have a research-related injury, you should contact Kevin Oware on 0723873505.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form I do not give up any rights that I have as a research participant.

Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Copies to: 1. Investigators
2. Study participant

SPECIMEN STORAGE AND USE OF YOUR DATA AND SAMPLES FOR FUTURE STUDIES:

Please initial and date one option:

_____ I DO agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____ I DO NOT agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

SPECIMEN SHIPMENT TO UNIVERSITY OF WASHINGTON

Please initial and date one option:

_____ I DO agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests

_____ I DO NOT agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Copies to: 1. Investigators
2. Study participant

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Dr. Elizabeth Bukusi	Site Principal Investigator	Kenya Medical Research Institute	0733617503
Dr. Zachary Kwena	Co-Investigator	Kenya Medical Research Institute	0722386714
Josephine Odoyo	Co-Investigator	Kenya Medical Research Institute	0733276275
Dr. Peter Mugo	Co-Investigator	Kenya Medical Research Institute	0738141494
Kevin Oware	Coordinator	Kenya Medical Research Institute	0723873505
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: 0723873505

Study location: Kisumu, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The primary purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya. Studies have also shown that the medications used to treat HIV infection can also be used to reduce the chance of transmission of HIV in an HIV-negative person who has recently been exposed to HIV; this concept is called post-exposure prophylaxis, or PEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PEP can only obtain PEP at clinics. This study will investigate whether if, upon completing PEP, individuals who initiated PEP at retail pharmacies will go on to initiate PrEP.
- **Duration.** This study will run for 6 months from January 2022 until the end of July 2022. Depending on when you enroll in the study, you may have up to 3 study visits in total. Your initial (enrollment) visit will last no longer than 2 hours. If you initiate PrEP, you will be invited to refill PrEP at a retail pharmacy one month later and quarterly thereafter until the study ends. Each follow-up visit will last no longer than 1 hour. If you initiate PEP, you will be invited to screen for PrEP one month later.
- **Procedures and activities.** At each study visit, you will be asked questions about your sexual behavior, fertility intentions, and drug adherence. If you are interested in initiating PrEP, we will provide PrEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP, PrEP (daily oral TDF/FTC, 300mg/200mg), and dried blood spot testing. If you are interested in initiating PEP, we will provide PEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PEP, PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg), and dried blood spot testing.

- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about sexual behaviors with the research assistant or that you may learn you are living with HIV from HIV testing. There are some potential health risks associated with PrEP and PEP, which range from upset stomach (mild, rare) to kidney damage (severe, very rare).
- **Benefits**. We expect some benefits from this study, as well. You will get access to PrEP at your local retail pharmacy for seven months. Also, you will contribute to developing new models for the delivery of PrEP for HIV prevention in Africa, which will help others in the future.
- **Costs**. While enrolled in this study, you will receive free HIV testing and, if eligible, free PrEP and/or PEP. You will not be charged anything for these services.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The primary purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities at each study visit:

- Enrollment visit: At this ~2 hour study visit, you will complete a survey, and if you are interested in starting PrEP or PEP, we will provide: 1) *PrEP* and/or PEP *screening* and *counseling*, 2) *HIV testing* to confirm HIV-negative status prior to dispensing PrEP or PEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 1-month supply) or *PEP* (daily oral, TDF/3TC/DTG, 300mg/300mg/50mg, 1-month PEP supply or TDF/3TC/ATV/r, 300mg/300mg/400mg, 1-month PEP supply), and 5) *dried blood spot collection*. You will be not be charged anything for PrEP or PEP at the pharmacy, and you will be scheduled for a follow-up pharmacy visit in 1 month if you initiated PrEP or PEP (with remote follow-up visits via phone at 7 days and 14 days after starting PEP to assess for and manage any side effects due to PEP).

- Follow-up visit: During this study, if you initiate PrEP and/or PEP, you will have a maximum of two follow-up visits, depending on when you enrolled. Each follow-up visit will last approximately 1 hour. At each follow-up visit, you will complete a survey. If you previously started PEP and were not given PrEP, we will invite you to be screened for PrEP. If you previously started PrEP and are interested in continuing, we will provide: 1) *PrEP counseling*, 2) *HIV testing t*o confirm HIV-negative status prior to dispensing PrEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 3-month supply), and 4) *dried blood spot testing*. You will not be charged to refill PrEP at the pharmacy. After your first PrEP follow-up visit, you may be scheduled for a second follow-up pharmacy visit in 3 months. At your last PrEP follow-up visit (1-4 months following enrollment, depending on when you initiated PrEP), you will receive a 3-month PrEP supply and be referred to a public HIV clinic to continue PrEP care.

- Surveys: At each study visit, you will complete a face-to-face survey with a research assistant that includes information on where you live, your sexual practices (e.g., number of recent sexual partners and condom use), how well you take your medications, and your experience of receiving services at the pharmacy. You do not have to answer any questions you do not want to answer.

- Dried blood spot collection: At each study visit, a research assistant will collect a dried blood spot from you. This sample may be tested at a later time to measure HIV viral load (if any) and/or the amount of PrEP drug in it as an indicator of PrEP use.

- Data: All survey data will be captured electronically and stored in a secure database. Some answers to survey questions will be audio recorded, transcribed, translated, and stored in a secure online folder. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.

- Optional initial at-home HIV self-testing: If you are interested in initiating PrEP at a pilot pharmacy, you will have the option to take home an HIV self-testing kit (blood-based or oral fluid-based) and complete the self-test at home before undergoing blood-based, assisted HIV self-testing with a pharmacy provider as required for PrEP initiation. The purpose of giving you this option is so you have the opportunity, if you wish, to learn of your HIV status in the privacy of your home. If you opt to complete an initial HIV self-test at home, you will receive the testing kit free of charge.

IF YOU BECOME HIV INFECTED

During the course of the study, if you are found eligible, we will provide you with PrEP or PEP and counseling on HIV prevention. However, it is possible you may become HIV infected. If you have a positive HIV test during the study:

- The study staff will talk with you about this test result and what this means for you.
- You will stop taking the PrEP or PEP medication.
- You will be referred to a nearby HIV clinic for further HIV testing and linkage to HIV treatment, provided for free by the Kenyan Ministry of Health.

IMPORTANCE OF NOT SHARING THE STUDY MEDICATION

It is very important that you do not share your PrEP or PEP medication with anyone else. Although the PrEP and PEP medications are also used to treat HIV infection, they are only effective for treating people who already have HIV infection if they are used in combination with other medications. Thus, PrEP and PEP by themselves are only for HIV-uninfected people.

USING YOUR DATA FOR FUTURE RESEARCH

The information and/or dried blood spot samples that we obtain from you for this study might be used for future studies. For example, the dried blood spot samples we collect from you may be stored and tested at a later time to measure HIV viral load (if any) and/or the amount of PrEP drug in it as an indicator of PrEP use. We may remove anything that might identify you from the information and/or dried blood spot samples. If we do so, that information and/or dried blood spot samples may then be used for future research studies on HIV, HIV-related diseases, and other sexually transmitted diseases or given to another investigator working on one of these topics without getting additional permission from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when talking about your sexual practices, ways to protect against HIV, and your HIV test results. You may become worried or anxious while waiting for your HIV test results. If you become infected with HIV, knowing this could make you worried or anxious. Talking about HIV, PrEP, or PEP and finding out your test results could cause problems between you and your sexual partners, including the potential for intimate partner violence (e.g., any physical, verbal, sexual, or economic harm). Trained study staff will help you deal with any feelings or questions you may have.

Risks and side effects related to PrEP and PEP include gastrointestinal intolerance and rarely more serious side effects; these are detailed on the package inserts. This project is not testing PrEP or PEP itself but its delivery. The medical risks of HIV testing using blood collection are small.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff are wearing face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You will get access to PrEP and PEP at your local retail pharmacy during this study. PrEP is not regularly available in other retail pharmacies in Kenya. You may not benefit directly from answering the survey questions; however, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

COSTS TO YOU

There are no costs to you for being in this study. If eligible, you will receive PrEP and/or PEP for free.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent if the study is stopped or cancelled or if staying in the study would be harmful to you. Specifically, you may be removed if the pharmacy provider determines your care is outside of their expertise and refers you to an HIV clinic.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. However, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Any publication of this study will not use your name or identify you personally. A description of this clinical trial will be available on http://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 website at any time.

RESEARCH-RELATED INJURY

We do not anticipate any research related injury. However, if you feel you are injured from participating in this study, you will be offered care at a nearby clinic free of charge. There is not a program of monetary compensation through this institution. You do not give up any legal rights by signing this consent form.

REIMBURSEMENT

You will receive Kshs 500 at every study visit (including survey completion) for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the United States National Institute of Mental Health and the Bill & Melinda Gates Foundation.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you have a research-related injury, you should contact Kevin Oware on 0723873505.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form I do not give up any rights that I have as a research participant.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date
_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Copies to: 1. Investigators
2. Study participant

Informed Consent Form – Aim 1c with STI testing: PROVIDERS & CLINICIANS
TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Dr. Elizabeth Bukusi	Site Principal Investigator	Kenya Medical Research Institute	0733617503
Dr. Zachary Kwena	Co-Investigator	Kenya Medical Research Institute	0722386714
Josephine Odoyo	Co-Investigator	Kenya Medical Research Institute	0733276275
Dr. Peter Mugo	Co-Investigator	Kenya Medical Research Institute	0738141494
Kevin Oware	Coordinator	Kenya Medical Research Institute	0723873505
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: 0723873505
Study location: Kisumu, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The primary purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya. Studies have also shown that the medications used to treat HIV infection can also be used to reduce the chance of transmission of HIV in an HIV-negative person who has recently been exposed to HIV; this concept is called post-exposure prophylaxis, or PEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PEP can only obtain PEP at clinics. This study will investigate whether if, upon completing PEP, individuals who initiated PEP at retail pharmacies will go on to initiate PrEP. Lastly, studies have shown that sexually transmitted infections (STIs), such as chlamydia and gonorrhea, are common among individuals with high HIV risk. Some individuals with high HIV risk may be good candidates for PrEP; therefore, this study will investigate whether offering STI testing alongside PrEP screening to individuals who are not currently using PrEP leads to them initiating PrEP.
- **Procedures and activities.** You will be trained on the delivery of PrEP, PEP, and STI testing in pharmacies. If you are a pharmacy provider, you will provide to interested clients STI testing (urine self-sample) and/or PrEP and PEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP or PEP, and, if client is eligible, PrEP (daily oral TDF/FTC, 300mg/200mg) or PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg). If you are a remote clinician, you will oversee pharmacy-based PrEP and PEP delivery remotely by making

yourself available for consultation via phone or WhatsApp (remote clinicians). At study baseline and once a month during the study, you will be asked to complete a survey with a research assistant about your experiences with pharmacy-based PrEP delivery and impressions of specific delivery strategies used.

- **Duration.** The overall study will run for 6 months from January 2022 until the end of July 2022. Each survey, if you decide to complete one, will take no longer than 1 hour to complete. The maximum number of surveys you will be invited to complete is 7; however, you may still participate in this study delivering PrEP, PEP, and STI testing even if you decide against completing any or all of the monthly surveys.
- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about experiences with pharmacy-based PrEP delivery to the study staff.
- **Benefits**. You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Africa, which will help others in the future.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities:

- Training: Prior to delivering PrEP, PEP, and/or STI testing in pharmacies, pharmacy providers will complete a training based on the Kenya Ministry of Health PrEP and PEP guidelines. This will include training on HIV risk assessment, counseling for sensitive subjects (e.g., number of sexual partners, condom use), provider assisted HIV self-testing, the prescribing checklist, remote clinician consultation, clinical safety and side effect assessment, drug dispensing, and the importance of maintaining client confidentiality. Pharmacy providers will also be trained on how to instruct clients who opt for STI testing to self-collect a urine sample, as well as study procedures for handling samples once collected. Remote clinicians will be trained on study procedures, including the prescribing checklist and how to provide consultation to pharmacy providers via phone or WhatsApp.

- PrEP and PEP prescribing and refilling: Trained pharmacy providers will deliver PrEP and/or PEP at pharmacies using a prescribing checklist that will guide procedures that need to be completed prior to PrEP/PEP dispensing (e.g., risk assessment, counseling, clinical safety assessment, testing for HIV). If clients does not meet criteria outlined on the checklist, the provider will either consult with a remote study clinician via phone or a WhatsApp group, or they will refer the client to the nearest public HIV clinic for care. If the client does meet the criteria outlined on the checklist, the pharmacy provider will dispense PrEP (daily oral TDF/FTC, 300mg/200mg, 1-month or 3-month supply) or PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg).

- STI Testing: Trained pharmacy providers will offer adult clients seeking STI treatment and/or diagnosis services the option to undergo free STI testing and instruct clients who consent to participate on how to self-collect a urine sample. Pharmacy providers will label the samples and contact a courier service to transport the sample to a prespecified clinic for testing. Study staff members will handle communication of positive test results to the client. If the client agrees to have a clinician affiliated with the research study write him or her a prescription for STI treatment, the pharmacy provider will fill the prescription.

- Surveys: At study baseline and once per month during the study, you will be asked to complete a survey. The maximum number of surveys you will be invited to complete is 7. These surveys are

voluntary, and you may choose not to participate in any of all of them. In this survey, a research assistant will ask you about your experiences with pharmacy-based delivery of PrEP, PEP, and STI testing and your impressions of specific delivery strategies used (e.g., any challenges you may have had, your thoughts on the price at which pharmacy-based PrEP should be delivered). Some of your survey responses will be audio recorded.

- Data: Some survey responses and study-related phone consultations with the remote clinician will be audio recorded, transcribed, translated, and stored in a secure online folder. All WhatsApp messages between pharmacy providers and remote clinicians will be securely stored in an online database and used as research data. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. Your information will be assigned a unique ID code and any identifying information linking you to this code will be stored in a secure location at the research site. If we use the information you give us or if we give it to another investigator for future research studies we will not get additional permissions from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when having conversations about HIV risk-related behaviors and other sensitive topics with pharmacy clients, who will likely be members of the local community. Additionally, sharing your experience with and attitudes towards pharmacy-based delivery of PrEP, PEP, and STI testing with study staff may be uncomfortable.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff wear face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

CONFIDENTIALITY OF RESEARCH INFORMATION

Your information will be kept private, and any publication of this study will not use your name or identify you personally. A description of this clinical trial will be available on http://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 website at any time.

REIMBURSEMENT

You will be invited to complete a survey at study baseline and once a month thereafter for the duration of the study. Each time you complete a survey, you will receive Kshs 500 for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

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SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the United States National Institute of Mental Health and the Bill & Melinda Gates Foundation.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you think you have been harmed by research participation, you should contact Kevin Oware on 0723873505.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

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Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
Witness Name (print)	Witness Signature	Date

Copies to: 1. Investigators
2. Study participant

Informed Consent Form – Aim 1a without STI testing: PROVIDERS & CLINICIANS
TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Dr. Elizabeth Bukusi	Site Principal Investigator	Kenya Medical Research Institute	0733617503
Dr. Zachary Kwena	Co-Investigator	Kenya Medical Research Institute	0722386714
Josephine Odoyo	Co-Investigator	Kenya Medical Research Institute	0733276275
Dr. Peter Mugo	Co-Investigator	Kenya Medical Research Institute	0738141494
Kevin Oware	Coordinator	Kenya Medical Research Institute	0723873505
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: 0723873505
Study location: Kisumu, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The primary purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya. Studies have also shown that the medications used to treat HIV infection can also be used to reduce the chance of transmission of HIV in an HIV-negative person who has recently been exposed to HIV; this concept is called post-exposure prophylaxis, or PEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PEP can only obtain PEP at clinics. This study will investigate whether if, upon completing PEP, individuals who initiated PEP at retail pharmacies will go on to initiate PrEP.
- **Procedures and activities.** You will be trained on the delivery of PrEP and PEP in pharmacies. If you are a pharmacy provider, you will provide to interested clients PrEP and PEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP or PEP, and, if client is eligible, PrEP (daily oral TDF/FTC, 300mg/200mg) or PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg). If you are a remote clinician, you will oversee pharmacy-based PrEP and PEP delivery remotely by making yourself available for consultation via phone or WhatsApp (remote clinicians). At study baseline and once a month during the study, you will be asked to complete a survey with a research assistant about your experiences with pharmacy-based PrEP delivery and impressions of specific delivery strategies used.
- **Duration.** The overall study will run for 6 months from January 2022 until the end of July 2022. Each survey, if you decide to complete one, will take no longer than 1 hour to complete. The maximum number of surveys you will be invited to complete is 7; however, you may still

participate in this study delivering PrEP, PEP, and STI testing even if you decide against completing any or all of the monthly surveys.

- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about experiences with pharmacy-based PrEP delivery to the study staff.
- **Benefits**. You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Africa, which will help others in the future.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities:

- Training: Prior to delivering PrEP and PEP in pharmacies, pharmacy providers will complete a training based on the Kenya Ministry of Health PrEP and PEP guidelines. This will include training on HIV risk assessment, counseling for sensitive subjects (e.g., number of sexual partners, condom use), provider assisted HIV self-testing, the prescribing checklist, remote clinician consultation, clinical safety and side effect assessment, drug dispensing, and the importance of maintaining client confidentiality. Remote clinicians will be trained on study procedures, including the prescribing checklist and how to provide consultation to pharmacy providers via phone or WhatsApp.
- PrEP and PEP prescribing and refilling: Trained pharmacy providers will deliver PrEP and/or PEP at pharmacies using a prescribing checklist that will guide procedures that need to be completed prior to PrEP/PEP dispensing (e.g., risk assessment, counseling, clinical safety assessment, testing for HIV). If clients does not meet criteria outlined on the checklist, the provider will either consult with a remote study clinician via phone or a WhatsApp group, or they will refer the client to the nearest public HIV clinic for care. If the client does meet the criteria outlined on the checklist, the pharmacy provider will dispense PrEP (daily oral TDF/FTC, 300mg/200mg, 1-month or 3-month supply) or PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg).
- Surveys: At study baseline and once per month during the study, you will be asked to complete a survey. The maximum number of surveys you will be invited to complete is 7. These surveys are voluntary, and you may choose not to participate in any of all of them. In this survey, a research assistant will ask you about your experiences with pharmacy-based delivery of PrEP and PEP and your impressions of specific delivery strategies used (e.g., any challenges you may have had, your thoughts on the price at which pharmacy-based PrEP should be delivered). Some of your survey responses will be audio recorded.
- Data: Some survey responses and study-related phone consultations with the remote clinician will be audio recorded, transcribed, translated, and stored in a secure online folder. All WhatsApp messages between pharmacy providers and remote clinicians will be securely stored in an online database and used as research data. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. Your information will be assigned a unique ID code and any identifying information linking you to this code will be stored in a secure location at the research site. If we use the information you give us or if we give it to another investigator for future research studies we will not get additional permissions from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when having conversations about HIV risk-related behaviors and other sensitive topics with pharmacy clients, who will likely be members of the local community. Additionally, sharing your experience with and attitudes towards pharmacy-based delivery of PrEP and PEP with study staff may be uncomfortable.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff wear face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

CONFIDENTIALITY OF RESEARCH INFORMATION

Your information will be kept private and any publication of this study will not use your name or identify you personally. A description of this clinical trial will be available on http://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 website at any time.

REIMBURSEMENT

You will be invited to complete a survey at study baseline and once a month thereafter for the duration of the study. Each time you complete a survey, you will receive Kshs 500 for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions to your job.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the United States National Institute of Mental Health and the Bill & Melinda Gates Foundation.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you think you have been harmed by research participation, you should contact Kevin Oware on 0723873505.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
Witness Name (print)	Witness Signature	Date

Copies to: 1. Investigators
2. Study participant

INFORMED CONSENT FORMS: THIKA

Pharmacy delivery to expand the reach of PrEP in Kenya:

Pilot study

NCT04558554

January 19, 2022

Informed Consent Form – Aim 1a pilot: CLIENTS (Thika)

TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Prof. Kenneth Ngure	Site Principal Investigator	Jomo Kenyatta University of Agriculture and Technology	067 222561
Peter Mogere	Co-Investigator	Partners in Health Research and Development	067 222561
Catherine Kiptinness	Co-Investigator	Partners in Health Research and Development	067 222561
International investigators			
Dr. Jared Baeten	Principal Investigator	University of Washington	+12065203817

Emergency number: 0733464299

Study location: Thika, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to joint or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya.
- **Duration.** Your initial visit will be no more than 2 hours, and you will be invited to refill PrEP at a retail pharmacy over the next 7 months (=4 visits in total).
- **Procedures and activities.** At each study visit, you will be asked questions about your sexual behavior, fertility intentions, drug adherence, HIV stigma, and COVID-19 risk. If you are interested in initiating PrEP, we will provide PrEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP, PrEP (daily oral TDF/FTC, 300mg/200mg), and dried blood spot testing.
- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about sexual behaviors with the researcher or that you may learn you are living with HIV from HIV testing. There are some potential health risks associated with PrEP, which range from upset stomach (mild, rare) to kidney damage (severe, very rare).
- **Benefits**. We expect some benefits from this study, as well. You will get access to PrEP at your local retail pharmacy for seven months. Also, you will contribute to developing new models for the delivery of PrEP for HIV prevention in Africa, which will help others in the future.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities at each study visit:

- Enrollment: At this ~2 hour study visit you will complete a survey and if you are interested in starting PrEP, we will provide: 1) *PrEP screening* and *counseling*, 2) *HIV testing* to confirm HIV-negative status prior to dispensing PrEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 1-month supply), and 4) *dried blood spot testing*. You will be charged a small fee to start PrEP at the pharmacy and scheduled for a follow-up pharmacy visit in 1 month.
- Follow-up: At these ~1 hour study visits, you will complete a survey and if you are interested in continuing PrEP, we will provide: 1) *PrEP counseling*, 2) *HIV testing* to confirm HIV-negative status prior to dispensing PrEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 3-month supply), and 4) *dried blood spot testing*. You will be charged a small fee to refill PrEP at the pharmacy and scheduled for a follow-up pharmacy visit in 3 months. At your last follow-up visits (7 months following enrollment), you will receive a 3-month PrEP supply and be referred to a public HIV clinic to continue PrEP care.
- Survey: At each study visit, you will complete a face-to-face survey with a research assistant that includes information on where you live, your sexual practices (e.g., number of recent sexual partners and condom use), how well you take your medications, and your thoughts on the COVID-19 outbreak. You do not have to answer any questions you do not want to answer.
- Dried blood spot collection: A research assistant will collect a dried blood spot from you. This sample may be tested at a later time to measure the amount of PrEP drug in it as an indicator of PrEP use.
- In-depth interviews: At the end of the study (month 7), you may be randomly selected to participate in a face-to-face interview (~1 additional hour). This interview is voluntary, and you may choose not to participate in it. In this interview, a research assistant will ask you about your experience with and attitudes towards pharmacy-based PrEP delivery and how the COVID-19 outbreak has affected your health seeking behaviors.
- Data: All survey data will be captured electronically and stored in a secure database. All interviews will be audio recorded, transcribed, translated, and stored in a secure online folder. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.

IF YOU BECOME HIV INFECTED

During the course of the study we will provide you with PrEP and counseling on HIV prevention. However, it is possible you may become HIV infected. If you have a positive HIV test during the study:

- The study staff will talk with you about this test result and what this means for you.
- You will stop taking the PrEP medication.
- You will be referred to a nearby HIV clinic for further HIV testing and linkage to HIV treatment, provided for free by the Kenyan Ministry of Health.

IMPORTANCE OF NOT SHARING THE STUDY MEDICATION

It is very important that you do not share your PrEP medication with anyone else. Although the PrEP medication is used to treat HIV infection, it is only effective for treating people who already have HIV infection if they are used in combination with other medications. Thus, PrEP by itself is only for HIV uninfected people.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when talking about your sexual practices, ways to protect against HIV, and your HIV test results. You may become worried or anxious while waiting for your HIV test results. If you become infected with HIV, knowing this could make you worried or anxious. Talking about HIV or PrEP and finding out your test results could cause problems between you and your sexual partners, including the potential for intimate partner violence (e.g., any physical, verbal, sexual, or economic harm). Trained study staff will help you deal with any feelings or questions you may have.

Risks and side effects related to PrEP include gastrointestinal intolerance and rarely more serious side effects; these are detailed on the package insert. This project is not testing PrEP itself but its delivery. The medical risks of HIV testing using blood collection are small.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff are wearing face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Screening you for COVID-19 symptoms at each pharmacy visit and screening research and pharmacy staff daily for COVID-19 symptoms. We will only allow people who are free of COVID-19 symptom to enter a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You will get access to PrEP at your local retail pharmacy. PrEP is not regularly available in other retail pharmacies in Kenya. You may not benefit directly from answering the survey questions; however, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

COSTS TO YOU

There may be nominal costs associated with PrEP initiation and refills at pharmacies. These costs are necessary to cover pharmacy staffing and space needs. There are no other costs to you for being in this study.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent if the study is stopped or cancelled or if staying in the study would be harmful to you. Specifically, you may be removed if you become pregnant or if the pharmacy provider determines your PrEP care is outside of their expertise and refers you to an HIV clinic.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. However, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Any publication of this study will not use your name or identify you personally.

RESEARCH-RELATED INJURY

We do not anticipate any research related injury. However, if you feel you are injured from participating in this study, you will be offered care at a nearby clinic free of charge. There is not a program of monetary compensation through this institution. You do not give up any legal rights by signing this consent form.

REIMBURSEMENT

You will receive Kshs 500 at every study visit (including survey completion) for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you think you have been harmed by research participation, you should contact Peter Mogere on 0736464299.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0717719477, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
Witness Name (print)	Witness Signature	Date

SPECIMEN STORAGE AND USE OF YOUR DATA AND SAMPLES FOR FUTURE STUDIES:

Please initial and date one option:

_____ I DO agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____ I DO NOT agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
Witness Name (print)	Witness Signature	Date

SPECIMEN SHIPMENT TO UNIVERSITY OF WASHINGTON

Please initial and date one option:

_____ I DO agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests

_____ I DO NOT agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests

Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
Witness Name (print)	Witness Signature	Date

Copies to: 1. Investigators
2. Study participant

Informed Consent Form – Aim 1a pilot: PROVIDERS & CLINICANS (Thika)

TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Prof. Kenneth Ngure	Site Principal Investigator	Jomo Kenyatta University of Agriculture and Technology	067 222561
Peter Mogere	Co-Investigator	Partners in Health Research and Development	067 222561
Catherine Kiptinness	Co-Investigator	Partners in Health Research and Development	067 222561
International investigators			
Dr. Jared Baeten	Principal Investigator	University of Washington	+12065203817

Emergency number: 0733464299

Study location: Thika, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to joint or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya.
- **Procedures and activities.** You will be trained on the delivery of PrEP in pharmacies. If you are a pharmacy provider, you will provide PrEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP, and PrEP (daily oral TDF/FTC, 300mg/200mg) to interested clients. Over the course of the study, patient actors will visit you clinic to assess how well you deliver PrEP and follow the checklist; they will not reveal to you that they are actors. If you are a remote clinician, you will oversee pharmacy-based PrEP delivery remotely by making yourself available for consultation via phone or WhatsApp (remote clinicians). You may be asked to complete an in-depth qualitative interview at the end of the study where you discuss your experiences with and attitudes towards pharmacy-based PrEP delivery with a research assistant.
- **Duration.** The patient actor visits will be the same duration as a normal client visit (~30 minutes). If you are selected to participate in an interview, it will last no longer than 2 hours.
- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about experiences with pharmacy-based PrEP delivery to the study staff.

- **Benefits**. You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Africa, which will help others in the future.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities:

- Pharmacy PrEP training: Prior to delivering PrEP in pharmacies, pharmacy providers will complete a training based on the Kenya Ministry of Health PrEP guidelines. This will include training on HIV risk assessment, counseling for sensitive subjects (e.g., number of sexual partners, condom use), provider assisted HIV self-testing, the prescribing checklist, remote clinician consultation, clinical safety and side effect assessment, drug dispensing, and the importance of maintaining client confidentiality. Remote clinicians will be trained on pharmacy PrEP study procedures, including the prescribing checklist and how to provide consultation to pharmacy providers via phone or WhatsApp.
- PrEP prescribing and refilling: Trained pharmacy providers will deliver PrEP at pharmacies using a prescribing checklist that will guide procedures that need to be completed prior to PrEP dispensing (e.g., risk assessment, counseling, clinical safety assessment, HIV testing). If clients does not meet criteria outlined on the checklist, the provider will either consult with a remote study clinician via phone or a WhatsApp group, or they will refer the client to the nearest public HIV clinic for care. If the client does meet the criteria outlined on the checklist, the pharmacy provider will dispense PrEP (daily oral TDF/FTC, 300mg/200mg, 1-month or 3-month supply).
- In-depth interviews: At the end of the study, you may be randomly selected to participate in a face-to-face interview. This interview is voluntary, and you may choose not to participate in it. In this interview, a research assistant will ask you about your experience with and attitudes towards pharmacy-based PrEP delivery (e.g., any challenges you may have had, your thoughts on the price at which pharmacy-based PrEP should be delivered) and the impact of COVID-19 on the provision of care; the interviews will be audio recorded.
- Data: All interviews will be audio recorded, transcribed, translated, and stored in a secure online folder. All WhatsApp messages between pharmacy providers and remote clinicians will be securely stored in an online database and used as research data. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.
- Patient actor visits (providers only): Over the duration of the study, four patient actors will visit each pharmacy once for PrEP initiation, and again for PrEP refills. The purpose of these visits is to evaluate how well you are delivering PrEP to clients, including how well you are following the prescribing checklist. The actors will not reveal themselves to you and will present like any normal pharmacy client. You are expected to provide the patient actors with standard pharmacy PrEP services. Following their visit to your pharmacy, the actors will complete checklists to assess your performance.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. Your

information will be assigned a unique ID code and any identifying information linking you to this code will be stored in a secure location at the research site. If we use the information you give us or if we give it to another investigator for future research studies we will not get additional permissions from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when having conversations about HIV risk-related behaviors and other sensitive topics with pharmacy clients, who will likely be members of the local community. Additionally, sharing your experience with and attitudes towards pharmacy-based PrEP delivery with study staff may be uncomfortable.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff wear face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Screening you for COVID-19 symptoms at each pharmacy visit and screening research and pharmacy staff daily for COVID-19 symptoms. We will only allow people who are free of COVID-19 symptom to enter a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

OTHER INFORMATION

Your information will be kept private and any publication of this study will not use your name or identify you personally.

REIMBURSEMENT

If you complete an in-depth qualitative interview, you will receive Kshs 500 for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions to your job.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you think you have been harmed by research participation, you should contact Peter Mogere on 0736464299.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0717719477, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

Participant Name (print)	Participant Signature/Thumbprint	Date
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
Witness Name (print)	Witness Signature	Date

Informed Consent Form – Aim 1c pilot with STI testing: CLIENTS (Thika)
TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Prof. Kenneth Ngure	Site Principal Investigator	Jomo Kenyatta University of Agriculture and Technology	067 222561
Peter Mogere	Co-Investigator	Partners in Health Research and Development	067 222561
Dr. Catherine Kiptinness	Co-Investigator	Partners in Health Research and Development	067 222561
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: 0733464299

Study location: Thika, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The primary purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya. Studies have also shown that the medications used to treat HIV infection can also be used to reduce the chance of transmission of HIV in an HIV-negative person who has recently been exposed to HIV; this concept is called post-exposure prophylaxis, or PEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PEP can only obtain PEP at clinics. This study will investigate whether if, upon completing PEP, individuals who initiated PEP at retail pharmacies will go on to initiate PrEP. Lastly, studies have shown that sexually transmitted infections (STIs), such as chlamydia and gonorrhea, are common among individuals with high HIV risk. Some individuals with high HIV risk may be good candidates for PrEP; therefore, this study will investigate whether offering STI testing alongside PrEP screening to individuals who are not currently using PrEP leads to them initiating PrEP.
- **Duration.** This study will run for 6 months from January 2022 until the end of July 2022. Depending on when you enroll in the study, you may have up to 3 study visits in total. Your initial (enrollment) visit will last no longer than 2 hours. If you undergo STI testing, you will be invited to also screen for PrEP. If you initiate PrEP, you will be invited to refill PrEP at a retail pharmacy one month later and quarterly thereafter until the study ends.. Each follow-up visit will last no longer than 1 hour. If you initiate PEP, you will be invited to screen for PrEP one month later.

- **Procedures and activities.** At each study visit, you will be asked questions about your sexual behavior, fertility intentions, and drug adherence. If you are interested in initiating PrEP, we will provide PrEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP, PrEP (daily oral TDF/FTC, 300mg/200mg), and dried blood spot testing. If you are interested in initiating PEP, we will provide PEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PEP, PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg), and dried blood spot testing. If you are interested in STI testing, we will provide STI screening and counseling, supplies for you to collect your own urine sample, notification via phone call if you test positive for chlamydia and/or gonorrhea", and, if eligible, treatment for the aforementioned STIs.
- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about sexual behaviors with the research assistant or that you may learn you are living with HIV from HIV testing. There are some potential health risks associated with PrEP and PEP, which range from upset stomach (mild, rare) to kidney damage (severe, very rare).
- **Benefits**. We expect some benefits from this study, as well. You will get access to PrEP at your local retail pharmacy for seven months. Also, you will contribute to developing new models for the delivery of PrEP for HIV prevention in Africa, which will help others in the future.
- **Costs**. While enrolled in this study, you will receive free HIV testing and, if eligible, free PrEP, PEP, and/or STI testing and treatment. You will not be charged anything for these services.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The primary purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities at each study visit (<1 hour):

- Enrollment visit: At this ~2 hour study visit, you will complete a survey, and if you are interested in STI testing, we will provide: 1) *supplies* to collect your own urine sample, which we will transport via courier to a nearby clinic for STI testing, 2) *notification* via phone call of any positive test result, 3) *STI treatment* if you test positive and have no contraindications for treatment, and 4) *dried blood spot collection*. If you are interested in starting PrEP or PEP, we will provide: 1) *PrEP* and/or PEP *screening* and *counseling*, 2) *HIV testing* to confirm HIV-negative status prior to dispensing PrEP or PEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 1-month supply) or *PEP* (daily oral, TDF/3TC/DTG, 300mg/300mg/50mg, 1-month PEP supply or TDF/3TC/ATV/r, 300mg/300mg/400mg, 1-month PEP supply), and 5) *dried blood spot collection*. You will be not be charged anything for PrEP, PEP, or STI testing services at the pharmacy, and you will be scheduled for a follow-up pharmacy visit in 1 month if you initiated PrEP or PEP (with remote follow-up visits via phone at 7 days and 14 days after starting PEP to assess for and manage any side effects due to PEP).
- Follow-up visit: During this study, if you initiate PrEP and/or PEP, you will have a maximum of two follow-up visits, depending on when you enrolled. Each follow-up visit will last approximately 1 hour. At each follow-up visit, you will complete a survey. If you previously

started PEP and/or underwent STI testing and were not given PrEP, we will invite you to be screened for PrEP. If you previously started PrEP and are interested in continuing, we will provide: 1) *PrEP counseling*, 2) *HIV testing t*o confirm HIV-negative status prior to dispensing PrEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 3-month supply), and 4) *dried blood spot testing*. You will not be charged to refill PrEP at the pharmacy. After your first PrEP follow-up visit, you may be scheduled for a second follow-up pharmacy visit in 3 months. At your last follow-up visit (1-4 months following enrollment, depending on when you initiated PrEP), you will receive a 3-month PrEP supply and be referred to a public HIV clinic to continue PrEP care.

- Surveys: At each study visit, you will complete a face-to-face survey with a research assistant that includes information on where you live, your sexual practices (e.g., number of recent sexual partners and condom use), how well you take your medications, and your experience of receiving services at the pharmacy. You do not have to answer any questions you do not want to answer.
- Dried blood spot collection: At each study visit, a research assistant will collect a dried blood spot from you. This sample may be tested at a later time to measure HIV viral load (if any) and/or the amount of PrEP drug in it as an indicator of PrEP use.
- Urine sample collection: If you undergo STI testing at your enrollment visit, you will be asked to self-collect a urine sample in a private backroom of the pharmacy. These samples will be delivered same-day to a nearby health facility for processing. After the urine sample is tested, it will be discarded. It will not be stored for any future use.
- Data: All survey data will be captured electronically and stored in a secure database. Some answers to survey questions will be audio recorded, transcribed, translated, and stored in a secure online folder. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.
- Optional initial at-home HIV self-testing: If you are interested in initiating PrEP at a pilot pharmacy, you will have the option to take home an HIV self-testing kit (blood-based or oral fluid-based) and complete the self-test at home before undergoing blood-based, assisted HIV self-testing with a pharmacy provider as required for PrEP initiation. The purpose of giving you this option is so you have the opportunity, if you wish, to learn of your HIV status in the privacy of your home. If you opt to complete an initial HIV self-test at home, you will receive the testing kit free of charge.

IF YOU BECOME HIV INFECTED

During the course of the study, if you are found eligible, we will provide you with PrEP or PEP and counseling on HIV prevention. However, it is possible you may become HIV infected. If you have a positive HIV test during the study:

- The study staff will talk with you about this test result and what this means for you.
- You will stop taking the PrEP or PEP medication.
- You will be referred to a nearby HIV clinic for further HIV testing and linkage to HIV treatment, provided for free by the Kenyan Ministry of Health.

IF YOU TEST POSITIVE FOR AN STI

If you choose to test for STIs (*C. trachomatis* or *N. gonorrhoeae*) at your enrollment visit, you will only learn your tests results if you test positive. If you test positive for an STI, a study staff member will call you to talk about what this test result means for you and will send a prescription for STI treatment (available for free pick up) to the pharmacy where you STI tested.

IMPORTANCE OF NOT SHARING THE STUDY MEDICATION

It is very important that you do not share your PrEP or PEP medication with anyone else. Although the PrEP and PEP medications are also used to treat HIV infection, they are only effective for treating people who already have HIV infection if they are used in combination with other medications. Thus, PrEP and PEP by themselves are only for HIV-uninfected people.

USING YOUR DATA FOR FUTURE RESEARCH

The information and/or dried blood spot samples that we obtain from you for this study might be used for future studies. For example, the dried blood spot samples we collect from you may be stored and tested at a later time to measure HIV viral load (if any) and/or the amount of PrEP drug in it as an indicator of PrEP use. We may remove anything that might identify you from the information and/or dried blood spot samples. If we do so, that information and/or dried blood spot samples may then be used for future research studies on HIV, HIV-related diseases, and other sexually transmitted diseases or given to another investigator working on one of these topics without getting additional permission from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when talking about your sexual practices, ways to protect against HIV, and your HIV test results. You may become worried or anxious while waiting for your HIV test results. If you become infected with HIV, knowing this could make you worried or anxious. Talking about HIV, PrEP, PEP, and/or STI testing and finding out your test results could cause problems between you and your sexual partners, including the potential for intimate partner violence (e.g., any physical, verbal, sexual, or economic harm). Trained study staff will help you deal with any feelings or questions you may have.

Risks and side effects related to PrEP and PEP include gastrointestinal intolerance and rarely more serious side effects; these are detailed on the package inserts. This project is not testing PrEP or PEP itself but its delivery. The medical risks of HIV testing using blood collection are small.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff are wearing face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You will get access to PrEP and PEP at your local retail pharmacy during this study. PrEP is not regularly available in other retail pharmacies in Kenya. You may not benefit directly from answering the survey questions; however, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

COSTS TO YOU

There are no costs to you for being in this study. If eligible, you will receive PrEP, PEP, and/or STI testing for free.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent if the study is stopped or cancelled or if staying in the study would be harmful to you. Specifically, you may be removed if the pharmacy provider determines your care is outside of their expertise and refers you to an HIV clinic.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. However, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Any publication of this study will not use your name or identify you personally. A description of this clinical trial will be available on http://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 website at any time.

RESEARCH-RELATED INJURY

We do not anticipate any research related injury. However, if you feel you are injured from participating in this study, you will be offered care at a nearby clinic free of charge. There is not a program of monetary compensation through this institution. You do not give up any legal rights by signing this consent form.

REIMBURSEMENT

You will receive Kshs 500 at every study visit (including survey completion) for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the United States National Institute of Mental Health and the Bill & Melinda Gates Foundation.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you have a research-related injury, you should contact Peter Mogere on 0736464299.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form I do not give up any rights that I have as a research participant.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date
_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Copies to: 1. Investigators
2. Study participant

SPECIMEN STORAGE AND USE OF YOUR DATA AND SAMPLES FOR FUTURE STUDIES:

Please initial and date one option:

_____ I DO agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____ I DO NOT agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

SPECIMEN SHIPMENT TO UNIVERSITY OF WASHINGTON

Please initial and date one option:

_____ I DO agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests

_____ I DO NOT agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Copies to: 1. Investigators

2. Study participant

Informed Consent Form – Aim 1c pilot without STI testing: CLIENTS (Thika)
TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Prof. Kenneth Ngure	Site Principal Investigator	Jomo Kenyatta University of Agriculture and Technology	067 222561
Peter Mogere	Co-Investigator	Partners in Health Research and Development	067 222561
Dr. Catherine Kiptinness	Co-Investigator	Partners in Health Research and Development	067 222561
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: 0733464299

Study location: Thika, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The primary purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya. Studies have also shown that the medications used to treat HIV infection can also be used to reduce the chance of transmission of HIV in an HIV-negative person who has recently been exposed to HIV; this concept is called post-exposure prophylaxis, or PEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PEP can only obtain PEP at clinics. This study will investigate whether if, upon completing PEP, individuals who initiated PEP at retail pharmacies will go on to initiate PrEP.
- **Duration.** This study will run for 6 months from January 2022 until the end of July 2022. Depending on when you enroll in the study, you may have up to 3 study visits in total. Your initial (enrollment) visit will last no longer than 2 hours. If you initiate PrEP, you will be invited to refill PrEP at a retail pharmacy one month later and quarterly thereafter until the study ends. Each follow-up visit will last no longer than 1 hour. If you initiate PEP, you will be invited to screen for PrEP one month later.
- **Procedures and activities.** At each study visit, you will be asked questions about your sexual behavior, fertility intentions, and drug adherence. If you are interested in initiating PrEP, we will provide PrEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP, PrEP (daily oral TDF/FTC, 300mg/200mg), and dried blood spot testing. If you are interested in initiating PEP, we will provide PEP

screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PEP, PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg), and dried blood spot testing.

- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about sexual behaviors with the research assistant or that you may learn you are living with HIV from HIV testing. There are some potential health risks associated with PrEP and PEP, which range from upset stomach (mild, rare) to kidney damage (severe, very rare).
- **Benefits**. We expect some benefits from this study, as well. You will get access to PrEP at your local retail pharmacy for seven months. Also, you will contribute to developing new models for the delivery of PrEP for HIV prevention in Africa, which will help others in the future.
- **Costs**. While enrolled in this study, you will receive free HIV testing and, if eligible, free PrEP and/or PEP. You will not be charged anything for these services.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The primary purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities at each study visit:

- Enrollment visit: At this ~2 hour study visit, you will complete a survey, and if you are interested in starting PrEP or PEP, we will provide: 1) *PrEP* and/or PEP *screening* and *counseling*, 2) *HIV testing* to confirm HIV-negative status prior to dispensing PrEP or PEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 1-month supply) or *PEP* (daily oral, TDF/3TC/DTG, 300mg/300mg/50mg, 1-month PEP supply or TDF/3TC/ATV/r, 300mg/300mg/400mg, 1-month PEP supply), and 5) *dried blood spot collection*. You will be not be charged anything for PrEP or PEP at the pharmacy, and you will be scheduled for a follow-up pharmacy visit in 1 month if you initiated PrEP or PEP (with remote follow-up visits via phone at 7 days and 14 days after starting PEP to assess for and manage any side effects due to PEP).

- Follow-up visit: During this study, if you initiate PrEP and/or PEP, you will have a maximum of two follow-up visits, depending on when you enrolled. Each follow-up visit will last approximately 1 hour. At each follow-up visit, you will complete a survey. If you previously started PrEP and are interested in continuing, we will provide: 1) *PrEP counseling*, 2) *HIV testing t*o confirm HIV-negative status prior to dispensing PrEP, 3) *PrEP* (daily oral TDF/FTC, 300mg/200mg, 3-month supply), and 4) *dried blood spot testing*. You will not be charged to refill PrEP at the pharmacy. After your first PrEP follow-up visit, you may be scheduled for a second follow-up pharmacy visit in 3 months. At your last PrEP follow-up visit (1-4 months following enrollment, depending on when you initiated PrEP), you will receive a 3-month PrEP supply and be referred to a public HIV clinic to continue PrEP care.

- Surveys: At each study visit, you will complete a face-to-face survey with a research assistant that includes information on where you live, your sexual practices (e.g., number of recent sexual partners and condom use), how well you take your medications, and your experience of receiving services at the pharmacy. You do not have to answer any questions you do not want to answer.

- Dried blood spot collection: At each study visit, a research assistant will collect a dried blood

spot from you. This sample may be tested at a later time to measure HIV viral load (if any) and/or the amount of PrEP drug in it as an indicator of PrEP use.

- Data: All survey data will be captured electronically and stored in a secure database. Some answers to survey questions will be audio recorded, transcribed, translated, and stored in a secure online folder. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.

- Optional initial at-home HIV self-testing: If you are interested in initiating PrEP at a pilot pharmacy, you will have the option to take home an HIV self-testing kit (blood-based or oral fluid-based) and complete the self-test at home before undergoing blood-based, assisted HIV self-testing with a pharmacy provider as required for PrEP initiation. The purpose of giving you this option is so you have the opportunity, if you wish, to learn of your HIV status in the privacy of your home. If you opt to complete an initial HIV self-test at home, you will receive the testing kit free of charge.

IF YOU BECOME HIV INFECTED

During the course of the study, if you are found eligible, we will provide you with PrEP or PEP and counseling on HIV prevention. However, it is possible you may become HIV infected. If you have a positive HIV test during the study:

- The study staff will talk with you about this test result and what this means for you.
- You will stop taking the PrEP or PEP medication.
- You will be referred to a nearby HIV clinic for further HIV testing and linkage to HIV treatment, provided for free by the Kenyan Ministry of Health.

IMPORTANCE OF NOT SHARING THE STUDY MEDICATION

It is very important that you do not share your PrEP or PEP medication with anyone else. Although the PrEP and PEP medications are also used to treat HIV infection, they are only effective for treating people who already have HIV infection if they are used in combination with other medications. Thus, PrEP and PEP by themselves are only for HIV-uninfected people.

USING YOUR DATA FOR FUTURE RESEARCH

The information and/or dried blood spot samples that we obtain from you for this study might be used for future studies. For example, the dried blood spot samples we collect from you may be stored and tested at a later time to measure HIV viral load (if any) and/or the amount of PrEP drug in it as an indicator of PrEP use. We may remove anything that might identify you from the information and/or dried blood spot samples. If we do so, that information and/or dried blood spot samples may then be used for future research studies on HIV, HIV-related diseases, and other sexually transmitted diseases or given to another investigator working on one of these topics without getting additional permission from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when talking about your sexual practices, ways to protect against HIV, and your HIV test results. You may become worried or anxious while waiting for your HIV test results. If you become infected with HIV, knowing this could make you worried or anxious. Talking about HIV, PrEP, or PEP and finding out your test results could cause problems between you and your sexual partners, including the potential for intimate partner violence (e.g., any physical, verbal, sexual, or economic harm). Trained study staff will help you deal with any feelings or questions you may have.

Risks and side effects related to PrEP and PEP include gastrointestinal intolerance and rarely more serious side effects; these are detailed on the package inserts. This project is not testing PrEP or PEP itself but its delivery. The medical risks of HIV testing using blood collection are small.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff are wearing face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You will get access to PrEP and PEP at your local retail pharmacy during this study. PrEP is not regularly available in other retail pharmacies in Kenya. You may not benefit directly from answering the survey questions; however, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

COSTS TO YOU

There are no costs to you for being in this study. If eligible, you will receive PrEP and/or PEP for free.

REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY

You may be removed from the study without your consent if the study is stopped or cancelled or if staying in the study would be harmful to you. Specifically, you may be removed if the pharmacy provider determines your care is outside of their expertise and refers you to an HIV clinic.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. However, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Any publication of this study will not use your name or identify you personally. A description of this clinical trial will be available on http://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 website at any time.

RESEARCH-RELATED INJURY

We do not anticipate any research related injury. However, if you feel you are injured from participating in this study, you will be offered care at a nearby clinic free of charge. There is not a program of monetary compensation through this institution. You do not give up any legal rights by signing this consent form.

REIMBURSEMENT

You will receive Kshs 500 at every study visit (including survey completion) for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

- You do not have to be in this study if you do not want to join.
- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the United States National Institute of Mental Health and the Bill & Melinda Gates Foundation.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you have a research-related injury, you

should contact Peter Mogere on 0736464299.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form I do not give up any rights that I have as a research participant.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date
_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Copies to: 1. Investigators
2. Study participant

SPECIMEN STORAGE AND USE OF YOUR DATA AND SAMPLES FOR FUTURE STUDIES:

Please initial and date one option:

_____ I DO agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____ I DO NOT agree to store my data and samples for future research into HIV, HIV-related diseases, and other sexually transmitted diseases.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

SPECIMEN SHIPMENT TO UNIVERSITY OF WASHINGTON

Please initial and date one option:

_____ I DO agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests

_____ I DO NOT agree to allow my biological samples to be shipped to University of Washington for specialized tests and used for future research tests

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date

_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date

Copies to: 1. Investigators

2. Study participant

Informed Consent Form – Aim 1c pilot with STI testing: PROVIDERS (Thika)
TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Prof. Kenneth Ngure	Site Principal Investigator	Jomo Kenyatta University of Agriculture and Technology	067 222561
Peter Mogere	Co-Investigator	Partners in Health Research and Development	067 222561
Dr. Catherine Kiptinness	Co-Investigator	Partners in Health Research and Development	067 222561
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: 0733464299
Study location: Thika, Kenya

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit.
- **Purpose**. Studies have shown that the medications used to treat HIV infection can also be used to prevent passing the virus; this concept is called pre-exposure prophylaxis, or PrEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PrEP for HIV protection can only start and refill PrEP at HIV clinics. The primary purpose of this study is to find out if PrEP could additionally be delivered at retail pharmacies in Kenya. Studies have also shown that the medications used to treat HIV infection can also be used to reduce the chance of transmission of HIV in an HIV-negative person who has recently been exposed to HIV; this concept is called post-exposure prophylaxis, or PEP, and it is safe. Right now, HIV-uninfected men and women in Kenya interested in PEP can only obtain PEP at clinics. This study will investigate whether if, upon completing PEP, individuals who initiated PEP at retail pharmacies will go on to initiate PrEP. Lastly, studies have shown that sexually transmitted infections (STIs), such as chlamydia and gonorrhea, are common among individuals with high HIV risk. Some individuals with high HIV risk may be good candidates for PrEP; therefore, this study will investigate whether offering STI testing alongside PrEP screening to individuals who are not currently using PrEP leads to them initiating PrEP.
- **Procedures and activities.** You will be trained on the delivery of PrEP, PEP, and STI testing in pharmacies. If you are a pharmacy provider, you will provide to interested clients STI testing (urine self-sample) and/or PrEP and PEP screening and counseling, HIV testing to confirm HIV-negative status prior to dispensing PrEP or PEP, and, if client is eligible, PrEP (daily oral TDF/FTC, 300mg/200mg) or PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg). If you are a remote clinician, you will oversee pharmacy-

based PrEP and PEP delivery remotely by making yourself available for consultation via phone or WhatsApp (remote clinicians). At study baseline and once a month during the study, you will be asked to complete a survey with a research assistant about your experiences with pharmacy-based PrEP delivery and impressions of specific delivery strategies used.

- **Duration.** The overall study will run for 6 months from January 2022 until the end of July 2022. Each survey, if you decide to complete one, will take no longer than 1 hour to complete. The maximum number of surveys you will be invited to complete is 7; however, you may still participate in this study delivering PrEP, PEP, and STI testing even if you decide against completing any or all of the monthly surveys.
- **Risks.** Most studies have some possible harms that could happen if you join. In this study, we expect that you may become embarrassed, worried, or anxious when talking about experiences with pharmacy-based PrEP delivery to the study staff.
- **Benefits**. You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Africa, which will help others in the future.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

DESCRIPTION OF RESEARCH

The purpose of this study is to find out if PrEP could be delivered at retail pharmacies in Kenya. If you decide to take part, you will engage in the following activities:

- Training: Prior to delivering PrEP, PEP, and/or STI testing in pharmacies, pharmacy providers will complete a training based on the Kenya Ministry of Health PrEP and PEP guidelines. This will include training on HIV risk assessment, counseling for sensitive subjects (e.g., number of sexual partners, condom use), provider assisted HIV self-testing, the prescribing checklist, remote clinician consultation, clinical safety and side effect assessment, drug dispensing, and the importance of maintaining client confidentiality. Pharmacy providers will also be trained on how to instruct clients who opt for STI testing to self-collect a urine sample, as well as study procedures for handling samples once collected. Remote clinicians will be trained on study procedures, including the prescribing checklist and how to provide consultation to pharmacy providers via phone or WhatsApp.

- PrEP and PEP prescribing and refilling: Trained pharmacy providers will deliver PrEP and/or PEP at pharmacies using a prescribing checklist that will guide procedures that need to be completed prior to PrEP/PEP dispensing (e.g., risk assessment, counseling, clinical safety assessment, testing for HIV). If clients does not meet criteria outlined on the checklist, the provider will either consult with a remote study clinician via phone or a WhatsApp group, or they will refer the client to the nearest public HIV clinic for care. If the client does meet the criteria outlined on the checklist, the pharmacy provider will dispense PrEP (daily oral TDF/FTC, 300mg/200mg, 1-month or 3-month supply) or PEP (daily oral TDF + 3TC + DTG, 300mg/300mg/50mg or TDF + 3TC + ATV/r for women and adolescent girls of childbearing potential, 300mg/300mg/400mg).

- STI testing: Trained pharmacy providers will offer adult clients seeking STI treatment and/or diagnosis services the option to undergo free STI testing and instruct clients who consent to participate on how to self-collect a urine sample. Pharmacy providers will label the samples and contact a courier service to transport the sample to a prespecified clinic for testing. Study staff members will handle communication of positive test results to the client. If the client

agrees to have a clinician affiliated with the research study write him or her a prescription for STI treatment, the pharmacy provider will fill the prescription.

- Surveys: At study baseline and once per month during the study, you will be asked to complete a survey. The maximum number of surveys you will be invited to complete is 7. These surveys are voluntary, and you may choose not to participate in any or all of them. In this survey, a research assistant will ask you about your experiences with pharmacy-based delivery of PrEP, PEP, and STI testing and your impressions of specific delivery strategies used (e.g., any challenges you may have had, your thoughts on the price at which pharmacy-based PrEP should be delivered). Some of your survey responses will be audio recorded.
- Data: Some survey responses and study-related phone consultations with the remote clinician will be audio recorded, transcribed, translated, and stored in a secure online folder. All WhatsApp messages between pharmacy providers and remote clinicians will be securely stored in an online database and used as research data. Any information about you will be identified only by code. The link between your name and code will be kept in a secure location at the clinic only.

USING YOUR DATA FOR FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. Your information will be assigned a unique ID code and any identifying information linking you to this code will be stored in a secure location at the research site. If we use the information you give us or if we give it to another investigator for future research studies we will not get additional permissions from you.

RISKS AND/OR DISCOMFORTS

You may become embarrassed, worried, or anxious when having conversations about HIV risk-related behaviors and other sensitive topics with pharmacy clients, who will likely be members of the local community. Additionally, sharing your experience with and attitudes towards pharmacy-based delivery of PrEP, PEP, and STI testing with study staff may be uncomfortable.

COVID-19 SAFETY MEASURES

We know that COVID-19 will be in our community for many months. Interacting with others may put you at risk of getting COVID-19. However, we will put efforts in place to minimize your risk of COVID-19 exposure while at the pilot pharmacies. These efforts will include:

- Ensuring that all pharmacy providers and study staff wear face masks. Additionally, we will provide you with a mask when you visit a pilot pharmacy.
- Providing adequate space and guidelines for social distancing and strictly enforcing this in pharmacy waiting areas.
- Maintaining effective infection control practices, including frequent disinfection of the pilot pharmacies.

BENEFITS

You may get no direct benefit from answering the questions. However, you will contribute to developing novel delivery models for PrEP in Kenya, which will help others in the future.

CONFIDENTIALITY OF RESEARCH INFORMATION

Your information will be kept private and any publication of this study will not use your name or identify you personally. A description of this clinical trial will be available on http://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 website at any time.

REIMBURSEMENT

You will be invited to complete a survey at study baseline and once a month thereafter for the duration of the study. Each time you complete a survey, you will receive Kshs 500 for your time and effort.

YOUR PARTICIPATION IS VOLUNTARY

Before you learn about the study procedures, it is important that you know the following:

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- You may decide not to take part in this study, or to withdraw from the study at any time, without any repercussions to your job.
- If you decide not to take part in this study, you can still join another research study later, if one is available and you qualify.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the United States National Institute of Mental Health and the Bill & Melinda Gates Foundation.

PROBLEMS OR QUESTIONS

If you ever have any questions about this research or if you think you have been harmed by research participation, you should contact Peter Mogere on 0736464299.

If you have questions about your rights as a participant, contact the secretary of the KEMRI Scientific and Ethics Review Unit, P.O. Box 54840-00200, Nairobi, Telephone number 020272-2541, 0722205901, 0733-400003. Email address: seru@kemri.org.

STATEMENT OF CONSENT AND SIGNATURES

I have read this form or had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that my decision whether or not to take part in the study is voluntary. I understand that if I decide to participate, I may withdraw at any time. By signing this form, I do not give up any rights that I have as a research participant.

_____	_____	_____
Participant Name (print)	Participant Signature/Thumbprint	Date
_____	_____	_____
Study Staff Conducting Study Consent Discussion (print)	Staff Signature	Date
_____	_____	_____
Witness Name (print)	Witness Signature	Date

Copies to: 1. Investigators
2. Study participant

Informed Consent Form – Aim 1c pilot without STI testing: PROVIDERS (Thika)
TITLE: Pharmacy delivery to expand the reach of PrEP in Kenya: Pilot study

INVESTIGATORS:

Investigator	Title	Institution	Telephone
Local investigators			
Prof. Kenneth Ngure	Site Principal Investigator	Jomo Kenyatta University of Agriculture and Technology	067 222561
Peter Mogere	Co-Investigator	Partners in Health Research and Development	067 222561
Dr. Catherine Kiptinness	Co-Investigator	Partners in Health Research and Development	067 222561
International investigators			
Dr. Katrina Ortblad	Principal Investigator	Fred Hutchinson Cancer Research Center	+1-2066677267

Emergency number: 0733464299
Study location: Thika, Kenya

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2. Study participant