Standardized Patient Encounters to Improve Counseling for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention to Adolescent Girls and Young Women (AGYW) in Kenya

Consent for Facility Managers

Study Investigators

NAME	POSITION	DEPARTMENT	TELEPHONE NUMBERS
Grace John-Stewart	Co-Principal Investigator	Global Health, UW	+1-206-543-4278
Pamela Kohler	Co-Principal Investigator	Global Health, UW	+1-206-616-7962
John Kinuthia	Site Principal Investigator	Kenyatta National Hospital	+254-0722-799-052
Felix Abuna	Study Coordinator	Kenyatta National Hospital	+254 721 230652
Harison Lagat	Study Coordinator	Kenyatta National Hospital	+254 716 977248
Jillian Pintye	Co-Investigator	Global Health, UW	+1-206-437-9983
Kristin Beima-Sofie	Co-Investigator	Global Health, UW	+1-206-685-8332
Kate Wilson	Co-Investigator	Global Health, UW	+1-206-685-0583

Emergency telephone number: Dr. Felix Abuna, Telephone +254 721 230652
Ethics and Research Committee Chairperson: Professor AN Guantai, Telephone 020-272-6300 Extension 44102
University of Washington Human Subjects Division: Telephone +1-206-543-0098.

A. Researchers' statement

1. Introduction

We are asking for your consent to volunteer for a research study. The study is being conducted by the Kenyatta National Hospital (KNH) and the University of Washington. The purpose of this consent process is to give you the information you will need to help you decide whether or not you want to participate. You may ask questions about the purpose of the study, what we would ask you to do, possible risks and benefits, your rights as a volunteer, and anything else about the study or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study. This process is called "informed consent." We will give you a copy of this form for your records.

2. Purpose

We are asking you to participate in this study because you work in one of 24 clinics in Western Kenya selected for participation in a clinical trial. The trial will assess the current quality of PrEP counseling services for HIV prevention and evaluate whether a training course using standardized patient actors (SPs) improves PrEP service delivery to adolescent girls and young women (AGYW) in Kenya.

3. Procedures

If you agree to take part in the study, we will ask you to in participate in a survey at the beginning of the study. A study team member will administer the survey to you using an electronic tablet. The survey will ask about services and characteristic at this facility related to HIV prevention and treatment. Please provide the most current and accurate information that you can about this

facility. Your name will not be documented in this study. All information related to you will be kept confidential.

In addition, this facility may be selected to participate in a two-day didactic and role-playing training that would occur during normal working hours. In that case, we will speak with you and your staff in advance about those activities. There will be separate consent forms for those activities. At the end of the trial, we will ask that you complete another survey about this facility. Each survey will take 10-15 minutes to complete. One you have finished the surveys, your role in this study will end.

Today, if you agree to participate, you will sign this consent form and will be given a copy of this form for your records.

4. Risks, Stress, and Discomfort

Questions on this survey may be may make you feel uncomfortable, because they address HIV prevention and care services available for AGYW. You can stop the survey at any time if you do not feel comfortable. You can skip any question that you do not want to answer. You can withdraw from participation in the training or the study at any time. We will not share any information about you with your employer.

5. Benefits

You may directly benefit from this study as you gain understanding about how to improve health care relationships with AGYW in clinical settings, including improved practices, counseling, and support strategies that may help to improve the way PrEP is provided to this population.

6. Other information

Your Participation is Voluntary

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to,
- You may decide not to join the study, or to stop the study at any time

Costs to You

There is no cost to you for participation.

Reimbursement

Staff from this facility who participate in the training will receive light refreshments and reimbursement for transport.

7. Source of funding

The study team and/or the University of Washington are receiving financial support from the National Institutes of Health in the United States.

8. Confidentiality of Research Information

The information you provide during the interview will be kept secret by the study staff. This information is about this facility and not you personally. We will not publish or discuss in public anything that could identify you. All paper forms will be stored in a room under lock and key. Electronic data will be stored on a password protected server. Only authorized study team members will have access to study data. Study results will have no identifiable data that can be traced back to you.

This trial will be registered at ClinicialTrials.gov and available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. This website will only include a summary of the results. You can search the website at any time.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The records of this discussion may be reviewed by assessment staff and representatives of:

- University of Washington, including the Institutional Review Board
- Kenyatta National Hospital and University of Nairobi Ethics and Research Committee

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the US federal government who needs it in order to review or monitor the research;
- People at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly

9. Research-Related Injury

It is unlikely that you will be injured as a result of participating in this discussion. There is no program for monetary compensation or other forms of compensation for injuries. You do not give up any legal rights by signing this consent form.

10. Concerns or Questions

If you ever have any questions about the study you should contact Dr. Felix Abuna, Telephone +254 721 230652. If you have questions about your rights as a research participant, or feel you have been harmed by the study, you should contact Professor Guantai, the Chair of the KNH/UoN ERC, at 2726300-Extension 44102. You can also contact the UW HSD at +1-206-543-0098.

B. Study Participant's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have more questions later, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the KNH/UoN Ethics and Research Committee at 2726300-Extension 44102. I will receive a copy of the consent form.

_____ _____

Participant's Name Date

_____

Signature

Copies to: Researcher
Participant

Larsen A, *et al. BMJ Open* 2020; 10:e035689. doi: 10.1136/bmjopen-2019-035689

Standardized Patient Encounters to Improve Counseling for Pre-Exposure Prophylaxis (PrEP) for HIV Prevention to Adolescent Girls and Young Women (AGYW) in Kenya

Consent for Health Care Worker Patient Encounter and Training

Study Investigators

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2. Purpose

We are asking you to participate in this study because you work in one of 24 clinics in Western Kenya selected for participation in a clinical trial. The trial will assess the current quality of PrEP counseling services for HIV prevention and evaluate whether a training course using standardized patient actors (SPs) improves PrEP service delivery to adolescent girls and young women (AGYW) in Kenya.

3. Procedures

If you agree to take part in the study, we will ask you to in participate in a quality of care assessment, and you may be selected to attend a training. If you consent to take part, you are agreeing to be evaluated by an unannounced standardized patient actor (SP). Unannounced SPs are trained actors who will portray an adolescent girl or young woman who is seeking PrEP

services at your clinic. SPs will come to your clinic, at any time, for the duration of the study period lasting 3 years. Even if you consent to participate, you personally may not have a visit with a SP since only a few SPs will visit each clinic. We ask that you do not inquire whether a patient is an SP. Instead, it is important that you treat the SP like any other patient. There is a high likelihood that you will not know that this patient is an SP. The SPs will not provide any feedback to you about care that they receive. After the visit, the SP will complete a brief checklist to evaluate the visit with a study team member. Your name will not be documented in this checklist.

At the beginning of the study, you will be asked to complete short surveys about your background, knowledge of PrEP guidelines, and your clinical and communication skills. You may be asked to take this survey again at the end of the study. Each survey will take 10-15 minutes to complete.

Your clinic may be selected to participate in a 2-day provider training. If selected, you would be invited to take part in this training. The training will consist of lecture, group discussion, and role-playing sessions, and will occur during normal working hours. Content will include review of national PrEP guidelines, counseling female adolescents and young adults about PrEP and communication skills.

The role-playing will include several encounters with trained SPs. In each encounter, the SP will play the role of a female adolescent or young adult using a pre-scripted scenarios. The sessions will be video-taped and may be shared with your training group, the SP, and the study trainer as part of a debriefing process. The SP actors will provide verbal and written feedback on the scenario.

If you agree to participate, you will sign this consent form and will be given a copy of this form for your records. We will ask you for your written permission to release your videos for future trainings and education.

4. Risks, Stress, and Discomfort

The encounters with the SPs may make you feel uncomfortable. You may not know when a patient is an SP. If you participate in the training, you will receive feedback on your performance from colleagues, the actor, and the trainers, which may make you uncomfortable . You may also feel uncomfortable if the actor presents concerns about sensitive or difficult topics like HIV risk behaviors, violence, or mental health issues. You can stop any role-playing session if you do want to participate any further. You can stop the debriefing session at any time if you do not feel comfortable. In addition, you can withdraw from participation in the training or the study at any time, including being recorded. We will not share any information about you or your performance with your supervisor.

5. Benefits

You may directly benefit from this training as you gain understanding about how to improve health care relationships with AGYW in clinical settings, including improved practices, counseling, and support strategies. What we learn from you may help to improve the way that PrEP care and counseling services are provided to AGYW in Kenya.

6. Other information

Your Participation is Voluntary

This consent form gives information about the study. We will discuss the study with you and answer any questions you may have. If you agree to take part, we will ask you to sign your name on this form. We will offer you a copy to keep.

It is important that you know the following:

- You do not have to be in this study if you do not want to
- You may decide not to join the study, or to stop the study at any time

Costs to You

There is no cost to you for participation.

Reimbursement

If you participate in the training, you will receive light refreshments and reimbursement for transport.

7. Source of funding

The study is funded by National Institutes of Health in the United States.

8. Confidentiality of Research Information

The information you provide during the interview will be kept secret by the study staff. We will not publish or discuss in public anything that could identify you. The video recordings of the role-playing sessions in the training will not be directly linked to your name or contact information. Video recordings from the sessions will be stored in a password protected file on a password protected computer. All paper forms will be stored in a room under lock and key. Electronic data will be stored on a password protected server. Only authorized study team members will have access to study data. You have the option sign a separate form that will authorized us to use video recordings for educational purposes. Study results will have no identifiable data that can be traced back to you.

This trial will be registered at ClinicialTrials.gov and available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. This website will only include a summary of the results. You can search the website at any time.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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_____ _____

Participant's Name Date

_____

Signature

Copies to: Researcher
Participant