Official Title: A Stigma Responsive Service Delivery Model for HPV-based Screening Among Women Living With HIV

NCT: NCT05736588

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INFORMATION SHEET AND CONSENT FORM
Women completing survey

Study Title: 'Elimisha' HPV: A stigma responsive service delivery model for HPV-based screening among women living with HIV in Western Kenya

Conducted by: The Kenya Medical Research Institute and Duke University

Researcher	Institution	Study Role
Dr. Megan Huchko	Duke University, USA	Principal Investigator
Dr. Elizabeth Bukusi	Kenya Medical Research Institute, Kenya	Site PI

RESEARCHERS' STATEMENT

I would like to tell you about a study being conducted by researchers from the Kenya Medical Research Institute (KEMRI) and Duke University in the United States. The purpose of this consent form is to give you the information you will need to help you decide whether you would like to be in the study or not. You may ask questions about why we would like you to join this study, what happens if you participate in the research, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called 'informed consent.' We will give you a copy of this form for your records. This study is funded by a grant from the National Institutes of Health in the United States.

A. WHAT IS THIS STUDY ABOUT?

This study aims to learn whether an educational program that is designed to avoid promoting negative beliefs and feelings about Human Papilloma Virus (HPV) and cervical cancer has worked. The program includes simplified information about HPV and a video of a woman who has successfully overcome her fears of HPV screening and treatment. HPV is the most common viral infection of the reproductive tract with more than 100 sub-types. There are 14 sub-types that cause cervical cancer. Vaccination and screening for these high-risk sub-types are two powerful tools to prevent cervical cancer.

You are being asked to participate in this study because you are a woman who is eligible for cervical cancer screening according to the Kenyan Ministry of Health guidelines, in one of the health facilities participating in the Elimisha HPV study.

B. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 804 women will take part in the study.

C. WHAT WILL HAPPEN IF YOU DECIDE YOU WANT TO BE IN THIS STUDY?

You will participate in a 30-60 minutes survey about various attitudes and beliefs about cervical cancer and HPV in your community. This will be done in person either at the clinic or in the community.

Some time since October 2023, a Community Health Volunteer, also called the Health Promoter (CHP), met with you to offer HPV cervical cancer screening as part of their role as a health promoter. You may or may not have collected an HPV sample to give to the CHP. We will review and collect information from the health records that the CHP documented such as whether the CHP offered that you watch a video about HPV; HPV test results, if you collected a sample; and information on any follow-up appointments you went to or you were asked to go to related to the HPV screening. This will help us understand if more women screen and get treated for HPV when a CHP receives extra training on HPV and cervical cancer.

Your participation in the study will end when we review your medical record or complete the interview.

D. WILL ANY PARTS OF THIS STUDY HURT OR HAVE OTHER RISKS?
Risks related to your participation in the study may include: you may feel that some of the questions asked in the survey are sensitive. However, you do not have to answer any questions that you do not want to answer. You may stop your participation in this study at any time.

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

E. BENEFITS
Taking part in this study will have no direct benefits for you.

F. WILL THERE BE COSTS TO ME TO BE IN THE STUDY?
You will not be charged for any of the study activities.

G. WHAT WILL I GET PAID FOR BEING IN THE STUDY?
You will be compensated Ksh.1000 for completing the survey.

H. WILL INFORMATION FROM THIS STUDY BE KEPT PRIVATE?
Since we are doing this study with Duke University, all information from the study will be shared with investigators and staff from Duke University. To protect your identity, only authorized KEMRI and Duke study staff, will be able to access information that could identify you. Your name will only appear on this consent form. On other documents, we will use a number that identifies you so that your name is not revealed when the study team analyzes the information.

When we present what we have learned, we will combine information from the surveys so that you are not identified. By agreeing to be in the study, you are consenting to the publication and presentation of study results. We will share results with participants, county health teams, the broader scientific, programmatic and funding community through meetings, posters and manuscripts.

We will store all information collected on paper in locked cabinets in secure offices. We will store all electronic information on password protected devices and/or secure drives.

A description of this clinical trial will be available on https://clinicaltrials.gov/. The study number NCT05736588.

I. WHAT IF YOU HAVE QUESTIONS?
You can contact the study staff at 0748-101241 with any questions or concerns you may have about this study. You may also contact the Secretary of the Ethical Review committee, Kenya Medical Research Institute at Tel. 0717719477. Email: SERU Secretariat via seru@kemri.go.ke and kemriseru18@gmail.com. This committee is concerned with the protection of volunteers in research projects.

J. APPROVED BY.
The study was approved by Scientific Ethics Review Unit (SERU) and National Commission for Science, Technology and Innovation (NACOSTI).

CONSENT
You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

Participant's Statement

This study described above has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have future questions about the research, I can ask one of the investigators listed above. If I have questions about my rights as a research subject, I can contact those listed above.

Do you provide consent to participate in this study?

❑ Yes ❑ No

Name of Participant (printed)

Participant Signature or Fingerprint* Date

Name of Study Staff Administering Consent (printed)

Signature of Study Staff Administering Consent Date

Name of Person Witnessing Consent (printed)

Signature of Person Witnessing Consent Date