

Study title: Kupewa: Optimizing Implementation Strategies for Cervical Cancer Prevention

NCT number: NCT07015957

Document date: 30 July 2025

*This consent form should be signed only
between
and
Approved by NHSCD Malawi on*

CLIENT CONSENT OVER 18 YEARS (ENGLISH)
Informed Consent Form
English Version

Research Study Title: Kupewa: Optimizing Strategies to Implement Provider Recommendation of HPV Vaccination for Adolescent Girls and Young Women with HIV in Malawi

Introduction: Hello. My name is _____ I work for Partners in Hope (PIH), and we are studying HPV vaccination in Malawi. We are carrying out this research in collaboration with researchers at New York University (NYU) and the University of California, Los Angeles (UCLA). We've contacted you today because you participated in a survey with us during (MONTH) 2025, and – as discussed at that time – we will be contacting you periodically over a one-year period for brief follow-up surveys.

Purpose: We are carrying out this research to learn about uptake of HPV vaccine in Malawi. The study aims to increase health workers' knowledge, skills, and memory to recommend HPV vaccination to girls and young women.

Procedures: If you agree to take part in the survey today, we will ask you questions about your recent ART visit. This survey will last approximately 10 minutes. You will be given MK6,000 for your time on today's survey; you must complete the survey in order to receive the payment, although you may skip any survey questions that you wish. We will connect the information you give across all these surveys for data analysis.

As a reminder, at the end of the study, we will also review your medical records from the health center to understand what your health care has looked like over the past year. Specifically, we will look at your HIV medications (prescribed and pill counts at your visits), your HIV-related test results, like viral loads and CD4 measurements when available, and any infections or other complications that may have arisen for you. We may ask you for some of this information from your health passport if we are unable to locate it on your health center mastercard.

Risks: There are minimal risks in participating in this research. To minimize the possibility that others can hear our conversation, we will confirm that you are somewhere private enough to speak. I am also in a private space wearing a headset to ensure privacy and confidentiality of your information. Before you decide whether you want to participate, it is important to listen to the following information carefully and discuss it with others if you wish.

Benefits: If you choose to answer these questions, there will not be a direct benefit to you, but you will help us to understand if and how to improve health services. Please ask me if there is anything that is not clear or if you would like more information.

Privacy and confidentiality: The information you provide will be kept confidential. We will collect your name, your date of birth, the name of the village/area where you live, and your phone number(s) (to contact you for the follow-up surveys), but if you do not want to answer any of these questions, you may skip it and will not be penalized for doing so.

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By continuing this survey, you freely provide consent for PIH to collect, process, and transfer information you share with us for the purposes of this research project. There are no anticipated risks from taking part in this survey. If you do not want to answer any question, you may skip it and will not be penalized for doing so.

PIH commits to comply with the principles of data protection in Malawi. You have the right to be informed on PIH's use of your data, access to your data that PIH holds, and request that PIH update, correct, or delete your data, or opt-out at any time.

We will collect the following data from you:

- General information about your household and about your background including your date of birth and the village/area where you live
- Contact information including your name and phone number(s)
- Information on your vaccination against HPV (if you received it and if yes, when and where)
- Information from your vaccine card and health passport

PIH may transfer your personal data inside Malawi or to the United States for the purposes of this research project. PIH has in place security measures, such as encrypted software, and limits access to your personal data on a need-to-know basis. Your personal data will only be retained as long as reasonably necessary for this research. Afterwards, PIH will either delete your personal data or anonymize your data to ensure you are no longer identifiable. These de-identified data may be kept for use in future research, and may be shared with the research community to advance scholarly knowledge. We plan to deposit the de-identified data in the Qualitative Data Repository, which is an online database that helps researchers share the information that they learn from their studies with one another, so we can all keep learning together. All information that could identify you will be removed before sharing the data or using it for other research studies. We will not ask you for additional permission before sharing the information.

Withdrawal: Participation in this research is completely voluntary. Choosing not to take part will not disadvantage you in any way. It is up to you to decide whether to take part or not. If you decide to take part, you are free to withdraw at any time and without giving a reason. You are also free to not answer any question that you do not wish to answer.

Questions and contacts: You can ask me any questions that you have about the research. If you have any questions or concerns at a later time about your rights as a research subject or concerns regarding ethical issues, you may contact the National Health Sciences Research Committee by calling

Dr Evelyn Chitsa Banda

P.O. Box 30377

Lilongwe 3, Malawi.

Telephone 0999-936-937

This committee has reviewed research protocol in Malawi and can guide participants on how to report any matters that perceived violation of any of their rights as participants.

If you have questions about your rights as a research participant or if you believe you have been harmed from the research, please contact the NYU Human Research Protection Program at +1-212-998-4808 or ask.humansubjects@nyu.edu

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Do you have any further questions at this time?

Consent

During this survey you may be audio recorded for quality assurance purposes. You and the person interviewing you will both not know when this recording may happen. The audio recording may only happen if you consent to it and you will not be recorded against your will. This recording will only be used for data quality assurance purposes only.

Do you consent to a possible audio recording? Yes No

If I have answered all your questions, do you agree to participate in this study and acknowledge that you are at least 18 years old? Yes No

IF NO END THE SURVEY AND THANK THE RESPONDENT FOR HIS/HER TIME.

Are you in a location where you can answer questions privately now? Yes No

If not, schedule a time to call back.