

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

NCT number: NCT07015957

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Consent form should be signed only
by _____ and _____
Approved by NHSRC, Malawi on _____

PROVIDER FOCUS GROUP CONSENT (ENGLISH ONLY)

Informed Consent: Provider Focus Group Discussions

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

This research study is a collaboration between investigators at New York University (U.S., Corrina Moucheraud), University of California Los Angeles (U.S., Risa Hoffman), and Partners in Hope (Malawi, Sam Phiri).

Introduction: You have been asked to participate in this study called “Kupewa: Optimizing Strategies to Implement Provider Recommendation of HPV Vaccination for Adolescent Girls and Young Women with HIV in Malawi” because you are a clinical officer, nurse, or medical assistant at this facility who interacts with parents or caregivers of girls aged 9-24 years. Your participation is entirely voluntary. You will now read more information about the study and are free to ask questions about anything you do not understand before deciding whether or not to participate.

Purpose: This study aims to understand ways to increase HPV vaccination in Malawi. These focus groups aim to understand health care workers’ experiences with the Kupewa intervention.

Procedure: If you consent and agree to take part, you will participate in a one-hour focus group discussion. The facilitator will ask questions about your experience with the intervention(s) your health facility was assigned to during this study. All study information will be stored without identifiers, so your thoughts and opinions voiced during the discussion cannot be linked back to you. You will receive MK 18,000 for your participation. Refreshments will also be provided during the focus group discussion. There will be no costs for participation.

Benefits: There will be no personal benefits for participating in the study. However, the data collected through this study could potentially have a positive effect on health systems, particularly for regions that have a high burden of cervical cancer, like Malawi.

Risks: Participation in the focus group discussion can present some risk of loss of confidentiality, but the study team will make every effort to protect the information you provide. The discussion will be conducted in a private space where no one outside of the study can hear your answers. At the beginning of the discussion, participants will be asked to respect the privacy of the group.

Privacy and Confidentiality: Your responses are confidential, and we will not collect any information about you that could be used to identify you in the future, such as name, date of birth, address, or other personal identifiers. All participants will be asked to keep what is said during the group discussion between the participants only. However, complete confidentiality cannot be guaranteed. The focus group discussion will be audio-recorded and all of the recorded content will remain confidential. Only members of the study team will have access to the recording. After completion of the data analysis, the audio recording will be destroyed.

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Authorized representatives of the Malawi National Health Sciences Research Committee (NHSRC), the New York University (U.S.) Institutional Review Board, and others who are responsible for ensuring the rules related to research are followed, may need to review records of study participants. When the results of the research are published or discussed in meetings, no information will be included that would reveal your identity. Any data related to the study will be kept on an encrypted computer in a locked cabinet in a locked office at Partners in Hope or NYU. Information not containing identifiers may be used in future research, shared with other researchers, or placed in a data repository.

Participation and Withdrawal: Your participation in the research is voluntary. You may stop at any time or choose to not answer any of the questions. Additionally, the research investigator may stop your participation in the discussion, if he or she feels this is best for you.

Study Approval: Institutional review boards that have oversight in this research include the National Health Sciences Research Committee in Lilongwe, Malawi, and the NYU Institutional Review Board, New York, USA (contacts below).

In the event of a research-related problem, please contact the investigators (contact information below). If you have any questions about the research, please feel free to contact either of the individuals listed below.

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If you have questions about your rights as a research subject or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please contact:

Dr. Evelyn Chitsa Banda The National Health Sciences Research Committee in Lilongwe,
Malawi
P.O. Box 30377
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Telephone 0999-936-937

Mr. Scott Fisher
New York University Institutional Review Board
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We will now continue with the oral informed consent process. Do you consent to participate in the focus group discussion? ☐ Yes ☐ No