UNCPM 22323 - Supporting oral pre-exposure prophylaxis decision making among pregnant women in Lilongwe, Malawi: a pilot study

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University of North Carolina at Chapel Hill
Consent to Participate in a Study
Adult participant – Study Staff/Health Care Worker Qualitative Interviews

Consent Form Version Date: Version 1.1 dated, November 6, 2024
IRB Study: UNC # 23-3102, NHSRC # 23/10/4211
Title of Study: UNCPM 22323 - Supporting pre-exposure prophylaxis decision making among pregnant women: a pilot study
Principal Investigator: Dr. Lauren M Hill
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Funding Source and/or Sponsor: National Institutes of Health

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Study Contact Email: tphanga@unclilongwe.org

CONCISE SUMMARY

The purpose of this research study is to find the best way to help pregnant women make personally appropriate decisions about HIV prevention during pregnancy and breastfeeding. This part of the study involves in-depth interviews with staff involved in the study and health care workers from the study site to understand perspectives on the acceptability and feasibility of the study decision support approach and other study procedures. Each interview is expected to take approximately 1 hour. There is no expected benefit to you for participating in this part of the study. The main risks are discomfort in discussing issues related to HIV risk or HIV prevention methods, and breach of confidentiality.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the local clinic. You do not have to be in the research study in order to receive health care.

UNC Chapel Hill and UNC Project Malawi management does not urge, influence, or encourage anyone who works for the organization to take part in a research study. Your participation in this study is completely voluntary. You may withdraw from the study at any time and for any reason. Your decision to not participate in the study, or a decision on your part to withdraw from the study, will have no effect whatsoever on your employment status at UNC Chapel Hill and UNC Project Malawi. You may refuse to participate, or you may

withdraw from the study at any time without penalty or prejudice.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be offered a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The main purpose of this study is to evaluate how well the HIV prevention decision support counseling meets women's needs and preference, and how helpful it is to support personally appropriate decision making about HIV prevention. By interviewing study staff and health care workers familiar with the main study, we are hoping to understand the acceptability and feasibility of the study intervention and study features. This will help us to improve the study intervention and design for future studies.

Are there any reasons you should not be in this study?
You should not be in this study if you are younger than 18 years old, or you do not wish to talk about your experience with the study.

How many people will take part in this study?
A total of approximately 15 individuals will take part in this part of the study.

How long will your part in this study last?
This one-time interview is expected to take approximately 1 hour.

What will happen if you take part in the study?
If you consent to participate, you will be interviewed by a member of the study staff. You will be asked to talk about your opinions and experiences of the study HIV prevention decision support counseling and study procedures. You will be asked to share suggestions to improve the counseling and procedures in the future.

The interviews will be conducted in a private room and will be recorded to help us have an accurate record of the information you provided.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. There are no expected benefits to you from participating in the interviews.

What are the possible risks or discomforts involved from being in this study?
Participation in research includes the risks of loss of confidentiality and discomfort with the personal nature of questions, particularly when discussing HIV infection or sexual behaviors. Investigators will make every effort to protect participant privacy and confidentiality. You may choose not to answer questions during the interview if you do not want, and you may end the interview at any time. Data that could identify you will not be collected during the interview. There may also be uncommon or previously unknown risks. You should report any problems to the researcher.

How will information about you be protected?
Every effort will be made to keep your personal information confidential. It will be your decision whether you share any information about this study with others in your home or community. We will not do so. Your study information will be identified by a code to protect your privacy. Any publication about the results will not use your name or identify you personally.

Your records may be reviewed by representatives of the ethical and regulatory committees in Malawi-National Health Sciences Research Committee (NHSRC) and the University of North Carolina Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research Protections, study staff, or study monitors. This is for quality control and safety purposes.

Audio recordings of the interviews will be deleted after the information has been reviewed. Any information that could identify you will not be used.

Use of de-identified data and/or specimens for future research without additional consent
We may use de-identified data and/or specimens from this study in future research without additional consent.

What is a certificate of confidentiality?
Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, for any reason. The investigators also have the right to stop your participation at any time.

Will you receive anything for being in this study?
You will receive the equivalent of 10$USD for transportation costs.

Will it cost you anything to be in this study?
Participants will not have any out-of-pocket costs for participating in the research.

Who is sponsoring this study?
This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

For further information or questions
If you have any questions about this research, please contact the Investigator named at the top of this form by emailing hilllm@email.unc.edu or by calling UNC Project-Malawi at +265 1 755 056.

If you have questions about your rights as a research participant
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may, anonymously if you wish, contact the Head of Secretariat for the Malawi Health Sciences Research Committee Dr. Evelyn Chitsa Banda at +265 999 936 937.

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Participant's Agreement:

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please sign your name or place your thumbprint** in the signature area at the bottom of this page**.**

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

_____	_____	_____
Participant Name (print)	Participant Signature	Date

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

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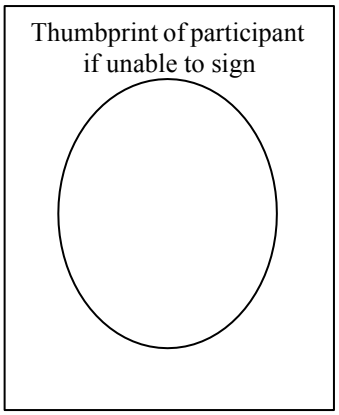
PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **impartial witness must write participant's name and date of consent** on the **SHADED AREA.**



Participant Name (print) Participant Thumbprint Date

Participant Name and Date Written By…….on…...……

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

Impartial Witness Name Impartial Witness Signature Date

(print)