Appendix 12A: Participants Information Leaflet and Informed Consent – Consultation and Validation Workshop English Version

Malawi Liverpool Wellcome Programme
P.O. Box 30096
Chichiri
Blantyre 3
Malawi
Tel +265 187 6444
Fax +265 187 5774
www.mlw.mw

PARTCIPANTS INFORMATION LEAFLET- MATERNITY FEEDBACK TOOL (CONSULTATION AND VALIDATION)

STUDY TITLE: Understanding vulnerable maternity service user experiences, developing and piloting maternity user feedback tool in Malawi.

STUDY SITES: Lilongwe, Mzimba and Mangochi.

PRINCIPAL INVESTIGATOR: Associate Professor Linda Nyondo Mipando

INTRODUCTION

You are invited to take part in a research study on **Understanding vulnerable maternity service user experiences, developing and piloting maternity user feedback tool in Malawi.** Whether or not you take part is your choice.

The study is funded by the National Institute of Health Research (UK) conducted by Malawi Liverpool Wellcome Programme in collaboration with Reproductive Health Department (RHD),Quality Management Directorate under Ministry of Health, Kamuzu University of Health Sciences, Malawi Epidemiology and Intervention Research Unit(MEIRU) and University of Liverpool(UoL).

The study has been approved by the College of Medicine and the University of Liverpool research ethics committees. The study will run for 12 months. Approximately 83 participants are expected to participate in this study.

This Participant Information Leaflet will help you to understand about the study and decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the

benefits and risks to you might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have.

You do not have to decide today whether you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, friends, or healthcare providers. Feel free to do this. If you or family members and friends need further information, please do not hesitate to contact us.

If you agree to take part in this study, you will be asked to sign the Informed Consent Form on the last page of this document. You will be given a copy of both the Participant Information Leaflet and the Informed Consent Form. Please make sure you have read or someone has read for you and you have understood all pages of this document.

WHAT IS THE PURPOSE OF THE STUDY?

Women's satisfaction with maternity services is important to healthcare providers, administrators, and policymakers to improve the quality of care. Using reliable and valid measures is key in assessing satisfaction with health care services. However, there are no maternity-specific feedback tools in Malawi. Having maternity tools will help in getting feedback on quality of care as it portrayed as low, with high maternal mortality rate, despite high ANC attendance and skilled birth. The purpose of this consultation and/ or validation meeting is to develop and implement user feedback systems in maternity settings in the three districts of Malawi.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen to participate in this study because you meet the inclusion criteria of being a representative of key policy making bodies, Safe motherhood coordinators, facility management staff, training institutions, patient and public involvement members, and partners in the districts.

By participating in this study, we will collect your personal data such as cadre and your location. As part of feedback tool development, you will be involved in either consultation or validation workshop. You are expected to share your views to ensure representation of all concerned parties in this tool development and share feedback and advice on the tool developed to ensure it is of high quality. All views shared during the workshop will be held securely on paper files in a lockable cabinet and computer files with password protected. The principal investigators will take responsibility for keeping your personal information confidential.

You are expected to be in the study for the duration of the workshop which is 1 day. After which your study participation is completed. The study staff will introduce topics for discussion. The study staff will

ensure all members are able to express themselves freely in an environment of collaboration, support, and respect.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

There are no direct benefits to you for participating in this study, however, your participation will contribute valuable scientific knowledge on how best to obtain and utilize maternity services end-user's views in improving quality of care. During participation in this study you may require explanations of the different topics proposed for discussion. All participants will be encouraged to ask questions freely. The participation is designed to allow maximum participation for those attending in an environment of respect and support. Any disagreements that arise will be considered and workshop is facilitated by trained research staff with a commitment to respect the views of all participants. It is the investigator's responsibility to ensure that you can express yourself freely during your participation in this study. If you feel unable to do so during the workshop, or upon reflection after the workshop has ended, our staff will provide support to you and offer you the opportunity to discuss and resolve any concerns you may have. There are no associated risks of participating in this study. However, if you feel uncomfortable with some of the topics under discussion you can freely ask the study staff to skip to another topic.

COVID-19 specific risks

Our staff have been trained in the appropriate use of Personal Protective Equipment (PPE), social distancing and hand washing in order to keep themselves and yourself safe during interviews. If you have any questions or concerns regarding these practices, please address them to the study team lead using the contact number below.

WHO PAYS FOR THE COSTS OF PARTICIPATING IN THIS STUDY?

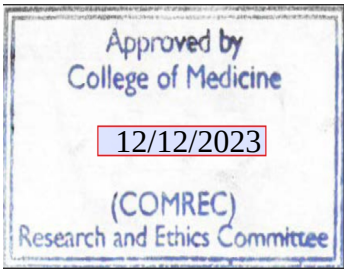
The study is funded by NIHR through Malawi Liverpool Wellcome Programme.

Participants in the workshop will receive a per diems according to government DSA guidelines and accommodation reimbursement if travel will be required.

WHAT ARE MY RIGHTS?

All information collected during the study will be kept strictly confidential. With your permission, some data may be shared with other researchers outside Malawi without your identity to help them with other studies that might benefit vulnerable women accessing maternity care.

You have the right to access information about yourself collected as part of the study and be informed about any new information that becomes available during the study. Your privacy and confidentiality will be safeguarded during your participation period in this study. Your study data are accessible to the study team in addition the Ethics Committee in charge, Malawian Regulators and study monitors may access the data.



You can stop taking part in the study at any time. You do not need to explain why. We will ask your permission to use any information or results we have obtained up until the point you stop taking part.

SAFEGUARDING

The MLW study team and data collectors are expected to always behave ethically and responsibly and follow the MLW staff code of conduct. This means that they must not ask you for any financial, physical, or sexual favors in return for taking part in this research. If you experience any abuse, harassment, or neglect by a study team member you can contact the MLW Safeguarding Team by calling 0993474061, or the principle investigator, or the ethics committee.

WHAT HAPPENS AFTER THE STUDY?

The findings of this study will be disseminated to policymakers, researchers, study participants and civil society organizations through websites, newsletters, social media, and seminars/conferences. In addition, a report will be submitted to various Institutional Review Boards. In Malawi, it will be submitted to the College of Medicine Research and Ethics committee (COMREC). The workshop outcome will be shared with wide stakeholders involved in maternity service prioritization meetings and policy briefs from other work streams within the whole safe motherhood project.
Study results will be published once all study data has been collected, validated, and analyzed.

Audios will be deleted soon after transcription, only the transcribed data will be stored for a maximum of 5 years after study ends.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

Feel free to ask any of our study team any questions at any time. You can contact the following;

Name: Associate Professor Linda Nyondo-Mipando
Position: Principal Investigator
Telephone number:0999441212
Email: lmipando@mlw.mw

Alternatively, you may contact the chairperson of the College of Medicine Research Ethics Committee by telephone on +265 1871911 EXT 334 and / or COMREC Chair 0888118993, by email at comrec@medcol.mw or by postal address at COMREC Secretariat, College of Medicine, P/bag 360, Blantyre 3.

Understanding vulnerable maternity service user experiences, developing and piloting maternity user feedback tool in Malawi

PARTICIPANT CONSENT FORM

Participant Name _____ Participant ID_____

[*Participant name and ID are completed after participant has signed the consent form*]

UNDERSTANDING VULNERABLE MATERNITY SERVICE USER EXPERIENCES, DEVELOPING AND PILOTING OF MATERNITY USER FEEDBACK TOOL IN MALAWI.

Please answer the following questions by putting your initials or your thumbprint to the response that applies.

1. I have read/I have been read the Participant Information Leaflet for this study and have had details of the study explained to me. ☐
2. My questions about the study have been answered to my satisfaction and I understand that I may ask further questions at any point. ☐
3. I have been informed that my recorded voice will be deleted soon after transcription. ☐
4. I understand that I am free to withdraw from the study at any time without giving a reason for my withdraw ☐
5. I agree to provide information to the researchers under the conditions of confidentiality set out in the Participant Information Leaflet. ☐
6. I agree to participate in the study under the conditions set out in the Participant Information Leaflet. ☐
7. I agree to share my anonymize data with researchers around the world (open data access) for a long time and for any purpose, and to have the information they learn put in scientific publications. ☐
8. I agree to share my anonymize data with policy makers in Malawi for a long time and for any purpose. ☐

PARTICIPANT CONSENT FORM

Participant Name _____ Participant ID _____

[Participant name and ID are completed after participant has signed the consent form]

UNDERSTANDING VULNERABLE MATERNITY SERVICE USER EXPERIENCES, DEVELOPING AND PILOTING MATERNITY USER FEEDBACK TOOL IN MALAWI

Name of Participant*	Date	Signature/Thumb print for illiterate participants
Name of Impartial witness (for illiterate participants and/or guardians)***		
Name of study team member administering consent		

***** These sections remain blank if study participant is illiterate