Malawi-Liverpool-Wellcome Trust
Clinical Research Programme
P.O Box 30096, Chichiri, Blantyre 3,
Malawi.
Tel. +265 1 876444 Fax +265 1 875774

Title: Investigating interventions to increase uptake of HIV testing and linkage into care or prevention for male partners of pregnant women in antenatal clinics in urban Blantyre, Malawi: an adaptive Phase II multi-arm multi-stage cluster randomised trial

Principal Investigator: Mr. Augustine Choko

[The following text must be read to the participant, who must have their own copy to take home]

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PQ24a: Participant Information and Consent Form for Trial Participants in the Self-Test Kits + a Low Financial Incentive Arm v1.0; 31st March 2016

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Procedure

After the group information about the study, now I would like to give you some more information about the study and also ask you some questions related to you and your partner. The interview will not exceed 10 minutes and will include questions about your and your partner's personal information and HIV testing. At the end of the interview I will give you a personalised invitation letter to give to your partner so that he can use the letter to come to our "male friendly clinic" alone or together with you. I will also give you two self-test kits to take home to allow your partner to self-test alone or together with you. At this clinic we are offering free confirmatory HIV testing for people who report a positive HIV test followed by facilitated HIV treatment initiation, a chance to be circumcised if HIV negative, and

information about birth preparedness. We will call your partner tomorrow and after five days to remind him to self-test and come to the male friendly clinic.

As part of the study we will want to have a final interview with you when you come back for your next ANC visit in four weeks' time. The main aim of this follow-up interview is to check if your bringing up this discussion with your partner led to any problems and whether or not your partner tested and linked to the "male friendly clinic". We will also ask you to bring back used or unused self-test kits at your next visit so that we can reconcile our stock with our main office.

Your participation is entirely voluntary. If you decide to take part, you may withdraw from the interviews or the study any time. You also have a right not to answer any particular question or questions that will be asked. Declining to participate in the study will not affect any health services that you or any person related to you may be currently receiving or may require in future.

Confidentiality

All personal information collected in this study will be kept strictly confidential. I will not share the information you provide with anyone who is not part of this research. But it may be shared with fellow researchers and may also be published through meetings or journals in a manner that does not reveal your identity. Before sharing in this manner, the information from you will be combined with that from other research participants. Information which could identify you or anyone related to you will never be released. This also means that names of study participants, including your own will not be included when sharing the data. Data collection equipment and the data collected will be kept with identifiers, locked, and only accessible to people that have authorised access.

Risks

You may be uncomfortable with some of the questions that I will ask. You are perfectly entitled to refuse to discuss issues that you do not want to.

Benefits

There are no direct benefits to you in your taking part in this study. However, what we learn from this study would help develop ways of successfully reaching out to male partners, offer them an HIV test and link them to appropriate follow-on services. It would thus help us inform health authorities in the Ministry of Health regarding which interventions truly hold potential to reduce the problem of low uptake of testing and linkage among male partners of pregnant women.

Compensation

You will not receive payment for participating in the study. You will however, be offered a small compensation for your time amounting to MWK1,000.

Contact details

This research has been approved by the College of Medicine Research Ethics Committee (COMREC) and the London School of Hygiene and Tropical Medicine Research Ethics Committee. If you have any questions regarding your rights as a research participant, or concerns on how you have been treated in the study, please feel free to contact **Mr. Augustine Choko** [+265 (0) 999 577 452] or [augutc@gmail.com]. If you have any questions regarding your rights as a research participant, or concerns on how you have been treated in the study, please feel free to contact COMREC Secretariat, College of Medicine, Private Bag 360, Chichiri, Blantyre 3 or call on 01871911 ext 334.

Consent Declaration

If you agree to voluntarily participate in the study, please sign or write your initial or your thumb print below to show that you understand the information above and that your consent is given voluntarily.

1. I have received and read or had read to me the information sheet provided by the Researcher that explains in detail the reasons for the study.
2. I have understood the purpose of the research.
3. I have asked all the questions that I have about the purpose of the research and feel that I have enough information about it.
4. I understand the reasons for this study.
5. I am willing to take part in the study.
6. I understand what I will be required to do if I participate in the study.
7. I know that I have the right to leave the study at any time or to refuse to answer any questions.
8. If I do not agree to take part in this study I understand that I will not be penalized for doing so by the researcher nor by any medical service providers in the future.
9. **I voluntarily agree to take part in this study**

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Signature/thumb print of participant Date

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Signature of person obtaining consent Date

If the participant gave verbal consent, please enter the name of person who witnessed the consent here, and their signature:

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Name of Witness (BLOCK CAPITALS) Date Signature or thumb print