**University of Illinois at Chicago**
**Research Information and Consent for Participation in Research**
**Group Antenatal Care in Malawi**
**Effectiveness Evaluation**

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.


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## Why am I being asked?

You are being asked to participate in a research study that compares two different types of antenatal care: usual antenatal care and group antenatal care.

You have been asked to participate in the research because you are a healthy pregnant woman who completed your first antenatal care visit and are 15 years old or over.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with this clinic. **If you decide to participate, you are free to withdraw at any time without affecting relationships.**

Approximately 2,100 women from seven antenatal care clinics in Blantyre District may participate in this research.

## What is the purpose of this research?

We are doing this research to learn which type on antenatal care is better for pregnant women and their babies, antenatal care in a group of 8 to 12 women or antenatal care offered to women individually (as usual). A study in the United States showed that group antenatal care reduced the risk for preterm birth. We want to know if this will happen in Malawi.

**What procedures are involved?**

This research will take place in a private space in this clinic, like the room we are in now. You will be asked to answer some questions in a survey today and three more times: once in late pregnancy, once at six weeks after birth, and once at 6 months after birth. We will ask you to answer the questions a total of four times. Each survey will take between 30-60 minutes to complete.

If you agree to participate in this study, the following will happen:

1. You will be assigned by chance to receive antenatal care in a group with other women or individually.

2. If you are assigned to individual care, you will attend antenatal care as you regularly would, which typically includes a total of 8 visits, plus visits at 1 week after birth and 6 weeks after birth. Each individual care visit will be conducted as usual at your clinic, where you will have a one-on-one visit with your midwife. You may also receive education in the form of a lecture or with your midwife.

3. If you are assigned to group care, you will attend antenatal care appointments, which typically includes a total of 8 visits, in a group of 8 to 12 women, plus two visits after birth. The 1-week after birth visit will be an individual visit as usual. The 6-week postpartum visit will be a group visit.
    - Group care visits include the same midwife assessments that occur in individual care, but you will be taught to take some of your own health measures. You will have a brief one-on-one private visit with the midwife. You will also receive education in the form of a group discussion.

4. We will ask you to complete four individual surveys. We will arrange to meet you at the clinic at a convenient time each time a survey needs to be completed.
    - Each survey will take between 30-60 minutes to complete. The first survey will take the most time (~60 minutes). Surveys 2 and 3 will take about 45 minutes and the last survey ~30 minutes.

    - The surveys ask questions about your household; previous pregnancies; knowledge about pregnancy, HIV, and prevention of mother-to-child transmission; if you were tested for HIV during your pregnancy and if you received the treatments you needed. In the third survey, questions are added about your birth experience, the health of your newborn, and infant care.

    - We may ask you to refer to the information on your Health Passport to remind you about the health services you have received including your infant's birth date, weight, whether the baby had a well-child visit and appropriate treatments.

5. Every time we see you for a survey, we will also do a fingerprick to measure your hemoglobin levels.

6. At the final interview, 6 months after birth, we will ask you for a sample of urine to do a pregnancy test to see if you are pregnant.

7. You will participate in the study for up to one year.

8. We will ask you for a phone number and/or address so that a team member can contact you between surveys. They will help schedule and remind you about the survey day and time.

☐ I agree to be randomly assigned to either individual or group ANC.

Initials or Thumbprint: _____

☐ I agree to allow a member of the research team to contact me at home or by phone to setup appointments to take the survey.

Initials or Thumbprint: _____

☐ I agree to take the four surveys and the fingerprick to measure my hemoglobin.

Initials or Thumbprint: _____

☐ I agree to take a pregnancy test at 6 months postpartum.

Initials or Thumbprint: _____

**What are the potential risks and discomforts?**

To the best of our knowledge, the things you will be doing as part of this study have no more risk of harm than you would experience in everyday life or during regular antenatal visits. Because this research involves a group of people, there is a risk that a breach of privacy (others will know that you are participating in this research) and confidentiality (accidental disclosure of information that has your name) may occur.

Because some topics discussed in the group and some questions on the survey are personal, you may experience some discomfort during the discussions. However, you are free to skip questions or sit quietly in the group. Also, if at any point you no longer want to participate, you may withdraw from the study at any time.

**Will I be told about new information that may affect my decision to participate?**

During the course of the study, you will be informed of any significant new research information (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the research. If new information is provided to you, your consent to continue participating in this research may be obtained again.

**Are there benefits to taking part in the research?**

Taking part in this research study may not benefit you personally, but we may learn new things that will help other pregnant women by improving antenatal care.

**What other options are there?**

You do not have to be in this study to attend antenatal care at this clinic.

**What about privacy and confidentiality?**

Your privacy is important to the research team. For those in individual care, only members of the research team will know that you are in the study. For those in group care, other members of your group will know that you are in this study.

No information about you will be disclosed to others without your written permission, except if necessary, to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects (OPRS) monitors the research or consent process) or if required by law.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for checking up on the research by the National Institutes of Health (NIH) and/or the UIC OPRS.

A possible risk of the research is that your participation in the research or information about you might become known to individuals outside the research. We will make every effort to prevent this from happening by doing the following:

- Also, to ensure that others will not be able to connect you to your survey answers, we will assign you a special number, and all of your information will be identified by this number. We will keep the list of the participants' names, contact information and special numbers separate from other study materials.
- A copy of your signed consent form will be stored in a locked office in a locked cabinet at the Kamuzu College of Nursing.
- Your contact information will be destroyed when we finish all of the surveys.

Although we ask everyone in the group to respect each other's privacy and confidentiality, and not to identify anyone in the group or repeat what is said during the group discussion, please remember that other participants in the group may accidentally disclose what was said.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

**What are the costs for participating in this research?**

There are no costs to you for participating in this research.

**Will I be reimbursed for any of my expenses or paid for my participation in this research?**

At the end of each of the four surveys you will receive $12, for a total of $48 at the end of the study.

**Can I withdraw or be removed from the study?**

If you decide to participate, you are free to stop participating at any time.

**Who should I contact if I have questions?**

Contact the researchers:

**Ellen Chirwa, PhD**
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**Crystal Patil, PhD**
Professor, UIC
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cpatil@uic.edu

- if you have any questions about this study or your part in it,
- if you have questions, concerns, or complaints about the research.

**What are my rights as a research subject?**

If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research subject, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

**Remember**:

Your participation in this research is voluntary. Your decision whether to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

**Signature of Subject**

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

_____ _____
Signature or Thumbprint Date

_____
Printed Name

_____ _____
Signature of Person Obtaining Consent Date (must be same as subject's)

_____
Printed Name of Person Obtaining Consent