

Informed Consent (for midwives participating in study)

Title: Group Antenatal Care to Promote a Healthy Pregnancy and Optimize Maternal and Newborn Outcomes: A Cluster Randomized Controlled Trial

Principal Investigators: Jody Lori, PhD, University of Michigan and Dr John Williams, Dodowa Health Research Centre

Co-investigators: Cheryl Moyer, PhD, University of Michigan

Study Sponsor: National Institutes of Health; Eunice Kennedy Shriver National Institute of Child Health & Human Development. Grant#: RO1HD096277

Invitation to be Part of a Research Study

The Dodowa Health Research Centre and the University of Michigan in the United States are leading a research study on group antenatal care. We want to find out how to help women in Ghana have safer births and healthier babies. You are being asked to be in this study because you are a midwife provider of antenatal care at one of the seven sites randomized to provide group antenatal care.

Important Information about the Research Study

The purpose of this evaluation is to learn about your experience and perceptions about providing antenatal care (ANC) in a group setting.

What will happen if you take part in this study?

If you take part in this study, you will be asked to complete an individual interview now and once more after completing seven group antenatal care meetings. We will audio record the interview to be sure we understand everything you say. You can choose not to be recorded and still participate. You will select your choice about the recording on the signature page of this form. If you are not recorded, we will write your answers on a data sheet. The data sheet will not have your name, only your answers to the questions. The recordings will only be used for research purposes. Once the interviews have been transcribed, the recordings will be destroyed. This process will take approximately one month. The interview will take approximately 40 minutes. You will also be observed by the research staff during two group sessions. The observation is an evaluation of the group ANC program.

How could you benefit from this study?

You will not get special treatment or rewards for providing group ANC, but we do hope that sharing your ideas might also benefit the health system of Ghana with program implementation and improved quality of care for pregnant women and their unborn babies. Sometimes people tell us they feel good about helping make things better for others.

What risks might result from being in this study?

Taking part in the interview is not likely to harm you; however, there is a small risk of breach of confidentiality. We don't think anything we talk about will be outside your activities as an ANC provider or upset you, but if it does you can decide not to answer that question(s) with no problem to you. If this does happen, we will still give you the opportunity to answer those questions you are comfortable with or opt-out of the interview. In case you get upset, we will direct you to people you can talk to who can help you get over being upset.

How will we protect your information?

The information you give us will be kept strictly confidential. Researchers will not discuss what is said in the interview outside the research team. We will not collect any information that identifies you. We will store and use your data for future research. We may share it with other researchers but we will not share any information that could identify you. If you do not want your data to be stored and shared you may choose to not be in the study. You will not be named in any reports or publications. Once the interview is transcribed, the recording will be destroyed. This process will take approximately one month.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

You will not be named in any reports (including www.clinicaltrials.gov) and at no time will a link between you and the answers you give be released.

How will we compensate you for being part of the study?

You will not be paid to be in the study, but you will receive training on how to provide group antenatal care.

Your Participation in this Study is Voluntary

You can choose to be in the study or not be in the study, it is up to you. If you choose not to be in the study, there will be no problem for you now or in the future. You can leave the study at any time without any problem to you now or in the future. Being in the study or not being in the study does not affect your role in the health care system in any way.

Contact Information for Study Team and Question about the Research

If you any questions concerning this study, you can ask me now or contact the study coordinator Ms Vida Kukula on 0208451202 at the Dodowa Health Research Centre or call her on 0208451202/0244167999.

If you have questions or concerns about the research, please contact the Principal Investigators, **Dr John Williams at Dodowa Health Research Centre on telephone number 0244755358 or Prof. Jody Lori. For international calls from Ghana to the US, +1734-763-0097 or email: jlori@umich.edu.** Please note the time in Michigan is 5 hours earlier than in Ghana.

Contact Information for Questions about Your Rights as a Research Participant

This research has been reviewed and approved by the Ghana Health Service Ethics Review Committee, the Institutional Review Boards of Dodowa Research Health Centre, and the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board.
2800 Plymouth Road, Building 520, Room 1169

Ann Arbor, MI USA 48109-2800

For international calls from Ghana to the US, +1734-936-0933 or email: irbhsbs@umich.edu.

Please note the time in Michigan is 5 hours earlier than in Ghana.

If you have any questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss concerns about this study with someone other than the researchers, please contact the following:

Administrator of Ghana Health Service Ethical Review Committee, Ms Hannah Frimpong on 0302681109/0507041223.

If you wish to find out more about the Dodowa Institutional Review Board, you may contact Ms Irene Honam Tsey on 0208420640.

CONSENT FORM

Statement of person obtaining informed consent:

I have fully explained this research to _____ and have given sufficient information, including about risks and benefits, to make an informed decision.

DATE: _____ SIGNATURE: _____

NAME: _____

Statement of person giving consent:

I have read the description of the research to my satisfaction. I understand that my participation is voluntary. I know enough about the purpose, methods, risks and benefits of the research study to judge that I want to take part in it. I understand that I may freely stop being part of this study at any time. I have received a copy of this consent form to keep for myself.

We will make an audio recording during the study so that we can be certain that your responses are recorded accurately only if you check the box below:

I give my permission for audio recordings to be made of me during my participation in this research study.

I do not give my permission for audio recordings to be made of me during my participation in this research study.

DATE: _____ SIGNATURE: _____

NAME: _____