Study Title: Prevention of Neonatal and Maternal Infection During Labor and Delivery in Rural Healthcare Sites in Zambia - Intervention Phase

ClinicalTrials.gov ID Number: NCT03809741

Document Date: Feb 20th, 2019

Information Sheet for Pregnant Women in Labor

Quantitative Study on Infection Control Interventions in the Labor and Delivery Services in Southern Province in Zambia

Background and Purpose

Hello, my name is _____ and I am a research assistant working with Right to Care-Zambia. We are conducting a study to investigate infection control practices in labor and delivery wards at rural health centers in Southern Province of Zambia. This study is funded by Fogarty International Center, National Institute of Health, USA. We are observing for how your provider cleans and disinfects during and after your labor so that you and your baby are as healthy as possible. This will allow us to find ways that your clinic can improve and better prevent infections. We want to find ways to help your clinic to provide the best possible care to women in your community. By observing the current infection control practices, we hope to improve the practices at this center and reduce rates of infection during labor and delivery.

What Happens in This Research?

A research assistant will be watching you and your health care providers while you are having your baby . She will be observing from the side or corner of the delivery room so she will not interfere with the care that is being provided for you. She will be filling out a paper chart detailing what the healthcare workers are doing during your delivery. After observing your delivery and the delivery of other women, we will look at the health center logbook to see how many women and babies had infections after delivery.

We understand that this is a very private moment for you. We assure you that our observation is solely for us to collect information on infection control.

Risks and Discomforts

There are no known physical risks for participating in this study. The major risk of this study is loss of confidentiality. You may also experience inconvenience or discomfort from having an observer present during your labor. If you ever feel uncomfortable with their presence, you can ask for the research assistant to leave.

Potential Benefits

There is a potential for direct benefit from this study, as improved sanitary practices and infection control during childbirth are known to improve the health of mothers and babies. In addition, the information we gather will be very important as we try to help protect other women in labor like you and seek ways to prevent these kinds of infection in the future.

Alternatives

Taking part in this study is optional. You can choose not to take part in this study. If you decide not to take part or withdraw from this study, you will continue to receive the same care for your delivery and for your baby. It is your choice to participate, and you can ask the researcher to leave at any time.

Participant Costs and Payments

There are no costs to you for participating and you will not be paid to participate in this research study

Participant's Rights

Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

You may obtain further information about your rights as a research participant by contacting the University of Zambia Biomedical Research Ethics Committee at 0977807860. The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time or if you think you have been injured by being in the study, please let the Investigator know right away. You can also contact Dr. Lawrence Mwananyanda on 0971254558 with further questions.

Confidentiality

The study team will do multiple things to make sure that the information gathered is kept confidential and are not linked to your name. If you agree to participate, you will be assigned a study identification number. All information from your observations will be kept under the study identification number.

Do you agree to participate in this study? Yes No

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

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Signature or thumb print **Printed Name** **Date**

If using thumb print, a witness signature is also required

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Witness signature **Witness Printed Name** **Date**

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Person Obtaining Consent Signature **Printed Name** **Date**