The AMANI Study: Accelerating Maternal and Newborn Survival in Kenya

Consent information for participation in facility staff surveys

Investigators – Local and International Collaborators:

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Primary Subject Contact and Emergency Telephone Number: Dr. John Kinuthia: +254722799052

We are conducting this study because we want to gather information that may help strengthen the Maternal and Perinatal Death Surveillance and Response (MPDSR) process in Kenyan health facilities.

Key information for you to consider

We are inviting you to take part in a study about strengthening the Maternal and Perinatal Death Surveillance and Response (MPDSR) process in Kenyan health facilities. This study is voluntary. You are being asked because you are a facility administrator, facility staff, or a member of an MPDSR committee.

Purpose: To test whether practice facilitation (mentorship and audit/feedback support) can improve how facilities conduct MPDSR and ultimately reduce preventable maternal and newborn deaths.

What you will do: You will be asked to complete surveys every twelve months.

Why you might join: You may wish to participate because your input can help strengthen MPDSR in your facility and inform national health improvements.

Why you might not want to join: You may wish not to participate if you feel the time commitment is too great or do not want to share your experiences with MPDSR.

Participation is voluntary. Whether or not you are in the study will have no impact on your usual work in this hospital.

If you decide to take part in the study, it should be because you really want to be a part of this study. Your employment will not change because of your participation. If you decide not to take part, you will not lose any services, benefits, or rights you would normally have. You can choose to withdraw from the study at any time.

1. PURPOSE OF THE RESEARCH

Maternal and newborn deaths remain high in Kenya, often from preventable causes. The Kenyan Ministry of Health recommends all facilities conduct MPDSR to learn from these deaths and take action to improve care. In practice, many facilities face challenges implementing MPDSR effectively.

The AMANI study will test whether external practice facilitators—experienced mentors who support health workers with audit and feedback and ongoing mentorship—can help improve how facilities carry out MPDSR.

2. STUDY PROCEDURES

If you agree to join the study, you will be asked to complete surveys about your experiences and knowledge of MPDSR. The surveys will take about 30–45 minutes and will be conducted at three points in time: at the start of the study, after 12 months, and after 24 months. After the main study is over, you may be asked to complete an additional short survey in the future about what MPDSR activities continue in your facility.

3. POTENTIAL RISKS, STRESS, OR DISCOMFORT

There are no physical risks from being in this study. Some people may feel uncomfortable discussing challenges related to maternal or newborn deaths with colleagues in the health facility. There is a small risk of loss of confidentiality, meaning that some people may know if you participate in a survey. However, all surveys will be confidential and all names or identifying information will be removed from records to protect the identity of participants. We will take strict measures to keep your information private

4. ALTERNATIVES TO PARTICIPATION

You may choose not to participate. If you do not participate, your employment, professional duties, and access to services will not be affected.

5. BENEFITS OF THE STUDY

You may not directly benefit from this study. However, your participation may help improve how MPDSR is carried out in Kenyan facilities and contribute to reducing preventable maternal and newborn deaths.

6. ALTERNATIVE PROCEDURES OR TREATMENTS

Participation is voluntary. Alternatives to study participation include continuing your usual work in this hospital.

7. SOURCE OF FUNDING

This study is funded by the National Institutes of Health (NIH) in the United States.

8. CONFIDENTIALITY OF RESEARCH INFORMATION

Confidentiality: We will keep your identity as a research subject confidential. Your responses to questions will be kept private. We will not publish or discuss in public anything that could identify you. Your survey responses will be identified by a code number, and not by your name. All of your information, including the link between your name and code number will be kept in a secure location. Once the study is completed, the link between your identifier and research data will be destroyed three years after study completion. We will only analyze anonymous data. Any publication of this study will not use your name or identify you personally. However, the study team may share identifiable information about you in the rare event that the study team becomes aware of possible harm to yourself or others.

Data banks: The National Institutes of Health (NIH) has developed data (information) banks that collect study data. The NIH will store your de-identified information in these data banks for other researchers to use in future studies on any topic. The researchers could be from government, academic, or commercial institutions. The information from this study will be stored in a public unrestricted data bank that anyone can use. This public information will not include your name or any other information that could identify you. You will not receive any results from allowing your data to be placed in the NIH data banks. You will not be able to withdraw your information after it has been submitted to the NIH data banks. Risks associated with sharing information data through NIH data banks include that it is possible that your information could be used to identify you when combined with information from other public sources.

It is your choice whether or not to have your information placed in NIH data banks for use in research in the future. If you say "No," you can still fully participate in this study.

The records of this discussion may be reviewed by assessment staff and representatives of the University of Washington, including the Institutional Review Board, and the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee.

We have a Certificate of Confidentiality from the U.S. federal National Institutes of Health which allows us to protect identifiable research information that is stored in the U.S. from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection, including reporting things like child or elder abuse, monitoring by the agencies conducting the research, and others as listed elsewhere in this consent form.

The Certificate expires when the National Institutes of Health funding for this study ends. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

A description of this study will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

A copy of your consent form will be scanned directly into your electronic study record and kept in a locked cabinet.

9. USE OF INFORMATION IN FUTURE RESEARCH

Your de-identified responses may be used in future research or shared with other investigators. If information that could identify you is ever to be used, a new review board decision will be made about whether new consent is required.

10. VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

- Participation is voluntary.
- You may skip questions you do not wish to answer.
- You may stop participation at any time without penalty.

11. COSTS AND REIMBURSEMENT

There is no cost to you for participation. You will receive a small reimbursement of KSh 1,000 for your time and transport at each data collection activity, as is customary practice.

12. RESEARCH-RELATED INJURY

This study poses no physical risks. If you have been harmed because of participation, you may contact:
Dr. John Kinuthia: +254722799052
Dr. Arianna R. Means: +12063700225

13. CONTACTS FOR QUESTIONS

- Study-related questions: Dr. John Kinuthia: +254722799052
- Questions about your rights: Ethics and Research Committee at Kenyatta National Hospital and the University of Nairobi, Tel: 020 2726300 EXT 44102 / 44355.

14. SUBJECT'S STATEMENT

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form.

It is your choice whether or not to have your information placed in NIH data banks for use in research in the future. If you say "No," you can still fully participate in this study. Do you agree to have your information shared through NIH data banks?

_____Yes	_____No.	I agree to be part of this study
_____Yes	_____No.	I agree to have my identifiers collected
_____Yes	_____No.	I agree to have my information shared through NIH data banks.

Printed name of subject _____

Signature of subject _____ Date _____

Printed name of study staff obtaining consent _____

Signature of study staff _____ Date _____