

TITLE: Leveraging interactive SMS messaging to monitor and support maternal health in Kenya (AI-NEO)

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KENYATTA NATIONAL HOSPITAL (KNH), UNIVERSITY of NAIROBI (UoN), and UNIVERSITY OF WASHINGTON (UW)

AI-NEO

Leveraging interactive SMS messaging to monitor and support maternal health in Kenya

CONSENT for COHORT STUDY

Investigators:

Name	Position	Department	Telephone Numbers
Keshet Ronen	Principal Investigator	Global Health, UW	+12065434363
John Kinuthia	Site Principal Investigator	Research & Programs, KNH	+254722799052
Noah Smith	Mentor	Computer Science and Engineering, UW	+12066853134
Grace John-Stewart	Mentor	Global Health, UW	+12065434278
Dror Ben-Zeev	Mentor	Psychiatry and behavioral sciences, UW	+12066859655
Jennifer Unger	Collaborator	Obstetrics and Gynecology, Women and Infants Hospital	+14012741122
Manasi Kumar	Collaborator	Psychiatry, UoN	+254717379687
Brian DeRenzi	Collaborator	Dimagi, Cape Town, South Africa	+27796890574

Emergency telephone number:

Dr. John Kinuthia: 0722799052

KEY INFORMATION ABOUT THIS STUDY

This study aims to understand if interactive SMS messaging between women and nurses, using a SMS platform that automatically detects client messages that might be urgent, can help improve the experiences of women, their children, and the nurses who message with them.

- *If you participate in this study, you will receive at least one SMS per week, sometimes more, until 6 weeks after your baby is born. You will also attend two study visits which would occur at the same times as your normally scheduled postnatal care visits, each lasting about 1 hour, where we will ask you questions.*
- *The main reason you might want to join this study is because you would receive information and support about pregnancy and infant health and be able to text with a nurse about concerns you may be having.*
- *The main reason you might not want to join the study is if you don't want to receive messages about youth health on your phone or you find it too challenging to come in for study visits.*
- *Possible benefits of participating include learning new information about caring for yourself and your baby.*
- *Loss of confidentiality is a possible risk of participating, if someone gains access to your phone and learns about your health concerns.*
- *Anyone who joins this study will provide information that may help improve health for all mothers and babies in Kenya.*
- *Participating in this study is completely voluntary – whether or not you participate will not affect your access to services at this clinic or any other clinic.*
- *You can choose to withdraw from the messages or the study at any time.*

Researchers' statement

We are asking you to be in a research study. The purpose of this form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Pregnant women and new mothers often have questions and concerns about their pregnancy and newborns. Antenatal and postnatal clinics provide information but women may benefit from additional education and counseling during this time. Mobile phones are one way to deliver information to people about their health. Through this study we want to understand if sending information by mobile phones is helpful to pregnant women and new mothers, and the best way to send this information in partnership with clinics. Our SMS system also includes a computer program that may help nurses prioritize messages sent by participants so they respond to the messages needing urgent responses first. We want to test whether this computer program helps nurses do their work more efficiently. Participation in this study will not affect the care you receive at this clinic. We aim to enroll 80 women into the study.

STUDY PROCEDURES

This is what will happen if you agree to participate in this study. We will ask you to read, discuss, and sign or make your mark on this form. After this form is signed or marked, the study staff will ask you questions about you, your contact information, your family, and your pregnancy. You will then begin receiving SMS messages from the study on your mobile phone. These SMS will contain information about general health, your delivery, your infant's health, and family planning. The messages will be delivered weekly to your phone. Two weeks before your due date, you will receive messages every day. You will be asked to inform the study nurse when you have delivered your baby. After you deliver your baby, you will receive two messages every day for two weeks, then every other day for 4 weeks. All messages will contain a question that asks for – but does not require – a response from you. We request that you respond to those questions. If no response is received from you, you will still continue to receive SMS.

You will also be able to send messages with concerns or questions to the study nurse at any time, although nurses will only respond during the day on weekdays. Charges associated with the messages will be paid by the study. You will not have to pay to receive or send any messages to the study nurse. You will be provided a free number to send messages to the study nurse.

It is very important that you contact us to inform us about your delivery. We will provide you with a card with instructions on how to contact the study when deliver your baby. We will also contact you on your expected delivery date if we have not heard from you.

Study visits

The study will last until 18 weeks after your baby is born or your pregnancy ends. We will ask you to meet with the study nurse today, and at 2 and 6 weeks after your delivery. Each visit should take approximately 1 hour. At each visit we will ask you questions about you, your health, and your baby's health. We will ask you questions about your fertility plans and family planning. We will also ask you for updated information on your phone contact and where you live.

After you deliver your baby you will:

- Be asked questions about your delivery

At the each visit you will:

- Be asked questions about your experiences in the study, and with SMS messages
- We will also ask you about your health and about the health of your infant
- We will also ask you about your mental health and if you are experiencing any mistreatment in your relationship (if you are in one).

It is very important that you come for all your scheduled clinic visits. If you are unable to make your clinic appointment, please call the clinic to make another appointment, or come to the clinic as soon as you are able. If you miss a visit with the study we will call you to remind you and reschedule.

If your infant experiences serious illness, we will schedule an additional visit with you to collect information about the illness.

Locator Information

At today's visit, we will collect information on how to contact you and where you live. We will use this information to contact you if you are unable to come to the clinic or we do not hear from you.

Phone calls

Also, if you have relocated or find it impossible to come into clinic at the time of your study visits we will administer the questionnaires to you over the phone.

Home visits

If you are comfortable having a home visit, we will visit your home after the first study visit to make sure we have an accurate way to contact you in case your phone contacts change. If you do not return for your study visits, we will also conduct a home visit at the end of the study to check on you. If there is a private location, we will administer the questionnaire to you at home.

Additional Contacts

At today's visit, we collect the names and contact information for people we can contact if we are unable to get in touch with you. If we are unable to reach you via phone or home visit, we will then contact these people to find you. We will not share information about your study participation.

Permission for future contact

We would like to be able to contact you after your participation has ended to see if you would be interested in participating in future studies. You can indicate your choice about future contact at the end of this form. Agreeing to future contact does not obligate you to participate in any future study activities.

MEDICAL RECORD INFORMATION

We will ask for access to your and your baby's clinic and pharmacy records to find out more information about your pregnancy, delivery, and postpartum care. If you agree to give us access to your medical records, we will get information from the facilities where you receive antenatal and postpartum care and delivered your baby, including: any health problems, medication adherence and side effects, and your baby's health information. We will use safety checks to ensure we protect your privacy when getting your information.

RISKS, STRESS, OR DISCOMFORT

In general, whenever you share information with a research study, there are many safety checks in place to keep your information safe. However, there is a small risk that your someone outside of the study could gain access to your information. If this happened, it could be embarrassing, cause you stress and discomfort and even cause problems at home. You may experience stress or discomfort if a partner learns of your study participation. There is risk that this disclosure could result in psychological harm or even physical harm although, that would be extremely rare.

You may become embarrassed or worried when we ask personal questions about you or your infant.

SMS: Receiving information by your mobile phone is generally safe, but it is possible that other people could see the SMS we send you. You may receive information about preparing for your delivery, ANC appointments, your health, infant health and family planning. In situations where phones are shared or stolen, someone you don't know could see the text messages and learn something about you. If you send sensitive questions or information over SMS, we recommend that you delete sensitive SMS you send from your phone.

ALTERNATIVES TO TAKING PART IN THIS STUDY

There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about. While participating in this study, however, we would prefer that you do not participate in others. **Whether or not you decide to participate in this research study, you can continue to receive your mother-child health care at this clinic.**

Your participation is voluntary

- You do not have to be in this study if you do not want to.
- You may withdraw from the study or refuse to answer any of the questions asked at any time without loss of benefit or penalty.
- You can stop receiving SMS at any time by texting the word "STOP" without loss of benefit or penalty.

BENEFITS OF THE STUDY

By participating in the study, you will contribute to our understanding of how to deliver education and counseling to help women, babies and their families. It will also help by providing information that can be used to improve services to ensure more women receive care and nurses can work more efficiently. It may help keep babies healthy or get them medical attention when they need it. You may personally benefit from receiving information and advice about delivery planning, encouragement and counseling about assessment of and advice about your infant's health. You may also personally benefit from being able to ask questions to a nurse about your infant's health, family planning and labor and delivery.

SOURCE OF FUNDING

The study team and/or the Kenyatta National Hospital and University of Washington are receiving financial support from the National Institutes of Health in the United States.

OTHER INFORMATION

Reasons why you may be withdrawn from the study

You may be removed from the study without your consent for the following reasons:

- The research study is stopped or cancelled
- The study staff feels that participating in the study would be harmful to you

Costs to you

There is no cost to you for participation in the study. Routine clinical care and services will not be provided by the study. However, you will continue to receive your care and treatment at the MCH clinic.

Reimbursement

You will receive Ksh 400.00 for your transportation costs and effort at each scheduled visit.

CONFIDENTIALITY OF RESEARCH INFORMATION

Confidentiality

We will keep your identity as a research subject confidential. Your responses to questions will be kept private. There are exceptions to this, particularly for your safety. When we assess participants' mental well-being, if we identify that you are at risk of self-harm or have depression, we will disclose this information to you. We will also refer you to a qualified medical provider who can help you with your mental health and we will disclose that information to the medical provider. We will not publish or discuss in public anything that could identify you. Your medical information that you share will be identified by a code number. 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 after the records retention period by law. 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 case the study team becomes aware of possible harm to yourself or others.

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you.

We have a Certificate of Confidentiality from the United States National Institutes of Health. These protections only apply to data held in the United States.

This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, 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. We will voluntarily provide the information to:

- *a member of the United States government who needs it in order to audit or evaluate the research;*
- *individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;*
- *individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;*
- *relevant authorities as authorized by other Federal, State or local laws.*

The Certificate expires when the NIH funding for this study ends. Currently this is 31 May 2022. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

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

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

Problems or Questions

If you ever have any questions about this study or think you may have been harmed by participating you should contact Dr. John Kinuthia at 0722799052.

If you have questions about your rights as a research participant, you should contact the Kenyatta National Hospital Ethics and Research Committee, at 2726300 Ext. 44102.

Printed name of study staff obtaining consent	Signature	Date
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If you do NOT want us to contact you in the future about additional studies please mark below:

☐ I do NOT want to be contacted in the future for additional studies.

Participant's statement

Participant literacy: ☐ literate ☐ illiterate

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the *Kenyatta National Hospital Ethics and Research Committee, at 2726300 Ext. 44102*. I will receive a copy of this consent form.

Printed name of participant	Signature or thumbprint of participant	Date
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If the potential participant cannot read the form herself, a witness (not a staff member who obtained the consent) must have been present during the entire consent process and must sign here:

I, the witness, was present while all information in this consent form was read to the potential participant. All questions were answered. The individual has agreed to take part in the research.

Witness Name	Witness Signature	Date
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Copies to: Researcher
 Subject
 Participant's Study Record