mHealth-Assisted Conditional Cash Transfers to Improve Timeliness of Vaccinations (MINT)

ClinicalTrials.gov ID NCT03252288

R-1. In-person recruitment script

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The purpose of this study is to understand why parents do or do not vaccinate their children and explore how parents may be motivated to vaccinate their children. The study will test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time. We are looking for individuals like you to be a part of the study. Would you be interested in hearing more about this study and how you may participate?

R-2 Email of phone recruitment script for key informant interviews

Dear <name>,

I was referred to you by <contact or method of recruitment>. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University and the University of South Carolina in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The purpose of this study is to understand why parents do or do not vaccinate their children and explore how parents may be motivated to vaccinate their children. The study will test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time. I would like to interview you about your professional opinions on childhood vaccination policies and programs in Tanzania. I anticipate the interview to last about 1 hour. The interview may be done in person, by phone, or by video conference.

I have attached information so that you may review the details of this project at your convenience. Please feel free to contact me or Dr. Mfinanga with any questions or concerns.

Thank you in advance for your time and consideration, and I look forward to speaking with you.

Best,

<Interviewer name>
(telephone number XXX)

Dr. Sayoki Mfinanga
(telephone number XXX)

C-0. Informed consent for pilot-testing of surveys

Introduction:

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The study is sponsored by the National Institute of Health and Duke University in the United States.

Research studies are voluntary. As I read this form to you, please take your time deciding whether to participate. Please ask me to explain anything that you do not clearly understand. The purpose of the study, procedures, risks, and benefits are described below.
The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time.
- Your decision to participate or withdraw from the study will not affect the medical services you receive.

Study purpose:

The purpose of this study is to understand why parents do or do not vaccinate their children and explore how parents may be motivated to vaccinate their children. The study will test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time.

Who Will Be In This Study and How Long Will This Study Last?

Up to 600 pregnant women from Mtwara region will participate in this study. Up to 100 additional persons will participate in the development and testing of questionnaires for this study. Your participation will end after the completion of today's survey. Your responses will be used to improve the quality of the questionnaires and may not be included in the final report.

Procedures: Each survey will take approximately 60 minutes.

- After you have signed and dated the consent form we will ask you questions about issues such as: your pregnancy, socio-economic characteristics, mobile phone use, your opinion on vaccinations and vaccination histories of any previous children.

Risks and discomforts:

There are no risks or discomforts associated with participation in the study.

Benefits:

You will not receive any direct benefits from participating. However, the information that you provide may help improve the larger study and vaccination programs in the future.

Confidentiality:

Study records will be kept confidential as required by law. Your records will be assigned a unique study number. All identifying information collected from you will be kept confidential and accessed only by authorized personnel associated with this study. When information from this study is presented at scientific meetings or in scientific journals, your identity will not be revealed.

Voluntary participation/right to withdraw

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you agree to participate, you may refuse to answer any question or stop the interview at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits, and will not affect your access to health care for you or your child. The information you provide to us will be used even if you choose to discontinue your participation. However, no new information will be collected once you discontinue from the study.

Cost to you:

There is no cost to you for taking part in this research study.

Payments to participants:

You will receive 3000 TSH for completing each survey.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Sayoki Mfinanga at NIMR (telephone number XXX)
If you decide to withdraw, please contact Dr. Mfinanga in writing and let him know that you are withdrawing from the study. His mailing address is XXX.
For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the NIMR Ethics Committee at XXX.

Optional permission for future contact:
I give permission for members of the research team for this study to contact me about other studies in the future that are linked to this study. It will be my choice whether or not to participate in those studies at that time.

_____ Yes _____No _____Initials

_____

Name of participant

(Fill in Block letters)

_____ _____

Signature of Participant Date

_____

Name of person obtaining consent

(Fill in Block Letters)

_____ _____

Signature of person obtaining consent Date

_____ _____

Signature of Witness Date

(Required if the research participant does not know how to read the consent form.)

[For data being sent to Duke, clicking accept on the electronic consent form will record a time and date stamp and indicate that the individual has provided consent]

C-1. Informed consent for enrollment in longitudinal study

Introduction:

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The study is sponsored by the National Institute of Health and Duke University in the United States.

Research studies are voluntary. As I read this form to you, please take your time deciding whether to participate. Please ask me to explain anything that you do not clearly understand. The purpose of the study, procedures, risks, and benefits are described below.
The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time.
- Your decision to participate or withdraw from the study will not affect the medical services you receive.

Study purpose:

The purpose of this study is to understand why parents do or do not vaccinate their children and explore how parents may be motivated to vaccinate their children. The study will test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time.

Who Will Be In This Study and How Long Will This Study Last?

Up to 600 pregnant women from Mtwara region will participate in this study. Each participant will complete up to three surveys: one survey after enrollment and up to two follow up surveys at 4 and 6 months after the birth of your child. Your participation will end after the completion of the follow up surveys.

Procedures: Each survey will take approximately 60 minutes.

- After you have signed and dated the consent form we will ask you questions about issues such as: your pregnancy, socio-economic characteristics, mobile phone use, your opinion on vaccinations and vaccination histories of any previous children. We will also ask you to provide us at least one mobile phone number where we can reach you for study-related communications.
- Once your baby is born, we will track his/her vaccinations for up to 6 months. We will give you information on how to notify us about the birth of your child. Close to the expected time of your child's birth, we may contact you or a family member you designate to ask about the birth. You will receive reminders about your child's upcoming vaccinations at a mobile phone number that you provide to us.
- If your child receives the vaccination on time you may receive a small incentive. You will be informed of the incentive amount in the reminder sent to your mobile phone. We will provide you with instructions for claiming this incentive.

- At the end of the study, we will record each vaccination provided to your child and ask you about your experience with reminders, vaccinations, and incentives. We may also review your and your child's medical record to confirm if you have received health services related to antenatal care and your child's vaccinations. In addition, the health provider vaccinating your child will notify us each time your child is vaccinated.

Risks and discomforts:

There risks or discomforts associated with participation in the study are similar to those you would encounter in your daily life:

- Your name, phone numbers and other contact or identifiable information will be used for study related purposes, including for contacting you about the study and for sending you reminders about your child's upcoming vaccination appointments. To reduce the risks associated with storing such data in the study, your information will be kept confidential and accessed only by authorized study personnel for the purpose of the study. If you provide consent to be contacted for future studies, this information may be used to contact you at a later date. If you feel uncomfortable sharing this data with us or do not wished to be contacted on your mobile phone, you should not participate in the study.
- If your child receives vaccinations, there may be temporary pain and/or redness at the injection site. In the event that you are concerned about a possible adverse reaction to vaccination in your child, you should notify the health care provider at your clinic immediately.

Benefits:

You will not receive any direct benefits from participating. However, the information that you provide about your child's vaccination may help improve vaccination programs in the future.

Confidentiality:

Study records will be kept confidential as required by law. Your records will be assigned a unique study number. All identifying information collected from you will be kept confidential and accessed only by authorized personnel associated with this study. When information from this study is presented at scientific meetings or in scientific journals, your identity will not be revealed.

Voluntary participation/right to withdraw

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you agree to participate, you may refuse to answer any question or stop the interview at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits, and will not affect your access to health care for you or your child. The information you provide to us will be used even if you choose to discontinue your participation. However, no new information will be collected once you discontinue from the study.

Cost to you:

There is no cost to you for taking part in this research study.

Payments to participants:

You will receive 3000 TSH for completing each survey.

You may also be eligible to receive a small payment when your child receives a timely vaccination at your local clinic. You will be notified in an SMS reminder message of your eligibility for an incentive, and of the payment amount. Not all women will receive incentives and you may not be offered an incentive for every visit related to your child's vaccinations. You will receive at most one incentive per vaccination visit, even though your child may receive multiple vaccinations at the visit.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Sayoki Mfinanga at NIMR (telephone number XXX)
If you decide to withdraw, please contact Dr. Mfinanga in writing and let him know that you are withdrawing from the study. His mailing address is XXX.
For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the NIMR Ethics Committee at XXX.

Optional permission for future contact:
I give permission for members of the research team for this study to contact me about other studies in the future that are linked to this study. It will be my choice whether or not to participate in those studies at that time.

_____ Yes _____No _____Initials

_____

Name of participant

(Fill in Block letters)

_____ _____

Signature of Participant Date

_____

Name of person obtaining consent

(Fill in Block Letters)

_____ _____

Signature of person obtaining consent Date

_____ _____

Signature of Witness Date

(Required if the research participant does not know how to read the consent form.)

[For data being sent to Duke, clicking accept on the electronic consent form will record a time and date stamp and indicate that the individual has provided consent]

C-2. Informed consent for longitudinal follow up

Introduction:

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The study is sponsored by the National Institute of Health and Duke University in the United States.

We are contacting you because you previously consented to be a part of this study to test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time. At this visit we will record each vaccination provided to your child and ask you about your experience with reminders, vaccinations, and incentives.

Research studies are voluntary. As I read this form to you, please take your time deciding whether to continue to participate. Please ask me to explain anything that you do not clearly understand.
The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time.
- Your decision to participate or withdraw from the study will not affect the medical services you receive.

Benefits:

You will not receive any direct benefits from participating. However, the information that you provide about your child's vaccination may help improve vaccination programs in the future.

Confidentiality:

Study records will be kept confidential as required by law. Your records will be assigned a unique study number. All identifying information collected from you will be kept confidential and accessed only by authorized personnel associated with this study. When information from this study is presented at scientific meetings or in scientific journals, your identity will not be revealed.

Voluntary participation/right to withdraw

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you agree to participate, you may refuse to answer any question or stop the interview at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits, and will not affect your access to health care for you or your child. The information you provide to us will be used even if you choose to discontinue your participation. However, no new information will be collected once you discontinue from the study.

Cost to you:

There is no cost to you for taking part in this research study.

Payments to participants:

You will receive 3000 TSH for completing this survey.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Sayoki Mfinanga at NIMR (telephone number XXX)
If you decide to withdraw, please contact Dr. Mfinanga in writing and let him know that you are withdrawing from the study. His mailing address is XXX.
For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the NIMR Ethics Committee at XXX.

Optional permission for future contact:
I give permission for members of the research team for this study to contact me about other studies in the future that are linked to this study. It will be my choice whether or not to participate in those studies at that time.

_____ Yes _____No _____Initials

_____

Name of participant

(Fill in Block letters)

_____ _____

Signature of Participant Date

_____

Name of person obtaining consent

(Fill in Block Letters)

_____ _____

Signature of person obtaining consent Date

_____ _____

Signature of Witness Date

(Required if the research participant does not know how to read the consent form.)

[For data being sent to Duke, clicking accept on the electronic consent form will record a time and date stamp and indicate that the individual has provided consent]

C-3. Informed consent for provider semi-structured interviews

Introduction:

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The study is sponsored by the National Institute of Health in the United States.

Research studies are voluntary. As I read this form to you, please take your time deciding whether to participate. Please ask me to explain anything that you do not clearly understand. The purpose of the study, procedures, risks, and benefits are described below.
The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time
- Your decision to participate or withdraw from the study will not affect your employment.

Study purpose:

The purpose of this study is to understand why parents do or do not vaccinate their children and explore how parents may be motivated to vaccinate their children. The study will test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time.

Who Will Be In This Study and How Long Will This Study Last?

Up to 15 healthcare providers from Mtwara region will participate in this study. We are contacting you because you are a healthcare provider at a clinic that provides vaccinations to children. If you choose to participate in the study, you will be asked to participate in an interview that will last approximately 1 hour. You will also be asked to help us record and track the vaccination status of infants coming to your clinic for vaccination. In order to do this, we will ask you to participate in a half-day training workshop where we will tell you how to send us vaccination information using a phone. Your participation in the study will end once all infants enrolled in the study and attending your clinic are approximately 6 months old.

Procedures:

If you choose to participate in the study, we will ask you a series of questions related to your work, the vaccination clinic, factors that influence whether or not a child received vaccinations at your clinic, and about your ability to use a mobile phone for collecting and reporting vaccination data. When a parent brings a child to the vaccination clinic, you may be asked to send us information about the child's vaccination using a mobile phone. At the end of the study, we will ask you about your experience vaccinating children and record the vaccinations actually provided to children attending your clinic. This interview will be audiorecorded for the purposes of note-taking. If you do not wish your responses to be audio-recorded, you may decline to participate.

Benefits:

There are no direct benefits to you from this study. However, the information that you provide about your child's vaccination may help improve vaccination programs in Tanzania in future.

Confidentiality:

All identifying information collected from you will be kept confidential and accessed only by authorized personnel associated with this study. You will not be identified personally in any publications resulting from this study.

Voluntary participation/right to withdraw

Participation in this study is voluntary. You may choose to discontinue your participation at any time during the study. Your decision to participate in the study or not will not affect your ability to continue working as a healthcare provider. The information you provide to us will be used even if you choose to discontinue your participation. However, no new information will be collected once you discontinue from the study.

Cost to you:

There is no cost to you for taking part in this research study.

Payments to participants:

You will receive 3000 TSH for completing the interview. You will also receive incentives for notifying us about a child's vaccination. You will only receive the incentives for the duration of your participation in the study.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Sayoki Mfinanga at NIMR (telephone number XXX)
If you decide to withdraw, please contact Dr. Mfinanga in writing and let him know that you are withdrawing from the study. His mailing address is XXX.
For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the NIMR Ethics Committee at XXX.
Optional permission for future contact:

I give permission for members of the research team for this study to contact me about other studies in the future that are linked to this study. It will be my choice whether or not to participate in those studies at that time.

_____ Yes _____No _____Initials

_____

Name of participant

(Fill in Block letters)

_____ _____

Signature of Participant Date

_____

Name of person obtaining consent

(Fill in Block Letters)

_____ _____

Signature of person obtaining consent Date

_____ _____

Signature of Witness Date

(Required if the research participant does not know how to read the consent form.)

[For data being sent to Duke, clicking accept on the electronic consent form will record a time and date stamp and indicate that the individual has provided consent]

C-4. Informed consent for enrollment in focus group discussions

Introduction:

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The study is sponsored by the National Institute of Health in the United States.

Research studies are voluntary. As I read this form to you, please take your time deciding whether to participate. Please ask me to explain anything that you do not clearly understand. The purpose of the study, procedures, risks, and benefits are described below.
The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time
- Your decision to participate in the study or not will not affect your ability to seek healthcare for you or your child.

Study purpose:

The purpose of this study is to understand why parents do or do not vaccinate their children and explore how parents may be motivated to vaccinate their children. The study will test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time.

Who Will Be In This Study and How Long Will This Study Last?

Up to 600 pregnant women from Mtwara region will participate in this study overall. A subset of those women will participate in these focus group discussions on childhood vaccinations. Each focus group discussion will last approximately 90 minutes. Your participation in the study will end after the discussion ends.

Procedures:

If you choose to participate in the study, we will ask you a series of questions related to your pregnancy, socio-demographic characteristics, and mobile phone use. This is a group discussion. We will also ask about your opinion on vaccinations, your experience at the vaccination clinic and vaccination histories of any previous children. We will also ask you about your opinion on using mobile phones for providing reminders on upcoming vaccinations. Your responses will be audio recorded. If you don't want to be recorded you should not participate. We hope that you will feel comfortable answering our questions, but do not feel obligated to share anything you would not want others to repeat.

Benefits:

There are no direct benefits to you or your child from this study. However, the information that you provide about your child's vaccination may help improve vaccination programs in Tanzania in future.

Confidentiality:

All identifying information collected from you will be kept confidential and accessed only by authorized personnel associated with this study. You or your child will not be identified personally in any publications resulting from this study.

Voluntary participation/right to withdraw

Participation in this study is voluntary. You may choose to discontinue your participation at any time during the study. Your decision to participate in the study or not will not affect your ability to seek healthcare for you or your child. The information you provide to us will be used even if you choose to discontinue your participation. However, no new information will be collected once you discontinue from the study.

Cost to you:

There is no cost to you for taking part in this research study.

Payments to participants:

You will receive 3000 TSH for participating in the discussion.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Sayoki Mfinanga at NIMR (telephone number XXX)
If you decide to withdraw, please contact Dr. Mfinanga in writing and let him know that you are withdrawing from the study. His mailing address is XXX.
For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the NIMR Ethics Committee at XXX.

Optional permission for future contact:

I give permission for members of the research team for this study to contact me about other studies in the future that are linked to this study. It will be my choice whether or not to participate in those studies at that time.

_____ Yes _____No _____Initials

_____

Name of participant

(Fill in Block letters)

_____ _____

Signature of Participant Date

_____

Name of person obtaining consent

(Fill in Block Letters)

_____ _____

Signature of person obtaining consent Date

_____ _____

Signature of Witness Date

(Required if the research participant does not know how to read the consent form.)

[For data being sent to Duke, clicking accept on the electronic consent form will record a time and date stamp and indicate that the individual has provided consent]

C-5 Informed consent for observations

Introduction:

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The study is sponsored by the National Institute of Health and Duke University in the United States.

Research studies are voluntary. As I read this form to you, please take your time deciding whether to continue to participate. Please ask me to explain anything that you do not clearly understand.
The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time.
- Your decision to participate or withdraw from the study will not affect the medical services you receive.

Study purpose:

The purpose of this study is to understand how vaccination clinics function in Tanzania. The information collected during this study will be used to develop strategies to that improve vaccination coverage among children in Tanzania.

Who Will Be In This Study and How Long Will This Study Last?

The study will involve an observation at the vaccination clinic where you work and may last for up to the entire working time of the clinic.

Procedures:

After you have signed and dated the consent form we will, during the course of the day, make written observations about how vaccination activities are conducted at the clinic. We may make notes on things such as the numbers and characteristics of individuals attending the vaccination clinic, vaccination encounters between you and the beneficiaries, vaccination clinic settings etc. We may periodically ask you questions about how vaccinations are provided at the clinic to get a thorough understanding of the processes. With your permission, we will take photographs during our observation of the vaccination clinic surroundings and supplies. Our photos will not include any people or their faces.

This is not a test or a report on your performance. We would like you to carry on with your responsibilities and procedures at the clinic as you normally would.

Risks and discomforts:

There are no risks or discomforts associated with participation in the study.

Benefits:

You will not receive any direct benefits from participating. However, the information recorded during the observations will help develop strategies to improve vaccination coverage in Tanzania

Confidentiality:

Study records will be kept confidential as required by law. The vaccination clinic location will be assigned a study ID number. No identifying information will be collected about you, the persons attending the clinic or about the clinic itself. Any information collected during observation will be kept confidential and accessed only by authorized personnel associated with this study. When information from this study is presented at scientific meetings or in publications, your identity will not be revealed.

Voluntary participation/right to withdraw

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. Even after you agree to participate, you may refuse to be observed at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits, and will not affect your employment. Any information you provide to us will be used even if you choose to discontinue your participation. However, no new information will be collected once you discontinue from the study.

Cost to you:

There is no cost to you for taking part in this research study.

Payments to participants:

You will receive 3000TSH for participating in the observations.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Sayoki Mfinanga at NIMR (telephone number XXX)
If you decide to withdraw, please contact Dr. Mfinanga in writing and let him know that you are withdrawing from the study. His mailing address is XXX.
For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the NIMR Ethics Committee at XXX.

Name of participant

(Fill in Block letters)

_____ _____

Signature of Participant Date

_____

Name of person obtaining consent

(Fill in Block Letters)

_____ _____

Signature of person obtaining consent Date

_____ _____

Signature of Witness Date

(Required if the research participant does not know how to read the consent form.)

[For data being sent to Duke, clicking accept on the electronic consent form will record a time and date stamp and indicate that the individual has provided consent]

C-6. Informed consent for enrollment in cross-sectional survey

Introduction:

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The study is sponsored by the National Institute of Health and Duke University in the United States.

Research studies are voluntary. As I read this form to you, please take your time deciding whether to participate. Please ask me to explain anything that you do not clearly understand. The purpose of the study, procedures, risks, and benefits are described below.
The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time.
- Your decision to participate or withdraw from the study will not affect the medical services you receive.

Study purpose:

The purpose of this study is to understand why parents do or do not vaccinate their children and explore how parents may be motivated to vaccinate their children. The study will test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time.

Who Will Be In This Study and How Long Will This Study Last?

Up to 600 pregnant women from Mtwara region will participate in this study. If you choose to participate in the study, you will be asked to complete a survey. Your participation in the study will end after this survey.

Procedures: Each survey will take approximately 60 minutes. After you have signed and dated the consent form we will ask you questions about issues such as: your pregnancy, socio-economic characteristics, mobile phone use, your opinion on vaccinations and vaccination histories of any previous children.

Risks and discomforts:

There are no risks or discomforts associated with participation in the study.

Benefits:

You will not receive any direct benefits from participating. However, the information that you provide about your child's vaccination may help improve vaccination programs in the future.

Confidentiality:

Study records will be kept confidential as required by law. Your records will be assigned a unique study number. All identifying information collected from you will be kept confidential and accessed only by authorized personnel associated with this study. When information from this study is presented at scientific meetings or in scientific journals, your identity will not be revealed.

Voluntary participation/right to withdraw

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you agree to participate, you may refuse to answer any question or stop the interview at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits, and will not affect your access to health care for you or your child. The information you provide to us will be used even if you choose to discontinue your participation. However, no new information will be collected once you discontinue from the study.

Cost to you:

There is no cost to you for taking part in this research study.

Payments to participants:

You will receive 3000 TSH for completing each survey.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Sayoki Mfinanga at NIMR (telephone number XXX)
If you decide to withdraw, please contact Dr. Mfinanga in writing and let him know that you are withdrawing from the study. His mailing address is XXX.
For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the NIMR Ethics Committee at XXX.

Optional permission for future contact:
I give permission for members of the research team for this study to contact me about other studies in the future that are linked to this study. It will be my choice whether or not to participate in those studies at that time.

_____ Yes _____No _____Initials

_____

Name of participant

(Fill in Block letters)

_____ _____

Signature of Participant Date

_____

Name of person obtaining consent

(Fill in Block Letters)

_____ _____

Signature of person obtaining consent Date

_____ _____

Signature of Witness Date

(Required if the research participant does not know how to read the consent form.)

[For data being sent to Duke, clicking accept on the electronic consent form will record a time and date stamp and indicate that the individual has provided consent]

C-7. Informed consent for traditional birth attendant semi-structured interviews

Introduction:

Hello, my name is _____. I am working with Drs. Jan Ostermann and Lavanya Vasudevan of Duke University in the United States and Dr. Sayoki Mfinanga of the National Institute for Medical Research in Tanzania to conduct research on the topic of childhood vaccinations. The study is sponsored by the National Institute of Health in the United States.

Research studies are voluntary. As I read this form to you, please take your time deciding whether to participate. Please ask me to explain anything that you do not clearly understand. The purpose of the study, procedures, risks, and benefits are described below.
The research team will give you a copy of this form. It is important that you know:

- Your participation is entirely voluntary;
- You may decide not to take part or to withdraw from the study at any time
- Your decision to participate or withdraw from the study will not affect your employment.

Study purpose:

The purpose of this study is to understand why parents do or do not vaccinate their children and explore how parents may be motivated to vaccinate their children. The study will test whether reminders sent to parents' mobile phones and incentives such as mobile phone credit are useful for improving the possibility that a child is vaccinated on time.

Who Will Be In This Study and How Long Will This Study Last?

Up to 15 traditional birth attendants from Mtwara region will participate in this study. We are contacting you because you are a traditional birth attendant. If you choose to participate in the study, you will be asked to participate in an interview that will last approximately 1 hour. Your participation in this study will end after this interview.

Procedures:

If you choose to participate in the study, we will ask you a series of questions related to your work, antenatal care practices about women in your community and their attitudes towards vaccinating their children. This interview will be audio recorded for the purposes of note-taking. If you do not wish your responses to be audio-recorded, you may decline to participate.

Benefits:

There are no direct benefits to you from this study. However, the information that you provide may broaden understanding of your role in vaccination programs and help improve vaccination programs in Tanzania in future.

Confidentiality:

All identifying information collected from you will be kept confidential and accessed only by authorized personnel associated with this study. You will not be identified personally in any publications resulting from this study.

Voluntary participation/right to withdraw

Participation in this study is voluntary. You may choose to discontinue your participation at any time during the study. Your decision to participate in the study or not will not affect your ability to continue working as a healthcare provider. The information you provide to us will be used even if you choose to discontinue your participation. However, no new information will be collected once you discontinue from the study.

Cost to you:

There is no cost to you for taking part in this research study.

Payments to participants:

You will receive 3000 TSH for completing the interview.

Whom do I call if I have questions or problems?
For questions about this study or if you have problems, concerns, questions, or suggestions about the research, contact Dr. Sayoki Mfinanga at NIMR (telephone number XXX)
If you decide to withdraw, please contact Dr. Mfinanga in writing and let him know that you are withdrawing from the study. His mailing address is XXX.
For questions about your rights as a research participant or to discuss problems or concerns related to the research contact the NIMR Ethics Committee at XXX.
Optional permission for future contact:

I give permission for members of the research team for this study to contact me about other studies in the future that are linked to this study. It will be my choice whether or not to participate in those studies at that time.

_____ Yes _____No _____Initials

_____

Name of participant

(Fill in Block letters)

_____ _____

Signature of Participant Date

_____

Name of person obtaining consent

(Fill in Block Letters)

_____ _____

Signature of person obtaining consent Date

_____ _____

Signature of Witness Date

(Required if the research participant does not know how to read the consent form.)

[For data being sent to Duke, clicking accept on the electronic consent form will record a time and date stamp and indicate that the individual has provided consent]