



INFORMATION STATEMENT

Parents/caregivers (Control)

Study ID

Study title: The added value of a mobile application of Community Case Management on Under-5 re-consultation, referral and hospitalization rates in Malawi: a pragmatic stepped-wedge cluster randomized trial

Lead Researcher

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Researchers' statement

On behalf of the study team, I would like to invite you to take part in a research study. The purpose of this form is to help you decide whether or not you would like to take part. Please read the form carefully. If there is anything you do not understand, please ask me to explain. When your questions have been answered you can decide if you want to be in the study or not. If you do not wish to take part, you are free to say no.

PURPOSE OF THE STUDY

In Malawi, many children who are sick get assessed by Health Surveillance Assistants (HSAs) like me using paper-based Community Case Management tool. The study team would like to find out how helpful Community Case Management is for identifying which children need urgent care. They would also like to know which children attend referral facilities, re-visit village clinics or are hospitalized, and the reasons why children attend or do not attend referral facilities when they are sick.

STUDY PROCEDURES

If you decide to take part, I will use Community Case Management to help me assess and treat your child, as I would do normally. I will also ask you to give me some additional information about you and your child. This will include a mobile phone number if you have one, which the study team will use to contact you. I will record this information at the bottom of this form.

The study team will telephone you in approximately 1 to 2 weeks' time. The reason they would like to telephone you is to find out if and when your child was taken to a referral facility, hospital or re-visited a village clinic. A member of the study team will look at records at the referral facilities, hospitals and village clinics you mention to record the dates of your child's visits.

You might also be asked to:

The study team might also contact you to invite you to complete a survey at a later date. If you are invited, you will be asked some questions about yourself and any costs you experience (such as time or money) taking your child for additional treatment at health facilities. This information will be collected from you over the telephone, or in person at a location convenient to you, and will take a maximum of 20 minutes to complete.

DURATION OF INVOLVEMENT

If you agree to take part in this study, you and your child will be involved for a maximum of 4-months. This includes your sick child visit today, until the time the study team has contacted you or finished collecting the dates your child visited referral facilities and village clinics.



RISKS, STRESS, OR DISCOMFORT

It may take more time than normal for your child to be treated today. This is because I need to ask your permission to collect some additional information about you and your child. If you are invited by the study team to take part in an interview, you may feel uncomfortable sharing your thoughts or self-conscious because the interview is being recorded.

BENEFITS OF THE STUDY

There are unlikely to be any benefits to you or your child other than the benefits you would normally receive when visiting a village clinic. Your involvement will help us understand reasons why children attend or do not attend referral facilities and village clinics when they are sick, which may help improve the care your child receives in the future.

CONFIDENTIALITY

Information collected from you will be coded so you cannot be identified. A link between your name and the code will be kept on a password-protected computer. A copy of your study records will be stored on the computer system, but will not be linked to your name. Access to the computer system will be limited to authorized members of the study team with passwords. If we publish the results of this study, your name will not be used. Representatives from the College of Medicine Research Ethics Committee (Malawi) or the University of Washington (USA) can sometimes review studies to make sure they are being done safely and legally. If this happens, information collected from you during this study may be examined. The reviewers will not be able to identify you. Study records will not be used to put you at legal risk of harm.

SPONSOR AND FUNDING

The University of Washington (USA) is the sponsor of this study. The study has received funding from the European Union’s Seventh Framework Programme (FP7) under grant agreement number 305292.

OTHER INFORMATION

Taking part in this study is your choice. If you decide not to take part, you and your child will receive the same standard of care you have always received.

STUDY CONTACT

If you have questions about this research or you decide you no longer wish to take part in the study or you have been harmed by participation in this study, you should **contact Winnie Mkandawire at winniemkandawire@gmail.com (Tel: +265 994 767 798)**

To be completed by the Health Surveillance Assistant:			
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NAME OF CHILD ¹	DATE OF BIRTH ²	GENDER ³	DATE ⁴
<hr/>			
NAME OF PARENT/CAREGIVER ⁵	TELEPHONE NUMBER ⁶	NAME OF VILLAGE	CLINIC ⁷