

# mHealth field study among community health workers in the Balaka and Salima districts of Malawi

<b>Submission date</b> 17/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/08/2023	<b>Condition category</b> Pregnancy and Childbirth	<input checked="" type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background

Since January 2010, the Institute of International Programs (IIP) and the National Statistical Office of Malawi (NSO) have collaborated on the Real-time Mortality Monitoring (RMM) project. One component of RMM evaluates the accuracy and reliability of deaths in children under 5 (under-five mortality) collected by Health Surveillance Assistants (HSAs), government employed community health workers, in the Salima and Balaka districts. Pregnancy tracking and birth and death documentation are activities already within the scope of work of HSAs, so RMM is a project that strengthens the current system. In an assessment run in December 2011, we found that that HSAs under-reported under-five mortality. The mHealth data quality intervention was designed and implemented to improve completeness of pregnancy tracking. Our primary objective is to improve the pregnancy outcome documentation by treatment groups. A complete pregnancy is a pregnancy that results in a live birth, abortion, miscarriage or stillbirth, or the pregnant woman moving out of the area (out-migration).

### Who can participate?

HSAs assigned to each of the 160 randomly selected catchment areas participated in the study.

### What does the study involve?

The intervention was implemented in two phases. Phase one ran for seven months between December 2012 and June 2013. Phase two ran for five months from July 2013 through November 2013. The HSAs were randomly assigned to either the treatment or control group. Those in the treatment group received high-intensity SMS with motivational and data quality content based on project data quality guidelines. For phase one, the treatment group received SMS three times a week. During phase two, the treatment group received SMS five times a week. The control group received minimal-intensity SMS with basic motivational content twice a week during the 12 month intervention period.

### What are the possible benefits and risks?

The participants should benefit from the SMS support by improving the tracking and documentation of pregnancies and pregnancy outcomes. There are no expected risks.

Where is the study run from?

The study is run from the National Statistical Office in Malawi, the in-country collaborator.

When is the study starting and how long is it expected to run for?

January 2010 to March 2014

Who is the main contact?

Olga Joos

ojoos1@jhu.edu

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Olga Joos

### Contact details

Department of International Health

Johns Hopkins Bloomberg School of Public Health

Baltimore

United States of America

21205

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

Evaluation of a mHealth data quality intervention to improve documentation of pregnancy outcomes by Health Surveillance Assistants in Malawi: a cluster randomized trial

### Study objectives

We hypothesize that Health Surveillance Assistants (HSA) receiving high-intensity, data quality short message service (SMS, or text messages) will improve complete pregnancy documentation by 25% as compared to control group HSA receiving minimal-intensity motivational SMS.

### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

1. National Health Sciences Research Committee, 13/02/2009, ref: Protocol #617
2. Institutional Review Board at the Johns Hopkins University Bloomberg School of Public Health, 30/07/2009, ref: IRB #2247

**Study design**

Cluster randomized trial with an interventional design

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Community

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

We are evaluating completeness of pregnancy documentation. We define a complete pregnancy as a pregnancy with a matched outcome: live birth, transfer-out of the pregnant mother, abortion, miscarriage, or stillbirth.

**Interventions**

We implemented the intervention in two phases. Phase one ran for seven months between December 2012 and June 2013. Phase two ran for five months from July 2013 through November 2013. Throughout both phases, the treatment group received high-intensity SMS with motivational content and data quality content based on project guidelines. For phase one, the treatment group received SMS three times a week. During phase two held from July 2013-November 2013, the treatment group received SMS five times a week. The control group received minimal-intensity SMS with basic motivational content twice a week during the 12 month intervention period.

The intervention was randomized and designed at the cluster level, health facilities, but the SMS were received directly by HSA assigned to the health facilities. We constrained the cluster randomization of 30 health facilities using three variables to improve balance between treatment arms. Once we completed the randomization and assigned 15 health facilities to the control group and 15 health facilities to the treatment group, we verified that the spread of clusters was evenly distributed between the two study districts.

**Intervention Type**

Behavioural

**Primary outcome measure**

An improvement in matched pregnancies during the intervention period in the treatment group compared to the control group. A matched pregnancy is defined as a pregnancy with a matched outcome: live birth, out-migration of the mother, abortion, stillbirth, or miscarriage.

### **Secondary outcome measures**

An improvement in matched pregnancies between baseline and intervention periods by group. Matched pregnancies will be evaluated for the control group and treatment group separately.

### **Overall study start date**

01/01/2009

### **Completion date**

30/03/2014

## **Eligibility**

### **Key inclusion criteria**

160 HSAs, one for each of the 160 randomized catchment areas selected for the RMM study

### **Participant type(s)**

Other

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

160

### **Key exclusion criteria**

Not fulfilling inclusion criteria

### **Date of first enrolment**

01/01/2010

### **Date of final enrolment**

30/10/2013

## **Locations**

### **Countries of recruitment**

Malawi

United States of America

**Study participating centre**  
**Institute for International Program**  
Department of International Health  
Johns Hopkins Bloomberg School of Public Health  
615 N. Wolfe Street, E8547  
Baltimore  
United States of America  
21205

**Study participating centre**  
**National Statistical Office**  
Zomba  
Malawi  
PO Box 333

## **Sponsor information**

**Organisation**  
Foreign Affairs, Trade and Development Canada

**Sponsor details**  
125 Sussex Drive  
Ottawa  
Canada  
K1A 0G2

**Sponsor type**  
Government

**Website**  
<http://www.international.gc.ca/international/index.aspx?lang=eng>

**ROR**  
<https://ror.org/0427vvt16>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Foreign Affairs, Trade and Development Canada

# Results and Publications

## Publication and dissemination plan

We tested the Real-time Mortality Monitoring approach in various African countries and plan to publish results and lessons learned in a collection of manuscripts. One manuscript will present results from the mHealth data quality intervention conducted within the RMM Malawi study. We plan to present changes in the completeness of pregnancy documentation, defined as a pregnancy matched to an outcome. We will compare matched pregnancy results between treatment groups during the intervention period and among treatment groups comparing pre- and post-intervention periods.

## Intention to publish date

31/12/2015

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Stored in publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	05/01/2016		Yes	No
<a href="#">Dataset</a>		16/03/2023	18/08/2023	No	No