

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

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

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21205

## Additional identifiers

## 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

### Primary study design

Interventional

**Study design**

Cluster randomized trial with an interventional design

**Study type(s)**

Other

**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(s)**

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.

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

Foreign Affairs, Trade and Development Canada

## Results and Publications

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              |