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

Submission date
17/07/2015

Recruitment status
No longer recruiting

Registration date
23/07/2015

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] 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
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Contact information

Type(s)
Scientific

Contact name
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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
Ottowa
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?
Results article	results	05/01/2016		Yes	No
Dataset		16/03/2023	18/08/2023	No	No