Improving Institutional Deliveries in Rural Zambia

Submission date 21/02/2015	Recruitment status No longer recruiting
Registration date 05/09/2015	Overall study status Completed
Last Edited 12/03/2024	Condition category Pregnancy and Childbirth

[] Prospectively registered

[] Protocol

[] Statistical analysis plan

[X] Results

[] Individual participant data

Plain English summary of protocol

Background and study aims

The number of women who die from birth related complications in Zambia is among the highest in the world, with 591 maternal deaths occurring per 100,000 live births. Most maternal deaths occur among the poorest communities, in rural areas. Some 59% Zambians live in poverty. Only 48% of deliveries are attended by a skilled health worker at an appropriate health care facility such as a hospital (referred to as institutional deliveries), despite there being high antenatal care coverage of 93%. One of the reasons behind such a low number of institutional deliveries include demands by service providers that mothers bring in commodities for delivery. Not being able to meet these demands, pregnant women have been left with no choice but to remain and deliver at home relying on family members who have no training. Providing non-financial incentives for pregnant women in form of mother-baby delivery packs containing basic hygienic delivery supplies will attract pregnant women to deliver in health institutions. This in turn will increase institutional deliveries in rural Zambia and eventual ly contribute to a reduction of maternal mortality. Addressing hidden barriers to institutional deliveries is a key intervention for reducing maternal mortality in poor rural Zambia. The study aims are to determine factors associated with place of delivery and the effect of provision of non-financial incentives in Monze district, a rural region in Zambia on health facilities deliveries.

Who can participate?

Pregnant women resident in the study area (Monze district) until delivery time and able to accept the incentives.

What does the study involve?

The study involves two rural regions in Monze separated in the middle by an urban region. One region is randomly allocated to be the intervention region. The other is assigned as the control region. Pregnant women living in the intervention region are given a mother-baby delivery pack containing basic hygienic delivery supplies (gloves, disinfectant, baby blanket, napkins, soap, bottle of vaseline, baby wrapper and insecticide treated mosquito net) and health education. Pregnant women in the control region receive routine health services. The number of institutional deliveries in both regions is then monitored over a period of one year, along with other outcomes such as attendance at antenatal care clinics and any birth related complications.

What are the possible benefits and risks of participating?

There are no direct medical benefits to participants in this study. However, participants receive information on the benefits of delivering in a health facility assisted by a qualified health worker. Other women may benefit in the future if the information gained from the study leads to reduced maternal deaths and its related complications. This study do not pose any risks, discomfort or embarrassment to participants.

Where is the study run from? Monze District (Zambia)

When is the study starting and how long is it expected to run for? January 2014 to December 2014

Who is funding the study? Financial support has been provided by Irish Aid, WHO and UNICEF

Who is the main contact? Dr Victor M Mukonka vmukonka@gmail.com

Contact information

Type(s) Scientific

Contact name Dr Victor Mukonka

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

PACTR202212611709509

Study information

Scientific Title

Community intervention trial to determine the effect of provision of non-financial incentives on increasing institutional deliveries in order to contribute to reduction of maternal mortality

VMM-RCT

Study objectives

The provision of a non-financial incentive in the form of a mother-baby delivery pack with key items mothers require for institutional delivery accompanied with a health education and information leaflet will increase the numbers of women delivered by skilled birth attendants at a health facility, with subsequent reduction in maternal and neonatal mortality and morbidity.

Ethics approval required Old ethics approval format

Ethics approval(s) Tropical Diseases Research Centre, Zambia, 10/09/2013, ref: TDRC IRB 00002911

Study design Prospective comparative community intervention trial with two comparable rural regions in Monze District, Zambia

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Community

Study type(s) Prevention

Participant information sheet Use contact details to request a information sheet

Health condition(s) or problem(s) studied Maternal mortality and morbidity

Interventions

Two comparable rural regions in Monze separated in the middle by urban region. 1. The intervention arm receives a non-financial incentive in the form of a mother-baby delivery pack containing basic hygienic delivery supplies (gloves, disinfectant, baby blanket, napkins, soap, bottle of vaseline, baby wrapper and insecticide treated mosquito net) 2. The control group continues with routine health services

Intervention Type

Other

Primary outcome measure

Increase in institutional deliveries by skilled birth attendants. Analysis will be comparison of number of institutional deliveries in the two arms over the period of one year and pre (2012 & 2013) and post (2014)

Secondary outcome measures

- 1. Antenatal care attendance
- 2. Birth preparedness
- 3. Delivery complications
- 4. Postnatal attendance
- 5. Under five clinic attendance

Overall study start date 01/01/2013

Completion date 30/11/2015

Eligibility

Key inclusion criteria

1. Resident in the study area until delivery time

2. Able to accept the incentives

Participant type(s) Healthy volunteer

Age group

Adult

Sex Female

Target number of participants 3000

Key exclusion criteria

- 1. Unable to reside in the study area until delivery
- 2. Unable to accept the incentives

Date of first enrolment 01/01/2014

Date of final enrolment 31/12/2014

Locations

Countries of recruitment Zambia

Study participating centre Monze District in Zambia Monze Zambia

Sponsor information

Organisation Irish Aid

Sponsor details

Embassy of Ireland 6663 Katima Mulilo Road P.O. Box 34923 Lusaka Zambia 10101

Sponsor type

Government

Funder(s)

Funder type Government

Funder Name Irish Aid

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	e Details	Date created	Date added	Peer reviewed?	Patient- facing?
<u>Abstract</u> <u>results</u>	Presented at the Global Forum on Research and Innovation for Health	01/08 /2015	01/09 /2021	No	No
<u>Results</u> article		11/03 /2024	12/03 /2024	Yes	No