

## **A Community intervention trial for improved health facility deliveries in rural Zambia: A step towards reducing maternal mortality**

Victor Mukonka <sup>1,2\*</sup>, Cephas Sialubanje<sup>2</sup>, Fionnuala M McAuliffe<sup>3</sup>, Olusegun Babaniyi<sup>4</sup>, Sarai Malumo<sup>4</sup>, Joseph Phiri<sup>5</sup>, Patricia Fitzpatrick<sup>6</sup>

<sup>1</sup>School of Medicine, Copperbelt University, Ndola, Zambia

<sup>2</sup>School of Public Health, Levy Mwanawasa Medical University, Lusaka, Zambia

<sup>3</sup>School of Medicine, University College Dublin, National Maternity Hospital, Dublin, Ireland

<sup>4</sup>World Health Organization, Country Office, Lusaka, Zambia

<sup>5</sup>National Malaria Elimination Centre, Ministry of Health, Lusaka, Zambia,

<sup>6</sup>School of Public Health, Physiotherapy & Sports Science, University College Dublin, Dublin, Ireland

## **Abstract**

### **Background**

Zambia is one of the countries with a high maternal mortality ratio currently at 252 deaths per 100 000 live births. WHO has shown that institutional delivery by a skilled birth attendant is the most effective way to reduce maternal mortality in developing countries.

**Aim:** This study aims to determine the effect of provision of a non-financial incentive on institutional deliveries in Monze, Zambia.

### **Methods**

This will be a one-year prospective community intervention trial (January to December 2014) in Monze, Zambia. Pregnant women in the intervention arm will receive ANC health education followed by a non-monetary incentive when they arrived at the health facility for delivery. Participants in the control arm will continue with routine ANC services. One way analysis of variance (ANOVA) will be conducted to test the effect of the intervention on the number of institutional deliveries after one year.

## **1. Introduction**

### **1.1. Background**

Zambia is one of the countries with a high maternal mortality ratio (MMR) currently at 252 per 100 000 live births [1], one of the highest in the world [2,3]. Home deliveries and limited access to institutional deliveries, especially in rural areas of the countries have been shown to be some of the reasons for the high MMR. The latest demographic and health survey (DHS) [4] shows that one third (33%) of rural women deliver at home without skilled birth attendants. Institutional delivery by skilled birth attendants has been demonstrated to be the most important strategy to reduce MMR in developing countries [5].

Limited access and socioeconomic factors are the main reasons influencing people's decision-making about utilisation of healthcare services in developing countries [5]. Despite maternal healthcare services being provided at little to no cost in most government-run health facilities in Zambia, expectant mothers incur several hidden costs. For instance, long distances and high poverty levels contribute to reduced access to health facilities. This is especially true for the 59% of Zambians living below the poverty datum line of one US dollar per day [6]. Costs to seeking healthcare include transportation, medications and supplies as well as the opportunity costs of travel time and waiting time lost from productive activities [7]. It is common practice for health facilities to request expectant mothers to provide their own supplies for delivery. These supplies include clothing for both the mother and baby, baby blankets, napkins, baby soap and delivery materials such as gloves and disinfectant [8]. Embarrassment at not being able to afford these basic requirements presents another relevant barrier to seeking professional care at health facilities [8]. Out-of-pocket financing of the costs of health facility delivery has been shown to have substantial financial repercussions on households which make families more vulnerable to impoverishment [9]. This cost is prohibitive in rural populations that often rely on subsistence farming for their livelihood. Reducing these inapparent costs may persuade more women to deliver in health facilities under the supervision of skilled birth attendants and contribute to reduction of maternal mortality. The World Health Organisation (WHO) has shown that institutional delivery by skilled birth attendants is the most important strategy to reduce maternal mortality in developing countries [10].

### **1.2. Objectives**

The aim of this study is to determine the effect of provision of additional health education during antenatal care (ANC) and a non-financial incentive on institutional deliveries in Monze, a rural district in Zambia. The non-financial incentive is in form of a mother-baby delivery pack containing delivery supplies and materials

provided in addition to routine ANC services. The study also aims to determine the effect of the intervention on delivery preparedness and postnatal care (PNC) utilisation by mother and baby. Evidence from the study is important for informing policy and interventions focusing on increasing institutional deliveries and improving maternal health outcomes.

## **Methods**

### **Trial design**

This will be a one-year prospective community intervention trial conducted in Monze district, Zambia, from 1st January to 31st December 2014. The district will be stratified into two rural regions separated in the middle by the town centre. The region on the western side will be allocated the intervention arm; the region on the eastern side as the control arm. A total of eight health facilities will be included in each arm. The inclusion criteria for the health facilities is that a health facility conducted deliveries. The town centre (district administrative centre), with a number of urban health facilities and one referral hospital, will serve as a buffer between the intervention and control arms. The physical separation of the research arms will prevent the spill over of relevant information on the non-financial incentives package. Given the transport challenges, it is deemed unlikely for an expectant mother to by-pass the more than 30km buffer and go for delivery in either of the study health facilities in the opposite arm. Both intervention and control regions have similar health facilities, in terms of the location (rural), size and the catchment population-both have similar socio-economic and demographic profiles. The two regions mainly serve peasant and subsistence farmers of the same tribe who share the same cultural, traditional practices and beliefs. To ensure that the two regions are comparable with regard to population size, population data for the two regions will be obtained from the Central Statistical Office in Zambia [11].

### **Study Participants and Setting**

Study participants will be pregnant women from the intervention and control sites in Monze district in the Southern Province of Zambia. The district has a population of 203,038 [11], with one General Hospital and 26 health centres. All the health centres (except for five) provide maternal and child health services and conduct deliveries. Monze General Hospital serves as the main referral hospital for the whole district, performs caesarean sections and deals with all complicated cases referred from the health centres.

To be included in the study, women need to be:

- Pregnant at any gestation and age. Assent was obtained from the parents or legal guardians for the participants who were aged below 18 years
- Residing in the study site catchment area for at least 3 months. Pregnant women who were new in the area were excluded from the study
- Willing to participate

## **Interventions**

In addition to the health education provided during routine ANC visits, pregnant women in the intervention arm will be provided with health education sessions. The additional health education will be delivered by the health facility midwives through one-to-one and group discussion sessions. The sessions will cover various aspects including birth preparedness, danger signs of pregnancy and complications. During the sessions, pregnant women will be informed about the mother-baby delivery pack they will receive if they deliver at the health facility; they will also be given detailed information on the content of the delivery pack. They will be informed that the non-financial incentives in the form of a mother-baby delivery pack contains two napkins, a bottle of Vaseline®, baby soap, a pair of delivery gloves, a baby vest, a chitenge and an insecticide treated mosquito net (ITN)) which will be given to pregnant women at the time of delivery in a health facility. The control arm will continue to receive routine standard ANC services.

## **Outcomes**

The primary outcome will be the difference in the mean number of institutional deliveries in the intervention and the control regions over a one-year period from 1st January to 31st December 2014. The secondary outcome measures will be 1) delivery preparedness; 2) postnatal care service utilisation by mother and baby; 3) under-five clinic service utilisation, 4) knowledge about pregnancy danger signs

## **Sample Size Estimation**

From the district total population of 203, 038 in 2013 [11,12] , we estimated the expected deliveries for the district (using the United Nations Inter-agency Group (WHO, UNICEF, UNFPA, World Bank) formula [13], which Zambia and other developing countries have adopted for estimating deliveries based on the population) to be 10,964. These would be pregnant and need maternal health services during the year. Allowing for 60% of the population living in the urban area of the district, along the trial buffer zone, we estimated our sample size to be 4,500, (that is, 3000 in the intervention arm and 1,500 in the control).

## **Recruitment**

In order to achieve the required sample, a decision will be made to recruit and enrol all the pregnant women attending ANC during the study period 1<sup>st</sup> January to 31<sup>st</sup> December, 2014. Recruitment and enrolment of the study participants will be done from the ANC clinics, when pregnant women go for their first ANC visit. With support from the principal investigator, a pair of trained midwives from each health facility will conduct the recruitment and enrolment of participants.

## **Data Collection Procedures**

Data collection will be conducted by a pair of trained midwives from each health facility from 1<sup>st</sup> January to 31<sup>st</sup> December, 2014. In order to establish baseline health facility delivery data prior to commencement of the intervention, year-long delivery records for 2012 and 2013 will be collected from the delivery registers at each health facility in the study sites, using a data extraction sheet. Prospective data will be collected using a paper-based questionnaire administered by midwives during ANC, delivery and PNC visits. Sections in the questionnaire will include demographic, socioeconomic and maternal history, ANC utilisation, knowledge about pregnancy danger signs, delivery preparedness, place of delivery, delivery and complications, PNC and under five children's clinic utilisation.

## **Quality Assurance**

To ensure quality assurance in the data collection process, the following measures will be taken: a) participant recruitment and enrolment will be done by trained health facility midwives, b) pre-tested paper-based data collection tools will be used; c) the principal investigator will periodically check on the data collection and verify the quality of data being collected; d) research assistants will have no access to completed data collection forms; data entry will be done by an independent individual who will not participate in data collection; e) data analysis will be done by two research team members.

## **Statistical Methods**

Data from the checklist and questionnaire will be entered into an Excel sheet and saved on a password-protected computer. After cleaning up, data will be transferred into SPSS version 21 (IBM) for analysis. Descriptive statistics will be used to summarise participant socio-demographic and clinical data as well as frequencies and proportions of institutional deliveries in intervention and control areas for each year (2012,

2013 and 2014). To compare the means and proportions between the two groups, independent T-test and Chi-square will be computed. Finally, one way analysis of variance (ANOVA) will be used to test the difference in the mean number of institutional deliveries between the intervention and control sites during the three years (2012, 2013, 2014) under investigation. First, the main ANOVA will be used to determine the overall effect of the intervention on institutional deliveries. Next, post hoc analysis using Bonferroni correction for pairwise comparison will be conducted to determine the mean number of institutional deliveries between the intervention and control sites during the baseline period (2012 & 2013) and after introduction of the intervention (2014). Pairwise comparison will be conducted to measure the difference in the mean number of institutional deliveries in the intervention sites between the baseline period (2012 & 2013) and after the intervention.

## **Ethical Considerations**

### **Ethical Clearance**

Ethical approval for the study will be obtained from the tropical disease research centre (TDRC) ethics committee. Authority to conduct the study will be sought from the Ministry of Health, Zambia. Ethical exemption will be obtained from University College Dublin, Ireland. Before participants are enrolled into the study, midwives will confirm the pregnancy status using the rapid gravid index test. Next, the purpose of the study will be explained to the women. Those who accept to participate in the study will be enrolled in the study register and informed consent will be obtained from them. In the case of minors, ascent will be obtained from guardians or parents. Individual informed consent will be btained from all the pregnant women enrolled in the study at delivery time at the health facility both in intervention and control regions before the questionnaire is administered to them.

## **RESULTS**

Results will be presented in form of tables with summary statistics and p- values.

## **Funding Statement**

World Health Organization, UNICEF and Zambian Ministry of Health (award/grant number: N/A). UNICEF bought 1,700 mother-baby delivery packs and WHO contributed fuel for both delivery of the packs and trips for supervision. The Zambian Ministry of Health bought all mosquito nets for the packs and provided transport for distribution of packs to the health facilities in the intervention region.

## Competing Interests

All authors declare that they have no conflicting interests in this work

## Data Sharing

Data are available upon reasonable request from the corresponding author and with permission of the TDRC ethics review board.

## Costs and payments

There will be no cash payment provided to participants for any portion of the study. Participants will volunteer their time taken to participate in the study. As part of the intervention, participants in the intervention arm will receive a mother-baby pack when they came to the health facility for delivery. Those in the control arm will not receive anything.

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