mHealth for Maternal and Perinatal Health

Evaluation of a smartphone application to reduce Adverse Pregnancy Outcomes in Ethiopia

STUDY PROTOCOL

Maternity Worldwide
Ethiopia and Denmark

University of Copenhagen
Denmark

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General information

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Responsibilities and partners
Maternity Worldwide is responsible for funding and implementation of the intervention.
University of Copenhagen is responsible for the scientific evaluation of the intervention including protocol development, data quality, analysis and dissemination of results. The content of the safe delivery smartphone application is developed in collaboration.

Timeframe
Data collection from August 2013 to August 2014

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## Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>AMTSL</td>
<td>Active Management of Third Stage Labour</td>
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<td>ANC</td>
<td>Antenatal care</td>
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<td>BEmO(N)C</td>
<td>Basic Emergency Obstetric and (Neonatal) Care</td>
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<td>CEmO(N)C</td>
<td>Comprehensive Emergency Obstetric (and Neonatal) Care</td>
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<td>EmO(N)C</td>
<td>Emergency Obstetric (and Neonatal) Care</td>
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<td>FMoH</td>
<td>Federal Ministry of Health</td>
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<td>HEP</td>
<td>Health Extension Programme</td>
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<td>HEW</td>
<td>Health Extension Worker</td>
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<td>IMHP</td>
<td>Integrated Maternal Health Project</td>
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<td>KFQ</td>
<td>Key Feature Questionnaire</td>
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<td>MDG</td>
<td>Millennium Development Goal</td>
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<td>mHealth</td>
<td>Mobile phones for health</td>
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<td>MMR</td>
<td>Maternal Mortality Ratio</td>
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<td>MWW</td>
<td>Maternity Worldwide</td>
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<td>MWWDK</td>
<td>Maternity Worldwide Denmark</td>
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<td>OSATS</td>
<td>Objective Structured Assessment Tool of Technical Skills</td>
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<td>PPH</td>
<td>Postpartum haemorrhage</td>
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<td>SBA</td>
<td>Skilled Birth Attendance</td>
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Abstract

Hypothesis  
A safe delivery smartphone application distributed to health workers in Ethiopia will decrease perinatal mortality and the incidence of postpartum haemorrhage. 
A safe delivery smartphone application distributed to health workers in Ethiopia will increase health workers knowledge and skills in intra-partum management of active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation

Intervention  
A safe delivery smartphone application with animated videos to improve clinical management during delivery will be introduced in the intervention clusters

Design  
Cluster randomized controlled trial with health facilities as the unit of randomization

Area  
Nole Kaba, Haru, Homa, Genji and Gimbie districts

Population  
Pregnant women and their newborns delivered in a randomized health facility. For secondary outcomes health workers at randomized health facilities.

Sample size  
77 health facilities with minimum 2 health workers per facility and 30 deliveries per health worker

Duration  
Pregnant women will be enrolled at delivery and followed to 7 days postpartum

Outcomes  
Primary outcomes are perinatal mortality and postpartum haemorrhage. Secondary outcomes are health workers knowledge and skills

Study time  
Data collection from August 2013 to August 2014
Introduction

Maternal death, stillbirth, early neonatal death are among the most devastating adverse outcomes of pregnancy. Over 270,000 maternal deaths, 2.65 million stillbirths and 3 million neonatal deaths occur each year worldwide.¹⁻³ Ninety-nine per cent of these deaths take place in low and middle-income countries with the populations of South Asia and sub-Saharan Africa carrying a disproportionately large burden.⁴⁻⁶

Most causes of maternal and perinatal deaths are similar, often obstetric in origin, and generally follow prolonged labour, preeclampsia, infection and obstetric hemorrhage.³⁻⁶ Birth asphyxia, or failure to initiate or sustain spontaneous breathing at birth, contribute to 30% of neonatal deaths in resource-limited countries. Almost half of stillbirths, 1.2 million, happen when the woman is in labour and are directly related to the lack of skilled care at this critical time for mothers and babies.³ A safe delivery generally requires a skilled birth attendant with the ability to recognize complications and provide a series of focused interventions.⁷ These interventions could avert the majority of maternal and perinatal deaths and have been grouped into basic and comprehensive Emergency Obstetric and Neonatal Care (EmONC). Unfortunately those women at greatest risk are least likely to have access to life saving interventions.⁸⁻⁹ Many are delivered at home without skilled attendance. Others die due to preventable causes related to poor maternal health and poor access to good quality health services.

Assuring health workers knowledge and skills in correct diagnosis and management of emergency obstetric complications is essential to reduce maternal and intrapartum related perinatal deaths.¹⁰⁻¹² Most obstetric complications are managed in the peripheral part of the health system, which is challenging to reach through conventional training programmes in resource limited settings. This out-reach gap might be overcome by use of the fast growing access to mobile phones and other information technology. Sub-Saharan Africa is experiencing a mobile revolution and with more than 600 million mobile phones, applying mobile phones in healthcare, mHealth, is increasingly prioritized to strengthen healthcare systems.¹³⁻¹⁴ The potential towards improving maternal health and reducing perinatal deaths is however still in its infancy. Research is needed to investigate the potential impact of mobile phone-based applications in improving the performance of health workers.

Maternity Worldwide and University of Copenhagen are presenting an innovative initiative using a safe delivery smartphone application with animated videos to improve clinical management during delivery with the ultimate aim to reduce maternal and perinatal mortality. Animation videos are attractive tools to create clinical instructions with a dual function of education and reference tool in clinical situations. Using smartphones enables reach to many health workers where they work, when they need it.

The following is a protocol for scientific evaluation of the effect of the safe delivery smartphone application on health workers knowledge and skills and adverse pregnancy outcomes.
Problem statement

Maternal and perinatal mortality: The Ethiopian context

Ethiopia has one of the highest maternal mortality ratios in the world, estimated at 676 deaths per 100,000 live births in the 2011. The neonatal mortality rate is also high at 37 deaths per 1,000 live births. Regional estimates states that direct obstetric complications accounts for more than 80% of deaths with the most important causes being post partum haemorrhage (34%), hypertension (19%), obstructed labour 11%, unsafe abortion (9%). Directly associated with the availability and quality of obstetric services, the major causes of neonatal mortality are infections (32%); birth asphyxia (29%); and complications associated with low birth weight (24%). The majority of pregnant women in Ethiopia, 60%, do not attend antenatal care and only 10% are delivered with a skilled delivery attendant. Although mortality has declined over time it is far from meeting the target MDG goal 5 of 218 maternal deaths per 100,000 live births and a two-thirds reduction in under-5 deaths by 2015.

The Ethiopian Federal Ministry of Health’s (FMoH) National Reproductive Health strategy 2006 – 2015 states that Ethiopia will significantly increase the number of midwives and the proportion of births attended by a skilled professional as well as provide emergency obstetric care to all women at all health centers and hospitals. The national target is to increase skilled delivery attendance to 60%. FMoH recognizes the need for increase in human resource capacity to lift this task, including more emphasis on skills needed to attend normal deliveries and manage simple obstetric complications, essential care for neonates including resuscitation as well as upgrading the skills of midwives and service provision guidelines.

A core strategy of the FMoH is the Health Extension Programme (HEP), launched in 2003 to accelerate expansion of primary health care coverage. A primary strategy of the HEP is the training of Health Extension Workers (HEWs) in a one-year program to implement a package of 16 healthcare activities at village level. The HEWs are trained on how to provide care to women through pregnancy, birth, and postnatal care. They are part of the formal health structure and receive a monthly salary. Since 2003 the government has trained more than 30,000 HEWs who are being deployed in 15,000 rural villages. Health posts, which are the operational units for HEWs, typically have basic equipment such as blood pressure apparatus, delivery kit, delivery couch and fetoscope but lacks basic infrastructures. Studies show that HEWs are effective in improving immunization, family planning utilization and antenatal care but not in health facility deliveries and skilled birth attendance coverage.

Ethiopia has recognized the potential of using mobile phones to strengthen the health system and has one of the most comprehensive mHealth strategies in the region. The FMoH prioritizes the use of mHealth particularly within 1) data exchange 2) commodity forecast and quantification 3) facilitation of referrals and 4) knowledge updates and learning.

This study will take place in the Oromiya region of West Wollega Zone. The region is like many others in Ethiopia characterized by high fertility rates and low utility of maternal health services. Only 30% receive antenatal care from a skilled provider and less than 10% deliver supervised by a skilled provider. The perinatal mortality rate is 45 per 1,000 births. The most important barriers to women’s access to health services are financial, long distances, lack of transport, and concerns of quality of care such as availability of drugs, equipment and health personnel.
Because obstetric complications cannot be predicted, skilled attendance at the time of delivery and access to emergency obstetric care remain the most effective and widely recommended strategies to reduce maternal and perinatal mortality. However, for skilled delivery attendance to have any impact on health outcomes, it implies that the quality of delivery care is adequate and includes emergency obstetric care. Ensuring quality of delivery care remains a challenge in developing countries such as Ethiopia. Research indicates that it is quite simple skills that are needed to save mothers’ and newborns’ lives and that these skills can be applied also in health facilities in the periphery of the health system with very limited resources and equipment needed.

The capacity and skills of health workers in Ethiopia to ensure good quality of care needs improvement. A recent assessment found that only 29% of HEWs had heard about giving misoprostol for the prevention of postpartum haemorrhage and only half had heard of “rubbing the womb” after delivery of the placenta to prevent and reduce bleeding. They also reported lower self-confidence in providing labour and birth care as compared to other services. In addition, it has been observed that retention of skills, early recognition, correct diagnosis and management of emergency obstetric complications remains a challenge even after skilled birth attendants have been trained in basic EmONC. This is due to many factors such as the lack of enough practical experience in managing cases, inability to correctly read and understand written protocols due to poor literacy levels and the fact that protocols are often written in English, which is often not mastered well. Medhanyie et al found that health posts had no protocols to aid HEWs in decision-making related to maternal health care.

There is an urgent need to design appropriate strategies to improve the performance of midwives and HEWs by enhancing their knowledge and competencies to manage deliveries and obstetric emergencies.

Solutions tried in the past

It has been documented that quality of EmONC can be improved through skills trainings and criterion based audit. Dynes et al showed significant higher post training scores on the topic areas of “prevent problems before baby is born” and “prevent problems after baby is born” amongst health workers. Similarly a study from Tanzania assessed a basic neonatal resuscitation training at hospital level and demonstrated a remarkable sustained 47% reduction in early neonatal mortality (within 24 hours) and a 24% reduction in fresh stillbirths. The authors suggested that the most plausible explanation for the reduction in fresh stillbirths was that most non breathing infants are in primary apnoea with a heart rate and will initiate spontaneous respirations in response to drying and stimulation only if implemented in a timely manner. Another study from a regional referral hospital in Tanzania documents that practical skills training with a hands-on and team approach almost halved the incidence of postpartum haemorrhage at vaginal deliveries from 33% to 18%, while the incidence of severe post partum haemorrhage was reduced from 9% to 4%. A pilot study from Kenya has also shown that training skills to prevent and manage postpartum haemorrhage seems to be as effective when delivered through passive video training compared to interactive simulation training.

The safe delivery application - a new innovative solution?

This study aims to assess the effectiveness of an innovative approach using the safe delivery smartphone application to improve quality of intrapartum care as well as maternal and newborn survival. The application primarily focuses on increasing the capacity of midwives and HEWs working in the periphery of the health system to manage normal deliveries and obstetric
emergencies, but it is also justified for use at hospital level. The safe delivery application will contain animated video instructions aimed to improve clinical management of active management of third stage labour, postpartum haemorrhage, manual removal of placenta and neonatal resuscitation. The application will be developed, and tested as a potential effective tool to overcome the barriers of health workers to provide good quality of care using simple life saving skills. Animated instructions are visual, matter-of-factly and transcend the written word. They can be used both to revise what has been learned at EmONC trainings and thus to heighten retention of skills, as well as a reference tool in the specific emergency situation to enhance early recognition, correct diagnosis and correct management of obstetric emergencies or situations. We hypothesize that the safe delivery smartphone application with animated clinical instruction will increase health workers’ knowledge and skills in intra-partum management and decrease the rate of postpartum haemorrhage and perinatal death.

**Perspective of study results**

This study will contribute to the existing evidence of approaches to improve health workers skills and retention of skills particularly in the periphery of the health system. There is an urgent need for innovative and feasible approaches to increase the capacity of midwives, and community health workers to provide good quality of care. This study will present a robust evaluation of whether the safe delivery smartphone application can increase health workers knowledge and skills and reduce postpartum haemorrhage and perinatal mortality. The results have strong global public health relevance as they indicate if and how policy makers in developing countries should consider mHealth solutions in the fight to improve maternal and newborn health and achievement of MDG 4 and 5.

**Literature review**

**Sexual and Reproductive mHealth**

Mobile phone use is rapidly expanding in Africa and it is estimated that half of all individuals in remote areas have a mobile phone. Mobile health or mHealth is the use of mobile telecommunication and multimedia in provision of health care. It is applied for instance in health promotion, emergency medical responses, point-of-care support, and data collection. There are an increasing number of mHealth pilot projects in low-income countries, most of which have a disease specific focus on HIV/AIDS. The 2012 Lancet report of technologies for global health identified only nine randomised controlled trials for mHealth in low-income countries and the evidence for effectiveness remains weak. Similarly a Cochrane Review concluded that there is moderate quality evidence that mobile phone text message reminders for health care appointments are more effective than no reminders. This review however included only four randomized controlled trials from China, Scotland, England and Malaysia and so external validity is limited.

Mobile health has a great potential for sexual and reproductive health to improve the accessibility, knowledge and quality of care. It is seen as a key area in achieving the goals of the United Nations and WHO's Global Strategy for Women's and Children’s Health. Providing village health workers with mobile phones makes it possible for instance calling for emergency care when needed, which can make emergency responses faster. Thus the mere introduction of mobile devices creates a possibility for saving lives. However, the interest to use mobile phones to promote reproductive
health and improve quality of care is not yet reflected in sufficient research evidence for effectiveness. A recent review of mHealth for maternal health identified 34 articles and reports of which only four had a quantitative design.\textsuperscript{28} Therefore, there is an urgent need of substantial evidence of mobile phone intervention benefits to maternal health services and its contribution to achievement of MDGs 4 and 5.\textsuperscript{28,29}

A major part of the evidence for sexual and reproductive mHealth comes from the use of text reminders. Studies primarily indicate potential to expediting emergency obstetric referrals and improve knowledge and awareness.\textsuperscript{27,33,34} A small randomized trial from Thailand reported higher satisfaction and confidence levels amongst women who received SMS support during antenatal care but found no difference in pregnancy outcome.\textsuperscript{39} A more substantial study has produced evidence of increased skilled delivery attendance amongst urban women benefiting from a mobile phone intervention (OR 5·73 95% CI 1·51-21·81).\textsuperscript{28} This is in accordance with the limited existing literature on mHealth as a tool for behavioural change.\textsuperscript{23-25,38} A review by Cole-Lewis et al found 12 studies and of nine sufficiently powered studies, eight concluded significant behavioural outcomes.\textsuperscript{24} However, all but one took place in developed countries and as such are incomparable due to socioeconomic and cultural differences also in use of mobile phones.\textsuperscript{18} Our results and a study from Kenya on effects of SMS messaging on antiretroviral treatment adherence that found significant improved self reported adherence in the intervention group indicate that similar positive behavioural effects can be reached in developing countries.\textsuperscript{23} Generally mobile phone applications for reproductive health are well accepted by women and health workers.\textsuperscript{28,35-37}

There are no published studies on the contribution of mHealth to improve clinical management and quality of care and generally the evidence for effectiveness of mHealth interventions particularly in developing countries is weak. Particularly health outcomes need a more robust reporting.\textsuperscript{38}

**Hypotheses and Study Objectives**

The primary aim of the intervention is to address the problems related to quality of intra-partum care and associated adverse pregnancy outcomes. The intervention is a smartphone application containing animated clinical instruction videos of 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation. The scientific evaluation focuses on the following aim, hypothesis, specific objectives and endpoints.

**General Objective**
To assess the effectiveness of the safe delivery smartphone application to improve quality of intra-partum care as well as maternal and newborn survival.

**Hypotheses**
1. The safe delivery smartphone application distributed to health workers in Ethiopia will decrease
   - The rate of perinatal death
   - The incidence of postpartum haemorrhage

2. The safe delivery smartphone application distributed to health workers in Ethiopia will increase
Health workers’ knowledge and skills in intra-partum management of active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation

Specific Objectives
The study has five specific objectives

Specific objective 1) To develop the safe delivery smartphone application including four animation videos aiming to improve quality of care in 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation

Specific objective 2) To validate four Objective Structured Assessment Tools of Technical Skills (OSATS) and four Key Feature Questionnaires (KFQ) on 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation

Specific objective 3) To assess the impact of the safe delivery smartphone application on health workers knowledge and skills in management of 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation

Specific objective 4) To assess the impact of the safe delivery smartphone application on perinatal mortality and incidence of postpartum haemorrhage

Specific objective 5) To explore health workers use and perception of the safe delivery smartphone application

Primary endpoints
To assess if animation videos decreases
- Perinatal mortality
- Postpartum haemorrhage

Secondary endpoints
To assess if smartphone based videos decreases
- Stillbirth
- Early neonatal deaths (24 hours, 7 days)
- Rates of mortality stratified according to gestational age and birth weight
- Severe postpartum haemorrhage (PPH>1000 ml)

To assess if smartphone based videos increase
- Health workers clinical performance in active management of third stage of labour, postpartum haemorrhage and manual removal of placenta
- Health workers clinical performance in management of neonatal resuscitation
- Health workers knowledge of management of active management of third stage of labour, manual removal of placenta and postpartum haemorrhage
- Health workers knowledge of management of neonatal resuscitation
Tertiary endpoints
To assess if the smartphone based videos increases process indicators
- Use of the application (when, how much and by whom)
- Stimulation of the newborn
- Suction of the newborn
- Face mask ventilation of the newborn
- Apgar score at 0 and 5 minutes
- Use of uterotonic drugs
- Emptying bladder
- Continuous uterus massage in case of PPH
- Bimanual compression in case of PPH
- Manual removal of placenta
- Intrauterine palpation
- Referrals

The intervention
The safe delivery smartphone application will be designed to train midwives and other birth attendants in developing countries in management of normal and complicated deliveries. The application is furthermore intended as a reference tool that could be used during clinical work for example for preparation before attending a birth, in a situation when a complication occurs, or for debriefing and self-evaluation after a complication. The application features two components; four animated videos with clinical instructions of 3-8 minutes duration and written lists of essential obstetric drugs (indications, contraindications, dosage and administration and side effects) and essential equipment for a safe delivery. To remind health workers of the content the application provides weekly “push messages” with links to the animated films.

Smartphones with the application will be implemented at intervention health facilities. Participating midwives and health extension workers will receive a one day introduction course in the smartphone application featuring a) training on how to use the smartphone and the installed application, using pictographic instructions and interactive exercises in small groups, and b) joint video viewing and discussion about the procedures of the videos. At the end of the training course,
the smartphones will be distributed to included health staffs, and the intervention data collection period begins the following day.

Figure 2. Example of an animated video sequence illustrating performance of bimanual compression in management of post partum haemorrhage.

The application contains four animated training videos of approximately ten minutes duration. The illustrations are simple and supported by voice instructions. The application contains a language selection between English and the local language Oromiffa.

To remind health workers of the content the application provides weekly push messages with links to the animated films.

At the non-intervention health facilities, the midwives and health extension workers will provide standard care without the assistance of the smartphone application. To ensure equal possibilities to provide standard care both the intervention and control site the study facilities the study will ensure availability of a minimum drugs and equipment package and supplement in facilities where not already available through regular mechanism. The minimum package of drugs and equipment to be available at all facilities are shown in appendix 1.

Methods

Study design
This study is a pragmatic cluster-randomised controlled trial with the health facility as the unit of randomisation. The study will observe the effect of the smartphone application on adverse pregnancy outcome, postpartum haemorrhage and health workers knowledge and skills. One group of health facilities, health workers and women attending those facilities will be randomized to receive the intervention, whereas the control facilities will receive no intervention.

Study area
The study will take place in Ethiopia; Oromiya Region, West Wollega Zone, from 2013 to 2014. West Wollega is one of the 18 administrative zones of Oromia Regional State. The population is approximately 1,600,000 people of which 90% live in rural areas, most are engaged in subsistence agriculture. Administratively, the zone has 21 districts, of which 19 are rural districts and 2 are urban administrations. Gimbie is the capital city of the zone located 441 km from the capital, Addis Ababa. The zone has 5 hospitals (3 governmental and 2 non-governmental), 53 health centers and 440 health posts (governmental). The area is vast and characterized by long distances between villages and nearest towns and health facilities, lack of infrastructure such as adequate road
networks and access to safe water.

The study will focus on the five districts of Nole Kaba, Haru, Homa, Genji and Gimbie. In the five districts there are two hospitals staffed with 10 midwives, 11 health centers staffed with 22 midwives and 116 health posts staffed with 233 health extension workers. All facilities refer patients to the two hospitals in Gimbie (Gimbie Government Hospital, Gimbie Adventist Hospital). Utilization of maternal health services is generally low. In 2012 there were 2,231 deliveries at the two hospitals, 1,031 deliveries at health centers and 512 deliveries at health posts (appendix 2).

Study population
The study population for the primary endpoint is women delivering at one of the randomized health facilities and their newborns. All women in active labour who are attending randomized facilities during the study period from August 2013 to August 2014 are eligible for study participation with their newborns. Women will be informed about the study and the consequences of accepting participation in the study. If the woman accepts participation she will be allocated an individual study identification number. Planned or acute caesarean sections will be excluded.

The study population for secondary outcomes are the midwives and HEWs working at health facilities eligible for randomization.

Sample size calculation
The primary, composite outcome is stillbirth or neonatal death within 7 days from delivery, among births > 1,000 g. The null hypothesis is that there is no difference between the probability of this outcome in the intervention and control groups. The design has three levels, namely health facility, health worker, and delivery. Therefore, correlations between births within the same health worker, and between births within the same health facility should be taken into account. Based on limited available information the proportion of births with the primary outcome is assumed to be 5%. Information about correlations is very limited. In a review of 5 community-based cluster randomized studies in LMIC, the intra-community correlations for our composite endpoint ranged between 0.0004 and 0.0031.39 We have no information about the correlation within health workers.

Assuming a 40% reduction in the primary endpoint due to the intervention (from 5% to 3%), an intra-health facility correlation of 0.003, an intra-health worker correlation of 0.01, 30 deliveries per health worker, and 2 health workers per health facility, it is estimated that 75 health facilities are needed to achieve a power of 80% at a significance level of 5%.40 With 79 health facilities available for randomization, the study will have reasonable power for most scenarios (see sampling technique below).

Sampling technique
All hospitals, health centers and health posts in the five districts will be selected for the study and assigned by simple random allocation to either the smartphone intervention or control group. Health facilities with less than three deliveries in 2012 will be excluded from randomization. This leaves a total of 77 health facilities eligible for randomization: two hospitals (10 midwives), 11 health centers (22 midwives) and 64 health posts (127 HEWs). Neither study participants nor clinic staff
will be masked because of the nature of the intervention requiring overt participation. Where relevant analysis will accounted for within-cluster correlation of women cared for at the same facility.

To optimize the control of potential confounders such as regional socioeconomic and cultural variations the randomization of facilities is stratified per district and level of care. Controlling potential confounders (such as parity, socio-economic status, and age) will also be addressed in the subsequent statistical analysis using multiple logistic regression analysis. Facilities without a midwife or health extension worker present full time during the study period will be excluded. The choice of randomizing facilities rather than individuals is done to avoid contamination between health workers in the same facility, such as health workers showing the application and animation videos to each other. In addition, during implementation intervention health workers will be asked not to show the safe delivery application to health workers from other facilities.

Variables and operational definitions
Clinical assessment of postpartum haemorrhage and perinatal mortality will be performed by the health workers (midwives and HEWs) who are used as research assistants following the definitions below.

One of the two primary outcomes is defined as the rate per thousand deliveries (live births and stillbirths) occurring at birth weight above 1,000g (equivalent to gestational age 28 weeks) for women who deliver in a cluster health facility as a composite of either of the following:

**Fresh Stillbirth:** all deliveries of a foetus with a birth weight above 1,000g birth weight who at birth has no signs of life (breathing, crying or movement) with intact skin.

**24-hour neonatal mortality:** all babies born alive with a birth weight above 1000 g who die on or prior to 24 hours.

**7-day neonatal mortality:** all babies born alive at with a birth weight above 1000 g who die on or prior to day 7.

The other primary outcome is defined as the incidence of postpartum haemorrhage defined as:

**Postpartum haemorrhage:** Measured bleeding one hour after delivery above 500 ml

**Severe postpartum haemorrhage:** Measured bleeding after delivery above 1000 ml

If either of these outcomes occurs the case will meet the criteria for the primary outcomes postpartum haemorrhage and perinatal mortality. Each of the variables that comprise the composite primary outcome also will be tested independently in the control vs. intervention facilities.
Data collection

Procedures and measurement methods
Data collection will be conducted in parallel in the intervention and control facilities using the same methodologies; structured questionnaires and clinical observations (appendix 3). Midwives or HEWs at the randomized facilities will serve as research assistants. Each will be responsible for conducting the inclusion, interviews and clinical assessment for the women recruited for the study in their facility.

Research assistants will receive a one-day training in data collection including registration of the postpartum blood losses by weighing blood collection drapes before and after blood collection. A supervisor will oversee the research assistant’s data collection and evaluate the accuracy of collected data on site. Data collection will be initiated two months before randomisation of health facilities and implementation of the intervention.

At inclusion the women will sign (by writing or fingerprint) an informed consent form and a registration form providing address, telephone number and a description to reach the address will be registered. Individual study identification number will be allocated and the woman will receive a card with her ID number. The research assistants will register delivery outcome, mode of delivery, postpartum haemorrhage and essential health information at the time of delivery in a delivery form.

All women included in the study will be subjected to a follow up visit at the women’s home 7 days postpartum. A structured questionnaire on background characteristics of women and their families will be performed, and the research assistant will record any death of newborns, including the number of days after delivery the death occurred. Data collection will be ongoing similarly in the intervention and control clusters to allow comparison of the outcomes.

In summary, each of the specific objectives has the following measurement methods.

Specific objective 1) To develop the safe delivery smartphone application including four animation videos aiming to improve quality of care in 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation

Experts in international obstetrics chose four themes based on criteria of relevance and potential for saving lives and the outcome of a stakeholder workshop in Ethiopia with participation of members from Ministry of Health. For each theme a short animation-video will be developed ensuring compliance to WHO recommendations and other scientific evidence. Face and content validity will be obtained through revision from first the international experts and subsequent four independent experts in Ethiopia. The animation-videos will be integrated into one smartphone application and will be pilot tested at the implementation site in Ethiopia with a focus on health workers understanding and use of the application. The application will be available in two languages, English and Oromiffa.

Specific objective 2) To validate four Objective Structured Assessment Tools of Technical Skills (OSATS) and four Key Feature Questionnaires (KFQ) on 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation
This objective is methodological in nature and focuses on development of appropriate research tools to measure differences in health workers knowledge and skills. The procedure part of the OSATS scale will be built by the two PIs on the content of international and clinical guidelines. Face and content validity of the checklist will be further improved with consensus seeking involvement of obstetricians and paediatricians using a modified Delphi technique. The Delphi technique is an anonymous process where responses are collected and analysed until consensus is achieved. Each item of the checklist will be rated from 1 to 5 point concerning its relevance and ability to assess a health workers performance in 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation. In addition, items may be excluded or added. The criteria for exclusion are if more than 20% of the delphi team members rate a item below 3. A new item will be included if recommended by more than 40% of Delphi group members.

Subsequent construct validity of the OSATS and KFQ will be assessed in Ethiopia. The tools ability to distinguish between skills and knowledge of different level will be tested on a low competence group consisting of ten HEW students and a high competence group consisting of ten medical doctors with experience in paediatrics or obstetrics. The OSATS assessment will consist of simulated scenarios with skills performance on dolls. The sessions will be recorded on video and subsequently scored by the two PIs. The sessions will take place in Ethiopia because management and pre-existing knowledge is context specific and we aim towards validating a tool for sub Saharan Africa. The KFQ testing will take place after the simulated scenarios in a classroom style and scored by the two PIs according to guides provided by the tool. Statistical analysis and interpretation will determine if the tools have sufficient sensitivity to distinguish skills and knowledge of different levels.

**Specific objective 3)** To assess the impact of the safe delivery smartphone application on health workers knowledge and skills in management of 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation

The clinical performance and knowledge of management in 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta and 4) neonatal resuscitation will be assessed using the OSATS and MCQ tools developed under specific objective 2. Assessments will be carried out during simulated sessions, as described above, of midwives and HEWs in both control and intervention facilities at the time 0 (e.g. prior to intervention implementation), 6 and 12 months after implementation.

**Specific objective 4)** To assess the impact of the safe delivery smartphone application on perinatal mortality and incidence of postpartum haemorrhage

At admission the women will be briefly asked for informed consent for participation and if she accepts be allocated an individual study ID number. Perinatal mortality, stillbirths, neonatal death will be assessed by registration of delivery outcome by research assistants in all included facilities. Postpartum haemorrhage will be assessed by collection of blood in the immediate postpartum period (<2 hrs.). The quantity of blood loss is assessed by weighing blood collection drapes before and after blood collection. Registration will be on hard copy in a delivery form. Each woman will receive a follow up visit after 7 days where a structured questionnaire with background information will be conducted including relevant information about death of the newborn and number of days
after delivery the death occurred. All newborns will be weighed at birth (including the stillborn) and at the follow up visit at 7 days. If a newborn dies the research assistants will establish the most plausible cause of death. The research assistants will perform the follow up visit. For deliveries at the two hospitals in Gimbie follow up visits will be performed by the research assistants nearest the residence of the woman or by phone if the residence is outside the five districts (Nola Kaba, Haru, Homa, Genji and Gimble).

**Specific objective 5) To explore health workers use and perception of the safe delivery smartphone application**

Use of the *safe delivery* smartphone application is automatically registered including which film is being watched as well as date, time and location. This information is transferred automatically in an excel format to a central server using GPRS network or manually. If manual registration is necessary the supervisors will do it during their regular supervision visits.

A qualitative research methodology of primarily focus group interviews followed up by key informant interviews will be applied to explore the health workers’ own perceptions of the smartphone application tool. The aim is to gauge the health workers’ level of acceptance of the tool including the perceived relevance of the tool to their work (knowledge, skills and management of the clinical situations and impact on health outcomes) as well as barriers to its acceptance and suggestions for improvements. In addition, the qualitative analysis will aim to tease out if the tool has any impact on non-clinical factors that impinge on the quality of care such as work motivation and attitudes towards clients.

**Data Management**

Sustained supervision of data collection is important. Each of the five districts will have one supervisor responsible for data collection and management and a research coordinator will oversee the whole process. Together with two data entry staffs they will form a Data Management Committee that will meet at least monthly.

Data will be collected prospectively and will be kept confidential. The data will be collected in the local language Oromiffa using hard copy forms, with only the individual study identification number on each form. The forms will be collected from health facilities by the supervisors daily at the hospitals and weekly at health centers/health posts, and brought to the mHealth office in Gimbie.

The forms will be keyed into the computers by two data entry staffs who are employed full time during the study period. The hard copy forms will then be scanned and retained in a secure location. Data will be entered using Epi-Data and transferred to SPSS where analysis will be conducted. Electronic data will be transferred from each data management computer to a single site, creating a complete data repository. The research coordinator will maintain the central database for the study under supervision of the PIs.

Data will be collected as described above using the research tools listed in appendix 2. Use of the smartphone application is automatically registered including which film is being watched as well as date, time and location. This information is transferred automatically in an excel format to a central server using GPRS network or manually. If manual registration is necessary the supervisors will do it during their regular supervision visits. The database is managed centrally at the mHealth office.
Health workers skills and knowledge will be assessed using the OSATS and KFQ tools at 0, 6 and 12 months for both intervention and control clusters. Assessment will be performed at the Health Centers including the associated midwives and HEWs of that specific health center.

In summary, data management will be organized in a Data Management Committee consisting of the research coordinator, five supervisors (one for each district) and two data entry staffs. The data management committee will perform data editing and error resolution as well as audits of incomplete data and send a monthly audit report to the two PIs.

Data analysis
Descriptive statistics will be reported by computing frequencies and percentages for categorical variables and means, standard deviations, and minimum and maximum values for continuous variables. Distribution of the variables will be examined to detect the outliers as a part of quality control and descriptive analysis of the data. In addition, the frequency of missing data for critical variables (e.g. perinatal mortality and postpartum haemorrhage) will be examined by and across clusters.

Primary analysis
The primary analysis will be to compare outcomes between intervention and control clusters post-intervention.

An intent-to-treat analytic approach will be used, in that any cluster assigned to the intervention will be considered treated, whether or not the health workers used the smartphone application. The primary outcome will be analysed using logistic regression analysis on the binary outcomes of perinatal mortality (yes or no) and postpartum haemorrhage (yes or no) to assess the impact of the intervention. Because facilities rather than individual women were randomized, we will use generalised estimating equations (GEE) of Liang and Zeger to account for within-cluster correlation in all statistical analysis. Regression adjustment for covariates and stratification according to health facility type (hospital, health center, health post) may also be applied. The statistical model will initially include all socioeconomic and health related covariates as explanatory variables (including two-factor interactions) in a logistic regression analysis. The model will be reduced by removing non-significant confounders using backwards elimination. If necessary, pre-randomisation data will also be used for possible confounder adjustment. Results will be expressed as odds ratios (ORs) with 95% confidence intervals (95% CI). Statistical significance was defined as P<0.05.

Secondary analysis
The secondary analysis focuses on health workers knowledge and skills and differences in OSATS and KFQ scored between intervention and control clusters.

Due to the sample size and nature of the results, a Gaussian distribution is not expected; therefore a non-parametric statistical test (Mann–Whitney U or Kruskal-Wallis) will be used to investigate differences between the intervention and control groups. A p-value < 0.05 will be considered significant. Scores will be presented as medians and quartiles.
Study Monitoring
A Data Management Committee (DMC) will review the data being collected at least every month and report to the PIs. The DMC reports will include information concerning enrolment, compliance, protocol violations, outcomes, and adverse events.

Outcome analysis for the study will be formally reviewed at approximately four time points. Assuming a 12-month intervention data collection period, these formal looks will be when 1/4 of the births have occurred (i.e., at approximately 3 months) and when 50%, 75% and 100% of the births have occurred. Adverse events (including death, life-threatening events, and hospitalization) will be defined by the investigators, monitored by the DMC and reported to PIs.

Quality Control
Quality assurance for the study will be conducted in a variety of ways and will include the following:

Training Supervisors: Supervisors will be selected by the research coordinator and MWW Country Director based on their clinical, leadership, and organizational skills. They will receive a course on data collection and be certified prior to data collection (refresher training may be conducted as needed). Supervisors will oversee the quality of the data collection in the districts which they are responsible.

Training Research Assistants: Research Assistants will be selected at all included facilities. They will receive a one-day course on data collection and be certified prior to data collection. The training will be conducted with the aid of a translator who prior to the training will receive in depth briefing on the tasks and job description of the research assistants. On site supervision and data control will be performed by the supervisors at least every 7 days and initially more frequently if needed. Research assistants will fill the four forms: informed consent, registration, delivery and 7 day postpartum.

Monitoring: Supervisors will work daily at facilities in their district and will directly monitor all aspects of the study intervention and data collection. The research coordinator will also visit the participating communities routinely. Monthly meetings will be held with the Data Management Committee with attendance and meeting minutes recorded.

Site visits: The PIs will conduct site visits, as needed, but at least two times annually. The PIs may also conduct follow-up training and evaluation during the initiation of the intervention.

Data Management Committee: The DMC will submit data to the PIs for interim analysis and monitoring purposes at least every 3 months.

Data entry: 10% of patients selected by the DMC will have data entered twice. In addition, inter and intra-form edits will be run to assure data consistency.
**Ethical considerations**
All participating women, midwives, health extension workers will give written informed consent prior to inclusion. The participants will be informed that the study is voluntary and that they can withdraw without consequences at any time. Health workers will be ensured complete anonymity and confidentiality and sign informed consent of participation in the study. Study data on individuals will not go beyond the research group. If the intervention is proven successful after 12 months it will be rolled out to also benefit control health facilities.

Before initiating the project, permission and ethical clearance will be obtained from the Ethiopian Ormomiya Regional Health Bureau. The trial will be registered with the international database for clinical trials (www.clinicaltrials.gov).

**Publications**
The study is expected to result in ten papers published in international peer reviewed scientific journals:

The suggested papers are

**Specific objective 1**
Development and validation of smartphone application with animation-videos to improve quality of intrapartum care
*Study population: N/A*
*Measures: N/A*

**Specific objective 2**
Postpartum Haemorrhage: development and test of a procedure specific rating scale
*Study population: 10 students, 10 MDs/obstetricians*
*Measures: OSATS scores*

Neonatal resuscitation: development and test of a procedure specific rating scale
*Study population: 10 students, 10 MDs/paediatricians*
*Measures: OSATS scores*

Postpartum Haemorrhage: development and test of a knowledge specific rating scale
*Study population: 10 students, 10 MDs/obstetricians*
*Measures: KFQ scores*

Neonatal resuscitation: development and test of a knowledge specific rating scale
*Study population: 10 students, 10 MDs/paediatricians*
*Measures: KFQ scores*

**Specific objective 3**
The impact of the safe delivery smartphone application on health workers knowledge and skills in management of 1) active management of third stage labour 2) treatment of post-partum haemorrhage 3) manual removal of placenta
*Study population: Midwives and Health Extension Workers in randomized health facilities*
*Measures: OSATS and KFQ scores*
The impact of the *safe delivery* smartphone application on health workers knowledge and skills in management of neonatal resuscitation
*Study population: Midwifes and Health Extension Workers in randomized health facilities*
*Measures: OSATS and KFQ scores*

**Specific objective 4**
The impact of the *safe delivery* smartphone application on perinatal mortality
*Study population: Newborns in randomized health facilities*
*Measures: Perinatal mortality*

The impact of the *safe delivery* smartphone application on postpartum haemorrhage
*Study population: Women delivering at randomized health facilities*
*Measures: Postpartum haemorrhage*

**Specific Objective 5**
Health workers use, attitude and perception of the *safe delivery* smartphone application
*Study population: Health Workers*
*Measures: Use of safe delivery application*

**Work plan**
The timeframe of the study is from March 2013 to December 2014. Implementation of the intervention and data collection will take place from August 2013 to August 2014. A detailed workplan can be found in appendix 5.

**Budget**
This protocol describes one of two study interventions under the project "mHealth for maternal health: the accelerated improvement of maternal health in Ethiopia using mobile tools with an open source strategy in Oromiya region of West Wollega Zone; Homa, Haru, Nole and Genji districts". The project was approved and signed on the 15th January 2013 by Maternity Worldwide Denmark and Oromiya Bureau of Finance and Economic Development. The total budget for the mHealth intervention implementation and data collection in Ethiopia (including specific objectives 2-5) is 229,038 USD. The development of the *safe delivery* smartphone application (specific objective 1) will be covered by Maternity Worldwide’s national budget in Denmark.
References


Liang KY, Zeger SL. Regression analysis for correlated data. *Annu Rev Public Health* 1993; 14:43-68
Appendix

Appendix 1: Minimum drugs and equipment package

<table>
<thead>
<tr>
<th>Table 1: Minimum drugs and equipment package</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivery kit</strong></td>
</tr>
<tr>
<td>Piece of soap</td>
</tr>
<tr>
<td>Plastic sheet of about one square meter</td>
</tr>
<tr>
<td>Clean razor blade or scissors</td>
</tr>
<tr>
<td>Clamp or clean cord ties</td>
</tr>
<tr>
<td><strong>Equipment</strong></td>
</tr>
<tr>
<td>Weighing scale</td>
</tr>
<tr>
<td>Self-inflating mask and bag for neonatal resuscitation</td>
</tr>
<tr>
<td>Sterile gloves</td>
</tr>
<tr>
<td>Intravenous cannula</td>
</tr>
<tr>
<td>Suture</td>
</tr>
<tr>
<td>Needle holder</td>
</tr>
<tr>
<td>Gauze</td>
</tr>
<tr>
<td><strong>Drugs</strong></td>
</tr>
<tr>
<td>Misoprostol</td>
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<tr>
<td>Intravenous fluids: normal saline or Ringer's lactate</td>
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Appendix 2: Health system in study area

<table>
<thead>
<tr>
<th>Table 2: Overview of targeted districts</th>
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</thead>
<tbody>
<tr>
<td><strong>District</strong></td>
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<tr>
<td>Population</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>Nole Kaba</td>
</tr>
<tr>
<td>Haru</td>
</tr>
<tr>
<td>Homa</td>
</tr>
<tr>
<td>Genji</td>
</tr>
<tr>
<td>Gimbie</td>
</tr>
<tr>
<td>Grant total</td>
</tr>
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</table>
Table 3: Overview of health facilities in targeted districts

<table>
<thead>
<tr>
<th>District</th>
<th>Hospital</th>
<th>Health Centre</th>
<th>Midwives</th>
<th>Health Posts</th>
<th>HEWs</th>
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<tbody>
<tr>
<td>Nole Kaba</td>
<td>Nole HC *</td>
<td>2</td>
<td>13</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ula Babu**</td>
<td>2</td>
<td>8</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Qoche (Siba)**</td>
<td>2</td>
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<tr>
<td>Haru</td>
<td>Haru*</td>
<td>2</td>
<td>15</td>
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</tr>
<tr>
<td></td>
<td>Ujommo**</td>
<td>2</td>
<td>7</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chonge**</td>
<td>2</td>
<td>7</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Homa</td>
<td>Homa*</td>
<td>2</td>
<td>10</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Genji</td>
<td>Genji*</td>
<td>2</td>
<td>18</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>Gimbie</td>
<td>Government Hospital</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adventist Hospital</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gimbi</td>
<td>2</td>
<td>33</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Jogir</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dalo-Gambel</td>
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<td></td>
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<td>Grant total</td>
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<td>11</td>
<td>32</td>
<td>116</td>
<td>233</td>
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</table>

* Included in MWW project 2011
** Included in MWW project 2013

Table 4: Number of deliveries per facility in 2012

<table>
<thead>
<tr>
<th>District</th>
<th>Hospital</th>
<th>HC</th>
<th>Health Posts</th>
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</thead>
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<tr>
<td>Gimbi</td>
<td>Gimbi Public Hospital</td>
<td>1,085</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gimbi Adventist Hospital</td>
<td>1,146</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gimbi</td>
<td>95</td>
<td>319*</td>
</tr>
<tr>
<td></td>
<td>Jogir</td>
<td>65</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Dalo-Gambel</td>
<td>89</td>
<td>-</td>
</tr>
<tr>
<td>Nole Kaba</td>
<td>Nole</td>
<td>207</td>
<td>60</td>
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<tr>
<td></td>
<td>Ula Babu</td>
<td>74</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Siba Qoche</td>
<td>43</td>
<td>8</td>
</tr>
<tr>
<td>Haru</td>
<td>Haru</td>
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<td>0</td>
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<td></td>
<td>Chonge</td>
<td>57</td>
<td>32</td>
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<tr>
<td>Homa</td>
<td>Homa HC</td>
<td>270</td>
<td>176</td>
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<tr>
<td>Genji</td>
<td>Genji HC</td>
<td>209</td>
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<tr>
<td>Grant total</td>
<td></td>
<td>2,231</td>
<td>1,031</td>
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</tbody>
</table>

* Data from June 2012 is missing

Gimbie Health Center

Nole Health Center

Nole Health Center has existed for 11 years and serves total population of 34,034. Nole is located 50 km from a referral hospital in Gimbi. The center does not have a transport service for a referral. The Health Center has 2 midwives and 6 clinical nurses, who attend deliveries. The center also provides antenatal care services and 12 to 15 deliveries every month. The facility does not have running water and only 50% of the time that they have electric power.
Haru Health Center
Haru Health Center has existed for 4 years and serves total population of 32,553. Haru is located 25 km from a referral hospital in Gimbi. The center does not have a transport service for a referral. The Health Center has 2 midwives and 5 clinical nurses who attend deliveries. The center also provides antenatal care services and 15 deliveries every month. The facility does not have running water and only 85% of the time that they have electric power.

Genji Health Center
Genji Health Center has existed for 4 years and serves total population of 70,000. Genji is located 60 km from a referral hospital in Gimbi. The center does not have a transport service for a referral. The Health Center has 2 midwives and 9 clinical nurses who attend deliveries. The center also provides antenatal care services and 10 deliveries every month. The facility does not have running water and only 30% of the time that they have electric power.

Homa Health Center
Homa Health Center has existed for 4 years and serves total population of 37,542. Homa is located 45 km from a referral hospital in Gimbi. The center does not have a transport service for a referral. The Health Center has 2 midwives and 8 clinical nurses who attend deliveries. The center also provides antenatal care services and 15 deliveries every month. The facility does not have running water and only 75% of the time that they have electric power.

Appendix 3: Research tools
The study will apply the following research forms

Maternal and newborn health registry forms
Data to be collected in all clusters for all pregnancies and deliveries that occur
W1: Informed consent
W2: Registration form
W3: Delivery form
W4: 7 day Follow up questionnaire (including demographic and socioeconomic characteristics)

Health workers skills and knowledge forms
Data to be collected in all clusters for all health workers (midwives and health extension workers)
H1: Informed consent
H2: Background questionnaire
H3: OSATS
H4: KFQ
H5: End of study questionnaire
Appendix 4: Research partners

Maternity Worldwide
Maternity Worldwide Denmark (MWW) is a development organization founded in Copenhagen in 2005 by six Danish women from the health and private sector. The initiator was a medical doctor who during an internship at Gimbie Adventist Hospital in West Wollega in Ethiopia was spurred to address the many tragic and unnecessary deaths and disabilities caused to women in pregnancy or labour. MWW Denmark was formed as a sister organization to Maternity Worldwide UK, founded in 2002. MWW was run on a voluntary basis up to 2010, where it sourced funding for the employment of a small Danish administration. The organisation raises all its funds from private foundations and trusts and from its yearly mother’s day campaign which has proved successful. In 2010, Her Royal Highness, Crown Princess Mary of Denmark, became protector of the organisation. MWW has since 2006 been implementing an Integrated Maternal Health Project in West Wollega Zone in Ethiopia. The focus is to enable safe deliveries for the population. MWW works in an integrated approach with an interlinked dual focus on enhancing the quality of health services and on mobilizing the community to make use of the services at the same time.

University of Copenhagen
The University of Copenhagen, founded in 1479, is a self-governing unit under the Danish state. It comprises eight faculties and more than 100 departments and research centers. The University of Copenhagen is the largest institution of research and education in Denmark, with around 38,000 students, 8,000 employees and a budget for 2009 at US$ 1.25 billion. In a recent international ranking, the University of Copenhagen was ranked 43 worldwide and highest in Scandinavia.

The Faculty of Health Sciences is renowned for research of high quality and rigorous academic training in a broad range of disciplines. Researchers at the Faculty of Health Sciences have been awarded four Nobel prizes.

Department of International Health, Immunology & Microbiology
The Department of International Health, Immunology and Microbiology (ISIM) is one of thirteen departments at the Faculty of Health Sciences and one of the twenty departments that form the Copenhagen School of Global Health (CSGH) [www.globalhealth.ku.dk]. ISIM host the secretariat for the CSGH.

ISIM employs approximately 360 researchers and administrative staff, including 50 PhD students. The research staff covers a great diversity of disciplines including basic sciences, clinical research, health systems and public health. Research projects, approximately 270 ongoing externally funded projects in 2009, focuses upon the major public health problems facing low and middle income countries including e.g. reproductive and child health; malaria; environmental health; HIV/AIDS; health systems; medical anthropology; and prevention and management of diabetes. Projects are conducted in close partnership with university and government partners in Sub-Saharan Africa, South Asia and South-East Asia. The department offers a series of specialised training courses, summer schools and full Master degree programs.
Appendix 5: Analysis plan

Definition of study population

1. Newborns to women delivering at one of the included health facilities
2. Health facility staffs (midwife or HEW) working at one of the included health facilities

Figure 1: Flowchart presenting the randomisation and adherence at follow-up.

Descriptive analyses

The distribution of background factors (defined in the table shells of Table A) in numbers and percentages will be compared (but not by a statistical test) between the randomisation groups.

<table>
<thead>
<tr>
<th>Health facilities</th>
<th>Intervention (%)</th>
<th>Control (%)</th>
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<tbody>
<tr>
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<tr>
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<td></td>
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<td>Age (years)</td>
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<td>&lt;20</td>
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<tr>
<td>20-24</td>
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<td>25-29</td>
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<td>&gt;35</td>
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<tr>
<td>Primary</td>
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<td>Secondary and above</td>
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<tr>
<td>3-4</td>
<td></td>
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</tr>
<tr>
<td>5+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple gestation pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single gestation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Place of delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home with health worker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health post</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health centre</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants secondary outcome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No of health workers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health extension worker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical nurse/midwife</td>
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<tr>
<td>Number of deliveries last month</td>
<td>1-5</td>
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</table>
Primary outcome

Table: Primary outcome: perinatal mortality, descriptives

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention</th>
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<th>Total</th>
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<tbody>
<tr>
<td>Primary outcome</td>
<td>n</td>
<td>n</td>
<td>n</td>
</tr>
<tr>
<td>Total births</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Live birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Still birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perinatal deaths</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Still birth rate (per 1000 births)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perinatal mortality rate (per 1000 births)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table: Primary outcome: perinatal mortality

Subjects
All children randomised will be analysed according to randomisation group.

Observation period
Inclusion – one week of age. Censoring first of migration, one week of age, death

Time scale
Time since randomization

Stratification
Randomisation was stratified by health facility. The analyses will take the clustering into account

Draft SPSS

Interaction
Intervention*background variables

Secondary outcomes

Table: Secondary outcomes: health workers knowledge and skills scores at 0, 6 and 12 months, descriptives

<table>
<thead>
<tr>
<th>Secondary outcome</th>
<th>Mean (SD)</th>
<th>Mean (SD)</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skills score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td></td>
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<tr>
<td>12 months</td>
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<td></td>
</tr>
<tr>
<td>Knowledge score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table: Secondary outcomes: mean difference of knowledge and skill scores at 6 and 12 months

<table>
<thead>
<tr>
<th>Subjects</th>
<th>All health workers randomised will be analysed according to randomisation group.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation period</td>
<td>Inclusion– 12 months after randomization. Censoring first of migration, death</td>
</tr>
<tr>
<td>Time scale</td>
<td>Time since randomization</td>
</tr>
<tr>
<td>Stratification</td>
<td>Randomisation was stratified by health facility. The analyses will take the clustering into account</td>
</tr>
<tr>
<td>Draft SPSS</td>
<td>Mixed models – linar - HF subject variables, study id within subject variables – skills and knowledge scores at 6 and 12 months respectively (two separate analysis) – covariate skills and knowledge scores at 0 months – intervention status fixed effects</td>
</tr>
</tbody>
</table>

**Significance level**

A significance level of 5% is used and 95% confidence intervals are calculated.

Analyses will be performed based on the “intention to treat” principle and all available data included in the analysis
## Appendix 6: Work plan

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
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<tbody>
<tr>
<td></td>
<td>3</td>
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<tr>
<td>General</td>
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<td>Protocol</td>
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<tr>
<td>Ethical permission</td>
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<td>Clinicaltrials.gov</td>
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<tr>
<td>1. Application</td>
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<tr>
<td>Development of app</td>
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<tr>
<td>Pilot of app in Ethiopia</td>
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<tr>
<td>2. Validation of tools</td>
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<td></td>
</tr>
<tr>
<td>Development OSATS &amp; KFQ</td>
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<tr>
<td>Delphi group review</td>
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<tr>
<td>Validation in Ethiopia</td>
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<tr>
<td>Scoring+finalization</td>
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<tr>
<td>3. Assessment knowledge &amp; skills</td>
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<td></td>
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<tr>
<td>OSATS+KFQ 0 months</td>
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<td></td>
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<tr>
<td>OSATS+KFQ 6 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSATS+KFQ 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Assessment PPH &amp; perinatal mortality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development research forms</td>
<td>Pre-assessment of health facilities</td>
<td>Procurement (phones, equipment, drugs)</td>
</tr>
<tr>
<td>---------------------------</td>
<td>----------------------------------</td>
<td>--------------------------------------</td>
</tr>
</tbody>
</table>

**5. Use and perception**

<table>
<thead>
<tr>
<th>Use</th>
<th>Focus groups/key informant interviews</th>
</tr>
</thead>
</table>

**Dissemination**

| Analysis | Presentation of preliminary results | Writing of articles (continued in 2015) |