

# Prevention of Postpartum Hemorrhage in Rural Ethiopia.

## Full Report

This policy brief was prepared by the Technology Transfer and Research Translation Directorate at the Ethiopian Health and Research Institute (EHNRI).

FINAL: March 2012

### Who is this policy brief for?

Policymakers, their support staff, and people with an interest in the problem that this policy brief addresses

### Why was this policy brief prepared?

To **inform deliberations** about health policies and programmes by **summarizing the best available evidence** about the problem which it addresses and solutions to that problem

### This evidence-based policy brief includes:

- The description of a health system problem
- viable options for addressing this problem
- strategies to implementing these options

### Not included:

#### Recommendations

### Executive Summary

The evidence presented in this Full Report is summarized in an

### What is an evidence-based policy brief?

Evidence-based policy briefs bring together **global research evidence** (from systematic reviews\*) and **local evidence** to inform deliberations about health policies and programmes

### What is a systematic review?

\* A summary of studies addressing a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise the relevant research, and to collect and analyse data from this research

**Authors**

Mamuye Hadis, MSc, PhD

Ruffael Gebeyehu, MSc

Augna Woyessa, MSc

Technology Transfer and Research Translation Directorate, Ethiopian Health and Nutrition Research Institute.

**Corresponding author:**

Mamuye Hadis

SURE project focal person

Director, Technology Transfer and Research Translation Directorate,

Ethiopian Health and Nutrition Research Institute (EHNRI)

P.O.Box 5654, Addis Ababa,

Ethiopia

Email: [mamuyeh@ehnri.gove.et](mailto:mamuyeh@ehnri.gove.et) / [mamuye.hadis@gmail.com](mailto:mamuye.hadis@gmail.com)

**Suggested citation:**

Hadis M, Gebeyehu R and Woyessa A. Prevention of Postpartum Hemorrhage in Rural Ethiopia (SURE policy brief). Addis Ababa, Ethiopia: Technology Transfer and Research Translation Directorate, Ethiopian Health and Nutrition Research Institute, 2012.  
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## Key messages

### *The Problem:*

#### Lack of access to uterotonics to prevent PPH in rural Ethiopia

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Ethiopia's maternal mortality rate is among the highest in the world with 676 deaths per 100,000 live births. Postpartum hemorrhage (PPH) remains to be the leading cause of maternal mortality in developing countries like Ethiopia. The problem is worse in the rural setting where there are not proper facilities and trained health workers to administer injectable uterotonics, which are the standard treatment for PPH. Using community health (health extension) workers (HEWs) or traditional birth attendants (TBAs) trained in the use of easier- to-use technologies could prevent PPH in rural Ethiopia.

### *Policy options:*

1/ Community-based delivery of misoprostol by HEWs or TBAs trained in its use

2/ Delivery of oxytocin in Uniject™ injection by HEWs or TBAs trained in its use

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Community-based delivery of misoprostol or oxytocin in Uniject™ by HEWs or TBAs trained in its use may help reduce PPH in rural Ethiopia.

- The current available evidence suggests that the first option is cheaper than the second option
- Given the limitations of the currently available evidence, rigorous evaluation and monitoring is warranted for both options

### *Implementation strategies:*

A combination of strategies is likely needed to effectively implements either option

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- A clear policy is imperative to ensure proper training and safe use of misoprostol by HEWs and TBAs.
- A clear policy that allows community health workers (HEWs or TBAs) to administer oxytocin injections is needed.

## Executive summary

### The Problem

As in many African countries PPH is a serious problem in rural Ethiopia. Reaching rural mothers through Health Extension Workers and/or Traditional Birth Attendants by using appropriate technologies like misoprostol and oxytocin in Uniject™ could address this problem. The objective of this policy brief is to summarize the best available evidence describing the problem and potential solutions for addressing the problem of PPH in rural Ethiopia where there are no health care facilities and skilled attendants.

### Size of the problem

Ethiopia's maternal mortality rate is among the highest in the world with 676 deaths per 100,000 live births which is far from the MDG 5 target for the country, 218 per 100,000. It is estimated that 90% of births in Ethiopia occur at home. Ten percent of maternal deaths in Ethiopia are attributed to PPH. However, this figure is much lower than the African average, 33.9% and could be due to under-diagnosis or under reporting, given the poor infrastructure and very low ratio of health professionals to the public prevailing in Ethiopia. Some unpublished documents claim PPH contributes 25-30% of maternal deaths in Ethiopia. Considering the big size of the country figures concerning PPH might not be representative of the whole country.

### Factors underlying the problem

Ethiopia is one of the 57 countries in the world with a very critical shortage of health workers (GHWA, 2008). For instance, there are only two physicians and 39 health workers per 100,000 people. The ratio of key health professionals working closer to the community, midwives and nurses, is very low, one per 74,086 and one per 4,250 people, respectively, leaving mothers without skilled assistance during child birth.

Only 6 percent of births are delivered with the assistance of a trained health professional, that is, a doctor, nurse, or midwife, and 28 percent are delivered by a traditional birth attendant. The majority of births are attended by a relative or some other person (61 percent). Five percent of all births are delivered without any type of assistance at all. The preference of Ethiopian mothers to deliver at home rather than at a health facility is the most important underlying cause of maternal mortality in Ethiopia.

Low awareness of danger signs and symptoms during pregnancy, labor, delivery and post-partum contribute to delays in seeking and receiving skilled care. Poverty discourages pregnant women from investing in skilled prenatal care, delivery assistance or postnatal care.

Public facilities face chronic shortages of supplies and equipment for obstetric care due to insufficient budget and poor management skills. Existing Ministry policies constrain the delivery of key emergency obstetric care by mid-level personnel (midwives and health officers) regardless of the fact that they make the majority of the health centre staff.

With Ethiopia's road network amongst the worst in the world, and too few ambulances, the majority of the rural dwellers (83.9 % of the total population) are left isolated with little or no access to a health facility.

Like most African countries anaemia is a severe problem both for pregnant (62.7%) and non-pregnant women of child bearing age (52.3%) exacerbating the problem of PPH as 12% of survivors of PPH suffer

from severe anaemia. In Ethiopia, blood transfusion is the least available service in district hospitals, worsening the consequences of PPH in the country.

## **Policy options**

Two options are proposed to prevent or treat PPH in rural Ethiopia. They are

- 1/ Community-based delivery of misoprostol by HEWs or TBAs trained in its use
- 2/ Delivery of oxytocin in Uniject™ injection by HEWs or TBAs trained in its use

The options are described below, including the advantages, disadvantages, and acceptability of each option.

Though there is agreement on benefits of active management of the third stage of labour for prevention of PPH, there is no consensus on the importance of individual components of this intervention particularly on choice of uterotonics. There are views which question the safety of misoprostol, especially when administered by community health workers, while others consider misoprostol to be the only option for mothers in poor rural settings. Though oxytocin is the drug of choice to prevent PPH its stability and need for skilled personnel for injection are concerns, among others.

The current available evidence suggests that the first option is cheaper than the second option.

### *Policy option 1:*

## **Community-based delivery of misoprostol by HEWs or TBAs trained in its use**

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### **Benefits**

Benefits from this intervention may include reduced:

- PPH morbidity due to PPH
- Need for additional uterotonics
- PPH related referrals

### **Advantages**

- Addresses home births (mothers in remote areas where there is no other uterotonic available can have access to the drug)
- Ease of use
- Relatively cheap
- Stable (no need for a cold chain)

### **Disadvantages**

- Can be used for purposes other than for PPH
- Has adverse effects like shivering and fever
- Limited data on its direct impact on maternal mortality
- Slightly less effective than oxytocin

### **Acceptability**

The acceptability of this option by policy makers is very high.

## *Policy option 2:*

### **Delivery of oxytocin in Uniject™ injection by HEWs or TBAs Trained in Its use**

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#### ***Benefits***

- Reduced PPH morbidity due to PPH
- Can be used for home births in remote areas
- Can be used by less trained health workers trained in its use
- Ensures that the loaded syringe is available within one minute after birth of the baby

#### ***Advantages***

- Slightly more effective than misoprostol
- Fewer side effects
- Ensures correct dose and sterility

#### ***Disadvantages***

- Relatively expensive
- Less stable in warmer areas
- Need skill for injection (more difficult to administer than misoprostol)
- Limited commercial availability

#### ***Acceptability***

- This option could be acceptable, as oxytocin is the standard treatment for PPH. However the cost and the involvement of injection could compromise its acceptability.
- The fact that the majority of Ethiopians (89.1%) live on highlands where the temperature is below 20°C, a temperature at which oxytocin is stable for around two years, might increase its acceptability.

#### **Implementation considerations**

Preventing PPH in rural Ethiopia through distribution of misoprostol or oxytocin in Uniject using HEWs or TBAs are two potential solutions that may be more feasible to scale up rapidly, in contrast to improving access to skilled birth attendance at well-equipped facilities. Implementing both options requires other changes, including policy changes. Strategies for implementing the options should take advantage of factors that enable their implementation as well as addressing barriers.

This policy brief was prepared upon the request of the Federal Ministry of Health of Ethiopia. Other enablers of prevention of PPH in rural Ethiopia include:

- Strong political commitment from the government for MCH care
- Major funding opportunities and public-private sector collaboration globally
- There are more than 30 thousand health extension workers who work at the grass root level who can be used for both options
- A number of global and local partners and civil society organizations work on prevention of PPH.

- The number of skilled health workers is on the rise in Ethiopia

Key barriers to implementing the policy options and implementation strategies to address these are summarized in the table below.

**Table 1. Implementation considerations for option 1**

Barriers	Description	Strategies for implementation
Misuse of misoprostol	Can be used outside the intended purpose (PPH): for labor induction and intrauterine fetal death (IUFD) which could result in uterin rapture when taken in high incorrect doses	Develop clinical protocols for misoprostol use for PPH prevention and treatment, for labor induction and IUFD.
Inadequate logistics	Poor road infrastructure, and poor setting for procurement in remote areas	Use experiences for vaccination programs
Financial constraints	Training HEWs and TBAs, cost of drug, procurement, and coordination incur additional costs.	-Resources mobilisation through coordination of governmental and non-governmental organizations -Establishing rural community-based health insurance system -Innovative public-private partnership models (Prata et al., 2011)
Shortage of TBAs	Available number of TBAs is not adequate	Train and deploy more TBAs based on local need
Lack of institutional arrangements for TBAs	TBAs are outside public health systme	A new policy which includes TBAs in the country's health system
Burn-out of HEWs (Prata et al., 2011)	There are 16 health packages for two HEWs	Redesign of HEW programmes to ensure reasonable expectations of HEWs, adequate support and appropriate motivation, use additional human resources such as Community-based reproductive health agents (CBRHs)[Prata et al., 2011]
No direct evidence on its impact on mortality	There is scarcity of data on misoprostol's impact on mortality	include monitoring and evaluation components in pilot programes

**Table 2. Implementation consideration for option 2**

Barriers	Description	Strategies for implementation
Instability of oxytocin in warmer areas of the country	Oxytocin is not stable at temperatures above 30°C if not used for more than one year (PATH, 2004)	-Use the experience of cold chain management for immunization programmes to ensure a more stable environment for Uniject oxytocin™ (Mathai et al., 2007) in warmer part of the country.  -Using oxytocin in cooler parts of Ethiopia. Majority of Ethiopians, 89 % , live in altitudes above 1500 masl whose temperature is a maximum of around 20°C (Table) [Anonymous, 1991], a temperature which can keep oxytocin stable for around two years (PATH, 2004), reducing for the need of a cold chain in much of Ethiopia.
No policy allowing HEWs and TBAs to administer oxytocin injections	HEWs are allowed to provide only vaccines and injectable contraceptives (Prata et al.,2011).	Developing a new policy which allows community health workers to administer injections other than vaccines and injectable contraceptives (Task shifting policy) (Sutanto et al., 1990).  There are evidences which support community health workers can safely and effectively administer injections (WHO, 2009)
Waste management could be a problem	Used injection devices could pose significant potential risks for communities and the environment	West disposable issues must be planned and addressed adequately at the community level
Oxytocin in Unijects™ are not commercially available		Well designed field trials and followed by purchase agreement with companies
Burn-out of HEWs	There are 16 health packages for two HEWs	Redesign of HEW programmes to ensure reasonable expectations of HEWs, adequate support and appropriate motivation

## **Preface**

### **The purpose of this report**

The purpose of this report is to inform deliberations among policymakers and stakeholders. It summarises the best available evidence regarding prevention of postpartum hemorrhage in rural settings of developing countries by using available community health workers and easy to use technologies.

The report was prepared as a background document to be discussed at meetings of those engaged in prevention of postpartum hemorrhage in the rural setting and people with an interest in those policies (stakeholders). In addition, it is intended to inform other stakeholders and to engage them in deliberations about those policies. It is not intended to prescribe or proscribe specific options or implementation strategies. Rather, its purpose is to allow stakeholders to systematically and transparently consider the available evidence about the likely impacts of different options for prevention of postpartum hemorrhage in rural Ethiopia.

### **How this report is structured**

The executive summary of this report provides key messages and summarises each section of the full report. Although this entails some replication of information, the summary addresses the concern that not everyone for whom the report is intended will have time to read the full report.

### **How this report was prepared**

This policy brief brings together global research evidence (from systematic reviews) and local evidence to inform deliberations about prevention of postpartum hemorrhage in rural settings in low income countries. We searched for relevant evidence describing the problem, the impacts of options for addressing the problem, barriers to implementing those options, and implementation strategies to address those barriers. We searched particularly for relevant systematic reviews of the effects of policy options and implementation strategies. We supplemented information extracted from the included systematic reviews with information from other relevant studies and documents. (The methods used to prepare this report are described in more detail in Appendix 1.)

### ***Limitations of this report***

This policy brief is based largely on existing systematic reviews. For options where we did not find an up-to-date systematic review, we have attempted to fill in these gaps through other documents, through focused searches and personal contact with experts, and through external review of the report.

Summarising evidence requires judgements about what evidence to include, the quality of the evidence, how to interpret it and how to report it. While we have attempted to be transparent about these

judgements, this report inevitably includes judgements made by review authors and judgements made by ourselves.

### **Why we have focused on systematic reviews**

Systematic reviews of research evidence constitute a more appropriate source of research evidence for decision-making than the latest or most heavily publicized research study.<sup>i,ii</sup> By systematic reviews, we mean reviews of the research literature with an explicit question, an explicit description of the search strategy, an explicit statement about what types of research studies were included and excluded, a critical examination of the quality of the studies included in the review, and a critical and transparent process for interpreting the findings of the studies included in the review.

Systematic reviews have several advantages.<sup>iii</sup> Firstly, they reduce the risk of bias in selecting and interpreting the results of studies. Secondly, they reduce the risk of being misled by the play of chance in identifying studies for inclusion or the risk of focusing on a limited subset of relevant evidence. Thirdly, systematic reviews provide a critical appraisal of the available research and place individual studies or subgroups of studies in the context of all of the relevant evidence. Finally, they allow others to appraise critically the judgements made in selecting studies and the collection, analysis and interpretation of the results.

While practical experience and anecdotal evidence can also help to inform decisions, it is important to bear in mind the limitations of descriptions of success (or failures) in single instances. They can be useful for helping to understand a problem, but they do not provide reliable evidence of the most probable impacts of policy options.

### **Uncertainty does not imply indecisiveness or inaction**

Reviews included in this report conclude that there is “insufficient evidence”. Nonetheless, policymakers must make decisions. Uncertainty about the potential impacts of policy decisions does not mean that decisions and actions can or should not be taken. However, it does suggest the need for carefully planned monitoring and evaluation when policies are implemented.<sup>iv</sup>

“Both politically, in terms of being accountable to those who fund the system, and also ethically, in terms of making sure that you make the best use possible of available resources, evaluation is absolutely critical.”  
(Julio Frenk 2005, former Minister of Health, Mexico)<sup>v</sup>

## Glossary

CHWs-Community Health Workers

EHNRI-Ethiopian Health and Nutrition Research Institute

FCHV-Female Community Health Volunteers

HEW-Health Extension Workers

PATH-Program for Appropriate Technology in Health

SURE – Supporting the Use of Research Evidence (SURE) in African Health Systems ([www.evipnet.org/sure](http://www.evipnet.org/sure))

TBA-Traditional Birth Attendants

VSI- Venture Strategies Innovations

WHO-World Health Organization

## The problem

### Background

More than half a million women die each year from complications of pregnancy and child birth in the world and around 95% of these deaths occur in sub-Saharan Africa and Asia (WHO, 2003). Maternal mortality is about one hundred times higher in resource-poor countries than in resource-rich countries (Mousa and Alfirevic, 2007). Among the complications, post-partum haemorrhage (PPH) continues to be the leading cause of maternal mortality accounting for one-third of all maternal deaths. Ninety nine percent of these deaths occur in developing countries among women who give birth outside of health facilities (Abou Zhar & Ryston 1991). PPH is usually defined as blood loss of 500 ml or more and severe PPH as 1000ml or more in the third stage of labour (the period from delivery of the baby until the delivery of the placenta and its membranes) (Gulmezoglu et al., 2007).

Injectible oxytocin and ergot preparations are the standard treatments for PPH (Gulmezoglu, 2007). However, oxytocin requires trained personnel for safe administration, sterile equipment for injection and special storage (refrigeration) to maintain stability especially in tropical climates. These factors limit its safe and effective use in low-resource countries (Walraven et al., 2005; Miller et al., 2004) where most of the births take place at home. Hence, the need for alternative uterotonic, which is more stable, easy to administer, and convenient to distribute at community level. Misoprostol, a prostaglandin E1 analogue, presents a potential option in reaching mothers in low-income countries. Its availability in tablet form, its stability at ambient temperature, and its widespread availability and low cost make it attractive to reduce rate of PPH and maternal mortality in low-income countries (Miller et al., 2004; Norman et al., 1991).

Decreasing maternal mortality is a top priority for the Federal Ministry of Health of Ethiopia. Ethiopia has adopted international guidelines for Active Management of the Third Stage of Labour (AMTSL) to prevent PPH. Recognizing the problem of PPH in the rural area of Ethiopia the Federal Ministry of Health of Ethiopia is considering implementing use of misoprostol to prevent PPH at community level (VSI, 2010). It has also conducted a consultative meeting on implementation research questions regarding the impact of misoprostol at community level for PPH prevention through Health Extension Workers in May 2010. Finally the FMOH has also asked the Technology Transfer and Research Translation Directorate of the Ethiopian Health and Nutrition Research Institute to prepare a policy brief on prevention of PPH by using misoprostol at the community level through Health Extension Workers. Since using misoprostol to prevent PPH is rather a solution than a problem, the team working on the intended policy brief has clarified the problem and changed the topic to prevention of PPH in rural Ethiopia. This brief seeks to summarize the best available evidence and provide PPH prevention options with which to inform an explicit policy on PPH prevention in rural Ethiopia.

## Size of the problem

Ethiopia's maternal mortality rate is among the highest in the world with 676 deaths per 100,000 live births which is far from the MDG 5 target for the country, 218 per 100,000. It is estimated that 90% of births in Ethiopia occur at home (Central Statistics Agency & ORC Macro, 2011). Ten percent of maternal deaths in Ethiopia is attributed to PPH (Ministry of Health, 2006). However, this figure is much lower than the African average, 33.9% (Khan et al., 2006); and could be due to under-diagnosis and/or under reporting given the poor infrastructure and very low ratio of health professionals to the public prevailing in Ethiopia. Some unpublished documents claim PPH contributes 25-30% of maternal deaths in Ethiopia (POPPI, 2006). Considering the big size of country figures concerning PPH might not be representative of the whole country.

## Factors underlying the problem

Ethiopia is one of the 57 countries in the world with a very critical shortage of health workers (GHWA, 2008). For instance, there are only 1.98 physicians per 100,000 people and 0.39 health worker per thousand populations (AHWO, 2010). The ratio of key health professionals working closer to the community, midwives and nurses, is very low, 1:74,086 and 1:4,250 (AHWO, 2010), respectively, leaving mothers without skilled assistance during child birth.

Only 6 percent of births are delivered with the assistance of a trained health professional, that is, a doctor, nurse, or midwife, and 28 percent are delivered by a traditional birth attendant. The majority of births are attended by a relative or some other person (61 percent). Five percent of all births are delivered without any type of assistance at all (Central Statistics Authority and ORC Macro, 2006).

Low awareness of danger signs and symptoms during pregnancy, labor, delivery and post-partum contribute to delays in seeking and receiving skilled care. Poverty discourages pregnant women from investing in skilled prenatal care, delivery assistance or postnatal care (MOH, 2006)

Public facilities face chronic shortages of supplies and equipment for obstetric care due to insufficient budget and poor management skills. Existing Ministry policies constrain the delivery of key emergency obstetric care by mid-level personnel (midwives and health officers) regardless of the fact that they make the majority of the health centre staff (MOH, 2006).

With Ethiopia's road network amongst the worst in the world, and too few ambulances, majority of the rural dwellers (83.9 % of the total population) [Population Census Commission, 2008] are left isolated with little or no access to a health facility.

Like most African countries anaemia is a severe problem both for both pregnant (62.7%) and non-pregnant women of child bearing age (52.3%)( Haidar and Pobocik, 2009) exacerbating the problem of PPH as 12% survivors of PPH suffer from severe anaemia (Chapman et al., 2009). In Ethiopia, blood transfusion is the least available service in district hospitals worsening the possible outcomes of PPH in the country (USAID, 2005).

## Framing of the problem

The focus of this problem is prevention of PPH in rural Ethiopia. The Federal Ministry of Health of Ethiopia is considering community based distribution of misoprostol by Health Extension Workers to

prevent PPH in rural Ethiopia and asked a policy brief be prepared on the issue. However, it is important to clarify what the problem is that this solution is intended to address in order to ensure that appropriate options and implementation strategies are considered.

The primary problem that community-based distribution of misoprostol is intended to address is prevention of PPH in rural Ethiopia. Community based distribution of misoprostol by HEWs is just one strategy that could be used to address this problem. Thus it is important to explore if there are other options to address the problem of PPH in rural Ethiopia.

## Policy options

The National Reproductive Health Strategy of the Federal Ministry of Health of Ethiopia targets to reduce the existing maternal mortality rate, 676 deaths per 100,000 live births by at least one-third to meet the Millennium Development Goal number 5. One of the strategies of the Federal Ministry of Health of Ethiopia to address this problem is by delivering basic community-based maternal and neonatal services, most notably through Health Extension Workers (HEWs) and mid-level service providers (MOH, 2006). The introduction of a uterotonic at community level to reduce PPH could contribute to achieve the stated target since PPH contributes 10% of the maternal mortality. We propose two options for addressing the problem of PPH at community level in rural Ethiopia. The first one is distribution of misoprostol by HEWs and/or Traditional Birth Attendants (TBAs). The second option is administering uniject oxytocine by trained HEWs and/or TBAs. These two options are presumed to address the underlying problems of shortage of skilled manpower and a cold chain in the rural settings to administer oxytocin for PPH, as misoprostol does not need cold chain and is easy to administer and oxytocin in uniject is easy to use technology.

### **Policy option 1: Community-based delivery of misoprostol by HEWs and/or TBAs trained in its use**

Though there are controversies on the choice uterotonics (Misoprostol vs Oxytocin) with regard to PPH (Mathai et al., 2007) the World Health Organization (WHO, 2006) has endorsed the administration of oral misoprostol for PPH prevention by unskilled providers 'trained in its use in settings where active management of the third stage of labour' (AMTSL) is not practised' in its guidelines on prevention of PPH. International Confederation of Midwives and the International Federation of Gynaecology and Obstetrics states that : 'In home births without a skilled attendant, misoprostol may be the only technology available to control PPH (ICM & FIGO, 2007). More than a dozen countries including Ethiopia have also approved the registration of misoprostol to prevent PPH (Fernandez et al., 2009).

## Current use in Ethiopia

According to Venture Strategies Innovations (VSI), misoprostol is being distributed throughout hospitals and clinics in Ethiopia for the prevention and treatment of post-partum haemorrhage. Around 7000 health workers including 1100 Health Extension Workers are trained in the use of misoprostol to prevent PPH (VSI, 2011). According to experts in the Ministry of Health, misoprostol is being used to prevent and treat PPH and induce labour at health post level. It is also being used for cervical ripening at hospital level and for abortion at health centre level and above. Oxytocin is used in hospitals to prevent PPH.

## Impacts of Misoprostol on PPH

A systematic review by Mousa and Alfirevic (2007) found two placebo-controlled randomised trials that compared different doses of misoprostol with placebo and found that (Table 1):

- Misoprostol reduces blood loss of 500 ml or more
- Misoprostol may reduce blood loss 1000 ml or more
- Misoprostol increases pyrexia

Table 1. Comparison of impact of Misoprostol versus placebo on PPH.

<b>Patient or population:</b> Patients with PPH <b>Settings:</b> South Africa (2004), Gambia (2004) <b>Intervention:</b> Misoprostol <b>Comparison:</b> Placebo				
Outcomes	Impacts	Number of participants (No. Of studies)	Risk ratio [95% CI]	Quality of the evidence
Bl ood loss 500 ml or more <sup>1</sup>	Misoprostol reduces blood loss	397 (2)	0.57 [0.34,0.96]	⊕⊕⊕⊕ <b>high</b>
Bl ood loss 1000 ml or more <sup>2</sup>	Misoprostol may reduce blood loss	397 (2)	0.65[0.17, 2.44]	⊕⊕○○ <b>low</b>
Maternal pyrexia <sup>1</sup>	Misoprostol increases the risk of pyrexia	392 (2)	6.4[1.71, 23.96]	⊕⊕⊕⊕ <b>high</b>
<sup>1</sup> from a support Summary by Chapman et 2009.  <sup>2</sup> a summary by one of the authors	*GRADE Working Group grades of evidence ⊕⊕⊕⊕ <b>High:</b> We are confident that the true effect lies close to what was found in the research. ⊕⊕○○ <b>Moderate:</b> The true effect is likely to be close to what was found, but there is a possibility that it is substantially different. ⊕○○○ <b>Low:</b> The true effect may be substantially different from what was found. ⊕○○○ <b>Very low:</b> We are very uncertain about the effect.			

## Impacts of community-based delivery of misoprostol by HEWs and/or TBAs trained in its use

There is no sufficient evidence with regard to safe use of misoprostol by community health workers to prevent PPH in rural settings. Inappropriate use of a powerful uterotonic like misoprostol can be associated with maternal and prenatal morbidity and/or mortality (Mathai et al., 2007).

However there are single studies which examined the use of community health workers in the distribution of misoprostol to prevent PPH. The following table summarizes some studies which used trained community health workers to distribute misoprostol to prevent PPH.

**Table 2. Single studies evaluating distribution of misoprostol by community health workers to prevent PPH.**

<b>Setting/Population/Intervention/Comparison</b>	<b>Type of Trained Community Health Worker</b>	<b>No. Of Participants</b>	<b>Impacts/Conclusions</b>
<b>Setting:</b> Rural Tigrai, Ethiopia, (Prata et al., 2009) <b>Population:</b> women giving birth at home <b>Intervention:</b> misoprostol <b>Comparison:</b> no misoprostol	TBAs	966	Misoprostol reduced cases referred for additional uterotonics by 50%  TBAs trained in misoprostol use can correctly administer misoprostol at the community level
<b>Setting:</b> Rural India (Derman et al., 2006) <b>Population:</b> women giving birth at primary health care <b>Intervention:</b> misoprostol <b>Comparison:</b> placebo	Auxiliary nurse midwives	1620	Significant reduction of PPH
<b>Setting:</b> Rural Banke, Nepal, (Rajbhandari, et al., 2010) <b>Population:</b> women given birth at home/ health facility <b>Intervention:</b> misoprostol <b>Comparison:</b> pre-and posintervention	FCHVs (Female Community Health Volunteers)		Reduced mortality: 72/100000 in misoprostol users vs 292/100000 among non users  safe and acceptable for community distribution
<b>Setting:</b> Rural Chitral, Pakistan (Mobeen et al., 2010) <b>Population:</b> Women giving birth at home <b>Intervention:</b> Misoprostol <b>Comparison:</b> Placebo	TBAs	1119	Reduces PPH by 24%  Can reduce PPH in community setting
<b>Setting:</b> Rural Gambia (Walraven et al., 2005)  <b>Population:</b> women giving birth at home <b>Intervention:</b> Misoprostol <b>Comparison:</b> Placebo	TBAs	1229	Reduction in PPH but not significant  Misoprostol promising in the rural setting
<b>Setting:</b> Rural Afghanistan, (Sanghvi et al., 2010) <b>Population:</b> Women giving birth at home <b>Intervention:</b> Misoprostol <b>Comparison:</b> No misoprostol	CHWs	3187	Community distribution of misoprotol is safe acceptable feasible and effective

## **Applicability, equity, costs, monitoring and evaluation**

### ***Applicability***

There is currently insufficient evidence that misoprostol can be safely used by community health workers providers in non facility setting. Inappropriate use of misoprostol , especially before child birth, can be associated with severe maternal and perinatal morbidity or death (Mathai et al, 2007). To date there is no direct evidence that shows postpartum misoprostol reduces maternal mortality ( Hofmeyr et al.,2011). A systematic review by Mousa and Alfrevic (2007) has concluded that more research is needed before misoprostol can be recommended as a first-line drug treatment; to be sure that maternal mortality is not increased.

### ***Equity***

When community health workers are used to distribute misoprostol, poor, illiterate mothers in remote areas will have access to the drug raising equity in medical care (Rajbhandari et al., 2010; Sanghvi et al., 2010; Prata et al., 2009; Mobeen et al., 2010; Walraven et al., 2005).

### ***Costs***

A cost-effectiveness analysis on a hypothetical cohorts of 10, 000 pregnant women delivering at home in rural India has shown that misoprostol is a cost-effective maternal mortality intervention for home births (Sutherland and Bishai, 2009).

However, there are contradictory reports regarding the cost of misoprostol when compared with oxytocin in ampoules or in unijects. According to Mathai et al. (2007), at programme level, oxytocin with disposable syringes and needles is currently less expensive to procure than misoprostol in the dose used for PPH prevention. Increased incidence of sever PPH, need for additional uterotonics in case of use of misoprostol when compared with oxytocin for prevention of PPH have significant programmatic implications, especially in settings where anaemia is common and access to emergency obstetrics care is limited (Mathai et al., 2007). On the other hand, according to PATH (2008a), the cost of misoprostol tablets is generally less expensive than oxytocin in a standard syringe. Oxytocin in Uniject are also more expensive than misoprostol according to a consensus statement issued by the participants in the meeting on 'The Role of Uterotonics in Reducing Postpartum Haemorrhage: What next?' The Hague, The Netherlands, 2011 (Anonymous, 2011).

### ***Monitoring and evaluation***

Since there is currently not sufficient evidence on safe use of misoprostol by community health workers (Mathai et al., 2007) future randomized controlled studies are required and should be large enough to assess maternal mortality and morbidity (Chapman et al.,2009).

## **Policy Option 2. Delivery of oxytocin in Uniject™ injection by Extension Health Workers and/or Traditional Birth Attendants**

Injectible oxytocin and ergot preparations are the standard treatments for PPH and evidences show that injectable uterotonic s are more effective than misoprostol in preventing both primary and sever PPH (Gulmezoglu et al., 2007).

Various studies have concluded that unijects™ have many advantages over the standard syringe both for care providers and recipients. Some of the advantages are (PATH, 2008b):

- Oxytocin in Uniject™ can be used for facility and home births
- Oxytocin i Uniject™ can be used by both highly trained and less trained health care providers
- Oxytocin in Uniject™ can be used for AMTSL or, where skilled birth attendants are not available, can be offered by a health worker trained in in itse use for prevention of PPH
- Oxytocin in Uniject™ can be used for management and treatment of PPH
- Oxytocin in Uniject™ can be used in areas of limited health facility infrastructure and or health worker shortages
- Oxytocin in Uniject™ ensures that the loaded syringe is available within one minute after birth of the baby

### Impacts of oxytocin on PPH

According to a systematic review by Gülmezoglu et al. (2007) there is moderate quality of evidence that injectable uterotonic s perform better than misoprostol.

**Table 3. Comparison of misoprostol versus injectable uterotonic s (Oxytocin, ergometrine-oxytocin, and ergometrine) on PPH. (Summary by one the authors)**

<b>Patient or population:</b> Women giving birth <b>Setting:</b> Ghana, India, Turkey, Australia, Canada, United Kingdom, WHO, Nigeria, Hong Kong, France, Belgium, Zimbabwe. <b>Intervention:</b> Misoprostol <b>Comparison:</b> Injectable Uterotonics				
Outcomes	Impacts	Number of participants (no. of studies)	Risk ratio [95% CI]	Quality of Evidence
Blood loss 1000ml or more	Injectable uterotonic s probably perform better than misoprostol	29042 (16)	1.32 (1.16, 1.51)	⊕⊕⊕○ Moderate
Blood loss 500ml or more	Injectable uterotonic s probably perform better than misoprostol	27931 (16)	??	⊕⊕⊕○ Moderate

Availing oxytocin as widely as possible is considered the primary aim for deliveries occurring outside hospitals at peripheral levels of the healthcare system or at home (Gülmezoglu, 2007; WHO, 2006).

However, oxytocin in conventional injection (ampoules and needles) requires trained personnel for safe administration, sterile equipment for injection and special storage (refrigeration) to maintain stability especially in tropical climates in remote areas in low income countries. To address some of these problems and overcome the challenges facing immunization programs, using new technologies that deliver medications more easily and accurately in remote settings such as that of disposable prefilled syringes e.g. Uniject are being suggested (PATH, 2005).

### Current use in Ethiopia

There are no data on use of oxytocin in Uniject™ by community health workers to prevent PPH in Ethiopia. However, there are reports and studies which concluded that community-based health workers can safely and effectively administer injectable contraceptives (Prata et al., 2011; WHO, 2009). In Ethiopia HEWs do provide injectable contraceptives using standard syringes (Prata et al., 2011) and vaccines using auto disposable syringes (Hoekstra et al., 2011).

### **Impacts of Delivery of oxytocin in Uniject™ injection by HEWs and/or TBAs trained in its use**

The World Health Organization estimates about 75% of injections given in some countries with syringes or needles are reused without sterilization raising the risk of transmitting blood born diseases (Hauri et al., 2004). The Uniject™ device is a prefilled, non-reusable syringe, which ensures an accurate dose in a sterile device with minimal preparation and minimum waste (PATH, 2010). Besides its easy to use nature allows use by health workers who do not normally give injections such as trained community health workers and auxiliary nurses (PATHb, 2008). This easy to use feature of the Uniject™ may greatly help births which occur out of health facilities or for homebirths. The introduction of Time-temperature Indicators (TTI) as part of the oxytocin Uniject™ enables providers to immediately determine if oxytocin has been exposed to heat levels that will reduce its efficacy therefore facilitates outreach by making oxytocin in Uniject™ available for home births or in facilities that have no cold chain available (PATH, 2008b).

Some studies have evaluated the acceptability of using the Uniject™ device to deliver vaccines and drugs in difficult scenarios by community health workers. The following table summarizes evaluations of the Uniject™ device when used by community health workers both for oxytocin and vaccines in Unijects™.

**Table4. Studies on use of oxytocin in Uniject™ by community health workers to prevent PPH**

<b>Drug/Vaccine</b>	<b>Country</b>	<b>Care provider/setting</b>	<b>Impacts and conclusions</b>
Oxytocin	Mali (PATH, 2008c)	Auxiliary midwives / Health Centres	PPH outcome not significantly different from oxytocin in ampoules, Easy to use, less time to train providers, providers easily evaluated whether the drug was exposed to extreme heat or not due to TTI attached to the Uniject™.
Oxytocin	Indonesia (Tsu et al., 2003)	Village Midwives/home births	PPH not significantly different when compared with Oxytocin in Ampoules, Easy to use, Unijects™ preferred than standard syringes
Tetanus Toxoid	Bolivia (Quiroga et al., 1998)	Traditional Birth Attendants/home births	Hi acceptability, reduced vaccine wastage
Hepatitis B Vaccine	Indonesia (Sutanto et al., 1999)	Village midwives/home births	Proper use of Uniject™, higher acceptability of the Uniject™ both by providers and recipients

### **Applicability, cost, equity, monitoring and evaluation**

#### **Applicability**

There are only two studies which evaluated the use of oxytocin in Uniject™ by trained community health workers in Mali ( PATH, 2008c) and Indonesia (Tsu et al., 2003 ), which concluded that they are more convenient to use by trained community health workers. Hence the need for piloting the use of oxytocin in Uniject™ to determine settings which are optimal and to identify challenges that need to be addressed prior to widespread introduction (PATH, 2008a)

#### **Cost**

Is addressed in the first option.

### *Equity*

Use of oxytocin in™s in the rural area potentially reduces inequities.

### *Monitoring and Evaluation*

Since there is currently no sufficient evidence on use of oxytocin in Unijects™ for prevention of PPH by community health workers in rural settings future pilot studies and monitoring and evaluations are required.

## **Implementation considerations**

Preventing PPH in rural Ethiopia through distribution of misoprostol or oxytocin in Uniject using HEWs or TBAs are two potential solutions that may be more feasible to scale up rapidly, in contrast to improving access to skilled birth attendance at well-equipped facilities. Implementing both options requires other changes, including policy changes. Strategies for implementing the options should take advantage of factors that enable their implementation as well as addressing barriers.

This policy brief was prepared upon the request of the Federal Ministry of Health of Ethiopia. Other enablers of prevention of PPH in rural Ethiopia include:

- Strong political commitment from the government for MCH care
- Major funding opportunities and public-private sector collaboration globally
- There are more than 30 thousand health extension workers who work at the grass root level who can be used for both options
- A number of global and local partners and civil society organizations work on prevention of PPH.
- The number of skilled health workers is on the rise in Ethiopia

## Option 1: Community-based delivery of misoprostol by HEWs and/or TBAs trained in its use

Table 6. Barriers to the use of HEWs and TBAs to distribute misoprostol at community level.

Barriers	Description	Strategies for implementation
Misuse of misoprostol	Can be used outside the intended purpose (PPH): for labor induction and intrauterine fetal death (IUFD) which could result in uterine rupture when taken in high incorrect doses	Develop clinical protocols for misoprostol use for PPH prevention and treatment, for labor induction and IUFD.
Inadequate logistics	Poor road infrastructure, and poor setting for procurement in remote areas	Use experiences for vaccination programs
Financial constraints	Training HEWs and TBAs, cost of drug, procurement, and coordination incur additional costs.	-Resources mobilisation through coordination of governmental and non-governmental organizations -Establishing rural community-based health insurance system -Innovative public-private partnership models (Prata et al., 2011)
Shortage of TBAs	Available number of TBAs is not adequate	Train and deploy more TBAs based on local need
Lack of institutional arrangements for TBAs	TBAs are outside the public health system	A new policy which includes TBAs in the country's public health system
Burn-out of HEWs (Prata et al., 2011)	There are 16 health packages for two HEWs	Redesign of HEW programmes to ensure reasonable expectations of HEWs, adequate support and appropriate motivation, use additional human resources such as Community-based reproductive health agents (CBRHs)[Prata et al., 2011]
No direct evidence on its impact on mortality	There is scarcity of data on misoprostol's impact on mortality	include monitoring and evaluation components in pilot programmes

## Option 2: Delivery of oxytocin in Uniject™ injection by HEWs and/or TBAs

Table 7. Barriers to the use of HEWs and TBAs to administer oxytocin in Uniject™ at the community level

Barriers	Description	Strategies for implementation
Instability of oxytocin in warmer areas of the country	Oxytocin is not stable at temperatures above 30°C if not used for more than one year (PATH, 2004)	<p>-Use the experience of cold chain management for immunization programmes to ensure a more stable environment for Uniject oxytocin™ (Mathai et al., 2007) in warmer part of the country.</p> <p>-Using oxytocin in cooler parts of Ethiopia. Majority of Ethiopians, 89 % , live in altitudes above 1500 masl whose temperature is a maximum of around 20°C (Appendix 2) [Anonymous, 1991], a temperature which can keep oxytocin stable for around two years (PATH, 2004), reducing for the need of a cold chain in much of Ethiopia.</p>
No policy allowing HEWs and TBAs to administer oxytocin injections	HEWs are allowed to provide only vaccines and injectable contraceptives (Prata et al.,2011).	<p>Developing a new policy which allows community health workers to administer injections other than vaccines and injectable contraceptives (Task shifting policy) (Sutanto et al., 1990).</p> <p>There are evidences which support community health workers can safely and effectively administer injections (WHO, 2009)</p>
Lack of skilled manpower to administer injections	Ethiopia has a critical shortage of skilled health workforce (AHWO, 2010). HEWs are allowed to provide only vaccines and injectable contraceptives (Prata et al.,2011).	<p>Developing a new policy which allows community health workers to administer injections other than vaccines and injectable contraceptives (Task shifting policy) (Sutanto et al., 1990).</p> <p>There are evidences which support community health</p>

		workers can safely and effectively administer injections (WHO, 2009)
Waste management could be a problem	Used injection devices could pose significant potential risks for communities and the environment	Waste disposal issues must be planned and addressed adequately at the community level
Oxytocin in Unijects™ are not commercially available		Well designed field trials and followed by purchase agreement with companies
Burn-out of HEWs	There are 16 health packages for two HEWs	Redesign of HEW programmes to ensure reasonable expectations of HEWs, adequate support and appropriate motivation
Shortage of TBAs	Available number of TBAs is not adequate	Train and deploy more TBAs based on local need
Shortage of TBAs	Available number of TBAs is not adequate	Train and deploy more TBAs based on local need

## Next steps

The aim of this policy brief is to foster dialogue and judgements that are informed by the best available evidence. The intention is *not* to advocate specific options or close off discussion. Further actions will flow from the deliberations that the policy brief is intended to inform. These might include:

- Careful consideration of the need for community-based delivery of misoprostol by HEWs and/ or TBAs to prevent PPH in rural Ethiopia.
- Careful consideration of the need for community-based delivery of oxytocin in Uniject by HEWs and/ or TBAs to prevent PPH in rural Ethiopia.
- Consideration of research parallel to implementation of misoprostol and oxytocin in Uniject programs which can address safety/efficacy at the community level
- Monitoring and evaluation of the suggested policy options and implementation strategies
- Consideration of developing simple and concise guidelines

However, we are not prescribing these policy options as the only available means to the ministry of health. But we are trying to put these available options to consider in that sense.

## Contributions of authors

All of the authors contributed to the policy brief.

## Competing interests

None known

## Acknowledgements

This policy brief was prepared with support from the “Supporting the use of research evidence (SURE) for policy in African health systems project. SURE is funded by the European Commission’s Seventh Framework Programme (Grant agreement number 222881). The funder did not have a role in drafting, revising or approving the content of the policy brief. Andy Oxman, principal investigator of the SURE project, guided the preparation of the policy brief. Susan Munabi-Babigumira has also enriched the manuscript through her invaluable comments.

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## Appendices

### Appendix 1. How this policy brief was prepared

The methods used to prepare this policy brief are described in detail elsewhere.<sup>vi,vii,viii...</sup>

The problem that the policy brief addresses was clarified iteratively through discussion among the authors, review of relevant documents and research. Research describing the size and causes of the problem was identified by reviewing government documents, routinely collected data, searching PubMed and Google Scholar, through contact with key informants, and by reviewing the reference lists of relevant documents that were retrieved.

Strategies used to identify potential options to address the problem included considering interventions described in systematic reviews and other relevant documents, considering ways in which other jurisdictions have addressed the problem, consulting key informants and brainstorming.

We searched electronic databases of systematic reviews, including: the Cochrane Library (CENTRAL, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects) and supplemented these searches by checking the reference lists of relevant policy documents and with focused searches using PubMed, Google Scholar, and personal contacts to identify systematic reviews for specific topics. The final selection of reviews for inclusion was based on a consensus of the authors.

One of the authors extracted the key findings of each review, assessed the quality of the evidence, and summarised important information regarding the interventions, participants, settings and outcomes; and considerations of applicability, equity, economic consequences, and the need for monitoring and evaluation. The quality of the evidence was assessed based on the GRADE approach and the key findings were expressed consistently so as to reflect the quality of evidence, using the approach developed for Cochrane plain language summaries.<sup>vii</sup>

Potential barriers to implementing the policy options were identified by brainstorming using a detailed checklist of potential barriers to implementing health policies. Implementation strategies that address identified barriers were identified by brainstorming and reviewing relevant documents. Systematic reviews of relevant implementation strategies were identified using the databases listed above for finding reviews of the policy options.

Drafts of each section of the report were discussed with the SURE Project team based at the Norwegian Knowledge Centre for the Health Services. External review of a draft version was managed by the Norwegian Knowledge Centre for the Health Services. Comments provided by the external reviewers and the authors' responses are available from the authors. A list of the people who provided comments or contributed to this policy brief in other ways is provided in the acknowledgements.

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## Appendix 2. Distribution of the Ethiopian Population with respect to altitude and temperature.

Majority of Ethiopians, 89 % , live in altitudes above 1500 masl whose temperature is a maximum of around 20°C (Table) [Anonymous, 1991], a temperature which can keep oxytocin stable for around two years (PATH, 2004), reducing for the need of a cold chain in much of Ethiopia. The following table displays distribution of the Ethiopian population by altitude and temperature:

<b>Altitude, climate and population in Ethiopia</b>			
Climatic regions	Altitude	Temperature	% population
Dega (Cool to cold temperature)	>2500 masl	10°C-16°C	89%
Weina Dega (Warm to cool temperature)	1500-2500 masl	16°C-20°C	
Kolla (Warm to hot temperature)	500-1500masl	20°C-30°C	11%
Bereha (Hot and arid climate)	<500masl	>30°C	