Reducing deaths due to postpartum haemorrhage in homebirths in Zambia

Full Report

Included:
- Description of a health system problem
- Viable options for addressing this problem
- Strategies for implementing these options

Not included: recommendations
This policy brief does not make recommendations regarding which policy option to choose

Who is this policy brief for?
Policymakers, their support staff, and other stakeholders with an interest in the problem addressed by this policy brief

Why was this policy brief prepared?
To inform deliberations about health policies and programmes by summarizing the best available evidence about the problem and viable solutions

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

*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

Executive Summary
The evidence presented in this Full Report is summarized in an Executive Summary

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ZAMFOHR - The Zambia Forum for Health Research is a Knowledge Translation institution that aims to promote evidence-informed decision-making among researchers and research users. It is not a funder of research but rather an institution designed to bring together the key producers and users of knowledge, serving researchers, institutes, the Ministry of Health, Cooperating Partners, practitioners and civil society. www.zamfohr.org

Republic of Zambia Ministry of Health - Ministry of Health, Zambia is the government ministry charged with administering the health system in Zambia. The Ministry’s work is driven by its vision to provide the people of Zambia with equity of access to cost-effective, quality healthcare as close to the family as possible. www.moh.gov.zm

SURE – Supporting the Use of Research Evidence (SURE) for Policy in African Health Systems – is a collaborative project that builds on and supports the Evidence-Informed Policy Network (EVIPNet) in Africa and the Regional East African Community Health (REACH) Policy Initiative. SURE is funded by the European Commission’s 7th Framework Programme. www.evipnet.org/sure

Alliance - The Alliance for Health Policy and Systems Research. The Alliance's overall goal promoting the generation and use of health policy and systems research (HPSR) as a means to improve health and health systems in developing countries.

ReproNet-Africa – The African Network for Research and Training in Sexual and Reproductive Health and HIV acts as an umbrella Regional network linking, coordinating, and strengthening existing reproductive health research and training institutions for the purpose of improving the RH status in Africa. www.repronet-africa.org

The Evidence-Informed Policy Network (EVIPNet) promotes the use of health research in policymaking. Focusing on low and middle-income countries, EVIPNet promotes partnerships at the country level between policymakers, researchers and civil society in order to facilitate policy development and implementation through the use of the best scientific evidence available. www.evipnet.org

The Canadian Coalition for Global Health Research (the CCGHR or “the Coalition”) is a network of people committed to promoting better and more equitable health worldwide through the production and use of knowledge. To achieve this vision, the Coalition networks, facilitates, coordinates and strengthens capacity with the ultimate aim of advancing equitable solutions to priority health challenges worldwide. www.ccghr.ca
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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 community-based prevention of postpartum haemorrhage in Zambia.

The report was prepared as a background document to be discussed at meetings of those engaged in developing policies for community-based prevention of postpartum haemorrhage 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 community-based prevention of postpartum haemorrhage.

*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 preventing postpartum haemorrhage at community level in Zambia. 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. 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. 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

Many of the systematic 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.

“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)
The problem

Background

Postpartum haemorrhage or excessive bleeding after childbirth is the leading cause of maternal deaths in Zambia.\textsuperscript{6-7} PPH is defined as any blood loss that causes a physiological change such as low blood pressure that threatens the woman’s life.\textsuperscript{8,17} In rural areas PPH is identified when two blood soaked ‘chitenges’ are observed at delivery. A ‘chitenge’ is a locally produced, sold and pre-cut (standard-sized rectangle of approximately 100 cm x 155 cm) cotton fabric.\textsuperscript{6,14} Although the maternal mortality ratio (MMR) has declined from 729 deaths per 100,000 live births in 2002 to 591 deaths per 100,000 live births in 2007, it is still far from the targeted fifth Millennium Development Goal (MDG 5) of 162 deaths per 100,000 live births.\textsuperscript{18}

A crucial constraint to PPH prevention is that a large number of women deliver at home without skilled care.\textsuperscript{1} Current evidence has revealed that less than 30 percent of women deliver in a health facility while 70 percent deliver at home without a skilled birth attendant (SBA) and only a traditional birth attendant (TBA) or relative who is incapable of managing pregnancy related complications should they occur. Although the majority of PPH related deaths occur in women who deliver away from health facilities a large number of deaths also occur in facilities that are either under equipped or lack adequately skilled staff.\textsuperscript{6,9,10} The Ministry of Health strongly discourages home births and emphatically advocates that all pregnant women deliver in health facilities in the presence of an SBA. The decision to seek obstetric care for many women particularly in rural areas is a complex one and is influenced by several factors such as the husband’s approval and distance to the health facility.\textsuperscript{10} For those women who are unable to get to the health facility, for whatever reason, in time to deliver, life-saving interventions like the active management of the third stage of labour (AMTSL) for prevention of postpartum haemorrhage are out of their reach.\textsuperscript{10}

Recent evidence indicates that between 60 percent and 80 percent of PPH cases could be prevented if all women have easy access to skilled care.\textsuperscript{1,12} Efforts to reduce maternal deaths due to PPH in Zambia have focused on two crucial approaches including: training and deploying SBAs; and improving access to EmOC facilities.\textsuperscript{26} Although these strategies have been shown to improve maternal outcomes they often profit women in urban areas more than those in rural areas. This is because these programs are not adequately scaled up to reach women living in remote areas of Zambia where women tend to be illiterate and have minimal exposure to mass media through which numerous public health campaigns are conducted. However the World Health Organisation reports that coverage of effective prenatal care, skilled birth attendance, institutional delivery and emergency obstetric care (EmOC) is less than 50 percent. Due to local conditions described below, increasing the number of skilled birth attendants, equipment etc will not happen now. For this reason in order to provide a certain level of protection from PPH to all women in the event they are unable to deliver in a health facility, advance distribution of misoprostol, a simple tablet, to pregnant women might provide a temporary solution for the prevention of PPH.

Skilled care can be defined as ‘the presence of a skilled attendant and other key professionals supported by an appropriate environment including policy support, access to basic supplies, drugs, transport and relevant emergency obstetric and newborn services for timely management of complications’.\textsuperscript{9}
The decision to focus this policy brief on reducing maternal deaths due to postpartum haemorrhage (PPH) or excessive bleeding after delivery in home births was arrived upon through an explicit priority-setting exercise hosted by the Zambia Forum for Health Research (ZAMFOHR).

The majority of maternal deaths are due to excessive bleeding after delivery or postpartum haemorrhage (PPH). Common causes of PPH include failure of the uterus to contract adequately after birth leading to atonic PPH, tears of the genital tract leading to traumatic PPH and bleeding due to retention of placental tissue.

Size of the problem
As earlier mentioned, PPH is responsible for the majority of maternal deaths in Zambia many of which occur in women who deliver without skilled care either at home, on the way to a health facility or in facilities that lack the most basic Emergency Obstetric Care (EmOC) equipment and adequately skilled attendants. Recent reports show that over 53 percent of women in Zambia deliver without skilled care. More specifically, 20 percent of women in urban areas and up to 70 percent of women in rural areas deliver away from a health facility with either a traditional birth attendant or a relative.

Unfortunately, there is no national statistical evidence indicating the actual burden of disease due to PPH within specific provinces or districts in Zambia. However, available evidence shows that when compared to other causes of maternal deaths such as obstructed labour, hypertensive disorders and unsafe abortions, PPH alone accounts for 25 percent (Table 1).

Table 1. Comparison of Causes of Maternal Deaths

<table>
<thead>
<tr>
<th>Cause of death</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postpartum haemorrhage</td>
<td>25%</td>
</tr>
<tr>
<td>Sepsis</td>
<td>15%</td>
</tr>
<tr>
<td>Unsafe abortions</td>
<td>13%</td>
</tr>
<tr>
<td>Eclampsia</td>
<td>13%</td>
</tr>
<tr>
<td>Obstructed labour</td>
<td>7%</td>
</tr>
<tr>
<td>Other direct</td>
<td>8%</td>
</tr>
<tr>
<td>Other indirect</td>
<td>19%</td>
</tr>
</tbody>
</table>

Source: Khan et al. 2006. Comparison of the size of PPH to other causes of maternal deaths

Regionally, the proportion of deaths due to PPH in Zambia is mirrored in many other sub-Saharan African countries for instance Tanzania (23 percent), Zimbabwe (19 percent), Burkina Faso (59 percent), Ivory Coast (37 percent), and Guinea (43 percent).

PPH occurs without warning and kills rapidly
PPH may also be defined as excessive bleeding of over 500 ml, the risk of death is increased by the health status of the woman in labour which has a bearing on the amount of blood loss that will endanger her life. PPH occurs without warning and may be classified as early PPH when it occurs within the first 24 hours after delivery or late PPH when it occurs after 24 hours but before 6 weeks after delivery. Regardless of whether PPH is torrential or rapid it is
complicated further by anaemia, malaria or HIV/AIDS. In the absence of adequately skilled attendants that can provide appropriate and timely lifesaving interventions, a healthy pregnant woman can die within 2 hours of the onset of PPH. Table 2 shows a comparison of the different pregnancy related complications and the time that elapses from onset to death.\textsuperscript{21, 22}

\begin{table}[h]
\centering
\begin{tabular}{|l|l|}
\hline
\textbf{Complication} & \textbf{Time from onset to death} \\
\hline
Severe haemorrhage & 2 hours - 12 hours \\
Ruptured uterus & 24 hours \\
Eclampsia & 48 hours \\
Obstructed uterus & 72 hours \\
Sepsis & 144 hours \\
\hline
\end{tabular}
\caption{Comparison of complications and time of onset to death}
\end{table}

Source: Sangvi and Lewison 2006. Comparison of PPH can kill a healthy woman within 2 hours if she is not properly attended to, a rate faster than any other complication such as ruptured uterus which takes 24 hours or sepsis that could take 144 hours.

\textbf{Potential Effects of Maternal Deaths Due to PPH on Families and Communities}

The death of a woman at childbirth is amongst the most devastating undesirable consequences of pregnancy. Her absence has a negative effect on her family as she is both a wife and mother and is therefore the center of her family’s existence.\textsuperscript{14} Her death may result in that of her newborn. Children are suddenly orphaned and may drop out of school and become street children or juvenile delinquents. They may face the risk of physical and sexual abuse by family or community members; they may also become ill, injured, malnourished and depressed as a consequence; and they may suffer social isolation. The husband or father may be grief stricken and angry and may blame the newborn for his wife’s death. He may also become depressed and face social isolation. He may marry another woman to take care of the children and this may lead to dissolution of the original family unit. Financially, hospital and funeral costs may result in reduced household income and dwindling resources.\textsuperscript{14}

A healthy woman not only forms part of Zambia’s workforce contributing greatly to the growth and development of the country, but also reduces on the national cost of health care. Her untimely death or disability would therefore, hinder progress on national development and result in increased national health care expenditure. At the community level a woman’s death results in increased one-parent households, orphans, and changes in responsibility for care of children, elderly and the disabled.\textsuperscript{14}

\textbf{Factors underlying the problem}

This section focuses on identifying the key underlying causes of deaths due to PPH in home births including risk factors such as anaemia and maternal age.\textsuperscript{14} We also consider both demand- and supply-side barriers to accessing obstetric care, such as lack of knowledge of obstetric problems like PPH and lack of adequately skilled birth attendants.\textsuperscript{23}
Risk factors

Anaemia is an important risk factor associated with PPH owing to its substantial prevalence in Zambia. It is rarely detected or treated during pregnancy and often exacerbated by malarial and other parasitic diseases. A woman who is already anaemic is at a greater risk of excessive blood loss at delivery and cannot tolerate even moderate amounts of blood loss. Other risk factors include increased maternal and gestational age; body mass index; prolonged labour; multiple pregnancies; fibroids; previous cesarean delivery and previous PPH. Unfortunately, however, even with the identification of the above risk factors PPH occurs in other women without warning. Research shows that two-thirds of PPH cases occur in women with no known risk factors.

Barriers to accessing obstetric care

Deciding whether and where to go for obstetric care at a health facility involves a number of multifaceted and possibly confusing options. These have been summarised in Figure 2 below which is a conceptual framework on the perceived factors that influence seeking obstetric care in Zambia. The barriers to accessing obstetric care have been categorised into three delays:

1. Delay at the household and community level
2. Inability to access health facilities
3. Delay in receiving care at the health facility

1st Delay: Decision Making at the Household and Community Level

Making the decision to go to a health facility for obstetric care can be influenced by sociocultural factors such as marital status. For instance some women are not permitted to go to a health facility without consent from the husband or mother in-law. Other sociocultural factors include marital age, parity, religion, literacy, education and fertility attitudes.

Community attitudes and beliefs relating to childbirth mould the way in which many women perceive their own health and can help create an encouraging environment for families to make the decision to seek obstetric care. For instance in some communities a caesarean section is considered a reproductive defeat and women fear the stigmatisation associated with it. For this reason some women would rather risk giving birth at home without skilled care. Another traditional belief is that the mother and her newborn must be confined together in a room for the first few weeks after delivery and not allowed to leave the house even for medical assistance.

Furthermore, in communities across Zambia, traditional birth attendants (TBA) contribute to the decision making process. They tend to be older, semi-literate, respected members of the community that not only perform important cultural rituals but also provide essential social support to women during childbirth. TBAs do not have the skills or tools to treat complications like PPH and may delay making the decision to refer the woman to a facility that offers skilled care. Other community influences include fertility attitudes among men and women, husbands approval of family planning and media use.
2nd Delay: Inability to Access Health Facility

Once the decision is made to go to the health facility the woman may face financial, geographic or logistical barriers to reaching the health facility. Financial accessibility is based on the mother’s or husband’s occupation. Evidence shows that distance to health facilities imposes a significant cost on women and their families especially in hard-to-reach areas and this reduces demand to seek care in a health facility. Incurred costs may include out-of-pocket expenses such as transportation costs. In most cases, ambulance services are limited and certain parts of Zambia do not have ambulance facilities. Where ambulance services are present they are unable to provide emergency supportive care during transfer to a health facility. Geographic barriers to accessing obstetric care include difficult terrains spread out across long distances, coupled with inaccessible roads that are worsened by flooding during the rainy season, which make travel to delivery facilities near to impossible for pregnant women living in these hard-to-reach areas.
**3rd Delay: Receiving Care at the Health Facility**

Once the woman reaches the health facility she may encounter delays in receiving EmOC mainly due to shortages of skilled health professionals, sporadic supply of medicines and technical and managerial problems.

As earlier mentioned the proportion of deliveries attended by a skilled attendant is one of the indicators of progress towards achieving MDG 5, the other is the MMR. Although the MMR has decreased over the years, the proportion of skilled attendants at birth has worsened (Table 4). Only 47% of deliveries were attended by a skilled attendant in 2009. This may have been due to inadequate numbers of skilled attendants many of whom are underpaid and poorly motivated; inadequate equipment, supplies and drugs in facilities.
Table 4: Trends in maternal mortality indicators in Zambia

<table>
<thead>
<tr>
<th>Indicator</th>
<th>1990</th>
<th>2002</th>
<th>2009</th>
<th>2015 MDG target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal mortality ratio/100,000 live births</td>
<td>649</td>
<td>729</td>
<td>590</td>
<td>162</td>
</tr>
<tr>
<td>Proportion of births attended by skilled health personnel</td>
<td>51%</td>
<td>43%</td>
<td>47%</td>
<td>80%</td>
</tr>
</tbody>
</table>


The ratios of population per skilled health provider are high for all cadres (doctors, clinical officers, midwives and nurses) across urban provinces (Copperbelt & Lusaka), rural provinces (averages for 7 provinces) and the total population of Zambia (Table 5).

Table 5: Ratios of population per health professional

<table>
<thead>
<tr>
<th>Population per</th>
<th>Medical doctor</th>
<th>Clinical officer</th>
<th>Registered midwife</th>
<th>Registered nurse</th>
<th>Zambia enrolled midwife</th>
<th>Zambia enrolled nurse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lusaka</td>
<td>6,247</td>
<td>7,544</td>
<td>12,397</td>
<td>3,799</td>
<td>5,243</td>
<td>1,577</td>
</tr>
<tr>
<td>Copperbelt</td>
<td>8,998</td>
<td>9,719</td>
<td>14,425</td>
<td>5,091</td>
<td>3,599</td>
<td>1,567</td>
</tr>
<tr>
<td>Average rural provincial</td>
<td>43,313</td>
<td>10,970</td>
<td>74,713</td>
<td>17,324</td>
<td>11,541</td>
<td>2,863</td>
</tr>
<tr>
<td>National</td>
<td>17,589</td>
<td>9,787</td>
<td>27,714</td>
<td>8,822</td>
<td>6,099</td>
<td>2,293</td>
</tr>
</tbody>
</table>

Source: Anyangwe et al. 2006.

This dearth of skilled personnel can be attributed to insufficient numbers of skilled attendants trained, which is worsened by the migration (“brain-drain”) of skilled personnel from Zambia to better endowed countries, particularly Britain and the USA. The brain-drain has also led to the depletion of the number of tutors in health training institutions, further reducing the numbers of skilled attendants being trained to replenish those lost to migration, retirement and death.

Inadequate infrastructure also plays a role in the delay to receive care at the facility. A recent study considered the efficiency and level of EmOC in Zambia based on reported capability for eight EmOC signal functions:

1. Injectable antibiotics
2. Injectable oxytocics
3. Injectable anticonvulsants
6. Assisted vaginal delivery
7. Caesarean section
8. Blood transfusion

The availability of the eight signal functions defines and distinguishes between the two main levels of care namely comprehensive EmOC (CEmOC) and basic EmOC (BEmOC). CEmOC services encompass all eight signal functions whereas BEmOC services include all but caesarean section and blood transfusion. There are currently 1,131 delivery facilities across Zambia. Of these delivery facilities 135 (12%) provide EmOC services with a minimum of seven of the signal functions, while 466 (41%) provide BemOC services with less than four signal functions.\textsuperscript{13} Error! Reference source not found.

\begin{center}
\begin{tabular}{|l|}
\hline
\textbf{In summary,} \\
\hline
\textbf{1.} The danger of excessive bleeding or postpartum haemorrhage (PPH) at delivery is unquestionable \\
\textbf{2.} If left untreated, PPH can result in disability or death and causes a ripple effect of grief and detriment to surviving family members \\
\textbf{3.} Seventy percent of women in rural areas deliver without skilled care and face a high risk of bleeding to death \\
\textbf{4.} The speed at which a woman can bleed to death demands timely management, which can be effectively achieved with the presence of adequately skilled attendants supported by an environment that includes policy support, access to basic supplies, drugs, transport and necessary emergency obstetric services \\
\textbf{5.} Community-based postpartum care is important for reduction of maternal death and morbidity; and emphasising healthy behaviours, particularly around the time of delivery \\
\hline
\end{tabular}
\end{center}
Three policy options

Increasing the number of women delivering in settings where skilled attendants are able to provide emergency obstetric care if complications arise, is commonly perceived as the most important strategy for reducing maternal mortality and morbidity. However, because of the local conditions in Zambia, described above, this is unlikely to improve quickly for women in rural areas. For this reason, the role of targeted integrated community-based postpartum care aimed at improving access to life saving interventions has never been more crucial. Strengthening health systems is arguably an excellent long term approach but it does not provide a solution to the immediate safe-delivery needs of the 70% of women in rural areas who will almost certainly deliver at home, without any skilled care.

This section discusses three possible policy options that can be considered in the absence of skilled birth attendance. The first option proposes to continue with the status quo and not make any policy changes. Options two and three focus on advance distribution of misoprostol, a low cost, thermostable uterotonic tablet as a possible temporary solution to managing PPH in settings where provision of emergency obstetric care is not feasible. The decision to focus on misoprostol as a possible temporary solution to preventing PPH in homebirths was arrived at after consultation with stakeholders including policy makers, and program managers. Misoprostol was selected over other conventional uterotonics (oxytocin and ergometrine) because it can easily be administered orally without the help of a skilled attendant; and it can be stored at room temperature without special storage facilities. With over 90% of women attending at least one antenatal care visit, it was agreed that in both options skilled attendants would disburse misoprostol tablets to women during their first ANC visit. Barriers to scaling up the two options are described below under ‘Implementation Considerations’

Policy option 1

Status quo

Currently, there is no intervention that provides protection for women delivering at home. The Ministry of Health focuses on emphasising the WHO guidelines, which state that all women are supposed to deliver in a health facility with a skilled attendant. The Ministry of Health and its partners have committed to safeguarding the lives of women at birth and have set in place several interventions aimed at tackling the three phases of delay to seeking health.

Misoprostol is administered as part of the active management of the third stage of labour (AMTSL). AMTSL is a three part process intended to augment the uterine contractions and prevent PPH caused by atony. The recommended AMTSL protocol is as follows:

1. Give a uterotonic drug, Oxytocin IM 10U within 1 minute of childbirth OR where oxytocin is not available, give 600 mcg of misoprostol orally.
2. Deliver the placenta by controlled cord traction on the umbilical cord and the counter-pressure to the uterus
3. Massage the uterus through the abdomen after delivery of the placenta
However, AMSTL is carried out in health facilities and only in the presence of a skilled care attendant.

This option therefore suggests that no policy changes be made concerning advance distribution of misoprostol for prevention of PPH until analyses from trials being conducted in other low and middle income countries are completed. For instance, a community-based cluster-randomised clinical trial is scheduled to commence in 2012 in Ethiopia. The main objective of the trial is to study the effect of community-based prophylaxis and treatment for common maternal obstetric complications in a low resource setting with a high burden of maternal disease and mortality.\textsuperscript{31}

Advantages and disadvantages of the status quo are as follows:

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• on the decision about whether to use misoprostol would be informed by evidence from randomised trials currently being carried out</td>
<td>• Women who give birth at home will continue to be at risk of bleeding to death as there is no other intervention currently available that offers protection against PPH</td>
</tr>
<tr>
<td>• If misoprostol is found not to be effective or to be harmful, resources will not be wasted and women will not be exposed to adverse effects of misoprostol.</td>
<td>• If misoprostol is found to be safe and effective, women will not have benefited in the interim, while waiting for the results of randomised trials</td>
</tr>
</tbody>
</table>

\textbf{Policy option 2:}

\textbf{Advance misoprostol distribution by skilled birth attendants (without an Impact Assessment)}

A skilled birth attendant is an accredited health professional – such as a midwife, doctor or nurse – who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate postnatal period, and in the identification, management and referral of complications in women and newborns.

In Zambia antenatal care attendance during pregnancy is high with 94% of women attending at least one antenatal care visit.\textsuperscript{18} Capitalising on antenatal care visits as a point of distribution of misoprostol to pregnant women could be an effective strategy to increase uterotonic coverage.\textsuperscript{28} A pilot project was conducted by the Ministry of Health and collaborating partners to assess the feasibility of distributing misoprostol to eligible women at antenatal care visits for use in after delivery if they were unable to reach a health facility.\textsuperscript{26} Furthermore, community organisations affiliated to certain health centres called Safe Motherhood Action Groups provided community education about birth preparedness, the importance of delivering in a health facility, the risks of PPH, and correct use of misoprostol.\textsuperscript{26} The results showed that 48% of women in the intervention area who delivered at home were protected by a uterotonic drug compared to less than 1% in the control area;
and 53% of women in the intervention area delivered in a health facility as compared to 40% in the control area.

**Impacts of advance misoprostol distribution by skilled attendants**

A recent systematic review assessing the impacts of advance distribution of misoprostol to women for prevention of PPH in home deliveries found insufficient evidence to support advance distribution of misoprostol for prevention and treatment of PPH. The authors recommend large and well-designed randomised trials to assess the benefits and dangers of this system.  

**Equity, costs, monitoring and evaluation**

To ensure equitable advance distribution of misoprostol tablets both static and outreach ANC clinics could be used as entry points for women to receive misoprostol tablets; and education on PPH and the use of misoprostol during delivery. Other communication strategies could be utilised to create awareness. Community awareness campaigns could focus on encouraging women to attend antenatal clinics where they will be able to get receive the tablets and instructions on the prevention of PPH at home births. The campaign could encourage women to attend ANC visits with a family member (one or more) of their choice, especially those who are likely to be present at the time of delivery (e.g. mother, sister, mother-in-law, etc.), so they can also receive the information. It is important to note that not all women would be eligible to receive misoprostol due to certain medical conditions such as high-risk pregnancy, expected to require Caesarean section, high blood pressure, diabetes, cardiac disease and allergies to prostaglandins.

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**Table 7. Cost parameters**  

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>Opportunity cost of provider training time</td>
<td>$2</td>
</tr>
<tr>
<td>Cost of 1 day training per provider; materials and teachers</td>
<td>$2.01</td>
</tr>
<tr>
<td>Cost of 600µg misoprostol</td>
<td>$0.66</td>
</tr>
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</table>

Source: Sutherland et al 2009. Additional costs of advance misoprostol distribution. The study also included that the cost of implementing a national scale up of advance misoprostol distribution could amount to $3 864 117 for the misoprostol for prevention package (Table 7). Overall this option would therefore involve the allocation of resources in the initial phase in order to support training of ANC providers and community health agents, information and education campaigns/behaviour change communications (IEC/BCC) messages, procurement of misoprostol tablets, evaluation and strengthening coordination.

The option would require stringent monitoring and supervision, which are key to quality assurance of the distribution of misoprostol at community level. A collaborative monitoring system would need to be agreed upon by the Ministry of Health and partner/organisations.
working to distribute misoprostol in order to secure resources and avoid duplication of efforts. Local level planning and coordination could help to maximise support for monitoring. For the purpose of assessing programmatic impact, mechanisms for tracking referrals to health facilities for treatment of PPH should be developed and process evaluation should be carried out.

**Policy option 3:**

**Impact Assessment on the Advance distribution of Misoprostol by Skilled Birth Attendants**

Because of the lack of evidence on the impacts of community-based delivery of misoprostol, the WHO advocates that proper research to evaluate misoprostol’s role in reducing maternal deaths should be conducted.\(^{32,38}\)

**Equity, costs, monitoring and evaluation**

Studies from Afghanistan and Nepal report successful use of misoprostol in home-based prophylaxis however, the effect of the intervention was not assessed. In rural Pakistan, a randomised double-blind placebo-controlled trial of 1119 deliveries has reported that home based provision of misoprostol can be administered by traditional birth attendants with the supervision of trained personnel and that the intervention reduced the incidence of severe post partum haemorrhage. No randomized controlled trial of home-based provision of 400 mcg misoprostol prophylaxis has been conducted in Africa.

A randomized double-blind placebo-controlled trial of 1119 deliveries in rural Pakistan has shown that home based provision of prophylaxis can be given by traditional birth attendants supervised by trained personnel and that the intervention reduced the incidence of severe post-partum haemorrhage\(^{(43)}\)

The study could would use the first ANC visit as a point of misoprostol distribution, thereby taking advantage of the 94% of women attending at least 1 ANC visit. All women delivering at home would be given standard care. The main objective of the study would be to assess the effectiveness and safety of advance misoprostol for prevention of PPH in a low resource setting with a high burden of maternal mortality. Women during the study that gave birth giving birth at home would form the study population

Postpartum haemorrhage (>1000 ml haemorrhage) would be defined by Hb < 7 g/dl after delivery or difference of more than 2 g/dl before/after delivery, need of blood transfusion/fluid resuscitation. In rural areas in Zambia PPH is identified when two blood soaked chitenges are observed at delivery. A chitenge is a locally produced, sold and pre-cut (standard-sized rectangle of approximately 100 cm x 155 cm) cotton fabric.\(^{6,14}\)

Standard care: clean delivery and cord care. Essential newborn care including; birth preparedness, breastfeeding promotion and danger sign during the first 2 weeks postpartum

The local communities, safe motherhood action groups (SMAGs), program coordinators of the districts and institutions would be sensitised on the aim of the study. Upon obtaining
consent from local leaders, a list of districts would be used to randomly allocate the selected districts to 4 intervention groups and one control group. Neither the SMAGs or project health workers would be blinded to the allocation. Analysis of the data could be based on all cases in the intervention districts intend to use community-based case finding and treatment. Case detection and treatment success rates for all districts could be calculated, and independent sample-test, weighted by cluster size, to compare the mean case detection and outcome by using district as a unit of analysis would be used.

Summary:

Policy option 1: status quo
No policy changes would be made and misoprostol use would be limited to health facilities during administering the active management of thirst stage of labour by a skilled attendant only

➔ Advantages of the status quo are as follows:
  • on the decision about whether to use misoprostol would be informed by evidence from randomised trials currently being carried out
  • If misoprostol is found not to be effective or to be harmful, resources will not be wasted and women will not be exposed to adverse effects of misoprostol.

➔ Disadvantages of the status quo are as follows:
  • Women who give birth at home will continue to be at risk of bleeding to death as there is no other intervention currently available that offers protection against PPH
  • If misoprostol is found to be safe and effective, women will not have benefited in the interim, while waiting for the results of randomised trials

2 options focusing on advance distribution of misoprostol:
➔ Take advantage of the 94% ANC attendance and involves distribution of misoprostol tablets by ANC providers to pregnant women during these visits
➔ Aim at providing protection against excessive bleeding for all pregnant women (only option 2 applies to all pregnant women. Option 3 would only apply to women in the experimental districts) especially those in hard to reach areas that may not be able to get to a health facility to deliver
➔ Could potentially be implemented quicker than other options, such as increasing skilled birth attendance and access to EmOC
➔ Would not provide an adequate solution for managing other obstetrical emergencies
Policy option 2: Advance misoprostol distribution by skilled birth attendants

- Scale up would be quick, if adequate resources are found, benefiting women sooner, if the intervention is safe and effective
- Women would be harmed, if misoprostol is not safe, and resources would be wasted, if misoprostol is not effective
- Would be implemented without an impact evaluation, despite having uncertain benefits and potential harms

Policy option 3: Impact Evaluation on the Advance distribution of misoprostol by skilled birth attendants in the context of an impact evaluation

- Would provide evidence of the impacts of the intervention and inform subsequent decisions about whether to scale up
- Scale up would be avoided, if the intervention is harmful or not effective
- Scale-up would be delayed, if the intervention is safe and effective
Implementation considerations

Key barriers and strategies for the implementation of community-based distribution of misoprostol for the prevention of PPH are summarised in Table 8 below. These barriers are relevant for both options. Additional barriers for the first option include finding adequate resources to rapidly scale up training and distribution of misoprostol and management of a rapid scale up. Additional barriers for the second option include finding resources and people to undertake an evaluation.

Table 8. Key barriers to implementing advance distribution of misoprostol by skilled attendants (without an impact evaluation)

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Competency and attitudes</th>
<th>Strategies for addressing barrier</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass media campaigns</td>
<td>ANC providers or pregnant women may not be fully aware of, or agree with the need for misoprostol due to lack of understanding of the importance of misoprostol</td>
<td>Mass media information on health-related issues may induce changes in health services utilisation, both through planned campaigns and unplanned coverage.</td>
<td>There is low quality evidence from interrupted time series analyses that mass media interventions may have an important role in influencing the use of health care interventions.(^{45,46})</td>
</tr>
<tr>
<td>Patient education materials</td>
<td>A wide range of patient education materials can be used to inform mothers about health care.</td>
<td>Overall there is insufficient evidence to support the use of interventions that provide information or education as a single component to improve adherence, knowledge or clinical outcomes - they are generally ineffective. However, there is some evidence that interventions including a patient education or information component in conjunction with other interventions can improve immunisation rates and adherence.(^{47})</td>
<td></td>
</tr>
<tr>
<td>Health Workers’ Competency and attitudes</td>
<td></td>
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<td>-----------------------------------------</td>
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<tr>
<td>Health workers may not feel competent or may lack competency to provide education on risk of PPH or misoprostol use. For this reason additional training is required for all antenatal care providers to ensure appropriate delivery of this intervention.48.</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Strategies for addressing barrier</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Educational meetings, outreach visits, audit and feedback</strong></td>
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<tr>
<td>Educational meetings (training workshops), educational outreach (a personal visit by a trained person to health workers in their own settings) and audit and feedback (a summary of performance over a specified period of time given in a written or verbal format) can be used alone or in combination with each other and other interventions to improve health worker practice.</td>
<td></td>
</tr>
<tr>
<td>Educational meetings alone or combined with other interventions, can improve health worker performance. The effect is most likely to be similar to other types of continuing medical education, such as audit and feedback, and educational outreach visits. Strategies to increase attendance at educational meetings and using mixed interactive and didactic formats may increase the effectiveness of educational meetings.45,49,50,51</td>
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</table>
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:

- Deliberation amongst policymakers and stakeholders regarding the two options described in this policy brief
- Refining the preferred option, for example by incorporating components of both options, removing or modifying components
- Establish a coordinator with authority and accountability to lead the development and implement of a plan and a team of people to work with that person in developing and implementing the plan within an acceptable time frame
Appendices

Appendix 1. How this policy brief was prepared

The methods used to prepare this policy brief are described in detail elsewhere.52-53,54

The problem that the policy brief addresses was clarified iteratively through discussion among the authors, review of relevant documents and research, discussion within the Zambia Forum for Health Research (ZAMFOHR) and external review of a preliminary description of the problem. 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 Health Systems Evidence database of systematic reviews of delivery, financial and governance arrangements, and implementation strategies (http://www.healthsystemsevidence.org/). This database include records of policy-relevant systematic reviews that were identified through electronic searches of MEDLINE, the Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effectiveness (DARE) and EMBASE.

Drafts of each section of the report were discussed with members of the reproductive health research to action group which included Dorothy Chanda, Alice Hazemba, Margaret Maimbolwa, and Mary Nambao; Lonia Magolo; Reuben Kamoto Mbewe, Fadi El Jardali, Andy Oxman; and participants of the policy dialogue representing various stakeholders. External review of a draft version was [text]. 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
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>PPH</td>
<td>Postpartum Haemorrhage</td>
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<td>MDG</td>
<td>Millennium Development Goal</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<tr>
<td>EmOC</td>
<td>Emergency Obstetric Care</td>
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<tr>
<td>TBA</td>
<td>Traditional Birth Attendant</td>
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<tr>
<td>AMTSL</td>
<td>Active Management of the Third Stage of Labour</td>
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<tr>
<td>SMAG</td>
<td>Safe Motherhood Action Group</td>
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<tr>
<td>ANC</td>
<td>Antenatal Care</td>
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<tr>
<td>IEC/BCC</td>
<td>Information and education campaigns/behaviour change communications</td>
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<tr>
<td>ZAMFOHR</td>
<td>Zambia Forum for Health Research</td>
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<tr>
<td>EVIPNet</td>
<td>The Evidence-Informed Policy Network</td>
</tr>
<tr>
<td>ReproNet-Africa</td>
<td>The African Network for Research and Training in Sexual and Reproductive Health and HIV</td>
</tr>
<tr>
<td>SURE</td>
<td>Supporting the Use of Research Evidence (SURE) for Policy in African Health Systems</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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</table>


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