Published by Oxford University Press in association with The London School of Hygiene and Tropical Medicine *Health Policy And Planning* 2013;**28**:339–346

doi:10.1093/heapol/czs068

# New hope: community-based misoprostol use to prevent postpartum haemorrhage

**Ndola Prata,[1]* Paige Passano,[1] Suzanne Bell,[1] Tami Rowen[2] and Malcolm Potts[1]**

[1]Bixby Center for Population, Health and Sustainability, University of California at Berkeley, CA, USA and [2]Department of Obstetrics, Gynecology and Reproductive Sciences, University of California at San Francisco, CA, USA

*Corresponding author. Associate Professor in Residence, School of Public Health & Scientific Director, Bixby Center for Population Health and Sustainability, University of California, Berkeley, 229 University Hall, Berkeley, CA 94720-6390, USA. Tel: +1-510- 643-4284. E-mail: ndola@berkeley.edu

**Accepted** 10 May 2012

The wide gap in maternal mortality ratios worldwide indicates major inequities in the levels of risk women face during pregnancy. Two priority strategies have emerged among safe motherhood advocates: increasing the quality of emergency obstetric care facilities and deploying skilled birth attendants. The training of traditional birth attendants, a strategy employed in the 1970s and 1980s, is no longer considered a best practice. However, inadequate access to emergency obstetric care and skilled birth attendants means women living in remote areas continue to die in large numbers from preventable maternal causes. This paper outlines an intervention to address the leading direct cause of maternal mortality, postpartum haemorrhage. The potential for saving maternal lives might increase if community-based birth attendants, women themselves, or other community members could be trained to use misoprostol to prevent postpartum haemorrhage. The growing body of evidence regarding the safety and efficacy of misoprostol for this indication raises the question: if achievement of the fifth Millennium Development Goal is truly a priority, why can policy makers and women's health advocates not see that misoprostol distribution at the community level might have life-saving benefits that outweigh risks?

**Keywords** Maternal mortality, postpartum haemorrhage, misoprostol, safe motherhood, traditional birth attendants, skilled birth attendants

## KEY MESSAGES

- Postpartum haemorrhage is a major contributor to maternal mortality.
- Training community-based birth attendants to use misoprostol to prevent postpartum haemorrhage has potential to reduce maternal mortality among women with poor access to skilled birth attendants.

## Introduction

Vast disparities in maternal mortality ratios (MMR) exist across the globe. In sub-Saharan Africa, the average women has a 1 in 22 lifetime risk of dying of maternal causes compared with a 1 in 8000 risk for women in industrialized countries (Singh *et al*. 2009). Between 1990 and 2008, the global MMR declined significantly; however, the decline has not been uniform (WHO *et al*. 2010). Ninety-nine per cent of maternal deaths still occur in developing countries and many of the least developed countries in sub-Saharan Africa have shown little to no progress in reducing MMR (Hogan *et al*. 2010). In recent years, advocates have worked to make childbirth safer within the formal health care system, but women who deliver outside of health facilities have not benefited from these improvements.

Just over half (54%) of all births worldwide take place in an institutional setting (UNICEF 2008). The other half occur primarily in the home of the woman, attended by a traditional birth attendant (TBA), a relative, or no one (Macro

International 2010). Until the late 1980s, TBAs were trained in risk assessment, clean deliveries and prompt referral. For many complex reasons, the MMR did not fall as it was hoped it would (Kamal 1998; Kowalewski *et al*. 2000; Carlough and McCall 2005; Mathole *et al*. 2005; Koblinsky *et al*. 2006; Ronsmans and Graham 2006; Velez *et al*. 2007). Risk assessment has low specificity and is difficult without proper diagnostic tools. Clean deliveries help to prevent infection, but they do not offer complete protection, especially if a woman has a pre-existing reproductive tract infection (Goodburn *et al*. 2000; Bergstrom 2001). Referral requires overcoming numerous household-level and environmental barriers in order to get a woman to the appropriate level of care (Alisjahbana *et al*. 1995; Sibley and Sipe 2004; Mathole *et al*. 2005; Velez *et al*. 2007).

By the late 1990s, a growing number of experts argued that training TBAs was an ineffective means to improve maternal survival rates (De Brouwere *et al*. 1998; Maine and Rosenfield 1999; Ravindran and Berer 1999; Weil and Fernandez 1999). In 2000, the Millennium Development Challenge refocused attention on the need to increase the density of skilled birth attendants (SBAs). In the years to follow, it became virtually taboo to discuss training TBAs to do anything directly related to labour and delivery. As funding and social acceptability of training TBAs disappeared, the safe motherhood community averted its gaze away from TBAs, but tens of millions of women continued to deliver with the support of TBAs and relatives, or by themselves.

We argue that misoprostol has the potential to mitigate postpartum haemorrhage (PPH), the leading cause of maternal mortality. Lower-level providers, and even women themselves, can be trained to administer misoprostol safely. In some low-resource settings, the community distribution of misoprostol may be the only way a country can substantially reduce MMR attributed to PPH.

## Methods

For this paper we reviewed existing literature in PubMed and Google Scholar on strategies to reduce maternal mortality, focusing on community-based distribution of misoprostol. This was not a systematic review, but rather a review of the evidence for use of misoprostol at the community level. The search was limited to literature published between 1995 and 2011. Key search terms included: maternal mortality, misoprostol, community-based distribution, traditional birth attendants, postpartum haemorrhage, eclampsia, obstructed labour, sepsis and abortion. We compared existing options for prevention and treatment for the most common causes of maternal death (unsafe abortion, obstructed labour, eclampsia, sepsis and PPH) at the facility and the community level, with and without misoprostol. We present the available options for treatment and prevention of these causes of maternal death using misoprostol in Table 1. Based on the expansive results from the literature review, we narrowed our focus for the remainder of the paper to the most common cause of maternal death, PPH, and the literature examining misoprostol-related interventions at the community level. We reviewed and addressed the primary arguments for and against misoprostol use at the community level, with recommendations for short- to medium-term strategies to reduce global MMR by addressing PPH attributable maternal death.

## Findings

### Misoprostol: the 'game changer'

Expecting TBAs' presence during deliveries to lead to a reduction in maternal mortality was unrealistic because TBAs had no real 'tools' at their disposal. Other than conducting clean deliveries, they had no effective method of preventing or treating the five most common causes of maternal death: PPH, eclampsia, sepsis, obstructed labour and unsafe abortion. Fortunately, technologies have advanced considerably in recent decades. The introduction of misoprostol, a generic, low cost, heat-stable uterotonic that can be administered in tablet form, has the potential to revolutionize the prevention and treatment of two major causes of death in women of reproductive age: PPH and unsafe abortion. Misoprostol has already been found to be safe and effective in preventing both indications, and recent evidence indicates that it can safely be used in the treatment of PPH as well (Derman *et al*. 2006; Blum *et al*. 2007; American College of Obstetricians and Gynecologists 2009; Blum *et al*. 2010; Ejembi and Prata 2010; Ministry of Health Zambia *et al*. 2010; Mobeen *et al*. 2011; Sheldon *et al*. 2012).

Table 1 illustrates the dearth of viable management options for community-based birth attendants during home deliveries. It compares currently available interventions at the facility level with what is currently possible in villages, and contrasts that with what *could* be possible if community-based interventions that used misoprostol were available. This is an important consideration, because there is no guarantee that a woman will reach a secondary or tertiary level facility that (a) is open at that time of her arrival, (b) has skilled personnel available, and (c) has the necessary equipment and supplies to save her life. The numerous barriers to swift emergency care are perhaps the strongest argument for preventative measures at the community level (Dehne *et al*. 1995; Sibley and Armbruster 1997; Koblinsky *et al*. 2006; Ronsmans and Graham 2006). Access to easy-to-use uterotonic drugs is a matter of health equity. It should not be contingent on where a woman happens to give birth, or if she has access to a skilled provider and/or a facility with surgical capacity. For home births, misoprostol is currently the only viable solution for effective prevention.

### Postpartum haemorrhage (PPH)

Of the five most common direct causes of maternal mortality, PPH (blood loss of 500 ml or more) claims approximately 35% of maternal deaths in developing countries (United Nations 2010). Over 1000 ml of blood loss marks the threshold of severe PPH. During home births, neither TBAs nor SBAs can replace blood loss, but both types of providers can prevent (or manage) bleeding if they have access to an uterotonic drug. Without any intervention, a woman can die from PPH within 2 hours of delivery (Gynuity 2006). Even if she survives the ordeal, severe anaemia may take years to overcome, compromising her overall health, energy levels, productivity and subsequent birth outcomes (AbouZahr 2003).

**Table 1** Direct causes of maternal mortality and existing management options

| Obstetric causes of maternal death | Potential options at the facility level | Potential options at the community level, with and without misoprostol | |
|---|---|---|---|
| | | Without misoprostol | With misoprostol |
| Unsafe abortion | • Treatment of incomplete abortion: medical and/or surgical interventions | • Referral | • Treatment of incomplete abortion: single dose of 600 mcg misoprostol administered orally<br>• Referral |
| Obstructed labour | • Assisted delivery<br>• Caesarean section | • Referral | • Referral |
| Eclampsia | • Administer anti-convulsants<br>• Administer anti-hypertensives | • Referral | • Referral |
| Sepsis | • Intravenous (IV)/oral antibiotics | • Referral | • Referral |
| Postpartum haemorrhage | • Blood loss measurement<br>• Active management of the third stage of labour (AMTSL)<br>• Administer intravenous or intramuscular uterotonic drugs<br>• Repair of tears or other surgical interventions<br>• Blood transfusion | • Blood loss estimation<br>• External uterine massage<br>• Referral | • Blood loss estimation<br>• PPH prevention: single dose of 600 mcg of misoprostol administered orally<br>• PPH treatment: single dose of 800 mcg administered sublingually – if blood loss exceeds 500 ml<br>• Referral |

## Misoprostol for postpartum haemorrhage

Several large, randomized controlled trials evaluated the use of 600 micrograms of misoprostol orally to prevent PPH at the community level (Walraven *et al*. 2005; Derman *et al*. 2006; Mobeen *et al*. 2011). Walraven *et al*.'s double-blind randomized control trial (RCT) comparing oral misoprostol to oral ergometrine in Gambia found that women randomized to receive misoprostol had a lower likelihood [relative risk (RR) = 0.91] of experiencing PPH (blood loss ≥500 ml) but the results were not statistically significant [95% confidence interval (CI) 0.67–1.24] (Walraven G *et al*. 2005). In rural India, Derman *et al*. illustrated that oral misoprostol was associated with reduced relative risk of PPH (RR = 0.53), and their findings *were* statistically significant (95% CI 0.39–0.74) (Derman *et al*. 2006). Most recently, Mobeen *et al*. demonstrated that TBAs in Pakistan could significantly reduce the risk of PPH (RR = 0.76, 95% CI 0.59–0.97) through oral administration of misoprostol at home births (Mobeen *et al*. 2011). These studies provide strong evidence that misoprostol has significant potential to reduce blood loss after delivery in low-resource settings.

Langenbach conducted a meta-analysis of 22 RCTs which tested the efficacy of misoprostol in the prevention of PPH. Selected outcomes included blood loss ≥500 ml, blood loss ≥1000 ml, and need for additional uterotonics. She concluded that the excess risk of PPH when using misoprostol (over conventional uterotonics) was 4%, 'a risk well within the range of expected results for all uterotonics'. She observed that misoprostol should not be compared with conventional uterotonics in settings where use of the latter is not feasible, because such research simply delays distribution of a potentially life-saving drug, which might result in preventable maternal mortality. Instead, the efficacy of misoprostol should be measured against no treatment at all (Langenbach 2006).

Without access to uterotonic drugs, a defined proportion of women can be expected to have severe PPH, requiring hospital transfer. Reducing the need for hospital referral will protect the lives of women in the poorest and least educated families, who face the greatest barriers to health facility transfer during emergencies. A number of field trials have demonstrated this, such as a study in Tanzania by Prata *et al*., which found that the necessity to refer women for emergency obstetric care (EmOC) was significantly lower in the misoprostol arm compared with the control arm (2% vs 19%) (Prata *et al*. 2005). Rajbhandari *et al*.'s study in Nepal of misoprostol distribution by community volunteers found that uterotonic use rose from 11.6% to 74.2%. The poor, the illiterate and the women living in remote areas benefited the most (Rajbhandari *et al*. 2010).

## Expanding the knowledge pool

There are two groups that should be integrally involved in the introduction of community-based misoprostol: those who administer the drug and those who distribute it. In order to ensure the safety of women and the correct usage of the drug, both groups need to be trained and well-informed on its dosage, correct usage, side effects and alternate uses. This proposal does not rely on training TBAs. In any context where SBAs were available, affordable and accessible *wherever* women choose to give birth, they would be the obvious first choice. Thus, depending on the country context, the available pool of providers and prevailing attitudes towards various providers, the 'administrator' of the misoprostol, following sufficient training, could be an SBA, a TBA, another type of community health worker, a relative, a community member or the pregnant woman herself. Women and family members can gain knowledge about the drug if this information is integrated into routine antenatal care or home visits during pregnancy.

A critical component of success is a well-designed Information, Education and Communication (IEC) campaign. This will help pregnant women, and any other community members likely to be present during births, understand the drug's correct usage and appropriate blood measurement

techniques, stressing the importance of timely hospital referral if necessary. Understanding that misoprostol is not a panacea for PPH is important and should be stressed during any IEC campaign. Designing appropriate trainings for community-based drug sellers will be an additional safeguard against incorrect usage and possibly adverse outcomes. With widespread knowledge disseminated throughout communities, TBAs are *one* avenue of distribution and/or administration of the drug, but not the only one. Depending on the context, local stakeholders and women's advocates should be empowered to participate in the decision on how best to reach women with the message and the drug.

## Concerns about misoprostol for postpartum haemorrhage

Opponents argue that TBAs (or birthing women themselves) will not be able to use misoprostol appropriately, expressing concern about incorrect timing or dosage, but there is no evidence that inappropriate use of misoprostol by community health workers is a major problem (Sanghvi *et al*. 2004; Sanghvi *et al*. 2010, Rajbhandari 2010). However, in any real world setting, the chance of error exists. Serious adverse maternal or foetal outcomes could occur if providers administer misoprostol before the onset of labour, during labour, or between the delivery of twins. While no drug can be used on a large scale without error, there are very few documented incidents of adverse outcomes from misoprostol in the hands of lower level providers (or the women themselves) who have been trained in correct use of the drug. For example, in a recent study in rural Afghanistan, 2021 women were offered misoprostol after being educated about proper use. Of those, 1421 women (70%) used it; not a single woman used it incorrectly, including 20 women who gave birth to twins (Sanghvi *et al*. 2010). In Nigeria, a recent study followed 1421 women who used misoprostol during home births, either self-administered or administered by a non-skilled attendant. Postpartum interviews confirmed that 1394 women (98%) took three tablets as directed and 1248 (88%) used the correct timing and suggested route of administration (oral) (Ejembi and Prata 2010).

Despite this evidence that misoprostol can be safely used at the community level, the potential for error necessitates careful and high-quality training reinforced by a well-designed IEC campaign.

## Does misoprostol reduce maternal deaths?

No study to date has demonstrated that community-based distribution of misoprostol has reduced the maternal mortality ratio attributable to PPH. Maternal mortality has never been the outcome of a large-scale study or programme evaluation. While it is of paramount importance to have rigorous evaluations of maternal health interventions, the fact that such a large and expensive study is yet to be conducted should not preclude government health sectors from looking at the promising evidence of reductions in PPH incidence that has been demonstrated. Two randomized placebo-controlled trials found reductions in PPH against placebo of 24–50% (Derman *et al*. 2006; Mobeen *et al*. 2011). If misoprostol reduces PPH, then it should reduce severe morbidity and mortality due to PPH—a woman cannot die of PPH if she does not experience excessive bleeding.

We know there are those who believe misoprostol only makes a difference among women with severe bleeding, but under this logic, it will still decrease severe morbidity and mortality among this subpopulation. This is still an improvement in maternal health outcomes and can be used to justify preventative use of misoprostol at the community level. Furthermore, the impact of blood loss after birth on haemoglobin levels is an important consideration, especially in countries marked by inadequate birth spacing and high levels of anaemia.

## Cost-effectiveness of misoprostol

Misoprostol has been demonstrated to be a cost-effective intervention for prevention and treatment of PPH. When analysing the World Health Organization (WHO) Mother-Baby Package interventions, Prata *et al*. found that the three most cost-effective interventions to save maternal lives were family planning, provision of safe abortion and the integration of misoprostol to prevent PPH into traditional antenatal care packages (Prata *et al*. 2010). In another modelling study using Monte Carlo simulation, researchers demonstrated how community-based distribution of misoprostol could be a cost-effective means of treating or preventing PPH. In the modelled scenario estimating the potential impact of misoprostol used for treatment, the drug was projected to lower mortality by 70% but raise costs by 6%. A second scenario examining the use of misoprostol for prevention projected that the drug could lower mortality by 81% but increase costs by 35%. The incremental cost was estimated at US$6 and US$170 per DALY saved, respectively. Both scenarios were found to be more effective in decreasing mortality than standard management. Researchers advised a scale-up plan that initially focuses on the treatment strategy (Sutherland *et al*. 2010).

Although the treatment option is more cost-effective, cost-effectiveness should not be the only consideration. Equity and feasibility in the implementation of a treatment protocol at the community level should also be considered. Today, the gold standard recommended action in facilities for prevention of PPH is active management of the third stage of labour (AMTSL). Misoprostol administration is the closest intervention to AMTSL that we have to date to offer women who deliver at home without a skilled attendant. However, the consideration of non-universal preventative administration of misoprostol is a valid option that should continue to be explored through research. In the interim, given the low predictive value of risk factors for PPH, universal prevention with uterotonics should be practised.

Few will contest that routine *non-use* of uterotonics (misoprostol or oxytocin) is life threatening. Experts argue over cost and marginal differences in effectiveness, but both drugs are inexpensive and highly effective compared with the devastation a household suffers when a maternal death occurs. Although oxytocin is the gold standard, making misoprostol available involves far less infrastructure if one factors in the cost of maintaining a cold chain, paying skilled providers and ensuring supplies are in place. Misoprostol also has the potential to avert exorbitant costs borne by families, including out-of-pocket transportation costs and hospital fees associated with PPH

treatment. From a health systems perspective, access to misoprostol is highly cost-effective: by reducing the incidence of severe PPH and subsequent need for hospital transfer, the cost of provider time, supplies, medications and bed space decrease (Bradley *et al*. 2007).

### Arguments against community-based distribution

Opponents of training TBAs to use misoprostol for PPH prevention will argue that TBAs lack the skills needed to accurately gauge blood loss, and that misoprostol use could delay TBA referral behaviour if providers are not trained well enough to recognize specific danger signs. However, researchers in Tanzania have demonstrated that TBAs *can* learn to accurately measure blood loss. Prata *et al*. documented the effectiveness of using several folded *kangas* (cotton garments) to measure blood loss following delivery. Because *kangas* have a fixed length and width, measurements were made to determine that two soaked *kangas* were equivalent to approximately 500 ml of blood loss, the appropriate threshold for transfer to a health facility (Prata *et al*. 2005). In addition, blood loss measurement was the main indicator in two RCTs testing misoprostol administered by TBAs. Both studies demonstrated significant decreases in PPH (Walraven *et al*. 2005; Mobeen *et al*. 2011).

Despite its tremendous potential, access to misoprostol has remained limited or prohibited in most regions where the MMR is high. Policy makers have been hesitant to allow the drug outside of hospitals, perhaps influenced by the WHO official position that community-based access to misoprostol is potentially dangerous and thus should be researched further before it is permitted (the WHO has recently changed their stance regarding misoprostol for PPH prevention). The WHO's high level of concern about the side effects that some women experience after taking misoprostol does not reflect the general consensus supporting misoprostol use for the prevention of PPH found in studies over the last decade (Bergstrom and Goodburn 2001; McCormick *et al*. 2002; FIGO/ICM 2004; Prata *et al*. 2005; Walraven *et al*. 2005; Chandhiok *et al*. 2006; Derman *et al*. 2006; Gynuity 2006; Patted *et al*. 2009; Ministry of Health Zambia *et al*. 2010; Rajbhandari *et al*. 2010; Mobeen *et al*. 2011). WHO argues that it is unknown how misoprostol's side effects might impact neonatal survival, despite the fact that there is no evidence that maternal side effects threaten either maternal or neonatal survival (Gulmezoglu *et al*. 2007; Patted *et al*. 2009).

A more understandable concern is the idea that making misoprostol available at the community level would encourage more women to deliver at home. However, existing studies have clearly documented an *increase* in facility deliveries, not a decrease, while community-based access to misoprostol occurs (Ministry of Health Zambia *et al*. 2010; Sanghvi *et al*. 2010). In Zambia, in a misoprostol study conducted in five rural districts, 54% of women in the intervention sites delivered in a health facility compared with only 40% of women from the control sites (Venture Strategies Innovations/Ministry of Health Zambia 2010). We are not attributing the difference in facility deliveries solely to misoprostol; it is likely in part due to the IEC campaign on birth preparedness. Regardless, the most important thing to note is that the availability of misoprostol for home births (in conjunction with an IEC campaign) did not decrease facility deliveries. To counter the possibility of a decrease in facility-based deliveries, misoprostol interventions should be coupled with similar community-based IEC campaigns that strongly encourage facility delivery and stress the risks of delivery at home, especially related to PPH. At the same time, governments need to prioritize increasing facility capacity while carefully monitoring the quality of EmOC services, which frequently deters women from delivering in facilities. Women are highly motivated to have safe deliveries. It is the responsibility of the public health community to ensure that women and their families have the necessary information and have access to the best available options.

Policy makers, politicians, community leaders and medical associations will continue to worry about the implications of drug distribution outside of clinics, especially when strategies include direct training of lower-level health providers or training women in self-administration. Many of these concerns are valid, such as the question of whether less skilled birth attendants will be able to differentiate between PPH caused by uterine atony and PPH due to other causes such as uterine rupture, cervical or vaginal lacerations, and placental abnormalities. Without accurate differentiation, it is feared that misoprostol use could lead to further delays in hospital transfer. These fears can only be allayed with good quality training, in which birth attendants are taught the signs of various types of bleeding. In such trainings, they can be encouraged to monitor patients closely and promptly refer women if bleeding continues *for any reason*. Since 50% to 70% of PPH occurs as a result of uterine atony (WHO 2010), misoprostol is an appropriate drug to use in most cases of PPH.

Another important concern about misoprostol use at the community level is the risks associated with using misoprostol for induction of labour. The dosage required for induction of labour is only a fraction of a misoprostol tablet, and a higher dose could result in serious adverse events to mother and foetus. For this reason, published guidelines and IEC materials related to misoprostol for PPH prevention in home births includes the warning that misoprostol should never be taken before delivery of the baby. Any training related to misoprostol must strongly reiterate this warning.

One of the most politically charged arguments against the availability of misoprostol at the community level is its use as an abortifacient and concerns of increases in the number of abortions. We found no evidence of increases in the number of abortions in existing literature. Furthermore, evidence seems to indicate that abortion-related morbidities may actually fall after the introduction of misoprostol in a country (Costa 1998; Miller *et al*. 2005).

Both oxytocin and misoprostol are effective and potentially life-saving uterotonics, but only misoprostol can be used during home births by community-based providers or women themselves. A growing body of evidence recommends using misoprostol if oxytocin is not feasible (Bergstrom 2001; McCormick *et al*. 2002; FIGO/ICM 2004; Prata *et al*. 2005; Walraven *et al*. 2005; Chandhiok *et al*. 2006; Derman *et al*. 2006; Gynuity 2006; WHO 2007; Ejembi and Prata 2010; Ministry of Health Zambia *et al*. 2010; Mobeen *et al*. 2011; Rajbhandari *et al*. 2010; Sheldon *et al*. 2012). Countless lives have been lost because PPH was previously unmanageable at the village level. Now that the evidence base indicates that PPH can be

prevented by training community-based birth attendants and women to use misoprostol, appropriate action should follow.

### Tailoring solutions to fit the context

Since fear of lower-level providers administering misoprostol may never completely disappear, self-medication should be encouraged as is recommended for other medical conditions. Sanghvi *et al*. demonstrated that self-administration is a viable option in places where even community-based birth attendants face difficulty in reaching homebirths on time. However, it is important to note that this study used women's self-reported data to ascertain information on use (Sanghvi *et al*. 2010). In countries where women prefer to deliver alone, such as in northern Nigeria (Save the Children 2011), self-administration may be the only option. Where women rely on family members (rather than TBAs), it makes sense to train the family members as a unit, as was done in Afghanistan. Women and their families clearly understood that protecting themselves from PPH using misoprostol was a 'Plan B' for those unable to reach a skilled provider (Sanghvi *et al*. 2010). Nonetheless, any current implementation or scale up of community-based administration of misoprostol for the prevention of PPH should continue to improve surveillance techniques that accurately assess how misoprostol is being administered in order to ensure that misuse is not occurring, regardless of who administers the drug.

The scope of practice of community health workers (CHWs) should be expanded only to the extent that the evidence base permits. In settings where facility-based deliveries are on the rise, CHWs should be aware of misoprostol's effect on PPH, and be able to explain its importance to women to motivate them to have facility deliveries. In settings where the barriers to facility deliveries remain high, trained birth attendants (and the families they serve) will need to learn safe administration of misoprostol to prevent PPH among women who cannot deliver in a health facility. Treatment protocols for HIV/AIDS, tuberculosis and pneumonia have been adapted to permit community health workers to assume new tasks to meet the overwhelming demand for treatment. The safe motherhood community is understandably cautious around the concept of demedicalization because of the technical skill required with EmOC. Despite this, we should learn from successes in other sectors (such as malaria, pneumonia and HIV/AIDS), which have demonstrated that prescription drugs have been safely administered by lower-level and mid-level providers to improve population health (Babigumira *et al*. 2009; Yeboah-Antwi *et al*. 2010; George *et al*. 2011).

## Conclusion

Training and deploying skilled birth attendants is a strategy of unquestionable importance. However, investments in non-skilled birth attendants are also needed. Community-based birth attendants (TBAs and other CHWs) serve a priority sub-population—women who face the highest risk of maternal mortality and morbidities. Given the fact that geographical, economic, cultural and political disparities in access to care cannot be eliminated, training and supplying birth attendants who serve their own communities is one way to ensure that more disadvantaged women will have a chance to have a safe and healthy delivery.

Community-based distribution of misoprostol is a complementary, short- to medium-term strategy that will benefit communities with a high proportion of home births and low access to SBAs (Prata *et al*. 2011). This is not a suggestion to backtrack to the ineffective strategies of the 1960s, 1970s and 1980s. The crucial difference between what was tried before and what we are currently proposing lies in the simplicity of misoprostol as a technology—this particular drug enables trained birth attendants, drug distributors and birthing women themselves to avert PPH in regions where SBAs are scarce. Further operations research should be conducted to demonstrate the potential reductions in maternal morbidity and mortality associated with community level administration of misoprostol and assuage remaining opponents' fears surrounding the demedicalization of misoprostol use.

When TBAs have been deliberately excluded from training programmes out of concern for women's safety, this exclusion has not necessarily made women safer. If the level of mutual scepticism between TBAs and SBAs becomes further reinforced by continuing to exclude TBAs from organized trainings, the women who rely on informal providers will not benefit at all from advances in safe motherhood technologies. TBAs and relatives will continue to be called upon by tens of millions of women throughout the developing world for decades to come. Until SBA access is a reality for most women, community-based access to misoprostol is a matter of social justice.

## Funding

None received.

## Conflict of interest

None declared.

## References

AbouZahr C. 2003. Global burden of maternal death and disability. *British Medical Bulletin* **67**: 1–11.

Alisjahbana A, Williams C, Dharmayanti R *et al*. 1995. An integrated village maternity service to improve referral patterns in a rural area in West-Java. *International Journal of Gynaecology and Obstetrics* **48**: S83–S94.

American College of Obstetricians and Gynecologists. 2009. ACOG Committee Opinion No. 427: Misoprostol for postabortion care. *Obstetrics and Gynecology* **113**: 465–8.

Babigumira JB, Castelnuovo B, Lamorde M *et al*. 2009. Potential impact of task-shifting on costs of antiretroviral therapy and physician supply in Uganda. *BMC Health Services Research* **9**: 192.

Bergstrom S. 2001. Appropriate obstetric technologies to deal with maternal complications. In DeBrowere V, Van Lerberghe W (eds). *Safe Motherhood Strategies: A Review of the Evidence*. London: JSI UK, pp. 175–94.

Bergstrom S, Goodburn E. 2001. The role of traditional birth attendants in the reduction of maternal mortality. *Studies in HSO&P* **17**: 77–95.

Blum J, Winikoff B, Gemzell-Danielsson K *et al*. 2007. Treatment of incomplete abortion and miscarriage with misoprostol. *International Journal of Gynaecology and Obstetrics* **99** (Suppl. 2):S186–9.

Blum J, Winikoff B, Raghavan S *et al.* 2010. Treatment of post-partum haemorrhage with sublingual misoprostol versus oxytocin in women receiving prophylactic oxytocin: a double-blind, randomised, non-inferiority trial. *The Lancet* **375**: 217–23.

Bradley SE, Prata N, Young-Lin N, Bishai DM. 2007. Cost-effectiveness of misoprostol to control postpartum hemorrhage in low-resource settings. *International Journal of Gynaecology & Obstetrics* **97**: 52–56.

Carlough M, McCall M. 2005. Skilled birth attendance: what does it mean and how can it be measured? A clinical skills assessment of maternal and child health workers in Nepal. *International Journal of Gynaecology and Obstetrics* **89**: 200–8.

Chandhiok N, Dhillon BS, Datey S, Mathur A, Saxena NC. 2006. Oral misoprostol for prevention of postpartum hemorrhage by paramedical workers in India. *International Journal of Gynaecology and Obstetrics* **92**: 170–5.

Costa SH. 1998. Commercial availability of misoprostol and induced abortion in Brazil. *International Journal of Gynaecology & Obstetrics* **63** (Suppl. 1):S131–9.

De Brouwere V, Tonglet R, Van Lerberghe W. 1998. Strategies for reducing maternal mortality in developing countries: what can we learn from the history of the industrialized West? *Tropical Medicine International Health* **3**: 771–82.

Dehne KL, Wacker J, Cowley J. 1995. Training birth attendants in the Sahel. *World Health Forum* **16**: 415–9.

Derman RJ, Kodkany BS, Goudar SS *et al.* 2006. Oral misoprostol in preventing postpartum haemorrhage in resource-poor communities: a randomised controlled trial. *The Lancet* **368**: 1248–53.

Ejembi C, Prata N. 2010. Prevention of postpartum hemorrhage at home births in five communities around Zaria, Kaduna State, Nigeria: Technical Report. Population and Reproductive Health Partnership & Venture Strategies Innovations.

FIGO/ICM. 2004. Joint Statement on the Prevention and Treatment of Post-partum Haemorrhage: New Advances for Low Resource Settings. London: FIGO/Geneva: ICM.

George A, Menotti EP, Rivera D, Marsh DR. 2011. Community case management in Nicaragua: lessons in fostering adoption and expanding implementation. *Health Policy and Planning* **26**: 327–37.

Goodburn EA, Chowdhury M, Gazi R, Marshall T, Graham W. 2000. Training traditional birth attendants in clean delivery does not prevent postpartum infection. *Health Policy and Planning* **15**: 394–9.

Gulmezoglu A, Forna F, Villar J, Hofmeyr G. 2007. Prostaglandins for preventing postpartum haemorrhage. *Cochrane Database of Systematic Reviews* **18** (3)CD000494.

Gynuity. 2006. *Postpartum Hemorrhage: Responding to the Challenge*. New York: Gynuity.

Hogan MC, Foreman KJ, Naghavi M *et al.* 2010. Maternal mortality for 181 countries, 1980–2008: a systematic analysis of progress towards Millennium Development Goal 5. *The Lancet* **375**: 1609–23.

Kamal IT. 1998. The traditional birth attendant: a reality and a challenge. *International Journal of Gynaecology and Obstetrics* **63**: S43–52.

Koblinsky M, Matthews Z, Hussein J. 2006. Going to scale with professional skilled care. *The Lancet* **368**: 1377–86.

Kowalewski M, Jahn A, Kimatta SS. 2000. Why do at-risk mothers fail to reach referral level? Barriers beyond distance and cost. *African Journal of Reproductive Health* **4**: 100–9.

Langenbach C. 2006. Misoprostol in preventing postpartum hemorrhage: a meta-analysis. *International Journal of Gynaecology & Obstetrics* **92**: 10–18.

Macro International. 2010. Stat Compiler. Online at: http://www.measuredhs.com/.

Maine D, Rosenfield A. 1999. The safe motherhood initiative: why has it stalled? *American Journal of Public Health* **89**: 480–2.

Mathole T, Lindmark G, Ahlberg BM. 2005. Competing knowledge claims in the provision of antenatal care: a qualitative study of traditional birth attendants in rural Zimbabwe. *Health Care for Women International* **26**: 937–56.

McCormick ML, Sanghvi HC, Kinzie B, McIntosh N. 2002. Preventing postpartum hemorrhage in low-resource settings. *International Journal of Gynaecology and Obstetrics* **77**: 267–75.

Miller S, Lehman T, Campbell M *et al.* 2005. Misoprostol and declining abortion-related morbidity in Santo Domingo, Dominican Republic: a temporal association. *British Journal of Obstetrics and Gynaecology* **112**: 1291–6.

Ministry of Health Zambia, Venture Strategies Innovations, The Bixby Center for Population. 2010. Misoprostol distribution at antenatal care visits for the prevention of postpartum hemorrhage. Lusaka: Ministry of Health.

Mobeen N, Durocher J, Zuberi N *et al.* 2011. Administration of misoprostol by trained traditional birth attendants to prevent postpartum haemorrhage in homebirths in Pakistan: a randomised placebo-controlled trial. *British Journal of Obstetrics and Gynaecology* **118**: 353–61.

Patted S, Goudar S, Naik V *et al.* 2009. Side effects of oral misoprostol for the prevention of postpartum hemorrhage: results of a community-based randomised controlled trial in rural India. *Journal of Maternal-Fetal and Neonatal Medicine* **22**: 24–28.

Prata N, Mbaruku G, Campbell M, Potts M, Vahidnia F. 2005. Controlling postpartum hemorrhage after home births in Tanzania. *International Journal of Gynaecology and Obstetrics* **90**: 51–5.

Prata N, Passano P, Rowen T *et al.* 2011. Where there are (few) skilled birth attendants. *Journal of Health Population and Nutrition* **29**: 81–91.

Prata N, Sreenivas A, Greig F, Walsh J, Potts M. 2010. Setting priorities for safe motherhood interventions in resource-scarce settings. *Health Policy* **94**: 1–13.

Rajbhandari S, Hodgins S, Sanghvi H *et al.* 2010. Expanding uterotonic protection following childbirth through community-based distribution of misoprostol: operations research study in Nepal. *International Journal of Gynaecology and Obstetrics* **108**: 282–8.

Ravindran TKS, Berer M. 1999. Preventing maternal mortality: evidence, resources, leadership, action. In Berer M, Ravindran TKS (eds). *Safe Motherhood Initiatives: Critical Issues*. Oxford: Reproductive Health Matters, Blackwell Science.

Ronsmans C, Graham W. 2006. Maternal mortality: who, when, where, and why. *The Lancet* **368**: 1189–200.

Sanghvi H, Ansari N, Prata NJ *et al.* 2010. Prevention of postpartum hemorrhage at home birth in Afghanistan. *International Journal of Gynaecology and Obstetrics* **108**: 276–81.

Sanghvi H, Wiknjosastro G, Chanpong G *et al.* 2004. Prevention of Postpartum Hemorrhage, West Java, Indonesia. Baltimore, MD: JHPIEGO.

Save the Children. 2011. Missing midwives. London: Save the Children UK.

Sheldon WR, Blum J, Durocher J, Winikoff B. 2012. Misoprostol for the prevention and treatment of postpartum hemorrhage. *Expert Opinion on Investigational Drugs* **21**: 235–50.

Sibley L, Armbruster D. 1997. Obstetric first aid in the community—partners in safe motherhood. *A strategy for reducing maternal mortality.* Journal of Nurse Midwifery **42**: 117–21.

Sibley L, Sipe TA. 2004. What can a meta-analysis tell us about traditional birth attendant training and pregnancy outcomes? *Midwifery* **20**: 51–60.

Singh S, Darroch J, Ashford L, Vlassoff M. 2009. Adding it up: the costs and benefits of investing in family planning and maternal and newborn health. New York: Guttmacher Institute and UNFPA.

Sutherland T, Meyer C, Bishai DM, Geller S, Miller S. 2010. Community-based distribution of misoprostol for treatment or prevention of postpartum hemorrhage: cost-effectiveness, mortality, and morbidity reduction analysis. *International Journal of Gynaecology and Obstetrics* **108**: 289–94.

UNICEF. 2008. *State of the World's Children 2009*. New York: United Nations Children's Fund.

United Nations. 2010. *The Millenium Development Goals Report 2010*. New York: United Nations.

Velez A, Ramsey K, Tell K. 2007. The Campaign to End Fistula: what have we learned? Findings of facility and community needs assessments. *International Journal of Gynaecology and Obstetrics* **99**: S143–50.

Venture Strategies Innovations/Ministry of Health Zambia. 2010. Prevention of postpartum hemorrhage project in five rural districts in Zambia. Anaheim, CA: Venture Strategies Innovations.

Walraven G, Blum J, Dampha Y *et al.* 2005. Misoprostol in the management of the third stage of labour in the home delivery setting in rural Gambia: a randomised controlled trial. *British Journal of Obstetrics and Gynaecology* **112**: 1277–83.

Weil O, Fernandez H. 1999. Is safe motherhood an orphan initiative? *The Lancet* **354**: 940–3.

WHO. 2007. *Recommendations for the Prevention of Postpartum Haemorrhage*. Geneva: World Health Organization.

WHO. 2010. Comments in response to the application to include mfor prevention of postpartum haemorrhage in WHO Model List of Essential Medicines. Geneva: World Health Organization.

WHO, UNICEF, UNFPA, The World Bank. 2010. *Trends in Maternal Mortality: 1990 to 2008*. Geneva: World Health Organization.

Yeboah-Antwi K, Pilingana P, Macleod WB *et al.* 2010. Community case management of fever due to malaria and pneumonia in children under five in Zambia: a cluster randomized controlled trial. *PLoS Medicine* **7**: e1000340.