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

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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 if (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 (Gyunto 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

<table>
<thead>
<tr>
<th>Obstetric causes of maternal death</th>
<th>Potential options at the facility level</th>
<th>Potential options at the community level, with and without misoprostol</th>
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<td>Treatment of incomplete abortion: medical and/or surgical interventions</td>
<td>Treatment of incomplete abortion: single dose of 600 mcg misoprostol administered orally</td>
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<td>Unsafe abortion</td>
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<td>Obstructed labour</td>
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<td>Caesarean section</td>
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<td>Eclampsia</td>
<td>Administer anti-convulsants</td>
<td>Referral</td>
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<td>Administer anti-hypertensives</td>
<td>Referral</td>
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<tr>
<td>Sepsis</td>
<td>Intravenous (IV)/oral antibiotics</td>
<td>Referral</td>
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<td>Postpartum haemorrhage</td>
<td>Blood loss measurement</td>
<td>Blood loss estimation</td>
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<td>Active management of the third stage of labour (AMTSL)</td>
<td>PPH prevention: single dose of 600 mcg of misoprostol administered orally</td>
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<td>Administer intravenous or intramuscular uterotonic drugs</td>
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<td></td>
<td>Repair of tears or other surgical interventions</td>
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<td>Blood transfusion</td>
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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; Moeen 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 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, Moeen 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 (Moeen 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) (Ejimbi 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; Moeen 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 uterotonic should be practised.

Few will contest that routine non-use of uterotonic (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 kanga 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. 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 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.

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**References**


