Community-Based Distribution of Misoprostol for Prevention of Postpartum Hemorrhage

An Innovative Approach in Ethiopia

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# Table of Contents

I. Introduction .......................................................................................................................................................... 3

II. The Evaluation Process ..................................................................................................................................... 3

III. Background ......................................................................................................................................................... 4

   The extent of the problem .................................................................................................................................. 4
   The promise of misoprostol ............................................................................................................................... 4

IV. The Project—Using lay workers to expand the reach of the health system .................................................. 5

   The project model .............................................................................................................................................. 6
   Changes in project implementation .................................................................................................................. 7
   Project outputs .................................................................................................................................................... 8

V. Evaluation Findings .......................................................................................................................................... 9

   Community-based access to misoprostol is viewed as effective and acceptable ............................................. 9
   Lay youth mentors successfully expanded outreach in the communities ....................................................... 10
   Reaching women with misoprostol at the time of delivery proved difficult ................................................ 10
   Parallel ministry structures prevented effective collaboration ....................................................................... 11
   Most stakeholders resistant to idea of giving the misoprostol to women in advance ................................ 11
   Policy makers and providers expressed concern about “misuse” of misoprostol for abortion ..................... 12
   Many believe that community distribution will undermine the Government’s new focus on increasing institutional deliveries ........................................................................................................................................... 13

VI. Recommendations ......................................................................................................................................... 14

   Recommended modifications to the model ....................................................................................................... 14
   Recommended actions to facilitate scale up in Ethiopia .................................................................................. 15
   Recommended action at the global level ........................................................................................................ 16

VII. Conclusion ...................................................................................................................................................... 17

Appendix A. Ethiopia Contacts List .......................................................................................................................... 19

Appendix B. Work by Other Organizations ........................................................................................................ 21

   Maternal and Newborn Health in Ethiopia Partnership ................................................................................ 21
   Venture Strategies Innovations ....................................................................................................................... 22
   GOAL .............................................................................................................................................................. 22
   Other organizations ............................................................................................................................................ 23

Appendix C. Availability of Misoprostol Product in Ethiopia ................................................................................ 24

   Misoprostol was registered and procured ....................................................................................................... 24
   Issues with product availability ..................................................................................................................... 24

References .............................................................................................................................................................. 27

Acknowledgements .............................................................................................................................................. 28
I. Introduction

Maternal mortality in Ethiopia is one of the highest in the world and postpartum hemorrhage is a major cause of death, particularly in areas where women do not have easy access to healthcare facilities, as is the case in much of this vast country. Misoprostol, an inexpensive pill that is heat-stable and readily available, has proven to be very effective in preventing and treating postpartum hemorrhage; it can save lives if made accessible to women when and where they are giving birth. In Ethiopia, this is most often at home.

From 2008 to 2012 the MacArthur Foundation supported the Population Council to pilot an innovative, community-based approach to postpartum hemorrhage prevention in the Amhara region of Ethiopia—lay youth mentors and health extension workers were trained to bring misoprostol information and services to women in their rural communities. This case study describes the findings of a process evaluation of the MacArthur Foundation’s work to scale up community-based distribution of misoprostol in Ethiopia. This collaborative model was only somewhat effective in reaching women with misoprostol at the time of delivery and policy changes and structural barriers prevented the project from being replicated or scaled up.

Although the project was ultimately not successful as a model for scale up, it did contribute important information to the discussion about how to address maternal mortality in a country where most women give birth at home. Recommendations rooted in the evaluation findings are suggested for consideration as the Ethiopian health authorities move forward to ensure that all women in Ethiopia deliver safely.

II. The Evaluation Process

In 2014, the MacArthur Foundation commissioned the Public Health Institute to conduct an evaluation of the Population Council’s project to prevent postpartum hemorrhage in Amhara. The purpose of this process evaluation was to gain a deeper understanding of how these projects were implemented, where they were successful, and where they would still face obstacles to scale up. A team of experts conducted a desk review of the literature and grantee reports, interviewed global experts and local key stakeholders (see Appendix A), and visited the project sites. The interviews and observations were complemented by focus group discussions with women who had used misoprostol as well as with youth mentors and health extension workers who had delivered the services. The evaluation was carried out between June and November 2014.
III. Background

The extent of the problem

All the 14 death reports that we received from the maternal death surveillance and response that we recently instituted in our region were due to postpartum bleeding.

—A Safe Motherhood Officer, Amhara Regional Health Bureau

Postpartum hemorrhage, defined as blood loss of 500 ml or greater within 24 hours of delivery,¹ is the leading cause of maternal mortality in the developing world, accounting for 27.1% of maternal deaths.² It is one of five main causes of maternal deaths in Ethiopia³,⁴ and is recognized as a serious problem throughout the country; health workers and community members alike are acutely aware of the effects of postpartum hemorrhage, having lost patients, sisters, wives, and neighbors to uncontrolled bleeding after giving birth.

With an estimated 2.6 million births annually and a one in 52 lifetime chance of dying from pregnancy related complications, Ethiopian women carry a disproportionately high burden of maternal morbidity and mortality.⁵ Ethiopia contributes 4% of maternal deaths globally and is one of the ten countries that together contribute 58% of maternal deaths worldwide; in 2013 the maternal mortality ratio was estimated to be 420 deaths per 100,000 live births, with estimates much higher in rural areas.⁶ One clear contributor to the very high rates of maternal death in Ethiopia is the still pervasively low institutional birth rate; births attended by skilled health personnel stood at 9.9% in 2011⁷ and 15.4% in 2014.⁸

The promise of misoprostol

We have witnessed the benefits of misoprostol for ourselves...we would like to see the lives of our sisters saved by continuously availing the drug in our community.

—A lay health worker, Dembia Woreda

One promising approach to preventing postpartum hemorrhage in areas where women have limited access to healthcare facilities is to give pregnant women misoprostol—an inexpensive pill that, when taken immediately after delivery, can reduce the risk of postpartum hemorrhage by between 24 to 47%.⁹¹⁻¹¹ Misoprostol was originally used to treat gastric ulcers but, since the late 1980s, has increasingly been used as a uterotonic (an agent used to induce contraction or stimulate muscle tone of the uterus). Misoprostol has multiple indications, including the prevention and treatment of postpartum hemorrhage, induction of labor, termination of pregnancy, and treatment of incomplete abortion.

Misoprostol is an important alternative to another uterotonic—oxytocin—which is commonly used in healthcare facilities to prevent postpartum hemorrhage. Oxytocin is considered by the World Health Organization to be the uterotonic of choice for postpartum hemorrhage prevention due to its higher effectiveness in clinical trials and reduced side effect profile compared to misoprostol.¹ However, because oxytocin is given by injection or intravenously and must be refrigerated to protect potency, it is most practical for use in healthcare facilities. In contrast, misoprostol is easy to administer and heat stable, making it a useful back up to oxytocin in healthcare facilities (in cases of stockouts or when potency has been compromised by heat exposure). Misoprostol also provides a practical tool for increasing uterotonic coverage for home births.¹²
Distributing misoprostol in communities is an effective strategy that has emerged over the past decade to reach women who for whatever reason—distance to a local clinic, finances, or personal or cultural preferences—give birth at home.\textsuperscript{13–15} Models of community-based distribution of misoprostol include:

- **Advance distribution.** This model involves giving a pregnant woman a supply of misoprostol tablets before her anticipated due date so she can take the medication immediately after delivery (either at home, at a facility that lacks oxytocin, or in transit to a facility). Tablets are typically distributed during antenatal care visits or during home visits by a community health worker or other community agent (e.g., youth mentor);

- **Distribution during home birth.** In this model, a woman giving birth at home is attended by a community health worker or traditional birth attendant who administers misoprostol immediately after delivery;

- **Hybrid models.** These involve a combination of the advance distribution and distribution during home birth models.

All of these models focus on trying to reach women who give birth at home and who, as a result, are at high risk of dying from postpartum hemorrhage.\textsuperscript{16–18} Increasingly, governments in countries like Ethiopia—where institutional deliveries are few and maternal deaths are high—are taking measures to register misoprostol in their countries and exploring how best to use it to reduce the postpartum hemorrhage in their rural communities.

### IV. The Project—Using lay workers to expand the reach of the health system

In 2008, the Population Council proposed to the MacArthur Foundation an innovative approach to providing misoprostol at the community level in a rural Woreda (district) of Amhara, Ethiopia. The project proposed training lay youth mentors to provide misoprostol to women living in rural communities where women, many while still adolescent, deliver at home. The youth mentors were members of “Meserete Hiwot” (Base of Life), a collaboration between the Population Council and the Ministry of Youth and Sports (now the Women, Children, and Youth Bureau) designed to support married adolescent girls.\textsuperscript{19} The plan was to have these lay mentors, working closely with community health workers from the Amhara Regional Health Bureau, expand outreach into the rural communities and thus serve all women.

Map of project area. The entire green area is the Amhara region, with the lighter green indicating the West Gojjam and North Gondar Zones.
(not just the adolescents) who might not have access to health facilities. The project covered 10 Woredas and 100 rural Kebeles in West Gojjam and North Gondar Administrative Zones of Amhara (see map).

The project’s goals were well-aligned with Ethiopia’s Health Sector Development Plan and National Reproductive Health Strategy\(^1\) (which has a goal to reduce the Maternal Mortality Ratio to 267 per 100,000 live births by 2015). The design capitalized on the government’s flagship health extension project, which has maternal and child health projects as its first priority, and built on the findings of another study that had just been completed in Tigray (a region in Northern Ethiopia), which successfully demonstrated that misoprostol could safely be provided in rural communities of Ethiopia.\(^2\)

**The project model**

The Population Council’s model involved sensitizing communities to the availability of misoprostol for postpartum hemorrhage prevention and home outreach by lay youth mentors and health extension workers (see figure below). Early project activities included defining roles and responsibilities and educating women, their family members, and community leaders about the project and about misoprostol to ensure understanding and support for the project.

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Training helped equip the mentors and the health extension workers with basic messages related to misoprostol to be conveyed at the household level. Supervisors and mentors received basic education about pregnancy and delivery, including the use of misoprostol, pregnancy complications, and referrals. (The trainings were done in collaboration with Venture Strategies Innovations.) The health extension workers also took part in this training to familiarize themselves with mentors and supervisors in their catchment areas and to jointly agree on actions to be taken in the case of hemorrhage and other obstetric emergencies.

Once trained, the mentors went house to house in their communities, registering the pregnant women, noting their expected delivery dates, and educating them, their family members, and community leaders about postpartum hemorrhage and misoprostol. As women neared their due dates, the mentors increased their visits to give advice on birth preparedness and share telephone numbers. The women were instructed to call the mentors and health extension workers when labor began. The mentors were responsible for bringing the misoprostol to the delivery, where either they or the health extension worker administered it a few minutes post-delivery (600 µg orally), after ensuring that it was not a multiple pregnancy. (See box below for the story of a typical beneficiary of the project as relayed to us by numerous focus group participants.)

Changes in project implementation

The project proceeded as planned with two notable exceptions. First, implementation was significantly delayed due to the protracted process to register misoprostol through the regulatory arm of the Ministry of Health. (Registration was handled by DKT International, an organization that focuses on social marketing of reproductive health products.) Misoprostol was finally registered for postpartum hemorrhage in June 2010 and the project received permission to begin the service delivery portion of the project in August 2010. Mentors and health extension workers distributed misoprostol and provided community-based services through the end of 2010.

One Woman’s Story

When I was pregnant, the health extension worker and the mentor visited me in my home about every two weeks. During these meetings, they taught me about how HIV is transmitted, how to use family planning methods, and encouraged me to get vaccinated during pregnancy. They also encouraged me to give birth in the nearby health center and told me about the possibility of postpartum bleeding and the availability of Miso.

They told me to call their mobile numbers when I was in labor and they would come to my home as soon as they could. They provided support and encouragement during labor and delivery. After the baby was born, the health extension worker massaged my abdomen, examined if there is another baby, and gave me three tablets to swallow. The placenta “dropped” immediately.
The project also underwent a major change in early 2011 when the Amhara Regional Health Bureau asked the Population Council to shift the focus of the project away from community distribution to training only health workers working in healthcare facilities (and not health extension workers or youth mentors working in the communities). In response to this request by the Regional government, the Population Council had no choice but to phase out the misoprostol distribution by mentors. Instead, they used the remaining funds to train regional health staff on a range of safe delivery topics, including misoprostol, and conducted a rapid assessment of health center and health post capacity in the project area. The request by the Regional Health Bureau anticipated the Federal Government’s renewed commitment to meeting the Millennium Development Goal 5 and its decision, in 2013, to focus on increasing facility deliveries to reduce the persistent high maternal mortality in the country.

**Project outputs**

During the initial phase of the project, mentors and health extension workers were able to reach about 50% of the 5,119 registered pregnant women in their catchment areas with information about facility delivery and misoprostol. However, only 351 of the 1,251 women who delivered during this time period (28%) actually received and took misoprostol after delivery. There were no serious adverse events reported among women receiving the misoprostol.

Additional key outputs of the first phase of the project included:

- Development of training materials for mentors and health extension workers on safe motherhood, including misoprostol for postpartum hemorrhage prevention, which have been incorporated into the Amhara Regional Health Bureau’s training curriculum;
- Training of 197 mentors, 97 health extension workers, and 10 supervisors serving 100 Kebeles, including a three-day training for all and a five-day training on active management of the third stage of labor for health extension workers.

Key outputs of the second phase of the project included:

- A rapid assessment of the capacity of 23 health centers and 36 health posts in the project area to provide emergency obstetric care and life-saving maternal health supplies, including misoprostol;
- Capacity building workshops for 90 staff from the regional, zonal, and Woreda health offices and health centers on emergency obstetric care;
- Training for 112 health workers, including nurses, midwives, health extension workers, and pharmacists (two-day trainings covering a range of maternal health information, including misoprostol for postpartum hemorrhage); and
- Distribution of misoprostol to participating health centers and health posts in the project sites.
V. Evaluation Findings

The Population Council attempted to test a community-based misoprostol distribution model to protect women who do not deliver in health facilities from postpartum hemorrhage; the model employed youth lay mentors to reach remote rural communities. An underlying challenge was the weakness of the healthcare system and the supporting infrastructures that impact access to care (transportation, communication). The rudimentary level of services available in this vast and geographically challenging country affects both the cause and the solution to the high rates of maternal mortality—it is the key reason for the high rates of home deliveries, the principal obstacle to providing care, and the very reason why community-based intervention (in addition to facility-based care) is so important.

The project demonstrated that using trained youth lay workers to provide community-based access to misoprostol at the time of home delivery is viewed as effective and acceptable by women, community members, and many health system stakeholders. However, while some of the elements of the model worked well, it was not ultimately sustainable or scalable. The evaluation identified a number of obstacles that prevented successful implementation of the Population Council’s model, including logistical challenges that prevented mentors and health extension workers from reaching women in labor in a timely manner, government concerns about the use of youth mentors who were not part of the health system, concerns about giving women access to the pills in advance, and fears that women would use the misoprostol to induce abortion. In addition, a strong concern that providing misoprostol at the community level would detract from the government’s efforts to encourage institutional deliveries emerged as an overarching obstacle to all efforts to achieve regional and national scale up of community-based distribution of misoprostol in Ethiopia. Each of these findings is described below.

Community-based access to misoprostol is viewed as effective and acceptable

Judging from the focus group discussions and interviews with stakeholders, the misoprostol was very well received by all involved; users, mentors, health extension workers, and Ministry staff across the project sites expressed a high level of satisfaction with having misoprostol available at the community level through the pilot project. In addition, there was a general appreciation for the clear reduction in hemorrhage that many experienced or observed. The perceived effectiveness of misoprostol in reducing hemorrhage was frequently commented upon, both by the women who had used it and by the workers who had distributed it. A woman who had benefitted from this project shared her story, which was typical of other stories shared with the evaluation team:

*My delivery and labor pains were excruciating with my first three children. When I bled, nobody would bother to take me to a health center. But with the fourth one, these tablets arrived (referring to the misoprostol); there was no bleeding, no horrifying shiver, nothing happened. For that reason I named my daughter “medhanit” meaning “medicine” because I thought I would go through the same pain as the other three and would stay long in bed, but that didn’t happen.*

Lay youth mentors and health extension workers reported that they did not encounter postpartum bleeding when misoprostol was available but are starting to see it again now that the pilot has ended.
For instance, a youth mentor in Dembia Woreda reported that she had encountered three maternal deaths in her village since the project phased out. Many voiced dismay at the fact that the project had been discontinued:

> Mothers ask about the reason for the discontinuation of the service; mothers are now dying...for example in our Kebele, four mothers died because of delivery last year and many people know that the deaths occurred because we are no longer giving them the tablets.

Women, health workers, and community leaders interviewed posed a recurring question:

> How can we get misoprostol services restored to our community?

**Lay youth mentors successfully expanded outreach in the communities**

The core element of the community-based model used in Amhara was the use of youth mentors to expand the distribution of misoprostol into the rural communities where many of the women deliver at home. The premise upon which the model hinged—that lay youth mentors could help reach women who might not otherwise be served—was proven true; the project successfully reached about half of the pregnant women in the project areas with information about misoprostol and administered misoprostol to 351 of the 1,251 women who delivered during the 5-month implementation time period. Ensuring that over 28% of women successfully used misoprostol is a significant increase from a baseline of zero women in a rural population that has limited access to healthcare facilities and services. This model did indeed increase the reach of the health extension workers and community health centers. As one mentor put it:

> The health extension workers are too busy to go to each and every house, but we used to go to each house and have brought changes in the community.

**Reaching women with misoprostol at the time of delivery proved difficult**

Even with the expanded outreach capacity of the lay mentors, reaching women with misoprostol at the time of delivery proved difficult. Difficulties mentioned include: the mentors and health workers were alerted too late to arrive in time to be present at delivery; most deliveries took place at night or early morning, making timely travel to the woman’s home difficult; the great distances and poor road conditions prevented them from arriving in time; health workers often had to travel long distances to collect supplies from a district office. One woman’s experience, shared by many in the focus groups conducted, captures the challenges of obtaining misoprostol at the time of delivery:

> The problem would be if the labor comes at night….or when the health extension workers go for a trip. When labor comes at night, we would spend the night in an excruciating pain (roasted is the word used here), and in the morning we would call them and sometimes they might not be at home (labor is unpredictable). They have other assignments also, sometimes the labor would come when nobody is around. We will ask someone from the neighborhood to get us the health extension worker. We would wait for their arrival rolling on the floor and give birth in pain and anguish. That is why we say it would be advantageous for mothers to have the tablets at home.
Parallel ministry structures prevented effective collaboration

The approach of having lay youth mentors support the work of health extension workers ultimately proved unsustainable. As the project progressed, the Amhara Regional Health Bureau became increasingly reluctant to allow the youth mentors to distribute the misoprostol, citing concerns about using parallel structures for health delivery at the community level and concerned about the challenges of having workers under two supervisory systems (the youth mentors were hired by the Women, Children, and Youth Bureau but were supervised by the health extension workers who in turn were supervised by the Health Bureau). Ultimately, due to the Regional Health Bureau’s desire to use the existing health infrastructure and involve only health workers in the delivery of misoprostol, the responsibility for administering the misoprostol was redirected to the health extension workers. Thus, the Population Council’s model never had the opportunity to be fully tested because the involvement of youth mentors was phased out in early 2011, after only five months of implementation.

Most stakeholders resistant to idea of giving the misoprostol to women in advance

As noted above, the project model to have a youth mentor or health extension worker bring misoprostol to a woman during delivery was not always successful given the unpredictable timing of labor and communication and transportation challenges. Basically, the only person who is guaranteed to be present when a woman delivers is the woman herself. Therefore, the most effective models of community-based distribution of misoprostol are those that give the misoprostol to the women ahead of time, along with education about how and when to use it. To test receptivity to this model, we asked key stakeholders and focus group participants if they thought advance distribution could help overcome some of the barriers faced by the project (difficulty of health extension workers and mentors in reaching women in time, difficulty of transportation to health facilities, etc.). Health personnel at the Regional and Woreda levels, health extension workers, and mentors all had reservations about providing the drugs directly to pregnant women. The most common reasons for these reservations were: a) women may not keep the drug in a safe and clean place; b) they may not take the drug at the right time and in the right amount; c) it could be “misused” for abortion; and d) women could not tell if there is a twin pregnancy and therefore might take the pills too soon, before the delivery of second baby, thereby causing complications. When probed, however, many supported the idea that women might be able to store and take the pills correctly if given proper instruction, as illustrated by the words of these two women:

*If we have the tablet at home, when we give birth we would take it. It will take long until they come to help us. If we wait until they come we would bleed to death.*

*I support giving women the tablets because things do not go as planned, they go God’s way. We trusted them (the health extension workers) and went to their houses, they were not at home. But if we have the tablets with us we will keep them safe in a box, and when in labor we will tell our mothers or sisters about it and then we will use it and sleep peacefully.*

While many of the objections to advance distribution raised in the stakeholder interviews are commonly held, they are not borne out in practice. For instance, a key stakeholder from the
demonstration project conducted in Oromia by the Maternal and Newborn Health in Ethiopia Partnership (MaNHEP) project (see Appendix B for description of this project) noted that:

…after having seen how carefully women keep their misoprostol tablets at home, we have absolute confidence in pregnant women’s capabilities to use the tablets as instructed.

Also, the MaNHEP project adapted their protocol to administer misoprostol after delivery of the placenta, thereby addressing concerns that community lay workers and women were not trained to identify multiple pregnancies. Perhaps the best rebuttal to the concerns raised about advance provision of misoprostol was the case of a woman who had been given misoprostol tablets from the MaNHEP project, took the tablets with her to the health center and, after giving birth, swallowed them after informing the health workers of what she was doing.

Policy makers and providers expressed concern about “misuse” of misoprostol for abortion

Related to the concern about providing misoprostol to women in advance was the strong concern that misoprostol would be “misused” for abortion; in almost every discussion about the feasibility of giving misoprostol directly to the women, the comment that women might use it for abortion was made. In addition, the health authorities at the Regional Health Bureau and Woreda health offices shared their fears that: a) providing misoprostol would encourage abortion; and b) community members might assume that the government is encouraging abortion.

These concerns voiced by providers and authorities contrasted starkly with what mentors and women reported during focus group discussions; neither group thought it likely that a woman who was about to deliver would give it to someone else to use for abortion. The strong desire that women in the focus groups indicated for access to this life saving drug during delivery would also argue against the notion that they would forgo preventive treatment for postpartum hemorrhage in order to use the pills later for abortion.

The level of concern about the potential for “misuse” of misoprostol is curious given that Ethiopia has loosened its restrictions around abortion and that DKT International, Ipas, Marie Stopes International, and Population Services International are actively working with the Federal Ministry of Health to improve access to safe abortion, including medical abortion. DKT’s medical abortion product appears to be widely available in pharmacies and we were able to purchase misoprostol without prescription, simply by going to a pharmacy and asking for it. Despite this clear availability of misoprostol in the private sector (see Appendix C) the concern about the dual use of this drug was pervasive. And the concerns seem to be increasing, not abating: one successful community-based misoprostol project in the Southern Nations, Nationalities, and Peoples’ region was recently asked to stop providing misoprostol for postpartum hemorrhage because of these concerns about misoprostol and abortion (see Appendix B).
Many believe that community distribution will undermine the Government’s new focus on increasing institutional deliveries

The newest and now perhaps greatest obstacle to scaling up any community-based distribution of misoprostol in Ethiopia is the government’s recent decision to increase focus on institutional deliveries as a strategy to reduce maternal and newborn deaths; in 2013, the government announced that its top public health priority would be to focus on facility deliveries, defined as health center or hospital deliveries. Having set a goal that by 2015, 62% of women will deliver in health institutions with a skilled attendant, all projects are being refocused towards that end. Although this decision was officially announced after completion of the Population Council’s project, the Amhara Regional Health Bureau’s decision to shift the focus of the project to capacity building at the facility level may have been an early sign of a national policy shift in this direction.

The belief that community-based distribution might undermine the government goal of increasing institutional deliveries persists and is not supported by evidence from projects conducted in other countries and in Ethiopia over the past ten years. In fact, there is evidence that community-based projects often lead to increased use of services. This was well demonstrated by a project in Ghana (also funded by the MacArthur Foundation) in which the percent of women delivering at a facility in the catchment area where a community-based approach was introduced increased from 30% to 69% between 2008 and 2012. Likewise, in the Population Council’s project in Amhara, women’s use of facilities also seemed to be increasing, not decreasing, in the project areas (the project ended too soon to document this but several of the nurse midwives reported increased use of their services and attributed it to the community education that the project provided).

Nevertheless, our key informants told us that since the announcement of this new national policy in 2013 the distribution of misoprostol at the community level through other projects has been severely curtailed, in large part due to the perception that community-based distribution of misoprostol (helping women safely deliver at home) does not contribute to (and possibly undermines) the government goal of increasing institutional delivery. The Population Council project was not the only misoprostol pilot to have failed to achieve scale up; many organizations have been involved in piloting and expansion of community-based use of misoprostol for prevention of postpartum hemorrhage across the country over the past eight to ten years (see Appendix B for a summary of work by other organizations). The scope and the geographic and population coverage of these projects was variable but the outcomes are not—they all brought convincing evidence of the potential benefits of using misoprostol at the community level to reduce postpartum hemorrhage. Yet none have achieved scale up more broadly within their regions or in other locations in Ethiopia. The current fear that availing the drug at the community level could undermine efforts to increase institutional delivery, along with the concern about use for abortion, appears to be preventing health authorities from actively supporting expansion of misoprostol services.
VI. Recommendations

The numerous pilot projects that have provided misoprostol for postpartum hemorrhage at the community level in Ethiopia provide strong evidence that such an approach can save lives and is valued by women, community members, and many healthcare providers. Still, numerous barriers to community-based distribution of this important drug exist in this very large country where the health infrastructure is weak and access to services is often very difficult, if not impossible.

The government of Ethiopia, committed to meeting its Millennium Development Goals, has recently decided to focus on increasing institutional deliveries as the primary means of reducing the very high maternal mortality and morbidity in the country. While there has been impressive progress toward the goal of facility delivery in Ethiopia—with the percentage of deliveries attended by skilled health personnel increasing from 23.1% in 2013 to 40.9% in 2014—universal facility delivery in rural areas is not within easy reach anytime soon. The challenges that will have to be overcome include but are not limited to: the traditional preference for home delivery; the shortage of skilled health personnel in very rural areas; the difficulties inherent in providing a continuous and regular availability of drugs and supplies; and the poor quality of the services (based on reports by women who participated in the focus groups about how they are treated in facilities). Achieving near universal facility delivery will also require significant time and financial resources to upgrade the healthcare system and its supporting infrastructure (including roads and ambulance services), particularly in Ethiopia’s vast rural areas. Because of these challenges, many women in Ethiopia will undoubtedly continue to give birth at home for some time to come. Almost all of the stakeholders interviewed agreed that until these challenges are addressed, misoprostol should be available as one strategy to address postpartum hemorrhage.

Community-based distribution of misoprostol could be positioned as a complementary effort to the focus on institutional deliveries, offering a lifesaving intervention in the interim. However, based on the findings of the evaluation, modified approaches will be needed. Recommended actions, based on the evaluation findings as well as the evidence and experience of other misoprostol projects in Ethiopia and other countries, are outlined below.

Recommended modifications to the model

Two aspects of the Amhara project model bear modification prior to any attempts to replicate it:

- **Provide misoprostol to women in advance of delivery.** As has been demonstrated by the MacArthur-funded projects in Nigeria and Ghana, the MaNHEP project in the Oromia region of Ethiopia, and numerous projects in other countries, advance distribution of misoprostol to pregnant women is safe and highly effective at increasing uterotonic coverage at delivery. Giving women misoprostol ahead of time would address the barrier the Population Council’s project encountered: the difficulty community health workers and lay mentors had in reaching women with misoprostol at the time of delivery. Distributing the pills to pregnant women in the months or weeks before expected delivery could easily be incorporated into the project model, which includes repeated contacts between pregnant women and health and lay outreach
workers. The evidence that advance provision of misoprostol for the prevention of postpartum hemorrhage is feasible and very effective in meeting the needs of women who deliver at home is incontrovertible;

- **Utilize the Health Development Army for community awareness and mobilization.**

  Established in 2011, the Health Development Army is a government volunteer structure comprised of nearly a half a million women’s groups with more than two million neighborhood networks, each of which reaches five households. This powerful network could function in a similar way to the lay mentors, helping health extension workers identify and register pregnant women as well as educate them about facility delivery and the option of misoprostol in situations when facility deliveries are not possible. In fact, several Army members participated in the focus group discussions, indicating that in some places this collaboration is beginning to happen. If an advance distribution model were to be adopted, Health Development Army members could either encourage pregnant women to get misoprostol from health extension workers before their due date or, if authorized, distribute it themselves. Because the Health Development Army is an established and far-reaching government project with a direct connection to the health project, it could provide a sustainable way to support and expand the misoprostol outreach efforts of health extension workers while overcoming the concern about workers from parallel ministries that proved problematic in the original project design.

**Recommended actions to facilitate scale up in Ethiopia**

The following recommendations suggest possible approaches to revitalizing discussion in Ethiopia about the role of community-based distribution of misoprostol as a complementary strategy to efforts to increase facility delivery.

- **Build understanding and support among policy makers.** Community-based distribution of misoprostol in Ethiopia now hinges almost entirely on government officials understanding that providing service to women delivering at home will not compete with the goal of increasing facility deliveries. There is an urgent need to bring clarity and build consensus on: whether community-based distribution of misoprostol would affect institutional deliveries; the need to deliver the drug at the community level; and the concerns about use of the drug for abortion. Possible approaches to building consensus among policy makers include:
  - A national convening led by the Federal Ministry of Health and relevant stakeholders, including partners who had been involved in community-based distribution of misoprostol for postpartum hemorrhage, to create an opportunity to position community-based distribution of misoprostol as an interim, lifesaving approach; examine the successes and lessons learned from efforts to date (both in Ethiopia and elsewhere); and chart next steps. Much has been learned in the past 10 years about using misoprostol to address postpartum hemorrhage that can help to inform decision making;
  - Framing community-based distribution of misoprostol as a harm-reduction strategy may be a successful approach to gaining policy maker support;
Studies to better understand perceptions and attitudes at the community and policy levels regarding advance provision of misoprostol to women could provide insights on how to address barriers to community distribution. (Note: The MaNHEP project is planning such a study.)

Integrate approaches to reducing maternal mortality. While some of the projects for community-based distribution of misoprostol were part of larger maternal, newborn and child health interventions, others were limited to misoprostol only. As much as death during pregnancy and child birth is multi-causal, it is suggested that both partners and health officials at national and subnational levels jointly work towards integrated interventions whenever feasible. This is particularly true for misoprostol in that it has multiple indications, including postpartum hemorrhage prevention, postpartum hemorrhage treatment, induction of labor, abortion, and postabortion care. Because Ethiopia is seen as a leader in Africa for having loosened restrictions around abortion, it offers a unique opportunity for exploring ways of providing truly comprehensive reproductive services. Greater collaboration between those organizations working with misoprostol for postpartum hemorrhage and those using the drug to reduce unsafe abortion and provide postabortion care could go a long way towards decreasing the strain the Ministry of Health staff may face in keeping the two activities separate, maximizing the impact of misoprostol, and ensuring correct use for each of its indications. A strategic priority could be to ensure a critical mass of informed health providers and program administrators through the inclusion of information about misoprostol (for all of its indications) in pre-service curriculum of nurses, midwives, health officers, and other cadres.

Troubleshoot product and logistics issues. The volume of misoprostol procured in Ethiopia has significantly increased over the past two years with the Pharmaceutical Fund and Supply Agency responsible for the bulk of the purchase. What is not known is who funds the purchase of the product, and where and how the product is distributed through the government system (see Appendix C for discussion about product availability). The Federal Ministry of Health and development partners could work together to jointly forecast needs, solicit funding, and ensure efficient distribution channels such that community level workers have a reliable supply of misoprostol. If an advance distribution model is adopted, registering a single-dose product for postpartum hemorrhage might help facilitate product distribution to and correct use by women, though the costs of this approach would need to be weighed against its perceived benefits.

Recommended action at the global level

Expedite recommendation about advance provision of misoprostol. The World Health Organization is expected to soon make a recommendation regarding the advance provision of misoprostol for postpartum hemorrhage prevention and treatment. A recommendation endorsing this practice as a life-saving measure for women who do not have access to a facility or skilled attendant at delivery would provide needed reassurance to policy makers as they consider how to reduce maternal death in Ethiopia.
VII. Conclusion

By funding the Population Council’s project in Ethiopia and simultaneously, community-based research on misoprostol in Zaria, Nigeria, the MacArthur Foundation established itself as an early leader in exploring the ways misoprostol can be used to reduce maternal mortality due to postpartum hemorrhage. The Ethiopia project (2008–2012) was ahead of its time in two significant ways: first, the project, with its focus on bringing misoprostol to women in their communities, was among the first to recognize misoprostol’s potential for addressing the challenges women face accessing delivery care, particularly in rural areas. Second, the project’s innovative use of lay workers to expand and support the health extension project demonstrated that provision of misoprostol can be successfully de-medicalized, resulting in a broader impact.

Ultimately, however, the Ethiopia project was unsuccessful in scaling up; this was due to logistical difficulties in reaching women with misoprostol at the time of birth, concerns about using non-health workers to distribute misoprostol and its potential use for abortion, and a change in the government’s priorities toward encouraging facility delivery. The logistical difficulties the health extension workers and mentors had reaching women at the time of delivery perhaps could have been predicted given the vast distances, rough terrain, and limited communication options in the rural project areas. The concern about involving lay workers who were not affiliated with the health system also might have been predicted from the outset given the initial reluctance of health officials to involve them and the potential challenges of scaling up a project involving personnel in parallel ministries. The government’s decision to shift its focus to promoting institutional delivery could not have been predicted, but will have a significant impact on all efforts to scale up community-based misoprostol distribution given the perception that the two efforts are incompatible.

Although the project was ultimately not positioned for scale up, the lessons learned can contribute important information to discussions about the role of misoprostol in addressing postpartum hemorrhage in Ethiopia. In particular, the project demonstrated the key role that lay workers can play in supporting health extension workers to reach pregnant women with information about safe delivery, including the role of misoprostol. The advent of the Health Development Army, which falls under the aegis of the health system, represents a significant opportunity to re-establish a lay mentor system for misoprostol education. The project’s finding that it is difficult to reach women with misoprostol at the time of delivery also provides clear support for the potential benefits of providing the tablets to women in advance of their need for them, a practice that is supported by a growing evidence base.

The way forward in Ethiopia will depend on identifying champions within the healthcare system who are able to advocate for misoprostol as a complementary approach to the government’s efforts to promote facility delivery. Whether such champions exist and can overcome the singular focus on facility delivery is unclear. As one key informant commented:

*Everything is in the air, based on the government focus on facility delivery.*
But the Ethiopian government is pragmatic and has shown in several instances to be willing and able to address challenging and even politically sensitive issues once convinced by evidence; their courageous and innovative embrace of medication abortion to tackle the seemingly intractable problem of unsafe abortion is but one example. One can hope that they will decide to do for postpartum hemorrhage what they have done for unsafe abortion—take the evidence and run with the promise that misoprostol offers for preventing maternal morbidity and mortality.

A few days ago a mother died in our Kebele, I told myself that if miso were here she would have been saved 100%. After she gave birth and after the placenta came out, she bled to death. The drug would have saved her life.

—A mentor
## Appendix A. Ethiopia Contacts List

<table>
<thead>
<tr>
<th>Organization</th>
<th>Person Contacted</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project Stakeholders</strong></td>
<td></td>
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</tr>
<tr>
<td>Federal Ministry of Health</td>
<td>Dr. Taye Tolera</td>
<td>Advisor &amp; Head, State Minister’s Office</td>
</tr>
<tr>
<td></td>
<td>Dr. Martha Minweylet</td>
<td>Deputy Director, MCH Directorate</td>
</tr>
<tr>
<td>Amhara Regional Health Bureau</td>
<td>Sr. Addis Zemen Chane</td>
<td>Safe Motherhood Officer</td>
</tr>
<tr>
<td>Amhara Region Bureau of Women, Youth and Children</td>
<td>Ato Endalew Giwen Tsega</td>
<td>Deputy Head</td>
</tr>
<tr>
<td></td>
<td>Ato Alemseged Wolde Gerima</td>
<td>Officer</td>
</tr>
<tr>
<td>Mecha Woreda Health Office, West Gojjan</td>
<td>Ato Gashaw Tamrat</td>
<td>Health Extension Project Coordinator</td>
</tr>
<tr>
<td></td>
<td>Ato Belete Mengesha</td>
<td>Licensing Officer</td>
</tr>
<tr>
<td>Reem Rural Kebele, Mecha Woreda</td>
<td>Ato Dessie Tegegn</td>
<td>Administrator</td>
</tr>
<tr>
<td></td>
<td>Wzo. Ayal Wolela</td>
<td>Leader, Government Development Team</td>
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<tr>
<td></td>
<td>Wzo. Feten Enquanhone</td>
<td>Leader, Government Development Team</td>
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<tr>
<td></td>
<td>Wzo. Enquanhonech Demelash</td>
<td>Health Extension Worker</td>
</tr>
<tr>
<td>Dembia Woreda Health Office</td>
<td>Ato Destaw Minalew</td>
<td>Head</td>
</tr>
<tr>
<td></td>
<td>Ato Dejen Adane</td>
<td>MCH Officer</td>
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<tr>
<td></td>
<td>Sr. Misa Tarekegn</td>
<td>Nutrition and Child Health Officer</td>
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<tr>
<td>Gondar Zuria Woreda Health Office</td>
<td>Ato Dires Abera</td>
<td>Maternal and Youth Health Officer</td>
</tr>
<tr>
<td>Zenjag Rural Kebele, Gondar Zuria Woreda</td>
<td>Wodaje Nega</td>
<td>Health Extension Worker</td>
</tr>
<tr>
<td></td>
<td>Tiruye Tarkegn</td>
<td>Health Extension Worker</td>
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<tr>
<td></td>
<td>Tirusew Megabiaw</td>
<td>Leader, Government Development Team</td>
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<td></td>
<td>Abeba Ambereber</td>
<td>Leader, Government Development Team</td>
</tr>
<tr>
<td><strong>Grantee</strong></td>
<td></td>
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<tr>
<td>Population Council</td>
<td>Dr. Annabel Erulkar</td>
<td>Country Director</td>
</tr>
<tr>
<td></td>
<td>Ato Getachew Kassa</td>
<td>Regional Director</td>
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<tr>
<td></td>
<td>Ato Sisay Melesse</td>
<td>Former Senior Project Manager RH (Project Manager for MNCH, Save the Children)</td>
</tr>
<tr>
<td>Organization</td>
<td>Person Contacted</td>
<td>Position</td>
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<tr>
<td><strong>Other Key Informants</strong></td>
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<tr>
<td>DKT International</td>
<td>Wzo. Dagmawit Girmay</td>
<td>Deputy Country Director</td>
</tr>
<tr>
<td></td>
<td>Ato Dagnachew</td>
<td>National Sales Coordinator</td>
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<tr>
<td></td>
<td>Alemayehu</td>
<td></td>
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<tr>
<td></td>
<td>Rory Harrington</td>
<td>Country Director</td>
</tr>
<tr>
<td>EngenderHealth</td>
<td>Dr. Yetnayet Asfaw</td>
<td>Former Country Director (now VP, based in Washington, DC, USA)</td>
</tr>
<tr>
<td></td>
<td>Ato Jamel Kassaw</td>
<td>Interim Country Director</td>
</tr>
<tr>
<td></td>
<td>Dr. Dereje Neussie</td>
<td>President, Ethiopian Soc. of Ob &amp; Gyn</td>
</tr>
<tr>
<td>GOAL, Ethiopia</td>
<td>Ato Fitsum Teshome</td>
<td>Urban and Rural Development Project Manager</td>
</tr>
<tr>
<td></td>
<td>Ato Anteneh Girma</td>
<td>Senior Health Advisor</td>
</tr>
<tr>
<td>Ipas</td>
<td>Dr. Tibebu Alemayehu</td>
<td>Senior Health Systems Advisor</td>
</tr>
<tr>
<td>JSI, Last 10 Km</td>
<td>Wzo. Wuleta Betemariam</td>
<td>Country Director</td>
</tr>
<tr>
<td></td>
<td>Dr. Nebreed Fisseha</td>
<td>Technical Director and Senior Expert, Maternal and Newborn Health</td>
</tr>
<tr>
<td>MacArthur Foundation</td>
<td>Kole Shettima, PhD</td>
<td>Director, Africa Office</td>
</tr>
<tr>
<td></td>
<td>Erin Sines</td>
<td>Acting Director, Population and Reproductive Health</td>
</tr>
<tr>
<td>MaNHEP, Ethiopia</td>
<td>Dr. Abebe G/Mariam</td>
<td>Project Director</td>
</tr>
<tr>
<td></td>
<td>Wzo. Aynalem H/Michael</td>
<td>Senior Facility Quality Improvement Advisor</td>
</tr>
<tr>
<td></td>
<td>Wzo. Lelisa Tadesse</td>
<td>Senior Maternal, Newborn and Child Health Advisor</td>
</tr>
<tr>
<td></td>
<td>Dr. Lynn Sibley</td>
<td>Director, MaNHEP</td>
</tr>
<tr>
<td>Planned Parenthood Federation of America Global</td>
<td>Mary Jane Wagle</td>
<td>Former Director of PPFA Global, now living in Addis and writing a book on Ethiopian Women Leaders</td>
</tr>
<tr>
<td>SafeHands</td>
<td>Nancy Durrell McKenna</td>
<td>Founder, Director</td>
</tr>
<tr>
<td>Venture Strategies Innovations</td>
<td>Nuriye Hodoglugil</td>
<td>Associate Medical Director</td>
</tr>
<tr>
<td></td>
<td>Ndola Prata</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Wide Horizons For Children</td>
<td>Debbie Mansfield</td>
<td>Deputy Director of Projects</td>
</tr>
</tbody>
</table>
Appendix B. Work by Other Organizations

In addition to the MacArthur Foundation funded project, there have been several other pilot projects in Ethiopia that have distributed misoprostol at the community level. These pilot projects used innovative approaches (e.g., training traditional birth attendants who live in communities to use misoprostol, direct distribution of misoprostol to women) to access women where they give birth. While these too have been successful in proving the feasibility and effectiveness of providing community-based misoprostol for postpartum hemorrhage prevention, there are currently no plans within the country for scaling up any of these models. As one key stakeholder at the regional level lamented, “we see pilot projects come and go without being scaled up, and that is a big problem.”

Maternal and Newborn Health in Ethiopia Partnership

Funded by the Bill and Melinda Gates Foundation and in partnership with Emory University and other local and international partners, the Maternal and Newborn Health in Ethiopia Partnership (MaNHEP) worked in the Amhara and Oromia regions (covering two Zones, six Woredas and 51 Kebeles)* to test a model for community-based distribution of misoprostol for postpartum hemorrhage prevention. The three year project ended in May 2013.

Misoprostol information was provided to women during antenatal visits, along with encouragement to go to the nearest health facility for institutional delivery. When labor set in, families called the health extension worker’s mobile phone or sent someone to fetch her. The health worker would then rule out a multiple pregnancy and administer misoprostol. At the later phases of the project, and in the absence of health extension workers, community volunteers and women themselves were taking misoprostol tablets after delivery of the baby and removal of placenta.

As in the Population Council project, a key finding of the MaNHEP project was that health extension workers were not always available during labor and delivery, resulting in only 20–30% of the eligible women receiving misoprostol during the initial phases of the project. Based on this low coverage rate, the project deployed a wider group of community volunteers and later the Health Development Army for community education and distribution of misoprostol. Officials from Oromia Health Bureau and the MaNHEP team also reached a consensus that “the best custodian is the woman herself” and issued an official letter from the Regional Health Bureau instructing Zonal and Woreda Health Offices to facilitate advance distribution of misoprostol to pregnant women. This strategy eventually led to a much wider uptake and acceptability of misoprostol in the Oromia region as compared to the Amhara region.

In an article that compares the trends in the two regions of women’s awareness and use of misoprostol authors describe:

…at end line, significantly more women in Oromia were aware of misoprostol compared with women who resided in Amhara (94% vs 59%); significantly more had received misoprostol (80% vs 35%); significantly more had received it during pregnancy (93% vs 48%); and significantly more had received it through varied sources. Most women who received misoprostol used it (95%) irrespective of age, parity, or education.26

* Note, these sites did not overlap with the Population Council project areas in Amhara.
These findings demonstrate that policy and project strategies that support multiple distribution channels are effective in increasing women’s access to and use of misoprostol, particularly because they offset distribution bottlenecks, such as when health extension workers are absent from their posts during holidays, training events, or maternity leave. The MaNHEP project also illustrated that although Federal Ministry of Health policies on use of misoprostol at the community level are unequivocal, health authorities at subnational levels have differences of opinion and approaches to implementation. For example, officials in Amhara adopted a strict interpretation of the Federal Ministry of Health policies that reflected their fear that misoprostol would be “misused” and that providing it for home deliveries would run contrary to the government’s policy to encourage facility births. In contrast, Oromia officials decided to adopt a more expansive distribution strategy for misoprostol as a way of reaching the broader national goal of reducing maternal mortality.

Venture Strategies Innovations

Venture Strategies Innovations (VSI) played a key role in the introduction of misoprostol in Ethiopia, first by demonstrating that misoprostol could safely be provided in a rural community in Ethiopia, and secondly, by collaborating with the Ethiopian Federal Ministry of Health, regional health authorities, and DKT International to register misoprostol for multiple indications. Between July 2005 and January 2007, VSI conducted a field intervention trial in rural Tigray (a region in Northern Ethiopia where access to services is particularly difficult) that demonstrated that traditional birth attendants could safely provide misoprostol during home deliveries, reducing the need for referral due to bleeding by half. This groundbreaking study in rural Tigray laid the groundwork for the Population Council’s proposal to use lay workers to reach rural communities in Amhara.

After the Tigray study, VSI continued working closely with the Federal Ministry of Health, developing a curriculum for training traditional birth attendants on misoprostol for postpartum hemorrhage management; training health extension workers in Tigray, Amhara, Oromia, and Southern Nations, Nationalities, and Peoples’ regions; and supporting Women’s Association meetings to raise awareness about misoprostol in official “Misoprostol Days” throughout these regions. VSI also trained health extension workers about misoprostol (used alone or with mifepristone) as part of a comprehensive abortion care project (this project was eventually shifted to facilities only).

VSI collaborated with the Population Council and the Regional Health Bureau during the Population Council’s project, providing technical leadership to all training activities. VSI ended operations in January 2015 and thus will not be involved in Ethiopia moving forward.

GOAL

GOAL Ethiopia is proposing to test approaches to community-based distribution of misoprostol for postpartum hemorrhage prevention in pastoralist communities in Borena Zone, Oromia region. Supported by CORDAID, the misoprostol research is part of a bigger project that includes rural development; basic emergency obstetric and newborn care; postabortion care; family planning; water, sanitation, and hygiene (WASH); and nutrition. Health extension workers will work in collaboration with lay workers to reach women with information and misoprostol. This project was informed by the national roadmap for accelerated reduction of newborn, child and maternal mortality which is being implemented by the health extension project as one element of the “Safe and Clean Delivery” package.
Lessons from this project will be applied to national scale up to other pastoralist communities in Ethiopia. Preparations are also underway to implement a similar project in selected Woredas in West Haraghe Zone, Oromia region.

**Other organizations**

Numerous large international donors (USAID, DFID, Gates, Merck for Mothers) are now focusing on maternal and neonatal health and in Ethiopia several maternal, neonatal and child health projects are integrating the use of misoprostol for postpartum hemorrhage into their projects. Two examples include the Integrated Family Health Project, a six-year (2008–2014) USAID-funded project, and USAID’s flagship Maternal, Child Health Integrated Project (MCHIP). There are also likely other smaller misoprostol pilot projects happening in Ethiopia, some that we identified (SafeHands) and others that we may not have detected. For example, we learned after our visit of a project in Shebedino Woreda of the Southern Nations, Nationalities, and People’s region that had trained health extension workers and traditional birth attendants to supply misoprostol for postpartum hemorrhage prevention until 2013, when the government asked the project to stop.  

In addition, many organizations are working in Ethiopia to introduce misoprostol for comprehensive abortion care. Since 2004, when the Ethiopian Parliament passed one of Africa’s most progressive abortion laws, many NGOs—including Ipas, Marie Stopes International, EngenderHealth, John Snow International, Pathfinder, VSI and DKT—have been partnering with the Federal Ministry of Health to expand women’s access to safe abortion services. The Anonymous Donor, DFID and USAID have poured a lot of funding into Ethiopia over the past ten years and many innovative service delivery approaches have been and are being tried to integrate comprehensive abortion care with government family planning projects; the use of misoprostol and mifepristone (another abortion drug) are at the heart of these services. As a result, many organizations are working on misoprostol projects for several indications, but in some cases their activities are not well integrated due to the separation of funding streams for the postpartum hemorrhage and abortion care indications.
Appendix C. Availability of Misoprostol Product in Ethiopia

Misoprostol was registered and procured

Over the last eight years (2003–2011), Ethiopia has accomplished: the introduction of misoprostol into the national list of essential drugs; registration of the drug by the regulatory wing of the Federal Ministry of Health; use of misoprostol to manage unsafe abortions; and provision of the drug for prevention of postpartum hemorrhage, including at the community level.

Misoprostol was included in the national list of essential drugs in 2006 and registered for prevention of postpartum hemorrhage in June 2010, making Ethiopia the twelfth country in Africa and the sixteenth globally to register misoprostol for use in prevention and treatment of postpartum hemorrhage. The registration enabled legal importation, distribution, and marketing of the drug as well as implementation of pilot projects to increase access in rural areas. The misoprostol product for the Population Council pilot project was supplied by DKT/Ethiopia, a large international social marketer who provides access to family planning products and safe abortion products in Ethiopia, which had approval to supply it pre-registration for use in pilot projects and studies for postpartum hemorrhage prevention. During project implementation, the misoprostol product was recalled due to quality concerns. However, because DKT had a backup supplier, there was no disruption to product availability in the pilot project.

DKT International has been the lead organization (in collaboration with the Federal Ministry of Health, Venture Strategies Innovations, Population Council, Ipas, and Engender Health) in ensuring misoprostol registration, importation, and distribution to public and private healthcare facilities. Since 2008, DKT has imported and distributed over two million tablets of misoprostol, of which slightly over 50% went to Regional Health Bureaus for use by health extensions workers trained in “safe and clean delivery” and about 40% went to private-for-non-profit organizations. DKT also distributes misoprostol to private pharmacies through its social marketing scheme, with particular focus in rural areas. In addition to being used for postpartum hemorrhage prevention and treatment, misoprostol is also used for postabortion care and induction of labor. According to DKT’s data, misoprostol appears to be in the Federal Ministry of Health’s drug supply chain. However, there was no evidence of its availability at the health post or health center level (an observation that was supported by statements from key stakeholders (see below). The Pharmaceutical Fund and Supply Agency (PFSA), mandated to centrally procure drugs and medical supplies to the public sector, purchased and distributed five million tablets of misoprostol in 2013. Recently, PFSA has awarded a bid for the procurement of an additional five million tablets of misoprostol to Famy Care (based in India). Although information about the source of funding for this purchase is not available, this development could be indicative of the increasing demand for misoprostol and the Federal Ministry of Health’s intention to scale up its distribution.

Issues with product availability

Several product-related issues affected implementation of the project and are potential obstacles to scale up, including weakness in the government supply system, limited options for private sector distribution of misoprostol, the lack of single-dose packaging, and the potential for confusion with other products containing misoprostol.
Although misoprostol was registered and procured, the Population Council reported that it never became readily available through the government supply system during the project period (only hospitals and some health centers had it). Recognition of this weakness in the health system infrastructure was one reason given for ultimately shifting the project’s emphasis to capacity building. We were told that distribution of misoprostol within the health system remains weak, with blockages in the supply system preventing misoprostol from getting to the health center and community level (none of the health centers or health posts visited had misoprostol in stock). For example, a regional official reported that they receive plenty of misoprostol through the government supply chain, but much of it goes unused and expires (the product has a two-year shelf life). Health extension workers and Kebele and Woreda leaders report that they request misoprostol but do not receive it, indicating a blockage in the supply chain system between the regional and Woreda levels. Whether this is due to poor communication, a weak supply chain, or reluctance to supply misoprostol to the community level is unclear. One possible reason, suggested from interview findings, is that health bureau officers and health providers who did not receive training about misoprostol (due to staff turnover, for example) were reluctant to have health extension workers distribute the drug.

While Ethiopia benefits from several strong reproductive health social marketing projects, private sector distribution options for misoprostol for postpartum hemorrhage are limited. This is because the government regulations limit distribution of a drug like misoprostol to authorized pharmacies; drug sellers, much more common and accessible in the rural areas than pharmacies, are not authorized distributors. DKT shared the example of the challenges of private sector distribution of misoprostol in safe and clean delivery kits; kits that contain misoprostol can be sold through pharmacies, which are largely located in urban areas where healthcare facilities are more accessible, but cannot be sold through drug sellers, which are largely located in rural areas. As a result, women who have less access to health facilities and therefore a higher need for misoprostol cannot purchase the kits that contain this potentially life-saving drug.

Misoprostol is currently available in Ethiopia in the form of the DKT product Misofem®. It is packaged as a set of twelve 200 µg tablets (three foil packs of four tablets each) and labelled for the prevention and treatment of postpartum hemorrhage. While this configuration is convenient for clinical providers and other healthcare workers who administer misoprostol after delivery, the multi-dose packaging is not ideally suited for community-based distribution approaches that provide misoprostol to women in advance of delivery (such as the MaNHEP project in Oromia and safe and clean delivery kits designed for one-time use). If Ethiopia moves toward an advance-provision model, a single-dose product (a packet containing three 200 µg tablets, instructions for postpartum hemorrhage prevention, and product expiration information) could facilitate distribution and correct use. Some countries have registered single-dose misoprostol products for postpartum hemorrhage (Burundi, Madagascar, Nigeria, Rwanda, Pakistan, and Senegal all have three-tablet packs available) while others, like Ethiopia, still rely on cutting up blister packs to provide the correct dose.

Finally, in addition to Misofem® packaged for postpartum hemorrhage indications, misoprostol is available throughout Ethiopia in private pharmacies as a component of DKT’s Safe-T Kit, a medication abortion product that contains one 200 mg tablet of mifepristone and four 200 µg tablets of misoprostol. There seems to be some confusion about the two misoprostol products on the part of customers.
and pharmacy staff. For instance, when we sent a mystery shopper in to several pharmacies asking for “misoprostol,” it was assumed she was seeking it for abortion and she was directed to the Safe-T Kit. The three pharmacists she spoke to seemed unaware of misoprostol’s use for postpartum hemorrhage, which may reflect the very low level of distribution of the Misofem® product through private sector vendors (reported as just 4% of DKT’s distribution). Similarly, the community health workers, mentors and women users we spoke with did not realize that they could obtain the misoprostol they so very much wanted for delivery by purchasing the abortion kit in a pharmacy and just using three of the misoprostol tablets. Cost did not seem to be the barrier—to quote one woman:

There is no price too high for a human life.

—but rather the lack of knowledge or understanding that the misoprostol pills in the abortion kit are the same as those they seek for postpartum hemorrhage.
References


Acknowledgements

We are grateful to the following groups and key informants who graciously gave of their time and shared their expertise: Amhara Regional Health Bureau; Amhara Women, Children, and Youth Bureau; Woreda health offices, community leaders; Health Extension Workers, and mentors; Population Council staff and all the key informants. We would also like to thank Tarra McNally, who contributed background research to this report.

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