

SYNTHESIS REPORT

Scaling up Access to Misoprostol at the Community Level to Improve Maternal Health Outcomes in Ethiopia, Ghana, and Nigeria

Findings from an Evaluation of Different Models



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I. Introduction

Over the past decade (2004–2014), the Population and Reproductive Health area of the MacArthur Foundation has focused on supporting projects aimed at reducing maternal mortality. In particular, it has supported efforts to use misoprostol to prevent postpartum hemorrhage, the anti-shock garment to aid in the treatment of hemorrhage, and magnesium sulfate to decrease deaths from eclampsia. In recent years, the Foundation has invested in a range of research and evaluation efforts to better understand these interventions, their effectiveness, and the extent to which successful pilot projects have been scaled up.

In 2014, the Foundation commissioned the Public Health Institute to evaluate the grants it had made to increase community-based access to misoprostol for postpartum hemorrhage prevention in Ethiopia, Ghana, and Nigeria. Specifically, the Foundation was interested in documenting the models and approaches used and the progress toward scaling up the respective models in the three countries. Between June and November 2014, the evaluation team reviewed grantee reports, proposals, and the literature; interviewed key informants and global, national, and local stakeholders; conducted focus group discussions with local stakeholders; and made observations during site-visits in each country. From this the team produced case study reports relating to misoprostol use in each country. This report is a synthesis of those three case studies, highlighting the common findings across the projects, identifying differences, and interpreting the lessons learned for broader use and scale up of misoprostol at the community level in Africa and globally.

II. Background

Postpartum hemorrhage—the extent of the problem

Postpartum hemorrhage is the leading cause of maternal mortality in low income countries, accounting for over 27% of maternal deaths^{1,2} and is arguably the most preventable.³ The risk of hemorrhage at birth is highest for women who deliver at home as they do not benefit from the support of skilled birth attendants and are less likely to receive care and medications that prevent or treat postpartum hemorrhage. Women who live in rural areas are particularly at risk due to limited health services and the myriad transportation challenges they may encounter trying to access those facilities that do exist.

In Ethiopia, Ghana, and Nigeria the incidence of maternal mortality due to postpartum hemorrhage is high and many women still deliver at home (see Table 1). The problem is widely recognized in all three countries—government officials, health providers, and community members are acutely aware of its effects, having lost patients, sisters, wives, mothers, and neighbors to uncontrolled bleeding after giving birth—and governments in all three countries are committed to reducing this heavy burden of maternal mortality.

Table I. Key indicators relating to maternal health in project countries

	Ethiopia	Ghana	Nigeria
Maternal Mortality Ratio*	420 (240–720)	380 (210–720)	560 (300–1000)
Annual maternal deaths	13,000	3,100	40,000
Antenatal care (at least one visit)	42.5%	96.4%	66.2%
Home delivery rate+	85%	33%	55%

*Deaths per 100, 000 live births (range of ratio in parentheses). The average estimated MMR in developed regions is 16 (with a range of 12–23).

+Typically higher in rural areas

Sources: Trends in Maternal Mortality: 1990 to 2013 Estimates by WHO, UNICEF, UNFPA, The World Bank and the United Nations Population Division; Central Statistical Agency [Ethiopia]. 2014. Ethiopia Mini Demographic and Health Survey 2014. Addis Ababa, Ethiopia; http://www.unicef.org/infobycountry/ethiopia_statistics.html; http://www.unicef.org/infobycountry/ghana_statistics.html; http://www.unicef.org/infobycountry/nigeria_statistics.html.

The promise of misoprostol

In home births without a skilled attendant, misoprostol may be the only technology available to control postpartum hemorrhage.

*—International Federation of Gynecology and Obstetrics/
International Confederation of Midwives 2006 Joint Statement⁴*

One promising approach to preventing postpartum hemorrhage 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%.^{5–7} Misoprostol was originally used to treat gastric ulcers (brand name Cytotec®) 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.³ 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.⁸

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.^{9–11} 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.

- **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 are at the highest risk of dying from postpartum hemorrhage. Increasingly, governments in countries like Ethiopia, Ghana and Nigeria—where institutional deliveries are low and maternal deaths are high—are taking measures to register misoprostol in their countries and exploring how best to use it to reduce postpartum hemorrhage in their rural communities.

The evidence from community-based distribution models

Evidence from models of community-based distribution of misoprostol for postpartum hemorrhage prevention in Asia and Africa, combined with the mounting global focus on improving maternal health indicators to meet the 2015 Millennium Development Goals, has sparked the interest of national governments and international funders to scale up cost-effective models for community-based distribution of misoprostol to prevent and treat postpartum hemorrhage.

A range of studies conducted in South Asia and Africa, have shown that community-based distribution of misoprostol is feasible, acceptable to users, safe, and effective;^{12,13} in Nepal, postpartum hemorrhage is no longer the leading cause of maternal death, thanks in large part to the community distribution of misoprostol, and in Zambia, based on the success of several pilot studies, the government is expanding the community distribution of misoprostol nationally.¹⁴ Pilot studies have shown that when used in home birth settings misoprostol reduced the risk of postpartum hemorrhage between 24 to 47%.⁵⁻⁷



A community health worker and traditional birth attendant talk to women about postpartum hemorrhage and the benefits of using misoprostol in a rural village in Gombe State, Nigeria.

One review of eighteen projects that used misoprostol for prevention of postpartum hemorrhage during home births found that women who self-administered the drug took it correctly, that very few women took the drug before birth (8 out of 12,000 women), and that no deaths were directly attributable to the use of misoprostol.¹⁰ Regarding concerns about side effects of the drug, a 2009 randomized controlled trial of oral misoprostol compared to a placebo for postpartum hemorrhage found the side effects of misoprostol were limited to shivering (52% vs. 17%) and fever (4.2% vs. 1.1%) at two hours postpartum.¹⁵

Based on the evidence from these studies, the World Health Organization, in 2011, added misoprostol to its List of Essential Medicines, and, in 2012, endorsed its use for prevention of postpartum hemorrhage by community health workers. But it stopped short of recommending it for advanced distribution to women, citing insufficient evidence and calling for more data on coverage, safety, and health outcomes.³ Several studies have since been conducted including a randomized, placebo-controlled trial in Uganda by Gynuity Health Projects that provides convincing evidence of the safety of advance distribution of misoprostol. It is anticipated that the World Health Organization will consider its endorsement to include advance provision of misoprostol as soon as the study is published.¹⁶

Worldwide, many governments, universities, and international nongovernmental organizations have recognized the promise of misoprostol at the community level and have collaborated to implement and evaluate models of community-based distribution of misoprostol to prevent postpartum hemorrhage. These partnerships and their outcomes have frequently pushed the frontiers of global maternal health practice and influenced international health bodies to move beyond the traditional medical paradigm and recognize that many women still give birth at home and remain at risk of postpartum hemorrhage despite the best efforts of governments to ensure access to healthcare facilities. Given that options to reach women who give birth at home are limited, particularly in remote and often insecure regions, many governments will continue to explore ways to protect these women from the risk of hemorrhage.

III. Grant-making to reduce maternal mortality using misoprostol

Recognizing the potential that misoprostol could have for addressing the problem of postpartum hemorrhage in Ethiopia, Ghana, and Nigeria, the MacArthur Foundation invested in a package of grants designed to explore and hopefully achieve sustainable and comprehensive solutions. Cognizant of the challenges of taking a good idea to scale in countries already strained by overburdened health infrastructures, the Foundation designed its grant-making approach with the key elements of successful scale up in mind (see box, The Challenge of Scale Up).

The Challenge of Scale Up

A significant challenge for any national healthcare system is scaling up interventions that are proven successful in small pilot projects so that they become integrated parts of ongoing national health services. While it is often assumed that scale up will easily follow a successful pilot, the realities surrounding pilot project implementation (significant funding, strengthened infrastructure in the pilot project site) are very different from the realities faced by health system's managers as they try to expand the model (limited funding, competing health priorities, weak infrastructure). The average time for taking a successful pilot to national scale is 15 years.¹⁷

Scale up is more likely to be successful if the intervention addresses a compelling need and is supported by evidence. Other important factors leading to successful scale up include being endorsed by credible sources; observable so that potential users can see the results in practice; easy to transfer and adopt; compatible with the system's established values, norms, and facilities; and able to be tested for feasibility before committing the potential user to full scale up.¹⁸

Even when the intervention to be scaled up is the “perfect solution” to a compelling problem, efforts to expand its use on a widespread basis require careful planning from the outset. The scale up plan should include a clear vision of what is to be scaled up as well as how each of the key steps in the process of bringing a successful intervention to scale (see figure below) will be addressed.

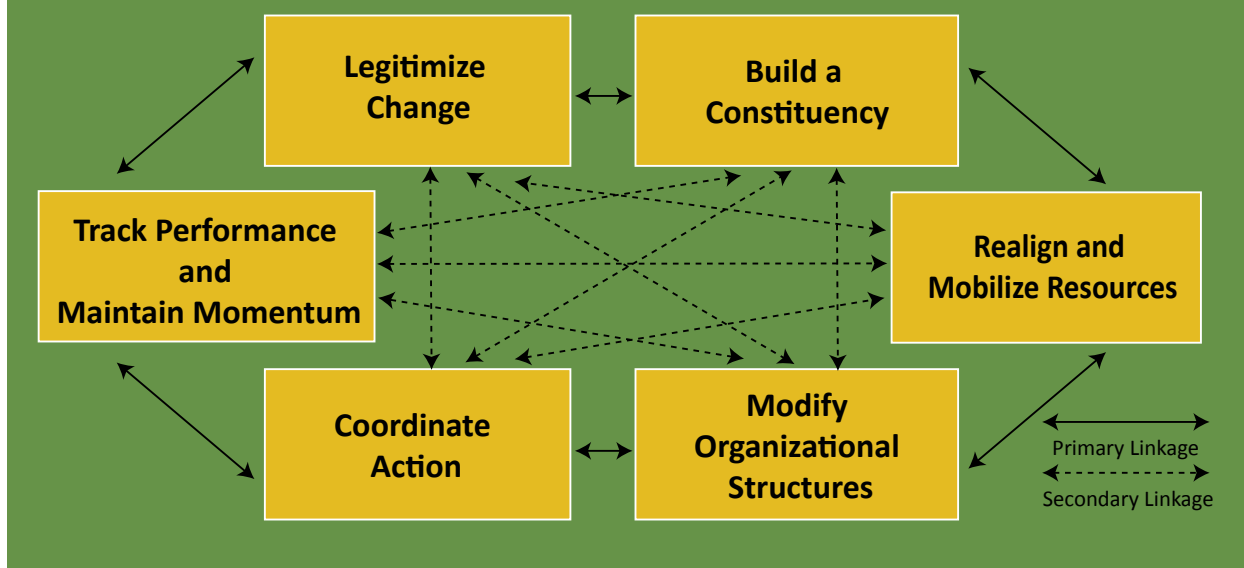
The scale up process typically starts by legitimizing the proposed change, which includes documenting the need for the intervention (in this case, high rates of postpartum hemorrhage and difficulty accessing facilities for delivery) and demonstrating that the proposed approach will address this need. This information is then used to build the support of the key constituencies who will be involved in implementing the intervention and those who will benefit from it, including policy makers, service providers, community groups, and the women who will ultimately receive the service. Constituent support can help to mobilize the financial and human resources that will be needed for managing the scale up

(continued)

The Challenge of Scale Up, *continued*

process as well as for providing ongoing services at the scaled up level. Scale up also may require modifying organizational structures to ensure that the new intervention becomes part of ongoing services. Changes may involve modifying policies, job responsibilities, pre- and in-service training protocols, or supervision. Because scale up happens at the system level, efforts are needed to coordinate action between overarching functional areas such as policy; drug regulation, procurement, and distribution; and community-based outreach systems. Finally, by tracking performance, programs can gain useful information for making improvements to the model, as well as evidence to legitimize the need for continuing the service.

Figure 1. Key elements of the scale up process¹⁷



The use of misoprostol to prevent postpartum hemorrhage is clearly a “scalable” intervention: numerous studies have demonstrated its safety and efficacy; it is endorsed by the World Health Organization for use when other uterotonics are not available or compromised; it can be provided within existing systems; its use results in a dramatic reduction in maternal mortality; and it addresses the strong community value of safe motherhood. So, to support efforts to reduce maternal mortality in Ethiopia, Ghana, and Nigeria, the MacArthur Foundation made grants to organizations in these three countries (see Appendix A for list of grants made). The overarching goal of the grants was to demonstrate and document effective approaches to increasing access to misoprostol at the community level and to work towards national scale up of successful models.

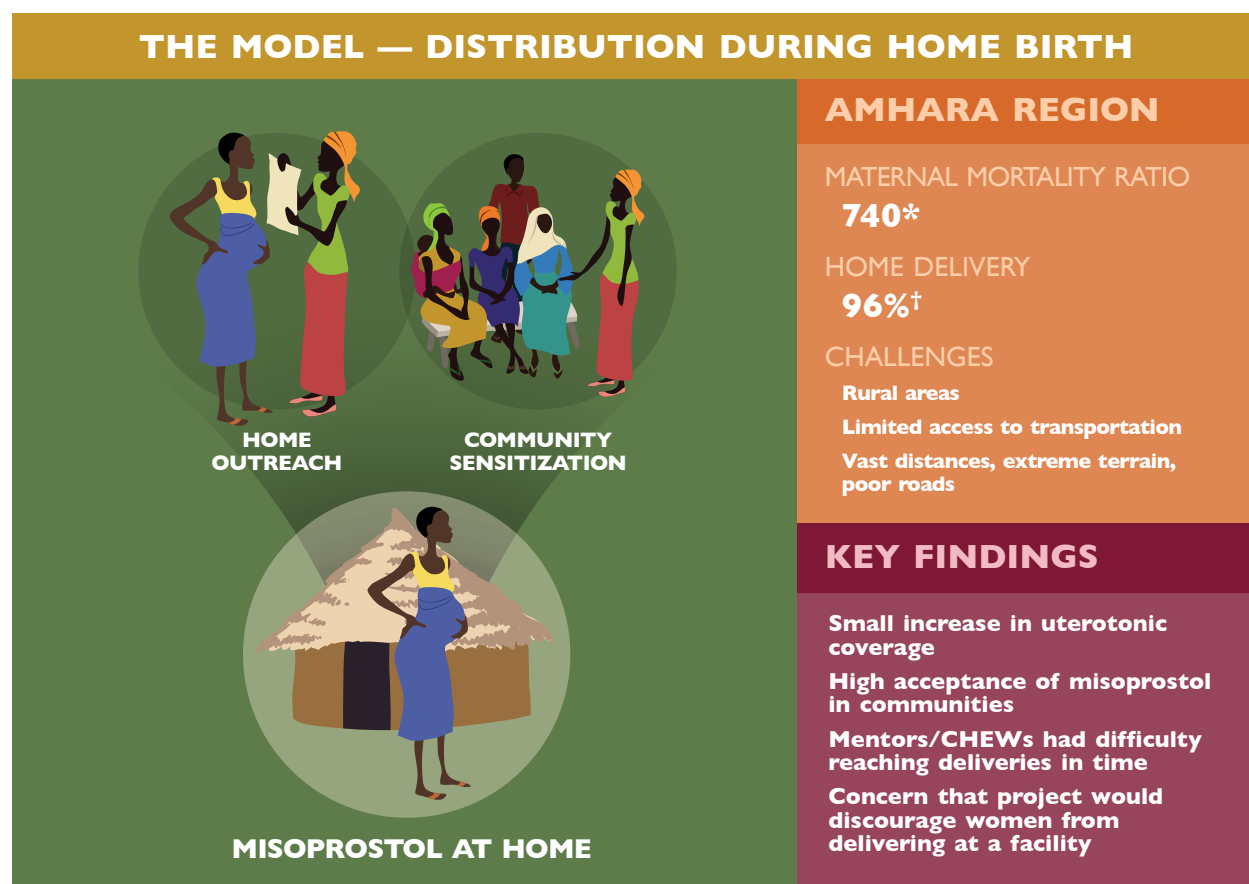
IV. Overview of the models and potential for scale up

The projects funded by the MacArthur Foundation explored different models for increasing access to misoprostol at the community level. The models are described below and are evaluated as to the level of success of their initial implementation and potential for achieving scale up in the future.

Ethiopia—Using lay workers to expand the reach of the health system

The Ethiopia project, funded in 2008, trained lay youth mentors to provide oral misoprostol to women living in rural communities where most women, many while still adolescent, deliver at home. The figure below provides an overview of the model approach, key maternal health indicators at the time of project inception, and the main findings of the evaluation.

The project was innovative in two significant ways: first, with its focus on bringing misoprostol to women in their communities, the project was among the first in Africa to



* Maternal Mortality Ratio (number of maternal deaths per 100,000 live births) (2005). Source: WHO, UNICEF, UNFPA, WorldBank. Trends in Maternal Mortality: 1990 to 2013 Estimates by WHO, UNICEF, UNFPA, The World Bank and the United Nations Population Division. 2014.

† Home Delivery Rate (2005). Source: Yesuf EA, Kerie MW, Calderon-Margalit R (2014) Birth in a Health Facility—Inequalities among the Ethiopian Women: Results from Repeated National Surveys. PLoS ONE 9(4): e95439. doi:10.1371/journal.pone.0095439.

recognize misoprostol's potential for addressing the challenges women face accessing delivery care, particularly in rural areas. Second, the project's use of youth workers to expand and support the community health extension program was an innovative attempt to de-medicalize the provision of misoprostol.

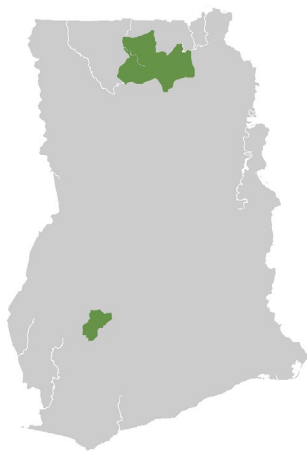
The youth mentors were members of “Meserete Hiwot” (Base of Life), a collaboration between the Population Council and the Ministry of Youth and Sports (now the Women, Children, and Youth Bureau).¹⁹ These lay mentors worked closely with community health extension workers (CHEWs) from the Amhara Regional Health Bureau to expand outreach into rural communities where great distances and transportation difficulties often prevented women from delivering at health facilities. The trained mentors went house to house in their communities, registering pregnant women, noting their expected delivery dates, and educating them, their family members, and community leaders about postpartum hemorrhage and misoprostol. 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, after ensuring that there were no other babies.

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 5,119 pregnant women in the project area with information about misoprostol and there was high acceptance of the medicine in the communities served. But because of the many difficulties the lay workers encountered in reaching women at the time of their deliveries, they were able to administer the misoprostol to only 351 of the 1,251 women who delivered during the five month project period.²⁰

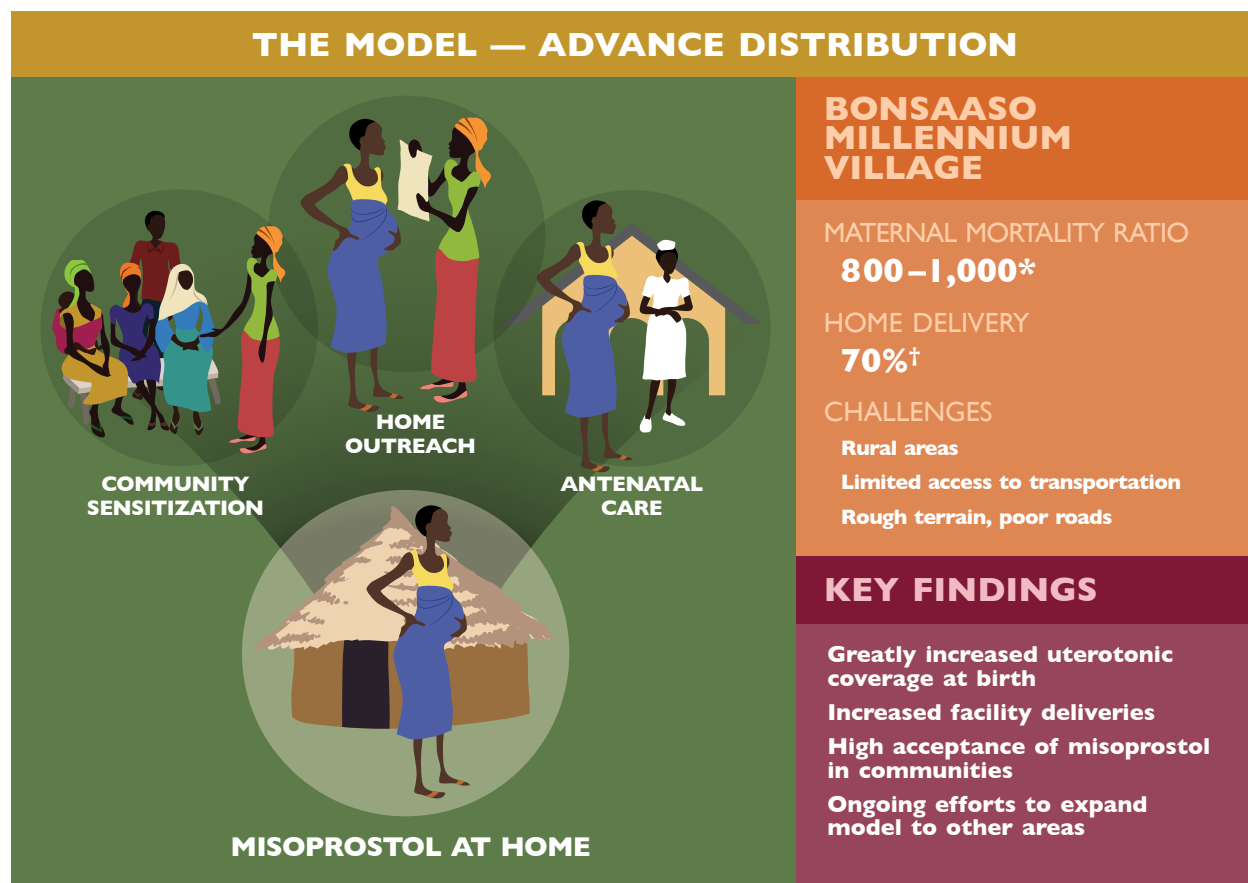
A number of obstacles prevented successful implementation of the Population Council's model including: logistical challenges that prevented mentors and community health extension workers from reaching women in labor in a timely manner, government concerns about the use of youth mentors who were not part of the health system, and concerns about giving women access to the pills in advance based on fears that women would not use the pills correctly or might use them instead to induce abortions. But what has emerged as the overarching obstacle to community-based distribution of misoprostol in Ethiopia is the widely held belief that the use of misoprostol at home will deter facility-based births. This belief—that community-based distribution might undermine the government goal of increasing institutional deliveries—is not supported by evidence from other projects.¹⁰ Nonetheless, given the government's renewed focus on increasing institutional deliveries, as long as the perception persists that the two approaches—distribution of misoprostol at the community level and use of health facilities to deliver—are incompatible, scaling up the use of misoprostol at the community level in Ethiopia is unlikely to happen.

Ghana—Advance distribution through a continuum of care model

The Earth Institute and University of Chicago’s project in the Bonsaaso Millennium Village, located in Ghana’s Amansie West district, successfully demonstrated that misoprostol, when distributed to pregnant women during antenatal visits for their use should they not make it to a clinic to deliver, could significantly reduce their risk of postpartum hemorrhage. The model’s three key elements—community sensitization; use of community health workers and traditional birth attendants to do outreach, education, and delivery assistance; and integration into the health system’s antenatal and delivery services (including the advance distribution of tablets)—were instrumental to its success at helping women have safe births, whether in a facility or at home. The figure below shows the components of the model, key maternal health indicators at the time of project inception, and the main findings of the evaluation.



Taking advantage of the fact that 95% of pregnant women in Ghana attend antenatal care at least once,²¹ the Ghana model focused on educating women about safe delivery at the third trimester antenatal care visit, recommending that they deliver in a facility while instructing them on how



* Maternal Mortality Ratio (number of maternal deaths per 100,000 live births) (2005, 2007). Source: Komfo Anokye Teaching Hospital. 2007 Annual Report. Kumasi: Komfo Anokye Teaching Hospital; 2008.

† Home Delivery Rate (2006). Source: Millennium Villages Project. Baseline Survey Report on Bonsaaso. http://mdgnet.undg.org/ext/MDG-Good-Practices/mdg5/MDG5A_Ghana_Millennium_Villages_in_Bonsasso.pdf. [Published 2006].

to use misoprostol if not possible to get to a facility. At that visit the women are given a package of misoprostol to take home. This project design integrated misoprostol into existing health services and positioned it as one part of the continuum of care for postpartum hemorrhage (the other services of the continuum included: early identification of hemorrhage and referral, ambulance transport, and facility-based deliveries). During the community sensitization phase of the project, community health extension workers visited women in thirty communities to educate and counsel them about safe delivery measures and the usefulness of misoprostol (community sensitization). Over the ensuing twenty one months (January 2011 to September 2012), midwives, attending women during their 7th-month antenatal visit, educated them about safe delivery, including both the recommendation for facility delivery and how to use misoprostol, and provided 654 women with a dose of misoprostol to take home; 14.7% of the women used misoprostol at home, 80.9% women delivered at a facility and did not use the misoprostol, and 1.1% brought the misoprostol with them to the facility and used it there.

Because of a strong concern by health officials that unused misoprostol should not be used for abortion at the community level, the project carefully tracked each dose of misoprostol to ensure that any unused product was returned. To encourage the return of unused misoprostol, women were required to get a guarantor before receiving misoprostol and project staff made home visits to retrieve misoprostol that was not used or returned. Almost all (98%) unused misoprostol was returned and there was no reported or observed use of misoprostol for abortion.

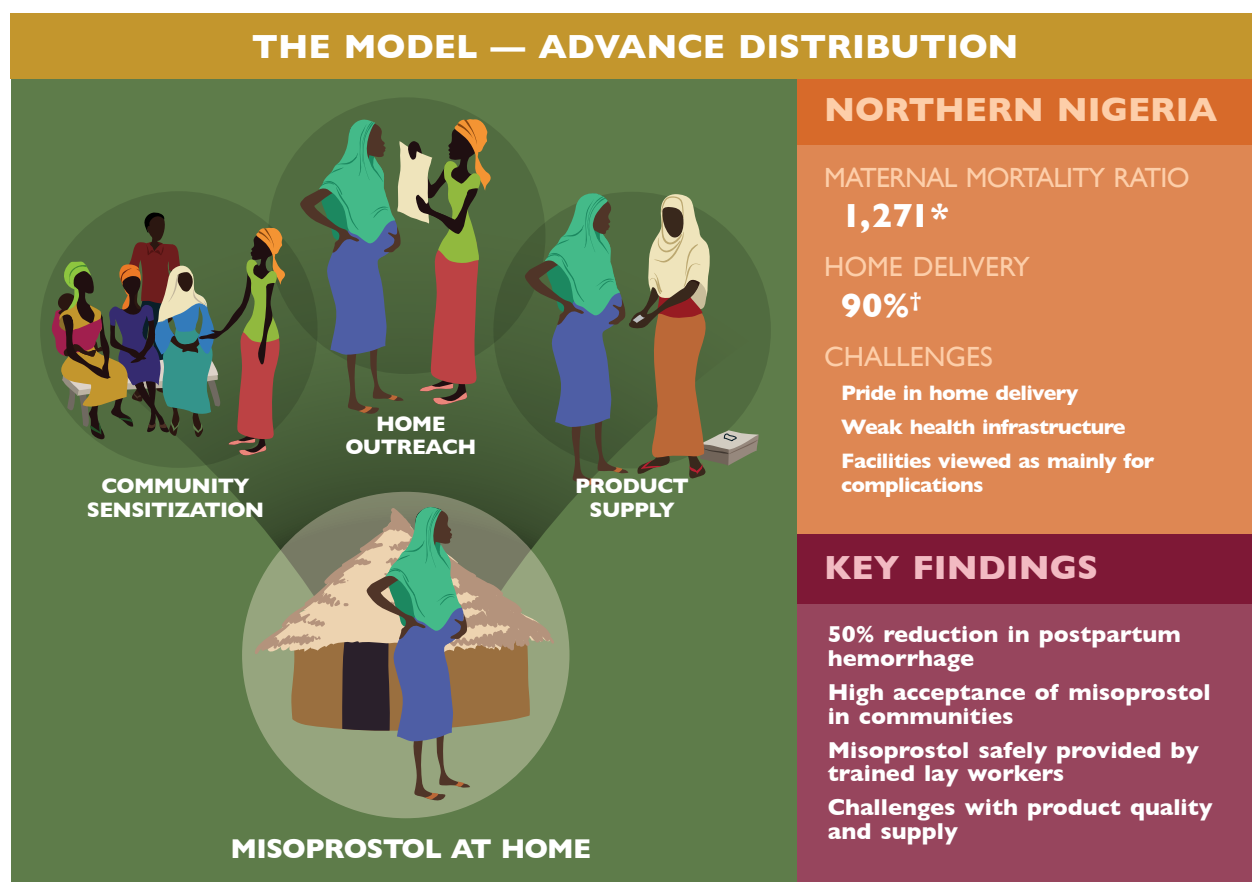
As a result of the successful collaboration between the Ghana Health Service and the Earth Institute, as well as similar work by Venture Strategies Innovations, Ghana is well poised to expand community-based misoprostol services to women in other rural communities. Yet, despite this evidence of a feasible and successful model, scale up to other rural areas is proceeding slowly. In 2014, the Ghana Health Service and the Earth Institute committed to expanding the project to more communities in the Amansie West district and to one more Millennium Development Village in the Northern part of the country. Yet many other rural areas would greatly benefit from these services. The evaluation found evidence that word is spreading about the life saving potential of misoprostol and that women, health-care providers, and policy makers alike from other rural districts are beginning to demand “*why don’t we have that here?*” The Ghana Health Service, which has garnered praise for its effective model of misoprostol distribution, may need to speed up the scaling up this lifesaving intervention to all rural areas or risk facing criticism for having acted too slowly to protect women’s lives.

Nigeria—Expanding community distribution for use during home delivery

In 2009, the Population and Reproductive Health Initiative at Ahmadu Bello University in Zaria, and Venture Strategies Innovations conducted a pilot study in five communities around Zaria, Nigeria, that demonstrated that misoprostol can safely and effectively be used by women delivering at home and that its use can reduce postpartum hemorrhage during home deliveries.²² In 2010, the MacArthur Foundation made a grant to Ahmadu Bello University to expand this model to additional communities in Kaduna State as well as to Sokoto State in the hopes that a successful replication of the “Zaria model” in other states would encourage scale up of the intervention throughout the country. The figure below shows the components of the model, key maternal health indicators at the time of project inception, and the main findings of the evaluation.



The model implemented in Kaduna and Sokoto employed the same two approaches that had been used in the Zaria pilot: community sensitization designed to gain support and create demand; and distribution



* Maternal Mortality Ratio (number of maternal deaths per 100,000 live births) (2010-2011). Source: Guerrier G et al. High maternal and neonatal mortality rates in northern Nigeria: an 8-month observational study. *International journal of women's health*. 2013; 5: 495.

† Home Delivery Rate (2008). Source: National Population Commission of Nigeria, ICF Macro. 2008 Nigeria Demographic and Health Survey. Abuja, Nigeria: National Population Commission and ICF Macro; 2009.

of misoprostol directly to the women in the communities by three cadres of community-based workers. Traditional birth attendants were recruited to counsel pregnant women about the risk of postpartum hemorrhage, the importance of delivery at a health facility, and the role of misoprostol in preventing hemorrhage. They also brought the misoprostol to the women—in the form of clean delivery kits that contained misoprostol, either before they delivered or during the delivery. Community Oriented Resource Persons (CORPS) were trained to counsel and support pregnant women, including encouraging them to use antenatal services and following up with the women to ensure compliance. Some of them doubled as drug keepers (see below). They also helped raise community awareness of the importance of misoprostol in saving a woman's life. Drug keepers were nominated by members of the community to be responsible for stocking, storing, tracking, and dispensing the pills to pregnant women, members of their families, and traditional birth attendants. Some drug keepers were also Patent Medicine Vendors, Village Heads (or members of their families), or traditional birth attendants.

The replication and expansion of the community-based model of distributing misoprostol in Kaduna and Sokoto States proved as feasible and successful in expanding access to misoprostol—and thereby reducing postpartum hemorrhage—as it had in Zaria. In the 2009 study²³ involving nearly 7,000 women in the project areas 83.6% of the women reported using misoprostol and of those, 97.5% used the correct dose. 6.2% of the 4,857 women who used misoprostol for prevention had bleeding and required treatment, as compared to 12.6% of the 1,344 women who did not take the misoprostol for prevention and did not have an injection of oxytocin—a 50% reduction in hemorrhage. 87.9% of the women who used misoprostol received it from traditional birth attendants while 11.4% received it from drug keepers. Birth attendants emerged as the most frequent source of information on misoprostol (52%) compared to other sources.

The Zaria model proved that community-based distribution of misoprostol is feasible and effective in preventing postpartum hemorrhage. The model has served as inspiration for other initiatives, the most notable being the USAID Targeted States High Impact Project (TSHIP) which has adapted several aspects of the model in its efforts to take community-based distribution of misoprostol to scale in Bauchi and Sokoto States. Yet its design may limit its replicability for scale up. This is because the model requires creating new structures within the community (CORPS and drug keepers) rather than integrating the approach within an existing structure in the community environment (such as the healthcare system, a social marketing program, or Ward Development Committees). But the biggest challenge the model now faces for scale up is a recently enacted national policy that limits the distribution of misoprostol to healthcare workers; as long as the Federal Ministry of Health rules that community health extension workers and traditional birth attendants are not considered “trained community agents,” the Zaria model will be difficult to replicate given that it revolves around the distribution of misoprostol in the communities by these community-based workers.

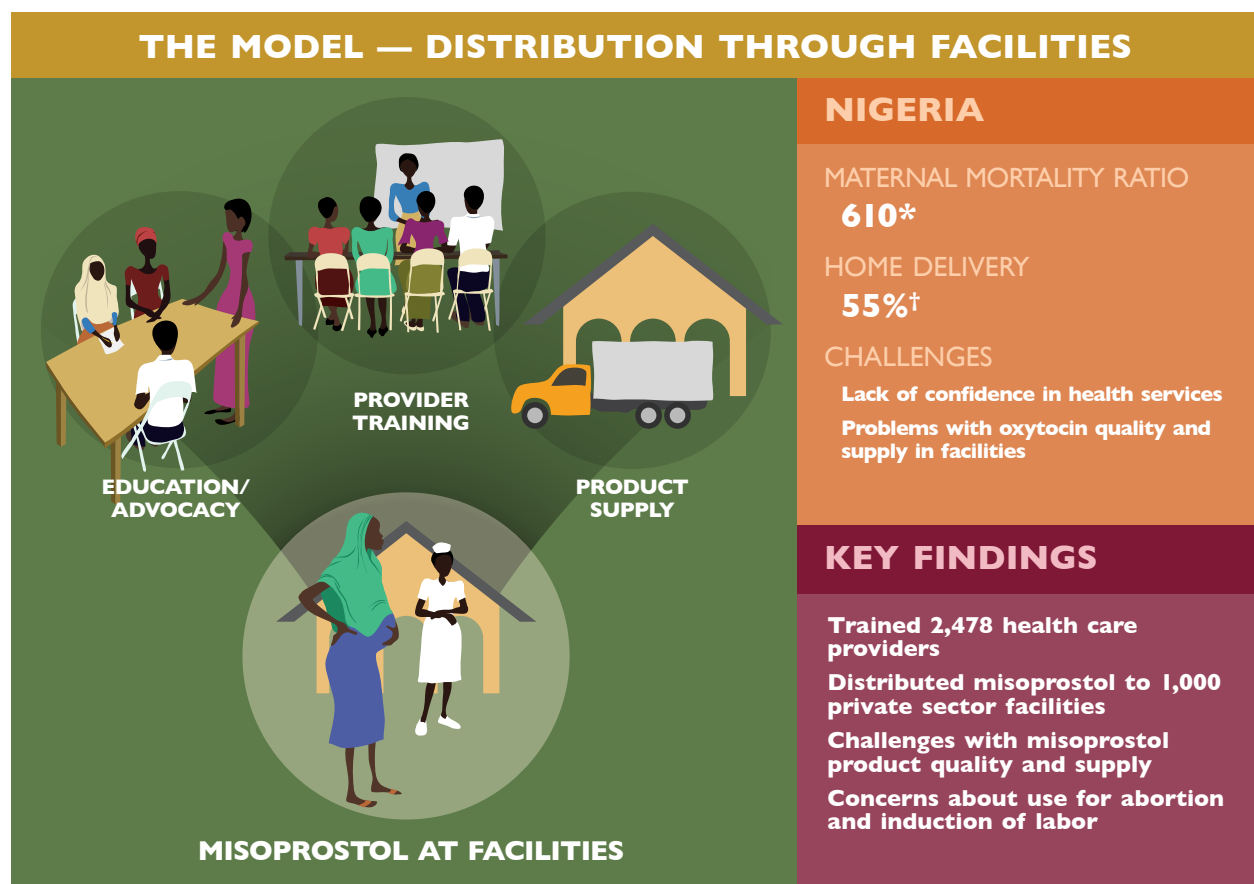
Nigeria—Raising awareness and increasing access through the private sector

Recognizing the many product issues Nigeria was facing with regard to misoprostol, the MacArthur Foundation gave a grant to Population Services International (PSI) and the Society for Family Health (one of the largest social-marketing organizations in Nigeria), to increase access to a misoprostol product and improve general knowledge about its potential to prevent and treat postpartum hemorrhage. The Society for Family Health project's primary focus was to increase the availability of misoprostol

through healthcare facilities in its franchise network to address the problem of poor oxytocin quality in facilities (the evaluation findings confirmed the significance of this problem, with “problems with oxytocin potency” being a recurring theme in the focus groups with providers). While not truly a community-based model, the project’s advocacy and education components helped to build a constituency for misoprostol in general as well as for distribution by community health extension workers in particular. The figure below shows the components of the model, key maternal health indicators at the time of project inception, and the main findings of the evaluation.

With the MacArthur Foundation’s support, the Society for Family Health (and PSI) worked to: educate communities about the potential of misoprostol (they engaged with a wide spectrum of stakeholders including policy makers, health practitioners, communities, and women users); train health workers in the use of misoprostol (they trained 2,478 healthcare providers across Nigeria, including nurses, midwives, community health extension workers, nursing attendants, doctors, and pharmacists); and ensure access to the drug (they procured misoprostol and used their extensive social franchise network to distribute 54,000 doses of the product to over 1,000 facilities nationwide).

The Society for Family Health model was not as successful as had been hoped in creating a reliable source of supply in the market, establishing price controls, and penetrating into communities. The number of doses distributed during the term of the project fell very short of their target; they had projected distributing 480,000 doses and instead distributed 54,000. Society for Family Health staff



* Maternal Mortality Ratio (number of maternal deaths per 100,000 live births) (2010). Source: WHO, UNICEF, UNFPA, The World Bank, and the United Nations Population Division. Trends in Maternal Mortality: 1990 to 2013. Geneva, World Health Organization, 2014.

† Home Delivery Rate (2008–2012). Source: www.unicef.org/infobycountry/nigeria_statistics.html.

attributed this failure to meet its distribution goal to growing competition; free product is being made available through primary healthcare facilities in some states (with free or subsidized products often provided by development partners) whereas their product is sold at cost recovery.

But the fact that Society for Family Health only reached 11% of its distribution goal suggests that a different approach may have been needed, perhaps one focused on creating demand in the communities, where the biggest share of the market for misoprostol lies, rather than focusing solely on the training of health providers. There is a need to address the problem of poor quality of oxytocin but the much larger need is that of women who are delivering at home with no access to an effective uterotonic such as oxytocin. While direct advertising of misoprostol is not allowed under their licensing agreement, had Society for Family Health found strategic ways to educate “end-users” (including pregnant women, their families, and trained community workers), instead of only health-care providers working in facilities, they might have generated more demand and come closer to meeting their distribution target.

V. Commonalities and differences across models

The four models used by the MacArthur Foundation grantees had many elements in common but also differed in significant ways. Table 2 compares the four models as to the approach used, the timing of drug availability, the organizational structures involved, and the successes and challenges encountered.

All of the models were successful at addressing several of the key elements necessary for scale up (see box, Section III). Common successes included:

- **Legitimizing misoprostol.** All projects used research to generate evidence that misoprostol can be successfully used at the community level to reduce postpartum hemorrhage;
- **Building constituencies.** All projects included community sensitization and were very well received by community members and leaders; all projects also successfully gained some level of support from policy makers, professional associations, and/or providers;
- **Modifying organizational structures.** The Ethiopia, Ghana, and Zaria models all successfully shifted responsibilities to community health extension workers and/or traditional birth attendants, resulting in increased provision of information and services to women in rural areas. The Society for Family Health used its existing franchise structure to expand access to misoprostol in the private sector.

Despite generating evidence that community distribution of misoprostol is feasible and safe, and cultivating a high level of buy in from a wide range of, but not all, constituents, none of the pilot projects distributing misoprostol at the community level has gone to national scale. Each model has faced challenges to critical components necessary for scale up:

- the Ethiopia model failed to structure the intervention in a way that was compatible with the health system;

Table 2: Comparison of the Community-based Distribution Models

	Ethiopia	Ghana	Nigeria—Zaria	Nigeria—SFH
Approach used	Lay youth mentors and CHEWs educate women during pregnancy, encourage facility delivery, and bring misoprostol to home births	CHEWs and TBAs educate pregnant women about misoprostol and facility delivery. Women receive misoprostol from midwife at seventh month antenatal care visit.	TBAs bring the misoprostol to the women—as part of clean delivery kits, either before they delivered or during the delivery. Drug keepers stock and dispense the pills to pregnant women, their relatives (including husbands), and TBAs.	Social marketing (misoprostol made available to private sector hospitals and pharmacies)
Timing of drug availability	At home during the delivery	In advance of delivery (used at home or taken to facility)	In advance of delivery and at home during delivery	At facility (mainly at private hospitals and clinics)
Organizational structures involved	Regional Health Bureau Ministry of Youth and Sports	Ghana Health Service	Created their own structures (including drug keepers, CORPS) and involved TBAs	SFH social marketing franchise facilities
Successes	Somewhat increased uterotonic coverage of home births Facility deliveries continued to increase	Greatly increased uterotonic coverage of home births Increased facility deliveries	Increased facility deliveries	Greatly increased misoprostol availability in private sector facilities
Challenges	Lay workers could not always reach women with misoprostol during home births. Project viewed as inconsistent with government emphasis on facility delivery. Concern about use for abortion.	Limited resources for expansion of model to other rural areas. Concern about use for abortion.	Community structures difficult to sustain. Difficulty ensuring consistent supply of misoprostol. Concern about use for abortion.	Model focused on providers and facilities rather than on ensuring access to misoprostol at the community level. Difficulty ensuring consistent supply of misoprostol. Concern about use for abortion.

- the Ghana model has yet to secure government commitment to fund expansion to other rural areas;
- the Zaria model created new community-based structures that were ultimately not sustainable and the government questioned a fundamental aspect of the project design (the definition of a trained community agent); and
- the Society for Family Health model was not structured in a way that addressed the need for misoprostol in the community at the time of birth.

The main challenges to scaling up access to misoprostol at the community level (encountered by all the models) are due to two aspects of the drug itself:

- misoprostol has to be taken immediately after delivery (allowing no time to transport or refer a woman to a facility), and
- misoprostol is also being used at the community level for two other indications, one that is often stigmatized and legally restricted (abortion) and another that is potentially very dangerous (induction of labor).

As a result of these two intrinsic characteristics, the introduction of misoprostol at the community level must overcome two major obstacles:

- reluctance of healthcare providers and decision or policy makers to give misoprostol to women in advance of their delivery and to trust them to use it correctly, and
- concerns about possible “misuse” of misoprostol—the belief that women or lay workers may use the drug for abortion or induction of labor rather than to prevent hemorrhage.

All of the models also faced challenges related to the misoprostol product, including packaging, distribution, and product quality.

Reluctance to give misoprostol to women in advance and concerns about “misuse”

All the projects encountered hesitancy on the part of the health providers and health authorities to allow women to access misoprostol in advance of birth. The reasons for these reservations stem from two preconceptions, neither of which are borne out by evidence but both of which are strongly held beliefs: 1) that women cannot be trusted to take (and store) the pills safely and correctly; and 2) that women might give the misoprostol to someone else to use for abortion. In addition to the lack of trust in women there is often a lack of trust in lower level or lay providers (midwives feared that traditional birth attendants would use the misoprostol to terminate pregnancies or induce labor). This mistrust has been the major driver behind the numerous regulations regarding which healthcare providers can deliver the drug, regulations which pose the biggest obstacle for the models that depend on lay workers (in particular the Ethiopia model and the Zaria model). The pervasive (but unsubstantiated) belief that women (or lay providers) might use the misoprostol for abortion instead of preventing hemorrhage is, in all three countries, a major obstacle to scale up (this is true even for Ethiopia and Ghana where the laws concerning abortion are less restrictive and where mifepristone and misoprostol are readily available through the health system for safe termination of pregnancy).

Just how pervasive and deeply held these concerns are and how much of a challenge they pose to the scale up of pilots aimed at distributing misoprostol at the community level to prevent postpartum hemorrhage is demonstrated by a comparison of two parallel efforts to reduce maternal mortality in Nigeria (both funded by the MacArthur Foundation) (see box: A Tale of Two Life-saving Medicines in Nigeria).

A Tale of Two Life-Saving Medicines in Nigeria: Reducing Maternal Mortality Using Misoprostol and Magnesium Sulfate

Another major cause of maternal deaths in developing countries is eclampsia, an acute and life-threatening complication of pregnancy characterized by the appearance of convulsions, usually in a woman who has developed pre-eclampsia. There is an inexpensive medicine that can prevent and treat this life-threatening pregnancy complication: magnesium sulfate has been shown to lower the risk of eclampsia by 58% and the risk of mortality from eclampsia by 45%.²⁴ Likewise, misoprostol is a simple and inexpensive way to prevent and treat postpartum hemorrhage.

Recognizing the potential of these two inexpensive drugs—misoprostol and magnesium sulfate—for addressing the two leading causes of maternal deaths in Nigeria, the MacArthur Foundation invested in a package of grants designed to achieve sustainable and comprehensive solutions for both postpartum hemorrhage and eclampsia. Interestingly, the two initiatives fared very differently, in spite of being implemented at approximately the same time, involving many of the same stakeholders, and including many of the same elements required for scale up.

The effort to scale up use of magnesium sulfate in the Nigerian health service delivery system was successful and the country is well on its way to fully integrating the use of this life-saving medicine into its maternal health services. In contrast, the pilot projects funded by the MacArthur Foundation to use misoprostol to prevent postpartum hemorrhage have not gone to scale, in spite of successfully demonstrating that community-based distribution of the drug does in fact reduce hemorrhage.

Why did the work to integrate the use of magnesium sulfate at the national scale succeed in Nigeria where efforts to expand access to misoprostol did not?

- The introduction of magnesium sulfate followed a clear path through the established health system, whereas misoprostol requires de-medicalization to get it into the community where it is truly needed.
- Misoprostol can be used for multiple indications, including for abortion (which is stigmatized, legally restricted, and politically sensitive) and labor induction (which is potentially dangerous).

Both the funding investment and the constellation of grantees were greater for magnesium sulfate than for misoprostol, resulting in a more multifaceted and coordinated approach. In sum, introducing misoprostol for prevention into a national health system requires two paradigm shifts that magnesium sulfate does not: 1) shifting from a “provider” frame to a “woman-centered” approach that trusts women to help themselves; and 2) de-stigmatizing misoprostol. Because these shifts are politically challenging, scaling up community-based distribution of misoprostol will continue to be more difficult than the introduction of a medicine such as magnesium sulfate, which requires a primarily clinical intervention.^{25, 26}

Problems with packaging, distribution, and quality of misoprostol

In all three countries, grantees faced similar challenges in ensuring a consistent supply of misoprostol. Product issues that will have to be resolved as models scale up include: packaging a single-dose misoprostol product for advanced provision to prevent postpartum hemorrhage; challenges inherent in assuring a steady supply of the drug throughout the delivery system; and the variable quality of available misoprostol products. Given that all three countries have strong pharmacy and medicine vendor networks as well as established social marketing programs, the private sector may be well situated to partner with the public sector in addressing these issues.

Packaging. In the models that provided misoprostol to women in advance (Ghana and Zaria), the misoprostol blister packs were cut and repackaged into 3-tablet packs, a labor intensive practice that does not seem efficient or sustainable for scale up. In addition, the resulting “product” often lacked critical information (such as use instructions and product storage and expiry information).

Ensuring supply. Ensuring a reliable supply of misoprostol is a generally recognized problem for all community-based distribution projects²⁷ and proved to be a significant challenge in all the models evaluated. In Ethiopia, misoprostol appears to be coming from the national level to the regional level but is not accessible to district and local levels, resulting in no availability at the community level and excess stock of expired product at the regional level. In Ghana, the government has yet to procure the product, continuing to rely on funding from the MacArthur Foundation and supplying misoprostol only in the original and new project areas (had the Foundation not made a follow up grant, it is not clear that the pilot project would have been replicated). In the Zaria model, community stakeholders reported that product was frequently not available and that efforts to ensure sustainability of supply following the pilot project were not successful. The Society for Family Health has continued to supply its franchise outlets with misoprostol following conclusion of MacArthur Foundation funding, but key informants mentioned difficulties with frequent stockouts.

Product Quality. Poor quality misoprostol was another issue that affected project implementation in all three countries; all experienced a product recall due to a problem with quality during the implementation period. Stakeholders involved with global procurement of misoprostol confirmed that product quality is a significant challenge and it is not uncommon to find degraded products with only partial potency.²⁸ Both the manufacturing and limited shelf-life of misoprostol (two years) contribute to this challenge.

VI. Lessons learned and recommendations

The collective experience of these four models provides important lessons learned and recommendations for these and other countries as they develop and scale up approaches to expand community-based access to misoprostol for the prevention of postpartum hemorrhage.

Misoprostol can save lives in countries where women still deliver at home

In all three countries, a significant proportion of women deliver at home: 85% in Ethiopia, 33% in Ghana, and 55% in Nigeria. Moreover, these national averages vary dramatically between urban and rural; for example, in rural Nigeria 73% of births take place at home while in urban areas only 36% do.²⁹ Community based distribution of misoprostol holds much promise for women delivering at home; indeed, project stakeholders interviewed regarding all of the projects funded by the MacArthur Foundation universally remarked on the dramatic reduction of postpartum hemorrhage in the project areas.

Ensuring access to misoprostol at the community level can greatly assist governments in meeting their goals to reduce maternal mortality while they continue their efforts to strengthen healthcare facilities and increase facility deliveries. But in some countries (Ethiopia in particular) the distribution of misoprostol at the community level is being severely curtailed due to the perception that helping women safely deliver at home undermines the government's goal of increasing institutional deliveries. This belief—that community-based distribution competes with or even undermines women's use of health facilities—is actually not supported by the evidence;^{30–34} for example, in the Ghana project, working in the communities and positioning misoprostol as part of a continuum of care actually increased women's use of facilities. As governments move to implement programs to prevent maternal deaths, they will need to build consensus around the promise of misoprostol and the need to deliver the drug at the community level. They will also need to correct the misperception that community-based distribution of misoprostol deters women from delivering in facilities.

Recommendations

- Position community-based distribution of misoprostol as an important part of the continuum of care that complements other efforts to improve maternal health, including prenatal care, early identification of hemorrhage and referral, ambulance transport, and facility-based deliveries.
- Engage women's advocacy groups and other civil society organizations and move from a health framework to a rights-based framework to generate demand for community-based access to the drug. Advocates have been making the case that high maternal mortality is human rights failure.³⁵ Given misoprostol's efficacy in preventing postpartum hemorrhage—a problem many women face and fear—it is going to become increasingly difficult to justify not giving women access to this simple, potentially life-saving pill.
- Identify and support champions within the healthcare system and convene relevant stakeholders to examine the successes and lessons learned from efforts to date, address misconceptions, and chart out next steps.

Advance distribution of misoprostol to women is the most successful approach but mistrust is stalling progress toward greater access

Among the community-based models evaluated, those that provided misoprostol to women in advance of birth were the most successful in ensuring that a uterotonic was available and used at the time of birth (whether at home or in a facility). The global evidence in support of advance distribution of misoprostol to women to prevent postpartum hemorrhage is clear and incontrovertible—there is no more need for pilot studies to demonstrate the feasibility or effectiveness of this approach.¹¹ Nonetheless, pervasive lack of trust in women’s capabilities to use misoprostol correctly and the widely held belief that women might “misuse” the pills (for abortion) persist, posing major challenges to scale up of advance distribution models. These beliefs (along with fears that providers will inappropriately use misoprostol for abortion and/or labor induction) are also the principal drivers behind the numerous restrictions regarding who can deliver the drug to women and pose the biggest obstacle for distribution models that depend on lay workers, who are often those most able to reach women in very rural areas.

These challenges to advance provision of misoprostol persist despite: the evidence from the projects that chose to track the pills being distributed (Ghana and Ethiopia) that virtually all the pills that were accounted for by the projects; lack of any evidence that pregnant women who receive misoprostol are giving the pills to someone else to be used for abortion; and the knowledge that women in all three of these countries have access to abortion drugs through the private sector (vibrant social marketing programs are successfully distributing mifepristone/misoprostol for abortion as well as the unauthorized distribution of misoprostol through pharmacies and other vendors). The concern about “misuse” for abortion is particularly puzzling in countries with progressive abortion laws, such as Ethiopia and Ghana. Given that these concerns are political, ethical, and social (and *not* medical), research and advocacy will be needed to both correct the misperceptions and legitimize the approach of advance distribution.

Recommendations

- Continue advocacy to legitimize advance distribution of misoprostol including by sharing existing evidence and appealing to the World Health Organization to issue guidelines endorsing advance distribution.
- Frame advance distribution of misoprostol as a harm-reduction strategy to gain public and policy maker support.^{36,37} Doing so might be a way for politicians to support the use of misoprostol without challenging public concerns around abortion.
- Support studies to better understand perceptions and attitudes at the community and policy levels regarding advance provision of misoprostol to women to provide insights about how to address barriers to advance distribution.

Distribution through existing systems provides stronger, more sustainable scale up potential

In the models evaluated, those that were most successful at creating sustainable, scalable approaches for reaching rural women with misoprostol were the projects that embraced existing structures and access points to women. Three natural areas of connection to established systems are antenatal care services, community health and lay workers, and private sector pharmacies and patent medicine vendors.

Antenatal care—The Ghana project capitalized on the high attendance rate for antenatal care (more than 95% of women attend at least one antenatal care visit), distributing misoprostol to women who attended in their seventh month of pregnancy. Ethiopia and Nigeria have moderate rates of antenatal care attendance that could be similarly leveraged (only 42.5% of women in Ethiopia and 66.2% in Nigeria seek antenatal care at least once during their pregnancy). Restricting distribution to later in pregnancy (as was done in Ghana) is not necessary and may be a barrier in countries where multiple antenatal visits are less common than in Ghana. Safe birth kits are another antenatal service that is being used in some places as a distribution mechanism for misoprostol.

Community health and lay workers—Allowing community health workers, traditional birth attendants, and other lay workers to disseminate information and distribute the pills was successfully used by the projects in all three countries, resulting in expanded reach of the health system to more rural areas. In particular, both the Ghana and Zaria projects recognized the substantial capacity of traditional birth attendants to reach women before and during birth and actively involved them in training, which helped build the capacity of this group to support the overall goal of uterotonic coverage at birth, including through referrals to facilities for delivery. While the Ethiopia project's use of lay mentors ultimately proved unsustainable due to their lack of connection to the health system, a powerful community-based structure that has been formed since the end of the project—the Health Development Army—presents an excellent structure through which misoprostol information and product could be distributed.

Private sector pharmacies and vendors—Private sector distribution chains have been used to successfully reach remote communities for a variety of products, including contraceptives and malaria medicines. The Society for Family Health capitalized on its existing social marketing franchise system, clearly demonstrating the significant capacity of the private sector to achieve broad product distribution. (Some 54,000 doses of misoprostol were distributed during the project; currently 35,000–38,000 doses are distributed each month).³⁸ The reach of the private sector to the most rural areas is often limited, however, as outlets may be more concentrated in urban and peri-urban areas. In addition the capacity of the private sector to reach women directly is limited by regulations that restrict direct advertising and distribution to women. Efforts to change regulations to authorize distribution of misoprostol through patent medicine vendors (which have a deeper reach into rural areas) and promote misoprostol as a preventive treatment for postpartum hemorrhage could greatly expand the potential reach of the private sector, particularly in countries with active social marketing programs (as is the case in all three countries).

Recommendations

- Update policies to allow trained lower level health and lay workers to educate about and distribute misoprostol.
- Advocate for policy changes to allow greater access to and marketing of misoprostol for postpartum hemorrhage through the private sector (including through patent medicine vendors).
- Train pharmacist and patent medicine vendors (many of whom are already providing misoprostol) about the correct use of misoprostol for all indications.

Product issues can hinder scale up

While the Society for Family Health model was the only project that tested product distribution on a large scale (the others involved limited distribution of misoprostol provided by the project rather than through the health system supply chain), it is clear that ensuring a steady supply of quality misoprostol will be a challenge when scaling up distribution of misoprostol at the community level. Efforts to incorporate misoprostol into the national health system supply chain will require mechanisms for forecasting, procurement, storage, requisition, and distribution; existing tools may provide helpful guidance in this area.^{39,40}

As countries move to expand the advance-provision model, a single-dose product (a packet containing three 200 µg tablets, instructions for postpartum hemorrhage prevention, and product expiration information) could reduce the burden on health system staff to repackage, help to ensure correct use, and facilitate distribution through established commodities distribution systems (including pharmacies). Having misoprostol packaged in the correct dosage for postpartum hemorrhage may also help to alleviate concerns about its use for abortion (which requires many more tablets). Single-dose misoprostol products for postpartum hemorrhage have been successfully registered and introduced in a number of countries. (Burundi, Madagascar, Nigeria, Rwanda, Pakistan, and Senegal all have 3-tablet packs available.) As with any decision, however, the potential higher product costs of this approach would need to be weighed against its perceived benefits.

Across all the models, there was a need for greater coordination between the public sector (the community-based services being implemented) and the private sector (the pharmacies and existing social marketing initiatives). Private distributors often have more flexibility in responding to local market demands than national health systems and are frequently the primary or secondary suppliers of government facilities in many countries; having product flow through both systems can help to prevent stockouts.

Recommendations

- Ensure that misoprostol is included in the national drug supply chain and that mechanisms are in place for access at the community and facility levels.
- Consider 3-tablet product packaging to facilitate distribution and correct use in programs that allow advance provision.
- Continue efforts to ensure product quality, such as the work of the Reproductive Health Supplies Coalition and the United Nations Population Fund (UNFPA) to establish pre-qualified vendors for misoprostol.⁴¹

The quality of facility services needs to be improved

While somewhat outside of the scope of the evaluation, the focus groups with women revealed that many women are reluctant to deliver in facilities because they are dissatisfied with the services that they receive there (women mentioned numerous instances of having been mistreated by midwives and other facility staff, being sent home because they presented for delivery too early, and being concerned about the safety of their babies). Women also questioned the necessity of facility delivery and reported not wanting to give up some of the benefits of delivering at home, such as the presence of family and special foods and traditions that typically accompany birth. Although the evaluation focus groups provide only anecdotal information, these concerns and desires are supported by other research in many countries.^{42–44}

Recommendation

- Efforts to encourage women to deliver at facilities also should address the quality of the interpersonal care that women receive at those facilities in addition to improving the clinical quality of the services

VII. Conclusion

Far too many women today, living in all too many countries, give birth without the care or assistance of skilled attendants. And far too many communities continue to lose wives, mothers, sisters, and friends to postpartum hemorrhage, a preventable and treatable cause of maternal death. Community-based distribution of misoprostol—and in particular, advance distribution—has the potential to help these women and significantly reduce the toll of these tragic losses. The projects implemented in Ethiopia, Ghana, and Nigeria, with support from the MacArthur Foundation, provide lessons learned about successful models of community-based distribution of misoprostol and point to the unique and common challenges such projects face as governments attempt to integrate them into existing health systems and scale up implementation to a national level.

Misoprostol has the potential to be a “game changer” when it comes to maternal health, but only if providers relinquish control of the drug and stop viewing it as a service that only they can “provide.”⁴⁵ Misoprostol is an important addition to providers’ clinical tool kit and it is also a drug women can safely and effectively take by themselves, in their homes, with little or no assistance from a healthcare provider. Making good on the promise of misoprostol to reduce morbidity and mortality amongst women who deliver at home will require moving away from the “provider” frame and addressing pervasive biases regarding women’s capability to help themselves. These projects have shown that it can be done. The challenge now is to do it on the national scale and ensure access to all women who could benefit from this simple yet effective technology.

Appendix A: MacArthur Foundation Grants for Misoprostol for Prevention of Postpartum Hemorrhage in Nigeria, Ghana, and Ethiopia

Name of Grantee/ Organization	Purpose	Duration of Grant	Size of Grant
Population Services International in partnership with the Society for Family Health (Nigeria)	Support to increase the availability, access, and use of misoprostol for the prevention and treatment of PPH. The project aims to improve acceptance through education and advocacy of misoprostol for postpartum hemorrhage, improve health workers' knowledge and practices in its use, and produce relevant materials including job aids.	33 months (2011; closed)	\$223,000
Ahmadu Bello University (Nigeria)	Testing the feasibility of community-based distribution of misoprostol in two sites within Kaduna and Sokoto states in Nigeria.	36 months (2010; closed)	\$300,000
Society of Gynecology and Obstetrics of Nigeria	Training of service providers on current evidence-based interventions for promoting safe motherhood, including magnesium sulfate for the prevention and treatment of eclampsia and misoprostol for the prevention of postpartum hemorrhage.	36 months (2007; closed)	A portion of \$250,000
Ipas (Nigeria)	Build the knowledge and skills of medical interns at three teaching hospitals to provide reproductive and maternal healthcare, including use of magnesium sulfate to prevent eclampsia and misoprostol to prevent and treat postpartum hemorrhage.	36 months (2013; in force)	\$500,000
Earth Institute, Columbia University and Millennium Villages project on behalf of the Ghana Health Service	Support to the Ghana Health Service to test the feasibility of community-based distribution of misoprostol in Ghana and later to scale up the distribution of the drug throughout the country.	27 months (2008; closed) 40 months 2009; closed) 16 months (2014, in force)	\$350,000, A portion of \$1M, and \$260,000
Population Council/ Ethiopia	Testing the feasibility of community-based distribution of misoprostol in Amhara. Later, assisting the Ministry of Health of Ethiopia in scaling misoprostol across Amhara.	46 months (2008; closed) 36 months (2011; closed)	\$275,000, \$50,000 of \$2.2M

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