

AFRICAN STRATEGIES FOR HEALTH

MISOPROSTOL POLICY AND SCALE-UP FOR THE PREVENTION OF POSTPARTUM HEMORRHAGE IN MADAGASCAR, MOZAMBIQUE, AND NIGERIA: A SYNTHESIS BRIEF



Photo by Warren Zelman

Introduction and Overview

Despite a nearly 44 percent global decline in the maternal mortality ratio (MMR; maternal deaths per 100 000 live births) from 1990 to 2015, the number of annual maternal deaths remains unacceptably high, particularly in low- and middle- income countries where 99 percent of these deaths occur.¹ Postpartum hemorrhage (PPH), or severe bleeding following childbirth, is the leading cause of maternal mortality in low-income countries and the primary cause of nearly one

quarter of all maternal deaths globally each year. PPH currently accounts for 34 percent of maternal deaths in sub-Saharan Africa (SSA), the region that alone carries 66 percent (201,000) of the estimated 303,000 maternal deaths worldwide each year.¹ The vast majority of deaths due to PPH can be effectively prevented or treated with uterotonics such as oxytocin and misoprostol, which are used to induce contractions or greater tonicity of the uterus. Oxytocin is currently the most widely used uterotonic and is recommended by the World Health Organization (WHO) to be administered immediately after childbirth to effectively reduce the risk of bleeding. However, oxytocin requires both administration via injection by a skilled provider and refrigeration, making it unfeasible in resource-poor settings or in areas where the majority of women deliver at home. In a region where more than 50 percent of births occur without attendance by skilled health personnel, access to an alternative uterotonic or intervention for the prevention of PPH is critical to achieving maternal mortality reduction in Africa.²

Over the past decade, the use of misoprostol for PPH prevention and treatment in developing countries has gained attention as an effective strategy to address PPH in settings where skilled birth attendance is low. Since the first misoprostol controlled trial for prevention of PPH in home births was conducted in India in 2005, dozens of studies on the distribution of misoprostol at the community level have been conducted globally as well as various reviews and evaluations of implementation. The

ABOUT ASH

African Strategies for Health (ASH) is a five-year project funded by the U.S. Agency for International Development's (USAID) Bureau for Africa and implemented by Management Sciences for Health. ASH improves the health status of populations across Africa by identifying and advocating for best practices, enhancing technical capacity, and engaging African regional institutions to address health issues in a sustainable manner. ASH provides information on trends and developments on the continent to USAID and other development partners to enhance decision-making regarding investments in health.

findings overwhelmingly support community-based distribution of misoprostol for prevention of PPH as safe, effective, and feasible in the absence of a skilled birth attendant.^{3,4} Misoprostol for prevention of PPH has since been included in various global clinical guidelines and in 2012, the WHO released a recommendation for the administration of misoprostol by a lay health worker in the absence of a skilled birth attendant.⁵ Furthermore, misoprostol is inexpensive, can be administered as a tablet, and does not require cold chain storage, making it an important intervention for the millions of women giving birth at home or in health facilities without reliable electricity, refrigeration, and/or qualified health providers. Despite this body of evidence and growing global consensus, few countries in Africa have adopted national policies or service-delivery guidelines for the introduction and scale-up of this intervention, and African women continue to die from postpartum hemorrhage.

In an effort to understand and inform the processes behind the development and adoption of policies and subsequent implementation of guidelines around community-based distribution of misoprostol for PPH prevention, the United States Agency for International Development (USAID) and its African Strategies for Health (ASH) project, implemented by Management Sciences for Health (MSH), conducted a review in three African countries. The study identifies key determinants contributing to the development and adoption of national policies, and explores progress towards implementation and scale-up of this intervention. Findings from the study countries – Madagascar, Mozambique, and Nigeria – present practical recommendations for countries beginning policy development and adoption, and offer lessons on the roll-out of misoprostol at the community level.

Table I. Summary of Findings and Recommendations

Policy Development Recommendations
<ul style="list-style-type: none"> ■ Ensure rigorous, local operations research is conducted with government and community support <ul style="list-style-type: none"> ➤ Findings from the three countries cite the availability of local data which complement global evidence as critical to gaining support for the intervention ■ Identify and engage a passionate national champion within the MOH who can effectively advocate at the highest levels <ul style="list-style-type: none"> ➤ The leadership of one individual within the MOH in Nigeria was cited by respondents as a key influential factor in starting the policy development process ■ Engage various types of stakeholders from the very beginning of the process, including national and local governments, professional associations, research institutions and universities, and implementing partners <ul style="list-style-type: none"> ➤ This creates ownership and buy-in and ensures interests and concerns are heard and addressed throughout the process ■ Establish a national level mechanism such as a Technical Working Group tasked with leading and moving the process forward <ul style="list-style-type: none"> ➤ A single entity comprised of representatives from various stakeholders contributes to greater accountability and continued leadership for the policy development process ■ Develop community mobilization strategies that include various advocacy and communication approaches including the media <ul style="list-style-type: none"> ➤ Communities can be an extremely effective advocate for and influencer of policy development when they are aware of the potential benefits a particular intervention can provide
Implementation and Scale-Up Recommendations
<ul style="list-style-type: none"> ■ Incorporate a national implementation strategy as a required, time-bound deliverable of the policy itself <ul style="list-style-type: none"> ➤ Findings show varying degrees of stagnation in roll-out following the official adoption of policy ■ Ensure a detailed financing plan for sustainable resource allocation from the national to the district level is included in the national implementation strategy and the national health budget <ul style="list-style-type: none"> ➤ The lack of resource planning was cited as a major constraint in the implementation and scale-up of the intervention in all three countries ■ Ensure implementation strategy is a phased approach with reviews, assessment, and revision of implementation guidelines after each phase <ul style="list-style-type: none"> ➤ Findings show the need for the implementation strategy to be a “living document” which allows for changes to be made based on lessons learned during the roll-out phases ■ Include a formal mechanism for monitoring and evaluation which facilitates frequent and regular reviews of data for decision-making in the national implementation plan ■ Employ targeted and strategic advocacy and community-mobilization approaches to increase knowledge, understanding, and support of community-based distribution of misoprostol amongst the general population <ul style="list-style-type: none"> ➤ Findings show the need for engaging traditional and religious leaders as well as local and national celebrities and influencers

Methodology

In an effort to develop recommendations for establishing a favorable policy and implementation environment, the overall goal of this study was to determine common factors which influence and enable policy development for community-based distribution of misoprostol for prevention of PPH, and to document the current status of implementation and scale-up, including successes and challenges. Specific study objectives were to:

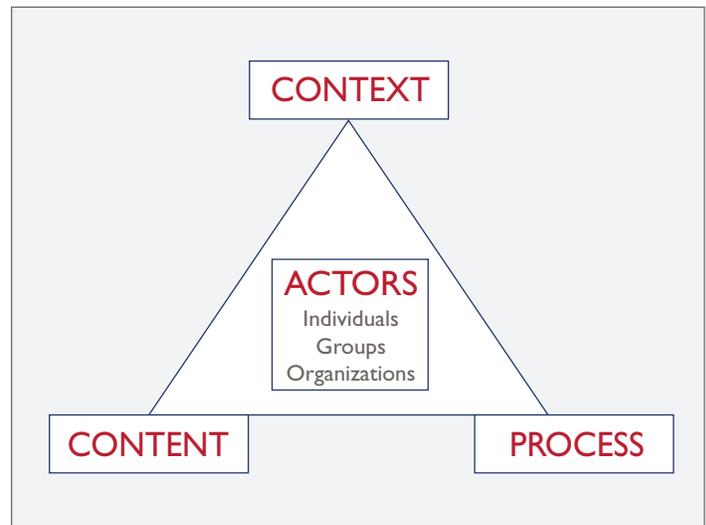
1. Analyze the policy-making process for national policies on community-based distribution of misoprostol;
2. Identify key facilitators/enablers critical to policy development and adoption;
3. Ascertain progress towards scale-up of the intervention since policy adoption as measured by specific benchmark indicators; and
4. Identify successes and challenges to policy development and implementation.

Madagascar, Mozambique, and Nigeria were identified as three of the few USAID Priority Countries for Ending Preventable Child and Maternal Deaths with a national policy for community-based distribution of misoprostol in place or in development.

To analyze the key determinants of policy development and adoption, the study applied a framework known as the policy triangle.⁶ This framework suggests that policy is influenced by a multitude of factors including policy content, context, actors, and processes, and by the interaction between these components (Figure 1). The status of implementation and scale-up of community-based distribution of misoprostol was documented through key benchmark indicators representing each of the eight WHO Health Systems Building Blocks (Table 2). Each indicator addresses an issue(s) critical to achieving effective impact at scale in a sustainable manner.

From April 2015 to April 2016, ASH conducted archival research, site visits, and interviewed key informants engaged in the policy development and/or implementation processes in each country. The extensive document review provided an understanding of structural and contextual issues regarding the use of misoprostol for PPH prevention at community level and included policy documents, research and technical reports, program implementation reports, and training curricula from the three study countries. Key informant interviews were conducted with individuals representing various stakeholders including the Ministry of Health (MOH), professional bodies, donors, civil society organizations, and community leaders (Madagascar n=15; Mozambique n=11; Nigeria n=12).

Figure 1. Health Policy Triangle



Source: Walt, G and Gilson, L. Reforming the health sector in developing countries: the central role of policy analysis. *Health Policy Plan.* (1994) 9 (4): 353-370.

Table 2. WHO Health Systems Building Blocks

Building Block	Indicator
Governance	<ul style="list-style-type: none"> ■ Is community-based distribution of misoprostol for the prevention of PPH included in current national strategies and practice guidelines? ■ Is community-based distribution of misoprostol for the prevention of PPH included in both national and subnational implementation plans?
Finance	<ul style="list-style-type: none"> ■ Is community-based distribution of misoprostol for the prevention of PPH included in MOH budgets?
Health Information	<ul style="list-style-type: none"> ■ Does the MOH currently collect, report, and use appropriate indicators/information on community-based distribution of misoprostol for prevention of PPH?
Commodities & Supplies	<ul style="list-style-type: none"> ■ Is misoprostol currently procured and distributed in sufficient quantities as part of the national logistics system?
Human Resources	<ul style="list-style-type: none"> ■ Are the appropriate health worker cadres authorized to distribute misoprostol? ■ Do the appropriate in-service and pre-service curriculum include community-based distribution of misoprostol for prevention of PPH?
Service Delivery	<ul style="list-style-type: none"> ■ Is community-based distribution of misoprostol for prevention of PPH included in MOH supervision schedules?

Source: World Health Organization. *Everybody's Business: Strengthening Health Systems to Improve Health Outcomes.* (2007).

Figure 2. Map of study countries



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Table 3. Country Context

	MMR (2015)	MMR decline, (1990-2015)	ANC coverage, at least 1 visit	ANC coverage, at least 4 visits	Skilled attendant at birth (2009-13*)	Institutional delivery (2009-13*)
Madagascar	353	55%	82% (2013)	51% (2013)	44%	38%
Mozambique	489	65%	91% (2011)	51% (2011)	54%	55%
Nigeria	814	40%	61% (2013)	51% (2013)	38%	36%

* Data refer to the most recent year available during the period specified
Source: WHO Global Health Observatory

Select Findings: Policy Development and Adoption

Madagascar

While a formal national policy for community-based distribution of misoprostol is not yet in place, the government has officially endorsed the intervention through the Campaign for Accelerated Reduction of Maternal Mortality in Africa (CARMMA) Action Plan launched by the MOH in September 2014. This action plan includes a roadmap focused on the introduction and scale up of high-impact, evidence-based interventions including misoprostol for the prevention of PPH and chlorhexidine for the prevention of newborn infection. Additionally, in December of 2014 the Minister of Health released a “ministerial note” which authorizes community-based distribution of misoprostol for prevention of PPH when oxytocin is not available. The note documents the government’s permission for the procurement, distribution, training, development of a monitoring and supervision system, and implementation to begin.

A national Technical Working Group (TWG) for misoprostol was cited as the most instrumental factor in the development

and adoption of the CARMMA roadmap, and in facilitating initial implementation of misoprostol pilot studies in country, both of which led to the release of the ministerial note in 2014. The TWG includes representatives from various MOH departments, United Nations agencies such as WHO and UNFPA, donors including USAID, and project staff from international nongovernmental organizations (NGOs). In March 2012, USAID partners organized a study tour for TWG members to Nepal to complete an in-depth review of their successful community-based misoprostol program for PPH prevention. Seeing first-hand the benefits of Nepal’s approach, participants were convinced of the intervention’s effectiveness and feasibility, and mobilized to introduce misoprostol for PPH in Madagascar.⁷ Following the study tour, the TWG worked closely with USAID/Madagascar and other maternal health partners to undertake a district level demonstration project to increase uterotonic coverage for both facility and home births. USAID’s Maternal and Child Health Integrated Program supported the community component to test the effectiveness of community distribution of misoprostol for PPH. Community health volunteers (CHVs) provided the drug to women for use during home birth when they were not able to access care at a facility. Different cadres of health providers successfully demonstrated the feasibility and effectiveness of dispensing and/or administering misoprostol

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for PPH in the context of home delivery in Madagascar's rural and remote communities. The assessment showed that CHVs were able to reach 47 percent of the target group; 86 percent of target women correctly took misoprostol; and 92 percent reported that they would use it in the future.⁷

Initial resistance and opposition from influential stakeholders advising the MOH, grounded on the concern that misoprostol can be used for termination of pregnancy by pregnant women, was cited as an important barrier to policy development throughout the process. This concern, also found in Nigeria and Mozambique, was addressed through targeted advocacy by members of the TWG, who relied on the international and local evidence from operations research to champion the need for a community-based solution to PPH. Additionally, the TWG developed guidelines for implementation to help prevent the misuse of misoprostol at the community-level and curb concerns of critics. The guidelines dictate that 1) CHVs are to wait until the 36th week of pregnancy to distribute the drug; 2) document the woman's name in their register as the recipient of three misoprostol tablets; and 3) explain that the woman must use the misoprostol immediately following delivery and return the empty package to the CHV, or, return the unopened package of three tablets if she did not use. Key informants also cited that coupling misoprostol with the non-controversial chlorhexidine for prevention of newborn infection in a community-based intervention package, helped to destigmatize misoprostol and garnered additional support from key stakeholders.

The TWG continues to advocate for the scale-up of misoprostol as the MOH develops a national introduction and implementation plan based on lessons learned from the demonstration sites.

Mozambique

The emergence of a national policy in Mozambique was greatly facilitated by leadership from the national government which enabled a favorable and supportive policy environment and by the availability of local research on the effectiveness and feasibility of the intervention led by a nationally recognized and respected professional association. In 2006, a national needs assessment revealed PPH as the leading cause of maternal mortality in Mozambique and spurred the MOH to accelerate efforts to address PPH and significantly reduce maternal deaths to achieve Millennium Development Goal 5. In 2009, in response to a request from the MOH for research to demonstrate the effectiveness of misoprostol for prevention of PPH at the community level in Mozambique, Associação Moçambicana de Obstetras e Ginecologistas (AMOG), Venture

Table 4. Key Facilitators, Enablers, and Challenges for Policy Development and Adoption of Misoprostol

Key facilitators and enablers

- Country specific evidence
- Champions in Ministry of Health
- Formal mechanism for diverse stakeholder engagement
- Community mobilization and sensitization
- Engagement of media for awareness raising

Key challenges

- Fear of misuse
- Concerns of administration by lay health workers
- Concerns of reductions in institutional deliveries
- Discordant interests/objectives by stakeholders

Strategies Innovations, Population Services International and the Bixby Center for Population, Health and Sustainability at the University of California at Berkeley commenced operational research to demonstrate that misoprostol distribution during ANC visits to women and by traditional birth attendants (TBAs) at delivery were appropriate strategies to increase protection against PPH in the context of Mozambique's health system. The goal of the operational research was to reduce maternal deaths due to PPH by educating women on birth preparedness and distributing misoprostol for use at home births.⁸

Leadership from AMOG played a critical role in building the case for misoprostol for PPH prevention in Mozambique. AMOG is at the forefront for supporting community-based interventions in Mozambique, has a wide membership of experienced providers and scholars promoting the judicious use of misoprostol, and a long-established relationship with the MOH with a history of assisting in policy decision-making. Informants cited AMOG as playing a critical role in both the generating of evidence and policy design. Involvement from partners, including USAID's Maternal and Child Health Program and UNFPA, was also cited as important for policy development, particularly to ensure policy alignment with global agendas for the reduction of maternal mortality.

Mozambique's fairly unchallenging policy development process demonstrates the effective interaction between actors and context in facilitating a favorable policy environment.



Photo by Sara Holtz

Nigeria

In January 2006, the Nigerian National Agency for Food and Drug Administration and Control approved the distribution of misoprostol for the prevention of PPH. In February of the same year, a policy meeting was convened in Abuja to discuss policy for misoprostol use, as well as to consider other strategies for reducing maternal mortality. While several meeting attendees advocated for the use of misoprostol at the community level, the government determined that misoprostol would be added to the national essential drugs list for the prevention and treatment of PPH and that immediate training of qualified health professionals for use at the facility level begin. It was also agreed that the potential role of less trained cadres of health providers and of patients in administering misoprostol would be reviewed as more country-specific information became available. In 2007, Nigeria's national council on health approved an Integrated Maternal, Newborn and Child Health Strategy, identifying community-based services as critical area of focus for the country. In recognition of the high burden of maternal mortality in the country and the challenging context in which at least two-thirds of all women deliver at home without the presence of a skilled birth attendant, a range of stakeholders came together to support the development of a policy that would address PPH at the community level.

The policy development process in Nigeria can be described in six distinct stages: 1) prioritization by the MOH to address maternal deaths due to PPH, 2) preliminary advocacy efforts to garner high-level support, 3) operations research, 4) engagement of varied stakeholders, 5) presenting findings at the national council of health, and 6) actual policy design and approval. Respondents described the overall process as long and difficult, with challenges seemingly unique to Nigeria, including the government's three tiered system and discordant objectives amongst several key stakeholders. The policy design phase was cited as the most tedious and trying due to the focus of certain stakeholders on the use of misoprostol for prevention

and treatment of PPH, while others were solely focused on advocating for a policy on the use of misoprostol for post abortion care (PAC). While the use of misoprostol for PAC seemed to increase controversy amongst concerned officials within the MOH, the final policy document approves both the use of misoprostol for PAC at health facilities and misoprostol for the prevention and treatment of PPH at the community level. Respondents cited the following two factors as the most influential in the success of policy adoption. First, country specific evidence that the intervention can be effective and feasible even in the most challenging areas of Nigeria was critical to buy-in at all levels. Operations research conducted in northern Nigeria, where nearly 95 percent of women deliver at home without skilled birth attendants, found that misoprostol protected 83 percent of women who delivered in the home against PPH who otherwise would not have been protected.⁹ Secondly, strong champions within the Federal MOH, including the minister of health at the initiation of the process, was key to enabling partnerships with various stakeholders for successful advocacy.

Select Findings: Implementation and Scale-Up

Madagascar

A national implementation plan which will incorporate various findings from the two demonstration sites is currently under development by the MOH. One particular lesson learned from the demonstration sites was that the name, packaging, and promotion of misoprostol is critical to community acceptance and uptake in a culturally-sensitive and religious environment like Madagascar. Working in close partnership with the supplier, concerns regarding language about termination of pregnancy and potential misuse of the drug were carefully addressed by UNFPA and the TWG. Demonstration sites also highlighted the need for the supply chain to be considered in its totality, from the procurement and manufacturing to the distribution of tablets by community agents to pregnant women. All steps in the process

“We invested a lot in community mobilization, sensitization, and engagement. The acceptance level was quite high especially when they saw that women were no longer dying” – *Nigerian Key Informant*

must be defined from the start, particularly in countries where the national supply chain stops at the district level, as is the case with Madagascar. In the demonstration sites, close collaboration with community agents and community health workers have enabled innovative approaches to address challenges in the supply chain, and have also been proved effective in addressing concerns related to the misuse of misoprostol. Findings also reinforce the importance of supportive supervision for community health workers in the effective distribution of misoprostol.

Mozambique

Following the final endorsement of the national policy and strategy in 2014, a two-year 35 district roll-out phase was initiated in April 2015. The initial roll-out was conducted in six districts and by September 2015, trainings to cover the remaining 29 districts began with plans for implementation in January 2016. The MOH is leading the strategy's management and implementation with support from partners including USAID, UNFPA, WHO, and Jhpiego. AMOG recently received funding to provide technical support at the provincial and district levels, monitoring and supervision, and for the development of training packages and information, education, and communication (IEC) materials.

Findings from the initial six districts are meant to inform future scale-up, however, respondents cited that at the time of the study they have not yet been required to provide data or feedback on their implementation experiences, and are eager to hear results from other districts. Respondents were particularly interested in information and data on misuse of the drug, impact on number of institutional births, general perception amongst beneficiaries and health personnel, and stock-out issues.

Nigeria

Nigeria's governance system, in which federal, state, and local governments have distinct enforcement abilities, has significantly impacted the minimal implementation of the policy for community-based distribution of misoprostol for PPH prevention. Study respondents cite a number of challenges including a lack of knowledge and resources at the local level to implement the policy, as well as a highly politicized process and lack of leadership for implementation. A few states have been successful in rolling-out this intervention, primarily through the support of programs and partners addressing advocacy and implementation issues at the local level. The USAID-funded Targeted States High Impact Project (TSHIP) successfully advocated for the introduction of integrated maternal and newborn health interventions, and in 2013, Sokoto state

launched the use of two life-saving drugs for newborns and mothers: misoprostol tablets for the prevention of PPH and chlorhexidine gluconate 7.1% gel for umbilical cord care.¹⁰ With support from TSHIP, Bauchi became the second state to introduce this approach and resourced a two-year supply of the commodity, a significant portion of the implementation budget. The successes in these two states serve as a model across Nigeria, and a number of visits from professional associations and state governments have helped to inform future scale-up initiatives. However, at the conclusion of this study, no other states had replicated the misoprostol element of the project.

Summary

Policy Development and Adoption

In all three countries, gains in policy adoption were influenced by a multitude of factors (policy content, context, actors, and processes) and the interaction between these factors. The following were identified as common facilitators or enablers across all three countries: 1) the availability of credible, local evidence on the effectiveness, safety, and feasibility of the intervention; 2) leadership and support from individual and groups of champions both within and external to the MOH; 3) engagement of a wide range of stakeholders including national and local governments, research institutions and universities, and implementing partners; 4) involvement of professional associations, who played a key role in addressing a range of concerns from various stakeholders, creating additional national buy-in and support; and 5) community mobilization and sensitization to the intervention and its potential benefits garnered powerful and effective support from the community.

Implementation and Scale-Up

Across the three countries, implementation and scale-up of community-based distribution of misoprostol for PPH prevention and treatment has varied. In Madagascar, a national implementation plan is still under development; in Mozambique, national implementation and scale-up have seen significant delays with roll-out in only six of the 35 pilot districts; and in Nigeria, despite the approval of a national policy in 2010, implementation has been limited and centered around a number of community projects led in large part through donor support, limiting sustainability of the intervention. The approval of a national misoprostol policy does not assure immediate or even timely implementation and scale-up. Common challenges in implementation and scale-up across all three countries include lack of local government leadership and/or slow government action, lack of sustainable financial resources, and failure to

Findings from the study countries – Madagascar, Mozambique, and Nigeria – present practical recommendations for countries beginning policy development and adoption, and offer lessons on the roll-out of misoprostol at the community level.

establish a national procurement and supply chain system. Study findings also reinforce the importance of the WHO's Health Systems Building Blocks to achieving effective impact in a sustainable manner.

Conclusion

As African governments begin development of plans to achieve the newly launched Sustainable Development Goals, including the Goal 3 target of reducing maternal mortality, community-based distribution of misoprostol for the prevention of PPH will become an increasingly critical intervention in a region where more than 50 percent of births occur without skilled attendance. While policy development can often be a long and arduous process, understanding the experience of countries in the region already successful in adopting national policies can garner important lessons and recommendations which facilitate more efficient and effective policy change. Similarly, successes and challenges faced in the subsequent implementation and scale-up of a policy can inform future policy development and implementation design. ■



Photo by Warren Zelman

ENDNOTES

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