

Stronger markets, increased access to essential maternal health supplies



A companion to Increasing Access to Essential Maternal Health Supplies: A scoping of market-based activities, gaps and opportunities (2016)









Introduction

In the last 15 years, global efforts have nearly halved maternal mortality worldwide. Similarly, Ethiopia has made significant progress, and it has reduced maternal mortality by 69 percent from estimates in the 1990s. However, Ethiopia still has one of the highest rates of maternal deaths per year, globally. Additional efforts are urgently needed to continue to reduce maternal mortality in Ethiopia.

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This paper outlines actions that decision-makers and civil society organizations in Ethiopia can take to increase access to lifesaving maternal health products.

Maternal mortality in Ethiopia

Between 2009 and 2016, maternal mortality accounted for a quarter of all deaths among women between the ages of 15–49 in Ethiopia. During this period, the maternal mortality ratio (MMR) stood at 412 deaths per 100,000 live births. Recognizing the gravity of the situation, the government of Ethiopia set an ambitious target by 2020 to reduce the country's MMR to 199 deaths per 100,000 live births, as part of Ethiopia's five-year public health strategy, The Health Sector Transformation Plan (HSTP).

Two leading causes of maternal death in Ethiopia include postpartum hemorrhage (PPH)— uncontrolled bleeding after childbirth—and preeclampsia/eclampsia (PP/E), a condition which causes high blood pressure and seizures during pregnancy. 5 Both conditions can be addressed with effective, low-cost maternal health products: oxytocin and misoprostol to prevent and treat PPH, and magnesium sulfate to treat PE/E.

In 2012, the United Nations Commission on Life-Saving Commodities for Women and Children (UN Commission) identified these three maternal health products as lifesaving and issued a global call to action to improve access.⁵ However, women worldwide, including in Ethiopia, still lack reliable access to essential maternal health products. When products are available, they are sometimes of poor or unverified quality.⁶

About this advocacy paper series

This advocacy paper is part of a series of four—each with a different geographic focus—all informed by an analysis published by the Reproductive Health Supplies Coalition (RHSC), in partnership with the Results for Development Institute (R4D) and PATH. The report, Increasing Access to Essential Maternal Health Supplies: A scoping of market-based activities, gaps and opportunities, maps current market strengthening efforts and identifies additional opportunities to improve the availability and quality of oxytocin, misoprostol, and magnesium sulfate for women in low-resource settings.

The report applies a global lens to current challenges and opportunities and then focuses in on three countries: Nigeria, Bangladesh, and Ethiopia.

The three focus countries were selected because they contribute to a significant proportion of global maternal deaths, accounting for 25 percent of all maternal deaths worldwide. There are also key variations in their health systems structures (i.e., centralized versus decentralized public-sector health systems) and in the presence and strength of local manufacturing capacity, resulting in diverse lessons across contexts that can be applied to improve access to maternal health products.

This advocacy paper aims to draw out the findings from the full report and translate them into actionable advocacy recommendations for advocates and decision-makers in Ethiopia.

Methodology

This paper draws on findings from a report published by the Reproductive Health Supplies Coalition (RHSC), in partnership with the Results for Development Institute (R4D) and PATH. The report, Increasing Access to Essential Maternal Health Supplies: A scoping of market-based activities, gaps and opportunities, describes challenges constraining access to maternal health supplies in Ethiopia, Bangladesh, and Nigeria. It identifies gaps and opportunities to improve the availability and quality of oxytocin, misoprostol, and magnesium sulfate for women in low-resource settings. Through document reviews, in-depth interviews, and field visits to Ethiopia and Bangladesh, the authors present evidence to inform market-shaping interventions.

What is market strengthening?

Market strengthening activities focus on influencing the practices of manufacturers, buyers, suppliers, governments, donors, health care providers, and/or consumers to improve how products are produced, procured, distributed, and delivered. Such interventions, when implemented by technical specialists with a strong understanding of markets and in coordination with all market actors, respond thoughtfully to the dynamics and failings of a specific market and seek to alter them to improve product access and, ultimately, public health outcomes.⁷

In global health, market strengthening interventions focus on improving the appropriateness, quality, affordability, availability, and awareness of health products.

This companion piece, published by PATH, translates the findings of the RHSC report into actionable policy and programmatic recommendations for decision-makers and civil society organizations — including nongovernmental organizations, professional associations, and others. Building on the evidence presented in the RHSC paper, and including supplemental information from desk-based research and key-informant interviews, this brief identifies policy gaps and related opportunities to increase the quality and availability of these key maternal health supplies in Ethiopia.

Objectives of this paper

- Assess gaps in the quality and availability of essential maternal supplies—misoprostol, oxytocin, and magnesium sulfate—in Ethiopia.
- Highlight policy and programmatic opportunities to improve the quality and availability of misoprostol, oxytocin, and magnesium sulfate.
- Recommend actions for decision-makers and civil society organizations in Ethiopia to take to increase access to quality maternal health products.

Addressing market shortcomings

To improve access, health leaders must work together to strengthen markets—the systems, structures, and institutions that facilitate the buying and selling of lifesaving health products. Decision-makers and civil society organizations likely recognize the visible symptoms of **market shortcomings** for health products in their contexts, which may include:

- Inconsistent or limited product availability.
- Products of poor or unverified quality.
- Unusable products due to locally inappropriate design.
- Lack of affordable products.
- Products are not known by providers and consumers.
- And often, a combination of several of the above issues.

Safeguarding quality

Many different actors have a role to play in safeguarding quality:

- Manufacturers should produce products in accordance with current good manufacturing practice (GMP). GMPs are the minimum requirements a manufacturer must meet to ensure product quality at the point of manufacture and to comply with internationally accepted quality standards.
- National medicines regulatory authorities (NMRAs) should choose to only register products verified to meet specified quality standards and can perform routine quality checks to ensure compliance.
- Donors and governments should choose to purchase products that have been verified to meet international quality standards and are registered by the country's NMRA.
- Suppliers, distributors, and providers should ensure they transport and store products in accordance with delineated storage conditions.

In Ethiopia, two main market shortcomings for oxytocin, misoprostol, and magnesium sulfate identified in the RHSC paper are the circulation of unverified and/or poor-quality products and limited product availability, especially at the "last mile." To address these shortcomings, the government of Ethiopia and civil society have a key role to play in strengthening the policy environment in which markets function.

Market shortcomings and policy recommendations



Quality: Context and challenges

General quality issues and safeguards

Access to quality assured maternal health products can mean the difference between life and death for women in pregnancy and childbirth. Poor-quality medicines can be ineffective or even harmful, potentially resulting in the death of mothers and their babies. Safeguarding the quality of maternal health products throughout the supply chain is therefore essential, but it is not easy. Success requires efforts at every step of the supply chain—from manufacturer to user—to assure that women receive a safe and efficacious product.

Quality of maternal health products in Ethiopia

Ethiopia has made strides in improving the quality of maternal health products in circulation. Yet gaps remain from regulation and registration, to procurement, to appropriate storage and distribution.

Registration and regulation

Registration of quality assured health products in Ethiopia is critical because only products registered by the country's NMRA, the Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA), can legally be purchased for distribution in the public sector or sale in the private sector. As of August 2017, one oxytocin product (Syntocinon®) and one misoprostol product (Cytotec®) for PPH verified to meet international quality standards were registered in Ethiopia. However, no magnesium sulfate products were registered.9

What are international quality standards?

Mechanisms that are internationally recognized and used to verify the quality of health products include:

- Approval by a Stringent Regulatory Authority (SRA)
- World Health Organization (WHO)
 Prequalification of Medicines Programme
- A "no objection to procurement" decision for a time-limited period by the WHO Expert Review Panel (ERP)*

When a product has been judged to meet one of the above quality standards, it is considered quality assured.

*A WHO ERP "no objection to procurement" decision is time limited, and suppliers are expected to be concurrently pursuing SRA approval or WHO Prequalification.

Local pharmaceutical manufacturing landscape

At the time of analysis, Ethiopia did not have any local manufacturers that produced oxytocin, misoprostol, or magnesium sulfate. According to the <u>National Strategy and Plan of Action for</u> Pharmaceutical Manufacturing Development in Ethiopia (2015–2025) produced by the Ethiopian Federal Ministry of Health and Ministry of Industry, the majority of pharmaceutical products and medical consumables are imported into Ethiopia by foreign-owned entities. There are an estimated 200 pharmaceutical and medical importers, of which only 22 are Ethiopian-owned suppliers and manufacturers—only 9 of which are manufacturing pharmaceutical products locally. Local manufacturers have limited product portfolios and are estimated to be able to supply only 90 of the more than 380 health products on the national essential medicines list. With no local manufacturers of maternal health products, Ethiopia relies on importation of registered products to support public- and private-sector needs.8



A 2013 study of the pharmaceutical regulatory framework in Ethiopia <u>published</u> in the *Ethiopian Journal of Health Science* revealed that Ethiopia possesses a comprehensive medicines regulatory framework that supports effective medicines regulation. However, to further improve access to quality assured health products, implementation of existing regulations should be strengthened. Specifically, the study cited weak regulatory enforcement, limited control of the informal private market, weak port control, poor cooperation between executive bodies, and resource constraints resulting in unregistered products and products of unknown quality on the market in Ethiopia.¹⁰

Procurement

The Pharmaceutical Fund and Supply Agency (PFSA) is the unit responsible for health product procurement within the Ethiopian Federal Ministry of Health (FMOH). PFSA procurement policy requires that suppliers meet Ethiopian GMP standards, which are based on the World Health Organization (WHO) GMP standards. However, at the time of analysis, public-sector procurement and tender policies did not

include a preference for suppliers providing products that have achieved international quality standards.⁶

According to the <u>National Strategy and Plan of Action</u> for <u>Pharmaceutical Manufacturing Development in Ethiopia (2015–2025)</u>, no pharmaceutical products manufactured in Ethiopia have achieved WHO Prequalification, though at least one company is actively pursuing prequalification. As local suppliers come on line, they should be encouraged to meet international quality standards, which may require additional incentives.

Ultimately, the registration of products of poor or unknown quality, coupled with the lack of prioritization of products verified to meet international quality standards in public-sector procurement, raises concerns regarding the quality of maternal health products provided to Ethiopian women. Stakeholders seeking to improve the quality of maternal health products in circulation in Ethiopia must work to better align registration and procurement requirements with international quality standards and support regulatory efforts to adequately enforce such standards.

Appropriate storage and distribution

In addition to registering and procuring products of assured quality, it's also critical to safeguard the quality of maternal health products during storage and distribution. For example, current guidelines recommend storing oxytocin between 2°C and 8°C, which requires cold storage throughout the distribution process, and this is largely not available in supply chains for essential medicines, including maternal health supplies.

In recognition of the storage challenges many countries face, in 2015, WHO and the United Nations Children's Fund (UNICEF) issued a joint statement encouraging integration of oxytocin into the national Expanded Programme for Immunization (EPI) cold chain. While this guidance offers one solution to maintaining potency of oxytocin, according to Ethiopia's EPI proposal to Gavi for health system strengthening support for 2016, 40 percent of the refrigerators/freezers at health-facility and administrative level were not functional during the latest effective vaccine management assessment.11 Additionally, program managers and providers often lack clarity on how to operationalize this normative guidance. These challenges have hindered cold chain integration efforts, and oxytocin is not yet provided through the EPI cold chain in Ethiopia.12

Further guidance may help ensure program managers are able to preserve potency throughout the incountry storage and distribution process. Recently, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, developed practical guidance to address obstacles to integrating oxytocin in EPI cold chains (Guidance on Elements to Consider when Planning for the Integration of Oxytocin into the EPI Cold Chain). 13 Additionally, FMHACA is currently working with the United States Pharmacopeial Convention (USP) to draft the country's first Good Storage and Distribution Practice manual, which provides another opportunity to strengthen management of cold chain products and facilitate integration of oxytocin into the EPI cold chain.6



Quality: Policy recommendations

Increase resources committed to the regulation of health products.

- Government: In Ethiopia, inadequate fiscal and human resources committed to health product regulation is a critical driver of the importation, manufacture, sale, and distribution of products of unknown quality. The Ministry of Finance and Economic Cooperation (MOFEC) and the FMHACA must increase and efficiently execute budgets that support adequate health product regulation and enforce adherence to quality regulations by all suppliers.
- Civil society organizations: CSOs should support the MOFEC and FMHACA to prioritize and efficiently allocate resources for health product regulation in their budgets. By highlighting the presence of poor- or unknown- quality health products, along with the staggering number of maternal deaths in Ethiopia, CSOs can make a strong case: increasing resources for the regulation of health products is a smart and efficient investment that saves lives and resources.

Align procurement requirements with international quality standards.

- Government: PFSA should include and prioritize international quality standards in health product procurements. Doing so will provide manufacturers with additional incentives to invest in achieving such standards and support the provision of quality assured maternal health products in public-sector facilities.
- Civil society organizations: CSOs, especially professional associations, should urge PFSA to include and prioritize international quality standards in health product procurements.

 Because quality assured products are typically more expensive, this goal can only be achieved if procurement and budget officials see value in spending more of their own resources to procure quality assured products. Therefore, CSOs should work to demonstrate to decision-makers that

there is demand for quality assured products. CSOs should document and share examples and stories from women that spotlight the costs and consequences of poor-quality products, with an urgent call to action to improve quality in Ethiopia.

Strengthen implementation of guidelines on the proper storage and distribution of maternal health products.

- Government: Regulatory and health officials in Ethiopia should ensure that global normative guidance on the storage and distribution of specific health products, such as oxytocin, is widely disseminated and adapted for local implementation by program and supply chain managers, staff, and providers, both public and private, as well as included in the Good Storage and Distribution Practice manual.
- Civil society organizations: While the UNICEF and WHO joint statement provides decisionmakers with additional impetus for integrating oxytocin into the EPI cold chain, program and supply chain managers have questions on how to operationalize the statement. CSOs should disseminate supporting evidence of additional research conducted under the UN Commission and push for the creation or adaptation of actionable guidelines for implementation of the joint statement. CSOs should also encourage the inclusion of appropriate guidance on the proper management of maternal health products in Ethiopia's Good Storage and Distribution Practice manual and call for resources to support implementation, including provider training.



Availability: Context and Challenges

To safeguard the lives of mothers and babies, maternal health products must be available when and where they are needed. Yet, consistent availability of lifesaving products is a challenge in Ethiopia, especially availability of magnesium sulfate and misoprostol at lower levels of care. Limited availability is driven by several factors, including supply chain bottlenecks, weak policy implementation, and low awareness among providers and community health extension workers (HEWs).

The health care system in Ethiopia

The government of Ethiopia is the main provider of health care services in the country. To improve access to care, Ethiopia has instituted a three-tier health delivery system connected by a referral system. Primary health care—which includes maternal health services—is provided through the first level, which consists of primary hospitals, health centers, and health posts. Health posts are expected to provide clean and safe delivery services, and health centers serve as the first point of referral for services not provided at health posts, such as basic and comprehensive emergency obstetric and newborn care. Finally, community health extension workers (HEWs)—who support Ethiopia's rural Health Extension Program—provide preventative and limited curative and rehabilitative services at the community and household levels.14

Supply chain

Even countries with centralized, public-sector procurement of health products and an integrated supply chain can encounter challenges with ensuring consistent availability across different levels of the health care system, as is the case in Ethiopia. PFSA is the agency responsible for supply chain management, including procuring, storing, and distributing all health products for the public sector. In 2009, PFSA in partnership with the USAID | DELIVER PROJECT, Supply Chain Management System (SCMS), and other partners launched the Integrated Pharmaceutical Logistics System (IPLS) to improve supply chains for essential health products. 15 The new system was intended to enhance forecasting and procurement planning, streamline distribution systems, strengthen the logistics management information system, and identify financial resources for procurement and supply chain operation. A few years later, the government of Ethiopia and partners initiated a monthly health post resupply program as part of the IPLS to help ensure essential medicines reach the "last mile"—health posts staffed by HEWs.16

Two assessments that examined the availability of oxytocin at hospitals and/or health centers documented fairly good availability. For instance, from 2013-2014, PFSA and the USAID | DELIVER PROJECT conducted a survey to measure the progress of the IPLS for 270 randomly selected public-sector hospitals, health centers, and health posts. The survey assessed a number of areas, such as availability of a subset of essential health products (17 products), including oxytocin.^a In hospitals, oxytocin was one of the most consistently available essential health products. Availability of oxytocin was less reliable at health centers, however, with the medicine experiencing the highest frequency of stockouts among the 17 health products. A separate 2013 Population Council assessment of the availability and use of maternal health supplies in ten districts in Amhara region's North Gondar and West Gojam zones found that oxytocin was available in all 23 health centers, with only one facility reporting stockouts in the past 12 months.17

Ensuring availability of misoprostol and magnesium sulfate at primary care facilities has been a persistent challenge. One cause may be that neither product has been fully integrated into the IPLS. Availability of maternal health care products may also differ greatly across geographies within Ethiopia. For example, a 2014 UNFPA survey found that misoprostol was available at 79 percent of service delivery points nationwide and magnesium sulfate available at 89 percent of delivery points. 18 However, the 2013 Population Council assessment in the Amhara region indicated misoprostol was available at only 39 percent of health centers and 6 percent of health posts. Magnesium sulfate was not available at any facility included in the assessment, and all health centers reported that the medicine had never been in stock before.17

Historically, these products have largely been dependent on donor funding and distributed mainly by international nongovernmental organizations (INGOs), ¹⁹ which makes them vulnerable to stockouts, as there would be no source of support for procurement and distribution of these products should INGOs shift priorities or lose funding.



Policy implementation and awareness

Although the government of Ethiopia has a number of key policies in place that promote availability and uptake of the three maternal health products, operationalization of these policies continues to be a challenge, especially at lower levels of care. All three products are on Ethiopia's Essential Medicines List (EML), which is critical for guiding the selection and procurement of health products for the public sector.¹⁹ Oxytocin is included on the EML for prevention and treatment of PPH, and misoprostol is included for the prevention of PPH at the community level and when oxytocin is not available. The government of Ethiopia recommends misoprostol be provided by HEWs at health posts. Magnesium sulfate is included in the EML for PE/E, and midwives, health officers, and clinical nurses at health centers are authorized to administer an initial dose of magnesium sulfate.20

While guidelines and service delivery protocols for the three maternal health products exist, they are not always available or used in health centers and posts.

a. Misoprostol and magnesium sulfate were not included as part of the representative list of essential health products.

For example, the 2013 assessment in the Amhara region found that service protocols on the prevention and treatment of PPH with oxytocin and treatment of PE/E with magnesium sulfate were available in less than half of the 23 health centers, and a training manual on safe and clean delivery that included information on misoprostol for PPH was available at only 14 percent of health posts and 17 percent of health centers. Perhaps not surprisingly, knowledge of these guidelines was reported to be low overall among health center providers and HEWS.²⁰

Limited availability of guidelines and service delivery protocols in health centers and health posts may in turn help fuel low awareness of the lifesaving maternal health products in general among health workers. The same 2013 assessment in the Amhara region documented low awareness of and demand for maternal health medicines among district and zonal health officials, particularly misoprostol for PPH and magnesium sulfate for PE/E. Many officials interviewed were unaware that magnesium sulfate was designated as a first-line treatment for PE/E, and most did not know whether misoprostol and magnesium sulfate were approved nationally or which service provider cadres were authorized to administer them.²⁰

A study exploring the knowledge, acceptability, and use of misoprostol for preventing PPH at home births in the Gode zone (Somali region) found women's knowledge of misoprostol for PPH to be low (only 42 of 829 participants were aware of misoprostol), and very few women reported that they had seen or heard of HEWs or traditional birth attendants administering the medicine. ²¹ Likewise, a study examining the availability of emergency obstetric services at three hospitals and 66 health centers in Gamo Gofa zone (Southern Nations, Nationalities, and Peoples' Region) observed that only 21 percent of facilities used anticonvulsants, such as magnesium sulfate, during eclampsia when indicated in the last three months. ²²

In summary, limited awareness and demand for maternal health products, driven in part by lack of dissemination of policies and guidelines, contributes to inconsistent and limited availability, especially for misoprostol and magnesium sulfate. If providers are not aware of or demanding these lifesaving maternal health products, then it is less likely that health centers and health posts will have them in stock.



Availability: Policy recommendations

Strengthen the supply chain for lifesaving maternal health products.

- Government: PFSA should fully integrate misoprostol and magnesium sulfate into the IPLS, ensure these products are part of the national supply system, and channel national resources toward their procurement and distribution. This would help address dependency on donors to supply misoprostol and magnesium sulfate, which leaves these products vulnerable to stockouts. The government of Ethiopia should also identify and address supply chain bottlenecks for misoprostol as part of the "last mile" health post resupply program, as this product is not reliably available at the community level.
- Civil society organizations: CSOs should encourage PFSA to include misoprostol and magnesium sulfate into the IPLS, while also urging the FMOH and Ministry of Finance to increase resource allocations for procurement and distribution. CSOs can also raise visibility and awareness of stockouts of lifesaving health products in their communities and continue to mobilize political will and resources to reach the "last mile" with essential maternal health products.

Improve dissemination and implementation of service delivery guidelines at the primary care level, especially for misoprostol and magnesium sulfate, to improve uptake and increase demand for these products.

 Government: The FMOH should widely disseminate existing policies and guidelines on the use of key maternal health products at lower levels of care, including which cadres of health providers are authorized to administer oxytocin, misoprostol, and magnesium sulfate. The FMOH

- should also support refresher trainings on essential maternal health products for health center providers and HEWs.
- Civil society organizations: CSOs should urge the FMOH to disseminate existing policies and guidelines on maternal health products to lower levels of care in a coordinated way and ensure that copies of guidelines and protocols are available in health centers and at health posts. CSOs should also work with the FMOH to prioritize and fund refresher trainings for health center providers and HEWs on essential maternal health products.

Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages.

Maternal Health Target: By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births.

Conclusion

As the international community builds on the achievements of the Millennium Development Goals and works toward the new Sustainable Development Goals (SDGs), countries worldwide—including Ethiopia—are reaffirming their commitment to the health and well-being of their citizens.

The SDGs continue to elevate maternal health and set ambitious targets to further reduce maternal mortality. To reach these and other targets, it will be critical to ensure that women have reliable access to lifesaving maternal health products. Strengthening the policy environment in which markets function will be fundamental to sustaining well-functioning markets and improving access.

The policy recommendations in this brief highlight critical opportunities for implementers and CSOs working to improve maternal health outcomes in Ethiopia. These groups have a vital role to play in raising the visibility of the costs and consequences of poor-quality maternal health products, communicating a sense of urgency, supporting increased resources to regulate and procure products, ensuring strong supply chains, and calling for the operationalization of key policies that impact the availability of essential maternal health products.

To learn more, access the full report: <u>Increasing Access</u> to Essential Maternal Health Supplies: A scoping of market-based activities, gaps and opportunities.

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