



Stronger markets, increased access to essential maternal health supplies



Global advocacy recommendations

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



RESULTS FOR
DEVELOPMENT



Reproductive Health
SUPPLIES COALITION

Summary of advocacy recommendations



Quality

- Prioritize international quality standards in health product procurements.
 - Donors, lending institutions, and funding mechanisms should mandate strict quality requirements for products purchased with their funds.
 - Public-sector procurement entities should include and prioritize international quality standards when procuring health products.
 - Advocates should urge donors and procurement entities to prioritize international quality standards in procurements.
- Strengthen the capacity and ability of national medicines regulatory authorities (NMRAs) to effectively regulate health products.
 - Donors should prioritize investments that build the capacity of NMRAs in low- and middle-income countries.
 - Ministries of Finance (MOFs) and NMRAs should increase and efficiently execute budgets for health product regulation and enforce adherence to quality regulations by all suppliers.
 - Advocates should highlight concerns regarding prevalence of poor- or unknown-quality products and encourage MOFs and NMRAs to prioritize health product regulation in their budgets.
- Ensure that global recommendations on storage and distribution of maternal health products are widely disseminated and reflected in national strategies, guidelines, and operational practices.
 - Donors and multilateral organizations should disseminate updated global recommendations to country governments and decision-makers.
 - Ministries of Health (MOH) should review updated global recommendations and assess opportunities to revise national policies and guidelines to align with them.
 - Advocates should raise awareness of research related to storage and distribution and push for actionable guidelines.



Availability

- Strengthen procurement practices to improve the availability of maternal health products.
 - Donors should continue funding technical assistance to procurement entities and support learning exchanges among countries with decentralized health systems.
 - Procurement and budget officials should explore mechanisms to coordinate and potentially pool public-sector procurements at subnational levels.
 - Advocates should raise visibility of stockouts and promote the value of coordinating and consolidating orders.



Appropriateness

- Increase investments in research and development (R&D) and market introduction for innovative maternal health products designed to improve appropriateness, acceptability, and use in low-resource settings.
 - Donors should provide robust, sustained resources for R&D and market introduction of maternal health products that are appropriate for low-resource settings.
 - Governments should sustain and/or increase investment in health R&D, as well as ensure national policies support innovation.
 - Advocates should elevate the importance of appropriately designed maternal health products and influence relevant policy vehicles to ensure needs of local populations are prioritized.

Introduction

In the last 15 years, spurred by momentum from the Millennium Development Goals (MDGs), global efforts have nearly halved maternal mortality worldwide.¹ Yet, too many women continue to die from preventable and treatable complications related to pregnancy and childbirth. In 2015, more than 300,000 women globally—one woman every two minutes—died from complications associated with pregnancy and childbirth.²

Globally, 40 percent of maternal deaths result from two causes: uncontrolled bleeding after childbirth, or postpartum hemorrhage (PPH), and a condition which causes high blood pressure and seizures during pregnancy, or pre-eclampsia/eclampsia (PE/E).³ 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.⁴

Despite this momentum, women in many countries worldwide still lack reliable access to essential maternal health products. Further, products that are available are sometimes of poor or unverified quality.⁵

Addressing market shortcomings

Advocates and decision-makers likely recognize the visible symptoms of **market shortcomings** for health products:

- Inconsistent or limited product availability.
- Products of poor or unverified quality.
- Unusable products due to locally inappropriate design.
- Lack of affordable products.
- And often, a combination of several of the above issues.

To improve access, the global health community must work together to strengthen markets—the systems, structures, and institutions that facilitate the buying

About this advocacy paper series

This global 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: Bangladesh, Ethiopia, and Nigeria.

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.

The advocacy papers aim to draw out the findings from the full report and translate them into actionable advocacy recommendations for advocates and decision-makers.

and selling of lifesaving health products. When markets function well, products that are appropriately designed, quality assured, and affordable are consistently available to the women who need them. Donors, governments, advocates, and influencers have a key role to play in strengthening the policy environment in which markets function.

This advocacy paper provides **specific and actionable recommendations that donors, governments, advocates, and key influencers can use to raise awareness of the urgent actions needed to push for positive policy change and improve the quality, availability, and appropriateness of essential maternal health products.**

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.⁶

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

Market shortcomings and advocacy recommendations



Quality: Context and challenges

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 paramount, 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.

Globally, significant progress has been made in improving the quality of maternal health products. Several organizations and initiatives—including the World Health Organization (WHO), the UN Commission’s Maternal Health Technical Resource Team, and the Concept Foundation—have worked with manufacturers to strengthen their quality management systems in support of achieving international quality standards, with notable

successes. For example, in 2010, prior to the UN Commission, no oxytocin, misoprostol, or magnesium sulfate products were prequalified by the WHO Prequalification of Medicines Program. By July 2016, one oxytocin and three misoprostol products were WHO Prequalified, and one misoprostol product had received a “no objection to procurement” by the WHO Expert Review Panel (ERP).⁷ Further, there are additional manufacturers of maternal health products, specifically two manufacturers of magnesium sulfate products, in the WHO ERP and Prequalification pipelines.⁸

Despite advances, countries around the world continue to grapple with a range of issues affecting the quality of maternal health products, including registration, procurement, and appropriate storage and distribution.

Registration

Registration of quality assured health products is critical because in many countries only products registered by the national medicines regulatory authority (NMRA) can be purchased for distribution in the public sector or sold in the private sector. However, the number of maternal health products available that meet international quality standards are limited in low- and middle-income country (LMICs) markets. To illustrate, according to the *Increasing Access to Essential Maternal Health Supplies* report, an analysis of seven high-burden maternal mortality countries found that an average of just over one oxytocin and misoprostol product is registered in each country that had been approved by an international quality assurance mechanism.⁹ Further, in the focus geographies of that analysis, a significant number of products of unknown quality had been registered. Thirteen oxytocin products that have not achieved international quality standards were registered in Nigeria. None of the six magnesium sulfate products registered in Bangladesh and Ethiopia and only one of the five magnesium sulfate products registered in Nigeria have achieved international quality standards.⁹ This increases the risk that maternal health products of poor or unverified quality are being provided to women in these countries.

In many countries, inadequate fiscal and human resources to appropriately regulate the quality of health products in circulation pose a significant challenge for governments and NMRAs. For example, in Bangladesh, to address resource shortfalls that affect quality control testing, the Directorate General of Drug Administration (DGDA) at times outsources quality control testing to the laboratories of pharmaceutical companies distributing and selling products in country, presenting a strong conflict of interest and raising concerns regarding the objectivity of the test results provided.¹⁰

Procurement

The procurement policies and practices of governments and donors also affect the provision of quality assured maternal health products globally. In many countries, including Bangladesh, Ethiopia, and Nigeria, public-sector procurement policies and tenders do not include a preference for suppliers providing products that have achieved international quality standards; the same is true of some lending institutions and funding mechanisms, such as the World Bank. The absence of preferences for stringent quality standards in national public-sector and some donor-funded procurements removes incentives for suppliers to pursue international quality standards and is contributing to the procurement of products of potentially substandard or unverified quality.

Storage and distribution

In addition to registering and procuring maternal health products of assured quality, it's also critical to safeguard the quality of products in storage and distribution. A study conducted in 2012 by the United States Pharmacopeia (USP) and the Ghanaian Food and Drugs Authority (FDA) assessing the quality of uterotonics (oxytocin and ergometrine) on the Ghanaian market determined that of the 169 oxytocin samples analyzed, 55.62 percent did not possess sufficient active pharmaceutical ingredient. In addition, of the 40 oxytocin samples also randomly selected for sterility testing, 97.5 percent failed to possess sufficient active pharmaceutical ingredient, failed sterility testing, or failed both tests.¹¹ Additional studies conducted by PATH in Ghana and a range of partners in Indonesia yielded similarly concerning findings regarding

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.

the quality of oxytocin products in circulation.^{12,13} While it's difficult to determine whether the quality of uterotonics analyzed was affected at point of manufacture, as a result of poor storage and distribution practices, or both, studies conducted by a range of partners suggest there is a need to clarify and further disseminate recommended storage conditions for specific oxytocin products globally.¹⁴

As new global recommendations are issued, such as updated WHO guidelines regarding the storage and distribution of specific health products, they must be cascaded into countries' national policies and appropriately implemented at national and subnational levels. For example, in 2015, the WHO and the United Nations Children's Fund (UNICEF) issued a joint statement encouraging integration of oxytocin into national Expanded Program for Immunization (EPI) cold chains, which has the potential to dramatically improve the quality of oxytocin provided to women globally.¹⁵ While many countries—including Benin, Niger, Senegal, South Sudan, and Togo—have updated their policies to permit cold chain integration, there remain many more countries that have yet to do so.¹⁵ Furthermore, in countries that have changed their policies, implementation has been hampered by a lack of clarity on how to operationalize the guidance. Additional work—by PATH and



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Management Sciences for Health (MSH), through the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, under the Maternal Health Technical Resource Team of the UN Commission—to identify challenges and solutions with integrating oxytocin into EPI cold chains will yield practical guidance to address obstacles.¹⁶ Locally contextualized guidance is needed to support countries in effectively integrating oxytocin into EPI cold chains to safeguard the quality of oxytocin products provided to women globally.

Quality: Advocacy recommendations

Prioritize international quality standards in health product procurements:

- **Donors:** Donors, lending institutions, and funding mechanisms, such as the World Bank and the Global Financing Facility, should mandate strict quality requirements for products purchased with their funds to support provision of quality assured health products and further incentivize achievement of international quality standards.
- **Governments:** Public-sector procurement entities should include and prioritize international quality standards in their health product procurements. Doing so will give both local and global manufacturers an incentive to invest in achieving such standards and support the provision of quality assured maternal health products in public-sector facilities.
- **Advocates:** Advocates should urge donors, as well as national and subnational procurement entities, 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 resources to procure quality assured products. Advocates should document and share stories from women that spotlight the costs and consequences of poor-quality products

and demonstrate to decision-makers that there is demand for quality assured products.

Strengthen the capacity and ability of national medicines regulatory authorities to effectively regulate health products:

- **Donors:** Donors should prioritize investments that build the capacity of regulatory authorities in LMICs to effectively and efficiently regulate health products.
- **Governments:** Ministries of Finance (MOFs) and regulatory authorities should increase and efficiently execute budgets for health product regulation, as well as enforce adherence to quality regulations by all suppliers.
- **Advocates:** Advocates should encourage MOFs and regulatory authorities to prioritize and efficiently allocate resources for health product regulation in their budgets. By highlighting persistent concerns regarding the prevalence of poor- or unknown-quality health products, advocates can make a strong case that increasing resources for the regulation of health products is a smart and efficient investment that saves lives and resources.

Ensure that global recommendations regarding the proper storage and distribution of maternal health products are widely disseminated and reflected in national strategies, guidelines, and operational practices:

- **Donors:** Donors and multilateral organizations should proactively and widely disseminate updated global recommendations regarding the storage and distribution of specific health products to country governments and decision-makers, as well as donor and other organizations' country offices. UNICEF and WHO should continue to encourage countries to assess opportunities to update their policies and operational practices to align with the 2015 joint statement on integrating oxytocin into EPI cold chains and support locally appropriate implementation.¹⁵
- **Governments:** Ministries of Health (MOH) should review updated global recommendations

related to the storage and distribution of specific health products and assess opportunities to revise national policies and guidelines to align with new global guidance, including the UNICEF and WHO joint statement. In addition, MOHs should widely disseminate revised guidelines and address program, supply chain manager, and health worker training needs related to updated storage and distribution guidelines for specific products.

- **Advocates:** Advocates should push for the creation or adaptation of actionable guidelines for implementation of new global guidance, including the UNICEF and WHO joint statement. Advocates are well-positioned to raise awareness of operational research and push for the creation and implementation of context-specific guidelines.



Availability: Context and challenges

To safeguard the lives of mothers and babies, maternal health products must be available when and where they are needed. Consistent availability is crucial, and strong forecasting and procurement practices are key to supporting availability. In many countries, however, public-sector procurement practices are contributing to misalignments between demand and supply of maternal health products, and actually undermining availability.

Public-sector procurement inefficiencies were observed across the geographies targeted for analysis and are particularly visible in Bangladesh and Nigeria, countries with decentralized public-sector health systems. In decentralized settings, inefficiencies exist between national and subnational procurement entities and among various subnational procurement units. In places where some or all health product procurement has been devolved to subnational levels, procurements are often fragmented, of smaller quantities, and on differing procurement schedules. This weakens procurers' ability to negotiate the best prices, because higher volumes typically lead to lower per-unit costs, and increases the risk of products of poor or unknown quality being procured, as quality standards may differ among subnational procurers.

For example, in Bangladesh, maternal health products are procured both centrally and at the district levels,

and procurement units at these two levels do not always communicate or coordinate effectively. At the national level, two public-sector agencies are responsible for procurement: the Central Medical Stores Depot within the Directorate General of Health Services and the Logistics and Supply Division within the Directorate General of Family Planning. Although a national forecast has been created on the two agencies' behalf by MSH under the SIAPS Program, and procurement plans can be viewed through an online system, in practice, there is little coordinated procurement planning between the two agencies.¹⁷ In addition, the number of procurement units at the district level—and the limited coordination among them—leads to fragmented, small volume orders, rather than consolidated orders based on coordinated demand forecasting and supply planning. As a result, the availability of maternal health products varies widely at the district levels in Bangladesh; stockouts are more common in some districts than in others.¹⁷



Availability: Advocacy recommendations

Strengthen procurement practices to improve the availability of maternal health products:

- **Donors:** Donors should continue funding the provision of technical assistance to procurement entities. Donors can also support learning exchanges among countries with decentralized health systems to discuss solutions and challenges related to implementing procurement best practices across subnational levels within resource-constrained environments.
- **Governments:** Procurement and budget officials should explore mechanisms that coordinate and potentially pool public-sector procurement across subnational procurement units. In decentralized settings, coordinating demand forecasts and budgets and pooling orders across states or districts strengthen buying power, support lower unit prices, reduce transaction costs for suppliers, and often result in better delivery terms. In addition, national and subnational procurement officials should consider strategic contracting mechanisms, such as framework contracts, to reduce lead times and avert stockouts.

- **Advocates:** Advocates should raise the visibility of stockouts of lifesaving maternal health products with local and global decision-makers. Advocates should also engage in conversation with local procurement units regarding the value of coordinating and consolidating orders as a means to both cost savings and improving availability.



Appropriateness: Context and challenges

Health products that work well for populations in high-income countries may not be appropriate or usable for those in LMICs, for reasons including poor delivery infrastructure (e.g., electricity, water, and roads), limited number of health professionals—especially with requisite training—and cultural preferences. Unfortunately, maternal health products currently on the market can sometimes be difficult to use in low-resource settings.

Oxytocin, misoprostol, and magnesium sulfate are manufactured in different formulations and presentations and have separate packaging and storage requirements to protect quality and ensure ease of use. These products face challenges when used in resource-constrained settings that contribute to quality degradation, wastage, and/or limited uptake. For instance, oxytocin must be stored between 2°C and 8°C to maintain product integrity, which is not often feasible in areas with hot and humid temperatures and without reliable electricity and/or refrigeration storage.¹⁸ Misoprostol is sensitive to humidity, which makes adequate packaging, in double aluminum layers, essential.¹⁸ In addition, the two-year shelf life of misoprostol and some magnesium sulfate products makes it challenging for product to arrive in country with adequate remaining shelf life (at least 75 percent shelf life as recommended by the UN), depending upon mode of shipping and point of manufacture.¹⁹ The route of administration for oxytocin and magnesium sulfate—intramuscular and intravenous—increases the need for trained medical providers to oversee treatment, which limits access at the community level.

Numerous products are in the development pipeline that would address some of these challenges.

Merck for Mothers,* Ferring Pharmaceuticals, WHO, and Concept Foundation are advancing a room temperature stable oxytocin analogue (a drug that produces a similar effect as oxytocin) called Heat Stable Carbetocin.²⁰ Monash University, GlaxoSmithKline, and other partners are developing a thermostable, inhalable form of oxytocin.²¹ PATH is working on a heat-stable, sublingual fast-dissolving tablet form of oxytocin.²² In addition, PATH and Gynuity are researching different ways to facilitate easier administration of magnesium sulfate, such as ready-to-use packs and reusable pump devices.^{23,18} Sustained investment will be needed to facilitate testing, regulatory approval, market entry, and scale-up of products currently under development, as well as for future innovations.



Appropriateness: Advocacy recommendations

Increase investments in research and development (R&D) and market introduction for innovative maternal health products designed to improve appropriateness, acceptability, and use in low-resource settings.

- **Donors:** Donors should provide robust, sustained resources for R&D and market introduction of maternal health products that are appropriate for low-resource settings. Donors are encouraged to take a long-term view of their investments and ensure resources are available, not only for product development, but also for introduction and scale-up of life-saving maternal health innovations.
- **Governments:** Increasingly, LMICs are prioritizing health R&D in their budgets. Governments should sustain and/or increase investment in health R&D, as well as ensure national policies support innovation.
- **Advocates:** Advocates should elevate the importance of appropriately designed maternal health products and influence relevant policy vehicles—such as R&D financing mechanisms and local and global innovation policies—to help ensure that products that are appropriately

designed in accordance with local populations' needs are prioritized.

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

With the international community now focused on building on the achievements of the Millennium Development goals and working toward new, more ambitious Sustainable Development Goals (SDGs), countries worldwide 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 appropriately designed, quality assured maternal health products. Strengthening the policy environment in which markets function will be fundamental to sustaining well-functioning markets and improving access.

The recommendations in this brief highlight critical opportunities for governments and donors to improve maternal health outcomes. They play a vital role in ensuring that global commitments and guidelines are translated into national- and subnational-level priorities and practices. At the same time, advocates working at all levels have a vital role to play in raising the visibility of the costs and consequences of unavailable or poor-quality maternal health products, communicating a sense of urgency, advocating for increased resources, and calling for increased prioritization at all levels of government. Achieving the SDG target for maternal health will require the dedicated commitment of global leaders and

* Known as MSD for Mothers outside the United States and Canada.

engagement from all countries. While the challenges and context will be different for each country, this paper illuminates some of the common gaps and solutions that can be employed to increase access and save lives.

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

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