



Stronger markets, increased access to essential maternal health supplies



Advocacy recommendations for Bangladesh

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



Summary of advocacy recommendations



Quality

- Increase investment to strengthen local manufacturing of health products.
 - Government and donors should partner with local manufacturers to identify policy solutions that increase access to capital and expertise.
 - Donors and other experts in strengthening quality management systems should intensify technical support to manufacturers.
 - Advocates should raise awareness of need for capacity development and technical assistance and advocate with government for supportive policies to incentivize local manufacturers.
- Increase resources committed to the regulation of health products.
 - Government should increase budgets to improve regulation.
 - Advocates should encourage the government to prioritize health-product regulation by highlighting persistent concerns about product quality and communicating a sense of urgency.
- Align registration and procurement requirements with international standards.
 - Public-sector procurement entities should include and prioritize international quality standards when procuring health products.
 - Advocates should urge procurement entities and donors to prioritize international quality standards by demonstrating demand for quality assured products.
- Strengthen implementation of guidelines on proper storage and distribution of maternal health products.
 - Regulatory and health officials should ensure that storage and distribution guidelines are widely disseminated and adapted for local use.
 - Advocates should raise awareness of research related to storage and distribution and push for actionable guidelines.



Availability

- Align national guidelines with global recommendations and support dissemination and training.
 - The government should conduct additional research to confirm the efficacy of a reduced dosage of misoprostol and disseminate guidance for use of magnesium sulfate.
 - Advocates should urge government officials to align guidelines with global recommendations.
- Improve communication and coordination among agencies responsible for health-product forecasting, supply planning, procurement, and budgeting.
 - National-, district-, and subdistrict-level agencies should create or support multi-stakeholder forecasting “task teams” to review and ensure accountability for forecasts and supply plans.
 - Advocates should highlight changes to policies that may impact demand for maternal health products and use costed forecasts to urge the government to allocate sufficient resources to meet demand.
- Address procurement inefficiencies to improve availability of maternal health products.
 - Procurement and budget officials should explore mechanisms to coordinate and potentially pool public-sector procurement at the subnational level.
 - Advocates should raise visibility of stockouts in their communities and promote the value of coordinating and consolidating orders with local procurement units.

Introduction

In the last 15 years, global efforts have nearly halved maternal mortality worldwide.¹ Bangladesh has contributed to these improvements; it is heralded as one of a handful of countries that have dramatically cut maternal mortality rates under the Millennium Development Goals.²

Despite this progress, however, Bangladesh still has the tenth-highest burden of maternal mortality in the world. Additional efforts are urgently needed. **This advocacy paper outlines actions that advocates and decision-makers in Bangladesh can take to increase access to lifesaving maternal health products to save mothers' lives.**

Maternal mortality in Bangladesh

In 2015, there were an estimated 176 maternal deaths per 100,000 live births in Bangladesh.³ About half of these 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).^{4,5} Both conditions can be addressed with effective, low-cost maternal health products: oxytocin and misoprostol, to prevent and treat postpartum hemorrhage, and magnesium sulfate, to treat pre-eclampsia and prevent eclampsia. 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.⁶

Despite this momentum, women in countries worldwide, including Bangladesh, still lack reliable access to essential maternal health products. Further, products that are available are sometimes of poor or unverified quality.⁷

Addressing market shortcomings

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

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: Bangladesh, Ethiopia, and Nigeria. This series of companion advocacy papers focuses on the same four geographies.

The three focus countries were selected because they contribute 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 in Bangladesh.

- 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

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.⁸

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

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. Advocates have a key role to play in strengthening the policy environment in which markets function.

This advocacy paper provides **specific and actionable recommendations that advocates and decision-makers can use to raise awareness of the urgent actions needed and push for positive policy change to improve the quality and availability of essential maternal health products.**

Market shortcomings and advocacy 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 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.

Quality of maternal health products in Bangladesh

Bangladesh has made strides in improving the quality of maternal health products in circulation. Yet there are still gaps, particularly with regards to registration, manufacturing, and appropriate storage and distribution.

Registration and manufacturing

Registration of quality assured health products is critical in Bangladesh, because only products registered by the country's national medicines regulatory authority (NMRA), the Directorate General of Drug Administration (DGDA), can be purchased for distribution in the public sector or sold in the private sector. While the DGDA has registered a number of maternal health products, as of March 2016, none of the oxytocin, misoprostol, or magnesium sulfate products registered in Bangladesh had been verified

Safeguarding quality

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

- Manufacturers should produce products in accordance with current good manufacturing practice (cGMP). 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 agencies (NMRAs) can choose to only register products verified to meet specified quality standards and can perform routine quality checks to ensure compliance.
- Donors and governments can choose to purchase products that have been verified to meet international quality standards and are registered in country by the NMRA.
- Suppliers, distributors, and providers can ensure they transport and store products in accordance with delineated storage conditions.

to meet *international* quality standards, increasing the risk that maternal health products of poor or unverified quality are being provided to women in Bangladesh.⁹

The absence of manufacturers in Bangladesh producing maternal health products that have achieved international quality standards stems from a lack of incentives. Often, seeking such quality approvals requires a sizeable, upfront financial investment, which can be cost-prohibitive for smaller, local manufacturers. In addition, investments in approval may require manufacturers to increase the price of their product to recoup costs, which may negatively impact sales, particularly if procurers do not recognize the value of quality assured products.

While manufacturers of health products, local or otherwise, should be expected to possess and implement a strong quality management system that ensures the production of safe and efficacious health products, the DGDA does not require suppliers to achieve international quality standards before importing, selling, or distributing their products in Bangladesh. In addition, the DGDA often does not have the needed resources, both fiscal and human, to enforce its own national quality standards. This underregulation of health products provides further disincentives for local manufacturers to strengthen their quality management systems and achieve international quality standards.

For example, reviews conducted by both the WHO and Management Sciences for Health (MSH), through the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, emphasized the urgent need for additional staffing and capacity building at the DGDA. A May 2015 assessment of the DGDA's good manufacturing practice (GMP) inspection program conducted by SIAPS found that the DGDA employed approximately 90 staff, up from just 25 employees in January 2014. However, considering the number of GMP inspections required per year—a total of 1,094 inspections of manufacturing facilities were reported in 2014—SIAPS determined that the number of GMP inspectors were inadequate.¹⁰ Such systemic resource challenges faced by many NMRAs around the world have contributed to lengthy timelines for market authorization for health products and an inability to

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.

adequately regulate the quality of health products in circulation within their borders.

The limited financial incentives for local manufacturers to pursue international quality standards coupled with an underresourced NMRA has raised concerns that many health products on the market in Bangladesh may be of poor or unknown quality.¹¹ In light of these concerns, stakeholders seeking to improve the quality of maternal health products must work to align registration and procurement requirements with international quality standards, improve the quality management systems of local manufacturers, and increase the resources committed to product regulation.

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 in storage and distribution. In Bangladesh, a consistent lack of cold chain storage and provider confusion regarding recommended storage temperatures pose a significant challenge in safeguarding the quality of oxytocin. For example, a significant proportion of public health facilities and private drug shops lack a functioning refrigerator. A study conducted in 2013



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by Population Council revealed that two out of nine drug stores in Gazipur District, six out of twelve drug stores in Zinaidah District, and one out of six drug stores in Comilla District stored oxytocin on shelves at room temperature rather than in refrigerators. In addition, for those drug sellers who stored oxytocin in the refrigerator, it was not on-site—no drug seller had a refrigerator on the premises.¹² 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, yet lack of clarity on how to operationalize this guidance has hindered cold chain integration efforts. Further work—by PATH and MSH (through the USAID-funded 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.¹³



Quality: advocacy recommendations

Increase investment to strengthen local manufacturing of health products:

- **Government and donors:** The government of Bangladesh (GoB) should engage and work with local manufacturers to jointly identify policy solutions that support increased access to the capital and expertise required to strengthen local manufacturing of health products. In addition, donors and organizations with expertise in strengthening quality management systems for the manufacture of health products should intensify technical support to manufacturers to improve adherence to quality standards.
- **Advocates:** Advocates have a critical role to play in raising visibility and awareness of the need for further capacity development among local manufacturers as a means to strengthen product quality. Advocates should engage with

donors regarding the continued need to support technical assistance for manufacturers interested in pursuing international quality standards. In addition, advocates should work with the GoB to identify and implement supportive policies and mechanisms that facilitate access to needed capital for production-facility renovations—such as equipment and material upgrades—and hiring of additional qualified staff.

Increase resources committed to the regulation of health products:

- **Government:** In Bangladesh, the underregulation of health products is a critical driver of the importation, manufacture, sale, and distribution of products of poor and unknown quality.¹⁴ The Ministry of Finance (MOF) and the DGDA must increase and efficiently execute budgets needed to support adequate health-product regulation and enforce adherence to quality regulations by all suppliers.
- **Advocates:** Advocates should encourage the MOF and DGDA to prioritize and efficiently allocate resources for health-product regulation. By highlighting persistent concerns regarding the prevalence of poor- or unknown-quality health products, including maternal health products, along with the staggering number of maternal deaths in the country, advocates 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 registration and procurement requirements with international standards:

- **Government:** Public-sector procurement entities should include and prioritize international quality standards in 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 national, district, and subdistrict procurement entities and donors 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, advocates should work to demonstrate to decision-makers that there is demand for quality assured products. Advocates 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 increase focus on quality in Bangladesh.

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

- **Government:** Regulatory and health officials in Bangladesh should ensure that global normative guidance on the storage and distribution of specific health products, such as oxytocin, are widely disseminated and adapted for local implementation by managers, staff, and providers, both public and private.
- **Advocates:** While the UNICEF and WHO joint statement provides decision-makers with additional impetus for integrating oxytocin into EPI cold chains, supply chain and program managers have questions on how to operationalize the statement. Advocates should raise awareness of additional research conducted under the UN Commission and push for the creation or adaptation of actionable guidelines for implementation of the joint statement.



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 clear evidence-based guidelines supported by strong procurement practices are key to supporting availability. In Bangladesh, however, misaligned and unclear guidelines and public-sector procurement practices are contributing to misalignments between demand and supply of maternal health products, and actually undermining availability.¹⁵

Misaligned and unclear guidelines

As international guidelines on the use of maternal health products—such as WHO treatment guidelines or Essential Medicines Lists—are updated to reflect the latest evidence, countries must revise and implement new national guidelines to reflect current recommendations. While Bangladesh has updated its guidelines to include the use of misoprostol for the prevention and treatment of PPH, the preventive dosage of misoprostol stipulated for PPH is lower than the WHO-recommended dosage (400 mcg versus WHO-recommended 600 mcg).¹⁶ This is anecdotally due to the smaller stature of Bangladeshi women. The reduced dosage translates to a reduction in the forecasted demand for and procurement of misoprostol for community-based provision (two 200-mcg tablets are provided instead of three 200-mcg tablets), without the needed research to confirm the efficacy of a 400-mcg dosage for the prevention of PPH.

In addition to differing global and national guidelines for PPH, guidelines related to the prevention and management of PE/E in Bangladesh remain unclear. WHO-recommended administration protocols for PE/E (Pritchard and Zuspan) have not been integrated into Bangladesh national guidelines, and there remains significant reported confusion among providers at all levels regarding recommended guidelines for the prevention and management of PE/E.¹⁷ This confusion among providers, in both public and private sectors, has a significant impact on the demand for and supply of magnesium sulfate and various magnesium sulfate formulations available. As a result, there remains significant fragmentation of magnesium sulfate formulations available in the Bangladeshi market, leading to inefficiencies for suppliers, procurers, and health professionals and further exacerbating availability.

Procurement in decentralized settings

Countries with decentralized health systems also encounter challenges coordinating procurement, both between national and subnational procurement units and among various subnational procurement entities. In places where some or all health-product procurement has been devolved to subnational

levels, procurements are often fragmented, of smaller quantities, and on different schedules. This weakens subnational 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.

In Bangladesh, maternal health products are procured both centrally and at the district and sub-district levels, and procurement units at these various 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 joint 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 planning of procurement between the two agencies.¹⁸ As in other countries, the number of procurement units at the national and district levels—and the limited coordination among them—lead 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 by district; stockouts are more common in some than in others.



Availability: advocacy recommendations

Align national guidelines with global recommendations and support dissemination and provider training:

- **Government:** The GoB should conduct additional research to confirm the efficacy of a reduced dosage of misoprostol for the prevention of PPH and develop and disseminate guidance for the treatment and management of PE/E using magnesium sulfate. Further, there is opportunity for procurers to standardize specifications in tenders and to demonstrate to suppliers there is demand for magnesium sulfate in the formulations outlined in WHO recommendations for the treatment and management of PE/E.



- **Advocates:** Advocates should urge GoB officials to align guidelines with global recommendations related to the prevention of PPH and the treatment and management of PE/E and to advocate for dissemination and provider training to support appropriate implementation. In addition, advocates can assist with flagging future changes to global recommendations that may affect current national guidelines.

Improve communication and coordination among agencies responsible for health-product forecasting, supply planning, procurement, and budgeting:

- **Government:** National-, district-, and subdistrict-level agencies should create or support multi-stakeholder forecasting “task teams” to regularly lead reviews and ensure accountability for comprehensive, costed forecasts and supply plans for essential health products, including maternal health products. Teams should include stakeholders responsible for forecasting, supply planning, procurement, budgeting, and program management, as well as implementing partners and civil society representatives. Under the Supply and Awareness Technical Resource Team of the UN Commission, John Snow International (JSI) developed guidance for countries regarding the establishment or expansion of existing supply coordination committees to include the full set of Reproductive, Maternal, Neonatal, and Child Health commodities and stakeholders. The guidance offers best practices for committees—including recommendations for developing terms of references, key membership, structure, and operations of supply coordination committees—and provides a range of resources the GoB can use to support implementation.¹⁹

Address procurement inefficiencies to improve availability of maternal health products:

- **Government:** Procurement and budget officials should explore mechanisms that coordinate and potentially pool public-sector procurement across subnational procurement units. In decentralized settings like Bangladesh, coordinating demand forecasts and budgets and pooling orders across 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 and awareness of stockouts of lifesaving health products in their communities. 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 access.

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 as it works toward the new Sustainable Development Goals (SDGs), countries worldwide—including Bangladesh—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 advocacy recommendations in this brief highlight critical opportunities for advocates working to improve maternal health outcomes in Bangladesh. Advocates 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, advocating for increased resources to regulate and procure products, ensuring policy coherence and the operationalization of key policies impacting forecasting and supply planning, and calling for increased coordination and collaboration among relevant government agencies.

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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