SAFEGUARDING PREGNANT WOMEN WITH ESSENTIAL MEDICINES

A global agenda to improve quality and access
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At the heart of good maternal health care is a set of basic, low-cost, but essential supplies, including medicines that prevent the leading causes of maternal death.

**The Reality**

**Every two minutes one woman dies**
from pregnancy or childbirth-related complications.

99% of them live in the developing world, with India and Nigeria bearing the greatest burden.

**This does not have to be the reality**
The two greatest causes of maternal deaths—which total 287,000 annually—are preventable.

- **Postpartum hemorrhage**, or excessive bleeding after childbirth, causes 25% of all maternal deaths. (#1 cause)
- **Pre-eclampsia and eclampsia**, which is caused by high blood pressure during pregnancy, is attributed to 23% of all maternal deaths. (#2 cause)

**The Solution is within reach**

- **Oxytocin** is the recommended medicine to prevent and treat excessive bleeding after childbirth.
- **Misoprostol** is used to prevent and treat excessive bleeding after childbirth when oxytocin is unavailable.
- **Magnesium Sulfate** is the most effective medicine to prevent and treat pre-eclampsia and eclampsia.

These lifesaving medicines cost less than **US$1 per dose**.

**Maternal health medicines save mothers’ lives**

If oxytocin and misoprostol were available to all women giving birth

**over 10 years = 41 million cases of postpartum hemorrhage could be prevented, and 1.4 million lives could be saved.**

Sources: World Health Organization, US Agency for International Development, UN Commission on Life-Saving Commodities for Women and Children 

PATH A catalyst for global health
Global agenda for action

Where a woman gives birth should not decide her fate, especially when affordable, effective medicines to treat and prevent the leading causes of maternal deaths—excessive bleeding after childbirth and deadly seizures during pregnancy—exist.

Developed with maternal health experts working across the globe, this targeted agenda for action will help global and national advocates, policymakers, and program implementers lead efforts to increase the quality, availability, and appropriate use of oxytocin, misoprostol, and magnesium sulfate—and, ultimately, save lives.

Generate data for decision-making

- Strengthen local and national data collection systems in order to improve forecasting of supply, demand, and use of maternal health medicines.

Ensure safety & efficacy

- Certify a select number of manufacturers able to produce quality maternal health medicines on a global scale.

- Enhance capacity for quality assurance by smaller manufacturers to enable national and local procurement organizations to purchase quality maternal health medicines within countries.

- Integrate oxytocin into existing public- and private-sector cold chains to ensure potency from the manufacturer to pharmacies and facilities.

- Create innovative heat-stable formulations for oxytocin and moisture-proof packaging for misoprostol tablets to protect them from temperature and humidity.

Address inappropriate use

- Enhance national policies as well as the knowledge and skills of health workers to support proper medicine administration at all levels of the health system.

- Conduct consumer research to understand and address issues related to client demand for and appropriate use of maternal health medicines.

- Invest in the development of acceptable, user-friendly medicines, such as simplified magnesium sulfate dosing and packaging, to expand access to quality services throughout the health system.

Strengthen national and local systems

- Invest in strengthening supply chain systems to ensure consistent supply and delivery of maternal health medicines to all women who need them.

- Improve education about, conditions of, and transportation to health facilities to increase the number of women giving birth with skilled attendants and access to maternal health medicines.

- Improve access to maternal health medicines for women who give birth at home by enabling distribution of misoprostol for prevention and treatment of postpartum hemorrhage in communities and expanding innovative drug delivery technologies to allow less-skilled health workers to administer medicines.
More than eight million women each year suffer from postpartum hemorrhage—characterized as excessive bleeding after childbirth—which is the leading cause of maternal deaths in the developing world, claiming the lives of nearly 71,800 women annually. These deaths are largely preventable and treatable with access to basic health services and effective medicines. Oxytocin, which is delivered through an injection, is the recommended medicine for preventing and treating postpartum hemorrhage, and misoprostol, which comes in tablets that are taken orally, can be used for prevention and treatment when oxytocin is not available. The need for these two medicines is universal, present wherever deliveries occur: from urban hospitals to rural clinics and homes, where more than 50 percent of women in developing countries deliver their babies.

The second leading cause of maternal death is pre-eclampsia and eclampsia—detected during pregnancy through elevated blood pressure or the presence of protein in urine—which when untreated can lead to seizures, kidney and liver damage, and death. These conditions claim the lives of an estimated 63,000 women each year, as well as the lives of many of their babies. Magnesium sulfate is the most effective medicine for preventing and treating pre-eclampsia and eclampsia. Administered by an injection, magnesium sulfate is needed at all levels of the health system where women seek care.

Although these medicines are inexpensive and produced around the globe, their impact is compromised by the absence of important data to help forecast demand, regulatory hurdles, the poor and uncertain quality of medicines as well as their inappropriate use, supply chain management challenges, and funding gaps.
In 2012, the United Nations Commission on Life-Saving Commodities for Women and Children highlighted the need to improve women’s and children’s health by increasing access to 13 high-quality, essential health supplies, including oxytocin, misoprostol, and magnesium sulfate. This high-level commission championed efforts to reduce barriers that prevent essential health products from reaching individuals and communities in the developing world by recommending a set of cross-cutting actions.

To better understand the issues brought forth during the roundtable discussions, PATH visited health facilities and homes throughout Ghana and Nigeria, where both innovations and challenges in maternal health care exist. This report synthesizes key areas of consensus from these discussions, and presents a targeted agenda for action for global and national advocates, policymakers, and program implementers. Together they can lead efforts to increase the quality, availability, and appropriate use of oxytocin, misoprostol, and magnesium sulfate—and, ultimately, save lives.

**UNITED FOR ACTION**

For far too long, affordable, effective medicines and simple health supplies have not reached the women and children who need them most. The United Nations Commission on Life-Saving Commodities for Women and Children—a new component of the Every Woman Every Child movement—was established to elevate the importance of these supplies and to break down barriers to accessing them. By advocating at the highest levels, the Commission established an important global platform for building consensus around priority actions to increase the availability and accessibility of specific commodities. See www.everywomaneverychild.org.

**GROUNDED BY COMMUNITY PERSPECTIVES**

Between May and July 2012, PATH brought together more than 130 stakeholders from across Asia, sub-Saharan Africa, Europe, and North America to participate in five roundtable discussions in Bangladesh, Tanzania, and the United States. To shape the agenda for these discussions, PATH also commissioned in-person interviews with 27 key stakeholders that represented donor countries, multilateral organizations, bilateral programs, product developers, and nongovernmental organizations. See full list of roundtable discussion participants on page 14.

Rukaya Abdulai, a community health officer, visits clients in the village of Kurawurakura, Ghana, where she provides a range of services, including administering oxytocin to women in order to prevent excessive bleeding after childbirth—the leading cause of maternal deaths.
Generating data for decision-making

Maternal health medicines are safe, effective, and essential to keeping women healthy throughout pregnancy and childbirth. But little is known about the supply, demand, and use of these products because very little relevant data exist, particularly in developing countries.

Without this information, local health systems cannot accurately budget or predict demand, organizations that procure maternal health medicines—from national and local governments to nongovernmental organizations—do not know how many lifesaving doses to purchase, and manufacturers do not know how much medicine to produce. This cycle leads to frequent stockouts and endangers the health of women across the developing world.

Improve availability and quality of local and national forecast data

To improve the availability and quality of data that will help forecast supply, demand, and use of maternal health medicines at the national and local levels, national governments should integrate data tracking and analysis of maternal health medicines into existing national logistics management information systems, where they are not already included. To encourage national ministries of health to collect information on maternal health medicines, donors should develop incentives, and major bilateral programs should support developing countries in their efforts to build and strengthen information systems at the national and local levels.

Existing bilateral programs that provide technical assistance to strengthen data-tracking systems for other health supplies offer an ideal platform for improving maternal health.

For example, incorporating oxytocin, misoprostol, and magnesium sulfate data-tracking into a program such as the US Agency for International Development’s (USAID) DELIVER Project—which works to strengthen reproductive health supply chains in more than 20 countries—could drastically improve information to support decision-making without creating new programs.

To provide policymakers with a strong evidence base, national governments should also integrate maternal health indicators into their health management information systems that track how—and how often—health services are used, and health outcomes within countries. The World Health Organization’s (WHO) global maternal health indicators, currently in development, will provide a universal platform for accomplishing this. Two of the WHO’s draft indicators specifically relate to maternal health medicines: administration of magnesium sulfate to women, and administration of uterotonicics like oxytocin and misoprostol to induce continued contractions immediately after a baby is born. National governments should also add a budget line-item to support the tracking of funds allocated to maternal health medicines.

Integrating maternal health medicines into the systems that track health commodities and relevant health outcomes will help strengthen comprehensive information management systems for essential medicines, and will help local governmental and nongovernmental organizations budget for—and purchase—enough medicines for women. As systems strengthen and more national and local data become available, developing countries should be incentivized to report into a global clearinghouse of data on maternal health medicines, offering an opportunity to identify global trends and engage more donor country representatives in supporting improved access to high-quality maternal health medicines.

INVESTING IN LOGISTICS MANAGEMENT AND COUNTRY OWNERSHIP

In 2008 the Logistics Management Division of the Government of Nepal began widespread expansion of a web-based logistics management system to collect data on the supply, demand, and use of all health products in the supply chain, including maternal health medicines.

With the support of the United Nations Population Fund, the UK Department for International Development, and the US Agency for International Development-funded Nepal Family Health Program II, the Nepalese government successfully introduced its logistics management system to all 75 districts in the country.

Today, the Nepalese government is able to better predict demand and avoid stock-outs, and it can allocate funding to support procurement as well as training for district staff.
Ensuring medicines are safe and effective

Even if medicines are widely available where women seek health care, they cannot prevent or treat life-threatening complications from pregnancy and childbirth if they are not sufficiently potent—a common challenge with maternal health medicines.

In many countries, markets are flooded with locally manufactured medicines. Amid this large supply, low and uncertain quality of maternal health medicines remains a major concern and makes it difficult for procurement agencies, such as national and local governments and nongovernmental organizations, to identify the best quality products.

Correcting quality issues requires coordination among multinational and national partners across the public and private sectors. These partners must establish and carry out important regulatory processes and implement oversight measures without placing too many requirements on local manufacturers, which can deter them from producing these low-cost, lifesaving medicines.

Increase purchase options for quality medicines
To help national and local governments and other nongovernmental organizations select maternal health medicines that meet important quality standards, the WHO and relevant partners should identify a select number of high-quality, affordable manufacturers that can produce adequate quantities on a global scale for each of the three maternal health medicines. They should take into consideration geographic diversity of manufacturers so that local procurement agencies can purchase medicines from regional manufacturers and avoid burdensome shipping costs.

“We have 40 manufacturers of misoprostol in our country,” a Ghanaian ministry official said. “How do we know of these 40, who is producing quality product?”

A small supply of misoprostol tablets sits in a bedside table in a delivery room in Nigeria. Misoprostol is susceptible to spoilage from exposure to humidity, which can easily occur when the tablets are not stored properly.

If necessary, once the producers have been identified, the WHO and other expert organizations should provide technical assistance to guide the manufacturers through the WHO prequalification process, which evaluates the quality of a manufacturer and its products. The WHO prequalification process is often used as a prerequisite for a product’s eligibility for purchasing by United Nations procurement agencies.

To help make locating and purchasing quality medicines easier, the selected manufacturers could supply medicines through a procurement agency that publishes a prequalified list of vendors—such as the UN Population Fund’s AccessRH procurement catalog of reproductive health supplies.

Enhance local capacity for quality assurance
While it is important to identify manufacturers that can produce large quantities of medicines at a global scale and that are recognized by the WHO as high-quality producers, it is also important to identify and strengthen the capacity of smaller, local manufacturers, as many national and local governmental and nongovernmental procurement organizations purchase medicines in their country.
Quality oversight is financially costly and time-consuming, and often there is little incentive for local manufacturers to pursue WHO prequalification—a complex and stringent process. It is widely recognized that many national and local procurement agencies do not require local manufacturers to receive WHO prequalification before purchasing their products.

To improve the overall quality of maternal health medicines and ensure quality consistency:

- Donor countries should fund technical assistance to support select local manufacturers in achieving the WHO’s prequalification status.

- Local policymakers should implement incentives to encourage manufacturers to seek prequalification.

- Where WHO prequalification is not feasible, global regulators should consider developing—and providing assistance to achieve—a less cumbersome quality evaluation program, such as one that uses a simple seal of approval to indicate that a product meets basic quality standards.

- Donor countries should invest in strengthening national regulatory capacity so developing country governments can provide necessary oversight to ensure that products are manufactured in line with global standards.

International, cross-sector partnerships to strengthen quality oversight at the national and local levels could help ensure that safe and effective maternal health medicines are produced by small local manufacturers, similar to the way USAID and the US Pharmacopeial Convention (USP) do for medicines that prevent and treat USAID priority diseases today. Through their Promoting the Quality of Medicines program, USP works with local and regional drug manufacturers in more than 35 countries and collaborates with international health organizations to help increase the supply of quality medicines.

Integrate for quality
The quality of maternal health medicines is impacted not only at the point of manufacturing. Once a product leaves the production facility, its effectiveness can be compromised by changing environmental conditions. While some

"There is nothing worse than a health worker at a local level giving oxytocin, and giving oxytocin, and giving oxytocin, and not knowing that it’s not working because it’s not potent,” said Catharine Taylor, Global Program Leader, Maternal and Child Health and Nutrition, at PATH.
manufacturers’ studies indicate that oxytocin can be stored at room temperature, the ambient temperature in tropical countries is often so high that it can render oxytocin less potent.

Multilateral health programs and manufacturers should include oxytocin in the distribution chain of other medical products that must be kept cool. For example, many vaccines are transported across the globe and to rural communities in temperature-controlled containers and often are administered at the same sites as oxytocin. To support the integration of maternal health medicines into temperature-controlled supply chains, advocates and implementing organizations must work to encourage enabling policies and practices with multilateral organizations as well as with bilateral and national programs.

Innovate for quality

Similar to the way oxytocin degrades when it is not kept in a cool space, misoprostol is sensitive to humidity and can lose its potency when the tablets are exposed to moisture. This often happens when the medicines are not stored properly, or when they are not packaged in materials that prevent moisture from reaching the tablets.

To better protect these medicines during transport and storage in warm, humid climates, donor countries should work with manufacturers and nongovernmental organizations through public-private partnerships to develop new heat-stable formulations for oxytocin, as well as more durable, moisture-proof packaging to protect misoprostol tablets as they move from the manufacturer to health facilities, pharmacies, and homes.

A woman waits in the delivery ward at a hospital in central Ghana, where supplies to treat pregnancy and childbirth complications are kept in nearby bins.
Addressing inappropriate use

Even the most effective medicines cannot fully safeguard a woman’s life during pregnancy and childbirth if they are not administered properly. In communities across Africa and Asia, misuse of maternal health medicines by misinformed health care workers occurs, preventing oxytocin, misoprostol, and magnesium sulfate from providing maximum protection or treatment.

For example, oxytocin is used to augment labor instead of to prevent postpartum hemorrhage because health care workers are unaware of its preventive capabilities, or because of cultural preferences for speedy births. Often, their misunderstanding can increase the likelihood of birthing complications. When oxytocin is incorrectly used to augment labor it can cause perforations to the uterus and asphyxiation of the newborn baby.

In other instances, alternative medicines are used, even though they are not the recommended medicine for prevention or treatment. Many health care providers give women the medicine ergometrine to prevent postpartum hemorrhage because they do not know that oxytocin is the first-line medicine for this purpose. Similarly, health providers often administer the medicine diazepam for severe pre-eclampsia and eclampsia, when expert bodies confirm that magnesium sulfate is the treatment of choice. This practice is perpetuated by fears about magnesium sulfate’s toxicity and the fact that the dosing for magnesium sulfate is difficult to calculate and administer in its current form.

Along with the creation of new formulations and packaging of maternal health medicines, misconceptions among health care providers and consumers must be corrected to ensure that after the medicines arrive at the place women seek care, the medicines are delivered correctly, keeping mothers and their babies safe.

Enhance policies, knowledge, and skills

Where not already included, oxytocin, misoprostol, and magnesium sulfate should be added to essential medicines lists, standard treatment guidelines, and national protocols to help facilitate education and proper use among health care workers.

Policies that unnecessarily restrict the administration of these medicines to highly skilled health workers should be rescinded. In the Democratic Republic of the Congo (DRC), for example, a prescription is required for magnesium sulfate, but midwives are not authorized to write them, and in Zimbabwe, magnesium sulfate can only be used in hospitals.

To reinforce new policies and guidelines, national governments must also prioritize the development of up-to-date pre-service training curriculums for new professionals and continuing education programs for trained health care workers.

Some countries have already experienced success with this approach. In Ghana, where the government has prioritized funding for health care worker training, a study in the Upper East Region demonstrated that increased training and mobilization of community health nurses resulted in reduced rates of maternal and child deaths.

Rosina Danso, a midwife in Kumasi, Ghana, holds a bottle of magnesium sulfate. Although calculating the correct dose can be difficult, Rosina and her colleagues administer magnesium sulfate to pregnant women to prevent and treat pre-eclampsia and eclampsia.
Increase demand and appropriate use through consumer research

Very little information is available on women's—and their families’—knowledge of oxytocin, misoprostol, and magnesium sulfate. But, as consumers, they are important stakeholders in ensuring these medicines are available and used properly.

Donor countries, nongovernmental organizations, and national and local governments should work together to determine if these medicines are acceptable in diverse environmental and cultural settings and if consumers know why and how they should be used and where to get them.

Armed with this information, nongovernmental organizations and national and local governments can more effectively educate women and their families about the importance of maternal health medicines and build proper demand for them.

Invest in the development of acceptable, user-friendly medicines

Donor countries have the opportunity to work with manufacturers and nongovernmental organizations through public-private partnerships to improve product design, labeling, and formulations to make maternal health medicines more acceptable to consumers, easier to use for both skilled and unskilled health care workers as well as patients, and more stable in warmer environments.

In partnership with manufacturers, donors should support work to evaluate a number of potential solutions, including:

- Packaging oxytocin and misoprostol each in two different volumes so health care workers can easily distinguish the proper dosage for preventing and treating postpartum hemorrhage.
- Creating new product labels that more clearly explain the appropriate purpose and use of the medicines.
- Developing a simplified dosing regimen and related packaging for magnesium sulfate to make easier to use for preventing and treating seizures that characterize severe pre-eclampsia and eclampsia.
- Investing in the market creation for these new products.

These improvements would allow greater access to maternal health medicines because more people would be able to administer them correctly and conveniently.
Strengthening national and local systems

Despite the widespread production of oxytocin, misoprostol, and magnesium sulfate by both global and local manufacturers, maternal health medicines often do not get to where they need to be: the location where women seek care. In order to deliver these medicines to the right people at the right time, the national and local systems in which these medicines are produced, transported, and delivered must change.

**Elevate the importance of the supply chain**

Breakdowns in local supply chains are often the most frequent barrier to ensuring the right product is available. While the solutions to this issue are straightforward—enhance logistics management systems, strengthen and grow human resources, and improve distribution channels—they are broad-scale endeavors that will not successfully result in improvements to supply chains without long-term political will and support.

Focused investments from donor countries, multilateral organizations, and national governments are critical. When supply chains are weak, even the best medicines and health care workers cannot be highly effective. Global commitments to strengthen supply chains will reinforce other focused improvements, such as updated packaging or improved data tracking, by improving the system that helps deliver care.

“We often hear the phrase, ‘no product, no program,’ but a product without systems also does not work,” said Joseph Ruminjo, clinical director of EngenderHealth’s Fistula Care project.

**Increase the number of facility births**

Addressing the supply chain is critical to increasing the supply of medicines available to women who deliver in health facilities; however, more than half of women in developing countries give birth at home. For example, more than 90 percent of Ugandan women receive care from a professional during pregnancy, but only about 40 percent return to a health clinic to deliver their baby.

To increase the number of women delivering their babies in health facilities, national and local governments, with the support of donor countries and nongovernmental organizations, should emphasize consumer education on the importance of facility-based births for better health outcomes. Parallel efforts to ensure consistent high-quality staffing at birth facilities must also take place. These advances should be reinforced by increasing the number of affordable, dependable transportation options that women can use when they need to seek care at a facility, as well as public programs that reduce the costs of pre- and post-childbirth care.

**Improve access in communities**

Although experts agree that giving birth in a health facility is usually the best, safest option for women, the reality is that not all women can or choose to deliver their newborns in a facility. With supportive policies and technologies in place, oxytocin and misoprostol can be used to prevent and treat excessive bleeding after childbirth outside of health facilities.

A novel single-dose injection device, called the Uniject™ injection system, is thought to be the safest mechanism for delivering oxytocin to women who give birth at home or in a small health facility with less-skilled health workers. Oxytocin in Uniject™, which is currently being tested in large-scale trials, has the potential to maximize safe use and minimize misuse of oxytocin. If found to be feasible, donor
Conclusion

Healthy mothers have a powerful ripple effect. To save a mother is to save a family. And to save a family is to lay the foundation for stronger communities.

Expanding access to quality, affordable maternal health medicines is critical to making progress in reducing maternal deaths. There are many complex challenges to improving maternal health: the absence of robust data on maternal health medicines, low-quality products and weak regulatory capacity, inappropriate use, supply chain challenges, and funding gaps. Correcting these shortfalls cannot be achieved without the sustained political will and financial commitment of international donors and national governments.

This report highlights specific health system improvements that donor countries, multilateral organizations, bilateral programs, and national governments should prioritize—and that program implementers and advocates should hold them accountable to—including:

- Improving data tracking systems for oxytocin, misoprostol, and magnesium sulfate.
- Ensuring medicines are safe and effective.
- Addressing inappropriate use.
- Strengthening national and local supply chain systems.

Building on the work of and global attention to maternal health medicines driven by the United Nations Commission on Life-Saving Commodities for Women and Children, advocates, program implementers, and policymakers should seize the opportunity to transcend often-overlooked barriers to accessing high-quality maternal health medicines and drive important improvements to save millions of women worldwide, establishing a cycle of health and prosperity for women, their families, and their communities.
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Rachel Jocb, who is pregnant with her second child, attends a prenatal clinic in Nigeria. Women participating in the clinic are examined and told what supplies to bring with them for delivery.

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