

ESSENTIAL MEDICINES FOR MATERNAL HEALTH



Ensuring
Equitable
Access
for All



photos: Evelyn Hockstein

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OVERVIEW



Every two minutes, a woman dies due to pregnancy and childbirth complications—this amounts to approximately 287,000 maternal deaths each year, with 99% occurring in low- and middle-income countries. Postpartum hemorrhage (PPH: excessive bleeding after childbirth) and pre-eclampsia/eclampsia (PE/E: dangerous elevation of blood pressure during pregnancy) are the two leading causes, accounting for nearly half of all maternal deaths. In almost all cases, these conditions are preventable or treatable. Women are dying every day, in many low- and middle-income countries, because they do not have access to essential medicines and to high-quality maternal health care.

There are affordable and effective medicines to treat PPH and PE/E and prevent maternal deaths. Three low-cost medicines, if they were made widely available, could save many of the women who die each year of PPH and PE/E:

- ▶ **Oxytocin** and **misoprostol** are proven, life-saving medicines for the prevention and treatment of PPH.
- ▶ **Magnesium sulfate** is the most effective medicine to prevent and treat deadly seizures caused by severe PE/E.

“A woman dies every two minutes due to pregnancy- and childbirth-related complications.”

Ensuring that women have access to these essential medicines—when they need them, and wherever they give birth—will save lives.

Although important progress has been made, these life-saving maternal health medicines remain out of reach for many women, particularly for the most vulnerable. Many countries lack the clear, supportive policies and adequate budgets needed to make them widely available, or have weak supply chains and logistical systems. Inadequate regulatory capacity, poor quality of medicines, and lack of information and guidance on correct

use are other common barriers to access. **International and national efforts to expand access to oxytocin, misoprostol, and magnesium sulfate must be intensified.**

“Making essential maternal health medicines available to every woman when she gives birth will save the lives of 1.4 million women in the next 10 years.”

We know that these challenges can be addressed and overcome. Ten years ago, access to family planning and other reproductive health supplies was limited by many of these same barriers. Although continued investment in family planning supplies is still needed, the past decade has seen significant improvements in their availability and use. Financing mechanisms have been developed, supply chains and distribution infrastructure have been strengthened, and a new alliance—the Reproductive Health Supplies Coalition—has become a powerful advocacy voice for continued improvements. As a result, access to a variety of high-quality, affordable family planning options has dramatically improved. **Similar improvements for maternal health medicines are possible, feasible, and urgently needed.**



WORKING TOGETHER TO CATALYZE CHANGE

Governments, policy makers, and national program implementers must build strong, effective partnerships to promote access to and use of life-saving maternal health medicines, and commit with national and international partners to ensuring:

- ▶ **Quality:** Quality of essential medicines is assured from the point of manufacture to the point of care.
- ▶ **Availability:** Maternal health medicines are available to every woman, where and when she needs them.
- ▶ **Choice:** Maternal health medicines are available from a range of skilled health providers and for the range of evidence-based indications.
- ▶ **Equity:** Life-saving medicines for maternal health are available to all women, wherever they live, at a cost appropriate for people of diverse incomes.

“Each of these essential medicines costs less than US\$1.00 per dose.”



ACTION IS NEEDED NOW! NATIONAL LEADERS MUST:

- ▶ Ensure a supportive policy environment and adequate financial investment of essential maternal health medicines.
- ▶ Strengthen information and supply chain systems to ensure medicines' availability and avoid stockouts.

Leveraging the Experience of the Reproductive Health Supplies Coalition (RHSC)

What is the RHSC?

The RHSC is a global partnership of 300 multilateral, bilateral, and foundation donors; governments of low- and middle-income countries; nongovernmental and civil society organizations; advocates; manufacturers; and procurers. It is dedicated to ensuring that all people in low- and middle-income countries can access and use affordable, high-quality reproductive health supplies.

What is the RHSC's role in efforts to expand access to maternal health medicines?

The RHSC has transformed a technical issue into a global movement. It has mobilized a wide range of partners to prioritize and invest in ensuring that all people have access to a range of high-quality reproductive health supplies, and has fostered the development of innovative funding mechanisms, sophisticated analytical tools, and effective partnerships. The RHSC will use this experience as a foundation for addressing the barriers that impede access to and use of essential maternal health medicines.

What is the Maternal Health Supplies Caucus?

Formed in 2012 as a working group of the RHSC, the Maternal Health Supplies Caucus brings together the maternal health and family planning communities to forge a common understanding of the challenges related to essential maternal health medicines, and to develop approaches for addressing the bottlenecks that undermine commodity security across health systems. The Caucus aims to:

- ▶ Leverage the RHSC successes in improving access to family planning commodities in order to address the challenges impeding access to maternal health medicines.
- ▶ Adapt the robust knowledge base and analytical tools that RHSC members have developed for family planning for use on maternal health medicines.

How to get involved

For more information, visit the Coalition webpage at www.rhsupplies.org.

- ▶ Ensure that high-quality medicines are procured, and that their quality is maintained.
- ▶ Improve the knowledge and skills of health providers so that they can appropriately administer these medicines to the women who depend on them.

“In the 75 countries where more than 95% of maternal deaths occur, delivering a package of maternal health services and essential medicines will cost less than US\$1.50 per person.”

WE KNOW WHAT TO DO. We know it is possible to overcome the challenges and bottlenecks that limit access to and use of essential maternal health medicines. The solutions are within reach if we build the political will and make the financial investments needed to make these essential medicines available to all women when they give birth.

WE HAVE THE OPPORTUNITY. Working together, global leaders, national governments, advocates, and other partners can make the difference that saves women’s lives. A global platform (see box right) has been developed to provide leadership, tools, and resources, so that

A Global Platform for Action

In 2012, the United Nations Secretary-General established the UN Commission for Life-Saving Commodities for Women’s and Children’s Health (UNCoLSC). This high-level commission works to spur action at the global and country levels to ensure that life-saving commodities and products, along the reproductive, maternal, newborn, and child (RMNCH) continuum, reach the world’s most vulnerable people. In particular, the UNCoLSC has highlighted the critical role of essential maternal health medicines in a well-supported and functioning health system, developed a range of cross-cutting tools and resources, and catalyzed country-level action to address gaps and inefficiencies. For more information, visit www.lifesavingcommodities.org.

we can ensure every woman’s access to essential maternal health medicines.

WE MUST ACT NOW. Leadership and investment to improve maternal health and ensure access to essential maternal health medicines are needed right now. Women are dying every day for lack of simple, available, and affordable medicines. Concerted, intensified, and sustained action is needed today.

Essential Medicines for Maternal Health: A series of seven policy briefs

This series of policy briefs provides information on three essential maternal health medicines (oxytocin, misoprostol, and magnesium sulfate) and showcases evidence-based strategies for addressing the key barriers to their widespread access and use, supported by case examples of successful interventions from around the world. Aimed at national policy makers and program managers, the briefs also highlight cross-cutting experiences and lessons from reproductive health to support improved access and use of essential maternal health medicines. The series includes the following briefs:

- ▶ This overview brief, outlining why maternal health medicines are important, identifying key gaps related to access, and setting out priorities for action
- ▶ Three briefs on the three essential maternal health medicines: oxytocin, misoprostol, and magnesium sulfate
- ▶ Three briefs focusing on cross-cutting issues: policy and financing; supply; and demand generation

OXYTOCIN



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COMMODITY PROFILE

Oxytocin is a natural hormone secreted during pregnancy, labor, and breastfeeding. It is also manufactured in synthetic form. Oxytocin is [recommended by the World Health Organization \(WHO\)](#) as the first-line uterotonic for both the prevention and treatment of postpartum hemorrhage (PPH), which occurs when the uterus does not adequately contract after childbirth. Administration of a uterotonic such as oxytocin can help stimulate contractions and stop excessive bleeding (see [Brief on Misoprostol](#) for information on its role in PPH prevention and treatment). To prevent PPH, the WHO recommends that oxytocin be administered by a skilled provider within one minute of delivery of the baby as part of active management of the third stage of labor (AMTSL). Oxytocin is listed in the WHO model list of essential medicines and included in many national lists of essential medicines and standard treatment guidelines.

Oxytocin is typically available in ampoule form in low- and middle-income countries. Administered by injection into a woman's vein (IV) or muscle (IM), oxytocin is highly effective, acting in just one to three minutes; has minimal side effects; and is widely available around the world. In its current formulation (an aqueous solution), oxytocin is sensitive to heat, and must be stored either at [controlled room temperature](#) (25°C or less) or in [refrigerated storage](#) (2°–8°C) to ensure that it remains effective.¹

THE CHALLENGE

Despite its proven safety and efficacy in preventing and treating PPH, key barriers affect the widespread use and quality of oxytocin in low-resource settings, including:

- ▶ **Availability of poor-quality products:** While there are many manufacturers of oxytocin, the quality of products produced by manufacturers can vary widely. National drug authorities often do not have sufficient capacity to guarantee the quality, efficacy, and safety of medicines in countries; as a result, poor-quality medicines can be procured for use in the public as well as the private sector.
- ▶ **A weak national distribution system** and supply chain that is unable to support a temperature-controlled system (cold chain) needed to maintain oxytocin's potency during

transport or storage. The [WHO](#) recommends that oxytocin be refrigerated “as much as possible”; however, it is not always possible to keep the medicine at the correct temperature, particularly in tropical climates with limited access to electricity. As a result, [oxytocin at the point of use](#) is still largely delivered outside of a temperature-controlled system in many low-income countries. (See brief on [Supply of Essential Medicines](#).)

- ▶ **Need for specialized skills and equipment:** Administering the oxytocin injection requires specialized skills, sterilized equipment, and proper disposal of medical waste. In many countries, skilled birth attendants able to administer oxytocin are in short supply; in addition, national guidelines in some countries restrict its administration to specific cadres of health workers (such as medical doctors).



Field studies conducted in **Ghana** and **Indonesia** analyzed samples of oxytocin and found significant lack of potency, either due to poor-quality products or exposure to high temperatures during transport or storage. Almost none of the samples were stored in the recommended temperature range of 2°– 8° C.

This brief outlines **key strategies for addressing the quality and potency of oxytocin**, and highlights findings from pilot projects and research studies from around the world. The brief also identifies cross-cutting lessons from the reproductive health community in securing quality reproductive health supplies.

THE STRATEGY: ENSURING QUALITY & POTENCY

A number of strategies and interventions are currently being developed or piloted to address the quality of oxytocin, and to ensure that oxytocin remains effective in preventing or treating PPH until the point of use.

ENSURING QUALITY MEDICINES ARE

PROCURED: A key strategy for ensuring quality is the procurement of products that are quality assured, either by the WHO Prequalification of Medicines Program, by a Stringent Regulatory Authority (SRA),² or by a national mechanism for ensuring quality assurance. While oxytocin is eligible for WHO prequalification, there are currently no WHO-prequalified or SRA manufacturers of oxytocin that market to low-resource countries. There are a number of products in the pipeline toward prequalification, and efforts are under way, under the auspices of the UNCoLSC and other partners, to provide

technical support to manufacturers to apply for WHO prequalification of oxytocin.

INCLUDING OXYTOCIN IN THE IMMUNIZATION COLD CHAIN:

A cold chain refers to the storage and transport equipment that enables medicines to be kept refrigerated from the point of manufacture to the point of use. In many countries, the Expanded Program on Immunization (EPI) has developed a functional system for maintaining the cold chain but has generally prohibited inclusion of other temperature-sensitive health commodities aside from vaccines. Historically, vaccines were often the only products requiring a cold chain. With the introduction and use of increasing numbers of heat-sensitive health commodities (for example, drugs for malaria, HIV/AIDS, and tuberculosis), countries are beginning to experiment with integrating multiple supply chains. There is anecdotal evidence that several countries (**Ghana, Senegal, Mali, and South Sudan**)



are using the vaccine cold chain for oxytocin; additional documentation and information are needed to identify lessons learned and best practices that can be used to support this practice in other countries.

While there are no written policies or documents that prohibit oxytocin from being included in the EPI cold chain, there is a general misconception among government decision makers and health workers that international standards do not allow other health commodities, including oxytocin, to be managed as part of the vaccine cold chain. The formal integration of oxytocin into the immunization cold chain can provide a critical step toward ensuring the availability of high-quality oxytocin. At the global level, the

UNCoLSC is making a concerted effort to ensure that oxytocin is integrated into the vaccine cold chain through:

- ▶ **High-level advocacy:** A formal policy statement issued by key international health agencies (WHO and UNICEF) supporting the inclusion of oxytocin in the immunization cold chain and calling on countries to take steps toward this integration.
- ▶ **Pilot operations research projects:** In select countries, operations research is being conducted to provide evidence on the feasibility and challenges of this integration, and to document the experiences of oxytocin in the vaccine cold chain. The data generated from the research will be provided to high-level government officials to support informed decision making. In **Malawi** and the **Democratic Republic of the Congo (DRC)**, officials have already prioritized efforts to improve supply chain management and to include the addition of oxytocin in the vaccine cold chain.

Innovations in Delivery

Work is under way to develop and introduce innovations in the delivery and presentation of oxytocin that are heat stable and/or easier to administer, by a range of health care workers. These include:

- ▶ **Time-Temperature Indicators (TTI).** These help to ensure that the medicine has not been exposed to excessive heat that could affect its potency. TTIs usually consist of labels on medicine or vaccine packages that change color when exposed to elevated temperatures. TTIs can help improve stock management by enabling health workers to make informed decisions about which doses to use first by checking the TTI.
- ▶ **Inhaled Oxytocin project:** Through the Inhaled Oxytocin project at Monash University, a low-cost, heat-stable dry powder delivery system is currently in the early stages of development. This delivery mechanism allows oxytocin to be inhaled and absorbed rapidly upon delivery to the lungs, providing an alternative delivery method that is safer and less invasive, without the use of injections and the need for sterile conditions or skilled medical personnel.
- ▶ **Sublingual tablet:** Another formulation being developed is a heat-stable oxytocin in a fast-dissolving sublingual (under the tongue) tablet. Benefits of this product are similar to the dry powder form: rapid absorption into the bloodstream; its needle-free format eliminates the need for injections and waste disposal, and enables low-level health providers to safely and effectively administer oxytocin to patients under the tongue.

ENSURING QUALITY: SUCCESSES FROM REPRODUCTIVE HEALTH

The reproductive health community has been successful in ensuring the availability of high-quality, affordable reproductive health supplies: the number of WHO prequalified products increased from 8 in 2011 to 21 in 2013, 11 of which were generics. The Quality of Reproductive Health Medicines program (QuRHM), funded by the U.K. Department for International Development (DFID) through the Reproductive Health Supplies Coalition, and implemented by Concept Foundation, has been effective in increasing the availability of affordable, quality-assured reproductive health medicines in low-income countries. This program has created awareness of the need for quality-assured products to manufacturers, procurers, and donors; demonstrated to companies a business case for getting their products prequalified; secured generic reproductive health medicines into the pipeline for prequalification; and made quality-assured products available at a more affordable price.

This approach provides a model that the maternal health supplies community can draw from to improve recognition by manufacturers and other stakeholders on the importance of WHO prequalification as an important mechanism in ensuring the availability of affordable, quality-assured products.

PRIORITY ACTIONS FOR ENSURING QUALITY AND POTENCY

Governments and implementing partners must take action to ensure oxytocin is of high quality, and that it maintains its quality from the point of manufacture to the point of use. This includes:

- 1. Procuring quality-assured products** either by the WHO Prequalification of Medicines Program, by a Stringent Regulatory Authority (SRA), or by a national mechanism for ensuring quality assurance.
- 2. Building the capacity of national regulatory authorities** to conduct regular and consistent quality monitoring.
- 3. Strengthening the national supply chain** and addressing weaknesses in maintaining a temperature-controlled system. This can include identifying opportunities for including oxytocin as part of the vaccine cold chain.

FOR MORE INFORMATION: KEY RESOURCES

Oxytocin: RHSC Product Brief (RHSC, 2013)

WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage (WHO, 2012)

Medicines for Maternal Health (UNCoLSC, 2012)

Oxytocin Product Profile (UNCoLSC, 2012)

¹ According to the WHO, oxytocin can remain without refrigeration for short periods: at 30°C not exceeding one month, or at 40°C for two weeks. WHO Action Programme on Essential Drugs and Vaccines. Stability of injectable oxytocics in tropical climates. 1993. Available at: <http://apps.who.int/medicinedocs/pdf/s2205e/s2205e.pdf>.

² A Stringent Regulatory Authority is the regulatory authority in a country that is a member of the International Conference on Harmonisation (ICH); this includes the European Union, Japan, and the United States of America.

MISOPROSTOL



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COMMODITY PROFILE

Misoprostol is a safe, effective, and low-cost medicine for the prevention and treatment of postpartum hemorrhage (PPH). This uterotonic stimulates strong contractions of the uterus, and softens and dilates the cervix in a way that is similar to the natural process of labor. Misoprostol is used for a number of maternal and reproductive health indications, including PPH, induction of labor, treatment of miscarriage and incomplete abortion, and induced abortion (in combination with mifepristone).

Misoprostol does not need refrigeration and is available in tablet form, and it can therefore be administered with no specialized equipment or skills. Misoprostol provides an effective alternative option for preventing and treating PPH in settings (such as home births and health facilities lacking electricity, refrigeration, and/or IV equipment) where oxytocin—the first-line choice for prevention and treatment of PPH—is not available or its administration is not feasible (see brief on Oxytocin). Misoprostol for PPH can be an important strategy for countries with a high proportion of home births and in poorly equipped health centers where mid- and low-level providers do not have access to oxytocin. Many countries have piloted community-based PPH prevention programs distributing misoprostol through a range of strategies, including advance distribution to women during antenatal visits¹ and administration at home births by community health providers (see next page).

The WHO recommends misoprostol for the prevention and treatment of PPH when oxytocin is not available or cannot safely be used. The WHO also recommends that misoprostol be administered by community and lay health workers for PPH prevention when skilled birth attendants are not present. In 2011, misoprostol for the prevention of PPH was added to WHO's

Essential Medicines List, guiding countries to include misoprostol in national essential medicine lists and to prioritize a safe and consistent supply.

THE CHALLENGE

Although there is evidence of misoprostol as a safe and effective alternative when oxytocin is not available, a range of **barriers** limit its widespread availability and effective use:

- ▶ National policy documents and clinical guidelines often **do not identify misoprostol as a strategy for PPH prevention or treatment**. Some countries do not include misoprostol in their national essential medicine lists.
- ▶ Although many countries have piloted misoprostol programs, most of these programs have not been taken to scale, and **misoprostol is often not routinely procured and available** in the public sector.
- ▶ There is often **opposition or resistance** to widely introducing misoprostol based on concerns about misoprostol's potential use for other indications, including abortion. There are also fears that widespread availability of misoprostol will promote home births and deter facility-based deliveries.

- ▶ The quality of misoprostol products varies widely depending on the manufacturer. Misoprostol is susceptible to spoilage from humidity when not packaged properly. In addition, only a few manufacturers produce the three-pill package for correct dosing for PPH and to prevent spoilage (see box below).
- ▶ Health providers do not have updated, evidence-based information and training on how to effectively administer misoprostol, including route of administration and dosage.

Despite these challenges, many countries have taken steps to increase access to and use of misoprostol for PPH. This brief outlines a key strategy—community-based distribution—along with examples illustrating **how community-based misoprostol programs are being implemented** from around the world. The brief also highlights important lessons and strategies from introducing or scaling-up community-based distribution of reproductive health supplies.

Ensuring a Quality Product Through Prequalification

There are many manufacturers who produce misoprostol; however, not all manufacturers produce a quality product, in the recommended packaging to maintain its potency, and in the required three-pill package for correct dosing. Governments should take steps to procure quality-assured products, ideally those that have been prequalified by WHO, by a Stringent Regulatory Authority (SRA), or a national mechanism for ensuring quality assurance. The WHO Prequalification Program was established in 2001 to guide procurement agencies in identifying medicines that meet established standards of quality, safety, and efficacy. There are two manufacturers (Cipla Ltd and Linepharma International) which have produced WHO-qualified products (Misoprost and GyMiso respectively) for the PPH indication.

THE STRATEGY: COMMUNITY-BASED DISTRIBUTION

Community-based distribution of misoprostol is being piloted in countries around the world as a key strategy for increasing access to and use of misoprostol for PPH. The methodology varies depending on the country context and includes the following key strategies:

- ▶ **Administration by community health providers at home births:** Community-based health providers (including skilled birth attendants and community health workers) have been trained to administer misoprostol at home births in Mozambique, Nigeria, Bangladesh, India, Ethiopia, and Kenya.

- ▶ **Advance distribution to women for self-administration immediately after birth:** This strategy involves training community health workers and antenatal care providers to counsel women and distribute misoprostol during antenatal care at the health facility or during home visits. Ugandan women are provided with misoprostol tablets directly or via vouchers during their antenatal care visits. In Afghanistan, misoprostol is distributed in women's homes by community health workers; in Bangladesh, misoprostol tablets are provided to pregnant women at or after 32 weeks of pregnancy through government and NGO field workers.

A review of published research studies and evaluation reports from programs that distributed misoprostol at the community level for PPH prevention showed that these programs can achieve high distribution and use of misoprostol through diverse program strategies. Results from these programs indicate that misoprostol can be safely and correctly used when administered by health providers or distributed by community health workers. Women who receive it ahead of time keep misoprostol safely and use it appropriately, provided there is adequate and clear instruction, and counseling. Specifically:

- ▶ In Nepal, advance distribution was piloted using trained Female Community Health Volunteers, as part of the broader maternal

health program. There were challenges in implementing the project (e.g., maintaining a reliable stock of misoprostol in remote areas), but overall, results indicated an increase in the number of women receiving a uterotonic from 11% to 74%, and the safe and correct use of the medicine. Those experiencing the largest gains were the poor, the illiterate, and those living in remote areas.

► In **Afghanistan**, a 2010 study found that 100% of women who self-administered misoprostol did so correctly, and 92% said they would use misoprostol in their next pregnancy. Uterotonic coverage was achieved for 96% of births in the intervention area, compared with only 25% of births in the control area.

Some countries are taking steps to scale up the use of misoprostol for PPH prevention as part of national maternal health programs. In 2012, **Nigeria's Sokoto State** became the first government in Nigeria to procure, using its own funds, misoprostol for PPH prevention and chlorhexidine to prevent newborn sepsis. These commodities are distributed through a cadre of trained community health volunteers and tracked using an innovative, community-based logistics and distribution system. At the national level, Nigeria committed to providing misoprostol to 80% of women delivering at home by the end of 2015. **Ethiopia** has committed to scaling up misoprostol through its national Community Based Newborn Care program.

COMMUNITY DISTRIBUTION: SUCCESSSES FROM REPRODUCTIVE HEALTH

Community-based distribution of family planning products has been an important strategy for increasing access to and use of contraceptives for over thirty years. Programmatic experience, along with research studies, has demonstrated that community-based distribution is acceptable, effective, and cost-effective. In a range of countries, direct contact with community-based distribution agents resulted in 3 to 10 times the amount of modern contraception use, though

the costs of these programs can be higher than other delivery methods (e.g., public clinics and social marketing). Community-based programs are particularly important to reducing inequities in access to services. As part of community-based programs, community health workers have served as an important channel for providing family planning information and



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services to rural and hard-to-reach populations who do not routinely use health facilities. For example:

► In **Peru**, working through community level health workers who shared commonalities (including language, culture, education, religion, social class, or sex) with their target populations proved to be an effective way to improve access and challenge sociocultural barriers to the uptake of family planning products.

► In **Kenya**, health providers were resistant to task shifting the distribution of injectable contraceptives to community health workers due to concerns about its feasibility, acceptability, and safety. A pilot program showed promising results: high-quality service delivery by community health workers, no reported adverse affects, and a fivefold increase in family planning uptake. This led to an update in Kenya's national policy, with the family planning guidelines revised to permit distribution of injectable contraceptives by community health workers.

► In **Ethiopia**, community-based health workers were key in the successful introduction and scale-up of a long-acting family planning method, Implanon. Community health workers received intensive training in how to insert Implanon through a competency-based curriculum; this was followed by supportive supervision and ongoing back-up from health center staff.

It is critical to build on these lessons from the reproductive health community. These experiences and successful strategies can be used to design and scale-up effective community-based misoprostol programs, provide evidence for advocacy to address misconceptions and fears, and to support effective monitoring and evaluation.

PRIORITY ACTIONS FOR COMMUNITY DISTRIBUTION OF MISOPROSTOL

Governments and implementing partners must take action to ensure that misoprostol for PPH is more widely available in the public sector. Scaling up misoprostol at the community level requires the following priority actions:

- 1. Establish clear and evidence-based policies** and guidelines that prioritize misoprostol's role in PPH prevention and treatment, and that support the distribution of misoprostol by community health workers and health providers.
- 2. Ensure a reliable supply of quality-assured misoprostol products by**
 - **Procuring quality-assured products** from manufacturers in sufficient quantities to ensure rollout at the community level;
 - **Allocating sufficient funds** in national (and sub-national, where appropriate) budgets that support misoprostol's expanded coverage through community-based distribution;

► **Strengthening the supply chain** to address inefficiencies and weaknesses to ensure availability at the community level.

3. Train and support community health workers and health providers on appropriate use and administration of misoprostol for PPH.

FOR MORE INFORMATION: KEY RESOURCES

Misoprostol for Maternal Health: RHSC Product Brief (RHSC, 2013)

Prevention of Post-partum Haemorrhage with Misoprostol (International Federation of Gynecology and Obstetrics, 2012)

Scaling Up Lifesaving Commodities for Women, Children and Newborns: An Advocacy Toolkit (PATH, 2013)

Scaling Up Misoprostol for Post-partum Hemorrhage: Moving from Evidence to Action (Family Care International, 2013)

Treatment of Post-Partum Haemorrhage with Misoprostol (International Federation of Gynecology and Obstetrics, May 2012)

WHO Recommendations on Prevention and Treatment of Postpartum Haemorrhage: Highlights and Key Messages from New 2012 Global Recommendations (MCHIP, 2013)

¹ Citing insufficient evidence, WHO has not endorsed self-administration of misoprostol for the prevention of PPH, and recommends this as a priority area for additional research.

MAGNESIUM SULFATE



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COMMODITY PROFILE

Magnesium sulfate is a safe, effective, and low-cost medication for preventing and treating preeclampsia and eclampsia (PE/E). PE/E is a life-threatening condition during pregnancy that is often characterized by elevated blood pressure, seizures, and kidney and liver damage. In severe cases, PE/E can result in the death of a pregnant woman and/or her baby. Magnesium sulfate is available in liquid form (as a solution), is administered as an injection into a woman's vein or muscle, and has limited side effects. While magnesium sulfate can be administered with relatively rare adverse events, it can be somewhat complex to dose and administer (see next section).

Magnesium sulfate is recommended by the WHO as the preferred medicine for the prevention and treatment of severe PE/E, and is included in the WHO EML. The medicine is also identified as a priority medicine in clinical guidelines, protocols, and in national EMLs of many countries around the world.

THE CHALLENGE

While there is strong evidence in support of magnesium sulfate as the safest and most effective medicine for PE/E, a range of barriers limit its widespread availability and effective use in low- and middle-income countries. These barriers include:

- ▶ **Lack of evidence-based clinical and standard treatment guidelines.** Many countries do not have clear, evidence-based, and comprehensive guidelines for effective use of magnesium sulfate. In some countries' clinical guidelines, for example, there is no reference to an intramuscular (IM) regimen. Less-effective medicines are still identified as first-line treatment for severe PE/E. Even when national guidelines include magnesium sulfate, they are not fully implemented in health facilities, especially at lower levels of care.
- ▶ **Lack of standardized presentations.** Some countries have a large variety of presentations available in the market, but these are often not

in line with the WHO recommendation. This requires health providers to prepare complicated dilutions, which may be incorrect or inaccurate. Health staff in many countries have found dosage preparation a key barrier to the use of the medicine because they have to calculate and prepare the dosage themselves.

- ▶ **Lack of information, training, and skills on how to administer magnesium sulfate.** Many health providers are unfamiliar with magnesium sulfate's safety and effectiveness in preventing and treating PE/E, and do not have the appropriate training and skills for correct timing and dosing. In addition, concerns and misconceptions persist about magnesium sulfate's safety and potential for toxicity.¹ As a result, health providers are reluctant to use magnesium sulfate due to the complexity of administration and unwarranted fear of adverse effects, and therefore use other, less-effective medicines, such as diazepam and phenytoin. Low demand and use among health providers can have a more systemic impact on the

availability of this medicine; for example, in some countries, the medicine is ordered from central medical stores only in response to requests from facility-based staff. When magnesium sulfate is not considered a priority medicine by health workers, it is not procured for use in health facilities (see brief on [Supply](#)).

THE STRATEGY: EDUCATION AND TRAINING FOR HEALTH WORKERS

One important strategy for increasing the availability and use of magnesium sulfate for PE/E is to support education and training of health providers. This brief outlines **country-level strategies and experiences in building and improving knowledge and skills** through training, coaching, and development of job aids and other tools. The brief also highlights cross-cutting lessons from the experience of building health workers' capacity to increase access to reproductive health supplies.

NIGERIA: Multi-Level Approach to Increasing Provider Use

In Nigeria, a comprehensive, multi-level approach integrated advocacy, collaborative protocol development, and health provider training to share evidence in support of magnesium sulfate's role in preventing and treating PE/E. A series of advocacy meetings with government officials highlighted the critical role of magnesium sulfate as a life-saving medicine. These meetings were followed by a series of training workshops with doctors and midwives on the administration of the medication and included the training of peers unable to attend the workshop. During the workshops, participants also developed a locally relevant treatment protocol and [national curriculum](#), accompanied by job aids and posters. Key staff at each facility were trained to provide pre-service training to nurses, midwives, and community health workers on managing PE/E with magnesium sulfate. As a result of this approach, 70 nursing and midwifery schools now provide this pre-service training, and the Nigerian Ministry of Health has updated a policy to allow community health workers to administer

an initial dose of magnesium sulfate at primary health facilities before referring patients to the hospital.

TANZANIA: Criteria-Based Audits Improve Quality of Care

In Tanzania, the use of criteria-based audits (CBA) was implemented in a tertiary hospital setting to improve clinical management and



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quality of care for women with PE/E. An audit does not only monitor changes in clinical practice, but also serves as an educational tool. CBAs provide a mechanism for improvement and can empower healthcare workers to conduct their own quality assessments and identify locally appropriate solutions. An initial review identified a range of management and staffing issues (including lack of adequate patient monitoring after initiation of treatment). The introduction of quality improvement approaches to emergency care of PE/E (including standardizing management guidelines, greater involvement of specialists in the management of eclampsia, and providing educational and training opportunities for junior staff) can lead to changes in the care being provided.

MEXICO AND THAILAND: Targeted Training on Magnesium Sulfate and Follow-Up Support

Mexico and Thailand implemented an educational strategy to improve overall clinical obstetric practice. Trainings included, but were not specifically focused on, PE/E. In spite of the training, the use of magnesium sulfate remained low in both countries; as a result, recommendations included developing a training strategy with clear and explicit guidance on magnesium sulfate; in addition, there is a need to identify the range of barriers related to uptake of magnesium sulfate that are specific to the local context. Clinical practice should also be routinely audited to ensure that evidence-based, quality care is provided.

Ensuring a Quality Product Reaches Women

The UNCoLSC and partners are leading efforts to address the main barriers to the availability and use of magnesium sulfate in low- and middle-income countries. These efforts include:

- ▶ Supporting the availability of quality-assured magnesium sulfate products in the market. This involves identifying manufacturers with potential for and interest in becoming prequalified by the WHO, providing them with necessary technical assistance to meet standards for WHO prequalification, and supporting their application for prequalification.
- ▶ Introducing and testing simpler, ready-to-use packs in selected countries. The UNCoLSC is developing a simplified application regimen to increase the use of magnesium sulfate. A prototype ready-to-use pack will be tested in two countries.

EDUCATION AND TRAINING FOR HEALTH WORKERS: SUCCESSES FROM REPRODUCTIVE HEALTH

The reproductive health community has faced similar barriers regarding the lack of information, training, and skills among health providers. For example, key challenges to more widespread use of emergency contraceptive pills (ECPs) include

lack of knowledge and negative attitudes among health providers. These knowledge gaps affect provider comfort and ability to counsel potential ECP clients. Research studies highlight strong biases among health providers concerning the administration of ECPs to certain populations. As the examples below illustrate, training and support to health providers on ECPs can lead to increased acceptability and use.

INDIA: Training on ECPs Address Knowledge Gaps

Health providers' knowledge, attitudes, and dispensing practices were assessed at government dispensaries in South Delhi before and after training. At baseline, only 32% of providers knew the correct prescribing dose; 49% knew the correct timing of administration. Health providers' misconceptions and apprehensions were identified as key barriers in women's use of ECPs. Training resulted in significant improvement in providers' knowledge, attitudes, and dispensing practice. In addition, behavior change communication strategies formed an effective part of training curricula and influenced changes in clinical practice.

KENYA: Mainstreaming Emergency Contraception (EC) through a Multifaceted Approach

A national initiative to mainstream EC in Kenya focused on improving overall awareness of EC (through a media campaign featuring radio spots, informational articles in print media, expert interviews on radio and TV, and EC messages in soap operas) and strengthening the quality of EC services in both the public and private sectors. In the public sector, the Ministry of Health updated the pre-service training curriculum for nurses to include EC; developed provider reference materials (including job aids and reference guides); and strengthened family planning providers' in-service training on EC through contraceptive technology updates. Overall knowledge among providers increased significantly over the life of the initiative, and those trained on EC under the contraceptive technology updates demonstrated more favorable attitudes and practices toward EC.

These examples highlight the effectiveness of a comprehensive, multi-level approach that brings together key stakeholders and supports evidence-based planning. Follow-up support through job incentives, professional development opportunities, and refresher classes can further increase uptake of life-saving medicines across the reproductive, maternal, newborn and child health (RMNCH) continuum.

PRIORITY ACTIONS FOR EDUCATION AND TRAINING OF HEALTH WORKERS

Governments and implementing partners must take action to ensure that health providers can correctly administer high-quality magnesium sulfate at all levels of the health system. Key actions include:

- 1. Develop and update national policy guidelines**, including the national EML, to include magnesium sulfate for PE/E; these guidelines must be supported by clear and practical clinical protocols that reflect evidence-based practices.
- 2. Ensure that national procurement secures a standard formulation** to avoid confusion and the need to prepare complicated dilutions.
- 3. Ensure that health professionals are appropriately trained** in the care of women with PE/E, which includes use of magnesium sulfate. Training should complement other approaches that build the skills and knowledge of health providers, such as behavior change communication, peer-to-peer training, and coaching. This can include suitable job aids and posters on how to effectively manage PE/E.

FOR MORE INFORMATION: KEY RESOURCES

Magnesium Sulfate: Product Brief (RHSC, 2013)

Magnesium Sulfate Product Profile (UNCoLSC, 2012)

Scaling Up Lifesaving Commodities for Women, Children, and Newborns: An Advocacy Toolkit (PATH, 2013)

Medicines for Maternal Health (UNCoLSC, 2012)

WHO Recommendations for Prevention and Treatment of Pre-eclampsia and Eclampsia (WHO, 2011).

Pre-Eclampsia/Eclampsia: Prevention, Detection and Management toolkit (MCHIP, 2011).

National Programs for the Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: A Global Survey, 2012 (MCHIP, 2013)

Barriers to Use of Magnesium Sulfate for Pre-eclampsia and Eclampsia Management in Low- and Middle-Income Countries: A Brief Review of the Literature (UNCoLSC, 2013)

¹ The fear of toxicity is a result of past medical training. Health providers may not be aware that calcium gluconate—a mineral supplement—is an antidote that can be used in the rare event of magnesium toxicity.

SUPPLY OF ESSENTIAL MEDICINES



Evelyn Hockstein

INTRODUCTION

Improving access to high-quality maternal health medicines means ensuring they are available where and when women, families, and communities need them. This requires a well-designed, operated, and maintained supply chain that can reliably provide an adequate supply of essential health commodities. A well-functioning public health supply chain provides the following core functions:

1. Regulation: Regulation includes registration, quality control, and quality assurance measures within the public and private sectors, and is considered to be the “market gateway” for manufacturers. Effective regulation is critical for ensuring that:

- ▶ Medicines on the market are safe, are effective, and consistently meet approved quality standards.
- ▶ Medicines are appropriately manufactured, stored, distributed, and dispensed.

2. Quantification (forecasting and supply planning): Forecasting is the process of estimating the expected consumption of commodities based on historical consumption, service statistics, morbidity, and/or demographic data, or on assumptions when data are unavailable. Supply planning involves estimating the quantities and costs of the products required for a specific health program, and determining when the products should be delivered to ensure an uninterrupted supply.

3. Procurement: Procurement includes the identification and purchasing of sufficient quantities of quality-assured and effective products, procured at the lowest possible prices and in accordance with national and international laws. Many countries use their

essential medicine list as the basis for procurement.

4. Distribution: Distribution includes storage, inventory management, transport, and reordering. These functions are important in getting health commodities to service delivery points and ultimately to consumers. Storage involves keeping medicines in good condition throughout the supply chain. Inventory management allows supply chain managers to manage their stock effectively—knowing how much stock to hold, when to order, and how much to order. An integrated logistics management information system (LMIS) supports effective distribution by providing timely and accurate data on how much stock is needed.

Reliable and regular access to medicines also depends on national-level factors such as supportive policies, adequate financing (see brief on Policy and Financing), and strong service delivery. In an ideal environment, a well-functioning health supply chain is supported by health professionals who can effectively forecast requirements, procure quality products on time, manage inventory, monitor supplies, maintain storage facilities, and distribute products securely.

THE CHALLENGE

In many countries, weaknesses in the public health supply chain limit the availability of quality maternal health medicines. Key barriers across the main supply chain functions include:

- ▶ **Weak regulatory policies and procedures** that can result in the availability of poor-quality medicines in the local marketplace. National regulatory authorities may not have the capacity to inspect pharmaceutical companies for compliance with national guidelines or to conduct regular and consistent quality monitoring.
- ▶ **Lack of accurate quantification and forecasting data.** For maternal health, there is often limited reliable data available on PPH and PE/E. This makes it difficult to accurately estimate demand for procurement purposes and to identify gaps in coverage. In many countries, this is further complicated by the lack of training and skills of health professionals to accurately forecast and manage inventory, and the lack of dedicated supply chain professionals who can carry out these tasks.
- ▶ **Weak or nonexistent logistics management information systems** that cannot reliably ensure that quality maternal health medicines reach the end user. In many countries, tracking and analysis of maternal health medicines is not included in existing national LMIS.
- ▶ **Weak infrastructure and supply chains at the “last mile”** that make distribution to households and peripheral health facilities difficult. With maternal health medicines, community-based distribution is an important strategy for reaching women in remote and hard-to-reach areas. In addition, existing vaccine cold chains are not designed to accommodate oxytocin (see brief on [Oxytocin](#)).
- ▶ **Lack of procurement of maternal health medicines.** Not only are essential maternal health medicines not procured in sufficient quantities, but they are often not procured at all. For example, misoprostol is not included in some countries’ national essential medicine lists, and it is not procured either due to insufficient funding and budget support, or because it is considered

not critical or appropriate for the health needs of the population (see brief on [Policy and Financing](#)).

THE STRATEGY: STRENGTHENING THE SUPPLY CHAIN

This brief identifies key strategies and tools for addressing these challenges and strengthening the public health supply chain, along with examples of case studies from around the world. It also provides important lessons and strategies from programs to improve and strengthen the reproductive health supply chain.

- ▶ **Improving the availability and quality of local and national forecast data.** For many countries, it is essential to obtain accurate data to assess a country’s theoretical need for essential medicines and compare this with actual procurement data. A tool, *Estimation of Medical Unmet Need for Essential Maternal Health Medicines: Addressing the Gaps between Forecasting and Procurement*, provides countries with the ability to develop more accurate quantification and forecasting information. The tool was pilot-tested in two countries (**Democratic Republic of the Congo** and **Bangladesh**) and provided an opportunity for government officials and other partners to review and discuss how to increase access to essential maternal health medicines through better and more reliable data and information.
- ▶ **Enhancing local capacity for supply chain management.** In many countries, health professionals lack proper training and capacity to carry out essential supply chain functions. Some countries do not have dedicated supply chain professionals, and healthcare workers, already overburdened and in short supply, are performing key logistics tasks.

Supply chain capacity-building activities can include training initiatives (including pre-service training), supervision, and mentoring. These training efforts can be complemented with the development of job aids (reference guides, procedures manuals, etc.) to reinforce what was learned in training.

To ensure that maternal health medicines reach the “last mile,” community health workers’ capacity in supply chain management should also be addressed since they are often the ones providing care to women during childbirth.

► **Including maternal health medicines in the logistics information system.** In **Nepal**, the government began integrating all logistics activities of the Ministry of Health into a single entity. Key to integration was a new LMIS that integrated all health commodities, including maternal health, into a program that enables program managers to track health commodities without having to manage day-to-day storage, transport, and deliveries. Nepal has since witnessed significant improvements, including an increase in vaccination coverage of 300% from 1993 to 2005; improved reliable availability of health commodities and supplies; and improved quality of health services, particularly among underserved populations.

IMPROVING SUPPLY: SUCCESSES FROM REPRODUCTIVE HEALTH

Experience from reproductive health shows that integrating and strengthening supply chain and logistics functions, including forecasting, procurement, storage, and distribution, have helped to ensure contraceptive product availability and improved contraceptive use. Analysis from 11 countries indicates that countries with well-functioning public-sector logistics systems have higher product availability and higher use of modern contraceptives. Key strategies include:

1. Integration of supply chains. Over the past two decades, there has been increasing integration of reproductive health supplies into a single logistics system for all essential medicines.

The following examples highlight how countries have integrated their supply chains:

NICARAGUA’S supply chain was vertical until 2005, when the ministry of health integrated the essential medicines system with contraceptives’ supply chain. A pilot test of the new integrated system led to positive and promising results, although during the transition, stockouts occurred. Gradually, additional products were



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added to the integrated system, which is automated to include all essential medicines.

ETHIOPIA: To address inadequate supply of essential medicines and weak stock management, the Ethiopian government (with the support of in-country partners) launched an integrated supply chain that includes all health program commodities and connects all levels of the supply chain with accurate and timely data for decision-making. A standard training curriculum was developed and implemented to prepare health facilities for implementation of the new integrated logistics system. Additional improvements included a computerized inventory management system at health facilities, and an integrated information management system that manages supply orders and stock-level information from various programs.

2. Public-private partnerships. The private and public sectors can collaborate effectively to address bottlenecks in the supply chain and improve access to high-quality supplies through innovative partnerships. In **Tanzania**, a public-private partnership with The Coca Cola Company (TCCC) helped Tanzania's government-run medicine distribution network increase the availability of supplies across the country. Prior efforts with TCCC had largely centered on transporting products such as condoms and bed nets on the back of Coca-Cola trucks. This innovative initiative shifted the relationship from this short-term solution and focused on the transfer of the company's core business expertise to improve the capacity of the country to distribute pharmaceuticals and medical supplies in Tanzania.

3. Contraceptive security committees. Many countries have established commodity security committees to bring together multiple supply chain stakeholders to support enhanced coordination, address long-term product availability issues, and reduce duplication and inefficiencies. In several countries in **Latin America and the Caribbean**, including Bolivia, the Dominican Republic, El Salvador, Honduras, Nicaragua, and Paraguay, these committees played a key role in making progress toward contraceptive security, including advocating for increased financial support for contraceptives, improving inventory management, developing standard operating procedures, publishing reports, and providing technical assistance.

4. Supply chain tools. The reproductive health community has developed a number of tools that have helped countries make significant improvements in forecasting, procurement, and other supply chain functions. These tools and resources can be used by country managers and implementers working to improve the supply of maternal health medicines:

► **AccessRH: Online Procurement and Information Service for Reproductive Health Supplies**

AccessRH is a reproductive supplies procurement and information platform that allows national governments, nongovernmental organizations

(NGOs), and others to order multiple products from a variety of manufacturers at prices negotiated upfront by UNFPA for delivery around the world. Those that purchase health products for the public sector can benefit from the volume pricing and quality assurance that comes with UNFPA-prequalified manufacturers. Misoprostol, oxytocin, and magnesium sulfate are included in AccessRH, in the pharmaceuticals section.

AccessRH includes [RHInterchange](#), which provides up-to-date online information on contraceptive shipments for more than 140 countries worldwide, and [Access Supplies](#), which provides tools, documents, and instructions for ordering reproductive health products (i.e., the AccessRH Catalog).



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► **Strategic Pathway to Reproductive Health Commodity Security (SPARHCS): Guiding Commodity Security at the Country Level** SPARHCS provides a framework, diagnostic guide, and process to help countries identify and prioritize key commodities security issues; to assess current capacity for commodity security among country or regional programs, systems, and policies; and to help shape subsequent commodity security strategic plans. It is being adapted for maternal health.

► **Supplies Information Database (SID): A Global Resource on Reproductive Health Commodities**

SID is an online reference library with more than 6,000 records on the status of reproductive health supplies at the country level, including studies, assessments, and other publications, providing access to the latest supply information on more than 230 countries and territories worldwide. This resource has been expanded to include maternal health.

PRIORITY ACTIONS FOR STRENGTHENING THE SUPPLY CHAIN

Governments and implementing partners must take action to ensure that high-quality maternal health medicines reach women and communities at the right time, at the right place, and in the correct quantities. Key actions include:

- 1. Quantify the unmet need for maternal health medicines** so manufacturers can adequately scale up to meet that need and so national procurement agencies can accurately forecast and procure the medicines they need.
- 2. Improve national regulatory capacity** to ensure that only quality medicines are available in the market.
- 3. Improve knowledge and skills of health providers** and supply chain managers to effectively forecast, procure quality products on time, manage inventory, monitor supplies, maintain storage facilities, and distribute products securely.
- 4. Include data tracking and analysis of maternal health medicines** in existing national logistics management information systems.
- 5. Establish or expand a commodities security committee or similar entity** at the national level to coordinate budgets, procurement, distribution/stockouts, and logistics for maternal health medicines.

FOR MORE INFORMATION: KEY RESOURCES

The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities (JSI, 2011)

Inventory of Tools for Maternal Health Supplies: Improving Quantification and Forecasting (UNCoLSC, 2013)

Private Sector Engagement: A Guidance Document for Supply Chains in the Modern Context: Lessons from the Commercial Sector (UNCoLSC, 2013)

Getting Products to People: Supply Chain Integration. Also available is an infographic on supply chain evolution, with guidance on how to adapt a commercial-sector maturity model to build an integrated supply chain (JSI, 2012)

Promising Practices in Supply Chain Management (MSH/USAID, 2014)

Challenges and Barriers Along the In-Country Supply Chain (UNCoLSC, 2014)

POLICY AND FINANCING



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INTRODUCTION

Oxytocin, misoprostol, and magnesium sulfate are low-cost and effective medicines that can save women's lives. Supportive policies, appropriately funded and effectively implemented, are vital to ensuring access to these medicines in health facilities and communities around the world.

POLICIES

A country's policies reflect its commitment to ensuring a consistent and regular supply of maternal health medicines; a national policy framework determines what medicines can be used in the country, how they should be used, by whom, and at which level of health facility. Policies also serve as the basis for education and training for health professionals.

A favorable policy environment meets the following criteria:

- ▶ All three maternal health medicines are included on national essential medicine lists (EMLs); PPH and PE/E are prioritized in national strategies and roadmaps.
- ▶ Evidence-based national standard treatment guidelines (STGs) are updated and guide clinical practice.
- ▶ Policies are fully and effectively implemented, and adequate budgetary support is available.

National policies are largely informed by recommendations of WHO—that is, [WHO's Model List of Essential Medicines](#) (the WHO EML) and global clinical guidelines on [PE/E](#) and on [PPH](#)—and then tailored to local public health needs. All three maternal health medicines appear on the WHO EML for PPH or PE/E; however, misoprostol is listed only for PPH prevention and not for PPH treatment.

FINANCING

Maternal health medicines can be funded by donors, by international or local organizations, or by public-sector health budgets. In most low- and middle-income countries, they are funded solely through the public sector, as there is limited external donor funding for maternal health medicines (in contrast to reproductive health supplies such as contraceptives and condoms). Maternal health medicines are typically included in general essential medicine budget lines and aggregated with other medicines, making it difficult to track actual allocations and spending. As countries move toward financing universal health coverage for their citizens, many have begun to prioritize inclusion of these essential maternal health medicines.

In addition to donor and public-sector support, the private sector is an important provider of maternal health care in many low- and middle-income countries. Misoprostol and oxytocin are available for purchase in the private market at pharmacies and medicine shops. The private sector often supplements the supplies available at public-sector facilities, and women and their families must purchase necessary medications from local pharmacies. At private-sector facilities, financing of maternal health commodities is usually supported by user fees.

THE CHALLENGE

Although many countries have prioritized these medicines in their national policies, a number of **key policy and financing barriers** limit access and use. For example:

► **Essential medicines are not always included in national EMLs or other key policy documents.** EMLs often dictate what medicines are procured for use in the public health sector. In some countries, misoprostol is not included in the EML for the PPH indication.

► **Policies are not always evidence-based or updated to reflect best practice.** National clinical guidelines, training curricula, and service delivery policies are often slow to reflect the latest research, hampering efforts to provide the most effective evidence-based health care—for example, they do not prioritize misoprostol use for PPH; they include recommendations for other, less effective medications for PE/E (diazepam or phenytoin); or they do not permit task-shifting administration of medicines to lower-level health workers. In addition, even though evidence-based practices are incorporated in national policies and guidelines, they are not consistently in use by health providers (see brief on [Magnesium Sulfate](#)).

► **Lack of funding for maternal health commodities** in public-sector health budgets creates a disconnect between policy and practice. Budgets are driven by country priorities and affected by limitations in national funding mechanisms. The funds allocated for procurement of these medicines are often insufficient to meet demand, or national decision makers do not prioritize these essential medicines for procurement due to under-funding.

This brief highlights **examples of how country stakeholders have successfully addressed these challenges through advocating for supportive policies and their effective implementation.** The brief also showcases key examples, strategies, and lessons learned from reproductive health in supporting efforts to change policies and support their effective implementation.

THE STRATEGY: EVIDENCE-BASED ADVOCACY FOR POLICY CHANGE

The policy environment for enabling access to and use of essential maternal health medicines is complex and variable. While there is no single strategy for establishing a supportive policy environment across countries, learning from experiences in different contexts can inform effective action. Some examples of advocacy interventions that have been successful in influencing policy change are:

► **Revising the EML to include misoprostol for PPH.** In **Burkina Faso**, a group of stakeholders advocated for the inclusion of misoprostol for PPH on the EML as an urgent national priority. A small advisory committee engaged with national authorities to review evidence, and gained



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support from high-level officials. In February 2014, Burkina Faso revised its national EML to include misoprostol for both the prevention and treatment of PPH. Other countries, including **Sierra Leone** and the **Democratic Republic of the Congo**, have also updated their EMLs to include misoprostol, a result of concerted efforts by the UNCoLSC and other partners.

► **Ensuring guidelines and clinical protocols are evidence-based and reflect the latest research.** **Nigeria** updated its guidelines

in 2010 to support community-based distribution of misoprostol for PPH prevention (see brief on [Misoprostol](#)). Operations research conducted in northern Nigeria provided evidence on the safety and effectiveness of community-based distribution of misoprostol. The research was shared with key government representatives at a dissemination workshop, and subsequently the Federal Ministry of Health supported the revision of facility-based guidelines to permit use by community health workers and self-administration by mothers. This culminated in [nationally approved guidelines](#) for the use of misoprostol at the community level.

► **[Disseminating guidelines to inform clinical practice](#)**. In 2007, **Nepal** updated the National Standard for Reproductive Health to list magnesium sulfate as the medicine of choice for treatment of PE/E; in 2008, the medicine was added to the national EML. To support the uptake of magnesium sulfate in health facilities, the Nepal Society of Obstetricians and Gynaecologists (NESOG) disseminated national guidelines on PE/E management through workshops and job aids. The NESOG members provided ongoing technical assistance and support in selected health facilities to enable health providers to correctly administer the medicine.

EVIDENCE-BASED POLICY CHANGE: SUCCESSES FROM REPRODUCTIVE HEALTH

The reproductive health community has confronted similar policy and budgetary barriers in scaling up access to reproductive health commodities and can provide a rich variety of experiences to draw from, including:

[LATIN AMERICA AND THE CARIBBEAN:](#)

Strategic Convenings Influencing Policy

In Latin America and the Caribbean, expert meetings, symposia, and workshops had a significant impact on policy changes relating to emergency contraception (EC). For example, in 1998, the first Latin American regional meeting on EC took place, and as a direct outcome, EC was included in the family planning guidelines of

Ecuador, El Salvador, Honduras, and Venezuela. A second international conference in 2002 spurred another round of positive policy changes that helped to further expand access to EC.

[UGANDA: Bringing Injectable Contraceptives to the Community](#)

A consortium of reproductive health institutions collaborated on a series of advocacy activities (one-on-one meetings, advocacy materials) urging the Ugandan Ministry of Health to amend the National Policy Guidelines and Service Standards for Sexual and Reproductive Health (SRH) to allow community health workers to provide injectable contraceptives. Subsequently, an addendum to the SRH guidelines was approved. The Ugandan government launched the new guidelines in March 2011, thereby officially allowing community-based distribution of injectable contraceptives by village health teams.

[INDONESIA: Making the Case for Contraceptive Commodities](#)

A District Working Group comprising local government officials, family planning champions, health professional associations, and non-governmental organizations was established to collect and synthesize the evidence on budget allocations to family planning in five districts. In each district, the working group presented the data to the district legislature and mayor; and identified which family planning initiatives to prioritize, and how much to budget in order for family planning to be cost-effective. From 2010 to 2013, mayors in all five districts increased their budgets for family planning between 20 and nearly 80 percent, in response to evidence showing the returns on their investment.

[MEXICO: Evidence-Based Budget Advocacy](#)

Civil society organizations in Mexico identified the two main obstacles to meeting the contraceptive needs of sexually active young people as the lack of government budgetary allocations and poor transparency regarding the national budget. They engaged in key budgetary debates using evidence-based advocacy, which resulted in a US\$8 million increase to the national allocation in 2010 alone.

TANZANIA: Increasing Funds for Family Planning Supplies

Following the advocacy efforts of a group of civil society partners that targeted its Ministries of Health and Finance, parliamentarians, and the media, the government of Tanzania decided to increase funding for family planning supplies from US\$2.65 million to US\$7.26 million for 2009–10. This action was seen as a major breakthrough in reproductive health supplies security in the country, as the investment was in line with the recommended minimum amount needed for procurement of contraceptives for that fiscal year.

These country examples illustrate the important role of advocacy in improving the policy and funding environment for essential medicines and supplies. Key elements of successful advocacy included:

- ▶ **Collecting the evidence:** identifying national or sub-national expenditures on family planning supplies;
- ▶ **Making the case:** developing and sharing messages on the role of family planning in achieving a country's development goals; and
- ▶ **Securing a broad base of support:** collaborating with a wide range of stakeholders, including health professional associations, civil society organizations, and the media.

PRIORITY ACTIONS FOR SUPPORTIVE POLICIES AND ADEQUATE FINANCING

Governments and implementing partners must take action to ensure that supportive policies and adequate financing are in place. Key actions include:

- 1. Identify national (and district-level) expenditures** for maternal health medicines so that any gaps between necessary and actual funding levels can be determined and filled.
- 2. Enact policies and standard treatment guidelines that are evidence-based** and promote improved maternal health through access to key commodities.

3. Ensure that national essential medicine lists identify oxytocin, magnesium sulfate, and misoprostol as essential medicines for maternal health.

4. Engage professional medical associations to revise clinical guidelines to include new best practices.

5. Update and revise policies to permit lower cadres of health workers to administer maternal health medicines where appropriate.

FOR MORE INFORMATION: KEY RESOURCES

Advocacy, Approval, Access: Misoprostol for Postpartum Hemorrhage: A Guide for Effective Advocacy (FCI, 2014)

Maternal Health Advocacy Messages: A Roadmap for Success (PATH, 2012)

Postpartum Hemorrhage: Prevention and Management Toolkit, Maternal and Child Health Integrated Program (The Knowledge for Health (K4Health) Project, 2011; updated 2013)

Safeguarding Pregnant Women with Essential Medicines: A Global Agenda to Improve Quality and Access (PATH, 2012)

Scaling Up Lifesaving Commodities for Women, Children, and Newborns: An Advocacy Toolkit (PATH, 2013)

From Advocacy to Access: Targeted Political Action for Change (IPPF, 2011)

Leading Voices in Securing Reproductive Health Supplies: An Advocacy Guide and Toolkit (RHSC, 2007)

GENERATING DEMAND



INTRODUCTION

Demand generation aims to increase awareness and use of health products or services among a particular audience through social and behavior change communication and social marketing techniques. For the three essential maternal health medicines (oxytocin, misoprostol, and magnesium sulfate), demand must be generated by individuals and communities and within the health sector.

Oxytocin and magnesium sulfate are used primarily by health providers (based at health facilities or at the community level); misoprostol can be administered either by women themselves or by health providers (see brief on Misoprostol). In order to increase demand for and use of these essential maternal health medicines, demand generation strategies can focus on two levels:

- ▶ Ensuring that **health providers** have updated, evidence-based information on effectiveness, safety, and side effects, and can correctly

administer these essential medicines. Health providers need to have accurate knowledge and skills, confidence in use of these medicines, and continuing education and peer/professional support to maintain their skills.

- ▶ Ensuring that **individuals, families, and communities** are informed of the causes, symptoms, and available services for maternal health, and exercise their right to access quality health care, including essential medicines. In a number of countries, demand generation efforts have shared information and

Demand generation can increase knowledge, change behavior, and improve attitudes among individuals and communities through the following key strategies and approaches:

- ▶ **Community mobilization and engagement** builds the capacity of individuals, groups, or organizations to design, conduct, and evaluate activities on a participatory and sustained basis. Through community mobilization, communities identify their own problems and devise their own solutions. Community engagement is important for ensuring the quality, availability, and utilization of health care. When communities are engaged and empowered, they are able to more effectively influence and shape healthcare programs so that they are locally responsive, of high quality, and acceptable to the people they serve.
- ▶ **Information and communication technologies (ICTs)** are electronic and digital technologies (such as mobile and smartphones, Short Message Service [SMS], and social media) that support communication and exchange of information.
- ▶ **Interpersonal communication (IPC)** is one-to-one communication (e.g., peer-to-peer, provider-client, or teacher-student)
- ▶ **Mass and traditional media** employs range of channels to communicate key messages and influence behavior. Mass media includes radio, television, and newspapers; and traditional media is usually carried out in community settings and involves drama, puppet shows, music, and dance.

mobilized communities in support of misoprostol's role in PPH through social marketing, traditional media, and other channels.

THE CHALLENGE

A range of social and behavioral barriers impede the use of essential maternal health medicines by health providers and by women, families, and communities. These include:

- ▶ **Lack of updated knowledge among health providers:** Many health providers are not familiar with the latest evidence-based guidelines and do not have adequate training in the management of PPH and/or PE/E.
- ▶ **Health provider bias:** Perceived or actual provider bias can affect the use of health services and products. For example, in the case of misoprostol, health providers can have a poor perception of misoprostol because of its alternative use for inducing medical abortion, which can be highly restricted in some countries (see brief on [Misoprostol](#)). Health providers hold an unwarranted fear of magnesium sulfate's side effects to the woman and her baby (see brief on [Magnesium Sulfate](#)) and thus are reluctant to use the medicine to treat PE/E.
- ▶ **Limited knowledge and understanding:** A lack of knowledge can prevent women and families from seeking routine care during pregnancy and when life-threatening complications occur. Women, families, and communities need information to recognize the symptoms of PE/E and PPH to prompt them to seek care when necessary. Even when women and their families know about the importance of regular checkups and danger signs, they may face financial, social, cultural, and religious barriers to accessing health care and obtaining life-saving commodities.

This brief identifies **key demand generation strategies for addressing these challenges**, supported by examples of case studies from around the world. The brief also provides examples of demand generation strategies for reproductive health commodities, including lessons learned.

THE STRATEGY: GENERATING DEMAND THROUGH PROVIDER TRAINING AND COMMUNITY AWARENESS

The following programs and initiatives provide examples from a range of countries of strategies for building demand for essential maternal health medicines:

ECUADOR: Collaborative Training to Support Oxytocin Use

In Ecuador, a training package on the use of oxytocin as part of the active management of the third stage of labor (AMTSL; see brief on [Oxytocin](#)) within health care settings included high-level advocacy with the ministry of health; development of new clinical guidelines; documentation of lessons and barriers related to AMTSL and oxytocin use; production of supporting communication materials, including posters and other job aids; and the provision of oxytocin. Another critical element was involving health workers in developing and disseminating new clinical guidelines, to help facilitate their adoption in clinical practice. The active participation of health providers in the development of such protocols was an effective way to overcome resistance to change when new guidelines or protocols were being implemented. Use of peer leaders as innovators or early adopters and continued reinforcement and retraining of providers were other strategies to address resistance and provider bias. During the project, the rate of oxytocin administration increased from 29% of women delivering vaginally (in 2003) to 38% (in 2006) and 75% (in 2009).

ZAMBIA: Building Community Awareness and Action on Misoprostol for PPH

In Zambia, an awareness campaign on birth preparedness and misoprostol for PPH prevention in home settings in five rural districts included radio, posters, pamphlets, and counseling sessions with antenatal health providers and community safe motherhood action groups. While antenatal care was the entry point for reaching women with information and with the provision of misoprostol, multiple strategies and channels were utilized to

convey information about misoprostol's role in preventing PPH. Community-level health workers reinforced messages through counseling sessions and disseminated leaflets, posters, and other materials with pictorial depictions on safe delivery and PPH prevention. An evaluation of the project showed that a majority of women (80%) used misoprostol correctly. Acceptability of the medicine was high: 90% of women reported they would use misoprostol after their next delivery; 88% would recommend it to others; and 80% would purchase the drug themselves.

DEMAND GENERATION: SUCCESSES FROM REPRODUCTIVE HEALTH

The following case studies illustrate promising practices in mobilizing demand for reproductive health commodities in a range of countries; these demand generation strategies have focused on health providers and/or on the individual, family, or community level, depending on the specific commodity. Specific strategies for promoting demand for reproductive health commodities are included below; these provide important lessons for supporting health providers' training and building community awareness:

USING ICTS TO SUPPORT EDUCATION AND TRAINING FOR HEALTH PROVIDERS:

ICTs—particularly mobile technologies—have been successful in training and updating the knowledge and practices of health facility staff and community health workers.

SENEGAL: Refresher training through mobile phones

Senegal is piloting an interactive voice response mobile learning platform that delivers training to health workers on their mobile phones with the aim of providing effective, affordable distance learning in a way that bridges urban/rural and literacy divides. Through this pilot, health workers receive a refresher course on managing contraceptive side effects and misconceptions on their mobile phones in the form of 20 audio questions with accompanying explanations. Initial results indicate that this training is feasible

to implement, well-liked by participants, and associated with significant increases in health providers' knowledge.



Richard Lord

MALAWI: Electronic learning for health providers

In Malawi, the ministry of health has established district health learning centers, electronic health information toolkits, and an SMS-based mobile telephone network to support health managers and service providers at the national, district, and community levels to improve family planning/reproductive health services. To centralize and increase information access, District Learning Centers (DLCs) have been established in district hospitals and offer print materials and opportunities for face-to-face training and

networking. An SMS-based mobile telephone network allows community health workers to send text messages between cell phones and other devices. Through the mobile network, the program alerts these health workers to new resources, training opportunities, changes in protocols, and other relevant information. As a result of these efforts, 60% of health workers at the national level and 40% at the district level are accessing information. Seventy-seven percent of community health workers have received telephones and are using SMS to report emergencies, make diagnoses, and communicate with supervisors.

SOCIAL MARKETING: Social marketing programs have successfully provided reproductive health products, including condoms and oral contraceptives, in many countries around the world. Social marketing makes contraceptive products accessible and affordable through private-sector outlets, such as pharmacies and shops, and uses commercial marketing techniques to promote their use and uptake among the target audience.

► **Working to Build Awareness in India**

Implemented in eight Indian states, The *Goli ke Hamjoli* (Friends of the Pill) project did not promote a specific brand, but instead aimed for an overall increase in oral contraceptive sales. Through a partnership with oral contraceptive manufacturers, the program used a combination of advertising, public relations, and outreach with traditional and non-traditional providers (including pharmacists, doctors and traditional practitioners, and beauticians) to reduce misconceptions about oral contraceptives and promote the benefits of this family planning method.

PRIORITY ACTIONS FOR INCREASING DEMAND

Governments and implementing partners must take action to ensure that high-quality maternal health medicines are available and can be used by women and communities at the right time,

in the right place, and in the correct quantities. Key actions for increasing demand for essential maternal health medicines include:

1. Support training and continuous education for health providers at all levels of the health system to ensure they can provide high-quality care to women and their families.

2. Ensure demand creation programs involve women, families, and communities and provide information on the causes and symptoms related to PPH and PE/E.



FOR MORE INFORMATION: KEY RESOURCES

Demand Generation for 13 Life-Saving Commodities: A Synthesis of the Evidence (Health Communication Capacity Collaborative, 2014)

Utilizing ICT in Demand Generation for Reproductive, Maternal, Newborn, and Child Health: Three Case Studies and Recommendations for Future Planning (Health Communication Capacity Collaborative, 2014)

Community Engagement and Reproductive, Maternal, Newborn, and Child Health (African Union, 2013)