
A Commodity Security Framework for Maternal Health

A White Paper Developed for the UN Commission on Life-Saving Commodities for Women and Children, Commodity Security Working Group of the Maternal Health Technical Resource Team

JSI Research & Training Institute, Inc.

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Abstract

This white paper describes the aim and 12 key components of a maternal health commodity security framework. It examines the barriers and facilitating factors of each framework component, as well as the commodity-specific issues for the three key maternal health commodities that the UN Commission on Life-Saving Commodities for Women and Children has identified: (1) oxytocin, (2) misoprostol, and (3) magnesium sulfate. The white paper also identifies and discusses emerging themes resulting from a literature search; reviews available data for those three commodities; and suggests next steps, including validating components of the framework, refining the framework, and identifying additional issues that emerge from dominant themes.



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Acronyms

ANC	antenatal care
BCC	behavior change communication
CHAM	Christian Health Association of Malawi
CHW	community health worker
CS	commodity security
CSBA	community-skilled birth attendant
DHS	Demographic and Health Surveys
EML	Essential Medicines List
EWEC	Every Woman Every Child
FBO	faith-based organization
FMOH	Federal Ministry of Health
HACS	HIV/AIDS commodity security
HMIS	health management information system
HSSP	Health Sector Strategic Plan
IEC	information, education, and communication
JSI	John Snow, Inc.
LMIC	low- and middle-income countries
LMIS	logistics management information system
LSC	life-saving commodity
MCHIP	Maternal and Child Health Integrated Program
MDG	Millennium Development Goal
MH	maternal health
MHCS	maternal health commodity security
MHTF	Maternal Health Task Force

MHTRT	Maternal Health Technical Resource Team
MNH	maternal and neonatal health
MOH	Ministry of Health
NGO	nongovernmental organization
PAI	Population Action International
PE	pre-eclampsia
PPH	postpartum hemorrhage
PRE/EMPT	Pre-eclampsia and Eclampsia Monitoring, Prevention and Treatment
RHCS	reproductive health commodity security
RHS	Reproductive Health Surveys
RMNCH	reproductive, maternal, neonatal, and child health
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SPARHCS	Strategic Pathway to Reproductive Health Commodity Security
STI	sexually transmitted infection
TRT	Technical Resource Team
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCoLSC	UN Commission on Life-Saving Commodities for Women and Children
UNFPA	United Nations Population Fund
UNICEF	United Nations Children’s Fund
USAID	United States Agency for International Development
VEN	vital, essential, necessary
WHO	World Health Organization

Executive Summary

Every minute, at least one woman around the world dies from complications related to pregnancy or childbirth¹; 99 percent of these complications and deaths occur in low- and middle-income countries.² As part of the Every Woman Every Child movement, the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) has identified 13 overlooked life-saving commodities that, if more widely accessed and properly used, could save the lives of more than 16 million women and children by 2015. Three of the thirteen commodities that the UNCoLSC identified as essential commodities are used to manage the leading causes of death during pregnancy or childbirth: oxytocin and misoprostol to prevent and treat postpartum hemorrhage (PPH) and magnesium sulfate to prevent and treat eclampsia. Together, these conditions account for more than half of all maternal deaths globally. By increasing the availability of these three key medicines, maternal mortality from PPH or eclampsia could be reduced by 1.4 million over 10 years. Despite evidence supporting the widespread use of these medicines, a number of barriers affect availability, accessibility, affordability, quality, and use.

Commodity security is broadly defined as the ability to choose, obtain, and use health commodities when and where they are needed. It is a concept that has proven successful in identifying the gaps in access to groups of commodities and in developing strategic plans to address them. Policymakers and implementers need a similar category-specific commodity security focus on maternal health (MH) commodities, so they can better understand, evaluate, and design solutions based on the unique characteristics of the commodities. This white paper proposes a framework for maternal health commodity security (MHCS) based on an integrated health system strengthening approach to improving availability, accessibility, and affordability of essential MH medicines.

Countries can use this MHCS framework to identify weaknesses or gaps at various levels and functions of the health system and develop strategies to address them. Using the framework, countries can identify specific components of their health system to strengthen, such as the organization, service delivery capacity, infrastructure, staffing, and resources that support equitable access to and rational use of key MH medicines. Once applied, countries can use the MHCS framework to monitor their progress toward attaining MH commodity security and to adapt or adopt the necessary changes for improvement.

The objectives of this white paper are to—

- describe the aim and 12 key components of the MHCS framework
- review the barriers and facilitating factors of each MHCS framework component
- examine the commodity-specific issues for the three key MH commodities
- identify and discuss recommendations that emerge from the dominant themes.

¹ <http://www.unicef.org/newsline/02pr07iwd.htm>

² <http://www.who.int/mediacentre/factsheets/fs348/en/>

The MHCS framework proposed in this paper is based on the assumption that health system strengthening is the means through which MHCS is achieved and improved MH is the outcome of system improvements that specifically address MH supplies. The proposed MHCS framework's components parallel health systems' organization, which is grouped by components at the (1) macro, (2) meso (intermediate), and (3) micro levels. At the macro level, the framework refers to the overarching architecture of the health system and its high-level stakeholders and decisionmakers. It includes elements such as policies and regulations, coordination, financing, and advocacy and leadership. Stakeholders at the macro level make decisions about the health system that inform the design, financing, and rights of beneficiaries of the system. Decisions made at the macro level result in programs created at the meso level. Organizational effectiveness and managerial decisions that influence service delivery, human resources, health supplies, supply chain, quality assurance, and monitoring and evaluation shape the programs. The micro level focuses on the way individuals—such as patients and providers—and families behave, communicate, and make day-to-day decisions. This level also includes population awareness.

The suggested next phase for development of the MHCS framework includes pilot testing it in select countries to validate its components and identify issues that emerge from dominant themes. The framework can then be refined, as necessary. Refinements may include the addition or deletion of components and organization of components or the issues identified for addressing barriers, challenges, successes and opportunities.

Background on UN Commission on Life-Saving Commodities for Women and Children

Every minute, at least one woman around the world dies from complications related to pregnancy or childbirth³; 99 percent of these complications and deaths occur in low- and middle-income countries (LMICs).⁴ Inaccessible, unaffordable, and poor quality care are the key underlying reasons for the high burden of maternal morbidity and mortality in LMICs. As part of the Every Woman Every Child movement, the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) has identified 13 overlooked life-saving commodities (LSCs) (figure1) that, if more widely accessed and properly used, could save the lives of more than 16 million women and children by 2015. They could also make a significant impact toward the achievement of the Millennium Development Goals (MDGs).

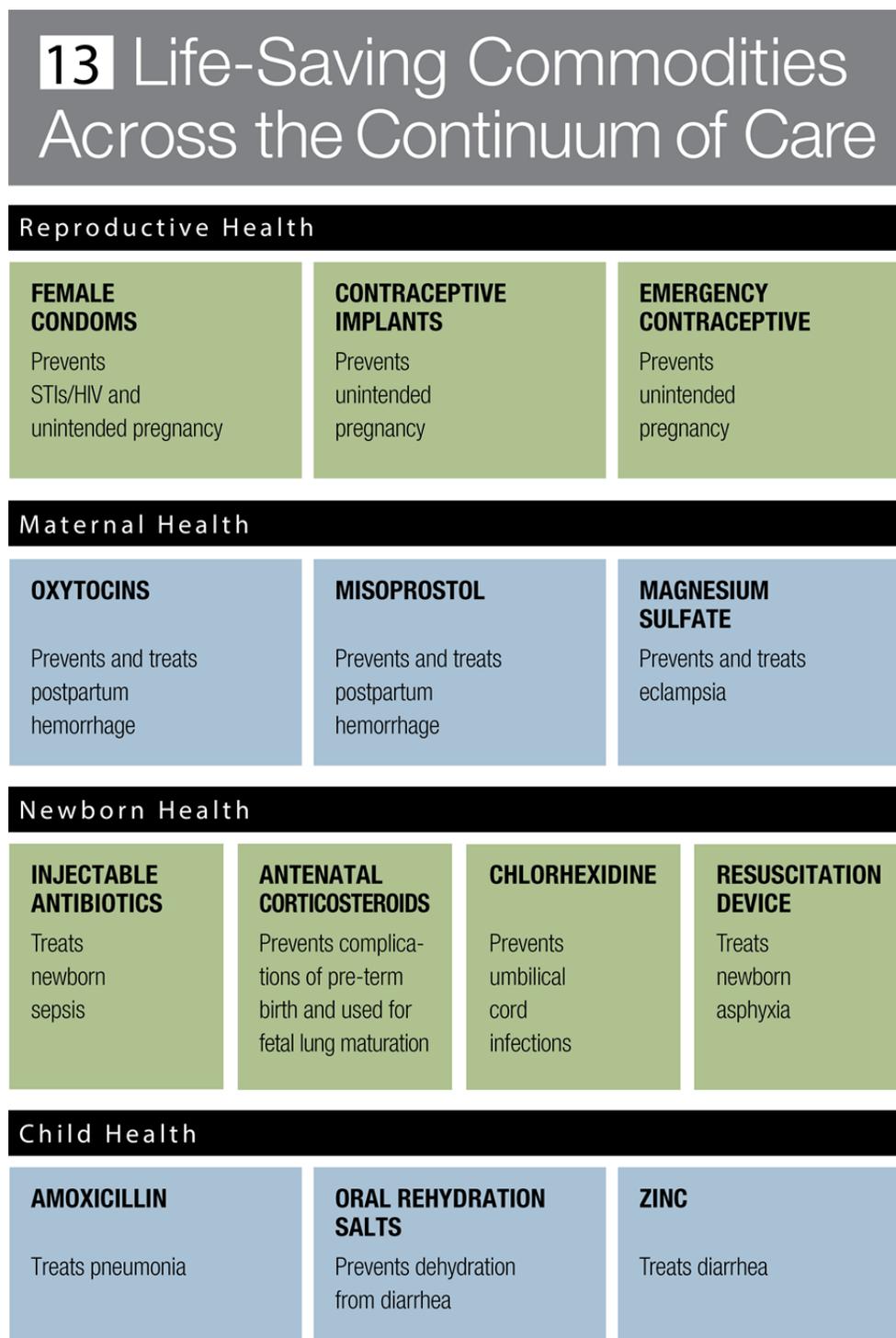
These life-saving medicines and health supplies fall along the reproductive, maternal, neonatal, and child health (RMNCH) continuum of care. They were selected based on three criteria:

- I. The diseases or conditions they address contribute substantially to the global burden of disease. Evidence also exists of their high impact and efficiency in reducing morbidity and mortality across the RMNCH continuum of care.
- II. Global funding for RMNCH commodities has not been adequate, although reportedly national funding has been improving.
- III. The commodities demonstrated untapped potential and opportunity for innovation and rapid scale-up in product development and market shaping.

³ <http://www.unicef.org/newsline/02pr07iwd.htm>

⁴ <http://www.who.int/mediacentre/factsheets/fs348/en/>

Figure 1. 13 Life-Saving Commodities



Source: Adapted from Supply and Awareness Technical Resource Team, UN Commission on Life-Saving Commodities for Women and Children. 2014. *Scaling Up Lifesaving Commodities for Women, Children, and Newborns*.

The UNCoLSC comprises nine expert groups⁵ known as technical resource teams (TRTs), one of which is the Maternal Health TRT (MHTRT). The MHTRT focuses on three essential commodities the commission identified as critical to treating the leading causes of death during pregnancy or childbirth: oxytocin and misoprostol to prevent and treat postpartum hemorrhage (PPH) and magnesium sulfate to prevent and treat eclampsia. Together, these conditions account for more than half of all maternal deaths globally. The UNCoLSC is building on the Global Strategy for Women and Children’s Health by working to ensure that these LSCs are available, accessible, affordable, high quality, and appropriately used—particularly in countries with a high burden of disease. While other MH commodities such as Mifepristone were considered, the TRT had to select only 3 to improve health. None of these three commodities address unsafe abortion, a major contributor to maternal deaths.

Despite evidence supporting the widespread use of the three essential medicines identified by the UNCoLSC, a number of barriers affect availability, accessibility, affordability, quality, and use. The UNCoLSC presented its findings in a report (UNCoLSC 2012) to the United Nations (UN) Secretary General in 2012 that highlighted three key interrelated barriers that affect the production, distribution, availability, and demand for commodities (Kade et al. 2013): (1) regulatory challenges, (2) market failures, and (3) supply and demand challenges. To address these barriers, the UNCoLSC defined 10 practical, time-bound, cross-cutting recommendations to strengthen health systems and to impact the supply, demand, and use of these LSCs. UNCoLSC solutions that address these recommendations must be grounded in experience and evidence and be operated nationally and subnationally.

The UNCoLSC’s 10 Recommendations

Improved markets:

1. **Shaping global markets** - By 2013, effective global mechanisms such as pooled procurement and aggregated demand are in place to increase the availability of quality, life-saving commodities at an optimal price and volume.
2. **Shaping local delivery markets** - By 2014, local health providers and private sector actors in all Every Woman Every Child countries are incentivized to increase production, distribution and appropriate promotion of the 13 commodities.
3. **Innovative financing** - By the end of 2013, innovative, results-based financing is in place to rapidly increase access to the 13 commodities by those most in need and foster innovations.
4. **Quality strengthening** - By 2015, at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products.
5. **Regulatory efficiency** - By 2015, all Every Woman Every Child countries have standardized and streamlined their registration requirements and assessment processes for the 13 live-saving commodities, with support *from* stringent regulatory authorities, WHO, and regional collaboration.

⁵ Other TRTs focus on reproductive, maternal, and child health; demand and performance; global markets; quality and regulations; local supply chains and markets; mHealth and ICT; and advocacy. A multiagency Strategy and Coordination Team (SCT) coordinates these groups. The United Nations Children’s Fund (UNICEF) hosts the SCT.

Improved national delivery:

1. **Supply and awareness** - By 2015, all Every Woman Every Child countries have improved the supply of life-saving commodities and built information and communication technology (ICT) best practices for making these improvements.
2. **Demand and utilization** - By 2014, all Every Woman Every Child countries, in conjunction with the private sector and civil society, have developed plans to implement at scale appropriate interventions to increase demand for and utilization of health services and products, particularly among under-served populations.
3. **Reaching women and children** - By 2014, all Every Woman Every Child countries are addressing financial barriers to ensure that the poorest members of society have access to the life-saving commodities.
4. **Performance and accountability** - By the end of 2013, all Every Woman Every Child countries have proven mechanisms such as checklists in place to ensure that healthcare providers are knowledgeable about the latest national guidelines.

Improved integration of private sector and consumer needs:

1. **Product innovation** – By 2014, research and development for improved life-saving commodities have been prioritized, funded, and commenced.

Source: Adapted from *UN Commission on Life-Saving Commodities for Women and Children Commissioners' Report*. September 2012.

Section 1: Introduction to Commodity Security

Commodity security (CS) is broadly defined as the ability to choose, obtain and use affordable, quality health commodities when and where they are needed⁶; this entails access to a regular supply of widely available essential health commodities as a necessary part of primary healthcare services (Hare et al. 2004). Improved health outcomes are predicated on the ability to achieve CS. CS is described in the maternal health commodity security (MHCS) framework as the common elements necessary to increase the availability of and access to medicines.

Category-specific approaches to CS have proven successful in identifying the gaps in access to groups of commodities and, subsequently, to developing strategic plans to address them. A focus on a limited range of medicines enables policymakers and implementers to better understand, evaluate, and design solutions based on the unique characteristics of the commodities (Hare et al. 2004). Examples of this approach include the frameworks for [reproductive health commodity security](#) (RHCS) (Hare et al. 2004) and [HIV/AIDS commodity security](#) (HACS) (Dowling et al. 2006).

RHCS Framework

The RHCS framework places the client at the center and describes the elements involved in securing a regular supply of reproductive health commodities. The framework emphasizes the importance of the context in shaping availability and access to reproductive health commodities—the socioeconomic conditions, political and religious norms, and competing national priorities. It also highlights the important role committed leaders and advocates have in developing and implementing policies for sustainable and adequately financed programs. The RHCS framework takes a multisectoral approach (government, donors, private sector, and consumers) and posits that interagency coordination is required to ensure effective allocation of resources, strategy development, and joint programming (Hare et al. 2004). It emphasizes the need for building human resource capacity to execute a range of functions, including policy development and implementation; commodity quantification, procurement, and distribution; service delivery; and monitoring and evaluation (Hare et al. 2004).

The RHCS framework was translated into the Strategic Pathway to Reproductive Health Commodity Security (SPARHCS) tool to help countries develop and implement strategies to secure essential supplies for family planning and reproductive health programs. SPARHCS can be adapted to meet local needs and resources. It can be used at the national, subnational, or regional levels, and it can focus on contraceptives, contraceptives and condoms (for HIV/STI prevention), or a broader set of reproductive health supplies.⁷ SPARHCS has been used in 50 countries, reflecting various stages of the RHCS experience, donor support, and health sector reform.

⁶ In the context of maternal health, the definition of commodity security only addresses the ability to obtain and use affordable, quality health commodities when and where they are needed.

⁷ http://www.who.int/rhem/didyouknow/rhsc/global_resource/en/

HIV/AIDS Commodity Security Framework

The HACS framework was adapted from the RHCS framework and shares much of the same conceptual underpinning. The ability of customers (patients and service providers) to obtain and use quality commodities is at the center of the HACS framework. It builds on a comprehensive, multiprogrammatic effort to secure a range of HIV and AIDS commodities. The framework emphasizes cross-cutting issues, such as leadership, human resources, financing, and the quality of products and services at all levels (Dowling et al. 2006). Like the RHCS framework, it highlights the need for coordination to bring all these elements together to shape a strategic response to CS for HIV and AIDS programs.

Maternal Health Commodity Security Framework

During the 68th General Assembly of the United Nations, the World Health Organization (WHO); the United Nations Population Fund (UNFPA); the Joint United Nations Programme on HIV/AIDS (UNAIDS); the United Nations Children’s Fund (UNICEF); and the UN Secretary General’s Special Envoy for Financing the Health MDGs and for Malaria, issued a Joint Statement on accelerating efforts to achieve the health MDGs. [The Joint Statement](#) highlighted efforts that increased access to HIV and AIDS and reproductive health commodities. While these efforts included CS frameworks for HIV and AIDS and reproductive health commodities, no framework exists for maternal health (MH). With 2015 fast approaching, the global community is increasing its focus on achieving [MDG 5](#), which calls for a 75 percent reduction in maternal mortality.

Quality MH services are critical for improving maternal and neonatal health (MNH). Health services rely on quality-assured health supplies that are readily available to patients and clinicians at service points. Recent experience with health supplies for other programs—notably immunization, family planning, and infectious diseases, such as HIV and AIDS and malaria—demonstrates that availability of health supplies at health facilities, communities, and other health service access points relies on a range of elements in the health system that need to be addressed and integrated. This principle also applies to life-saving MH supplies.

In March 2014, the USAID Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program published [Estimation of Unmet Medical Need for Essential Maternal Health Medicines](#). The publication presents an approach for national program managers and other key stakeholders to assess a country’s theoretical need for three life-saving MH commodities—oxytocin, misoprostol, and magnesium sulfate—described as “overlooked” (Malik and Yeager 2014). The MHCS framework proposed in this paper complements the SIAPS guidance by providing a model to strengthen availability, accessibility, and affordability using an integrated approach. Because these three MH commodities have unique challenges, a framework that specifically addresses them is warranted.

Purpose

The purpose of this white paper is to introduce a commodity security framework for maternal health. Countries can apply the MHCS framework to identify weaknesses or gaps at various levels and functions of the health system and develop strategies to address them. Countries can use the framework to identify specific components of their health system to improve. These components include the organization and structure, service delivery capacity, infrastructure, staffing, and resources that support equitable access to and rational use of key MH medicines. Once applied, countries can use the MHCS framework to monitor progress toward attaining MHCS and to adapt or adopt the necessary changes for improvement. In recent years, many countries have established CS committees that could play a role in implementation. Guidance and resources for establishing CS committees focused on RMNCH commodities can be found in [Guidance and Resources for Inclusion of Reproductive, Maternal, Newborn, and Child Health Commodities in National Commodity Supply Coordination Committees](#). The UNCoLSC's Supply and Awareness TRT developed and published the document.

Objectives of the White Paper

The objectives of the white paper are to—

- describe the aim and 12 key components of the MHCS framework
- consider the barriers and facilitating factors of each MHCS framework component
- examine the commodity-specific issues for the three key MH commodities
- identify and discuss recommendations that emerge from the dominant themes.

The development of the MHCS framework and the white paper does not endeavor to cover all components of the health system; rather, the authors anticipate the need to continue refining both through a dynamic process, following review by in-country stakeholders.

Section 2: Description of the MHCS Framework

“Women and their health providers can equitably access and rationally use essential, quality, lifesaving, maternal health commodities made available and affordable throughout the continuum of care by inter-sectoral collaboration and integrated service delivery.”⁸

-Maternal Health Technical Resource Team

The MHCS framework centers on the principle that women’s and their healthcare providers’ equitable access to and rational use of quality MH commodities are enabled by intersectoral collaboration and integrated service delivery. Commodities must be accessible, available, and affordable throughout the continuum of care; for the three MH commodities, the continuum of care includes the antepartum, intrapartum, and postpartum periods. The framework supports rational use of the three key MH commodities (as defined by the UNCoLSC), so they are prescribed, dispensed, or sold appropriately and patients use them correctly (WHO 2012a). In many ways, the conceptualization of the MHCS framework is simplified and does not address the many other commodities required for safe motherhood; however, the work of the MHTRT is focused on the three MH commodities identified in this paper. The authors recognize that while these commodities are necessary to improve MH outcomes, they are not sufficient to manage all causes of poor MH and mortality.

The MHCS framework is based on the assumption that health system strengthening is the means through which MHCS is achieved, and that improved MH is the outcome of system improvements that specifically address MH supplies. MHCS may be achieved by focusing on strengthening the health system—the organizations, service delivery capacity, infrastructure, people, and resources that support equitable access to and rational use of key MH medicines.

WHO defines health systems functionality as “all organizations, people and actions whose primary intent is to promote, restore or maintain health” (WHO 2007). These functions are grouped into six categories or “building blocks” that have been incorporated into the structure of the MHCS framework:

- service delivery
- health workforce
- health information systems
- medical products
- vaccines and technologies
- health systems financing and
- leadership and governance.

The MHCS framework’s components parallel health system’s organization, which is grouped by elements at the (1) macro, (2) meso, and (3) micro levels (Goffman 1986). At the macro level, the framework refers to the overarching architecture of the health system and its high-level stakeholders and decisionmakers. It includes elements such as policies and regulations, coordination, financing, and advocacy and leadership. Stakeholders at the macro level make decisions about the health system that

⁸The aim of MHCS as defined by the Commodity Security Working Group of the Maternal Health Technical Resource Team.

inform the design, financing, and rights of beneficiaries of the system. Decisions made at the macro level are transformed into programs created at the meso level. Organizational and managerial decisions that consider service delivery, human resources, health supplies, supply chain strengthening, quality assurance, and monitoring and evaluation shape the programs. The micro level focuses on the way individuals—such as patients and providers—and families behave, communicate, and make day-to-day decisions. This level also includes population awareness.

The MHCS framework shown in figure 2 requires a high degree of collaboration among stakeholders, including national governments, multilateral organizations, nongovernmental organizations (NGOs), faith-based organizations (FBOs), the private sector, and civil society.

Figure 2. MHCS Framework



Components of the MHCS Framework

Macro Level

The “macro” level of the MHCS framework comprises the policy, economic, political, and organizational contexts for MH, including elements of gender equity.

Policies and Regulations

Policies and regulations that directly or indirectly influence and support the public or private sector's role in securing MH medicines are vital to shaping availability, quality, and affordability of MH medicines. Policies and regulations for MH medicines may be formulated using economic, demographic, and epidemiologic data. Supportive policies and regulations are elements of an enabling environment that signal government commitment to the availability of and access to high quality and affordable MH products. Examples include the prominence of MNH supplies in the country's Essential Medicines List (EML), importation and taxation considerations, and financial management policies. National regulatory authorities implement laws and regulations that decide product-specific formulations. Pharmaceutical producers, distributors, and other actors that are active in medicines management set norms. While these actors engage in medicine management, they are complying with these regulations and considering rich and unique contextual and environmental requirements.

Finance

Adequate and sustainable government funding for procurement of MH products is critical as MH commodities are not donor procured. Government funding is necessary to support the public network of facilities and, where applicable, NGOs and private sector facilities. Funding is also necessary to perform other aspects of logistics management and MH programming, such as information, education, and communication (IEC) campaigns; training; and supervision. Sustainable financing must consider individuals' and families' out-of-pocket spending and minimization of financial barriers, especially for the poor.

Financing for life-saving MH products may come from a range of sources, including households, third party payers (e.g., insurers, employers), governments, and donors. The mix of funding sources may include government budget lines drawn from internally-generated revenues, donor grant funds, loan credits, or families' direct payments. Funding support may also come from donors who provide direct financing of MH programs or in-kind donations of MH commodities and supplies.

Advocacy and Leadership

Advocates and leaders raise awareness for MH supplies by actively engaging stakeholders to address gaps in global and national plans, policies, and initiatives to increase the availability and use of MH medicines. Leaders and advocates can provide strategic input to advance the implementation of recommendations for increasing availability and use of the three key MH commodities. A range of partners—civil society, academia, the voice of women's health advocates, media, and other health partners—can be effective advocates by participating in advocacy campaigns and activities. Advocacy efforts must continuously inform policymakers, program managers, and development partners of the gaps and effective solutions to address the gaps. Advocacy efforts provide the information policymakers need to undertake policy directives and to support activities aimed at increasing availability and use of these LSCs.

Coordination

Coordination is necessary across stakeholders, levels, and functions of the health system. Formal and informal coordination mechanisms are necessary to bring stakeholders from different sectors together. They need to come together to facilitate information flow, efficient use of resources, and effective implementation of policies and regulations. The different sectors include international and domestic donor organizations, government agencies, NGOs, social marketing and private providers, and technical agencies. Coordination mechanisms require formalizing processes, roles, responsibilities, and authority to ensure effectiveness of advocacy and monitoring efforts. Other program coordination mechanisms include coordination councils and committees with membership representing a variety of stakeholders, such as government (central, national, regional, and state levels), donors, NGOs, health FBOs, and the private sector. These mechanisms become even more important in environments that involve decentralized financing and decisionmaking. Cooperation between the public and private sectors (including professional organizations and research institutions) via improved coordination mechanisms can help increase availability and access to MH commodities, but each sector's roles and responsibilities must be clearly communicated.

Meso (Intermediate) Level

At the “meso” level, the critical components of MH programming are transformed from policies into programs. This level includes service delivery, human resources, health supplies, supply chain strengthening, quality assurance, and monitoring and evaluation.

Supply Chain Strengthening

Strong supply chains are necessary to increase access to MH medicines and to improve MH outcomes. Supply chain strengthening focuses on streamlining and standardizing processes at all levels and functional areas of the supply chain to address system problems and overcome challenges. Because challenges differ based on the country context and the unique and diverse characteristics of MH medicines, the range of supply chain strengthening activities must always take into consideration these unique requirements. Supply chain strengthening activities can include system assessments, participatory design and implementation of in-country supply chains, development of national and subnational supply chain processes and procedures, capacity building in quantification and warehouse management, among others. Examples of context-specific supply chain needs include—

- better quantification for accurate estimates for the procurement of MH products, which does not occur at the global or national levels
- adequate transportation for punctual distribution of products according to the design of the system
- cold chain for temperature-sensitive oxytocin
- double-aluminum single-dose blisters for misoprostol to protect against humidity and for ease of administration at the time of delivery

- injection supplies to administer oxytocin and magnesium sulfate.

Service Delivery

The delivery of high quality MH services by healthcare providers must be organized around the health needs of women and their communities. This encompasses delivery of health services that uphold the pillars of the [Safe Motherhood Initiative](#) and includes provision of services for health promotion, disease prevention, diagnosis, treatment, and disease management through different levels and sites of care within the health system.⁹ Healthcare providers must be guided by standard guidelines and protocols based on best practices and enabling policies for access and use of MH medicines. Guidelines and protocols must be harmonized and made consistent for different cadres of healthcare providers at the national, subnational, regional, and community levels. An important aspect to bear in mind is the vital role of the market-based sectors (e.g., private and commercial sectors), including private physicians, midwives, and pharmacies—the full range of providers and places where services are provided—in making quality services available.

Health Supplies, Diagnostics, and Devices

Accurate diagnosis of PPH and pre-eclampsia (PE) and eclampsia requires diagnostics to detect abnormal hematocrit, blood pressure, and protein levels in the urine, among other things. Consumable health supplies such as alcohol swabs and gloves are required for the safe, hygienic administration of the three LSCs. Each of the three MH commodities has unique additional health supply requirements. Magnesium sulfate requires intravenous (IV) catheters and tubing for IV administration and syringes and needles for intramuscular administration; oxytocin requires cold chain storage in some countries; home- and community-based administration of misoprostol should be an element of safe delivery, as well as the use of clean delivery kits, which may be distributed with misoprostol. It is important to consider all the sectors—public, private, and commercial—where health supplies, diagnostics, and devices are manufactured, distributed, sold, and purchased. Complementary to understanding the need for and use of these services (and supplies), a health management information system (HMIS) is required to identify where these supplies are being used and where gaps exist.

Human Resources Development

Human resources are an essential component of high-performing health systems that meet the needs of MH clients and service providers. Workers must be provided in sufficient numbers, they must be adequately trained, motivated, and competent in the skills required to fulfill the essential roles required for MH services.

Quality Assurance

The quality, safety, and efficacy of MH medicines are ensured through quality assurance measures, regulatory agencies, pharmaceutical producers, distributors, and other actors involved in medicines

⁹ <http://www.who.int/healthsystems/topics/delivery/en/> The continuum of care includes contraception, pre-conception counseling, antepartum, intrapartum, and postpartum care.

management. For medicines such as oxytocin that requires cold chain to maintain the stability and potency of products, quality assurance measures are especially critical to make sure the integrity of the product has been maintained throughout the supply chain. Drug registration and monitoring of good manufacturing practices are essential to ensure that only quality-assured products reach the marketplace.¹⁰

Monitoring and Evaluation

Regular collection, analysis, and use of programmatic and population data for planning and decisionmaking are cross-cutting themes throughout the framework since monitoring and evaluation must occur at all levels of a health system, including at the macro and micro levels. Monitoring and evaluation provides evidence for determining programmatic adjustments. Indicators and targets should routinely be linked to outputs and outcomes, be specific, and include data sources and plans for analysis. National or subnational research studies, such as Demographic and Health Surveys (DHS), Reproductive Health Surveys (RHS), and behavioral studies, should supplement these measures. An efficient monitoring and evaluation function supports managerial decisionmaking by providing evidence to determine progress and by identifying challenges and opportunities for meeting strategic objectives.

Micro Level

The “micro” level of the MHCS framework focuses on social contexts, women and men as individuals, family and community members, consumers and providers of goods and services, and the population. It focuses on behavior, communication, and decisionmaking processes.

Population Awareness

Increasing acceptability, demand, and use of life-saving products is essential to improving MH outcomes. Awareness-raising campaigns and behavior change communication (BCC) and IEC interventions can influence the decisions health providers, managers, families, and patients make. These types of interventions can inform health-seeking behaviors of individuals and families and help facilitate communication between patients and providers. Interfaces between these levels of the population are susceptible to weakening under various conditions, such as devolution, decentralization, or weak management systems.

Patient, Provider, and Family Behavior, Communication and Decisionmaking

Health-seeking behaviors, communication, and day-to-day decisionmaking processes of individuals and families, as well as provider biases and beliefs, are influenced by the various components of the health system. They are also influenced by cultural considerations—most notably by awareness-raising BCC and IEC interventions, which can also help facilitate communication between patients and providers, as well as family and community members.

¹⁰ WHO pre-qualification guidelines are a resource for ensuring global standards of quality, safety, and efficacy as part of the manufacturing and procurement processes.

Section 3: Preliminary Observations from Field Research and Experience

This section reviews selected barriers, challenges, successes, and opportunities for each MHCS framework component. They were identified through desk-based research and key informant interviews and are limited to those sources.

Methodology

The authors performed a desk review and conducted key informant interviews via telephone or in-person meetings in Burkina Faso, Ethiopia, and Nigeria.

Desk Review

Using the 12 components of the MHCS framework, the authors developed a data extraction form for the desk review that included a checklist and space to enter specific data points; questions to gather information about barriers, challenges, facilitating factors, and opportunities in dichotomous and open-ended formats; and space for elaboration.

Documents for the desk review included—

- materials that UNCoLSC MHTRT and its subgroups created
- peer-reviewed and grey literature listed in Google, POPLINE, and MEDLINE
- policy documents that UNCoLSC prepared for the five pathfinder countries (Ethiopia, Malawi, Sierra Leone, Tanzania, and Uganda) that explored specific barriers and opportunities for MH commodities
- Bangladesh, Ethiopia, India, Nigeria Tanzania, and Uganda case studies that Maternal Health Task Force (MHTF) and PAI prepared.

The desk review examined one of the documents created by the Magnesium Sulfate Subgroup of the MHTRT—*Barriers to Use of Magnesium Sulfate for Pre-eclampsia and Eclampsia Management in Low and Middle Income Countries*. This document reviewed 28 information sources, including seven peer-reviewed papers focusing on country experiences in Cameroon, India, Mexico, Nigeria, Pakistan, and Zambia; websites; reports; PowerPoint presentations; and a survey by the Maternal and Child Health Integrated Program (MCHIP) of 37 national programs for prevention and management of PPH and PE, which a peer-reviewed journal subsequently published (Smith et al. 2014).

Among the peer-reviewed literature were papers from China, India, Kosovo, Madagascar, Nigeria, and Pakistan that addressed at least one of the MH medicines of interest. Twelve papers on oxytocin were included. They represented experience from Ecuador, Egypt, India, Indonesia, Lebanon, Palestine, Tanzania, and Vietnam. We also reviewed three papers on misoprostol for PPH: a multicountry survey of 23 LMICs and studies on country experiences from Ghana and Malawi. Grey literature included briefing documents the MHTRT Oxytocin and Misoprostol subgroups prepared and the comprehensive report from MCHIP's survey. We also reviewed data on oxytocin and misoprostol from MCHIP's *MAISHA*

Quality of Maternal and Newborn Care Study of Mozambique, Tanzania and Yemen. See annex 3 for a complete list of the documents and websites reviewed.

Observations made in this white paper were drawn from the original source documents noted above, but with a view to examine the issues through the CS-specific components of the MHCS framework. Issues and data from various source documents were pulled together in this paper using a CS perspective, with an aim to frame the issues and facilitate readers' access to the information.

Key Informant Interviews

To complement the information obtained from the desk review, the authors conducted key informant interviews with in-country stakeholders in pathfinder countries, where possible. Stakeholders generously provided their time and knowledge of the issues; however, it should be noted that their responses do not necessarily reflect the views of their country governments. The authors developed and used an interview guide for these telephone calls or, where feasible, in-person interviews. The questions in the interview guide sought to gain the interviewees' perspective on the MH commodities situation in their countries by asking questions related to the successes or opportunities and barriers or challenges for each MHCS framework component. Interviews were conducted in Ethiopia, Nigeria, and Burkina Faso.

Limitations

Limitations of this review include the lack of original field work commissioned as part of this activity. Instead, the review relied on secondary analysis of existing data sources. Budgetary limitations prevented in-country field work. This influenced access to and rigor of country-specific information and the ability to test or validate framework components during this phase of the work. The authors hope these limitations can be addressed in Phase II.

Table 1 is a compilation of selected findings from the desk review and key informant interviews. The findings are arranged by level (i.e., micro, meso, and macro), and MHCS framework components are viewed as successes and barriers. The successes can also be viewed as opportunities since if replicated, they may result in expanded availability, accessibility, and affordability. The barriers can also be seen as challenges since if not rectified, they may continue to limit availability, accessibility, and affordability of MH supplies. The findings are detailed in annex 1. Annex 2 is organized by individual product, so that issues that might be specific to one of the three commodities are readily apparent.

Table 1. Key Successes, Opportunities, Barriers, and Challenges to Commodity Security for Maternal Health Supplies

MHCS FRAMEWORK COMPONENT	SUCSESSES AND OPPORTUNITIES	BARRIERS AND CHALLENGES
<i>Macro Level</i>		
Policies and Regulations	<ul style="list-style-type: none"> • Emerging MH policies that support CS (Bangladesh) • Evidence of inclusive participation of stakeholders in multisectoral and participatory policy development (Uganda) • Specific mention of MH supplies in national policy documents, including the National Roadmap Strategic Plan to Accelerate Reduction of Maternal, Newborn and Child Deaths (Tanzania) • High degree of product registration in the countries reviewed 	<ul style="list-style-type: none"> • Weak political commitment • Policy discord between EMLs and national guidelines, WHO standards, and medicines on EMLs • Policies are not specific, measurable, or harmonized. While policies may mention medicine supply, they do not explicitly address supply issues in many countries. • Weak policy implementation • Substantial variation in health policies between national and subnational levels; local-level situation is even more complex in decentralized settings.
Coordination	Evidence of strategic plan for coordination; regulatory documents define the operation, responsibilities, and composition of technical committees relating to reproductive health commodities (Burkina Faso)	<ul style="list-style-type: none"> • Poor public-private coordination and poor coordination between levels of the health system • Fragmentation between the public and private sectors leads to faulty program management decisions based on inaccurate or insufficient data on a country's commodities situation. • Private sector provides about 50 percent of healthcare services, yet strategy development and implementation remain fragmented. (Uganda)

MHCS FRAMEWORK COMPONENT	SUCSESSES AND OPPORTUNITIES	BARRIERS AND CHALLENGES
Finance	<ul style="list-style-type: none"> • Functioning CS committee for other products (e.g., family planning) suggests that it can be an effective mechanism for identifying funding gaps and solutions. • Approaches to financing include user fees through revolving drug funds, voucher schemes, and waiver policies; CS committees can provide implementation oversight to monitor and evaluate their impact and to advocate for scale-up of effective approaches. 	<ul style="list-style-type: none"> • Significant gaps exist in research and data on financing of MH commodities in many countries; it is uncertain whether allocated funds will be disbursed or whether allocation of funds is sufficient for MH commodities in the budgeting process. • Budget lines associated with commodities only include the cost of commodities and shipping and omit supply chain management costs, such as storage, staffing, and monitoring and other service provider training. (Tanzania) • Policies for free supplies in the public sector do not eliminate heavy financial burden on households caused by out-of-pocket spending, as service delivery does not cover many costs associated with delivery and complementary services. (Tanzania)
Advocacy and Leadership	<ul style="list-style-type: none"> • Evidence of civil society agencies and coalitions functioning as agents for advocacy (e.g., Bangladesh’s Postpartum Hemorrhage Task Force) • In Nigeria, the media and civil society are working together on advocacy efforts, and better coordination is expected over the next year. • In Uganda, a number of organizations (e.g., Medicines Transparency Alliance, Securing Uganda’s Right to Essential Medicines, Stop the Stock Outs) have identified essential medicines as a priority to improve health outcomes. However, the extent to which these organizations prioritize MH medicines is not clear since precise data are not available. 	<ul style="list-style-type: none"> • Discrepancy between political rhetoric and annual budget lines and available resources • Data to inform advocacy efforts are inadequate.
<i>Meso Level</i>		
Health Supplies, Diagnostics, and Devices	Information is limited for the health supplies, devices, and diagnostics that are required to support MH commodities. Further research is needed on this topic.	Inconsistent availability of required consumable supplies (e.g., IV tubing and solutions and diagnostic equipment)

MHCS FRAMEWORK COMPONENT	SUCSESSES AND OPPORTUNITIES	BARRIERS AND CHALLENGES
Service Delivery	Improved MH service delivery is attributed to training on and availability of updated clinical guidelines on diagnosis and management of PPH and PE (2010 in Uganda) at higher- and lower-level facilities.	Issues cited in quality of care include poor bedside manner and privacy concerns, which may be factors in inhibiting or delaying women from seeking medical assistance.
Human Resources Development	<ul style="list-style-type: none"> • Task-shifting strategies can be used to rationalize workloads. • Clinical staff shortages can be effectively addressed by implementing CHW or health extension worker programs such as one in Ethiopia where health extension workers perform a range of RMNCH-related activities. • Uganda is experiencing a slow scale-up of effective village health team programs. Sierra Leone is considering performance-based incentives that reward unpaid CHWs by providing a stipend. 	<ul style="list-style-type: none"> • Compromised quality of health services and low staff morale are due to high staff turnover, staff shortages, insufficient training in how to administer MH medicines. • In-service training of public sector providers is notably weak; the lack of training affects the provision of oxytocin, misoprostol, and magnesium sulfate. (Uganda) • Few providers in lower-level facilities are trained in the use of magnesium sulfate or are actively using it. • In Tanzania, while only 50 percent of births occur in facilities, national guidelines dictate that only higher-level health care professionals administer oxytocin and magnesium sulfate. This leaves a significant gap in the other half of births that occur in lower-level facilities or in the home. (Tanzania)
Quality Assurance	Quality assurance improves when its strategies are aligned with plans for supply chain strengthening across all agencies and levels of government. For example, in Burkina Faso, stakeholders at Central Purchasing Generic Essential Drugs (CAMEG); the General Directorate of Pharmacy, Medications and Laboratories (DGPML); and the national public health laboratory are coordinating quality assurance measures.	<ul style="list-style-type: none"> • Insufficient systems to identify counterfeit medicines and to dispose of expired medicines • Commitment to quality assurance is low. • Quality assessment guidelines are not widely disseminated. (Uganda) • Nascent pharmacovigilance programs (Malawi) • Financing challenges for quality assurance measures for products once in the distribution cycle (Burkina Faso) • Many countries lack certified laboratories or have partially certificated laboratories and inconsistent postmarketing surveillance. • Scarce regulation of domestic pharmaceutical industry (Bangladesh)

MHCS FRAMEWORK COMPONENT	SUCSESSES AND OPPORTUNITIES	BARRIERS AND CHALLENGES
Monitoring and Evaluation	<p>Effective implementation of HMIS strategy that reliably collects and analyzes monthly facility- and community-based data to support data-based monitoring of RMNCH program indicators (Uganda)</p>	<ul style="list-style-type: none"> • No globally agreed-upon MH indicators for availability • Multiple standard treatment guidelines (STGs) for the three MH commodities, agreed or recommended by the WHO, but no global indicators to monitor the implementation of STGs for administration • Lack of standardized and well-disseminated data collection tools and poor guidance on how to define the flow of information and reporting cycles
Supply Chain Strengthening	<ul style="list-style-type: none"> • Supply chain effectiveness improves when coordinated system strengthening plans, such as Ethiopia’s Pharmaceutical Logistics Master Plan and Tanzania’s ILS Gateway (an mHealth application providing stock status via SMS), are in place. • Incorporating and coordinating supply chain elements into national policies improve procurement and logistics management. (Bangladesh) • A single national electronic logistics management information system (LMIS), such as in Tanzania (the ILS Gateway), for all commodities nationwide in the public sector improves reporting of commodities and stock levels. By using SMS, the ILS Gateway provides real-time information on facility stock status for 20 tracer commodities. This model system avoids parallel and vertical distribution systems. 	<ul style="list-style-type: none"> • Poor planning for the cost of medicines’ distribution and inability of existing funding sources to pay • Poor planning for warehousing and storage at peripheral levels of health system • Weak warehousing capacity and guidelines for good warehousing and adequate stock levels are not consistently followed; weak security, transport, and management capacity • Frequent staff turnover in high-level directorates responsible for managing supplies, lack of skilled logistics planners and managers, and inadequate supervision of supplies and facilities • Fragmented LMIS that leads to inaccurate or insufficient data on which to base management decision • Major infrastructure issues influence the availability of MH medicines. (Nigeria)

MHCS FRAMEWORK COMPONENT	SUCSESSES AND OPPORTUNITIES	BARRIERS AND CHALLENGES
<i>Micro Level</i>		
Population Awareness	<ul style="list-style-type: none"> • Increased awareness and demand for community administration of misoprostol follows strong community education and mobilization programs. • Assessments of a pilot project of misoprostol use at the community level in Bangladesh found an increased demand for the medicine, an increased awareness of labor complications, and in at least one study an intention to reuse misoprostol for future deliveries. By incorporating a strong community education or mobilization component, the project raised awareness among women about misoprostol's use and availability. 	<ul style="list-style-type: none"> • Private providers inconsistent use of uterotonics • Some countries estimate that private providers use uterotonics in about half of the deliveries they attend. • Older providers may be less familiar with current oxytocin guidelines than recently trained providers.
Patient and Family Behavior, Communication and Decisionmaking	Availability of supplies appears to be a factor in health-seeking behavior.	Out-of-pocket costs influence health- seeking behavior; in some countries, patients pay 2 to 64 times the international reference prices for medicines, leading many to borrow for health spending.

Section 4: Recommendations

Recommendations

The following recommendations are based on an analysis of the preliminary findings from the field. They also incorporate the recommendations emerging from the pool of available literature.

Macro Level

Policies and Regulations

Supportive MH policies should be strengthened at the national and subnational levels. The development of an MHCS framework can be built on existing CS frameworks for essential medicines. A variety of stakeholders representing different sectors should be involved in the development of policies. Strong political commitment at the highest levels is imperative for effective implementation and the transition of policy into practice. Financial commitment is an especially critical component of political commitment; dedicated budget lines are needed to implement and monitor and evaluate these policies. Effective policies for MH commodities should be transparent and specific, with quantifiable targets. Policies should address local challenges and the strategies to overcome them. Policy efforts should be harmonized and reflect concordant content.

Finance

Budget line items must be comprehensive and include the provision of costs for not only MH commodities but for associated logistics and service delivery costs. Budgets at all levels should specifically include MH commodities. Better financial tracking processes are needed to monitor the flow of funds for MH commodities. This includes the need to document and track private sector financial flows to understand their impact on access to MH commodities. Collecting this data can help to guide the definition of a clear role for the private sector in providing equitable access to key supplies.

Policies and initiatives concerning user fees and voucher systems for MH care and commodities, including related supplies, should be well analyzed to understand their impact.

Coordination

Multisectoral coordination strategies spanning the national and subnational levels and various organizational aspects are needed. A particular focus should be to better engage the private sector to learn more about its role and impact and to encourage its effective participation. Technical committees, strategies, and policies should be better aligned across the public and private sectors. The UNCoLSC's *Guidance and Resources for Inclusion of Reproductive, Maternal, Newborn, and Child Health Commodities in National Commodity Supply Coordination Committees* provides considerations, tools, and resources. Countries can use the document to establish or expand an existing supply coordination

committee to include the full set of RMNCH commodities and to better align the work of various stakeholders.

Advocacy and Leadership

A collaborative approach involving the spectrum of stakeholders is needed to develop effective advocacy strategies and campaigns. Advocacy efforts for MH commodities can be built on existing health campaigns and be evidence based. Data about the impact of advocacy efforts are necessary and can be obtained by mapping advocacy programs, efforts, and initiatives.

Meso Level

Supply Chain Strengthening

Several strategies are required to strengthen the supply chain. The particular needs of MH commodities should be specifically addressed to improve product availability. Building the capacity of national registration bodies and regional and local manufacturers is key. A streamlined supply chain system that coordinates sectors and levels will minimize inefficiencies, waste, and delays. Adequate physical infrastructure, accurate forecasting, appropriate budgeting, and trained and skilled logistics personnel are necessary. Procurement challenges are of utmost importance and require country-specific strategies. Data tracking and analysis of MH medicines and the development of harmonized logistics management information systems (LMIS) need to be linked.

Building on successes in good packaging practices that are conducive to use (such as exact dose – 3 x 200 mcg tablets for misoprostol) can be translated to other commodities. It will be useful to undertake studies on providers' behavior to better understand their attitudes and implement strategies for generating more provider demand for commodities. Finally, mHealth applications should be explored to support referrals, provider decision support, program monitoring, optimized targeting for follow-up, and feedback on important information on individual performance.

Quality Assurance

Commitment to quality assurance is critically important. Financial commitment, along with a coordinated strategy across all levels, is needed. Certified laboratories and routine postmarketing surveillance are important components of the quality assurance strategy, and personnel must be adequately trained. Special attention should be given to counterfeit and expired medications and the measures taken to address these issues. In the case of oxytocin, cold storage capacity and appropriate product monographs are paramount to ensuring quality.

Human Resources Development

Deployment of the three key MH supplies requires a trained workforce that may need capacity development at the facility level, particularly at the peripheral facilities where the needs are often the greatest. Requirements for training and certification need to be developed and implemented with

effective supervision in place. To reach the periphery and community levels, task shifting may be a necessary consideration, with resources allocated for implementation.

Efforts should be made to address staff shortages and retention. Staff should receive adequate training in antenatal and postnatal care, as well as specific training for administering the three key MH commodities. Continuing education should be available online and include supervision and monitoring classes, seminars, refresher courses, daily interdisciplinary ward rounds, and weekly lectures at hospitals. The design and format of continuing education should be relevant for the cadre of healthcare workers. Similarly, roles and responsibilities of each level or cadre of healthcare workers should be clarified. Evidence regarding providers' skill levels and comfort and ability to administer critical supplies should be collected to improve training and supply chain practices.

Service Delivery

As the majority of PE-related deaths in LMICs occur in the community, interventions ought to be focused at this level (Firoz et al. 2011). If treatment began prior to transfer to a higher-level facility, the negative effects of delayed triage, transport, and treatment would be mitigated. Community-level care and task shifting for community-based distribution of misoprostol and magnesium sulfate can address staff shortages and improve service delivery.

All health workers need to be aware of policies, practices, and guidelines on MH methods and medicines. Guidelines and protocols should be consistent. Practices of the private sector should be documented and comparable with that of the public sector.

The UNCoLSC is addressing issues around effective magnesium sulfate administration and delivery, the complexity of dosage, and pervasive myths about who is qualified to administer the drug. The presentation and administration of magnesium sulfate should be simplified and accompanied by clear guidelines and job aids distributed to all levels of health provision.

Monitoring and Evaluation

Many countries lack routine monitoring and evaluation. Development and implementation of effective data collection tools and their inclusion in other monitoring and evaluation activities, as appropriate, is necessary.

Micro Level

Population Awareness

Education campaigns should target women, their families, and healthcare providers to raise awareness about pregnancy complications and the purpose of and indications for MH commodities. Successful awareness strategies used in some countries include community sensitization campaigns and mobilization efforts. Appropriate educational and BCC materials for patients and community members should be developed and disseminated. Approaches should be developed for bringing community members and providers together to discuss respective perceptions of high quality care and indications

for oxytocin. Strategies to increase the number of deliveries in a health facility or with a skilled birth attendant may increase the demand for MH commodities. Maintaining a reliable supply of MH commodities at all levels of health facilities, particularly at lower-level facilities where needs are often greatest, may also encourage communities to increase advocacy for services because they know supplies will be available.

Building on existing advocacy campaigns or strategies that specifically target MH commodities can be an effective platform on which to build campaigns for MH commodities. In Africa, efforts such as the MAMA campaign could be used as a platform to advocate for MH commodities. The campaign works to accelerate reduction of maternal mortality via the Red Ribbon Alliance, Breaking Silent Suffering, Saving Mothers Giving Life, and Saving One Million Lives. In countries that have women's health-related campaigns (such as Sierra Leone's Presidential Commission to reduce teenage pregnancy and awareness campaigns for HIV-related stigma, child violence, and female genital mutilation) but lack ones for MH, lessons learned from these campaigns could be used to develop effective MH and MH commodities campaigns.

Section 5: Next Steps

Refinement of Framework

The suggested next phase for development of the MHCS framework includes pilot testing it in select countries to validate its components and identify issues that emerge from dominant themes. The framework can then be refined as necessary. Refinements include the addition or deletion of components and organization of components or the issues identified for addressing barriers, challenges, successes, and opportunities.

Development of Assessment Procedures

Following validation and refinement of the framework, the next steps may include—

- I. developing a guide to support in-country implementation
- II. assisting countries so they can use the pilot-tested and revised framework to develop their CS strategies
- III. monitoring implementation and progress toward MH CS.

Ongoing support for dissemination of the MHCS framework can be achieved through collaboration with organizations conducting workshops under the UNCoLSC umbrella and with projects that bilateral and multilateral organizations support. It can also be achieved by holding regional MHCS framework dissemination workshops.

Harmonization with Other Policy Tools

Future steps should be undertaken to harmonize with other RMNCH CS frameworks, align with other key policy documents, and expand the list of life-saving MH commodities.

The MHCS framework is complementary to the RHCS framework (SPARHCS). It is important to consider MH commodities and reproductive health supplies along the same RMNCH continuum despite the differences between the aims and components of the frameworks. Contraception such as female condoms, implants, and emergency contraception included under reproductive health are essential for MH. The RMNCH continuum of care includes service delivery through all aspects of a woman's reproductive life; family planning is one of the four pillars of the [Safe Motherhood Initiative](#). A recent study shows that meeting unmet need for contraception could avert 104,000 maternal deaths per year (29 percent reduction) (Ahmed et al. 2012). Thus, contraception is an essential commodity for reducing maternal mortality.

MH is also closely linked to neonatal health. Maternal complications can result in pre-term birth and subsequent poor outcomes for the baby. The UNCoLSC has identified four commodities for newborn health: injectable antibiotics, antenatal corticosteroids, chlorhexidine, and neonatal resuscitation equipment. These commodities address complications resulting from pre-term birth, neonatal sepsis,

and respiratory distress.¹¹ The UNCoLSC acknowledges the strong ties between maternal and neonatal health, so linking the maternal health and neonatal health TRTs is a priority. Currently, the MHTRT is working with the TRT for antenatal corticosteroids.

The MHCS framework serves as a practical adjunct to two recent policy publications: Estimation of Unmet Medical Need for Essential Maternal Health Medicines and Scaling up Life-Saving Commodities for Women, Children and Newborns: An Advocacy Toolkit. Several challenges for the estimation of unmet need of MH commodities intersect with issues identified in the MHCS framework, making the two tools complementary, and the framework for MH CS described in this paper may be used as an additional tool to advocate for the life-saving commodities identified by the UNCoLSC.

Finally, harmonization with WHO's Priority Life-saving Medicines for Women and Children list will allow for consistent messaging for policymakers and national governments (WHO 2012b). It will also provide an opportunity to consider expanding the scope of MH conditions and commodities. Conditions such as maternal sepsis, pre-term labor, and common infectious diseases (e.g., HIV and AIDS, tuberculosis, malaria, and tetanus) are included in WHO's Priority Life-Saving Medicines for Women and Children list. Commodities for consideration that are on this list include—

- calcium gluconate as an antidote to magnesium sulfate
- antihypertensive agents for the treatment of severe hypertension related to PE and eclampsia
- oral and parenteral antibiotics for the treatment of maternal sepsis
- misoprostol for the provision of safe abortion or management of incomplete abortion and miscarriage
- vaccines for tetanus, antiretrovirals, antimalarials, and tuberculosis drugs for key infectious diseases.

¹¹ <http://www.everywomaneverychild.org/about/what-is-every-woman-every-child>

Section 6: Summary

The global community has an opportunity to improve MH and save lives by taking action to address the key interrelated barriers that prevent access to and use of the three LSCs reviewed in this paper. The MHCS framework presumes that health system strengthening is a primary means through which MH CS is achieved. It also presumes that improved MH is the outcome of system improvements that specifically address MH supplies. We hope countries can use the framework to improve key components of health systems to increase availability of oxytocin, misoprostol, and magnesium sulfate.

References

- Ahmed, Saifuddin, Qingfeng Li, Li Liu, and Amy O. Tsui. 2012. Maternal Deaths Averted by Contraceptive Use: An Analysis of 172 Countries. *The Lancet*. 380(9837): 111–25. <http://www.ncbi.nlm.nih.gov/pubmed/22784531>
- Bazant, E., J. P. Rakotovo, J. R. Rasolofomanana, V. Tripathi, P. Gomez, R. Favero, and S. Moffson. 2013. Quality of Care to Prevent and Treat Postpartum Hemorrhage and Pre-eclampsia/Eclampsia: An Observational Assessment in Madagascar's Hospitals. *Médecine et Santé Tropicales*. 23(2):168–75. <http://www.ncbi.nlm.nih.gov/pubmed/23694783>
- Bergeson-Lockwood, Jennifer, Elizabeth Leahy Madsen, and Jessica Bernstein. 2010. *Maternal Health Supplies in Bangladesh*. Washington, DC: Population Action International.
- Bigdeli, Maryam, Shamsa Zafar, Hafeez Assad, and Abdul Ghaffar. 2013. Health System Barriers to Access and Use of Magnesium Sulfate for Women with Severe Pre-Eclampsia and Eclampsia in Pakistan: Evidence for Policy and Practice. *PLoS ONE*. 8(3): e59158. <http://www.ncbi.nlm.nih.gov/pubmed/23555626>
- Center for Health, Human Rights, and Development (CEHURD). 2011. *Monitoring Access to Maternal Health Commodities in Uganda*. Kampala, Uganda: CEHURD.
- Chaturvedi, Sarika, Bharat Randive, and Nerges Mistry. 2013. Availability of Treatment for Eclampsia in Public Health Institutions in Maharashtra, India. *Journal of Health, Population and Nutrition*. 31(1):86–95. <http://www.ncbi.nlm.nih.gov/pubmed/23617209>
- Deepak, Nitya Nand, Ellie Mirzabagi, Alissa Koski, and Vandana Tripathi. 2013. Knowledge, Attitudes, and Practices Related to Uterotonic Drugs during Childbirth in Karnataka, India: A Qualitative Research Study. *PLoS One*. 8(4):e62801. <http://www.ncbi.nlm.nih.gov/pubmed/23638148>
- Dowling, Paul, Lisa Hare, Yasmin Chandani, and Alexandra Zuber. 2006. *HIV/AIDS Commodity Security: A Framework for Strategic Planning*. Arlington, Va.: DELIVER, for the U.S. Agency for International Development.
- Fikree, Fariyal F., Ali M. Mir, and Inaam-ul Haq. 2006. She May Reach a Facility but Will Still Die! An Analysis of Quality of Public Sector Maternal Health Services, District Multan, Pakistan. *Journal of Pakistan Medical Association*. 56(4): 156–63. <http://www.ncbi.nlm.nih.gov/pubmed/16711335>
- Firoz, Tabassum, Harshad Sanghvi, Mario Meriardi, and Peter von Dadelszen. 2011. Pre-eclampsia in Low and Middle Income Countries. *Best Practice & Research Clinical Obstetrics & Gynaecology*. 25(4): 537–48. <http://www.ncbi.nlm.nih.gov/pubmed/21592865>
- Gao, Yu, and Lesley Barclay. Availability and Quality of Emergency Obstetric Care in Shanxi Province, China. 2010. *International Journal of Gynecology and Obstetrics*. 110(2):181–5. <http://www.ncbi.nlm.nih.gov/pubmed/20570261>

- Goffman, Erving. 1986. *Frame Analysis: An Essay on the Organization of Experience*. Boston: Northeastern University Press.
- Hare, L., C. Hart, S. Scribner, C. Shepherd, T. Pandit (ed.), and A. Bornbusch (ed.). 2004. *SPARHCS: Strategic Pathway to Reproductive Health Commodity Security. A Tool for Assessment, Planning, and Implementation*. Baltimore, MD: Information and Knowledge for Optimal Health (INFO) Project/Center for Communication Programs, Johns Hopkins Bloomberg School of Public Health.
- Harvard School of Public Health—Maternal Health Task Force (MHTF). May 22, 2012. “Maternal Health Commodities: Case Studies from Bangladesh, India, Ethiopia, Nigeria, Tanzania, and Uganda.” Boston: MHTF. Available at <http://www.mhtf.org/2012/05/22/maternal-health-commodities-country-case-studies-for-bangladesh-india-ethiopia-nigeria-tanzania-and-uganda/>. (blog accessed on November 25, 2014)
- Hill, Suzanne, Annie Yang, and Lisa Bero. 2012. Priority Medicines for Maternal and Child Health: A Global Survey of National Essential Medicines Lists. *PLoS One*. 7(5):e38055. <http://www.ncbi.nlm.nih.gov/pubmed/22675435>
- Kade, Kristy, Elesha Kingshott, Ashley Latimer, Billie-Jean Nieuwenhuyus, Michel Pacque, Susan Fox, and Nejlja Lias. 2013. *Scaling Up Lifesaving Commodities for Women, Children, and Newborns: An Advocacy Toolkit*. Washington, DC: PATH.
- Lalani, Shifana, Tabassum Firoz, Laura A. Magee, Diane Sawchuck, Beth Payne, Rebecca Gordon, Marianne Vidler, and Peter von Dadelszen. Pharmacotherapy for Preeclampsia in Low and Middle Income Countries: An Analysis of Essential Medicines Lists. 2013. *Journal of Obstetrics and Gynaecology Canada*. 35(3): 215–23. <http://www.ncbi.nlm.nih.gov/pubmed/23470109>
- Leahy Madsen, Elizabeth, Jennifer Bergeson-Lockwood, and Jessica Bernstein. 2010. *Maternal Health Supplies in Uganda*. Washington, DC: Population Action International.
- Malik, Maheen, and Beth Yeager. 2014. *Estimation of Unmet Medical Need for Essential Maternal Health Medicines*. Arlington, Va: Management Sciences for Health.
- Mothers and Infants, Safe, Healthy, Alive (MAISHA). 2013. *MAISHA Quality of Maternal and Newborn Care Study—Key Findings: Essential Newborn Care 2010–2012*. Tanzania: MAISHA.
- Prata, Ndola, Clara Ejembi, Ashley Fraser, Oladapo Shittu, and Meredith Minkler. 2012. Community Mobilization to Reduce Postpartum Hemorrhage in Home Births in Northern Nigeria. *Social Science & Medicine*. 74(8):1288–96. <http://www.ncbi.nlm.nih.gov/pubmed/22377106>
- Prata, Ndola, Godfrey Mbaruku, Amy A. Grossman, Martine Holston, and Kristina Hsieh. 2009. Community-Based Availability of Misoprostol: Is It Safe? *African Journal of Reproductive Health*. 13(2): 117–28. <http://www.ncbi.nlm.nih.gov/pubmed/20690255>

- [Shamsuddin, L.](#), K. Nahar, B. Nasrin, S. Nahar, S. Tamanna, R. M. Kabir, M. J. Alis, and S. A. Anwary. 2005. Use of Parenteral Magnesium Sulphate in Eclampsia and Severe Pre-eclampsia Cases in a Rural Set Up of Bangladesh. *Bangladesh Med Res Counc Bull.* 31(2): 75–82. <http://www.ncbi.nlm.nih.gov/pubmed/16967813>
- Sherris, J., A. Bingham, M. A. Burns, S. Girvin, E. Westley, and P. I. Gomez. 2005. Misoprostol Use in Developing Countries: Results from a Multicountry Study. *International Journal of Gynecology and Obstetrics.* 88(1): 76–81. <http://www.ncbi.nlm.nih.gov/pubmed/15617717>
- Smith, Michael Jeffrey, Sheena Currie, Tirza Cannon, Deborah Armbruster, and Julia Perri. 2014. Are National Policies and Programs for Prevention and Management of Postpartum Hemorrhage and Preeclampsia Adequate? A Key Informant Survey in 37 Countries. *Global Health: Science and Practice.* 2(3): 275–84.
- Smith, Michael Jeffrey, Richard F Lowe, Judith Fullerton, Sheena M Currie, Laura Harris, and Erica Felker-Kantor. 2013. An Integrative Review of the Side Effects Related to the Use of Magnesium Sulfate for Pre-eclampsia and Eclampsia Management. *BMC Pregnancy & Childbirth.* 13:34.
- UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC). 2012. *Commissioners' Report: September 2012.* New York: UNCoLSC.
- Van Dijk, Marieke G., Mónica García-Rojas, Xipatl Contreras, Abigail Krumholz, Sandra G. García, and Claudia Díaz-Olavarrieta. 2014. Treating Patients with Severe Preeclampsia and Eclampsia in Oaxaca, Mexico. *Salud Pública de México.* 56(5): 426–7,
- Wick, L., N. Mikki, R. Giacaman, and H. Abdul-Rahim. 2005. Childbirth in Palestine. *International Journal of Gynecology and Obstetrics.* 89(2):174–8. <http://www.ncbi.nlm.nih.gov/pubmed/15847891>
- World Health Organization (WHO). 2007. *Everybody Business: Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action.* Geneva: WHO.
- . 2012a. *The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences.* Geneva: WHO.
- . 2012b. *Priority Live-saving Medicines for Women and Children 2012: Improving Health and Saving Lives by Ensuring Access to Priority Medicines.* Geneva: WHO.
- . 2012c. *Optimizing Health Worker Roles to Improve Access to Key Maternal and Newborn Health Interventions through Task Shifting.* Geneva: WHO.

Annex 1: Summary of Observations from Field Research and Experience

Many factors influence the availability of quality MH products. This annex provides a narrative summary of the barriers and successes identified from the desk review and key informant interviews. Applying the MHCS framework at the country level identifies barriers to overcome and successes to support to achieve the goal of MH CS.

Macro Level

Policies and Regulations: *Barriers and Challenges*

Political Commitment

In several countries, political commitment to MH CS is weak. Countries with decentralized health systems, such as Nigeria, require strong political commitment to maintain focus on the availability of MH products at the national and subnational levels. Other challenges include lack of transparency in policies and the lack of sufficient funds to implement, monitor, and evaluate their impact (Harvard School of Public Health—Maternal Health Task Force [MHTF] 2012).

Specific and Measurable Policies

While many countries have supportive MH policies, some lack specificity and quantitative targets to effectively measure progress. Additionally, policies might address MH care and services but not directly address supply of MH commodities. In Bangladesh, policies lack specific, quantifiable targets to improve MH, including areas such as supply chain management (Harvard School of Public Health—MHTF 2012). While some existing policies in Bangladesh mention medicine supply, they do not explicitly address supply issues. Policies should specify quantifiable targets and strategies to address shortages and stockouts (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010; Harvard School of Public Health—MHTF 2012). In other countries, policies did not include quantifiable targets to measure improvements in access to supplies (Harvard School of Public Health—MHTF 2012).

Harmonization of Policies

Increased attention and stakeholder interest in MH may result in development of policy documents or guidelines that are not harmonized. In some countries, such as Ethiopia, existing policy documents such as the *Health Sector Strategic Plan* and *The Road Map for Accelerating the Reduction of Maternal & Neonatal Mortality and Morbidity* could be better harmonized within a national-level RMNCH strategy.

Discordance between Policies

Policy discord can exist between EMLs and national guidelines, such as between national guidelines, WHO standards, and medicines on EMLs. Essential medicines and devices lists need to reflect current WHO guidelines around LSCs and align with job aids and training materials. Ethiopia

is strongly pushing the alignment of national processes with WHO guidelines as a response to MH medicines that have been entering the country in advance of revisions to the EML and Medical Equipment Catalogue. (Harvard School of Public Health—MHTF 2012). Among Nigeria’s 36 states, substantial variation in health policies exists, and the situation at the local level is even more complex (Harvard School of Public Health—MHTF 2012).

Policy Implementation

Although supportive MH policies have been enacted in some countries, on-the-ground implementation has not occurred. In Bangladesh, changes and improvements in MH service delivery that should have quickly followed revised policies have been slow to be implemented (Harvard School of Public Health—MHTF 2012). In Malawi, new policies and benchmarks are in place or in process at the higher levels, but district-level planning, financing, and implementation of RMNCH initiatives require additional resources, political commitment, and coordination (Harvard School of Public Health—MHTF 2012).

Policies and Regulations: *Successes and Opportunities*

Supportive Policies and Strategic Plans

Supportive MH policies, such as the ones in Bangladesh, elevate maternal and child health to the highest priority. For example, the Health Population and Nutrition Sector Development Program emphasizes improving the quality of and access to MH supplies. The National Population Policy includes the need to ensure an adequate supply of essential commodities and a client-centered approach for the provision of reproductive health services. The 2009 National Neonatal Health Strategy discusses the potential scale-up of community-based distribution of misoprostol, the need to ensure proper use of oxytocin, and the authorization of community-based skilled birth attendants to administer the loading dose of magnesium sulfate before referring patients to emergency obstetric care facilities (Harvard School of Public Health—MHTF 2012).

In Tanzania, MH supplies are specifically mentioned in several national policy documents, including the *National Roadmap Strategic Plan to Accelerate Reduction of Maternal, Newborn and Child Deaths*. Burkina Faso has implemented a strategic plan with some success, according to a key informant. Facilitating factors include formation of a directorate for development policies and development of regulatory documents defining the operation, responsibilities, and composition of technical committees that work on reproductive health commodity issues.

Involvement of Stakeholders in Policy Development

In Uganda, the National Health Policy was created using an inclusive, multisectoral, and participatory process involving technical working groups, various government ministries, private sector partners, NGO representatives, and local government officials (Harvard School of Public Health—MHTF 2012).

Existing CS Frameworks for Essential Medicines

Existing CS frameworks provide an opportunity to introduce the MHCS framework as a tool. Ethiopia and Burkina Faso have CS frameworks for essential medicines; the one in Burkina Faso

includes MH supplies (magnesium sulfate, oxytocin, misoprostol, contraceptives, antibiotics, folic acid, among others), but Ethiopia's reportedly does not.

High Degree of Product Registration

All three MH commodities have registered products in the countries reviewed in the Landscape Analysis MHTF case studies and key informant interviews. This represents an important early step in making these products available; absence of registered products is a significant obstacle to making products available. As new products, doses, and formulations become available, efficiency of registration processes will continue to be important.

Coordination: *Barriers and Challenges*

Better coordination between stakeholders is needed at multiple levels, including the international, country, district, and facility levels. The need for stronger coordination between the public and private sectors emerged as a dominant theme.

Public-Private Coordination

The private sector provides about half of all health services in many countries. Where this occurs, private sector contributions are crucial to quality MH services and availability of MH medicines. Many countries lack coordination between public and private sectors. In Malawi, coordination is fragmented between the public sector and the Christian Health Association of Malawi (CHAM), a major partner in the healthcare system. Better coordination of medicines procurement and distribution through a partnership between CHAM and the government would strengthen services for MH patients. In Nigeria, effective public sector engagement with the private sector is necessary to increase coverage and quality of MH services and availability of MH medicines. In Uganda, the private sector plays an important role in the delivery of RMNCH services by providing about 50 percent of healthcare services, yet strategy development and implementation remain fragmented (Harvard School of Public Health—MHTF 2012).

When private sector practice is not aligned with the public sector, fragmentation between the public and private sectors is evident in the reporting of services and commodities. This can lead to faulty program management decisions based on inaccurate or insufficient data. In Ethiopia, the lack of reporting alignment between the public sector and private drug importers and suppliers prevents a full understanding of the country's commodities situation (Harvard School of Public Health—MHTF 2012).

Information about the Role of the Private Sector

While the private sector plays an active role in many healthcare systems, little is known about its specific role in supplying MH commodities. Most countries report that the three MH commodities are available in the private sector, but there are little to no data documenting cost, availability, and use. It is not clear whether fees women pay in private facilities cover all services and supplies for safe delivery or whether women and their families must purchase essential commodities outside the facility (Harvard School of Public Health—MHTF 2012).

Coordination: *Successes and Opportunities*

Strategic Plan for Coordination

In Burkina Faso, a key informant cited a strategic plan for coordination between the various Ministry of Health (MOH) units, public and private institutions, and the General Directorate of Pharmacy, Medications and Laboratories (DGPMML). The directorate for development policies has produced regulatory documents defining the operation, responsibilities, and composition of technical committees relating to reproductive health commodities.

The reproductive health technical committee is responsible for the coordination and management of reproductive health products. Committee members evaluate information collected on health products supply and propose and evaluate risk management plans for availability, accessibility and quality. The committee also has responsibility for specific program inputs, such as quantification, procurement planning, and oversight of implementation. A steering committee is responsible for regularly monitoring the implementation of the strategic plan for RH CS. It is also responsible for making recommendations to strengthen interventions to improve RH CS and assure monitoring of advocacy for RH commodities.

The national committee is responsible for coordinating activities for rational management of diagnostic products, prevention and treatment of target diseases for priority programs, and estimation of needs at the national level.

Finance: *Barriers and Challenges*

Government Funding for Essential Medications

A variety of funding sources and mechanisms is used to finance MH medicines. In some countries, such as Ethiopia, government drug expenditures are a mix of contributions from federal and regional governments (10 percent), NGOs (16 percent), bilateral and multilateral donors (27 percent), and household out-of-pocket payments (47 percent) (Harvard School of Public Health—MHTF 2012). While a steady increase in public sector spending for essential medicines and health supplies is needed in most LMICs, too often the reverse is happening in some countries.

Many national, state, and local budgets are inadequate for procurement of MH medicines. The MHTF case studies reveal that in Tanzania, the budget lines associated with commodities only included the cost of commodities and shipping; they omitted supply chain management costs, such as storage, staffing, and monitoring, and other service provider training (Harvard School of Public Health—MHTF 2012). These costs sometimes may be catered for in other budget categories; however, this method to circumvent the problem is seldom done adequately, particularly for new products.

Gaps in Data on Financing of MH Commodities

All six MHTF case studies found significant gaps in research and data on financing of MH commodities, signaling a need for further analysis and monitoring. Although details were available about financing drugs as a whole, the funding allocated to MH commodities was not available, indicating a need for better tracking of MH commodity expenditures (Harvard School of Public

Health—MHTF 2012). Increases in budget lines for health spending do not necessarily correlate to increased allocations for MH commodities, as they are not mandated. In the case of Bihar state in India, the state has to appropriate the allocated funding. However, regulatory authority is not in place to adequately monitor and ensure that these appropriations are made (Harvard School of Public Health—MHTF 2012).

Out-of-Pocket Spending

Several countries, such as Bangladesh and Tanzania, have policies for free supplies in the public sector. However, implementation challenges result from lack of clarity on how to effect exemptions. This lack of clarity results in patient (who are willing to pay for essential MH medicines) directly purchasing from the private sector due to poor commodity availability (Harvard School of Public Health—MHTF 2012). In Tanzania, the policy of free service delivery does not cover many costs associated with delivery and complementary services. This raises concerns about policies failure to address comprehensiveness of care (Harvard School of Public Health—MHTF 2012).

Limited information on out-of-pocket spending for MH commodities limits policymakers' ability to factor this funding stream into strategic planning. A commitment to understanding this function is needed.

Finance: *Successes and Opportunities*

Mechanisms to Manage User Fees Effectively

Countries address user fees through revolving drug funds, voucher schemes, and waiver policies. Some of these approaches have a long history, while others are new. They all need implementation oversight and monitoring and evaluation (Harvard School of Public Health—MHTF 2012). CS committees can monitor and evaluate the results and advocate for scale-up of effective approaches.

Advocacy and Leadership: *Barriers and Challenges*

Political Will

An annual budget line for MH commodities signals strong political commitment to MH. The MHTF case study on Uganda found that “the extremely low disbursement rate of the government’s annual budget line item for reproductive health supplies, including those for the prevention and treatment of direct causes of maternal mortality, is an indication of the gap between policy rhetoric and expenditure of resources” (Harvard School of Public Health—MHTF 2012). Similarly, while some governments are described as being committed to MH, this has not necessarily translated into increased financial commitment, a clear signal of political will (Harvard School of Public Health—MHTF 2012).

Coordination

Several countries identified a number of organizations that are involved in advocacy efforts. However, these efforts require increased coordination between these organizations, which can

pose a significant challenge. In Nigeria, the media and civil society are working together on advocacy efforts, and better coordination is expected over the next year.

Data to Inform Advocacy Efforts

In Uganda, several organizations (e.g., Medicines Transparency Alliance, Securing Uganda’s Right to Essential Medicines, Stop the Stock Outs) have identified essential medicines as a priority to improve health outcomes. However, the extent to which these organizations prioritize MH medicines is not clear since precise data are not available. A key informant in Ethiopia raised the issue that obtaining MH medicines data to inform advocacy is challenging.

Advocacy and Leadership: *Successes and Opportunities*

Involvement of Multiple Stakeholders in Advocacy Efforts

Countries identified collaboration among different sectors as a key strategy to successful advocacy efforts. In Burkina Faso, advocacy efforts are coordinated between sectors and occur at all levels of a community using the Individual, Family, Community approach, which was introduced in 2006. The approach is aimed at strengthening the capacity of communities through health promotion efforts, specifically targeting the health of the mother and child through a multilevel community approach. The approach has several components, including capacity building, improving quality of care, and strengthening relationships.

In Bangladesh, local and international NGOs are involved in all aspects of MH, from direct service delivery to policy and advocacy efforts. Civil society also works with government and donor agencies such as USAID and the World Bank to implement MH projects and policies (Harvard School of Public Health—MHTF 2012). One example is the Postpartum Hemorrhage Initiative, which convened experts from organizations such as EngenderHealth, the national OB/GYN society, USAID, and the government. The Postpartum Hemorrhage Task Force, a subgroup of the initiative, represents a key civil society effort to address specific MH priorities through policy.

Meso Level

Supply Chain Strengthening: *Barriers and Challenges*

Infrastructure

In several countries, major infrastructure issues influence the availability of MH medicines. The Malawi Landscape Analysis identified the need for more and better warehousing, security, transport, as well as management capacity (Harvard School of Public Health—MHTF 2012). In Burkina Faso, warehousing capacity is weak in most districts, and guidelines for good warehousing and adequate stock levels are not consistently followed. In Nigeria, needed upgrades to physical infrastructure include timely repair of leaky roofs; investments in tools are needed to monitor fluctuations in temperature (Harvard School of Public Health—MHTF 2012).

Parallel Systems

In Malawi, vertical programs operate parallel systems to procure and distribute medicines, including emergency RMNCH supplies. While donors funded these systems to deliver medicines to

communities where they are most urgently needed, this parallel system could erode the capacity of the national procurement agency (Central Medical Stores Trust) over the long term (Harvard School of Public Health—MHTF 2012). This underscores the importance of long-term planning and coordination to ensure that activities are not working at cross-purposes and to the detriment of future CS.

Forecasting

Several themes emerged around forecasting. In Malawi, forecasts are intended to be consumption based, but because accurate consumption data are unreliable, forecasts may have a high margin of error (Harvard School of Public Health—MHTF 2012). In Ethiopia, centralized forecasting of MH medicines is challenging due to limited availability of consumption data. This results in commodity estimates based on demographic and morbidity data, which may not represent the actual need (Harvard School of Public Health—MHTF 2012). Effectively linking with and obtaining information on consumption at health posts (the lowest level of the chain where community health workers [CHWs] are based) are thought to be the most significant challenge since no consistent method for obtaining those data exists, making it difficult to forecast accurately.

A key informant in Burkina Faso raised the point that while forecasting data are thought to be of good quality, the country lacks a national forecasting team. This indicates an opportunity for organizational strengthening in addition to accurate forecasting models and processes.

Fragmented LMIS

Key informants identified fragmented LMIS as a challenge. In one country, each level of the health system uses an isolated system: An electronic enterprise management system links national central medical stores and regional stores (but it is not fully functional and does not generate useful reports); health facilities use a manual system; and CHWs use an mHealth SMS-based system that is not integrated with the national LMIS (Harvard School of Public Health—MHTF 2012). In another example, Burkina Faso has not included the three MH commodities in its LMIS.

In Tanzania, FBOs, which account for 12 percent of health facilities, use the national LMIS only if the government recognizes the facility. Private sector facilities (6 percent) function completely outside of this system (Harvard School of Public Health—MHTF 2012).

Procurement Delays

Procurement challenges are a critical barrier to accessing MH commodities. A case study in India demonstrated the weaknesses in local-level procurement; currently, all three MH commodities face procurement challenges in Bihar state (Harvard School of Public Health—MHTF 2012). In Bangladesh, public sector supply chains are prone to procurement delays, shortages, and stockouts at all levels (warehouses and facilities). Facilities risk running low on supplies because the government conducts one procurement per year (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010).

Supply Chain Human Resources

A number of capacity issues emerged, including frequent staff turnover in high-level directorates responsible for managing supplies; lack of skilled logistics planners and managers; inadequate

storage space; slow, complicated distribution processes; and inadequate supervision of supplies and facilities.

Supply Chain Strengthening: *Successes and Opportunities*

Integrated Supply Chain Plan

A coordinated plan for supply chain strengthening can improve efficiency. One such example is the Ethiopian Federal Ministry of Health's (FMOH) Pharmaceutical Logistics Master Plan. This plan aims to coordinate actors, levels, and functions of the supply chain to facilitate a reliable and sufficient stream of medicines and supplies at the lowest cost for public sector health facilities. In addition, the FMOH has implemented the Business Process Review, which restructures regulatory and procurement agencies for medicines into a single national commodity supply chain.

Procurements and donations are coordinated through a central warehouse and then transferred to regional hubs or warehouses. The hubs manage distribution to hospitals and health centers, which then distribute commodities to health posts.

While other countries may not have as strong a strategy, some do incorporate supply chain elements into national policies. One example is Bangladesh, which incorporates a plan to improve procurement and logistics management in the Health, Population and Nutrition Sector Development Program (Harvard School of Public Health—MHTF 2012).

Single LMIS

Tanzania has developed an electronic LMIS (the ILS Gateway) for all commodities in the public sector nationwide, which extends from central level to zonal medical stores. The ILS Gateway provides month-to-month reporting of commodities and stock levels. By using SMS, the system provides real-time information on facility stock status for 20 tracer commodities. This model system avoids parallel and vertical distribution systems (Harvard School of Public Health—MHTF 2012).

Quality Assurance: *Barriers and Challenges*

Commitment to Quality Assurance

Quality assurance is critically important for the three MH products, especially since one is temperature sensitive (oxytocin). However, in many countries, health ministries do not appear to prioritize quality assurance. In Bangladesh, quality assurance receives little scrutiny, and shortfalls in funding for the Directorate of Drug Administration occur (Harvard School of Public Health—MHTF 2012). In Uganda, Data Quality Assessment Guidelines developed in 2012 are not widely disseminated (Harvard School of Public Health—MHTF 2012). Pharmacovigilance programs are nascent in Malawi (Harvard School of Public Health—MHTF 2012). In Burkina Faso, a key informant identified financing challenges for quality assurance measures for products once in the distribution cycle.

Laboratory Certification and Postmarketing Surveillance

Several countries appear to either not have a certified laboratory or have a partially certified laboratory, while postmarketing surveillance appears to be inconsistent. In the case of Malawi, no

certified laboratory or postmarketing surveillance exists. Ethiopia has a local laboratory with partial WHO certification; postmarket surveillance takes place on an ad hoc basis, with random testing done on primary priority commodities. Sierra Leone has a WHO pre-qualified class B¹² laboratory that conducts postmarket surveillance based on random spot checks; it uses ancillary labs in Ghana and South Africa (Harvard School of Public Health—MHTF 2012).

Regulation of the Pharmaceutical Industry

In Bangladesh, 95 percent of drugs are produced locally—something the National Drug Policy cites as having increased the affordability and accessibility of supplies and having improved the quality of drugs. However, the domestic pharmaceutical industry faces little competition and is not well regulated; as a result, a key informant cites, “the quality of pharmaceuticals on the local market is highly variable.” There are few restrictions on access to medicines in Bangladesh and no prescription or other authorization is required to obtain any supplies available in private shops. Pharmacies and unregistered drug stores often provide medical advice on a range of health issues, despite the lack of skilled staff to diagnose, prescribe, and administer drugs. Sometimes shops lack a qualified person to sell the pharmaceuticals (Harvard School of Public Health—MHTF 2012).

Counterfeit and Expired Medications

In Uganda, 20 to 30 percent of drugs are estimated to be counterfeit, but the percentages of these counterfeit medicines that are marketed as MH commodities are unknown. In 2012, a strategy of rapid testing was deployed, and the results indicated that expired medications seem to be a growing concern for MH commodities (Harvard School of Public Health—MHTF 2012). In Nigeria, it is estimated that 17 percent of medications are counterfeit (Harvard School of Public Health—MHTF 2012).

Quality Assurance: Successes and Opportunities

Coordinated Quality Assurance Strategy

In Burkina Faso, the strategy for quality assurance is aligned with the plan for strengthening the supply chain across all participating agencies and levels. Stakeholders at Central Purchasing Generic Essential Drugs (CAMEG); General Directorate of Pharmacy, Medications and Laboratories (DGPML); and the national public health laboratory coordinate quality assurance measures. The central warehouse has a quality assurance coordination function.

¹² Class B: Methods designed to detect and quantitate impurities in a bulk drug substance or finished dosage form.

Human Resources Development: *Barriers and Challenges*

Staff Shortages

One of the most prominent themes to emerge from the desk-based review and supported by numerous country examples is the capacity challenge in the healthcare workforce. Administrative-level staff frequently turn over in Bangladesh (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010). In public and private sectors in Uganda, staff shortages and turnover are high, resulting in long waiting times, heavy workloads, compromised quality of health services, and poor health worker motivation and attitude (Center for Health, Human Rights, and Development [CEHURD] 2011). Task shifting has shown some success in reducing the burden on clinicians by limiting their nonclinical tasks, such as supply management. Addressing staff shortages requires explicitly organizing services and ancillary functions and making staffing adjustments.

Training

Lack of provider training influences the provision of oxytocin, misoprostol, and magnesium sulfate.

In Uganda, in-service training of public sector providers appears weak and affects the provision of oxytocin, misoprostol, and magnesium sulfate. Poor training can render these products of little use even when they are available (Harvard School of Public Health—MHTF 2012). Access to quality maternal healthcare largely relies on highly trained midwives, nurse-midwives, and doctors because only higher-level providers are permitted to administer MH medicines. These healthcare providers are poorly paid and overworked in the public sector. Only 45 percent of higher-level facilities have staff trained in antenatal care (ANC).

In Bangladesh, while 75 percent of facilities provide delivery care, only 2 percent are prepared for obstetric first aid. This requires three medications: magnesium sulfate, oxytocin, and antibiotics (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010).

In-Service Training

In many countries, although health staff at lower-level health facilities can administer MH medicines, responsibility for this service is limited to higher-level healthcare professionals. The literature consistently identifies low rates of facility births as a barrier to client use, highlighting the disconnection. For example, in Uganda, few providers in lower-level facilities have been trained in the use of magnesium sulfate or are actively using it. In-service training of public sector providers is notably weak in Uganda; the lack of training affects the provision of oxytocin, misoprostol, and magnesium sulfate (Leahy Madsen, Bergeson-Lockwood, and Bernstein 2010). In Tanzania, while only 50 percent of births occur in facilities, national guidelines dictate that only higher-level healthcare professionals administer oxytocin and magnesium sulfate (Harvard School of Public Health—MHTF 2012).

Human Resources Development: *Successes and Opportunities*

Community Health Worker Programs

To address widespread staff shortages that affect quality of care and ability to effectively respond to patients' needs, several countries have implemented CHW programs. Depending on the country, the name and role(s) of the CHW differs. For example, Ethiopia has established a health extension worker program to perform a range of RMNCH-related activities. These activities include ANC, postnatal care, newborn resuscitation, administration of misoprostol during home deliveries, and management of newborn sepsis and other newborn conditions (Harvard School of Public Health—MHTF 2012). Uganda is experiencing a slow scale-up of effective village health team programs (Leahy Madsen, Bergeson-Lockwood, and Bernstein 2010). Sierra Leone has identified a need to expand access to LSCs to CHWs at lower levels of care. It is also considering performance-based incentives that reward unpaid CHWs by providing a stipend (Harvard School of Public Health—MHTF 2012).

Additional opportunities exist to harmonize the roles and responsibilities of CHWs as suggested in the evidence-based WHO guidance document on task shifting for MNH (WHO 2012c). For example, country job aids and guidelines could be aligned with the WHO guidance document, so delivery and provision of services are evidence based and consistent. One paper cited that 29 out of 37 countries (78 percent) reported that midwives were authorized to diagnose severe PE and eclampsia and to administer magnesium sulfate, a finding that did not appear to be aligned with WHO recommendations (Smith et al. 2014; WHO 2012c).

Health Supplies, Diagnostics, and Devices: *Barriers and Challenges*

In Uganda, health workers report inconsistent and insufficient availability of MH supplies as one of the biggest challenges in the provision of maternal and newborn services; commodities reportedly had also not reached the desired levels for universal access (Harvard School of Public Health—MHTF 2012). Health supplies in insufficient supply are found in MAMA kit packages, which contain a one meter piece of cotton cloth (baby wrapper), one laundry soap, a pair of gloves, a piece of cotton wool, two gauze pieces, cord ligature, a meter of polythene sheet for use on the delivery table, and eight sanitary pads for the mother (CEHURD 2011).

Service Delivery: *Barriers and Challenges*

Quality of Care

In Uganda, issues cited in quality of care include poor bedside manner and privacy concerns, which may be factors in inhibiting or delaying women from seeking medical assistance (Harvard School of Public Health—MHTF 2012). Many of the challenges previously cited undermine quality of care.

Service Delivery: *Successes and Opportunities*

Harmonizing Guidelines and Training Curricula

Updated guidelines and training curricula were identified as facilitating factors leading to better health service delivery. In 2010, the Uganda Clinical Guidelines were revised and updated with practical and useful information for upper and lower health facilities on the diagnosis and management of common conditions, including PPH and PE (Harvard School of Public Health—MHTF 2012). The landscape analysis in Sierra Leone revealed a need to further refine the new integrated RMNCH curriculum, so it was aligned with changes to the EML and national guidelines. In a landscape analysis the UNCoLSC conducted in Sierra Leone, a strong recommendation was made for a training of trainers (Harvard School of Public Health—MHTF 2012).

Monitoring and Evaluation: *Barriers and Challenges*

Monitoring and Evaluation Systems

A need exists to determine and implement globally-agreed MH indicators to inform MH service provision and the incorporation of medicines into countries' logistics and health management information systems. Yemen lacks health information systems and facility-level data, undermining effective monitoring. Thus, reliable data on commodities and stockouts are lacking (Mothers and Infants, Safe, Healthy, Alive [MAISHA] Yemen). Key informants identified lack of data collection tools and poor guidance on how to define the flow of information and reporting cycles as significant barriers.

Monitoring and Evaluation: *Successes and Opportunities*

Development of HMIS Strategy

An example of a good monitoring and evaluation system is Uganda's HMIS Strategy (2009/2010–2014/2015). It is a key data source to monitor RMNCH program indicators listed in the HSSP, and it facilitates reporting requirements. Facility- and some community-based data are included. Data collection mechanisms are relatively well established, and monthly reporting rates are high (Harvard School of Public Health—MHTF 2012).

Micro Level

Population Awareness: *Barriers and Challenges*

Affordability

While women may hypothetically be willing to pay for essential medicines, user fees and other costs play a role in discouraging them from using health services. Studies have found that patients in Nigeria paid between 2 and 64 times the international reference prices for medicines (Harvard School of Public Health—MHTF 2012). In India, despite financial barriers, consumers had high demand for whichever commodity their doctor or RMP prescribed, leading many to borrow for health spending. Consequently, 71 percent of health spending is out-of-pocket, forcing 4 percent of the population into poverty every year (Harvard School of Public Health—MHTF 2012). In

Nigeria, magnesium sulfate is particularly inaccessible due to its high cost (Harvard School of Public Health—MHTF 2012). While some policies and programs seek to reduce the price that women pay for commodities with the aim of increasing demand, they fall short either because they only cover services in secondary public facilities or the funding is not forthcoming (Harvard School of Public Health—MHTF 2012). Any effort to identify, build, or meet demand for these commodities among consumers must involve some effort to address the issue of cost to the patient.

Availability of Maternal Health Commodities

Several case studies cited that the availability of health commodities drove consumer demand. The Ugandan public noted that adequate availability of supplies was the primary issue in accessing effective healthcare in the nation; availability of supplies also appeared to be a factor in care-seeking behavior (Harvard School of Public Health—MHTF 2012). In Bangladesh, the perception that essential medicines were more likely to be in stock contributed to patients' decisions to seek care in private facilities, if they could afford it (Harvard School of Public Health—MHTF 2012). The MHTF case study in Bangladesh found that women had expectations that oxytocin would be available at lower-level facilities to induce labor (Harvard School of Public Health—MHTF 2012).

Population Awareness: *Successes and Opportunities*

Community Education

Regarding community administration of misoprostol, the documents included in the review revealed that strong community education and mobilization have resulted in women's increased awareness and demand. One study on community-based availability of misoprostol concluded that the medicine was acceptable in these communities and even more so among the drug's users. Women said they were significantly more likely to use misoprostol again in the event of PPH in a future pregnancy, to recommend misoprostol to a friend, and to be willing to purchase the tablets (Prata et al. 2009).

Assessments of a pilot project of misoprostol use at the community level in Bangladesh found an increased demand for the medicine; an increased awareness of labor complications; and in at least one study, an intention to reuse the drug at future deliveries. By incorporating a strong community education or mobilization component, the project raised awareness among women of misoprostol's use and availability (Harvard School of Public Health—MHTF 2012).

Other Issues

In Bangladesh, an issue was raised around provider training regarding pharmaceutical companies conducting extensive direct outreach to providers and the material they provide, including job aids. Job aids are often the primary source of education on updated protocols and medicine administration to providers at all levels. Seemingly, this practice could pose a conflict of interest and, due to a weak regulatory structure, may merit closer examination (Harvard School of Public Health—MHTF 2012).

Annex 2: Commodity-Specific Issues

Commodity-Specific Issues

Listing on Essential Medicines List

A total of 57 EMLs from 70 LMICs in Africa and Asia were available for analysis, 28 percent of them published since 2010.¹³ Listing on EMLs for each of the commodities follows below.

Magnesium Sulfate

In aggregate, magnesium sulfate was listed in 75 percent (43/57) of countries. In comparison, two published papers on the topic found that magnesium sulfate was present in 85 percent (77/91) and 50 percent (45/89) of the EMLs (Lalani et al. 2013; Hill, Yang, and Bero 2012). Twenty-six EMLs specifically listed “eclampsia,” “seizures,” “anti-convulsant,” or “anti-epileptic” as an indication for magnesium sulfate. With respect to concentration, only two EMLs listed 50 percent, 26 countries listed 20 percent, and 5 countries listed both.

The vital, essential, necessary (VEN) classification is a system used to set priorities for purchasing medicine and keeping stock; medicine is divided according to its health impact into vital, essential, and necessary categories.

Misoprostol

Misoprostol is listed in about 49 percent (28/57) of EMLs (figure 4). Lalani et al. (2013) found that misoprostol was listed in 40 percent of EMLs, while Hill, Yang, and Bero (2012) found it to be 35 percent. Only eight EMLs (14 percent) specifically listed PPH as an indication. Doses are variable, depending on the country. Most countries listed “tablet,” and it was not possible to determine whether the suggested route was oral or vaginal. Four countries using the VEN system listed misoprostol as “vital” and two as “essential.” *Using the VEN system, only 5 out of 43 countries listed magnesium sulfate as vital, and none listed it as essential.*

Oxytocin

Oxytocin is listed in about 93 percent (53/57) of the authors’ analysis compared with about 98 percent of the 91 EMLs in the Lalani et al. (2013) analysis and 62 percent of the 89 EMLs Hill et al. analyzed. Only three countries (5 percent) listed PPH as a specific indication for use. Twelve out of fifty-three EMLs listed five IU/mL, 25 listed 10 IU/mL, nine listed both, and six EMLs listed other concentrations.¹⁴

¹³ PAI defined the country classifications; they are not consistent with WHO regional classifications. <http://www.who.int/about/regions/en/>

¹⁴ The three analyses used different sets of EMLs, which may be a factor in the variances between the analyses.

Magnesium Sulfate

Despite the literature review suggesting a high awareness of the efficacy of magnesium sulfate for the prevention and treatment of eclampsia, a number of barriers exist for proper use.

Policy Implementation

While recommendations for the use of magnesium sulfate have been incorporated into policy in many countries, this has not often translated into practice. Implementation guidance has been vague, resulting in a lack of well-coordinated implementation strategies.

Clear Protocols and Guidelines

A number of issues relating to guidelines and protocols were identified:

- 1) poor dissemination of guidelines
- 2) guidelines not present in clinical settings
- 3) guidelines unclear
- 4) no guidelines.

In the absence of clear guidelines or any guidelines and protocols, large variations in dosage quantity exist, most of which diverge from international guidelines (MHTRT Report). In China, one study found that smaller than standard doses were being used, and no maintenance doses were being administered (Gao and Barclay 2010). Similarly, researchers in Oaxaca, Mexico, found that magnesium sulfate was being used inconsistently; also, doses that were administered were not standardized (Van Dijk et al. 2014).

This complexity is further reflected in the following statement from a leading physician at Pathfinder International in India: “There is huge confusion in the field about intravenous and intramuscular (IM) doses. Even medical doctors are unable to calculate the accurate doses for magnesium sulfate.” Incorrect calculations, he says, sometimes lead to complications, and the antidote, calcium gluconate, may not be available. This has created a myth in India that magnesium sulfate injection is a complex injection, and only specialists (OB/GYNs) can administer it (MHTRT Report; Barriers to Magnesium Sulfate).

Studies also found that women were referred immediately to higher-level facilities without any emergency management, creating greater risk for the patient (MHTRT Report). This occurs because some health personnel believe the drug must be administered at a tertiary facility and because no protocols for its use or guidelines for referral exist (MHTRT Report).

Availability of Magnesium Sulfate

While magnesium sulfate generally is becoming more available as the MCHIP survey shown by the MCHIP survey (76 percent of facilities surveyed in 2012 compared with 48 percent of facilities surveyed in 2011), it still remains a concern in many settings (Smith et al. 2014). In Pakistan, magnesium sulfate was available at the tertiary facility but not at other comprehensive emergency obstetric care facilities, despite nearly 40 percent of all maternal deaths in 2002 attributed to eclampsia (Fikree, Mir, and Haq 2006). Reported stockouts are common and occur every few months (even at higher-level facilities in Bangladesh). Availability of magnesium sulfate was rare at public sector facilities (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010). Only 42 percent of district hospitals, 23 percent of

Upazila health complexes, and 10 percent of Maternal and Child Welfare Centers reported having the injection in the facility for use.

Availability of Related Supplies

Limited supply of magnesium sulfate and related supplies at the healthcare facility level is a barrier to use as are the high costs of related and necessary supplies, such as proteinuria dipsticks, IV equipment, and calcium gluconate. Equipment at basic and comprehensive facilities was generally short of the minimum expected levels to enable the effective running of a Safe Motherhood program. Although supplies of magnesium sulfate have improved, a study found that most countries reported availability of magnesium sulfate at their ministry of health stores (86 percent) rather than at the health-facility level (76 percent), reflecting a supply and distribution concern (MHTRT Report). In some countries, physicians report that not having the drug is an obstacle, yet pharmacists only procure it if there is demand by practitioners (MHTRT Report).

Cumbersome Presentation

An important constraint at the facility level, which has received little attention in the literature, is the presentation and administration of magnesium sulfate. Providers in the Bigdeli et al. (2013) study clearly identified this challenge. According to health staff members who participated in focus group discussions and interviews, dosage preparation is one of the biggest barriers to use of magnesium sulfate since care providers must recall, calculate, and prepare the dosage (MHTRT Report). According to physicians in the Oaxaca study, the time it takes to find and prepare magnesium sulfate can take too long, especially in overcrowded, understaffed facilities, which are common in the region. Instead, a more readily accessible and less time-intensive drug such as diazepam is chosen (MHTRT Report).

Provider Knowledge

Insufficient awareness, education, and training were mentioned as barriers in nearly all the articles the MHTRT Magnesium Sulfate subgroup reviewed and additional documents the authors of this paper reviewed. In one study, staff members were aware that magnesium sulfate is the first line treatment for eclampsia, but many were not aware of its use for severe PE. The majority of staff—providers and pharmacists—did not have formal training in the use of magnesium sulfate, and their knowledge of how to use it properly was poor (Bigdeli et al. 2013). Formal training was also found to be suboptimal; pre-service curricula did not emphasize evidence-based care of eclampsia and PE.¹⁵ Unless providers are based in a high-volume facility and are frequently called upon to treat severe PE and eclampsia, they will lack the knowledge and skills that are necessary to confidently provide the treatment. In China, refresher training was essentially nonexistent since there had been no in-service training for most of the doctors and midwives for many years (Gao and Barclay 2010).

The authors' review revealed that healthcare providers are concerned about magnesium sulfate side effects and its monitoring. Few staff members were available to monitor magnesium sulfate, studies found; also, only higher-level professionals could use the medication (Harvard School of Public Health—MHTF 2012). According to Smith et al. (2013), provider fears about harmful effects of magnesium sulfate are largely unfounded. Studies Smith and colleagues reviewed show the drug to be a safe and effective

¹⁵ It is not clear from the literature whether pre-service curricula refer to nursing curricula or medicine curricula or both.

treatment for PE and eclampsia, with relatively rare adverse events. Additionally, they determined that concerns regarding an inability to provide adequate nursing care and laboratory analysis were unfounded since serum levels only need to be examined when clinical signs of toxicity are seen, such as changes in blood pressure, heart rate, or level of consciousness, which nurses would readily identify (Smith et al. 2013).

Use of Less Effective Medications

Less effective modalities are still listed as first line treatment. An MCHIP survey showed that 25 of the 37 surveyed countries listed diazepam as first line treatment. The authors' review of the literature found similar results (Harvard School of Public Health—MHTF 2012; Leahy Madsen, Bergeson-Lockwood, and Bernstein 2010).

Supply Chain Weakness

The literature identified a number of supply chain challenges. The market for magnesium sulfate is small, so it can be a deterrent for suppliers because of the corresponding prospects for revenue and breaking even or profitability. In many countries, use remains low because of a fragmented system of registration, procurement, and distribution. In some countries, facilities below the hospital level rarely procure magnesium sulfate (Leahy Madsen, Bergeson-Lockwood, and Bernstein 2010). Countries raised concerns about poor inventory management and noted an urgent need for updated inventory methods (Chaturvedi, Randive, and Mistry 2013; Harvard School of Public Health—MHTF 2012).

Other Issues

A number of other issues were cited in the literature, including a lack of a national strategy to ensure that all partners in the health system support the use of magnesium sulfate (Bazant et al. 2013) and government participation in health financing (Bazant et al. 2013). Poor monitoring process were also cited (Deepak et al. 2013). Often, there is a misconception or fear surrounding the use of magnesium sulfate, although an integrative review of the side effects related to its use for PE and eclampsia management demonstrates the lack of toxicity (Smith et al. 2013). A few papers on evidence-based obstetric practice have been published in Chinese, but no regularly updated Chinese-language website exists (Gao and Barclay 2010). Physical examination scores that nurses and doctors use for eclampsia were mainly “poor,” although management scores—especially among doctors—depicted a better trend (Fikree, Mir, and Haq 2006).

Current Strategies

To address the complexities of magnesium sulfate dosing, WHO, in conjunction with the UNCoLSC, is proposing a standardized concentration of 50 percent. This would avoid errors around dosing calculation and hopefully alleviate provider fears.

A second strategy is the shift toward intramuscular use of magnesium sulfate at the community level for the loading dose.¹⁶ For example, in Bangladesh, magnesium sulfate is intended to be used at lower-level health centers that can provide a loading dose of magnesium sulfate then refer patients to higher-level facilities. Furthermore, there have been pilot studies on low-level community health providers (referred

¹⁶ CLIP trial - cluster RCT of community level IM magnesium sulfate and oral antihypertensives

to as CSBAs) administering loading dose of magnesium sulfate ([Shamsuddin et al. 2005](#)). NGO programs are testing the distribution and training of CHWs and volunteers, so they can give a loading dose in the case of severe PE or eclampsia and then refer patients to a facility for treatment (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010).

Misoprostol

Scaling-Up Community Administration of Misoprostol

Training CHWs to administer misoprostol to women in labor in the home has been a successful strategy to increase misoprostol access. Some countries have participated in pilot studies of community-based programs, but little has been done to scale up the intervention (MAISHA 2013). In Yemen, for example, no organized community-based program for PPH prevention using misoprostol with home births exists, even though they constitute over 60 percent of deliveries (MAISHA Yemen).

Availability of Misoprostol

While availability of misoprostol is increasing in Asia and sub-Saharan Africa (where the majority of deaths from PPH occur), an interesting finding is the relative decrease in availability of misoprostol as availability of oxytocin increases. One example is a study conducted in Tanzania where availability of misoprostol dropped by 14 percent from baseline to endline as availability of oxytocin increased by more than a third (Harvard School of Public Health—MHTF 2012).

Quality

A Concept Foundation study showed that significant problems with many misoprostol finished products existed when analyzed for content and purity. According to analysis of a sample of misoprostol products, the active ingredient degraded rapidly between three months and one year. Because of this rapid degradation, pre-shipment testing may be of little value for an inappropriately manufactured or packaged product. Samples of misoprostol have been shown to have 100 percent content when purchased but have as little as 20 percent potency six months later (MHTRT for the UN Commission on Life-Saving Commodities for Women and Children “Misoprostol Briefing Document” [unpublished document, 2013] UN Commission on Life-Saving Commodities intranet).

Provider Knowledge

A multicountry survey showed that providers at all levels wanted additional evidence-based information and guidance on how misoprostol is used. Specifically, providers wanted more information on use, dosage, route, timing, effectiveness, side effects, cautions, and contraindications (Sherris et al. 2005). Variability exists within countries regarding the level of provider administering misoprostol.

Negative Perceptions of Misoprostol

The association with and potential use of misoprostol in cases of abortion in places where the practice is prohibited may present a barrier for its use and scale-up for treatment of PPH. For example, in Bangladesh, providers were wary about the widespread use of misoprostol. They feared that it might be used as an abortifacient, although the dose and timing for its use as an abortifacient differ from its use as a treatment for PPH (Harvard School of Public Health—MHTF 2012).

Population Awareness

A multicountry survey showed that women and their providers did not have clear and appropriate information about misoprostol (Sherris et al. 2005). In Nigeria, a study found that low community sensitization was a barrier to community-level administration of misoprostol (Prata et al. 2012).

Oxytocin

The review for this paper revealed three oxytocin success stories. The PPH policies, guidelines, and strategies of most countries list oxytocin, and most identify it as the first line choice for treatment. Secondly, in many countries, nearly all health facilities—including lower-level facilities—and most cadres of workers are permitted to use oxytocin. In Bangladesh, nearly all health workers are permitted to use oxytocin at the community level (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010). In Uganda, midwives, clinical officers, and doctors can administer oxytocin (Leahy Madsen, Bergeson-Lockwood, and Bernstein 2010).

Finally, manufacturers appear to be present in all regions. The USAID | DELIVER PROJECT has identified most of the products being marketed worldwide and the companies that are manufacturing the finished pharmaceutical product. The project lists 255 products available worldwide. Of these, some 50 percent are from Asia (India 12 percent, China 7 percent), 23 percent are from Europe (including Russia), and 16 percent are from Latin America. However, this does not enable calculating the number of manufacturing sites, since some brands are imported and others are obtained from contract manufacturers; it is likely that the actual number of manufacturers is around 100. Based on this, it may be possible to propose a business case for oxytocin (MHTRT for the UN Commission on Life-Saving Commodities for Women and Children “Oxytocin Briefing Document” [unpublished document, 2013] UN Commission on Life-Saving Commodities intranet). Despite these successes, a number of challenges still remain to make the supply of oxytocin secure.

Quality

A series of PATH and USP studies in Ghana, India, and Indonesia have raised concerns about the quality of oxytocin, as well as product sterility. Each study has shown considerable problems with the quality of oxytocin formulations. The Indonesia study collected 110 samples of four products (three being generics); 13 failed the content assay (three failed due to too high a content). The USP report on Ghana showed a considerably worse situation: 55.6 percent of the samples failed specification assays, per the monograph in BP2012. Sterility was also determined to be a serious problem as 35 of 40 samples tested for sterility failed. This problem could give rise to a public health crisis and undermine patients’ and providers’ trust in the treatment (MHTRT for the UN Commission on Life-Saving Commodities for Women and Children “Oxytocin Briefing Document” [unpublished document, 2013] UN Commission on Life-Saving Commodities intranet).

Guidance in Pharmacopoeial Monographs

The Oxytocin Briefing Document reveals a lack of appropriate guidance in pharmacopoeial monographs—a particular challenge that has consequences for transport and storage. Inappropriate transport and storage may expose the product to temperatures that lead to degradation. A report found that some product monographs stated “store between 2 and 8°C” while others stated “store below 25°C.”

For many products it is not known whether satisfactory stability data exist to support the labeling on the vial.

Drug Availability

A key informant in Burkina Faso identified the maintenance of acceptable stock levels as an important strategy to increase access and use of oxytocin. Yet a number of countries identify stockouts as a barrier. In 2007, Mozambique experienced stockouts approximately 20 percent of the time in bigger health facilities and 40 percent of the time in smaller health facilities (MHTRT for the UN Commission on Life-Saving Commodities for Women and Children “National Needs Assessment” [unpublished document, 2007] UN Commission on Life-Saving Commodities intranet). However, data from the latest (2012) nationally representative UNFPA estimates of stockouts for oxytocin showed rates of less than 10 percent in all levels and types of facilities (MAISHA Mozambique). As in many countries, drug availability is a problem in certain zones in Tanzania (Harvard School of Public Health—MHTF 2012).

In Bangladesh, CSBAs are supposed to carry a range of delivery supplies, including oxytocin and misoprostol; however, it is unclear whether a functioning or established process exists to resupply CSBAs in the community (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010).

Variable Use and Coverage

Several countries had variable coverage and use of oxytocin depending on the setting, sector, or type of provider. In Bangladesh, a study of health facilities found that only 55 percent of district hospitals and 38 percent of Upazila health centers reported having oxytocin (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010). In Mozambique, estimates indicated an overall 44 percent rate of national uterotonic coverage between public and private sectors. Confidence exists in the coverage estimates in the community (0 percent) and in private facilities (100 percent). However, uncertainty exists regarding uterotonic coverage in public sector facilities, where coverage estimates for uterotonic in the third stage of labor vary between 62 percent and 94 percent (MAISHA Mozambique). While no independent evaluation of private providers exists, an expert panel in Tanzania believes that private providers do not consistently use uterotonics, whereas more recently trained providers are more likely to use oxytocin. They estimate that uterotonics are used about half of the time in deliveries in private individual provider settings (MAISHA 2013).

In Yemen, facility estimates for the access rate for uterotonic use was based on a combination of factors, including availability of stock, availability of private pharmacies, ability to pay, and frequency with which facilities provide it to women who cannot afford the drugs (MAISHA Yemen). Finally, an important issue was raised in Mozambique: Skilled attendants did not deliver at home, so injectable uterotonic use was nearly zero (MAISHA Mozambique).

Cold Chain Capacity

It is not surprising that a lack of cold chain capacity was identified as a significant challenge. In Bangladesh, storage capacity at all facility levels lacked space and temperature control. Only 4 percent of facilities could store oxytocin at appropriate temperatures (Harvard School of Public Health—MHTF 2012). Similar issues were identified in India and Burkina Faso (Harvard School of Public Health—MHTF 2012). In Bangladesh, concerns surrounded CHWs’ administration of oxytocin, as cold chain

capacity was not available at the community level outside of certain facilities (Harvard School of Public Health— MHTF 2012).

Concerns around Rational Use

The inappropriate use of oxytocin was identified in several countries. In Palestine, seven out of eight hospitals observed reported high caseloads and overcrowding. As a consequence, oxytocin was frequently used to expedite normal labor, despite the risks involved with its use in situations where labor is not closely monitored (Wick et al. 2005). In India, concerns that the drug would be used inappropriately for induction and augmentation of labor were reported (Deepak et al. 2013). WHO has raised concerns about the administration of oxytocin prior to delivery in peripheral health facilities or by low-level health workers. Those actions may result in inappropriate use, which may lead to uterine rupture, fetal asphyxia, or fetal demise.

Provider Knowledge

A number of gaps in provider knowledge were identified, ranging from physicians holding a variety of misbeliefs regarding oxytocin and inconsistent indications for using the medicine. In India, most providers did not know how or under what conditions to store oxytocin in facilities. The study also found that some healthcare providers were not aware of the potential side effects (Deepak et al. 2013). Concerns were raised about community level CSBA training in Bangladesh not being sufficient to ensure that attendants were competent in home deliveries (Bergeson-Lockwood, Leahy Madsen, and Bernstein 2010).

Patient Perceptions of Oxytocin

In India, misconceptions were identified around the use of oxytocin. Women and family members were not fully aware of the effects and purpose of uterotonic. They thought that oxytocin only increased labor pains and sped up delivery. Still, some women present to health facilities insisting on receiving uterotonic; women and their families routinely pressure healthcare workers to provide oxytocin (Deepak et al. 2013).

Annex 3: Resources

- 1) Background of the development and use of various CS frameworks—
 - SPARHCS: (<http://www.policyproject.com/pubs/monographs/SPARHCS.pdf>)
 - HIV and AIDS:
(http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/HivaCSFram.pdf)
 - Essential medicines:
(http://deliver.jsi.com/dlvr_content/resources/allpubs/policypapers/CSEssMedChall.pdf)
- 2) Barriers to Magnesium Sulfate Literature Review by subgroup, specifically the section on availability of supplies; List of Manufacturers
- 3) Harvard School of Public Health Maternal Health Taskforce, Maternal Health Commodities: Case Studies from Bangladesh, India, Ethiopia, Nigeria, Tanzania, and Uganda
<http://www.mhtf.org/2012/05/22/maternal-health-commodities-country-case-studies-for-bangladesh-india-ethiopia-nigeria-tanzania-and-uganda/>
- 4) Misoprostol Briefing Document
- 5) Other lists of essential, priority, or life-saving medicines for women and children developed by international organizations, such as—
 - WHO Priority Medicines for Mothers and Children 2011
(<http://www.who.int/medicines/publications/A4prioritymedicines.pdf>)
 - WHO Priority Medicines for Mothers and Children 2012
(<http://apps.who.int/medicinedocs/documents/s19290en/s19290en.pdf>)
 - 2006 *Interagency List of Essential Medicines for Reproductive Health*
(http://whqlibdoc.who.int/hq/2006/WHO_PSM_PAR_2006.1_eng.pdf)
- 6) Oxytocin Briefing Document
- 7) PAI case studies and reports listed in the work plan (Bangladesh and Uganda
<http://populationaction.org/topics/maternal-health/>)
- 8) PATH report *Safeguarding Pregnant Women with Essential Medicines*
(http://www.path.org/publications/files/ER_mhs_policy_rpt.pdf)
- 9) Priority Medicines for MCH: A Global Survey of EMLs
- 10) Reproductive Health Supplies Coalition resources and tools
(<http://www.rhsupplies.org/resources-tools.html>)
- 11) UNCoLSC Advocacy Working Group recently launched an advocacy toolkit called Scaling Up Lifesaving Commodities for Women, Children, and Newborns.

- 12) UNCoLSC Pathfinder countries landscape analysis
(<http://www.mhtf.org/2012/05/22/maternal-health-commodities-country-case-studies-for-bangladesh-india-ethiopia-nigeria-tanzania-and-uganda/>)
- 13) UNCoLSC Recommendation 6, Outcome 1: Good Practice in Supply Chain Management: Challenges and Barriers along the In-Country Supply Chain (<http://siapsprogram.org/wp-content/uploads/2014/07/14-076-Barriers-Supply-Chain-Format.pdf>)
- 14) UNFPA contraceptive/commodity security implementation results documents, such as—
- *Ten Good Practices in Essential Supplies for Family Planning and Maternal Health* (<http://www.unfpa.org/public/home/publications/pid/11457>) and
 - *Key Data and Findings: Medicines for Maternal Health* (<http://www.unfpa.org/publications/medicines-maternal-health>)
- 15) USAID-supported MCHIP resources and tools (toolkits, operation research, acceptance studies, integrated reviews, implementation reports, pilot studies, etc.)
- <http://www.mchip.net/resources>
 - <http://www.mchip.net/node/2115>
 - <http://www.mchip.net/sites/default/files/Miso%20Expansion%20Guide.pdf>
 - National Programs for PPH and PE/E Global Survey, 2012
 - MCHIP country reports
 - MCHUIP QOC briefs
- 16) Various peer-reviewed articles on the three MH commodities identified through a MEDLINE/PUBMED cross-cutting search using the content identified through the conceptual framework components
- 17) Wilson Center – *Delivering Success: Scaling Up Solutions for Maternal Health* (http://www.wilsoncenter.org/sites/default/files/Delivering_Success.pdf)

