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Increasing Access to Essential Maternal Health Supplies

A scoping of market-based activities, gaps and opportunities

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RESULTS FOR DEVELOPMENT

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Foreword

When the Reproductive Health Supplies Coalition commissioned our partner R4D to develop this landscape study, it was with the knowledge that nearly 40 percent of all maternal deaths could be prevented by greater access to just three maternal health medicines: magnesium sulfate, misoprostol, and oxytocin. In this study, R4D explores the role effective market shaping could play in making these supplies more affordable, safer, and ultimately more accessible to all who need them. The application of market shaping—which seeks to leverage the purchasing power of buyers to increase the availability, quality, and equitable distribution of key reproductive health (RH) supplies—has grown in recent years, especially in the family planning (FP) space. Indeed, more than 20 organizations currently work on FP market-shaping interventions, with investments reaching as high as $315 million.[1] Many of these interventions were undertaken under the auspices of the Coalition, with the result that today we are widely seen as both a repository of critical lessons and source of new ideas. In 2014, we published, together with Dalberg Global Development Advisors, a comprehensive analysis of opportunities to improve the effectiveness of family planning markets which remains as a guiding text for market shaping efforts.

While the benefits of market shaping are certainly evident across the family planning space, the same cannot be said for maternal health. Lower prices, smaller volumes and fragmented procurement undermine many of the market shaping opportunities present in the market for contraceptives. So in 2015, we launched a new effort to leverage our knowledge of the marketplace for the benefit of key maternal health supplies. With generous funding from the MacArthur Foundation, we have begun exploring the role market shaping can play in increasing access to maternal health supplies. And this report constitutes the first step in that process. By focusing its work on three diverse country contexts: Nigeria, Ethiopia and Bangladesh, the study draws on input from relevant supply- and demand-side actors, to map the MHS market. It then identifies gaps and opportunities as a basis for recommending future market shaping interventions.

Ensuring access to safe and affordable Maternal Health Supplies has been an ongoing priority for the Coalition – for they too are reproductive health supplies. It has led to the establishment of a distinct community of practice known as the Maternal Health Supplies Caucus. It has inspired our active engagement with at least two Technical Resource Teams of the UN Commission on Lifesaving Commodities. And with the winding down of Commission activities later this year, it has prompted a groundswell of support to take on what remains of the Commission's unfinished agenda.

This report represents in many ways the foundation stone for what we hope will be a host of new initiatives in the years to come. Some of these will be financed through our small grants program, the Innovation Fund; others through the work of individual member organizations. Either way, we see the benefits of market shaping as offering brighter, safer future for millions of women and their children.

John P. Skibiak
Director, Reproductive Health Supplies Coalition

Acronyms

ADDO	Accredited Drug Dispensing Outlet
Amox DT	Amoxicillin dispersible tablets
BEmONC	Basic Emergency Obstetric and Newborn Care
CARhs	Coordinated Assistance for Reproductive health supplies
CHAI	Clinton Health Access Initiative
CMSD	Central Medical Stores Department
CRVS	Civil Registration and Vital Statistics
CSP	Coordinated Supply Planning
DfID	United Kingdom's Department for International Development
DGDA	Directorate General of Drug Administration
DGFP	Directorate General of Family Planning
DGHS	Directorate General of Health Services
DHS	Demographic and Health Survey
DMSMA	Drug and Medical Supplies Management Agency
EAC	East African Community
EMA	European Medical Agency
EPI	Expanded Program on Immunization
ERP	Expert Review Panel
FDA	US Food and Drug Administration
FMHACA	Food, Medicine and Health Care Administration and Control Agency
FMOH	Federal Ministry of Health
GFF	Global Financing Facility
GMP	Good Manufacturing Practices
HMIS	Health Management Information System
IM	Intramuscular
IMPAC	Integrated Management of Pregnancy and Childbirth
ISO	International Organization for Standards
IU	International Unit
IV	Intravenous
JSI	John Snow, Inc.
LGA	Local Government Authority
LMICs	Low- and middle-income countries
LMIS	Logistics Management Information System
LTA	Long-term agreement
MAS	Mobile Authentication Services
MDAWG	Market Dynamics Approaches Working Group
MDGs	Millennium Development Goals

MHS	Maternal health supplies
MNCH2	Maternal Newborn and Child Health Program
MSH	Management Sciences for Health
NAFDAC	National Agency for Food and Drug Administration and Control
NDRA	National Drug Regulatory Authority
OGSB	Obstetric and Gynecological Society
PE/E	Pre-eclampsia/eclampsia
PEPFAR	President's Emergency Plan for AIDS Relief
PFSCM	Partnership for Supply Chain Management
PPH	Post-partum hemorrhage
PPMR	Procurement Planning and Monitoring Report
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
R&D	Research and development
R4D	Results for Development Institute
RFP	Request for Proposals
RHSC	Reproductive Health Supplies Coalition
SDGs	Sustainable Development Goals
SCMS	Supply Chain Management System
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SMOH	State Ministry of Health
SPHCDA	State Primary Health Care Development Agency
SRA	Stringent Regulatory Authority
TFDA	Tanzanian Food and Drug Authority
TRT	Technical Resource Team
TTI	Time-Temperature Indicator
UN	United Nations
UNCoLSC	United Nations Commission on Life-Saving Commodities for Women and Children
UNHCR	United Nations High Commission for Refugees
UNICEF	United Nations Children's Fund
UNIDO	UN Industrial Development Organization
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
USD	United States dollars
USP	United States Pharmacopeia
VSI	Venture Strategies Innovations
WHO	World Health Organization
WHO CR	World Health Organization Collaborative Registration procedure

Executive summary

At the launch of the Sustainable Development Goals (SDGs) period, it is important to reflect on the progress made during the previous Millennium Development Goals (MDGs) era, and to look forward to advancements needed. Notably, while the global maternal mortality ratio has declined by 45% since 1990,[2] it is far short of the 75% reduction target set by MDG 5, causing maternal health to be the most lagging of the development goals.[3] In this next phase of the global development agenda, maternal health has again been prioritized; the very first target of the health-related SDGs is focused on reducing the number of women who die in pregnancy or childbirth to less than 70 per 100,000 live births by 2030 (currently, 239 mothers die per 100,000 live births in the developing world).[4,5]

Globally, the two leading causes of maternal mortality are post-partum hemorrhage (PPH) and pre-eclampsia/eclampsia (PE/E) – together comprising 40% of all maternal deaths.[6] Fortunately, treatments exist for combatting these conditions. Oxytocin and misoprostol are both used to prevent and treat PPH, while magnesium sulfate is the most effective agent for treating seizures associated with PE/E. Although all life-saving commodities are important, these three maternal health supplies (MHS)[a] are often essential during fatal, emergency circumstances. As such, increasing the availability, affordability and quality of these MHS is critical to reduce pregnancy-related deaths.

To catalyze these efforts, the Reproductive Health Supplies Coalition (RHSC), under a generous grant from the John D. and Catherine T. MacArthur Foundation, commissioned Results for Development Institute's (R4D) Market Dynamics practice area to map existing market shaping activities, and identify key gaps and opportunities where market interventions could help strengthen the availability of high-quality oxytocin, misoprostol, and magnesium sulfate in the public sector.

The scope of the analysis focuses on four key market areas – quality assurance and verification mechanisms, and product appropriateness on the supply side; and forecasting and procurement practices on the demand side[b]. Through desk research, in-depth interviews with over 120 key stakeholders, and two country visits, R4D analyzed the MHS public sector market at the global level and in three focus geographies — Ethiopia, Nigeria (with a focus on analyzing the market at the national level and in Kaduna State), and Bangladesh. These three countries across Africa and South Asia represent 25% of all global maternal deaths,[7] diverse levels of market centralization, and varied local manufacturing capacity, providing rich lessons on scaling up access to MHS.

Supply: Currently, only two oxytocin, three misoprostol and one magnesium sulfate high quality verified products[c] (across global and local manufacturers) are registered in at least one low- and middle-income country where the burden of maternal mortality disproportionately lies. Across seven of these countries, just over one high-quality verified oxytocin and misoprostol products are registered on average in each country. More concerning is the fact that a high quality verified magnesium sulfate product is only registered in one of the seven countries, Nigeria,[8] signaling that access to high quality verified products is extremely limited. Simultaneously, National Drug Regulatory Authorities (NDRAs) are registering products that are not WHO-PQ or SRA approved or WHO-ERP recommended, possibly contributing to the prevalence of substandard MHS. For example, 65% of oxytocin samples collected from ten countries had sterility issues,[9] and 70% of misoprostol products are estimated to be of substandard quality in Nigeria.[10]

a In this report, maternal health supplies (MHS) will exclusively refer to oxytocin, misoprostol and magnesium sulfate.

b This report uses the term 'forecasting' to refer to the full forecasting and supply planning process. It should be noted that this is slightly different than the definition offered by the United Nations Commission on Life Saving Commodities, which considers these two activities to be separate, though both part of the quantification process

c In this report, "high quality verified" refers to manufacturers and products that have gained approval or recommendation from internationally recognized quality assurance mechanisms, specifically a Stringent Regulatory Authority (SRA), the World Health Organization Prequalification program (WHO PQ), or WHO Expert Review Panel (WHO ERP).

Additionally, MHS products can be difficult to store and use in low-resource settings, resulting in quality degradation, wastage and limited product uptake. Specific challenges include limited shelf life, cold chain storage requirements, inefficient product formulation fragmentation, and mandatory intravenous or intramuscular administration. As a result of these quality assurance and product appropriateness inefficiencies, mothers in high burden countries are often exposed to suboptimal products and care.

Based on the insights gathered from stakeholders and experts, and in-depth analysis of the data collected, R4D has identified several recommendations for future activities to address supply-side inefficiencies. While the market inefficiencies identified are undoubtedly complex and nuanced, these recommendations aim to offer overarching solutions that can then be adapted to local and regional contexts.

- *Increase the number of high quality verified products registered at country-level*: Ongoing efforts supporting international and local MHS manufacturers to seek approval from high quality verification mechanisms have been successful, and should continue and intensify. Additionally, reducing the information asymmetry between suppliers and national public sector actors – through country-specific business cases, and increasing awareness of national registration processes – could increase the number of registered high quality verified MHS in high burden countries. Lastly, harmonizing registration processes could reduce transaction costs faced by manufacturers and NDRAs. For example, the WHO collaborative registration procedure has helped to expedite the registration process across 27 participating NDRAs, including Ethiopia and Nigeria.[11]
- *Conduct research to identify and scale up cost-effective tools to combat substandard and counterfeit drugs:* The important work to improve governments' capacity to prevent, identify and remove substandard and counterfeit drugs should continue. Simultaneously, a number of anti-counterfeit tools are currently helping consumers identify low quality products in many countries, including Ethiopia, Nigeria, and Bangladesh. Research to determine the effectiveness of these mechanisms, such as anti-counterfeit packaging designs, Mobile Authentication Services, and hotlines, would help identify those that are the most cost-effective and should be scaled. Given that substandard and counterfeit drugs are challenges across many health commodities, coordination with other health sectors could help ensure the efficient use of resources.
- *Provide guidance on usage, and improve appropriateness of MHS in low-resource settings:* To address challenges related to MHS product appropriateness, guidance on implementing oxytocin integration into national Expanded Program on Immunization cold chains and consistent communication around the storage requirements of oxytocin, would be beneficial. For magnesium sulfate, rationalizing (i.e. thoughtfully reducing) product formulations from as many as ten different concentrations (ranging from 1% up to 50%) to two (20% and 50%) could facilitate easier and faster treatment of women with PE/E. In the long term, continuing research to develop thermostable oxytocin as well as misoprostol and magnesium sulfate that have longer shelf-lives, in addition to investing in market shaping strategies for forthcoming product formulations, such as inhalable oxytocin and thermostable carbetocin, could facilitate rapid scaling of improved MHS commodities.

Demand: At global- and country-levels, a lack of robust and actionable forecasts, paired with inefficient procurement practices, have contributed to inconsistent availability of affordable MHS in high burden countries, especially in the case of misoprostol and magnesium sulfate. In a 2014 progress report of the United Nations Commission of Life-Saving Commodities, 80% of health facilities across ten countries did not have misoprostol in stock.[12] Similarly, approximately 25% of facilities globally fail to stock magnesium sulfate. [13]

Jhpiego's 2014 business cases for oxytocin, misoprostol and magnesium sulfate, which included estimates of addressable market sizes by region[14,15,16] have greatly increased market visibility for MHS. These cases should be built upon to project future demand, which would help suppliers and procurement agencies plan their capacities and orders moving forward. Ideally, such global projections would be informed by robust national forecasts; however, there are a number of factors impeding the development of high-quality quantifications at the country-level. In a review of six forecasts across the focus geographies of this report,[d] two key weaknesses were identified: limited high quality underlying data and inconsistent methodologies. For example, consumption data was not included in any of the six forecasts, and five of the six

d This report reviewed one forecast from Ethiopia, four from Nigeria (one national forecast and three from Kaduna State), and one from Bangladesh.

forecasts also lacked morbidity data. Furthermore, forecasts were often not linked to supply planning, reducing the probability that the required commodities would be procured. This consequence is particularly evident in Kaduna State in Nigeria where only 17-49% of forecasted MHS need was procured from 2013 to 2015.[17]

Fragmented procurement also contributes to noted availability issues. Limited coordination amongst numerous global, national and sub-national MHS procurers has created some challenges in understanding current supply volumes and being able to respond quickly to mitigate stockouts. In Bangladesh, where there are several public sector procurers, surveyed facilities stocked out of oxytocin and magnesium sulfate almost 50% of the year, and misoprostol almost 25% of the year.[18] In addition, the fragmented landscape means that each procurement agent places smaller individual orders, which decreases their ability to negotiate lower prices. Despite the relatively low unit costs of the MHS, the highest-priced MHS product procured across three global entities in a single year costs ten times the lowest price. As a result of these forecasting and procurement practice inefficiencies, oxytocin, misoprostol and magnesium sulfate are not consistently available when expecting mothers need these life-saving commodities the most.

Based on the insights gathered from stakeholders and experts, and in-depth analysis of the data collected, R4D has identified several recommendations for future activities to address demand-side inefficiencies.

- *Strengthen country-level data collection systems:* Existing platforms, such as national Demographic and Health Surveys (DHS) and Civil Registration and Vital Statistics (CRVS), should be leveraged and adapted to collect country-specific, or even state-specific maternal mortality and morbidity information. Additionally, stakeholders should continue their work to build countries' capacities to continuously track MHS availability and consumption data through strengthening and integrating Health Management Information Systems and Logistics Management Information Systems, and ensuring maternal health indicators are included. These efforts are key foundations for improved forecasts.
- *Improve forecast development:* Ongoing work to increase countries' capacities to utilize robust methodologies when developing forecasts should continue and intensify. Such efforts should ensure wastage and buffer stock, commodities' multiple uses, and appropriate product formulations are considered. It will also be important for projections to reflect the gradual changes in demand of MHS as guidelines are updated and providers are trained. Lastly, it is critical for forecasts to inform supply plans. As such, existing stock levels and geographic-specific MHS prices should be accounted for, and relevant budgeting and procurement stakeholders should be included in forecast development.
- *Reduce lead times and coordinate procurements, when possible:* Long-term agreements and other means being explored to reduce MHS delivery lead times, such as the United Nations Population Fund's pilot of holding dedicated stock at wholesalers, can be helpful in reducing stockouts. Efforts to coordinate procurement are also meaningful to explore. This could be accomplished by replicating or integrating MHS into existing successful mechanisms, such as RHSC's Coordinated Supply Planning or the Coordinated Assistance for Reproductive Health Supplies. Similar efforts to consolidate MHS procurement at the country-level could also be explored.
- *Increase market transparency on price ranges:* Increasing market transparency could help rationalize pricing and improve affordability. For example, existing platforms, including AccessRH, could be leveraged to list a range of MHS prices provided by manufacturers, wholesalers, and procurement agencies. This information could better equip procurers during their sourcing and negotiation process with MHS suppliers, which should help stabilize prices.

As noted above, the barriers limiting access to high-quality and affordable MHS are complex. In particular, the fragmented nature of procurement as well as product appropriateness challenges, including product formulation and usage issues, requires longer-term, and more national, or even sub-national level, interventions. Such activities are sometimes referred to as "market development" and are seen to be distinct from "market shaping"[19] efforts that are typical in more centralized commodity markets. R4D hopes that the analysis described in detail in this report will contribute to more efficient markets for the essential MHS, and in turn, a dramatic reduction in mothers' deaths.

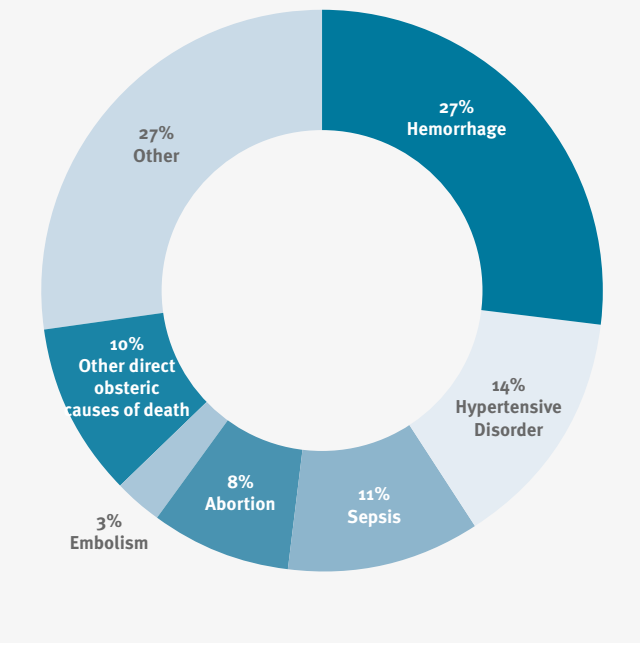
1. Introduction

Since 1990, maternal mortality has declined by 45% around the world. However, approximately 800 women still die every day from preventable causes related to pregnancy and childbirth.[20] As the period for achieving the Millennium Development Goals (MDGs) comes to an end, it is noteworthy that of all the MDGs, the goal of reducing maternal mortality by 75% has seen the least progress.[21] Further, the vast majority of the maternal mortality burden continues to be borne disproportionately by women in low- and middle-income countries (LMICs), where 99% of maternal deaths occur.[22] The two leading causes of maternal mortality globally are post-partum hemorrhage (PPH) and pre-eclampsia/eclampsia (PE/E) – which, combined, comprise about 40% of all maternal deaths (Figure 1).[23]

The United Nations Commission on Life-Saving Commodities for Women and Children (UNCoLSC) has identified three essential products to prevent maternal mortality globally — oxytocin, misoprostol, and magnesium sulfate. Oxytocin and misoprostol are both used to prevent and treat PPH, while magnesium sulfate is the most effective agent for treating seizures associated with PE/E. These products are relatively low-cost, averaging $0.70 US dollars (USD)[e] for a course of PPH treatment with oxytocin and $1.38 for a course of PPH treatment with misoprostol, while a course of PE/E treatment with magnesium sulfate, depending on the treatment regimen, costs on average $7.94 or $10.54.[24] For comparison, a course of treatment for tuberculosis averages $2,000.[25]

Despite this, many expecting mothers in high burden countries do not have access to these three essential maternal health supplies (MHS), particularly high quality verified products.[f] While oxytocin is relatively available in health facilities in high burden countries, the quality of those products are of serious concern, with 65% of oxytocin samples across ten low-income countries found to be of substandard quality.[26] Misoprostol and magnesium sulfate are relatively less available than oxytocin; in the 2014 progress report of the UNCoLSC, 80% of health facilities across ten countries did not have misoprostol available.[27]

Figure 1. Causes of maternal mortality globally[22]



Similarly, approximately 25% of facilities globally fail to stock magnesium sulfate.[28]

In response to these challenges, the Reproductive Health Supplies Coalition (RHSC), under a generous grant from the John D. and Catherine T. MacArthur Foundation, commissioned Results for Development Institute's (R4D) Market Dynamics practice area to scope the market shaping gaps and opportunities in the public sector for the three maternal health commodities.

The term "market shaping" has been previously defined as referring to "activities by global health actors that seek to proactively influence the dynamics of a given market. Such interventions are typically short-term in nature and are explicitly intended to redress disruptions impeding desired key health outcomes."[29] Such activities center on improving affordability, availability, quality, and market introduction timelines of appropriate medicines. Various actors have been implementing market shaping activities in the maternal health space. For example, the World Health Organization (WHO), the UNCoLSC Maternal Health Technical Resource Team (TRT),

e In this report, all prices listed are in U.S. Dollars (USD).

f In this report, Maternal Health Supplies (MHS) refers to oxytocin, misoprostol, and magnesium sulfate. High quality verified products are those that are Stringent Regulatory Authority-approved, WHO Prequalified or WHO Expert Review Panel-recommended.

and the Concept Foundation, in collaboration with RHSC's Generic Manufacturers Caucus, have been working with MHS suppliers to improve the manufacturing base of high quality products. Meanwhile, on the demand side, John Snow, Inc. (JSI) and Management Sciences for Health (MSH) have been working with countries to improve forecasts and procurement practices of MHS. Additional ongoing market shaping activities are described in Section 6.1.

With these activities as context, this report specifically seeks to take stock of key remaining challenges and to highlight future opportunities to shape the markets for oxytocin, misoprostol, and magnesium sulfate, by accomplishing the following:

1. Identify existing maternal health market shaping activities and the inefficiencies they are addressing;
2. Analyze supply-side barriers specifically related to the quality of existing MHS in the market and the availability of products appropriately designed for low-resource settings;
3. Analyze demand-side barriers specifically related to the availability of high-quality forecasts and optimal procurement practices; and
4. Develop recommendations and next steps to improve the MHS market.

The analyses focus on the global level but also include a deeper study into three countries with distinct health environments: Ethiopia, Nigeria, and Bangladesh.

It is worth noting that MHS and other life-saving commodities face some common market barriers – such as, quality concerns around local manufacturers and the presence of counterfeit drugs on the supply-side, and problematic forecasting methodologies and inefficient procurement practices on the demand-side. As such, some of the analyses and recommendations included in this report are relevant for multiple product areas, particularly low-cost life-saving commodities.

Ultimately, the objective of this report is to increase the understanding of gaps in the MHS markets, and of potential future market-based activities to ensure all expecting mothers, regardless of where they live, have access to high-quality and affordable maternal health commodities.

2. Methodology

In consultation with the RHSC, R4D focused its scope on four key areas of the MHS markets – quality assurance and verification mechanisms as well as product appropriateness[g] on the supply side; and forecasting and procurement practices on the demand side.

These analyses were conducted at the global level, with a particular emphasis on the opportunity to improve the supply side of these markets. In addition, three countries were chosen as focus geographies for deep-dive explorations — Ethiopia, Nigeria (with a focus on both national level and Kaduna State), and Bangladesh. The inclusion of country-specific analyses is particularly relevant for the demand side of the market, given how significantly forecasting and procurement practices vary at the national level and sub-national level. (For stakeholders interested in an overview of the oxytocin, misoprostol, and magnesium sulfate markets in other countries, the UNCoLSC has compiled dashboards that provide a helpful overview of markets in 87 countries.[30])

The focus geographies of this report were selected based on two criteria — level of maternal mortality burden and health system structure — and were optimized to ensure diversity of learnings with potential for broader application. Ethiopia, the fourth largest contributor to global maternal mortality,[31] has a highly centralized health system, with national level forecasting and procurement mechanisms. In contrast, Nigeria, the largest contributor,[32] is very decentralized, with varying sub-national health system structures. Within Nigeria, Kaduna State is an interesting case study, as the third most populous state in the country, and a maternal mortality rate that is nearly 50% more than that of the national average – 1,025 deaths per 100,000 live births compared to 704 deaths per 100,000 live births respectively.[33] This high burden is thankfully coupled with the presence of multiple non-governmental organizations (NGOs) working to increase access to the essential MHS, and a new initiative by the state government to track all causes of maternal mortality. Across both Ethiopia and Nigeria, there are currently no local manufacturers of the MHS. Offering a useful comparison, Bangladesh has a vibrant local manufacturing sector, which includes the three essential MHS. The country ranks as the 10th highest contributor to maternal mortality,[34] and has a moderately decentralized health system. Together, these three East African, West African, and South Asian countries represent 25% of all global maternal deaths,[35] diverse levels of market centralization, and varied local manufacturing capacities, providing rich lessons on scaling up access to MHS that could potentially be adapted to other geographies.

To inform our analyses, R4D collected global and country-level data from three sources: document review, in-depth stakeholder interviews, and field visits.

Document review

R4D collected a variety of qualitative and quantitative data from a rigorous document review process. The types of documents reviewed included:

- Global and national treatment guidelines for post-partum hemorrhage and pre-eclampsia/eclampsia;
- Government documents on health system structure and public procurement agency practices;
- Market-sizing exercises for the essential MHS, conducted by Jhpiego in collaboration with RHSC;
- Forecasts and quantifications of the MHS, performed by a variety of public and non-governmental organizations; and
- Research on a variety of topics, including quality levels of products currently on the market, effectiveness of anti-counterfeit programs, and forthcoming product innovations.

In-depth interviews

Research was also conducted through a series of key in-depth stakeholder interviews, both over the phone and in-person. Stakeholders interviewed included global and country-level (from the three focus countries) representatives of pharmaceutical companies and wholesalers, procurers, non-governmental agencies, government officials from the health sector, and product innovators and researchers. In total, in-depth interviews with over 120 stakeholders were conducted.

g "Product appropriateness" refers to whether or not the product's design and qualities are appropriate for low-resource settings.

Focus geography field visits

Field visits to two of the three focus geographies – Ethiopia and Bangladesh – were also conducted. Over the course of about a week in each country, R4D team members met with stakeholders to discuss key challenges and opportunities in the local public sector MHS markets, and to collect data. Visits to health centers also enhanced R4D's understanding of the operational environments.

Once R4D gathered data from these three sources, the team conducted a series of quantitative and qualitative analyses, the results of which are outlined below. Each key area is discussed in detail, beginning with a brief summary of the current landscape, followed by descriptions of specific market inefficiencies (in bold and underlined font) and the impact on the MHS market. Each market inefficiency description concludes with recommendations for market-based activities at both the global- and country-levels.

3. Supply-side market analysis

3.1. Quality assurance and verification mechanisms

Through the efforts of many stakeholders, there have been significant accomplishments in the realm of quality assurance (QA) for MHS. For example, a number of organizations, most notably the WHO, the UNCoLSC Maternal Health TRT, the Concept Foundation and RHSC have worked with generic MHS manufacturers to improve production practices and achieve WHO Prequalification (WHO PQ). While there are Stringent Regulatory Authority (SRA)-approved MHS products, many of these are only available in developed countries. WHO PQ is one mechanism that helps increase access to MHS by setting high quality standards for products that are available in LMIC markets.

An "Invitation for Expressions of Interest" for PQ for oxytocin, misoprostol and magnesium sulfate was issued by the WHO in 2010. However, the first oxytocin product was only prequalified in April 2015. Similarly, the first misoprostol product was prequalified in April 2014, with a second one added to the WHO PQ list in November 2014 after gaining approval through European Medicines Agency (EMA) article 58.[40, h] To date, there are no magnesium sulfate products on the WHO PQ list. In the future, the number of prequalified MHS products may increase, as it has been reported that at least two additional oxytocin, one additional misoprostol, and two magnesium sulfate products are currently pursuing WHO PQ.[41] Separately, there are two or more additional oxytocin products with SRA approval available in LMICs, and one WHO Expert Review Panel (WHO ERP)-recommended misoprostol product.[i] While there are SRA-approved magnesium sulfate products, those manufacturers that are known are supplying mostly to developed countries.[42,43] (See Figure 2 for descriptions of WHO PQ, SRA, and WHO ERP mechanisms.) Collective efforts have catalyzed the availability of high quality verified MHS and should continue; however, additional activities to increase country-level registration of such products, and reduce the presence of unknown quality commodities are also needed (see Figure 3 for descriptions of "high quality verified," "unknown quality," "substandard," and "counterfeit" terms).

h EMA article 58 is a piece of legislation that allows the EMA to offer a "scientific opinion," with support from the WHO, that certain medical products be available for use outside the European Union, including LMICs.

i There is another misoprostol product with SRA approval, but it is not registered for the PPH indication.

Figure 2. Descriptions of international QA mechanisms

Quality Assurance (QA) mechanism	Descriptions
WHO Prequalification (WHO PQ)	The WHO PQ program increases the availability of high quality medicinal products in LMICs by assessing the quality, safety and efficacy of products.[36]
Stringent Regulatory Authority (SRA)	SRAs are national drug regulatory authorities (NDRAs) that are members, observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This includes the NDRAs from Australia, Canada, the European Union, Japan, the United States, and others.[37]
WHO Expert Review Panel (WHO ERP)	A rapid quality risk assessment mechanism for needed pharmaceutical products that have not completed a stringent assessment. It is a short-term solution (WHO ERP is valid for 18 months for reproductive health products[38]) used to encourage more manufacturers to seek WHO PQ.[39]

Figure 3. Key terminology used to describe quality of MHS products

Term	Descriptions
High quality verified	In this report, "high quality verified" refers to medicinal products that have achieved SRA approval, have been included on the WHO PQ list or have a positive WHO ERP recommendation. Using the three stated quality mechanisms is in alignment with the policies of international procurers, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the Global Drug Facility and United Nations (UN) agencies.[44]
Unknown quality	In this report, "unknown quality" refers to medicinal products that have not achieved an SRA or WHO PQ approval or a recommendation from the WHO ERP. While wholesalers, NGOs and NDRAs each have their own quality assurance mechanisms, the stringency of these mechanisms vary greatly. Given these differences, products without approval from an internationally recognized QA mechanism (i.e. SRA, WHO PQ, or WHO ERP) will be considered to be of "unknown quality" in this report.
Substandard	Substandard medicines are products available in markets whose "composition and ingredients do not meet the correct scientific specifications, and which are consequently ineffective and often dangerous to the patient. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting."[45]
Counterfeit	Counterfeit medicines are products that have been "deliberately and fraudulently mislabeled with respect to identity and/or source," including products with the "correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients."[46]

HIGH QUALITY VERIFIED MHS PRODUCTS ARE LIMITED IN THE GLOBAL MARKET

Currently there are only two oxytocin, three misoprostol, and one magnesium sulfate high quality verified products registered in a few LMICs (see Section 6.2 for a list of known high quality verified MHS manufacturers). This limited pool of MHS accessible in LMICs is driven by a combination of supply-side issues outlined below, and demand-side issues, which are addressed in more detail in Section 4.

With only a few high quality verified suppliers, global procurers' leverage to negotiate rationalized pricing is constrained,[47] causing some pricing inefficiencies. Looking at the procurement of one leading global procurement agency, oxytocin prices peaked in 2015 at 40% higher than the previous two years. More troubling, the highest-priced misoprostol product in 2015 was eight times more expensive than the lowest priced product, and the highest-priced magnesium sulfate product was almost twice as expensive as the lowest priced product. [48,j] In addition, while there is reported consensus that global supply is sufficient to meet current global demand of MHS, it is unclear if capacity could expand rapidly enough to meet potential increases in demand (addressed in more detail in Section 4.1) in the future. If there are capacity constraints, procurers' power to negotiate prices would be further reduced.

Lastly, the limited options of high quality verified MHS, and the very recent completion of the PQ and ERP processes for these products, has meant that international procurement agencies have often been conducting individual product-specific Quality Control (QC) checks on manufacturers (typically on those suppliers that already have factory-level WHO Good Manufacturing Practices, GMP,[k] approval), resulting in potential duplication of efforts and resources.

Recommendations for future market-based activities

Given the limited number of high quality verified MHS products available in the market – especially for magnesium sulfate – existing efforts mentioned above aimed at encouraging and supporting manufacturers in seeking high quality verification should continue to be supported. These efforts could expand to include helping manufacturers understand when they may see a return on investing in these

j While not all of these products are high-quality verified, all have undergone quality testing by established international procurement agencies.

k The WHO defines Good Manufacturing Practices (GMP) as "the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification."

quality improvement and verification mechanisms. (Some MHS suppliers that have achieved high quality verification have reported experiencing limited volume growth in relation to being able to recoup their financial outlays, though such volumes have been growing in recent years.)[49] In conjunction, demand-side efforts could be scaled to create more accurate forecasting and to improve procurement practices so that high quality verified MHS products are preferred to products of unknown quality among high-burden countries.

There may also be additional opportunities to leverage mutual regulatory recognition initiatives, such as EMA article 58, which enabled Linepharma's misoprostol to be available in LMICs. This provision allows the EMA to offer a "scientific opinion," with support from the WHO, on certain medical products of major public health interest that are intended exclusively for use outside the European Union.[50] Similar mechanisms that allow SRA-approved products to achieve both WHO PQ status and market authorization, such as the US Food and Drug Administration (FDA) program currently in place for HIV products,[51] could help increase the number of high quality verified MHS products available in high burden countries.

BOTH HIGH QUALITY VERIFIED MHS AND MHS OF UNKNOWN QUALITY ARE BEING REGISTERED IN HIGH BURDEN COUNTRIES

Turning to the country-level, while a number of organizations, including Venture Strategies Innovations (VSI)[l] and the UNCoLSC Maternal Health TRT, have supported an increased number of high quality verified MHS products registered in high burden countries, unknown quality MHS products are also being registered. Indeed, more oxytocin and misoprostol products of unknown quality are registered than their high quality verified counterparts in many LMIC markets. For example, only one of the three current WHO PQ oxytocin and misoprostol products are registered in high burden countries,[52] and this product is only registered in nine countries (which does not include the three focus countries of this report).[53] Looking beyond WHO PQ to include relevant SRA-approved and WHO ERP-recommended products, we find that across seven high burden maternal mortality markets, an average of just over one high-quality verified oxytocin and misoprostol products are registered in each country (see Figure 4).

Concentrating on the three focus geographies of this report (Ethiopia, Nigeria, and Bangladesh), the number of registered high quality products varies. In both Ethiopia and Nigeria, two SRA-approved oxytocin products are registered. However, only one high quality verified misoprostol product is registered in Nigeria, and none are registered in Ethiopia. In Bangladesh, no high quality verified oxytocin and misoprostol products are registered. Meanwhile, there are a number of products of unknown quality registered in all three markets. Indeed, thirteen oxytocin products of unknown quality are registered in a single country (Nigeria).[54]

The National Drug Regulatory Authorities (NDRAs) in the three focus geographies have also registered magnesium sulfate products – however, none of the six products registered across Ethiopia and Bangladesh are high quality verified, and only one of the five registered in Nigeria is from a high quality verified source.[61]

l VSI has since been absorbed into the activities of the Bixby Center at University of California, Los Angeles.

Figure 4. Number of high quality verified MHS products registered in seven high burden countries [55,56,57,58,59,60]

Country	Oxytocin	Misoprostol
Bangladesh	0	0
Ethiopia	2 SRA	0
India	Unknown	1 WHO PQ
Indonesia	0	0
Nigeria	2 SRA	1 WHO ERP
Tanzania	1 SRA	1 WHO PQ
Uganda	1 SRA	1 WHO PQ

The registration of mixed quality MHS has trickle-down effects on procurement and availability in both the public and private sectors in LMICs. In particular, among a constrained pool of high quality verified products registered in countries, price competition among those may be limited, potentially amplifying price-quality tradeoffs. This issue can become especially problematic in countries like Nigeria and Bangladesh with sub-national procurement systems that are operating with limited oversight and resources. Furthermore, should there be an exogenous shock (such as a sudden reduction in supplier capacity or increased demand for these products,) there may be high quality verified MHS supply security concerns, which in turn could further increase the presence of unknown quality products on the market. Lastly, if suppliers do not perceive that NDRAs value WHO PQ, SRA approval, or WHO ERP, as evidenced by the registration of unknown quality products, they may be less likely to seek these certifications.

Recommendations for future market-based activities

Short term recommendations

To ensure improved accessibility of high quality verified MHS in LMICs, it will be important to continue and intensify existing efforts to encourage country-level registrations. While all countries have distinct registration processes that involve fees, there are a number of strategies that can help suppliers as they enter new markets. Firstly, because many high quality verified MHS manufacturers do not have a local presence in high burden countries, there is often an information gap limiting suppliers' knowledge of national markets. Increasing awareness of countries' registration processes, and leveraging the existing global market sizing exercises[m] to develop country-specific business cases, could improve market transparency among suppliers, thereby reducing the amount of market assessment manufacturers undertake before pursuing registration. Additionally, letters from international organizations, such as the WHO and the United Nations Population Fund (UNFPA), to NDRAs listing high quality verified MHS could catalyze registration where NDRAs may otherwise be unaware of existing high quality verified products. R4D has implemented a similar strategy for amoxicillin dispersible tablets (amox DT), which is one of the thirteen UNCoLSC commodities and is the first-line treatment for childhood pneumonia. By sharing publicly-available country-level forecasts and detailed national registration processes with manufacturers, while updating NDRAs on high quality verified suppliers, R4D has seen an increase in high quality verified amox DT dossier submissions in LMICs. Further, connecting high quality verified manufacturers with in-country partners that are able to support communications with NDRAs and dossier submissions could help facilitate country registrations.

Secondly, maternal health stakeholders could continue efforts to work with partners from other sectors to leverage existing registration harmonization efforts for MHS, such as the WHO collaborative registration procedure (WHO CR). Under this program, the WHO shares prequalified product and quality information (with permission from the supplier) with 27 participating NDRAs, including Ethiopia and Nigeria. There has been early success, with countries registering products through WHO CR (e.g. 22 products in Nigeria[62]), and suppliers reporting a decrease in the length of the registration process from two to three years down to just four months.[63] To date, MHS have not been prioritized, and support is needed to ensure this program is effectively utilized for increased high quality verified MHS registration.

Long term recommendations

Regional harmonization mechanisms may also offer another opportunity to decrease transaction costs faced by both NDRAs and manufacturers during the MHS registration process; for example, the East African Community (EAC), with support from the WHO, is in the process of setting up a harmonized procedure that would allow for one streamlined registration across Tanzania, Uganda, Kenya, Burundi, and Rwanda.[64] The growing momentum around registration harmonization will make it operationally and financially more efficient for high quality verified MHS manufacturers to enter LMIC markets, and it will be important to ensure MHS are included in these efforts.

As long as products of unknown quality are registered in LMICs, donors and financiers can mandate strict quality requirements for products purchased with their funds to ensure national public sector agencies procure high quality verified MHS. For example, the Global Fund the Global Fund to Fight AIDS, Tuberculosis and Malaria requires that all pharmaceuticals purchased through their grants must be WHO PQ, SRA-approved, or WHO-ERP certified.[65] Similar quality standards should be set by other financing facilities operating in the maternal health space, including the World

m Specifically, the co-published RHSC and Jhpiego business cases for investing in production of high-quality MHS (misoprostol, oxytocin, and magnesium sulfate) for low-resource settings.

Bank (in terms of their International Bank for Reconstruction and Development Loans & International Development Association Credits), and the recently-launched Global Financing Facility (GFF). In addition, maternal health donors and financiers could mandate the use of wholesalers with strict QA policies and verification mechanisms already in place for MHS procurement. For example, the United Kingdom's Department for International Development (DfID) is financing the coordination of MHS procurement across six state-level drug management agencies in Nigeria beginning in 2016. All products will be purchased through Crown Agents, an international wholesaler with independent, verified QA procedures. These efforts, alongside other demand-side interventions – such as advocating that public sector national procurement agencies include high quality verification standards in MHS tenders – could help incentivize greater demand and country-level registration of high quality verified manufacturers.

Harmonizing registration and setting quality standards for products financed by international donors and lending agencies are activities that benefit not just MHS, but all medicinal products. As such, it would be valuable for maternal health stakeholders to work with counterparts across the health sectors to ensure efforts are coordinated and resources are used efficiently.

PRODUCTS OF UNKNOWN QUALITY ARE BEING REGISTERED BY NDRAS

Another area that may be limiting access to high quality verified products – for maternal health and more broadly – is the quality of products registered by NDRAs, particularly those that are manufactured locally. While there has been a lot of work done to assist local manufacturers in reaching international quality standards, many have yet to achieve high quality verified status. Additionally, some NDRAs prefer to register locally manufactured products, occasionally in spite of the manufacturers not meeting their own country's quality standards. This preference, combined with large investments needed to attain approvals from high quality verification mechanisms, can dis-incentivize local manufacturers from seeking WHO PQ approval or WHO ERP recommendation.

Certain national governments, including two of the three focus geographies (Ethiopia and Bangladesh), prefer to register and procure from local manufacturers over international ones, even those with WHO PQ or SRA approval, or WHO ERP recommendation. In Ethiopia, although there are currently no local MHS manufacturers (though one reports being able to start manufacturing magnesium sulfate within a few months), the Food, Medicine and Health Care Administration and Control Agency (FMHACA) has historically given preference to locally manufactured drugs, even if they do not meet Ethiopian GMP standards. In contrast, any non-Ethiopian manufacturer seeking registration must meet Ethiopian GMP standards.[66] Similarly, Bangladesh's NDRA, the Directorate General of Drug Administration (DGDA), has only registered locally manufactured MHS products, none of which are WHO PQ or SRA approved, or WHO ERP recommended.[67] While all registered products in theory meet local QA standards, limited DGDA capacity makes enforcing such quality standards challenging. Indeed, a 2008 study revealed that only about 12% of the 300 pharmaceutical companies in Bangladesh comply with Bangladesh's GMP standards.[68] While this study was not specific to MHS, Concept Foundation and UNFPA are preparing to test samples of oxytocin and misoprostol products currently available in the Bangladesh market, which will offer greater insight into the quality of these locally manufactured MHS products.

Another barrier preventing local manufacturers from seeking WHO PQ and WHO ERP is the relatively high financial outlay required. Jhpiego cites that the WHO PQ process could add between 5-12% to the end product cost,[69] and an MHS manufacturer reported having to increase prices by 12.5% after achieving international quality standards, to account for related costs incurred.[70] National procurement agencies typically make tender selections based on multiple considerations, including price and quality. As such, local manufacturers have to make a calculation on whether seeking WHO PQ would lead to more favorable considerations, or price them out of the market.

Since NDRAs do not require local manufacturers to seek global QA approvals, local suppliers are not incentivized to do so. If an NDRA has limited capacity, the quality of local manufactured MHS products is unknown and possibly sub-standard. This not only risks the health of patients, but could lead to patients and providers losing confidence in MHS when sub-standard products are not as effective. In turn, there are reports that this would result in a reduction in usage as providers move to alternative treatments,[71] or to an inappropriate increase in usage as providers unscientifically administer higher doses to compensate for perceived lower therapeutic efficacy of each dose.[72]

Recommendations for future market-based activities

Short term recommendations

In countries where locally manufactured products already exist and are being procured, it is important to continue to explore how to assist local suppliers in achieving high quality verification. This can be accomplished by helping local MHS manufacturers that are already registered to comply with WHO and SRA standards. Continued technical support, through United States Pharmacopeia (USP), Concept Foundation, the UN Industrial Development Organization (UNIDO), and other QA experts, will help local manufacturers understand and map the necessary improvements to achieve high quality verified status. For example, Concept Foundation is already encouraging at least one MHS manufacturer in Bangladesh to seek WHO PQ for an MHS product.[73] While these types of approaches can be resource-intensive, they have helped improve the quality of locally produced drugs in other sectors, and explorations in ways to adapt them to the maternal health space should continue. For example, with support from USP, an Ethiopian supplier was able to improve the quality of their locally manufactured ethambutol, an anti-tuberculosis drug, and it is now ready for the WHO PQ process.[74]

Long term recommendations

As previously mentioned, demand-side interventions that encourage public sector agencies to align national quality standards and registration requirements with international norms, regardless of whether manufacturing sources are local or international, could incentivize more MHS manufacturers to seek WHO PQ or ERP. In countries where governments typically prefer registering and procuring from local manufacturers but where there are no current local MHS manufacturers (such as in Ethiopia), WHO GMP certified local manufacturers could be encouraged to begin production of MHS and meet WHO PQ standards. For oxytocin and magnesium sulfate, local companies manufacturing injectables could be amongst the prioritized targets. These proactive actions could prevent NDRAs from registering MHS with unknown quality in the future.

SUBSTANDARD AND COUNTERFEIT DRUGS ARE PREVALENT IN THE PRIVATE SECTOR

While this report is focused on the public sector, a number of stakeholders in markets with sizeable private sectors – specifically, Nigeria and Bangladesh – were concerned about the prevalence of substandard and counterfeit MHS products available at the country-level. This issue is partially due to the limited capacity of some NDRAs to consistently and comprehensively test quality levels and implement consumer verification mechanisms.

In Nigeria, while the efforts of the local NDRA – the National Agency for Food and Drug Administration and Control (NAFDAC) – have dramatically reduced the prevalence of counterfeit products to around 10% of pharmaceuticals on the market,[75] substandard products remain a significant concern. Additionally, counterfeit drugs have been reported to increase when there are product shortages – suppliers in Nigeria noted that when there are stockouts of popular brands, companies will push out counterfeit versions with similar packaging to capitalize on unmet demand.[76] Bangladesh has also faced challenges with such medicines – the most recently published data estimates that the prevalence of counterfeit or substandard life-saving drugs in Bangladesh was as high as 70% to 80%.[77] Many stakeholders cited limited human resources devoted to QA and QC as the primary reason for substandard drugs being available in the market. Indeed, only one-third of the 3,500 products entering the market in Bangladesh each year are tested by the government.[78] To overcome the resource challenge, DGDA is left to outsource quality testing – including, at times, through utilizing the labs of the pharmaceutical companies themselves.[79] Finally, in Ethiopia, counterfeit and substandard drugs were not highlighted as key challenges, perhaps due in part to a small private sector. FMHACA reports that 7% of drugs in the market are substandard and 0% are counterfeit,[80] with some stakeholders estimating that as little as 3% of drugs currently in the market are substandard.

At the global level, substandard and counterfeit oxytocin and misoprostol appear to be relatively common. An UNCoLSC study undertaken by WHO found that about 65% of oxytocin samples collected in ten countries had sterility problems.[81] PATH and USP quality assessments of oxytocin in India and Indonesia raised similar concerns around sterility of oxytocin products.[82] This suggests that suppliers are not implementing best practices when manufacturing oxytocin. Meanwhile, the Concept Foundation found misoprostol products in the market that degraded three months to one year after production, instead of the standard two-year shelf life. This appears to be due to manufacturing processes that expose the tablets to humidity before packaging, and the utilization of packaging that are not the recommended double-aluminum blister packs.[83] The impact is especially evident in Nigeria, where 70% of misoprostol products are estimated to be of substandard quality.[84]

The availability of substandard and counterfeit drugs in the market further subjects mothers to higher morbidities and a greater risk of mortality. As previously mentioned, it also potentially has two effects on demand — lower efficacy may decrease patient and provider confidence in these products, thereby reducing demand, but there have also been reports of providers increasing treatment doses to unscientifically compensate for perceived lower efficacy. The latter behavior would artificially inflate total demand. Furthermore, manufacturers are dis-incentivized to produce and register high quality verified MHS products in markets where counterfeit drugs are widely available as their brand reputation may be at risk.

Recommendations for future market-based activities

Short term recommendations

At the global level, introducing packaging systems to allow consumers to differentiate between high quality verified products and those of unknown quality may be helpful. For example, one international pharmaceutical wholesaler interviewed for this report includes its brand on all products and inserts its own instructions to allow for their products to be more easily identified.[85] A standardized quality label for WHO PQ, or SRA-approved or WHO ERP recommended products could also help indicate to consumers that products are high quality verified. This type of approach has been undertaken by USP for dietary supplements in the United States as a way to convey QA to the consumer — all USP approved products are affixed with a recognizable quality seal on the label.[86]

At the country-level, given that data on the quality of MHS are still quite limited, additional financial and technical support to conduct external quality tests would be valuable. Many NDRAs are unable to complete quality testing, as it is quite expensive – an oxytocin assay test costs an estimated $150, while currently a misoprostol assay test costs upwards of $1000[87] – and a limited number of labs have sufficient capacity to perform these tests. The efforts of Concept Foundation, UNFPA, United States Agency for International Development (USAID), USP and others to conduct pre- and post-market tests for MHS are welcomed and should be expanded to help NDRAs better understand the extent to which substandard and counterfeit MHS are a problem.

Additionally, as innovative consumer quality verification tools are developed and used in high burden countries, steps to determine which are most effective would be helpful. For example, Mobile Authentication Services (MAS) are being used in Nigeria to combat counterfeit products. MAS companies like Sproxil, which has an established partnership with the Federal Ministry of Health (FMOH) and Marie Stopes Nigeria, print a unique code on products at the point of manufacturing. Consumers can then text the code to a toll-free number to verify authenticity of the medicine. Three other MAS companies are also operating in Nigeria (mPedigree, PharmaSecure, and Savante). In Bangladesh, the DGDA is looking to set up a similar SMS system. The cost of using these services does not appear to increase product price by more than a few percentage points;[88] however, there is still a need to research the effectiveness of MAS in reducing counterfeit drugs. Another consumer quality verification tool is an Ethiopian hotline (8482) staffed by experts who respond to citizens' questions and concerns of medicines and consumer packaged goods on the market. Similar to MAS systems, the impact of this hotline on increased identification of substandard or counterfeit drugs has yet to be measured. Additional research would help stakeholders determine the effectiveness of MAS tools and/or hotlines before they are scaled more broadly in high burden countries.

Long term recommendations

MHS stakeholders' work to improve NDRAs' capacities to test drugs and increase transparency in the private sector should continue and intensify. Maternal health stakeholders could build off of the extensive work done to date by USAID and USP's Promoting the Quality of Medicines Program (PQM),[89] and collaborate with other health partners (as this is a challenge across health products) to build the capacity of NDRAs to perform some of this testing in-country, and/or invest in regional International Organization for Standards (ISO) certified labs. In the private sector, increasing governments' oversight and the visibility of registered drug shops can be particularly helpful. Unregistered drug shops are not mandated to comply with national QA guidelines, increasing the risk that they will procure counterfeit or substandard drugs. This is especially a challenge in Bangladesh, where it is estimated that about one-third of drug shops are not registered with the DGDA.[90] An example of an initiative to increase government oversight and public awareness of registered drug shops is the Accredited Drug Dispensing Outlet (ADDO) program in Tanzania, where the Tanzanian Food and Drug Authority (TFDA) has trained and licensed independent, private sector drug shops to sell a list of essential medicines.[91]

Another activity that could help address sub-standard and counterfeit drugs in the market is conducting research to determine the most cost-effective anti-counterfeit packaging system. A number of different anti-counterfeit systems have started to emerge on both international and country markets. For example, the EMA is expected to implement a new "track and trace" mechanism and require unique identifier codes to be printed on all medicinal products by July 2016,[92] and there have been discussions around a global barcoding program.[93] Country-level agencies have also started enforcing anti-counterfeiting requirements. In Nigeria, NAFDAC requires suppliers to place holographs on their products, and Ethiopia's FMHACA is exploring the use of scratch-off labels on products' packaging. Individual suppliers also use packaging adaptations to help consumers distinguish them from counterfeit products. For example, a local manufacturer in Ethiopia prints its brand name on capsules and uses pilfer-proof bottle caps, both of which reportedly increase the barrier to counterfeiting.[93] While such packaging requirements may be costly for manufacturers, one supplier noted that the additional cost is worthwhile if it proves effective in reducing counterfeits. However, little data has been collected on the most cost-effective mechanism for counterfeit reduction through packaging innovations. Once conducted, this research can be used to determine which anti-counterfeiting mechanism should be applied more broadly to MHS products in high burden countries.

As with many of the recommendations in this section, substandard products and counterfeiting are not challenges unique to maternal health products. Collaboration with other health sectors to ensure efficient use of resources and effective implementation should be explored.

3.2. Product appropriateness

The three essential maternal health commodities are manufactured in very different formulations, and require distinct packaging and storage conditions to ensure high quality and ease of use. Oxytocin must be stored in two to eight degree Celsius to preserve product integrity, which is challenging to adhere to in many low-resource settings.[95] It is an injectable solution with a three-year shelf life typically packaged in the form of a 5 or 10 International Unit (IU) ampule, and is administered to a mother either intramuscularly (IM) or intravenously (IV). Given the required delivery mechanisms and storage requirements, oxytocin use is often restricted to health centers and facilities.

Misoprostol comes in the form of a tablet and has a two-year shelf life when packaged in a double-aluminum blister strip to protect the product from humidity.[96] Misoprostol also has a number of other uses, ranging from the treatment of gastric ulcers to use as an abortifacient. In order to ensure the correct dosing of misoprostol, it is important to ensure that instructions specific to PPH are listed on packaging inserts.[97]

Magnesium sulfate is an injectable solution given through IM or IV. Magnesium sulfate products have a two- to five-year shelf life, depending on the storage conditions and manufacturer. While magnesium sulfate is mostly used in healthcare facilities, efforts have been made to allow a loading dose of magnesium sulfate to be delivered at the community level, before referral to a higher level of care.

As treatment guidelines have evolved and demand for these products has grown, concerns regarding product quality and formulation appropriateness have become increasingly relevant. For example, one pressing issue in the earlier scale-up of misoprostol was the inadequacy of product packaging; misoprostol tablets were being sold in bottles or in plastic-aluminum blister packs, both of which exposed the product to humidity that sped degradation. The Concept Foundation, in collaboration with RHSC, conducted a post-market QA survey to demonstrate the inadequacy of plastic-aluminum packaging, and advocated for countries to exclusively procure double-aluminum packaged products.[98] As a result of these efforts, all products considered for WHO PQ are now required to utilize double-aluminum packaging, and countries are encouraged to only procure products meeting these specifications.[99]

While these and other efforts continue to yield improvements in the formulation of available products, there are remaining concerns regarding the appropriateness of current MHS product characteristics' for distribution and use in settings with limited resources.

SPECIFIC PRODUCT CHARACTERISTICS ARE CHALLENGING IN LOW-RESOURCE SETTINGS

Across the three MHS – oxytocin, misoprostol, and magnesium sulfate – there are various product-related challenges that limit access to high quality maternal health commodities. Below is a brief description of challenging characteristics of each of the products.

Lack of clarity on stability of available oxytocin products: There are differing reported temperature levels at which currently available oxytocin products should be stored. These variations in stability guidance have caused mixed understanding and thereby storage practices, as well as challenges with effectively integrating oxytocin into existing cold chains. Currently, almost all oxytocin products report storage requirements of two to eight degrees Celsius in order to maintain product quality.[100] However, cold chain penetration is limited in many high burden countries (see below for additional information on constrained cold chain accessibility), which makes maintaining quality of these products challenging. As a result, countries have been requesting oxytocin products that are purported to be stable at higher temperatures. At present, at least two manufacturers report that they have developed oxytocin that is stable up to 25 degrees Celsius, and some international procurers, including UNFPA, have explored ordering these. While there have been several studies done to assess this reported stability at higher temperatures, including by the Partnership for Supply Chain Management (PFSCM) with support from Purdue University, the results have not been published. Additionally, a number of independent experts have expressed that these products are not truly "thermostable", and that it is "dangerous to suggest" that oxytocin can be safely stored outside of a cold chain for longer than one month.[101]

IV and IM administration for oxytocin and magnesium sulfate: Oxytocin must be delivered via IM or IV, which limits its administration to higher-level healthcare workers in facility settings. Previous research into the Uniject device — a preloaded, disposable injection tool for IM administration at the community level — was promising, but too expensive even at scale; at $1.10 per dose, oxytocin in Uniject was more expensive than current delivery methods (about $0.27 per dose, excluding administration equipment such as a syringe).[102] Similarly, magnesium sulfate must also be delivered via IM or IV injection. While WHO guidelines allow for the use of a loading dose of magnesium sulfate via IM, if convulsions continue and if IV is unavailable, additional doses must still be delivered through an IV in a health facility. When magnesium sulfate is delivered through an IV, the medicine must flow slowly through a drip, with new doses administered every four hours. This treatment protocol is quite time- and labor-intensive for healthcare workers, and it can be difficult to carefully monitor a patient's IV in crowded hospitals and maternity wards.[103] The IM and IV delivery channels for oxytocin and magnesium sulfate increase the need for higher-level care providers to oversee treatment, thereby limiting access to life-saving treatments.

Product fragmentation of magnesium sulfate: The two administration protocols (Pritchard and Zuspan) for magnesium sulfate for pre-eclampsia/eclampsia require multiple drug formulations and quantities to be administered over an extended time. The WHO EML includes two different ampule sizes (2ml and 10ml) of a 50% concentration of magnesium sulfate,[104] and the WHO Integrated Management of Pregnancy and Childbirth (IMPAC) guidelines include an additional two ampules sizes (10ml and 20ml) of 20% solution.[105] However, there are many more than these four product formulations available on the market. Across 99 countries' EMLs, at least ten different concentrations of magnesium sulfate, ranging from 1% to 50%, and seven ampule sizes, ranging from 2 to 50ml, are listed.[106] Furthermore, of the national EMLs that specify the concentration of magnesium sulfate to be used, one-third include concentrations other than those on the WHO EML; of those specifying ampule size, just over 20% fail to comply with WHO recommendations.[107] The presence of additional formulations that are not aligned with PE/E treatment guidelines is reportedly inefficient for suppliers, procurers, and healthcare professionals. For example, in Bangladesh, stakeholders reported that the 50% concentration of magnesium sulfate for IM administration is only available in 5mL ampules, as opposed to the 10mL ampules specified by the WHO.[108] As a result, not only do procurement agencies have to procure double the number of ampules in order to meet demand, but healthcare workers administering a loading dose are required to give a woman four injections instead of two.

Limited shelf life of essential MHS: The two-year shelf life of misoprostol, most oxytocin, and some magnesium sulfate formulations means that shipments must arrive in countries within six months of manufacture to adhere to the United

Nations (UN) agencies' standard of having at least 75% of shelf-life remaining at port/airport of entry.[109] Some suppliers report that a five and a half-month lead time from time of order to port/airport of entry is common, leaving only two weeks to address any unforeseen circumstances or complications,[110] thus increasing the risk of wastage.

Recommended future market-based activities

Short term recommendations

To ensure the proper storage and quality maintenance of oxytocin products, it would be helpful to address the lack of clarity on the procurement and use of oxytocin claiming to be stable at temperatures outside of two to eight degrees Celsius. One way to do so is by supporting independent research and publication of large-scale stability studies on current products that make such claims. Additionally, clear guidance could be developed by international bodies, such as the WHO, on whether oxytocin products labeled to be stable in temperatures as high as 25 degrees Celsius, can be stored outside the cold chain, and if so, for how long. This would help national procurement agencies and health systems better assess product options and supply chain requirements.

There are a number of products in the pipeline (described in more detail below and in Section 6.3) that tackle oxytocin's cold chain requirement as well as IV and IM administration characteristics of oxytocin and magnesium sulfate. While market entry for such innovations is still several years away, market-shaping work can begin to help speed product introduction. For example, Merck for Mothers[n]/Ferring Pharmaceuticals and Monash University/GlaxoSmithKline are preparing the market for their respective oxytocin and other uterotonic innovations by establishing partnerships with the WHO and country governments to ensure a quick approval process and revision of EMLs and treatment guidelines. They are also working to ensure sufficient production capacity is in place, exploring ways to lower cost of goods sold (COGS), establishing licensing agreements with generic manufacturers, and increasing volumes. Additional support for these activities across all three MHS innovations would be valuable to ensure quick market entry and product scale-up.

For magnesium sulfate, efforts to address product fragmentation should continue. In particular, MH stakeholders could work with suppliers and procurement agencies to reduce the number of formulations available in the market. A similar approach has been undertaken by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund in the ARV market to reduce the number of ARV products available (in different sizes, concentrations, etc.) from 200 to just 30 products.[111] Some stakeholders[112,113] encourage further exploration into simplifying magnesium sulfate guidelines – such as using 50% concentration for both the loading and delivery doses, thereby eliminating the need for the 20% concentration – and emphasize the need for additional research.[114] Efforts such as these could help rationalize the market and make procurement and administration of magnesium sulfate as straightforward as possible.

Lastly, to address problems associated with limited shelf life, there is an opportunity to work with suppliers and procurers to decrease lead times, particularly for misoprostol. Possible options for maximizing shelf-life for consumers include implementing programs to set aside dedicated MHS stock in wholesaler warehouses – a strategy currently being piloted by UNFPA and explored further in Section 4.2 – and sharing updated and robust forecasts with suppliers to facilitate advanced supply planning.

Long Term Recommendations

To adequately address these product-related challenges, it will be important to continue to invest in research and development (R&D). While there are a number of innovative product formulations in the pipeline, varying levels of investment have been made in each of the three product areas to date. In the uterotonic market, a number of promising products are being explored, including inhalable oxytocin, thermostable carbetocin, and sublingual oxytocin,[115] though additional clinical data is needed to move product introduction forward. In the case of misoprostol, improvements have been made to the packaging and stability of existing products, but there is little research into extending their shelf life – an innovation that could help streamline supply chain management and reduce wastage. In the magnesium sulfate space, PATH and Gynuity are both researching innovations to facilitate easier administration, including ready-to-use packs and reusable pump devices,[116] but additional investment is needed before these products can be introduced into the market. Developing optimal MHS products will help ensure high-quality, affordable, and easy-to-use products are available in high burden countries.

n 'Known as "MSD for Mothers" outside the United States and Canada'

COLD CHAIN REQUIREMENTS FOR OXYTOCIN ARE DIFFICULT TO MAINTAIN IN HIGH BURDEN COUNTRIES

To date, the limited access to cold chain equipment in LMICs and the difficulty of implementing existing storage guidelines in low-resource settings have negatively impacted oxytocin storage practices. Across all three focus countries, oxytocin is often inappropriately stored outside of the recommended two to eight degree Celsius range. These poor storage practices are due in part to a lack of reliable cold chain equipment and infrastructure. This is evident in Ethiopia, where only one-third of health centers are reported to have adequate power to support a refrigerator, compromising the efficacy of the already scarce cold chain.[117] A similar complication is evident in Nigeria, where, in 2013, only 47% of local government authorities (LGAs) and health facilities had cold chain functionality.[118] The government has started installing solar panels to act as secondary power sources for medical centers; however, just 30% of health centers in Kaduna State currently have solar capacity.[119] The lack of adequate cold chain storage for oxytocin increases the risk of product wastage, and reduces its efficacy in treating PPH, putting women at risk.

However, even when functional cold chain equipment is available, a lack of actionable guidelines and standards for oxytocin supply chain management and incorrect storage behaviors can exacerbate poor storage practices. In Ethiopia, for example, over 3,400 healthcare workers need to be trained on cold chain management,[120] but national standards on appropriate storage and distribution for pharmaceuticals have yet to be finalized. While both Nigeria and Bangladesh have clear guidelines for proper storage, these guidelines are not always implemented. In Bangladesh, for example, only 13% of public sector facilities and 33% of private facilities surveyed in a 2013 study were storing oxytocin in refrigerators,[121] and similar observations have been reported in Nigeria.

Proper storage of oxytocin should improve given the 2015 release of the WHO and United Nations Children's Fund (UNICEF) joint statement, drafted with support from the UNCoLSC Maternal Health TRT, which endorses the scale up of Expanded Program on Immunization (EPI)-oxytocin cold chain integration systems.[122] While many countries, including Benin, Niger, Senegal, South Sudan, and Togo,[123] have already updated their policies to allow for cold chain integration, specific global guidelines around how countries can implement the new policy would be beneficial. Some healthcare providers managing existing EPI systems have raised questions regarding how best to add oxytocin to the refrigerators, citing a fear that storing multiple products in the same space will cause confusion for healthcare providers.[124] Additionally, EPI equipment is often locked up at night, preventing healthcare workers from accessing essential medicines for women who go into labor after hours.[125] Actionable guidelines relating to the joint statement that specifically address these issues, and draw upon learnings from the countries where this integration has already taken place, could help facilitate uptake and increase cold chain capacity for maternal health products.

Recommended future market-based activities

Short term recommendations

To address poor storage practices for oxytocin, countries should create and widely distribute guidelines for proper storage of oxytocin. For countries that do not currently have storage protocols, such as Ethiopia, efforts to develop national guidelines should be supported. Ethiopia has already started to address this gap – FMHACA is currently working with USP to draft the country's first Good Storage and Distribution Practice manual,[126] which includes specifications for cold chain drugs. Once countries have proper storage guidelines in place, further activities to widely circulate and possibly train providers could also be beneficial. Additionally, there may be a role for innovative technologies to help change providers' behavior. For example, PATH has developed a time-temperature indicator (TTI) to help alert providers to the importance of consistent cold-chain storage.[127] TTIs, placed on the packaging of oxytocin during production, change color depending on the temperature of the product. By implementing a visual indicator of quality, providers may be more likely to follow cold chain storage guidance. In the absence of thermostable oxytocin, it is important that providers are trained and sensitized to the importance of storing oxytocin appropriately.

The new 2015 WHO-UNICEF joint statement, which encourages the integration of oxytocin into national EPI cold chains, is a unique opportunity to help ensure oxytocin is stored correctly, but more work is needed to operationalize the guidance at the country level. The UNCoLSC Maternal Health TRT and PATH have conducted operational research to identify key challenges with integrating vaccines and medicines into the same cold chains and have developed guidance on how to overcome these challenges.[128] Once the results of this operational research are ready, sharing them

with country-level champions could help shift national protocols and ensure adoption. Additionally, a space to share solutions across geographies may help address specific challenges; for instance, in Kaduna state, clinics have started stocking maternity wards with small quantities of oxytocin each night to ensure supplies are still available even when EPI rooms are locked.[129]

In the short term, there will continue to be contexts where the lack of infrastructure will make consistent cold chain storage for oxytocin unlikely. For these scenarios, it is important to develop best practices for providers to ensure women receive the highest quality care available. For example, ensuring that country treatment guidelines and trainings emphasize the use of misoprostol not only when oxytocin is not available but also when it has not been appropriately stored, could help mitigate improper usage of drugs.[130] Without such guidance, healthcare providers may be unsure of all the circumstances when it is appropriate to substitute misoprostol for oxytocin for PPH.[131]

Long term recommendations

Recently, there have been increased resources dedicated to expanding the infrastructure of countries' cold chain systems. In 2013, Gavi distributed $119 million to more than 25 countries for health systems strengthening, which includes cold chain strengthening, and in 2014 UNICEF Supply Division procured $40.6 million of cold chain equipment. MHS stakeholders could coordinate with actors from other health sectors to optimize the use of such investments. For example, MSH/ Systems for Improved Access to Pharmaceuticals and Services (SIAPS) in Bangladesh distributed 200 refrigerators to sub-district health facilities to ensure proper storage of tuberculosis medicines – reportedly, these refrigerators could potentially be used for oxytocin storage as well.[134]

4. Demand-side market analysis

4.1. Forecasting and Supply Planning

Forecasts are important tools for procurers to anticipate future demand, facilitate appropriate budgeting, develop effective supply plans, and thereby ensure appropriate stocking of oxytocin, misoprostol and magnesium sulfate at critical points of care. Should budgeted resources fall below the amount needed to procure required supplies, forecasts can also serve as key advocacy tools to mobilize additional funds to fill financing gaps. Lastly, accurate country-level forecasts are instrumental in increasing demand visibility for high quality verified suppliers, thus enabling them to make informed plans around investing in manufacturing capacity, quality approvals, and country-level registrations.

The business cases for the three essential MHS[135,136,137] developed by Jhpiego in 2014 were important steps in increasing the transparency of these commodity markets. The cases included estimated addressable market sizes, providing suppliers with insight into theoretical current global need, and demographic-based potential volumes specific to three high burden regions. Efforts should be made to build upon these cases and project future demand. While key stakeholders have not reported serious concerns around current supply capacity, a number of global procurers are unsure if existing high quality verified MHS manufacturers will be able to adequately address growing demand.[138] Updating and projecting market size estimates going forward, alongside understanding future planned capacity of high quality verified manufacturers, would help determine the extent to which planned supply capacity aligns with forecasted demand. It would also help suppliers understand how these markets will grow, and the potential corresponding need for increased capacity and investments. Ideally, these analyses should be aggregated from robust country-level forecasts, which unfortunately have yet to be developed for many geographies.

At the country-level, robust national MHS forecasts that take stock of relevant factors affecting demand, including those related to treatment guidelines, are key. In the past five years, the development of such forecasts has improved, in large part due to the efforts of JSI and MSH/SIAPS — in partnership with the UNFPA, UNICEF, and USAID — to develop forecast methodology guidelines for the thirteen life-saving commodities, including the essential MHS.[139] These guidelines were validated and updated after conducting forecasting exercises in a number of countries including Nigeria and Bangladesh, as well as the Democratic Republic of Congo, India, Indonesia, Mozambique, Myanmar, and Tanzania. Despite these helpful guidelines and technical support, several challenges to ensuring high-quality country forecasts remain.

Forecast accuracy is limited partly because the rate of MHS uptake, associated with revised guidelines and related provider trainings, are often not taken into consideration. Indeed, a number of changes to international guidelines in the last few years are relevant for MHS, and will have implications on future demand. Firstly, misoprostol was added to the WHO EML in 2011 for the prevention of PPH, and in 2015 for the treatment of PPH – the last of the three essential MHS to be included. Various partners highlighted that the addition of misoprostol has been highly politicized at the country level, given its additional use to induce abortions. While this has slowed some countries from fully adopting misoprostol for PPH, the three focus geographies of this report – Ethiopia, Nigeria (both at the national level and in Kaduna State), and Bangladesh – have all updated their EMLs to include misoprostol.[140]

Countries are at various stages of revising and implementing their national guidelines to emulate the WHO's recommendations for PPH[141] and PE/E[142] that were updated in 2011 and 2012 respectively (see Figures 5 and 6). In particular, these guidelines included recommendations on community-level use of misoprostol to prevent PPH. For example, community health workers are recommended to refer women to health facilities if hemorrhaging is suspected, and if there is no oxytocin available, to administer a second-line treatment such as misoprostol. Ethiopia has adopted the new WHO guidelines for health centers and hospitals.[143] Bangladesh has also updated its guidelines, but the preventive dose of misoprostol for PPH is stipulated as only 400 mg instead of the WHO-recommended 600 mg.[144] Nigeria's national guidelines have been updated to reflect the WHO's new guidelines as well;[145] however, each state is able

Figure 5. Summary of WHO PPH guidelines[147]

WHO recommended doses and delivery of oxytocin and misoprostol for Post-Partum Hemorrhaging

Prevention	› Oxytocin (10 International Units (IU), IV/IM) › If oxytocin unavailable: injectable uterotonics (ergometrine/methylergometrine or the fixed drug combination of oxytocin and ergometrine) or misoprostol (600 mcg) › If community health worker: misoprostol (600 mcg)
Treatment	› Oxytocin (10 IU, IV/IM) › If oxytocin unavailable: ergometrine IV, oxytocin-ergometrine fixed dose, or a prostaglandin drug (including sublingual misoprostol, 800 mcg)

Figure 6. Summary of WHO PE/E guidelines[148]

WHO recommended doses and delivery of magnesium sulfate for Pre-Eclampsia / Eclampsia

Loading Dose	› IV delivery: 4g of magnesium sulfate (20ml of 20% solution) slowly over 20 min; AND › IM delivery: 10g of magnesium sulfate. Two doses of 5g (10 ml of 50% solution) with 1 ml of 2% lignocaine › If unable to give IV, give IM only
Continued Convulsions	› IV delivery: 2g of magnesium sulfate (10 ml of 20% solution) over 20 minutes › If the referral is delayed, 5g of magnesium sulfate (10 ml of 50% solution) with 1 ml of 2% lignocaine every 4 hours until 24 hours after birth or after last convulsion (whichever is later)

to modify these guidelines, and not all states have fully adopted the new recommendations. For example, in Kaduna State, guidelines have been updated to reflect the use of misoprostol for the prevention of PPH, but not for the treatment of PPH.[146] Given that guidelines are continuously being updated, it is important that forecasts appropriately account for measured MHS uptake as these changes in protocol are rolled out.

LACK OF HIGH-QUALITY DATA LIMITS THE ROBUSTNESS OF FORECASTS

The focus countries of this report have developed national forecasts that include the three essential MHS. In Nigeria's decentralized market, some states have also developed their own specific forecasts. To better understand the quality of country-level forecasts, R4D analyzed six forecasts across the focus geographies – one from Ethiopia,[149] four from Nigeria (one national and three for Kaduna State),[150] and one from Bangladesh.[151] While these forecasts are helpful for estimating demand, their accuracy is hindered by a lack of updated, geography-specific data.

A best practice when developing a country forecast for any health commodity is to use national-level morbidity and consumption data. Unfortunately, in many countries, such underlying data for maternal health is not currently being tracked. Indeed, stakeholders cited the lack of country-specific morbidity information as a key concern,[152] and it is reported that only half of all countries have data on causes of maternal death.[153] For example, the incidence rate of PE/E ranges from 2-10% in the developing world; determining the appropriate percentage for each country would be key in quantifying future demand of magnesium sulfate. Additionally, it is not uncommon for country logistic management information systems (LMIS) – a tool for tracking product consumption data – to exclude maternal health commodities.[155] The resulting lack of country-specific maternal morbidity and MHS consumption data severely limits the robustness of MHS forecasts, which in turn makes supply planning more difficult and may increase the frequency of stockouts.

All six forecasts reviewed lacked consumption data, and five of the six forecasts also lacked morbidity data. As a result,

forecast developers utilized potentially inaccurate assumptions. For example, Ethiopia's forecast assumes that magnesium sulfate is needed for all cases of severe eclampsia; however, in reality, many healthcare providers are uncomfortable using magnesium sulfate due to the perceived risk of toxicity, and instead use diazepam to treat eclampsia.[156] In fact, several Basic Emergency Obstetric and Newborn Care[o] (BEmONC)-trained health center providers in Ethiopia reported expired stock of magnesium sulfate, partly due to a reliance on diazepam.[157] While this points to the need for additional healthcare worker training, it also highlights the importance of tracking product consumption for improved forecasting, stocking, and resource utilization. In Bangladesh, existing country morbidity data was used to develop the national MHS forecast, but the sources used were somewhat dated, including the 2010 Bangladesh Maternal Mortality Survey. More recent data, had it been available, would likely have increased the accuracy of forecasts.

Recommended future market-based activities

Short term recommendations

One opportunity to improve the collection of maternal morbidity data and increase the accuracy of forecasts is to leverage existing platforms, including national Demographic and Health Surveys (DHS) and Civil Registration and Vital Statistics (CRVS) systems. These resources could be used to gather more specific data around maternal morbidity, including country-specific incidence rates of PPH and PE/E. Ensuring that the appropriate maternal health indicators are included in these ongoing efforts could help improve the quality of morbidity data used in national MHS forecasts.

Long term recommendations

Longer-term efforts to improve country-level data tracking should also continue and be scaled. Of primary importance is continuing to ensure that all Health Management Information Systems (HMIS) and LMIS[p] collect maternal health and essential MHS indicators. For example, JSI and USAID has worked closely with Supply Chain Management Systems (SCMS) and the Ministry of Health and Social Welfare of Tanzania to include maternal health commodities in their electronic-LMIS system, allowing for real-time tracking of product supply and distribution.[158] Efforts such as these could be scaled and introduced to other countries. Secondly, UNCoLSC, with support from Clinton Health Access Initiative (CHAI), JSI, MSH, PATH and other partners, is currently working to integrate HMIS and LMIS systems for better tracking and linking of morbidity and consumption data, and is looking to expand these to multiple geographies. Support for these steps will be helpful to address information gaps. Finally, building national and state buy-in to improve data collection for maternal health can lead to unique approaches. For example, in Kaduna State, the governor recently created an initiative to ensure incidence and cause of maternal deaths are reported to the State Ministry of Health (SMOH), which would improve the quality of maternal mortality data.

INCONSISTENT METHODOLOGIES CONTRIBUTE TO DISCREPANCIES BETWEEN FORECASTS AND AFFECT ACCURACY

The forecasting methodology guide developed by JSI and MSH/SIAPS is a useful tool for countries. It outlines forecasting algorithms for each of the thirteen essential commodities, including the three MHS, and provides guidance on identifying sources of necessary data, generating assumptions, and incorporating program-specific considerations into final estimates.[159] However, countries may not have the capacity to fully utilize these guides, and a number of methodological challenges (listed on the next page) were identified after reviewing the three national and three state forecasts from the focus geographies of this report. These challenges limit the robustness of the forecasts, and thus constrain their usefulness to both suppliers and procurers.

Wastage and buffer stock: Given that a small percentage of products that are shipped out of a manufacturer's warehouse may be damaged or subjected to theft, it is best practice to include a wastage estimate in forecasts. Similarly, it is helpful to have buffer stock on hand to guard against uncertainties and mitigate risks of stockouts. Unfortunately, both of these assumptions were not consistently included in the forecasts reviewed. Ethiopia did not include wastage and buffer stock in misoprostol estimates and somewhat problematically accounted for them in oxytocin and magnesium sulfate estimates, by assuming that each mother would require ten ampules of each product, instead of the recommended one to two ampules of oxytocin and six to eight ampules of magnesium sulfate. One Kaduna State forecast and the Bangladesh national forecast included wastage in their MHS forecasts for all three commodities, but none of the Nigerian

o Basic Emergency Obstetric and Newborn Care, or BEmONC, refers to the six basic functions that a trained care professional can provide to avert maternal and newborn morbidity and mortality (http://www.jica.go.jp/project/philippines/0600894/04/pdf/bemoc_guide.pdf).

p HMIS and LMIS are national data collection systems for tracking health and medical supply chain data.

and Bangladesh forecasts accounted for buffer stock. Including these assumptions in commodity forecasts is important to decrease the risk of stockout due to commodities being wasted, or demand increasing unexpectedly.

Other uses: Although this report focuses on how oxytocin, misoprostol, and magnesium sulfate are used to address PPH and PE/E, it is important that all uses of these commodities are considered when developing forecasts. This is to ensure that stocks budgeted for the stated two maternal health conditions are not depleted by healthcare providers for other uses. The Ethiopia forecast accounted for other uses for the three essential MHS, but the Nigeria (national and Kaduna state) and Bangladesh forecasts did not. Such exclusions may lead to an underestimation of total demand, which in turn may increase the likelihood of stockouts of these commodities.

Product formulation: Lastly, it is important that forecasts reflect country-specific norms. The Bangladesh forecast assumed the use of 10IU ampules for oxytocin, but the Central Medical Store Department (CMSD), one of Bangladesh's national agencies procuring the essential MHS, procures mostly 5IU ampules.[160] As such, the procurement agency will need to adjust forecasts to reflect procurement practices, which may increase the likelihood of human error during the procurement and budgeting process.

The use of inconsistent methodologies can lead to forecasts for the same country geographies providing different forecasted volumes. For example, forecasted volumes for oxytocin needed in Kaduna State varied by up to 40% between two forecasts for 2015 (see Figure 8 below). Conflicting information is then provided to procurement agencies and manufacturers, which exacerbates opacity and inefficiencies in the MHS markets.

Recommended future market-based activities

In order to strengthen country-level forecasts, it will be important to increase the capacity of the public sector to develop regular forecasts using consistent and robust methodology. While organizations including JSI, MSH and UNFPA have been working with countries to improve forecasting, it appears that follow-up training would be beneficial; experts state that just two of the ten states in

Figure 7. The extent of implementation of forecasting best-practices in Ethiopia, Nigeria (National and Kaduna State), and Bangladesh

Forecasts	Wastage	Buffer	Other Uses	Product Formulation
Ethiopia	X (not misoprostol)	X (not misoprostol)	X	X
Nigeria (National)				X
Kaduna State #1	X			X
Kaduna State #2				X
Kaduna State #3				X
Bangladesh	X			

Figure 8. Forecasted quantities for the essential MHS in Kaduna State, 2015

Product	Unit	Forecast #1	Forecast #2	Percentage Difference
Oxytocin	10IU ampules	159,810	223,251	40%
Misoprostol	Tablets	884,366	762,393	14%
Magnesium sulfate	50%, 10 ml vials	30,578	37,355	22%

Nigeria where 2015 forecasts were developed will have the capacity to repeat these exercises without external support.[161] (Unfortunately, organizations who have supported previous forecasting exercises, are not able to commit to follow-up activities due to funding uncertainties.) Additionally, ensuring that other high burden countries also benefit from such trainings on forecasting maternal health products would ensure a broader impact. Activities like the recent Concept Foundation- and WHO-hosted quantification workshop, held in Kampala, Uganda and attended by a number of East African government officials,[162] are excellent opportunities to build capacity and share common challenges and lessons learned across geographies. Improving the quality of public sector forecasts would also limit the need for multiple civil sector forecasts, which may be confusing for suppliers and public sector procurers.

Lastly, given that these methodological challenges are not unique to the MHS, and quantification exercises are often conducted for many health commodities at once, ongoing advocacy efforts to improve forecasting across other commodity areas can be leveraged to improve MHS forecasts.

FORECASTS OFTEN FAIL TO ACCOUNT FOR CHANGES IN GUIDELINES AND PROVIDER BEHAVIOR

As countries update and implement maternal health guidelines to reflect WHO recommendations, demand for MHS will change. Indeed, several MHS manufacturers and wholesalers have noted that procurement volumes of all three commodities have increased substantially over the last five years. For example, since 2011, one global procurement agency has seen orders of misoprostol increase from 18,000 tablets in 2011 to almost five million tablets in 2015, and volumes of magnesium sulfate (50%, 10 ml ampules) procured by the same agency increased more than seven times in the same time period.[163] Another procurement agency has also seen growth across all three MHS, with orders for oxytocin and misoprostol doubling from 2011 to 2015.[164] While there are a number of reasons for these increased volumes, it is hypothesized to be due in part to countries updating maternal health guidelines and conducting provider training. Unfortunately, such policy updates and training roll-outs have not been fully reflected in country forecasts, making supply planning challenging.

For public sector agencies to procure health commodities, they typically must be listed on the national EML. In recent years, countries have been updating national EMLs to include misoprostol since its inclusion in the WHO EML in 2011. National guidelines are also being updated to specify the appropriate medicine and dosage to prevent and treat PPH and PE/E. As part of this process, some countries adapt international guidelines to the local context. For example, in Bangladesh, instead of the WHO-recommended 600 mcg of misoprostol to prevent PPH, country guidelines outline that 400 mcg should be used, ostensibly based on the smaller stature of Bangladeshi women. This unique dosage is reflected in the Bangladesh national forecast, which estimates two 200 mcg tablets per community-based delivery, instead of three tablets. However, stakeholders also cited that research is needed to confirm 400 mcg as the optimal dosage.

Beyond EMLs and treatment guidelines, other government policies can influence demand for MHS. Many high burden countries, including the three focus countries of this report, are implementing campaigns to increase deliveries in healthcare facilities, which affects the use of MHS. For example, as more women deliver in health facilities, more oxytocin will be demanded, and misoprostol use may decrease. This policy change and the estimated effects on MHS demand was not included in the Ethiopian forecast and two of the Nigeria forecasts. Furthermore, accounting for realistic policy-driven shifts in patient care-seeking behavior can improve stocking of these essential MHS at different points of care. In 2012, the Ethiopian government initiated the “Home Delivery Free” campaign, and has since been intensively supporting a move to 100% of births taking place at a health facility. The introduction of this policy has led to an effective elimination of misoprostol supplies in the Ethiopian market — only 1% of outlets surveyed as part of PSI’s FPWatch project are stocking misoprostol. This is in spite of the fact that the latest HMIS data in 2015 estimates that 40% of births still occur in homes.[165]

Looking forward, the outcomes of ongoing research into community-level administration of misoprostol for PPH treatment and magnesium sulfate, and their impact on guideline changes, should be tracked and appropriately accounted for in future forecasts. For example, Gynuity is conducting research to determine if community-based healthcare providers are able to appropriately use misoprostol to treat PPH.[166] In Bangladesh, a number of partners, including Population Council, icddr,b, MaMoni (part of the USAID funded-Maternal and Child Survival Project, MCSP), and the Obstetrical and Gynecological Society of Bangladesh (OGSB)

are working together to determine the feasibility of training female welfare visitors (FWV) to deliver a loading dose of magnesium sulfate at the community level to women suffering from seizures associated with PE/E.[167] Similar efforts are taking place in other high burden countries as well, including Nigeria, Mozambique, India, and Pakistan.[168] Should such research activities prove persuasive, it is possible that national or international guidelines could be changed to allow community distribution of magnesium sulfate, increasing accessibility and thus demand.

In addition to updating guidelines, healthcare providers must also be trained on how to use oxytocin, misoprostol and magnesium sulfate once the guidelines outline their proper use. In some of the focus geographies analyzed, training coverage levels are unfortunately low and often sporadic, in part due to resource constraints. In Ethiopia, for example, it is currently estimated that only about 25% of providers have been trained on BEmONC.[169] If providers are not trained appropriately, they may be more comfortable using sub-optimal products, limiting demand of essential MHS. This effect was seen during a visit to a health center in Ethiopia where BEmONC-trained healthcare providers reported that while a 10 IU dose of oxytocin was used for PPH prevention, ergometrin was the preferred treatment for PPH. When there is a stockout of ergometrin, patients experiencing PPH are referred to a hospital without first receiving oxytocin, even if oxytocin is available. The same visit revealed that health professionals feared using magnesium sulfate due to toxicity concerns, and thus opted to administer diazepam for PE/E.[170] Current forecasting exercises do not account for such use of alternative medicines, and as such reflect inaccurate demand, which could lead to inefficient use of resources and wasted products.

Inconsistent use of appropriate MHS can also be caused by incomplete training, leading to confusion around proper protocol. In Kaduna State, a training on the use of magnesium sulfate was conducted two years ago, but there has been no follow-up training since.[171] Stakeholders in Kaduna State also reported conflicting understandings of the appropriate dosing guidelines for misoprostol — for PPH prevention, responses on dosage ranged from 0-600mcg, while for treatment, it ranged from 600-1200mcg.[172] The range of dosage for PPH treatment is particularly interesting, as Kaduna State's guidelines do not include misoprostol for PPH treatment at all.

If providers are potentially using different dosing regimens, not only is patients' safety in danger, but it is difficult to forecast and procure the appropriate amount of MHS to meet demand.

Recommended future market-based activities

Short-term recommendations

To ensure forecasts accurately account for the impact of policy updates on demand, countries should be supported to consider comprehensive changes to EMLs, treatment guidelines, and policies supporting facility-based deliveries. Forecasts should then be modified to account for these changes in a nuanced manner, reflecting dissemination timelines and the resultant pace of provider sensitization, and could draw upon similar updates made in other health areas and countries. Provider training is another critical area to be factored into national forecasts. Governments typically have roll-out plans for facility- and community-level healthcare provider training by sub-regions. Incorporating the increasing geographic coverage levels, and the corresponding percent of providers that thus receive supportive tools and resources in MHS uptake assumptions, could lead to more accurate demand estimates. For example, if a country plans to train community-level midwives in one-third of states each year on revised guidelines that include the use of misoprostol for PPH prevention, the annual demand forecast should account for the 33% annual coverage increase while adjusting for state-specific data, such as relevant population, rates of home birth, etc.

Long-term recommendations

Conclusions emerging from ongoing research into task-shifting of treatment of PPH and PE/E at the community level should be observed and, if proven effective, guidelines and forecasts should be updated to reflect lessons from this research. For example, if a loading dose of magnesium sulfate at the community-level is shown to be feasible and effective, this will likely be reflected in global and national treatment guidelines, and commodity forecasts would have to be adjusted appropriately. In some cases, additional research could be undertaken, such as research to determine if 400 mcg of misoprostol is effective in preventing PPH in Bangladesh. The results of this study could be used to develop future policies and forecasts at the international, national and sub-national level.

EXISTING FORECASTS ARE OFTEN NOT LINKED WITH PROCUREMENT PRACTICES

Despite issues around data availability and methodologies, the presence of forecasts for all three MHS in the focus geographies is encouraging, and can be used as a starting point for refining estimates for future quantifications. Forecasting is most meaningful when used to inform procurement; unfortunately, many countries' forecasts are not currently effectively linked to supply planning and procurement. This is due to a variety of challenges, including:

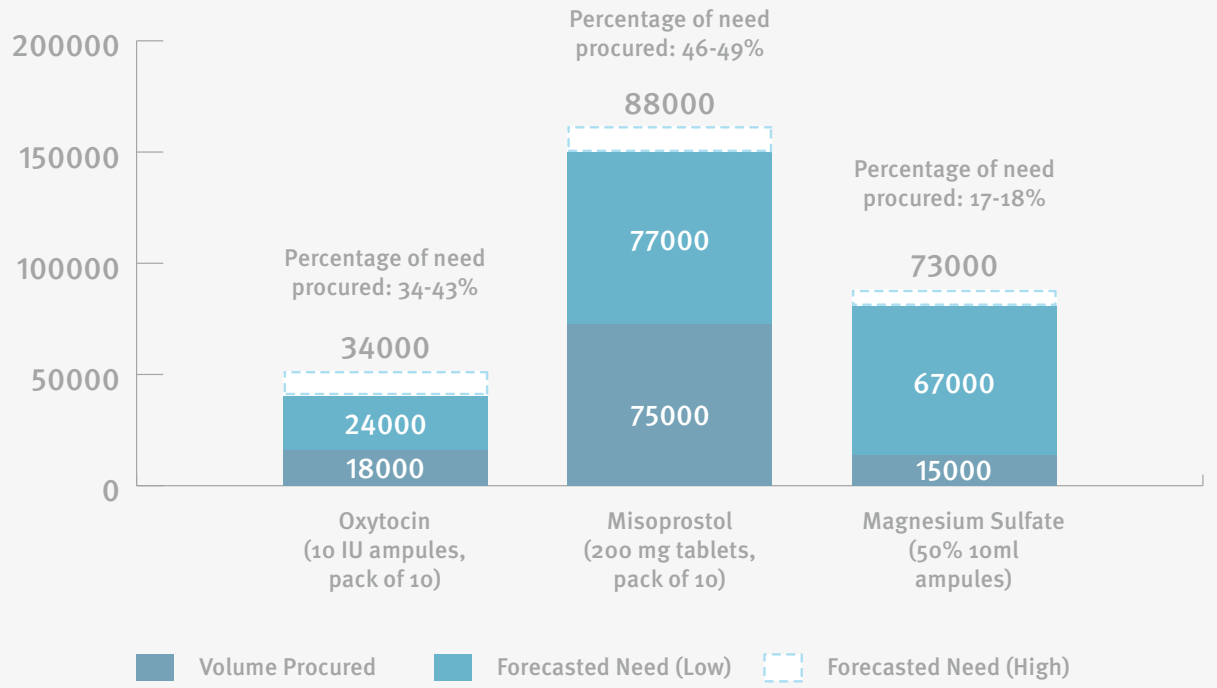
Existing stock is unaccounted for: To estimate the amount of forecasted demand that needs to be procured, it is important to consider existing inventory – both stock on hand and stock in the pipeline. However, only one of the three forecasts from Kaduna State accounted for existing stock; none of the other forecasts (including the national ones from Ethiopia, Nigeria and Bangladesh) incorporated this information. In the case of de-centralized procurement systems, such as Nigeria and Bangladesh, it can be difficult for national governments to know how much stock is in the system, as sub-national procurement orders are typically made without their knowledge. This omission increases the likelihood that forecasts will overestimate the volume of essential MHS required, as commodities already available will not be factored into the final procurement volumes. This in turn increases the risk of waste from expired products.

Forecasts are not costed: Comprehensively costing forecasted volumes makes quantifications more actionable for budgeting and procurement. This includes incorporating commodity prices, and other cost components related to ensuring commodities are delivered to points of care. Such components include freight, clearance, storage and distribution. Two of the three focus geographies' reviewed forecasts (Ethiopia and Bangladesh) did not include prices of the three MHS. Additionally, for those forecasts that were costed, price data utilized were not always geography-specific, rendering final cost estimates less useful for state- and national-budget planning. For example, in one of the Kaduna State forecasts, while some cost data was specific to the state, other price points were from the UNFPA supply catalogue, which reports the highest product price quoted by suppliers.[173] This price data may artificially inflate total financing need for MHS in Kaduna State, leading to inefficient use of resources. Conversely, if international pricing is lower than prices available at the country-level, this could lead to an underestimated budget, which may increase the risk of stock-outs. Across all forecasts, additional related costs around shipping, clearing, storing and distributing of products were not incorporated.

Limited involvement of budgeting and procurement stakeholders in forecast development: In decentralized systems, challenges in linking forecasting to financing and procurement are often compounded by a disconnect between agencies. For example, in Kaduna State, the State Primary Health Care Development Agency (SPHCDA) is involved with setting the budget for the state's procurement of essential commodities, based on forecasts done in consultation with Local Government Authorities. However, the SPHCDA is not involved in the next step of actually procuring these commodities, and notes that simply including a budget line item for maternal health commodities does not guarantee that it will actually get financed and procured.[174] Limited communication and coordination between agencies responsible for forecasting, budgeting, and procurement limits the usefulness and follow-through of forecasted volumes. According to one stakeholder, in Kaduna State "there is no serious attempt to link supply [of the essential commodities] with demand."[175] Repercussions of the disconnect between forecasting and procurement are evident when comparing the volumes of the essential MHS procured by the public sector in Kaduna State over the last three years with forecasted levels of demand.

Figure 9 (next page) displays the significant inconsistencies between procurement levels and forecasted need. Between 2013 and 2015, less than 50% of forecasted demand for all three commodities has been procured by the public sector. Magnesium sulfate appears to experience the largest procurement (and likely financing) gap, with less than 20% of forecasted demand procured since 2013. While there are a number of inefficiencies in the procurement landscape that may be affecting MHS volumes ordered in Kaduna State, improving the linkages between forecasted demand, financing, and procurement may help to correct the clear mismatch observed above. Similar disconnects were observed in Bangladesh, where stakeholders reported being familiar with the national forecast, yet procurement planning at the central-level was largely based on available finances, without accounting for demand estimates.[177] For example, 4.9 million misoprostol tablets were forecasted for 2015, but the CMSD and Logistics and Supply Unit at Directorate General of Family Planning (DGFP) only planned to procure about 30% of demand (around 1.5 million tablets).[178]

Figure 9. Kaduna State public sector procurement and forecasted need for the essential MHS, 2013-2015[176]



Recommended future market-based activities

Short term recommendations

To improve visibility of MHS stock levels and ensure current inventory is included in national forecasts, existing data collection resources for other health commodities could be leveraged. For example, there are several successful initiatives in the reproductive health space that provide valuable supply chain monitoring information for family planning supplies, and it may be possible to collect similar information for MHS. RHInterchange is one such tool that collates data on shipments of contraceptive supplies being delivered to more than 140 countries.[179] If similar data could be collected for maternal health products as well, the additional insight could help suppliers and procurement agencies better plan for global demand, while providing information to national agencies involved in developments of future forecasts.

Similarly, FPWatch collects data on the availability of contraceptives and misoprostol in public and private sector facilities in a number of countries, including Ethiopia and Nigeria. Adding oxytocin and magnesium sulfate to the FPWatch survey could shed light on current MHS stock levels, including the extent to which stockouts and wastage are occurring. This information could inform national forecasts accordingly. (It is worth noting that any expansion of surveys would likely have to be accompanied by additional resources.) There is precedence for such suggested partnerships. For example, amox DT was introduced in 2011 as the WHO-recommended treatment for childhood pneumonia.[180] To better understand amox DT availability, stakeholders partnered with PSI and FPWatch's counterpart, ACTWatch, to have amox DT-related questions added to ongoing surveys. As a result, availability, price and volume data for amox DT was helpfully collected in existing planned surveys across several countries. In Bangladesh, where FPWatch is currently not operating, it may be valuable to conduct a study to determine current stock levels at public sector health facilities. Indeed, several stakeholders, including government officials, were eager to have a better sense of the extent to which MHS is (or is not) available to expecting mothers.[18]

Additionally, to ease the transition from forecasting to budgeting and finally to procurement, stakeholders should continue to promote the adoption of forecast development tools that promote the inclusion of pricing data and total comprehensive costs, including costs related to freight, clearance, storage, and distribution (which can add more than 30% to product costs[182]). This includes the Quantification Guide developed by JSI and MSH/SIAPS, which has been utilized for several state- and country-level forecasts, but is still being introduced to some high burden countries. Excluding pricing data from forecasts can greatly impact the availability of products. For example, in one Sub-Saharan African country, the cost of clearance was not considered for a recent order of life-saving commodities, which resulted in the products being stuck at the port for eight months until a donor agency agreed to pay the cost required to clear customs,[183] dramatically reducing shelf-life and delaying the delivery of this essential commodity. Training country stakeholders responsible for product forecasts on how to implement the guidance set forth in the Quantification Guide may help facilitate better estimates, including budgeting for clearance costs. Additionally, ensuring that forecasting task teams are gathering information from stakeholders involved at various points of the pharmaceutical supply chain, including shipping, customs clearance, and product distribution, will allow price estimates to reflect the "fully-loaded" commodity cost.

Long term recommendations

To make forecasts more actionable, it will be important to continuously revisit estimates. Forecasts can be updated to use the most recent data, improve methodologies, address changes in policies and provider behavior, and adjust pricing levels – all described in detail above. Creating forecasting "task teams" or "committees" within state or national agencies and supporting them to regularly lead reviews will help create accountability for this process and improve forecasts over time. The same forecasting committees should include country stakeholders responsible for national procurement planning and budgeting. These officials can provide critical insights to facilitate the translation of forecasts into robust supply plans, while also gaining a better understanding of the methodology and intent behind the exercise. This also allows for a multi-directional flow of information between agencies, and improves the connection between forecasting exercises and commodity procurement. For example, one Sub-Saharan African country currently assembles a cross-sectional group of regulators (who influence budgets), procurers, and implementers from the public and private sectors to quantify national-level demand for essential life-saving commodities every two years. In addition, updates to these quantifications are planned every six months to account for any real-time changes.[184]

4.2. Procurement practices

The procurement of MHS for the public sector occurs at both the global and country levels. Global procurers include UN agencies such as UNFPA and UNICEF, NGOs like Marie Stopes International (MSI) and Population Services International (PSI), and international wholesalers such as Crown Agents, IDA Foundation, Medical Export Group (MEG) and Imres. Countries themselves usually have at least one national procurement agency, and some decentralized healthcare systems may have sub-national public sector procurers as well. The numerous procurers of MHS have led to a fragmented market, which is further complicated by limited market visibility and a lack of coordination. These factors, coupled with insufficient financing (discussed in Section 5), contribute to availability challenges in the public sector for all three MHS, particularly misoprostol and magnesium sulfate. In turn, these public sector stockouts drive purchasing to the private sector, where quality is less assured and prices are higher.

Many actors have been working to improve public sector procurement practices, including UNFPA, which has been exploring a number of strategies recently, discussed in detail below. At the country-level, JSI and MSH have collaborated with public sector procurement agencies; in Bangladesh, MSH/SIAPS worked with the CMSD to decrease the time span from procurement plans being approved to contracts being signed by almost 50%.[185] The efforts of these organizations and others should continue, though additional support may be needed to specifically address challenges around fragmentation, market transparency, and coordination among procurers.

FRAGMENTED AND UNCOORDINATED PROCUREMENT LEADS TO INCONSISTENT AVAILABILITY

The fragmented procurement of oxytocin, misoprostol and magnesium sulfate constrains the availability of MHS in the public sector. At the global level, UNFPA plays a key role as one of the largest purchasers of high quality verified MHS, and by offering financial and procurement support when country government resources are limited. However, due to a broad mandate and funding constraints, UNFPA's budget for MHS is just 10% of the budget for contraceptives,[186] and its procurement of the three maternal health commodities is less than 15%[q] of the global potential market.[187] In addition to UNFPA, there are several other procurement agencies involved in the MHS landscape. However, many of these efforts are conducted independently and the limited coordination has created some challenges in understanding current supplies in countries, and in being able to respond quickly to mitigate stockouts. In particular, a number of global procurers reported facing challenges in fulfilling emergency orders of MHS.[188]

Fragmentation at the country level can also make supply planning extremely challenging. In Nigeria and Bangladesh, a lack of coordination among various procurement agencies leads to multiple, small-volume procurements instead of consolidated orders based on forecasted need. In Kaduna State in Nigeria, while there is only one government procurer – the Drug and Medical Supplies Management Agency (DMSMA) – the DMSMA works with several additional public sector procurers, including MSI, CHAI, Crown Agents, and UNFPA. Public sector health centers can also procure as needed, either from wholesalers or directly from manufacturers. Unfortunately, even with various MHS public sector procurers in Kaduna State, recent surveys reveal that no magnesium sulfate is currently available in health centers or central medical stores.

Similar inefficiencies exist in Bangladesh, where maternal health products are procured nationally by two public sector agencies – the CMSD and Logistics and Supply Unit at the DGFP. Although a joint forecast has been created and procurement plans can be viewed through an online system, in practice there is little coordinated supply planning and purchasing between the two organizations. In addition, many maternal health commodities are not procured through CMSD or DGFP centrally, but rather at the district or sub-district level. In a recent study, 40% of all oxytocin in surveyed DGHS facilities and 92% in all surveyed DGFP facilities were procured locally.[190] Such uncoordinated supply planning contributes to the low availability of MHS, with surveyed public sector facilities stocking out of oxytocin and magnesium sulfate almost 50% of the year, and misoprostol almost 25% of the year.[191]

Recommendations for future market-based activities

Short term recommendations

To improve capacity to respond to emergency orders and spot procurements, MHS suppliers and wholesalers could explore holding a percentage of estimated annual demand in stock, thereby reducing lead times. UNFPA is in the process of piloting such a system; this year, they will contract a number of wholesalers and manufacturers to keep set stock levels of the three MHS available throughout the year.[192] One wholesaler, who was approached to keep oxytocin in stock, estimated that they would maintain approximately two months' worth of oxytocin supply for UNFPA at any given time, replenishing stocks when a certain minimum threshold was reached.[193] Given the relatively low levels of stock being stored, the wholesaler believed that this initiative would strike an appropriate balance, as the same stock could be used to fill other orders should UNFPA's needs decrease. As the pilot gets under way, the shelf-life of MHS should be considered to identify the ideal level of stock on hand that balances shortened lead times and minimized wastage.

At the country-level, some national and sub-national procurement agencies have effectively used long-term agreements (LTAs) with suppliers, which set expected volumes and prices in advance over a period of time. This reportedly reduces lead times on spot procurements, improves predictability of orders, and cuts down on administrative costs. For example, one global procurer has established an LTA with a misoprostol manufacturer that allows them to leverage guaranteed minimum volumes to negotiate shorter lead times.[194] An additional benefit of such structures is the ability to incentivize manufacturers to improve product quality. One international procurement agency revealed that they were able to leverage their volume guarantee with an MHS manufacturer to incentivize the supplier to reach an improved quality standard.

q UNFPA's procurement addresses 1% of estimated global potential market for misoprostol and 4% of estimated global potential market for oxytocin. Depending on what assumptions are used, UNFPA addresses 4-14% of the global potential market for magnesium sulfate.

Long term recommendations

Moving forward, it will be important to improve coordination amongst the multiple MHS procurers. Learnings can be drawn from other health commodity areas, where coordination mechanisms have been developed. For example, the Coordinated Supply Planning (CSP) group of the RHSC works with international donors and countries to coordinate forecasts and supply planning for select family planning products.[195] Recently, a country alerted the CSP that they needed additional contraceptives. UNFPA was unfortunately not able to fulfill the order until May 2016; however, upon hearing the news of an emergency request, USAID was able to re-route an order that was about to be canceled to the country in need.[196] A similar coordination mechanism for MHS could greatly improve global procurers' capacity to quickly respond to emergency orders, though given the low cost of MHS, such a mechanism would have to be designed to involve fairly low transaction costs.

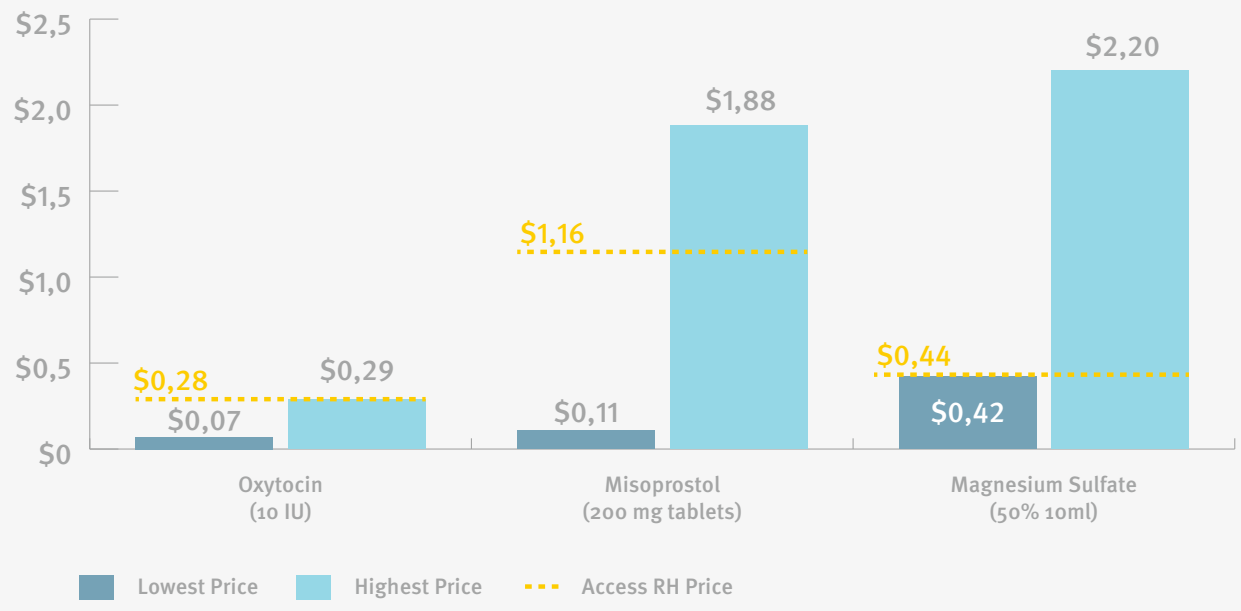
Another RHSC coordinating mechanism is the Coordinated Assistance for Reproductive health supplies (CARhs), which brings together key reproductive health global procurers and country partners to discuss pending supply shortages and try to address them. They also release a monthly Procurement Planning and Monitoring Report (PPMR), which describes stock status of contraceptives in 26 countries. Including MHS in these reports and ensuring key MHS global procurers are involved in CARhs could increase market visibility and improve coordination across MHS procurers, improving MHS supply planning at the global level.

INEFFICIENT PROCUREMENT PRACTICES LIMIT BUYER POWER AND DECREASE MARKET VISIBILITY

Fragmentation decreases individual order volumes for each procurement agency, which in turn decreases procurers' abilities to negotiate lower prices. In the MHS markets, constrained buyer power contributes to a wide range of prices across the market, despite the relatively low unit costs of oxytocin, misoprostol and magnesium sulfate. Across three global procurers, the highest price points for MHS products[r] ranged from three to 16 times larger than the lowest prices (see Figure 10).[197] While price is not the only factor to consider in the procurement of MHS (e.g. quality), with more rational

r While not all of these products are high-quality verified, all have undergone quality testing by established international procurement agencies.

Figure 10. MHS price comparisons across three global procurement agencies and AccessRH[198]



pricing, the same amount of resources could be used to purchase more MHS and treat more women.

At the country level, in decentralized health systems, like Nigeria and Bangladesh, fragmented procurement can have similar distortionary effects on prices. For example, in Bangladesh, the price of misoprostol procured at the district or sub-district level is twice as high as that procured by the national agencies,[199] resulting in a halving of potential supply volumes. Combining district and sub-district volumes with national procurements could give these sub-national procurers greater power to negotiate lower prices and better insight into market trends.

A lack of transparency in the MHS markets, particularly on pricing for these products, has compounded price variations for these commodities. While some MHS prices are listed publicly, including on the AccessRH Product Catalog[200] and the UNICEF Supply Catalogue,[201] there is no consistently updated source that lists a range of current prices for MHS. Prices from the AccessRH Product Catalog, with the exception of magnesium sulfate, also skew high on the range of unit price for the essential MHS (see Figure 10) – a potential market signal of the lack of buyer visibility into lower available prices. The lack of a platform for MHS procurers to compare and share current pricing information reduces their capacity to negotiate a reasonable price for the essential MHS.

Recommendations for future market-based activities

Short term recommendations

Given that various UN agencies – UNFPA, UNICEF, United Nations High Commissioner for Refugees (UNHCR,) etc. – procure MHS, it may be possible to consolidate orders and rationalize prices by selecting one UN body to procure MHS on behalf of all UN programs. The UN is discussing this strategy for all medicinal products, and is identifying a "lead agency" for the respective maternal health supplies. While such an approach could help limit market fragmentation, price mark-ups may occur as a result of the additional step in the supply chain.[202] Careful analysis comparing the possible savings from price reductions on higher volumes, to potential additional costs associated with a more complicated supply chain, should be conducted to ensure this strategy is indeed cost-effective.

In addition, there are a number of activities that could improve price transparency in the MHS market. Firstly, while UNFPA helpfully shares the prices at which they buy essential MHS on AccessRH, the website currently only lists the highest price, which provides an incomplete signal to suppliers and other procurers[203] (see Figure 10 for a comparison of AccessRH prices with procurement agency ranges). Instead, listing the average price, as the UNICEF Supply Catalogue does, could provide more helpful information for other procurers to better understand current price levels. In addition, creating an up-to-date online platform that lists a range of current MHS prices would be helpful. The MSH Drug Price Indicator Guide[204] is one example of where this information could be housed, though it will need to be updated to reflect current prices. The AccessRH website may also be a suitable platform for this information, given UNFPA's role in the essential MHS markets. Lastly, the previously mentioned procurement coordination mechanisms could help improve information flow among global MHS procurers, and could be used to share pricing information.

Long term recommendations

At a country-level, it could be beneficial to explore mechanisms that consolidate public sector procurement and improve procurers' buying power. In decentralized markets like Nigeria and Bangladesh, consolidating demand forecasts and budgets, and pooling orders across states/districts could increase procurement volumes, thereby potentially lowering prices and reducing the transaction costs of placing multiple, small orders in an ad-hoc manner. An early pilot of how to implement such activities is underway in Nigeria, where the DFID-funded Maternal Newborn and Child Health Program (MNCH2) project is combining the MHS orders across six states and using Crown Agents, a global wholesaler, to procure all commodities for 2016.[205] This project, and others like it, should be carefully monitored to determine the value of these market shaping activities, and best practices for the future.

In addition, a forthcoming report from RHSC's Market Dynamics Approaches Working Group (MDAWG) entitled "Assessing Misalignments in the Procurement of Contraceptives: Improving Procurement Practices to Achieve the Goals of FP2020"[206] puts forward a recommendation for the family planning market that Requests for Proposals (RFPs) and tenders should be harmonized and that joint-RFPs should be encouraged. Joint RFPs in the MHS markets, either among public sector procurement agencies in the same country or across countries, could also help create economies of scale and improve market visibility across countries, giving procurement agencies greater power to negotiate fair prices.

5. Conclusion

While supply- and demand-side market challenges described in this report affect the availability of high quality products for all three MHS, broadly speaking, the most salient market challenges observed for misoprostol and magnesium sulfate are around availability, whereas for oxytocin, they are related to quality. R4D's analyses identified several key drivers for the lack of misoprostol and magnesium sulfate's uptake in the public sector – chiefly, demand-side barriers relating to poor forecasting, inconsistent use, and fragmented procurement. In the case of misoprostol, cultural sensitivities around its additional use for abortions also limits demand. For oxytocin, supply-side barriers are the key challenges – relating primarily to challenges with proper storage due to its cold chain requirement. It should be noted that misoprostol has also experienced challenges with quality, but these challenges appear to largely be due to poor packaging, which several actors are already working with manufacturers to address.

Of the three MHS, oxytocin is the most available due to a combination of factors that are unique and unfortunately inapplicable to the misoprostol and magnesium sulfate market. For example, unlike misoprostol, oxytocin does not suffer from controversial multiple-indications usage, and it has been used by healthcare providers and patients for PPH for much longer – misoprostol was only recently added to the WHO EML for the prevention of PPH in 2011 and for the treatment of PPH in 2015,[207] whereas oxytocin has been on the WHO EML since its inception in 1977.[208] It is also important to note that demand for oxytocin is much higher and more consistent than demand for magnesium sulfate – a prophylactic dose of oxytocin is recommended for all pregnant mothers, whereas magnesium sulfate is only used in a small number of pregnancies with complications associated with PE/E.

One cross-cutting market challenge that was out of scope for this report, but emerged over the course of the analysis, is the lack of financing for MHS. Similar to other low-cost life-saving commodities, the MHS markets suffer from a funding paradox. Their relative affordability leads international donors to prioritize financial support for other higher-priced health commodities, with the belief that country governments will be able to pay for these lower-cost products. Yet, low-income government resources are often severely constrained, particularly when considering the array of maternal, newborn and child health commodities they are expected to purchase. For example, in Ethiopia, the government strives to provide subsidized or free essential drugs to its people, but the most recent data suggests that it is able to spend less than $0.50 per citizen on all medicines each year.[209]

Looking forward, there are a number of market-based activities that could increase women's access to high quality, affordable MHS, preventing maternal deaths all over the world. As outlined in the report, there are no short-term fixes. Rather, given the complex barriers in these markets – especially the fragmented nature of procurement, as well as product formulation and usage issues – the recommended interventions are longer-term and require more national and even sub-national engagement. However, if partners, both within the maternal health space and across health areas, can work together to tackle these challenges, the world might succeed in achieving the Sustainable Development Goal (SDG) of reducing the global maternal mortality ratio to less than 70 deaths per 100,000 live births. The success of reaching this goal would not just save the lives of hundreds of thousands of women, but vastly improve the welfare of many families around the world.

6. Appendices

6.1. Appendix I: Summary of market-based activities for maternal health supplies*

Key Area	Initiative Name	Implementers	Donors	Description	Year Range	Commodity	Countries
Policy	Updating EMLs and treatment guidelines	WHO, Gynuity, UNCoLSC Maternal Health TRT	Bill and Melinda Gates Foundation (BMGF), UNCoLSC	Work with countries to update national EMLs and treatment guidelines	2009-present	All three	Global
	Updating EMLs	Jhpiego Accelovate	USAID	Work with countries to update national EMLs to include magnesium sulfate for PE/E	2013-present	Magnesium sulfate	Uganda, Kenya
	Essential maternal health supplies policy briefs	Family Care International, RHSC	RHSC	Aimed at policy makers, seven MHS policies briefs that highlight cross-cutting lessons from the RH space	2014	All three	Global
	Global call to action	Engender Health	MacArthur Foundation, Clinton Global Initiative, University of Oxford	Call to action for country governments to update treatment guidelines	2007-present	Magnesium sulfate	Global
	Country dashboards for the 13 life-saving commodities (LSC)	UNCoLSC	RMNCH Trust Fund	Developed dashboards showing market environment for the 13 LSC, including MHS, in 87 countries	2015	All three	Global
	Advocate for simplified dosing regimens	The Concept Foundation, UNCoLSC Maternal Health TRT	RHSC, UNCoLSC	Advocate for simplified magnesium sulfate dosing regimens	2010-present	Magnesium Sulfate	Global
	GREAT Network	14-member Executive Committee, chaired by WHO and St. Michael's Hospital (Toronto)	Canadian Institutes of Health Research	Provide guidance and support to country stakeholders to implement evidence-based guidelines for maternal and perinatal healthcare	2012-present	All three	Global

*This table is meant to be an illustrative example of current market shaping activities, and is not exhaustive of all ongoing market shaping work for the essential MHS

Key Area	Initiative Name	Implementers	Donors	Description	Year Range	Commodity	Countries
Quality Assurance	Support to manufacturers to improve quality	The Concept Foundation, USP, WHO, Jhpiego Accelovate, PFSCM	DfID, BMGF, USAID, UNCoLSC	Provide technical support and assistance to manufacturers to increase quality standards and achieve WHO PQ status	2009-present	All three	Global
	Quality Assurance Manual for manufacturers and NDRAs	Concept Foundation	DfID, BMGF	Guidance manual for manufacturers and NDRAs to improve quality assurance mechanisms	2015	All three	Global
	Mobile Authentication Services	mPedigree, Sproxil, PharmaSecure, Savante	Ashoka, World Economic Forum, Clinton Global Initiative	Verify that drugs, including MHS, are non-counterfeit	2009-present	All three	Global
	Public sector anti-counterfeit measures	NAFDAC, Sproxil		Anti-counterfeit program in collaboration with Sproxil mobile authentication services	2010-present	All three	Nigeria
	Promoting the Quality of Medicines program	USAID, USP	USAID	Works in developing countries to strengthen quality assurance systems and increase the supply of quality assured medicines	2009-present	All three	Global
	Post-market quality surveys	USAID - USP, Concept Foundation, UNFPA , PATH	USAID, BMGF, Gynuity	Post-market surveys of product quality have been conducted in a number of geographies	2009-present	Misoprostol, oxytocin	Global
	Access to Quality Assured Oxytocin	Jhpiego Accelovate, USP-Promoting Quality of Medicines program, WHO, PFSCM, Concept Foundation	USAID, UNCoLSC	Technical Assistance to ensure countries have access to and supply chain management support for high quality oxytocin	2014-present	Oxytocin	Global
Product Appropriateness	Cold chain integration	WHO, UNICEF	UNCoLSC	A joint statement advocating for the integration of oxytocin into existing EPI cold chains	2015	Oxytocin	Global
	Cold chain integration – operational research	PATH, MSH	UNCoLSC	Review of current practices regarding oxytocin in the cold chain, and working towards best practice guidelines	2014-present	Oxytocin	Ghana, Mali

Key Area	Initiative Name	Implementers	Donors	Description	Year Range	Commodity	Countries
Product Appropriateness	Time-Temperature Indicator (TTI)	PATH		Indicator placed on oxytocin ampules during packaging to alert distributors and providers to temperature fluctuations in oxytocin storage conditions	2014-present	Oxytocin	Global
	Standardized labeling for magnesium sulfate	Maternal Health TRT and Concept Foundation	RHSC	Advocating for the simplification of product labeling for magnesium sulfate	2014-present	Magnesium Sulfate	Global
	National training manual and job aids	Population Council	The MacArthur Foundation	Develop national training tools, job aids, and posters to help providers feel more comfortable with magnesium sulfate administration	2010	Magnesium sulfate	Nigeria
	Mobile phone app for dosing instructions	PATH, University of Washington	USAID	Piloting an app that will walk healthcare providers through the administration of magnesium sulfate	2014-present	Magnesium Sulfate	Global
	Improved post-partum hemorrhage diagnostic tools	Gynuity	BMGF	Training community health workers to diagnose post-partum hemorrhage based on non-objective blood loss measurement tools	2009-present	Misoprostol	Pakistan, Afghanistan
	Community-level loading dose administration	Population Council and Engender Health	Clinton Global Initiative, MacArthur Foundation, University of Oxford	Training community health workers to administer a loading dose of magnesium sulfate	2007-present	Magnesium sulfate	Global
	Ending Eclampsia	Population Council	USAID	Working to expand community-level use of magnesium sulfate by community health workers	2014-2019	Magnesium Sulfate	Bangladesh, Ethiopia, Nigeria, Pakistan
	CLIP trails	PRE-EMPT	BMGF, Saving Lives at Birth through Grand Challenges Canada	Cluster randomized trials to improve community-level care for pre-eclampsia, including via community-level administration of magnesium sulfate	2014-present	Magnesium Sulfate	Nigeria, Mozambique, Pakistan, India
	New product research	PATH, Merck for Mothers, Ferring Pharmaceuticals, Gynuity, Monash University, GlaxoSmithKline	Grand Challenges Canada, BMGF, Saving Lives at Birth	Product design and clinical trials are being conducted for innovations that include inhalable oxytocin, thermostable carbetocin, and non-electric pumps for magnesium sulfate administration.	2011-present	Oxytocin, Magnesium Sulfate	Global
	Ready-to-use packs	PATH	UNCoLSC	Pre-diluted, color coded magnesium sulfate doses packaged with syringes for easy use	2014-present	Magnesium Sulfate	Global

Key Area	Initiative Name	Implementers	Donors	Description	Year Range	Commodity	Countries
Forecasting	UNCoLSC forecasting	JSI | DELIVER and MSH/SIAPS	USAID	Developed forecasts for the 13 UN Commission on Life-Saving Commodities in several geographies	2014-2015	All three	Bangladesh, DRC, India, Indonesia, Mozambique, Myanmar, Nigeria, and Tanzania
	Regional training workshop	The Concept Foundation, MSH, WHO, CHAI	UNCoLSC	Hosted a quantification workshop for East African stakeholders to improve forecasting practices	2015-2016	All three	East Africa
	Forecasting templates	Jhpiego	RHSC and USAID	As part of the business cases for the essential maternal health supplies, excel templates for national quantifications were developed	2014	All three	Global
	Quantification of Health Commodities: RMNCH Supplement	Supply Chain TRT, USAID, UNICEF, JSI, MSH/SIAPS	USAID	Guidance for the quantification of the UN Commission on Life-Saving Commodities products for use at the country level	2014	All three	Global
	FPWatch	PSI	BMGF	Research project collecting market data on family planning and misoprostol supplies	2015	Misoprostol	Ethiopia, Nigeria, Myanmar, DRC, India
Procurement	Tool to estimate unmet need	UNCoLSC Supply Chain TRT	USAID	Developed a tool to help compare estimated need with procurement data, and better link forecasting and procurement practices	2014	All three	Bangladesh, DRC
	Pooled procurement	MNCH2, Crown Agents	DfID	Consolidating forecasts and budgets across six states in Nigeria and pooling procurement through Crown Agents	2015	All three	Nigeria
	AccessRH	UNFPA	RHSC, BMGF, USAID	Provides safe and reliable commodities at competitive prices and decreased wait times	2008-present	All three	Global

Key Area	Initiative Name	Implementers	Donors	Description	Year Range	Commodity	Countries
Demand generation	Promoting misoprostol use at the community level	Jhpiego, Gynuity, Family Care International, PATH, PSI	USAID, DfID, WHO, UNICEF	Supporting research and training programs on the use of misoprostol at community level	2001-present	Misoprostol	Rwanda, Indonesia, Nepal, Afghanistan, Pakistan, Uganda, Tanzania, Nigeria, Somaliland, Zambia
	Demand generation I-Kit for underutilized, life-saving commodities	Health Communication Capacity Collaborative, PSI, International Consortium on Emergency Contraception, PATH, Jhpiego	USAID, RMNCH Trust Fund	Guide to developing communication strategies to increase demand for underutilized RMNCH commodities	2015	Misoprostol, Magnesium Sulfate	Global

6.2. Appendix II: WHO PQ approved and ERP-recommended manufacturers of maternal health supplies

	Oxytocin	Misoprostol	Magnesium Sulfate
WHO PQ	Grindeks	Cipla Linepharma	N/A
ERP	N/A	Zizhu	N/A

6.3. Appendix III: illustrative list of WHO PQ approved and ERP-recommended maternal health suppplies available and additional products undergoing R&D*

Product Type	Product name	Manufacturer	PQ or ERO?
Oxytocin	Oxytocin-Grindeks	Grindeks	WHO-PQ (cold chain product only)
Misoprostol	Misoprost	Cipla	WHO-PQ
Misoprostol	Misoprostol Tablets	Zizhu	ERP
Oxytocin analogue	Forthcoming thermostable carbetocin	Ferring (Merck for Mothers)	N/A
Oxytocin	Forthcoming inhalable oxytocin	GSK (Monash)	N/A
Oxytocin	Forthcoming sublingual oxytocin	PATH	N/A
Magnesium Sulfate	Forthcoming IV administration pump	U/K (PATH)	N/A
Magnesium Sulfate	Forthcoming IV administration pump	Go Medical (Gynuity)	N/A

*There may be other products available in the market or in the pipelines, but the products listed are those mentioned by stakeholders.

6.4. Appendix IV: List of stakeholders consulted

	Organization	Role*
Global	Bixby Center for Global Reproductive Health	Research, policy and guideline advocacy
	Cipla Pharmaceuticals	Manufacturer
	Clinton Health Access Initiative (CHAI)	Technical assistance, implementation
	Concept Foundation	Technical assistance, implementation
	Crown Agents	Wholesaler
	Department for International Development (DFID)	Donor
	Family Care International	Research, policy and guideline advocacy, technical assistance
	Grindeks	Manufacturer
	Gynuity	Research, policy and guideline advocacy, technical assistance
	i+solutions	Technical assistance
	IDA Foundation	Wholesaler
	Imres	Wholesaler
	International Federation of Gynecology and Obstetrics (FIGO)	Research, policy and guideline advocacy
	Jhpiego	Technical assistance, implementation
	John Snow International	Technical assistance, implementation
	Linepharma	Manufacturer
	Management Sciences for Health/Systems for Improved Access to Pharmaceuticals and Services (SIAPS)	Technical assistance, implementation
	Marie Stopes International (MSI)	Technical assistance, procurement, service provision
	Martindale	Manufacturer
	Medical Export Group (MEG)	Wholesaler
	Merck for Mothers	Manufacturer, research
	Monash University	Manufacturer, research
	Naari	Manufacturer
	Partnership for Supply Chain Management (PFSCM)	Procurement, technical assistance
	PATH	Research, technical assistance
	Pfizer	Manufacturer
	Population Council	Research, policy and guideline advocacy
	Population Services International (PSI)	Technical assistance, research, procurement and service provision
	RotexMedica	Manufacturer
	Sigma Pharmaceuticals	Manufacturer
	United Nations Children's Fund (UNICEF) Supply Division	Wholesaler
	United Nations Population Fund (UNFPA)	Wholesaler, technical assistance
	United States Agency for International Development (USAID)	Donor, policy and guideline advocacy
	World Health Organization	Quality assurance, policy and guidelines
	Zizhu Pharmaceuticals	Manufacturer

*Role descriptions are focused on those most pertinent to the analyses addressed in this report and are meant to be illustrative, not comprehensive.

	Organization	Role*
Ethiopia	Clinton Health Access Initiative	Technical assistance, implementation
	DKT Ethiopia	Technical assistance, implementation
	E-Pharm	Manufacturer (potential for MHS)
	Ethiopia Society of Obstetricians and Gynecologists (ESOP)	Technical assistance
	Federal Ministry of Health Pharmaceuticals Logistics Management Unit (FMOH PLMU)	Forecasting
	Food, Medicine, and Healthcare Administration and Control Agency (FMHACA)	Registration, quality assurance
	John Snow Inc. Last 10K Program	Technical assistance
	Marie Stopes International	Procurement, service provision
	Pharmaceuticals Fund and Supply Agency (PFSA)	Forecasting, procurement
	Population Council	Research
	United Nations Fund for Children (UNICEF)	Donor, procurement
	United Nations Population Fund (UNFPA)	Donor, procurement
	United State Pharmacopeia	Technical assistance
	United States Agency for International Development (USAID)	Donor
Nigeria	Clinton Health Access Initiative	Technical assistance, implementation
	DKT Nigeria	Technical assistance, implementation
	Health Strategy and Delivery Foundation	Technical assistance
	John Snow Inc, USAID DELIVER Project	Technical assistance, implementation
	Kaduna State Drug and Medical Supplies Management Agency (DMSMA)	Procurement
	Kaduna State Primary Health Care Development Agency (SPHCDA)	Forecasting, service provision
	Marie Stopes International	Technical assistance, service provision
	Maternal Newborn Child Health Program (MNCH2)	Technical assistance
	Pharmaceutical Society of Nigeria, Kaduna State (PSN)	Quality assurance, service provision
	Planned Parenthood Federation of Nigeria	Technical assistance, implementation
	Tyonex Pharmaceutical	Wholesaler
	Zolon Pharmaceuticals	Wholesaler
Bangladesh	Acme Laboratories Ltd	Manufacturer
	Bangladesh Rural Advancement Committee (BRAC)	Service provision
	Central Medical Stores Division (CMSD)	Procurement
	Crown Agents	Wholesaler
	Directorate General of Drug Administration	Registration, quality assurance
	Directorate General of Family Planning, Logistics Supply Unit (DGFP)	Forecasting, procurement
	Directorate General of Health Services (DGHS)	Forecasting, service provision
	Incepta Pharmaceuticals	Manufacturer
	International Center for Diarrheal Disease Research, Bangladesh	Research
	MaMoni (Maternal and Child Survival Program)	Technical assistance, implementation

	Organization	Role*
Bangladesh	Management Sciences for Health/Systems for Improved Access to Pharmaceuticals and Services (MSH/SIAPS)	Technical assistance, implementation
	Population Council	Research, policy and guideline advocacy
	Renata Ltd.	Manufacturer
	United Nations Population Fund (UNFPA)	Donor, procurement

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The Reproductive Health Supplies Coalition

The Coalition is a global partnership of public, private, and non-governmental organizations dedicated to ensuring that everyone in low- and middle-income countries can access and use affordable, high-quality supplies for their better reproductive health. It brings together agencies and groups with critical roles in providing contraceptives and other reproductive health supplies. These include multilateral and bilateral organizations, private foundations, governments, civil society, and private sector representatives.

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