Maternal Health Task Force

Global Health Visions

U.N. Commission on Life Saving Commodities for Women and Children: Country Case Studies

May 2012

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The authors would like to thank the following individuals for their contributions to the development and conceptualization of these case studies:

Oliver Sabot	Clinton Health Access Initiative
Hans Hogerzeil	Groningen University
Patricia Mechael	mHealth Alliance
Catherine Taylor	PATH
Kanika Bahl	Results for Development Institute
Julia White	UN Secretariat
Kabir Ahmed	UNFPA
Mark Young	UNICEF
Renee van de Weerdt	UNICEF
Deborah Armbruster	USAID
Jennifer Lockwood-Bergeson	USAID
Michael Mbizvo	WHO

The authors would also like to thank the following individuals who provided key insight into maternal health commodities in Bangladesh, Ethiopia, India, Nigeria, Tanzania and Uganda:

Samit Tandon	Blue Lotus Advisory
Abhijit Das	Center for Health and Social Justice
Billy Stewart	DFID
Abu Jamil Faisel	EngenderHealth
Manju Shukla	IntraHealth
Peter Haulohner	JSI
Anteneh Tsige	MSH
Albert Kalangwa	Uganda Ministry of Health
Michael Tekie	UNFPA
Asia Kassim Hussein	UNICEF
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Acronyms

General

AMTSL	Active Management of the Third Stage of Labor
BEmONC	Basic Emergency Obstetric Newborn Care
CEmONC	Comprehensive Emergency Obstetric and Newborn Care
CIDA	Canadian International Development Agency
DFID	UK Department for International Development
DHS	Demographic and Health Survey
EML	Essential Medicines List
EmOC	Emergency Obstetric Care
EmONC	Emergency Obstetric and Newborn Care
MCHIP	Maternal and Child Integrated Program (USAID)
MDG	Millennium Development Goal
MgSO4	Magnesium sulfate
MH	Maternal Health
MMR	Maternal Mortality Ratio
MoH	Ministry of Health
NGO	Non-Governmental Organization
PE/E	Pre-eclampsia/Eclampsia
POPPHI	Prevention of Postpartum Hemorrhage Initiative
PPH	Postpartum hemorrhage
RH	Reproductive Health
RHCS	Reproductive Health Commodity Security
SDPs	Service Delivery Points
STGs	Standard Treatment Guidelines
SWAps	Sector wide approaches
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
WHO	World Health Organization

Bangladesh

BMMS	Bangladesh Maternal Mortality Survey
CMSD	Central Medical Stores Depot
CSBA	Community-based Skilled Birth Attendant
DDA	National Directorate of Drug Administration
DGFP	Directorate General of Family Planning
DGHS	Directorate General of Health Services

EDL	Essential Drugs List
HPNSDP	Health Population and Nutrition Sector Development Program
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
MOH&FW	Ministry of Health and Family Welfare
PPH Task Force	Postpartum Hemorrhage Task Force

Ethiopia

BPR	Business Process Review
DACA	Drug Administration and Control Authority
EDHS	Ethiopian Demographic and Health Survey
FMHACA	Food, Medicine, and Health Care Administration and Control Authority
FMOH	Federal Ministry of Health
GoE	Government of Ethiopia
HEP	Health Extension Program
HEW	Health Extension Worker
HSDP	Health Sector Development Program
NHA	National Health Accounts
PASDEP	Plan of Accelerated and Sustainable Development for the Eradication of Poverty
PFSA	Pharmaceutical Fund and Supply Agency
PLMP	Pharmaceutical Logistics Master Plan
RDF	Revolving Drug Fund
RHB	Regional Health Bureaus
WorHO	Woreda Health Offices

India

ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
BPL	Below Poverty Line
CHARM	Center for Health and Resource Management
DCGI	Drug Controller General of India
DHAP	District Health Action Plan
DPCO	Drug Price Control Order
JSY	Janani Suraksha Yojana
MOHFW	Ministry of Health and Family Welfare
NMBS	National Maternity Benefit Scheme
NRHM	National Rural Health Mission
PHC	Primary Health Centre
PSUR	Periodic Safety Update Report

RMP	Rural Medical Practitioner
TNMSC	Tamil Nadu Medical Services Corporation

Nigeria

DRF	Drug Revolving Fund
EML	Essential Medicines List
FG	Federal Government
FMOH	Federal Ministry of Health
FMS	Federal Medicines Store
IMNCH Strategy	Integrated Maternal Newborn and Child Health Strategy
LGA	Local Government Area
LGA	Local Government Area
MSS	Midwives Service Scheme
NAFDAC	National
NDP	National Drug Policy
NPHCDA	National Primary Health Care Development Agency
NSHDP	National Strategic Health Development Plan
PHC	Primary Health Center
SMS	State Medicines Store
TSHIP	Targeted States High Impact Project (USAID)

Tanzania

CMS	Central Medicines Store
EAC	East African Community
ILS	Integrated Logistics System
MCHIP	Maternal and Child Health Integrated Program
MOHSW	Ministry of Heath and Social Welfare
MSD	Medical Stores Department
NEMLT	National Essential Medicines List for Tanzania
NEPAD	New Partnership for Africa's Development
STG	Standard Treatment Guidelines
TFDA	Tanzania Food and Drugs Authority
TZS	Tanzanian Shilling
ZMS	Zonal Medicines Store

Uganda

EAC	East African Community
EMLU	Essential Medicines List of Uganda
HSSP	Health Sector Strategic Plan
JMS	Joint Medical Store
MeTA	Medicines Transparency Alliance
MMR	Maternal Mortality Ratio
NEPAD	New Partnership for Africa's Development
NMS	National Medical Store
RCQHC	Regional Centre for Quality of Care
SURE	Securing Uganda's Right to Essential Medicines
UCG	Uganda Clinical Guidelines
UGX	Ugandan Shillings

Executive Summary

I. Introduction

Although there has been substantial progress toward reducing maternal mortality in the past decade, nearly 300,000 women still die each year from causes related to pregnancy and childbirth, most of which are preventable or treatable. Most of these deaths occur in sub-Saharan Africa and South Asia, where the majority of women give birth at home or in poorly-equipped clinicswhere proven interventions are too often out of reach.

Two of the leading causes of death are post-partum hemorrhage (PPH), excessive bleeding after childbirth, and pre-eclampsia/eclampsia (PE/E), extremely high blood pressure that can result in seizures. These common complications need not be fatal. PPH can be treated and, in many cases, prevented using uterotonic medicines such as oxytocin and misoprostol, while magnesium sulfate is the most effective treatment available for managing PE/E. All three medicines now appear on the WHO Model Lists of Essential Medicines (EML) as well as in many national policies and clinical protocols. However, there are still enormous gaps between what these documents say and the conditions in communities, clinics and hospitals around the world. Weak logistical capacity within health systems contributes to stock-outs and shortages, and government oversight often falls short of assuring quality. Although these medicines are comparatively cheap, the heavy reliance on out-of-pocket spending may put medicines beyond the reach of poor women. In addition, shortcomings in health worker training, widespread misperceptions of side effects, and the inability of women, their families, or health workers to recognize complications in time to seek treatment also contribute to the confluence of barriers that continue to keep these medicines from having an impact.

The case studies that follow focus on six countries that carry a high burden of maternal mortality: Bangladesh, India, Ethiopia, Nigeria, Tanzania, and Uganda. The studies are based on a desk review of available evidence regarding barriers to access of magnesium sulfate, misoprostol, and oxytocin, and build upon a global landscape conducted by PATH, MSH, UNFPA, and USAID, with input from a number of other organizations, which resulted in the working paper *Medicines for Maternal Health*, prepared for the United Nations Commission on Life-Saving Commodities for Women and Children in March 2012. The studies seek to identify specific barriers to access to three medicines: oxytocin, misoprostol, and magnesium sulfate. They also highlight innovations and best practices that may have a major impact on access to maternal health commodities, and identify critical areas for further research and action in each of these countries.

II. Innovations and Best Practices

A number of innovations show promise for increasing access to key maternal health commodities, and best practices are being identified. Mobile technologies, such as text messaging, are being used to collect and transmit information ranging from documenting stock levels of particular commodities to disseminating information to women on where and how to access maternal health care. Meanwhile, advances in medical and technological research and development are producing innovative tools for the diagnosis and treatment of PPH and PE/E in low-resource settings. Tools like solar-powered refrigerators, and single-dose, disposable injections hold promise for bridging gaps in current delivery systems while

others, like inhalable oxytocin, may one day make constraints such as the need for cold storage obsolete. Task-shifting to less-trained cadres of health workers is an important strategy, for which there is mounting evidence of safety and effectiveness. In particular, community-based distribution of misoprostol could dramatically expand to the use of uterotonics to prevent PPH. For this to be effective, however, supply chains must be strengthened in a way that is geared toward community-based distribution programs. At both the country and international levels, pooled procurement, in which various governments or institutions act collectively to procure commodities, is an important strategy for increasing supply and lowering costs of a variety of medicines and supplies. These innovations address a full range of barriers to access to maternal health commodities and provide viable options for expanding availability to women in developing countries.

III. Recommendations and Next Steps

Several clear recommendations have emerged from the initial assessment of three maternal health commodities in six countries. Common findings, such as the mismatch between policy environments that generally support access to essential commodities and the reality on the ground, emerged as critical areas for further investigation. While there are country-specific recommendations provided for each country study, the researchers collectively identified a common set of recommendations that seek to guide further in-depth research and, hopefully, will help to spur more explicit attention to these commodities by policymakers, donors, and health programmers alike.

IV. Bangladesh Case Study

Bangladesh has achieved dramatic reductions in maternal mortality in recent decades, and current policies reflect the government's strong commitment to improving maternal health. Although essential maternal medicines are, by policy, free to all women; in reality, access to medicines relies heavily on the ability of women and their families to purchase them, often in unregistered, poorly regulated private stores. Inefficient procurement and inadequate management of critical logistics lead to shortages and stock-outs of magnesium sulfate and oxytocin. The cost of medicine often poses a barrier to access for poor women, and discourages women of all income levels from seeking care in public facilities. A new policy to promote large-scale distribution of misoprostol at the community level holds enormous potential. That policy's impact now depends on the development of new investments in training and logistical management that prioritize delivery of supplies to the community level. Likewise, expanding access to magnesium sulfate and oxytocin will rely on continued efforts to collect evidence on providers' abilities and preferred formulations of each commodity; the influence of aggressive marketing by pharmaceutical companies; and the strengthening of existing partnerships between technical experts and policymakers.

V. Ethiopia Case Study

Despite the impressive steps Ethiopia has taken in recent years to expand the health workforce and increase access to health services, a lack of access to and infrequent use of skilled birth attendants and low levels of facility based births persist. With an estimated 94% of births occurring at home, most women never have access to life-saving interventions, including maternal health commodities. While

oxytocin, misoprostol, and magnesium sulfate are all included in Ethiopia's Essential Medicine List, guidance on treatment protocols is muddled. There are several guiding documents, but they do not consistently indicate oxytocin and misoprostol for PPH or magnesium sulfate for PE/E. Further, while Ethiopia has prioritized maternal health in many recent national strategies, there is very little attention paid specifically to these essential commodities.

VI. India (Bihar) Case Study

Bihar demonstrates the growing pains of a state trying to restructure a dismal maternal health system to provide more equitable and efficient access to health care. It has made great strides in reducing maternal mortality through a combination of national and state initiatives. However, uncoordinated activities between agencies; an ineffective national procurement and distribution system; a continual lack of resources dedicated to rural regions; and insufficient trained health care workers, are just a few examples of challenges that Bihar faces in efforts to expand access to maternal heath commodities. Although the use of magnesium sulfate, misoprostol, and oxytocin are all currently supported in formal health care guidance, such as the National List of Essential Medicines, inefficiencies in the health system prevent these policies from translating into action. There is both a need and an opportunity for magnesium sulfate, misoprostol, and oxytocin to be utilized effectively in reducing maternal mortality amongst women in Bihar. However, additional research is needed in order to more fully understand and address the structural barriers that continue to impede access to these essential medicines.

VII. Nigeria Case Study

Nigeria's national policies acknowledge that the country's high burden of maternal mortality requires swift action to be remedied. Yet low public spending, coupled with a complex, decentralized system of governance means that these policies have little impact on access to critical interventions, including magnesium sulfate, misoprostol and oxytocin. At present, neither government policies nor donor strategies to improve supplies of essential commodities include explicit attention to this set of medicines. As a result of this neglect, there is a general sense that supplies of all three commodities are inadequate and often out of reach. However, there is a fundamental lack of data on how many women currently lack access to these supplies, how procurement and supply chains are managed, or whether health care providers are prepared to administer these medicines appropriately. In order to realize the potential of recent policy developments, such as the Midwives Service Scheme, which seeks to improve quality of care in primary health facilities, these supplies must be given explicit attention by the government and major donors alike.

VIII. Tanzania Case Study

Tanzania has a number of policies in place to address maternal health commodities, and commodities are considered a priority by the government and other actors. The East African Community has taken steps towards regional registration of commodities and has developed a plan for promoting manufacturing in the region. Tanzania has piloted community distribution of misoprostol for PPH, but has not yet taken it to scale even though it has been found to be safe and effective. Working with the USAID Deliver Project, the government has also implemented an Integrated Logistics Systems for

procurement and distribution of life-saving commodities. While these are important signs of progress, critical barriers remain. Chief among them is the fact that, although ostensibly free, women often have to pay for antenatal care and delivery services, including essential medicines. In addition, little of the research on commodities in Tanzania directly addresses maternal health commodities, so the work of identifying the particular challenges and opportunities related to these commodities remains incomplete.

IX. Uganda Case Study

Support for life-saving commodities in Uganda is still far from ideal: for example, misoprostol is not included on the current Essential Medicines List for Uganda, and the government has done little to encourage local manufacturing of essential drugs. However, there are a number of developments that hold promise for improving access to supplies. Studies have shown that there is a high demand for medicines among the Ugandan public, and a number of organizations have identified commodities as key to improving health and are working to improve access. At the same time, the Uganda's government has developed a hybrid system for distribution of commodities that combines aspects of push and pull systems. The East African Community has taken steps towards regional registration of commodities and has developed a plan for promoting manufacturing in the region. While these steps have thus far been insufficient to guarantee access to life-saving commodities for mothers, more focused attention to the specific issues that inhibit steady supplies and appropriate administration of maternal health commodities is needed.

X. Conclusion

This report is meant to serve as an aggregation and review of readily available information regarding these three key maternal health commodities in six target countries with high burdens. While findings differ across countries, one aspect is clear – significantly more research is needed to fully capture the state of maternal health commodities in these countries, and probably others. Building on this initial review, a well-planned series of consultations with in-country stakeholders is a critical next step. A comprehensive understanding of the status and accessibility of these commodities is a necessary component of ensuring access to high quality maternal health services for millions of women around the world.

I. Introduction

Background

Despite important gains in recent decades, maternal mortality persists as a global burden. Still nearly 300,000 girls and women die each year from pregnancy- and childbirth-related complications, almost all of which are preventable or treatable.[3] This affects not just women themselves, but also the families, communities, and nations that lose them.

The burden of maternal mortality is concentrated in the developing world, with more than half of deaths occurring in sub-Saharan Africa and one-third in South Asia.[4] The majority of women in the developing world give birth at home and often without the presence of a skilled birth attendant,[5] which puts them at increased risk for injury and fatality. Yet disadvantaged women giving birth in ill-equipped and under-staffed clinics are not much better off. The gap between rich and poor, and chronic inequities in access to health care, leave too many women without lifesaving access.

Worldwide, maternal deaths and injuries are directly attributed to just a handful of causes. The two leading causes are common complications: postpartum hemorrhage (PPH), excessive bleeding after childbirth, and pre-eclampsia/eclampsia (PE/E), extremely high blood pressure during pregnancy and childbirth. Together, they affect more than eight million women each year.[6] These complications need not be fatal, but because of a lack of access to critical interventions, they are disproportionately so for women living in resource poor settings.

Fortunately, affordable and effective solutions to treat and prevent PPH and PE/E exist, and access to them can drastically reduce the number of maternal deaths worldwide. However, a confluence of barriers in nearly every facet of the healthcare system – including cost, lack of knowledge among women and providers, and supply stock-outs – persist, making pregnancy and childbirth one of the riskiest ventures women in the developing world can undertake. Understanding and addressing these barriers, which keep interventions for PPH and PE/E out of reach for too many, is a hurdle that stands before the

[3] "Trends in Maternal Mortality: 1990 to 2008" Estimates developed by WHO, UNICEF, UNFPA, and the World Bank. http://whqlibdoc.who.int/publications/2010/9789241500265_eng.pdf
[4] WHO. Factsheet No 348: Maternal Mortality. May 2012. http://www.who.int/mediacentre/factsheets/fs348/en/index.html
[5] Montagu, et al. "Where Do Women in Developing Countries Give Birth?" PLoS ONE. February 2011; Volume 6, Issue 2, e17155. http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0017155
[6] Carroli G, Cuesta C, Abalos E, Gulmezoglu AM. Epidemiology of postpartum haemorrhage: a systematic review. *Best Practice & Research Clinical Obstetrics and Gynaecology*. 2008;22:999–1012; EngenderHealth. Balancing the Scales: Expanding Treatment for Pregnant Women with Life-Threatening Hypertensive Conditions in Developing Countries; A Report on Barriers and Solutions to Treat Pre-eclampsia & Eclampsia. http://www.engenderhealth.org/ files/pubs/maternal-health/EngenderHealth-Eclampsia-Report. Pdf.

global maternal health community. Overcoming this is critical to strengthening maternal health programs and health systems broadly, and ultimately saving the lives of girls and women worldwide.

Addressing PostPartum Hemorrhage: Misoprostol and Oxytocin

PPH occurs when the uterus does not adequately contract after childbirth, and excessive bleeding ensues. This leading cause of maternal mortality accounts for one out of every four maternal deaths. Yet PPH can be prevented or treated with the swift administration of uterotonics, medicines that cause the uterus to contract and reduce bleeding, during active management of the third stage of labor (AMTSL) – a common approach to preventing PPH. Uterotonics include such medicines as oxytocin and misoprostol, which, if available to all women giving birth over a ten-year period (2006-2016), could prevent an estimated more than 40 million PPH cases and save approximately 1.4 million lives.[7]

Oxytocin, a natural hormone secreted during pregnancy, labor, and breastfeeding is also available in synthetic form. When administered, it takes effect quickly – faster than any other uterotonic – and produces slow, regulated contractions of the uterine muscles. It is administered as an injection into the muscle or vein (usually in 1 ml glass vials, containing either 5 international units/IU or 10 IU), and must be stored at a regulated temperature in order to remain viable. It costs less than US$0.20 for 10 IU, and is produced by more than 100 manufacturers around the world. Oxytocin is recommended by the World Health Organization (WHO) as the first line treatment and is the most commonly used intervention in Active Management of Third Stage of Labor (AMTSL), during which a trained birth attendant administers an uterotonic to the woman within one minute after birth, delivers the placenta with controlled cord traction, and massages the uterus after the placenta delivers.[8]

Misoprostol is a synthetic hormone-like substance that was originally developed to treat gastric ulcers. Misoprostol, like oxytocin, causes the uterine muscles to contract, making it an effective medicine to treat PPH. It may also be used to treat incomplete miscarriage or induce abortion where approved, and is used in conjunction with the medicine mifepristone for medication abortion in the US. WHO recommends 600 micrograms orally for the prevention of PPH, but permits up to 800 micrograms under the tongue as the third line of treatment. Misoprostol costs about US$.15 per tablet and is manufactured by more than 50 companies globally (about 35 of which are developing countries manufacturers).

Accessibility and Barriers

Misoprostol and oxytocin are recognized by WHO and many governments as key interventions for PPH. Yet guidelines and recommendations for their use, as well as their availability, affordability, and appropriateness, vary dramatically depending on the setting, between countries, and even among providers within countries.

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[7] Seligman, Barbara and Xingzhu Liu. Economic Assessment of Interventions for Reducing Postpartum Hemorrhage in Developing countries. Abt Associates Inc.; 2006. http://www.abtassociates.com/reports/EconReducPPHDevCo.pdf

[8] JHPIEGO. *Preventing Postpartum Hemorrhage: Active Management of the Third Stage of Labor–A Maternal and Neonatal Health Program Best Practice.* Available at: http://www.reproline.jhu.edu/English/6read/6issues/6jtn/v4/tn110hemor.htm.

Oxytocin takes effect much faster than misoprostol and is generally trusted by providers, but requires cold chain storage, a burdensome process whereby the medicine must be kept at a consistently low temperature over time. This presents a major barrier in rural and low-resources settings, particularly in tropical climates with unreliable access to electricity converge. The medicine must also be administered through injection into the woman's vein or muscle. While oxytocin is the most widely recognized medicine for treating PPH, and is largely included in national guidelines, there is a chronic lack of clarity around these guidelines and insufficient capacity building and training at the provider level to ensure proper administration of the medicine. Recent innovations, such as the delivery of oxytocin through Uniject, could address some of these challenges and improve the efficacy of oxytocin in low-resource settings.

In contrast, misoprostol is easily stored without refrigeration and can be administered orally, with only the most basic training. As such, it is ideal for use in non-clinic or rural settings, yet there remains some uncertainty among providers about whether it is as effective as oxytocin for treating PPH. Indeed, the 17th edition of the WHO Model Lists of Essential Medicines (EML) recommends misoprostol for prevention of PPH, but only where oxytocin is unavailable or cannot be safely used. Misoprostol is not recommended for primary use or for self-administration. This may be due, in part, to some stigma that the medicine retains because of its potential use as an abortifacient.

Variance in national policies on which cadre of providers is authorized to administer the medicines, the implementation of those policies, and the unreliability of public sector supply chains all contribute to patchwork accessibility for women during obstetric emergencies. For example, in India, midwives are authorized to administer oxytocin for PPH, yet a USAID-supported national survey in 2011 found that oxytocin was not regularly available at health facilities.[9] In Uganda, the same survey found that while misoprostol is approved for PPH and listed on the country's EML, it is not being piloted or scaled up for use during home births, where a large proportion of PPH complications occur.[10]

Further, even where misoprostol and oxytocin are available and being used, additional challenges remain around medicine quality assurance and adequate knowledge of recommended dosage among both providers and pharmacists. A 2004 WHO report found that 90% of national regulatory authorities in Africa lacked the capacity to guarantee the quality, efficacy, or safety of medicines in their country. Finally, in part because there is a range of recommended and acceptable doses for both the treatment and prevention of PPH with oxytocin and misoprostol (according to WHO guidelines), there is some disparity and confusion among providers. And where a dose may be either harmful or ineffective, it is always the woman who will bear the primary consequences.

[9] Fujioka A, Smith J. *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* Maternal and Child Health Integrated Program (MCHIP); 2011. Available at: http://www.k4health.org/system/files/PPH_PEE%20Program%20Status%20Report.pdf.
[10] *Ibid*.

Addressing Pre-Eclampsia/Eclampsia: Magnesium Sulfate

PE/E is sudden hypertension or increase in high blood pressure during pregnancy and childbirth. It may lead to seizures, kidney and liver failure, and eventually maternal and infant mortality if left untreated. The condition is common and treatable, but unnecessarily fatal for women in developing countries who are 300 times more likely to die as a result of PE/E than women in developed countries.[11] PE/E is the second leading cause of maternal death worldwide, and in 2005 WHO estimated that it contributed to the deaths of 63,000 women.[12]

The WHO has included magnesium sulfate on its EML, recognizing it as the most effective, safe, and affordable intervention for treating the life threatening seizures brought on by PE/E. In addition to magnesium sulfate, medicines that are riskier and less effective are also still frequently used in developing countries to treat PE/E, in part due to fear of potential side effects, and lack of provider knowledge about dosage and implications. Magnesium sulfate costs just about US$1.00 per dose and is administered as an injection into the woman's vein or muscle.

Accessibility and Barriers

Most national policies, in addition to global WHO guidelines, support the use of magnesium sulfate to treat PE/E, but a gap remains between policy and practice. For example, a USAID survey implemented in Tanzania and Bangladesh in March 2011 found that while magnesium sulfate was listed on the essential drug list, national policies were in place to support its use for PE/E, and midwives were authorized to administer it, magnesium sulfate was not regularly available in facilities in either country.[13]

Although PE/E remains a leading cause of maternal death throughout the world, there is still a considerable lack of knowledge among providers regarding warning signs and steps to prevent and treat it. Programs on the prevention of PE/E are generally less developed than those to address PPH, resulting in arguably less provider knowledge around the use and implications of magnesium sulfate than around that of oxytocin and misoprostol.

However, similar barriers around accessibility exist across all three maternal health commodities. In sum, while national policies and clinical protocols support their immediate use in obstetric emergencies to prevent maternal deaths, there is often miscommunication over dosage, health worker permissions, perceived side effects, and logistical barriers such as stock-outs and the lack of quality-assured medicines.

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[11] EngenderHealth. Balancing the Scales: Expanding Treatment for Pregnant Women with Life-Threatening Hypertensive Conditions in Developing Countries; A Report on Barriers and Solutions to Treat Pre-eclampsia & Eclampsia. Engender Health; 2007. http://www.engenderhealth.org/ files/pubs/maternal-health/EngenderHealth-Eclampsia-Report. pdf.
[12] *Ibid*.
[13] Fujioka A, Smith J. *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* Maternal and Child Health Integrated Program (MCHIP); 2011. Available at: http://www.k4health.org/system/files/PPH_PEE%20Program%20Status%20Report.pdf.

Methodology

The findings in these case studies are based on a desk review of available evidence, including data, and policy information, as well as assessments by key informants regarding barriers to access of magnesium sulfate, misoprostol, and oxytocin. The study builds upon a global landscape conducted by PATH, MSH, UNFPA, and USAID, with input from a number of other organizations, which resulted in the working paper *Medicines for Maternal Health*, prepared for the United Nations Commission on Life-Saving Commodities for Women and Children in March 2012.

The review included international and country-specific guidelines and publications, national and international strategic frameworks, national surveys, project documents and reports, journal articles, and technical briefs. The documents were provided by partner organizations and identified through targeted searches of relevant public websites and subscription databases.

In our review, we sought research and policy documents that were as current as possible. Given the quickly changing nature of access to essential commodities and maternal health services, and the ongoing revision of relevant policies, we focused on literature – including policy documents – published in the past five to ten years, with a strong bias toward literature published more recently. In determining global burdens of maternal mortality and morbidity, we relied on the latest available global estimates, from the Institute of Health Metrics and Evaluation (2011).

This data was supplemented by the most recent Demographic and Health Survey results published for each country (either final or preliminary) and interviews with numerous in-country stakeholders in the target countries and a number of individuals at the headquarters level. These interviews were used to validate and expand upon the findings from the document review.

In conducting our research, we sought to answer guiding research questions to the extent possible, given clear time and resource limitations, while identifying questions that may not be answerable given current, readily available information and which will guide future, in-depth investigation within each country.

Scope

The working paper principally written by PATH, UNFPA, and USAID in March 2012 for the UN Commission on Life-Saving Commodities for Women and Children served to stimulate discussion around maternal health commodities access and provide a review of current conditions and available evidence on maternal health medicines, as well as potential actions and areas for continued study. One recommendation from the working paper was the undertaking of in-depth country case studies to better understand the specific barriers and access issues for key maternal health commodities.

As follow-up to these recommendations, we were tasked with conducting a concerted literature review in addition to selected interviews with country-level and headquarters stakeholders and completing case studies for six high-burden countries: Bangladesh, India (Bihar), Ethiopia, Nigeria, Tanzania, and Uganda. Our goal was to uncover a more detailed picture of the specific barriers, bottlenecks, and opportunities for research and around three key maternal health commodities: magnesium sulfate, misoprostol, and oxytocin. Based on findings from the working paper, we focused our review on seven topics surrounding maternal health commodities: policy, regulatory, manufacturing, supply chain management, information

systems, financing, and demand (providers and consumers). The scope of our work was informed by discussions with UNICEF, UNFPA, USAID and the chairs of the working groups of the Commission.

Limitations

Our efforts were limited by considerable time constraints (20 working days), given that case studies aimed to inform the Commission's meeting on May 22, 2012. In addition, our capacity was limited by our role as researchers new to the Commission support processes underway. While we mobilized all networks and resources available within the given timeframe, our work primarily entailed a desk-side literature review supplemented by select stakeholder interviews in key countries. While the case studies included here provide additional detail on current barriers and opportunities for ways forward, their limit in scope given constraints – and the necessity for further research – should be emphasized.

We reviewed policy documents, program evaluations, and primary and secondary research, which were readily available through public websites or select subscription databases, such as PubMed. We also conducted a small set of key informant interviews with country-level contacts in the maternal health field, provided through our own networks or by partners of the Maternal Health Task Force, UNICEF, USAID, or UNFPA.

As such, access to information that resides inside government offices and ministries, health facilities and pharmaceutical companies was extremely limited. Given more time, this would be an important sphere to access and level of input to solicit. In addition, we found and had limited access to information on the knowledge, attitudes, and medicine preferences of in-country providers, as well as information regarding the demand and incentives or disincentives to utilization of these commodities from the client and consumer side.

Our limited research affirmed that further in-depth investigation is needed in follow-up to the Commission's working paper, including many more in-depth interviews with an expanded set of key stakeholders in-country. Expanded stakeholders in interview may include: contacts in state health departments, ministries of health, pharmaceutical and medicine authorities/ regulators, private sector actors, as well as health workers on the ground, and non-governmental and civil society partners. In addition, more up-to-date and reliable data from National Family Health Surveys and District Household Surveys, as it becomes available, would provide a more comprehensive picture of barriers and opportunities to accessing essential maternal health commodities.

II. Innovations and Best Practices

A number of key innovations and best practices are being put into practice to increase the availability and accessibility of maternal health interventions. Exploring the possibility of scaling up these approaches in the target countries for oxytocin, misoprostol, and magnesium sulfate offers additional considerations for addressing postpartum hemorrhage (PPH) and pre-eclampsia/eclampsia (PE/E).

Key developments for increasing accessibility of maternal health commodities include: 1) the use of information and communication technologies (ICT), particularly mobile technology; 2) advances in medical research and development that improve diagnosis and treatment modalities; 3) community-based distribution of commodities and task-shifting to less-trained cadres of health workers; and 4) supply chain improvements, including innovative procurement methods for key commodities.

There is considerable overlap among these themes, with the most promising interventions capable of addressing multiple bottlenecks. The list of innovations and best practices that appear in this section are not meant to be exhaustive or fully representative of all innovations and best practices for maternal health commodities, but rather provide an overview of the types of interventions occurring in low-resource settings.

	Program	*Country(ies)*	*Implementer(s)*	*Summary*
ICT and mHealth	SMS for Life	Tanzania, Ghana, Kenya	Novartis Foundation, Vodafone, Medicines for Malaria Venture (MMV), Roll Back Malaria Partnership, IBM, Tanzania MOH	A successful SMS solution for increasing access to anti-malaria medicines
	"Pill-check week"	Kenya, Malawi, Uganda, Zambia	Stop Stock-outs	Researchers checked for 10 essential medicines in public health facilities and mapped stock-outs via SMS
	Use of RapidSMS by CHWs	Rwanda	Rwanda Ministry of Health	A mobile data system has helped Rwanda to become a model in the utilization of community health workers
	Using Cell Phones for Obstetric Emergencies	Tanzania	Ifakara Health Institute (IHI)	Providing mobile phones to mid-level providers to enhance communication with district level for consultations, counseling, referrals, and resupply service.
	Malezi-Bora	Kenya	Zoe Alexander Ltd.	Saving Lives at Birth awardee promotes viral sharing of MH information
M edi	Uniject-oxytocin	Field evaluations in Ghana, Guatemala,	PATH (licensed to Becton, Dickinson and Company (BD))	A prefilled, single-dose syringe that can be used to

		Honduras, Indonesia, Mali, Vietnam		deliver a 10 IU dose of oxytocin intramuscularly for routine AMTSL or in an emergency.
	Aerosol delivery for oxytocin (in development)	Global	Monash University, Australia	An aerosol formulation of oxytocin to be inhaled by patients that does not require cold storage
	CoolComply	Ethiopia (for TB treatment)	Innovations in International Health at MIT, Global Health Committee, Massachusetts General Hospital	Measures the temperature of medicines and sends information wirelessly to health providers along with compliance data
	PIERS on the move	Global	University of British Columbia, Vancouver, Canada	Pre-Eclampsia/Eclampsia Integrated Estimate of Risk assessment on a mobile phone equipped with a pulse oximeter
	"Super Skin" Sensing Strip for PE/E	Global	Stanford University	Solar powered strip detects changes in electrical current associated with biomarkers for PE/E
	Automatically Deflating Air Postpartum Tamponade (ADAPT)	Global	Johns Hopkins University	Auto-deflating device that is inflated in the uterus to apply pressure and cause the uterus to contract to manage PPH.
	Homeostatic foam device for treatment of PPH	Global	Arsenal Medical	Device can be inserted into the uterus following childbirth and expands to control bleeding.
	Novel hemostatic agent to treat PPH	Global	Z-Medica Corporation	A new hemostatic agent based on QuikClot (kaolin) to control PPH in remote settings.
	Circumferential abdominal-pelvic pressure (CAPP) device	Field evaluation in Nepal	Global Health Partnerships	Device designed to control PPH by decreasing blood flow to pelvic organs; can be constructed locally using materials such as bicycle tires.
CBD/Task-Shifting	Kigoma, Tanzania misoprostol distribution through TBAs	Tanzania	Venture Strategies Innovations (VSI)	Longest-operating community-based distribution of misoprostol demonstrates high degree of acceptability, safety, and effectiveness for this practice
	Randomized controlled trial of misoprostol	India	R. Derman, et al.	Auxiliary nurse midwives able to safely and effectively administer misoprostol

	for prevention of PPH			
	Mayer Hashi Project	Bangladesh	EngenderHealth, USAID	CBD project is example of good practices in a number of areas, including evidence-based advocacy, community mobilization, and technological innovation.
	Community mobilization to reduce PPH in home births in northern Nigeria	Nigeria	Venture Strategies Innovations (VSI)	Several field evaluations have shown that misoprostol can be used safely at the community level for prevention of PPH.
	Social marketing of misoprostol for PPH	Nigeria, Somaliland, Tanzania, Uganda and Zambia	Population Services International (PSI), Venture Strategies Innovations (VSI)	Successful, culturally appropriate communications and branding strategies to foster acceptance for misoprostol for PPH.
Pooled procurement	Centralized procurement for the state of Tamil Nadu	India	Tamil Nadu Medical Services Corporation (TNMSC)	TNMSC is considered a model of centralized procurement for other states in India.
	Organisation of Eastern Caribbean States Pharmaceutical Procurement Service (OeS/PPS)	Antigua and Barbuda, Dominica, Grenada, Montserrat, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Anguilla, British Virgin Islands	Organisation of Eastern Caribbean States	Pools procurement of key commodities for 9 member states, reducing prices by 25%.
	The Group Purchasing Programme of the Gulf Cooperation Council	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates	Gulf Cooperation Council	Example of successful regional procurement
	WHO Prequalification of Medicines Programme	Global	World Health Organization (WHO)	Can facilitate pooled procurement, however, there are currently no prequalified forms of oxytocin, misoprostol, or magnesium sulfate.
	AccessRH	Global	UNFPA, The Reproductive Health Supplies Coalition	Provides countries and NGO clients with access to RH commodities, reducing lead time by keeping certain commodities in stock.

ICT and mHealth

Information and communication technologies (ICT) are among the most significant drivers of innovation in the field of global health. The use of mobile communication devices to enhance public health, often called mHealth, has a range of important applications for increasing access to essential maternal health commodities. These uses include supply chain management, training and diagnostic assistance for health workers, providing information and guidance to mothers, and geographically locating patients for emergency referral.

SMS for Supply Chain Management

One of the most powerful uses of mHealth technology with respect to essential commodities is the ability to rapidly collect data about stock levels of key medicines. The mobile communications technology known as short message service (SMS) has the potential to improve supply chain management to reduce or eliminate stock-outs of essential commodities. SMS utilizes technology and equipment (mobile phones) that are inexpensive and widely available even in the most remote areas. With even just a network of mobile phones carried by health workers and a single computer with internet access, information management can improve enough to significantly increase access to important medicines.

The SMS for Life program in Tanzania is one example of a successful SMS intervention for increasing access to the anti-malarial medicines ACT (artemisinin combination therapy) and injectable quinine. This public-private partnership among the Novartis Foundation, Vodafone, the Medicines for Malaria Venture (MMV), the Roll Back Malaria Partnership, IBM, and the Tanzania Ministry of Health has dramatically improved access to anti-malarial medicines in Tanzania. In a six month pilot project, the use of SMS technology reduced stock-outs of ACT medicines from 26% to 0.8%, providing access to anti-malarial therapy to an additional 300,000 people by the end of the pilot program.[14] The percentage of clinics carrying no quinine decreased from 17% to 3%, and the percentage of health facilities experiencing stock-outs decreased from 90% to 6%.[15] Following the successful pilot, this technology was rolled out in all 5,070 public health facilities in Tanzania in 2011.[16]

The system is comprised of SMS and a web-based mapping technology. Health workers receive a message on a weekly basis requesting stock information. The response rate during the pilot program was 95%.[17] Health workers reply to the message with current stock numbers and receive free mobile airtime as an incentive for timely reporting. The stock data is compiled in real time in a central database. Mapping technology can then be used to display stock-outs by health facility and district, as well as to calculate medicine utilization. Distribution of essential commodities can be directed accordingly. SMS for Life was subsequently rolled out in Ghana and Kenya. It is also being used to track other essential

[14] SMS for Life: Managing the malaria medicine supply chain. Access to Medicine, Vodafone mHealth Solutions, mHealth.vodafone.com.
[15] *Tanzania - SMS Used to Prevent Stock-outs of Anti-Malarials*. SMS in Action. https://smsinaction.crowdmap.com/reports/view/150
[16] *SMS for Health Supply Chain Management and Disease Tracking*. Vodafone mHealth Solutions. http://mHealth.vodafone.com/global/solutions/access_to_medicine/supply_logistics_safety/malaria/index.jsp
[17] *SMS for Health Supply Chain Management and Disease Tracking*. Vodafone mHealth Solutions. http://mHealth.vodafone.com/global/solutions/access_to_medicine/supply_logistics_safety/malaria/index.jsp

commodities beyond ACT and quinine, such as rapid diagnostic tests, bed nets, and antibiotics. Successful mHealth interventions like this one are important examples that can be adapted in designing supply management systems for maternal health drugs.

FrontlineSMS[18] is open-source software that can be used to collect data via SMS as well as to distribute information. Interactive mapping/visualization software, such as the Resource Mapping Tool created by InSTEDD,[19] and the open-source Ushahidi platform,[20] can be used to map stock-outs that are reported via SMS and make this data available online.

A 2009 campaign by the organization Stop Stock-Outs utilized this strategy during a "pill-check" week, during which researchers checked for ten essential medicines in public health facilities throughout Kenya, Malawi, Uganda and Zambia. Results were collected via SMS and mapped using the web-based Ushahidi platform. The maps show stock-outs for each of the ten selected commodities, and can be viewed online by anyone with internet access. [21] Although oxytocin, misoprostol, and magnesium sulfate were not among the selected commodities, these technologies could be applied to improve the functioning of the supply chain for essential maternal health commodities.

Integrated mHealth Applications

Mobile and SMS technologies also have additional applications for improving the overall quality and availability of maternal health care, such as remote medical consultations, medical data collection, and patient follow-up. SMS technologies also hold potential for increasing demand for commodities among both clients and health workers. For example, SMS tools can be used to train and educate health workers about emergency obstetric care procedures and the use of obstetric commodities. Specialized tools are being developed for SMS training and educational functions. FrontlineSMS has developed software called FrontlineSMS:Learn that is currently available in beta.[22] In addition, mHealth technologies are being used in integrated systems that combine education efforts aimed at mothers with medical data collection. Increasing women's access to maternal health care connects them to the health system, improving the likelihood that they will be able to access referrals and essential commodities in the event of a health crisis.

For example, a mobile data system has helped Rwanda to become a model in the utilization of community health workers (CHW) to combat maternal and infant mortality. RapidSMS, an open-source SMS framework, has been used since 2009 to allow CHWs to better track their pregnant clients, conduct referrals and transfers in emergencies, and collect more detailed and accurate data. The data is analyzed by the Rwanda Ministry of Health to target interventions against maternal and infant mortality, including providing needed health commodities in correct quantities.[23]

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[18] http://www.frontlinesms.com
[19] http://instedd.org
[20] http://ushahidi.com
[21] *Medicine stock-outs still plague Kenya, Malawi, Uganda and Zambia.* Stop Stock-outs. http://stopstock-outs.org/ushahidi
[22] *FrontlineSMS:Learn Now Available (in Beta).* FrontlineSMS. http://learn.frontlinesms.com.
[23] Rasmussen, Mariko. Celebrate Solutions: Training and Mobile Health Technology in Rwanda. Women Deliver. October 12, 2010. http://www.womendeliver.org/updates/entry/celebrate-solutions-training-and-mobile-health-technology-in-rwanda

The Ifakara Health Institute (IHI) is using mobile technology to increase access to emergency care for mothers in Tanzania, in cooperation with the mobile phone company ZAIN and district councils. The aim is to evaluate how providing mobile phones and service plans to mid-level providers might improve communication between those providers and senior medical staff at the district level. The hope is that it will facilitate consultations, counseling, referrals, and resupply service in more remote areas. IHI will be evaluating the cost, feasibility, and implementation challenges associated with this mHealth technology.[24]

A Saving Lives at Birth Grand Challenge awardee, Zoe Alexander Ltd. of Nairobi, Kenya, created a mobile application known as Malezi-Bora, which distributes audio content on maternal and newborn health via mobile phone technology in local languages. The application promotes viral sharing of the content among mothers. It can be used to spread important messages about PPH and PE/E warning signs, and explain which medicines and services are locally available. It is hoped that the data generated by the application will improve understanding of the functioning of village social networks and identify key individuals who can help to distribute maternal health messages. Such information would be useful for social marketing of key commodities. It also utilizes location-mapping software to help health workers quickly find mothers who require immediate access to commodities. Features like these could contribute both to increased demand for maternal health medicines from better-informed mothers as well as improved emergency service delivery in remote areas.[25]

Medical Research and Development

There are several technologies emerging from medical research and development (R&D) that hold promise for improved treatment of PPH and PE/E. In the case of oxytocin, they tend to address two major barriers to its use: its requirement for cold chain storage, and the need for a skilled health worker to administer the injection. In the case of PE/E, advances tend to focus on improved diagnostics, so that women at risk of complications can be identified and referred for treatment with magnesium sulfate before the onset of eclampsia. The various technologies are at very different stages of development, ranging from initial prototyping to scale-up and marketing of a validated product.

Uniject™

Uniject™ is an injection technology that attempts to address both of the main barriers to use of oxytocin. It is a disposable, prefilled, single-dose syringe developed under PATH's HealthTech program. It can be used to deliver a 10 IU dose of oxytocin intramuscularly for routine active management of the third stage of labor (AMTSL) by a skilled birth attendant, or without AMTSL by a health worker trained to administer oxytocin for prevention of PPH.[26] Due to its ease of use, Uniject can be administered by health workers who do not normally give injections. It is particularly helpful for births in peripheral health settings, home

[24] *MHTF Supported Projects from 2011 to 2013. Ifakara Health Institute Using Cell Phones for Obstetric Emergencies*. Maternal Health Task Force. http://maternalhealthtaskforce.org/collaborate/projects
[25] Use of mobile technology and pay-it-forward business model http://www.savinglivesatbirth.net/summaries/34
[26] *WHO Recommendations for the Prevention of Postpartum Haemorrhage*. WHO. 2006. http://www.pphprevention.org/files/WHORecommendationsforPPHaemorrhage.pdf.

births, and emergency situations.[27] The Uniject packaging can also be designed to include a time-temperature indicator (TTI) to ensure that the oxytocin has not been exposed to excessive heat that could affect its potency. Use of a TTI offers increased flexibility in storage and transport of oxytocin beyond the cold chain because it measures cumulative temperature exposure.[28]

Studies conducted throughout the 1990s,[29] by PATH and third parties, validated the efficacy and acceptability of the Uniject device for both institutional and home use for a variety of medicines and vaccines, including uterotonics.[30] [31] [32] Several studies showed that Uniject could be used effectively by less-trained health workers, such as traditional birth attendants (TBAs). [33] [34] [35] [36] A 2009 study focusing specifically on oxytocin-Uniject in Guatemala found a high degree of efficacy and acceptability among community health workers.[37]

The collaboration of several international agencies as well as private-sector corporations has been integral to the successful development and launch of the Uniject device. In 2009, PATH partnered with two pharmaceutical manufacturers to produce oxytocin in the Uniject device: Instituto Biologico Argentino in Argentina and Gland Pharma in India. Regulatory approvals have been granted in several Latin American countries and India. [38]

Addressing Cold Chain Challenges

The cold chain storage required for oxytocin is one of the key barriers to increased distribution of this preferred uterotonic in remote areas. Several finalists in the Saving Lives at Birth Grand Challenge are seeking to address this challenge by developing alternative technologies for prevention and treatment of

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[27] *Technology Solutions for Global Health, Oxytocin in Uniject*. PATH. May 2010. http://www.path.org/publications/files/TS_update_uniject_oxytocin.pdf

[28] *Introducing Oxytocin in the Uniject Device: An Overview for Decision Makers*. PATH, USAID. September 2008. http://www.path.org/publications/files/TS_oxy_uniject_overview.pdf

[29] *A Health Tech Historical Profile: The Uniject Device*. PATH, USAID. June 2005. http://www.path.org/publications/files/TS_hthp_uniject.pdf

[30] *Reducing Postpartum Hemorrhage in Thanh Hoa, Viet Nam: Assessing the Role of Active Management of Third Stage of Labor and of Oxytocin in Ampoules and Uniject Devices.* Reproductive Health Department (Ministry of Health, Viet Nam), PATH. Research report. Seattle: PATH, March 2005.

[31] Tsu VD, Sutanto A, Vaidya K, Coffey P, Widjaya A. *Oxytocin in prefilled Uniject injection devices for managing third-stage labor in Indonesia*. International Journal of Gynaecology and Obstetrics. 2003;83(1):103–111

[32] Abdel-Aleem H, et al. *Carboprost trometamol in the management of the third stage of labor*. International Journal of Gynaecology and Obstetrics. 1993;42:247–250.

[33] Quiroga R, et al. *A prefilled injection device for outreach tetanus immunization by Bolivian traditional birth attendants.* Pan American Journal of Public Health. 1998;4(1):20–25.

[34] Nelson C, Widjay A, Wittet S. *Using Uniject to increase the safety and effectiveness of Hepatitis B immunization.* Seattle: PATH; 2002.

[35] Sutanto A, et al. *Home delivery of heat-stable vaccines in Indonesia: outreach immunization with a prefilled, single-use injection device*. Bulletin of the World Health Organization. 1999;77(2):119–126.

[36] Otto B, et al. *At-birth immunisation against hepatitis B using a novel pre-filled immunisation device stored outside the cold chain*. Vaccine. 2000;18:498–502.

[37] *Technology Solutions for Global Health: Oxytocin in Uniject.* PATH. May 2010. http://www.path.org/publications/files/TS_update_uniject_oxytocin.pdf

[38] *A Health Tech Historical Profile: The Uniject Device*. PATH, USAID. June 2005. http://www.path.org/publications/files/TS_hthp_uniject.pdf

PPH. For example, researchers at Monash University in Australia are developing an aerosol delivery system for oxytocin. Patients will inhale the medicine from a disposable device following delivery, eliminating the costs and risks associated with needles. The aerosol formulation will be more stable than the injectable form and will not require cold-chain storage.[39]

A solar-powered refrigerator called CoolComply has been developed by Innovations in International Health at MIT, in partnership with the Global Health Committee and Massachusetts General Hospital. The device is currently being tested in rural communities in Ethiopia with multi-drug resistant tuberculosis patients. It measures the temperature of the medicines and sends the information wirelessly to health providers along with compliance data.[40]

Diagnostic Advances

Researchers at the University of British Columbia in Vancouver, Canada received a Saving Lives at Birth Grand Challenge grant for their work in improving technology for prediction of adverse outcomes associated with PE/E. A primary challenge associated with PE/E is diagnosing it accurately, as well as predicting which women with high blood pressure during pregnancy will go on to suffer more serious complications. The innovation combines a predictive score known as the Pre-Eclampsia/Eclampsia Integrated Estimate of Risk (PIERS) with a mobile phone-based pulse-oximeter, which is used to measure blood oxygen saturation, a predictor of complications from PE/E. Together these clinical signs and symptoms are used to produce a risk assessment. The integrated mobile technology then facilitates referral and treatment by providing medical recommendations and transmitting health information directly to the referral center. If this tool proves to be successful, community health workers could use it to accurately diagnose PE/E before a patient becomes critical and make timely referrals to facilities, thereby increasing use of and demand for magnesium sulfate and improving outcomes.[41]

Another innovation currently in development for diagnosing PE/E is a low-cost sensing strip referred to as a "super skin." It was designed by a researcher at Stanford University, who received a grant through the Bill & Melinda Gates Foundation Grand Challenges Explorations competition for her work. The strip is solar powered and detects changes in electrical current associated with biomarkers for PE/E.[42]

Alternative Therapies

A range of alternative therapies for PPH have been proposed that seek to alter characteristics of interventions that make them difficult to administer. It is important to note, however, that most of the challenges associated with delivery of key maternal health commodities will not be addressed by a new device or substance. Fundamentally, health systems must be improved in ways that increase the number of women with access to maternal health care and increase the availability of the best-known therapies.

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[39] *Low cost, needle-free and non-refrigerated treatment for PPH.* Saving Lives at Birth. http://savinglivesatbirth.net/summaries/40

[40] CoolComply. Maternova. April 17, 2012. http://maternova.net/health-innovations/coolcomply

[41] *PIERS on the move: Pre-Eclampsia/Eclampsia Integrated Estimate of Risk assessment on a mobile phone*. Saving Lives at Birth. http://www.savinglivesatbirth.net/summaries/37

[42] *Sensing Strip for Pre-Eclampsia/Eclampsia*, Maternova, July 11, 2011, http://maternova.net/health-innovations?page=7

With those qualifications in mind, there are several products that may become significant innovations for treatment of PPH in remote areas.

Johns Hopkins University will start human trials of a balloon tamponade in 2013. The Automatically Deflating Air Postpartum Tamponade (ADAPT) is a sterile device that is inflated in the uterus to apply pressure and cause the uterus to contract to manage PPH. It will automatically deflate to allow the uterus to contract while maintaining pressure on the uterine walls. It is expected to cost less than $10.[43]

A similar innovation, a homeostatic foam device, is being developed by Maria Palasis of Arsenal Medical. The US-based bioactive composites company has received funding from the Gates Foundation for development of the device. The device can be inserted into the uterus following childbirth and expands to control bleeding.[44]

QuikClot is a hemostatic agent that uses kaolin, an inert mineral that promotes blood clotting. It is used by the US military in a gauze form for battlefield injuries. The Z-Medica Corporation of Wallingford, Connecticut, USA, a Saving Lives at Birth Grand Challenge finalist, is working to develop a new hemostatic agent based on this validated product that would control PPH in remote settings. The product is intended for use by less-skilled health workers.[45]

Finally, a circumferential abdominal-pelvic pressure (CAPP) device is in development by Nancy Kerr and Mark Hauswald of Global Health Partnerships. The device is designed to control PPH by decreasing blood flow to the pelvic organs. It can be constructed locally in the developing world using materials such as bicycle tires. The researchers are using a grant from the Bill & Melinda Gates Foundation to evaluate the device's acceptability in Nepal. [46]

Detecting Counterfeit and Substandard Commodities

Counterfeiting and substandard medicines are a serious threat to public health in many developing countries. Handheld spectroscopy devices, such as the device marketed as TruScan[47] could become key tools in countries' efforts to eliminate ineffective medicines. The TruScan device uses an optical laser to analyze the chemical makeup of a substance in liquid, powder, or pill form. TruScan provides a "pass/fail" decision on the medicine's authenticity within 30 seconds and can be used through plastic packaging.[48] TruScan device is currently being used by the Nigerian Agency for Food and Drug Administration and Control to identify and remove counterfeit and substandard medicines from the market.[49] A

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[43] *The ADAPT device will decrease mortality rates of PPH, the leading cause of maternal death across the globe.* Dell Social Innovation Challenge. http://www.dellchallenge.org/projects/adapt

[44] *Foam to control Hemorrhage*. Maternova. July 27, 2011. http://maternova.net/health-innovations/foam-control-hemorrhage.

[45] *Intrauterine application of a kaolin-based hemostatic agent for PPH*. Saving Lives at Birth: A Grand Challenge for Development. http://www.savinglivesatbirth.net/summaries/93.

[46] *Tire/Pressure CAPP Device for Hemorrhage*. Maternova. January 12, 20012. http://maternova.net/health-innovations?keys=CAPP&tid=All.

[47] TruScan is manufactured by Ahura Scientific, Inc., Waterford, Ireland,

[48] *TruScan Rapid Material Verification with Handheld Raman Spectroscopy*. Ahura Scientific, Inc. BTSRMv1.0 Copyright 2007.http://www.antech.ie/media/file/Handheld/TruScan%20Antech%20Brochure.pdf

[49] *TruScan & the Pharmaceutical Counterfeiting Problem*. Antech, Inc. http://www.antech.ie/truscan2.shtml

spectroscopy device that can accurately determine whether oxytocin has expired would be an especially useful application of this technology.

Bright Simons, a 2008 Ashoka Fellow, created the mPedigree Network, a registry service which is designed to be used by consumers to confirm the authenticity of the drugs they purchase. Using a regular mobile phone, consumers send an SMS containing a code found on the pharmaceutical product. The consumer receives a response in real time, indicating whether the product is authentic. The service is free to the consumer, funded by pharmaceutical manufacturers who have an interest in protecting their brands. The mPedigree Network is based in Ghana, and is also being implemented in Nigeria.[50]

Community-based distribution and task-shifting

The limited number of trained health providers in remote areas is a key barrier to delivery of essential health commodities. Efforts to facilitate the use of maternal health commodities by making them available to less-trained cadres of health workers are important strategies.

Community-based Distribution of Misoprostol

Increasing access to uterotonic medicines through community distribution shows promise for prevention of postpartum hemorrhage in the most remote settings, but is not without controversy. Misoprostol (for PPH) is the commodity best-suited to this approach because it is easy to administer in its tablet form and does not require cold chain storage. WHO currently does not recommend the community distribution of misoprostol to TBAs or to pregnant women, either for routine or emergency use. Rather, WHO prefers the use of oxytocin in a clinical setting, and recommends the administration of misoprostol at 200 to 800 microgram dose by a trained health provider only as a last resort, without active management of the third stage of labor.[51] Misoprostol has been included on the WHO *Model List of Essential Medicines* for PPH only since 2011. WHO points to misuse of misoprostol at incorrect doses, or for induction of labor, as a significant risk of community distribution. However, WHO specifically does not condemn community-based distribution of misoprostol during pregnancy. [52]

Those critical of WHO's cautious approach argue that several studies have shown misoprostol can be used safely at the community level for prevention of PPH.[53 54 55 56] TBAs in Kigoma, Tanzania have used

[50] *Bright Simons*. Ashoka Innovators for the Public. https://www.ashoka.org/fellow/bright-simons
[51] *WHO Statement regarding the use of misoprostol for postpartum haemorrhage prevention and treatment.* Department of Reproductive Health and Research. WHO/RHR/09.22. http://whqlibdoc.who.int/hq/2009/WHO_RHR_09.22_eng.pdf
[52] *Clarifying WHO position on misoprostol use in the community to reduce maternal death* WHO/RHR/10.1. http://whqlibdoc.who.int/hq/2010/WHO_RHR_10.11_eng.pdf.
[53] Prata N, Mbaruku G, Grossman A, Holston M, Hsieh K. *Community-Based Availability of Misoprostol: Is It Safe?* African Journal of Reproductive Health. Vol 13 No 2 June 2009.
[54] Derman R, Kodkany B, Goudar S, Geller S, Naik V, Bellad M, et al.: Oral misoprostol in preventing postpartum haemorrhage in resource-poor communities: a randomised controlled trial. *The Lancet* 2006; 368: 1248
[55] Prata N, Mbaruku G, Campbell M, Potts M, Vahidnia F: *Controlling postpartum hemorrhage after home-births in Tanzania.* International Journal of Gynecology & Obstetrics 2005; 90: 51-55.
[56] Walraven G, Blum J, Dampha Y, Sowe M, Morison L, Winikoff B, et al.: *Misoprostol in the management of the third stage of labour in the home delivery setting in rural Gambia: a randomised controlled trial*. BJOG 2005; 112: 1277.

misoprostol since a 2003-2004 trial of misoprostol for prevention of PPH in home births. A 2007 evaluation of this study cohort represents the longest-term study of misoprostol use at the community level. The evaluation reports a high degree of acceptability, safety, and effectiveness for this practice.[57] Similarly, a randomized controlled trial in India found that auxiliary nurse midwives were able to safely and effectively administer misoprostol. The intervention was highly effective, with one case of PPH prevented for every 18 women treated.[58]

The scale-up of community-based distribution of misoprostol in Bangladesh has been built off of EngenderHealth's Mayer Hashi project , which was supported by USAID. Among the challenges that Mayer Hashi which notes must be addressed are: not only ensuring consistent availability of misoprostol through government channels, but also adding misoprostol reporting into the government's management information system; and "marketing/distributing misoprostol for PPH prevention in a special package, with a specific name, shape, and color of the tablet (to avoid misuse)."[59] The pilot project relied on donated supplies in customized three-tablet packs—an innovation that may or may not be preserved as it is taken to scale. Overall, Bangladesh's experience with misoprostol distribution is seen as source of good practices in a number of areas, including evidence-based advocacy, community mobilization, and technological innovation.

Another successful community distribution effort in Bangladesh focused on including misoprostol and Quaiyum's mat (a tool for measuring blood loss) in the existing distribution system for clean delivery kits. Because failure to recognize the onset of hemorrhage is a major challenge, providing a tool like Quaiyum's mat is a helpful practice. In Nigeria, a plastic blood collection drape has been used to help providers accurately measure blood loss.[60] Another common practice is to teach the *kanga* method, in which the soaking of pre-determined number of absorbent cloths (kangas) can be used to signal excessive blood loss.

Community Mobilization

As community-based distribution of misoprostol becomes more common, innovative methods and approaches are being used and reported on. For example, a recent study of one initiative in northern Nigeria demonstrated the importance of community mobilization to ensure successful community distribution of misoprostol for prevention of PPH. The community mobilization effort consisted of community dialogues, information sessions, and dramas. It engaged 29 community-oriented resource persons (CORPs), 27 drug keepers, and 41 TBAs. Women showed a high degree of comprehension about

[57] Ndola Prata, Godfrey Mbaruku, Amy A. Grossman, Martine Holston, Kristina Hsieh. Community-Based *Availability of Misoprostol: Is It Safe?* African Journal of Reproductive Health. Vol 13 No 2 June 2009.
[58] Derman R, Kodkany B, Goudar S, Geller S, Naik V, Bellad MB, Patted S, Patel A, Edlavitch S, Hartwell T, Chakraborty H, Moss N. *Oral misoprostol in preventing postpartum haemorrhage in resource-poor communities: a randomised controlled trial.* The Lancet. Vol 368 October 7, 2006. www.thelancet.com.
[59] *Community-based distribution of misoprostol in Bangladesh: from pilot to scale Mayer Hashi Project and the RESPOND Project.* EngenderHealth
[60] *Low Tech Saves Lives*. Global Health Magazine. http://www.globalhealthmagazine.com/cover_stories/low-tech_solution_saves_lives

the use of misoprostol. Those who identified TBAs or CORPs as the most important sources of information about misoprostol were greater than three times more likely to report correct usage. [61]

Social Marketing

Population Services International (PSI) conducts promotion, training, and distribution of misoprostol to health workers in communities in Nigeria, Somaliland, Tanzania, Uganda and Zambia.[62] The social marketing approach used in Somaliland is particularly innovative. Due to cultural and religious beliefs that make reproductive health topics taboo, women generally have low levels of health literacy. In addition, sensitivities about the use of misoprostol as an abortifacient made its acceptance for PPH especially challenging. Together with Venture Strategies Innovations (VSI), PSI designed a culturally appropriate communications strategy and a brand of misoprostol called *Ummul-gargaar*, or "new mother helper" to increase acceptance for misoprostol as well as to encourage other safe motherhood practices. A major limitation of the program is that TBAs have not been authorized to distribute misoprostol in Somaliland. However, the effective introduction of misoprostol for PPH in a culturally appropriate way remains a major achievement. [63]

Improving the Supply Chain for Maternal Health Commodities

A well-functioning supply chain is critical to any effort to improve access to maternal health commodities. "No product, no program" has become a mantra within many global health organizations, but the design and maintenance of effective logistics systems continues to present many challenges. Best practice in integrated supply chain management calls for a whole-system approach. [64] [65] For example, rather than looking at procurement separately from distribution, or malaria programs separately from maternal health programs, the supply chain for essential commodities should be viewed as a cohesive whole. However, this integrated view does not imply that all vertical supply chains must necessarily be merged. Instead, segmentation analysis calls for identifying common characteristics among health commodities and using this information to inform decisions about which products should be grouped to increase efficiency.

Another key to developing a well-functioning medicine supply chain is data collection followed by evaluation and meaningful public disclosure. Supply chain reforms should involve increased transparency and accountability at all stages of the medicine supply chain, from procurement to distribution.[66] The

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[61] Prata N, Ejembi C, Fraser A, Shittu O, Minkler M. *Community mobilization to reduce postpartum hemorrhage in home births in northern Nigeria.* Social Science & Medicine 74 (2012) 1288e1296.
[62] *Misoprostol to Reduce Postpartum Hemmorhage.* Population Services International. http://www.psi.org/our-work/healthy-lives/interventions/misoprostol-reduce-postpartum-hemorrhage
[63] *Case Study: Somaliland. Prevention and Treatment of Post-Partum Hemorrhage in Somaliland: Navigating a Complex Course to Greater Health Impact*. PSI. http://www.psi.org/sites/default/files/publication_files/Somaliland%20PPH%20Case%20Study-Letter.pdf
[64] Owens R, and Warner T. *Concepts of Logistics System Design*. Arlington, Va.: John Snow, Inc./DELIVER, for the U.S. Agency for International Development (USAID). 2003.
[65] *Getting Products to People: The JSI Framework for Integrated Supply Chain Management in Public Health*. John Snow, Inc. January 2012. http://www.jsi.com/JSIInternet/Resources/Publications/healthlogistics.cfm
[66] The MeTA Model, http://www.medicinestransparency.org/uploads/media/The-MeTA-Model_01.pdf

Medicines Transparency Alliance (MeTA) is a partnership that emphasizes these principles in an effort to "improve access, availability and affordability of medicines for the one-third of the world's population to whom access is currently denied."[67] They conducted a 2009-2010 pilot program in Peru, Kyrgyzstan, Jordan, Ghana, Zambia, Uganda and the Philippines.

Some highlights in supply chain innovation include: pooled procurement; the use of third party logistics (i.e. privatization); supply chain solutions for community distribution programs, and ensuring quality and authenticity of medicines in the supply chain.

Pooled Procurement

The main purpose of pooled procurement is to take advantage of bulk discounts, but it can also serve to create more stable demand for essential commodities, encouraging more producers to enter the market. For this reason, multi-year contracting is recommended to ensure stable supply. Pooled procurement can be done on a country, regional, or international basis. The Tamil Nadu Medical Services Corporation, a central-procurement service for the Tamil Nadu state in India, is an example of how centralizing supply management at the sub-national level can lead to gains in efficiency and lower costs.

Regional procurement has been successful in a number of cases. The nine member countries of the Organization of Eastern Caribbean States have a Pharmaceutical Procurement Service (the OeS/PPS) for shared procurement of key commodities. The OeS/PPS pools procurement of key commodities for nine member states. Under the OeS/PPS, the prices of key commodities were more than 25% lower than individual country prices with pooled procurement.[68] The Group Purchasing Program of the Gulf Cooperation Council is another example of successful regional procurement.

Regional and global bulk purchasing are facilitated by the WHO Prequalification of Medicines Program (PQP), a service that assesses the quality, safety and efficacy of medical products.[69] The process starts when manufacturers submit an expression of interest to have their formulation of a medicine prequalified under the PQP. This prequalification of medicines facilitates pooled procurement and bulk purchasing. Since they are listed on the WHO Model List of Essential Medicines, oxytocin, misoprostol, and magnesium sulfate are all eligible for prequalification. To date, however, there are no prequalified formulations of any of the three commodities.

The Global Fund has sought to deal with the rapid increase in procurement of HIV, TB and malaria medicines through a program of Voluntary Pooled Procurement (VPP). The VPP is considered a short-term solution for getting medical commodities to their final delivery points as quickly and inexpensively as possible. The Partnership for Supply Chain Management (PFSCM) is the service agent that conducts

[67] Medicines Transparency Alliance (MeTA) http://www.medicinestransparency.org
[68] *Multi-country Regional Pooled Procurement of Medicines. Identifying key principles for enabling regional pooled procurement and a framework for inter-regional collaboration in the African, Caribbean and Pacific Island Countries.* World Health Organization, 2007. WHO/TCM/MPM/2007.1
[69] *Prequalification of medicines by WHO*. Fact sheet N°278. August 2010. http://www.who.int/mediacentre/factsheets/fs278/en/index.html

the procurement on behalf of the Global Fund VPP program.[70] The Global Fund also offers Capacity Building Services/Supply Chain Management Assistance (CBS/SCMA) to its grant recipients as a longer-term strategy to address bottlenecks in the supply chain. According to the Global Fund, 42 countries utilized VPP, totaling US$384 million by September 2010. The effect has been to create sustainable markets and stabile prices for key health commodities.[71] The Global Fund does not include maternal health drugs in the VPP program, nor is the inclusion of these drugs being considered. Rather, the VPP arrangement serves as an example of how a UN-backed international consortium can approach the challenge of drug procurement.

The Reproductive Health Supplies Coalition is a global partnership that includes organizations from the public and private sectors. RHSC's secretariat is managed by PATH, and its members include foundations, NGOs, companies, and country governments. Its areas of work include advocacy, innovation, collaboration, and technical solutions. In February 2011, RHSC launched AccessRH, a procurement program led by UNFPA that aims to supply RH commodities to country governments and NGO clients. In the first year, the program processed 122 orders, and reduced the wait times for condoms by over 10 weeks.[72] A key innovation is the program's *RHInterchange* website, which provides up-to-date information on global contraceptive orders for 144 countries.[73]

Supply Chain Management for Community Distribution Programs

There is a range of effective methods for managing supply chains for community-based distribution (CBD) programs. Choosing the best practice for a particular program is highly context-specific. There are four primary models used for CBD: the kit system, the two-bin system, the delivery top-up system, and the meet-up and resupply system.[74]

With the kit system, CBD workers are given a predetermined quantity of a few key medical commodities. At a predetermined interval, they receive a new kit.

The two-bin system works best for distribution of a single type of commodity or for a small number of commodities. It involves the use of two equal-sized bins. The emptying of the first bin prompts the CBD worker to procure replacement stock. The second bin then becomes the first bin.

The "Delivery Team Topping Up" (DTTP) system, is an approach developed through the USAID Deliver Project. Rather than requiring time and effort from health providers for assessing and ordering inventory, this approach calls for a delivery truck to come directly to the health facility and for the delivery team to conduct the counting and restocking. This frees up health personnel to perform their

[70] *Global Fund Voluntary Pooled Procurement (VPP)*. John Snow, Inc. http://www.jsi.com/JSIInternetProjects/InternetProjectFactSheet.cfm?dblProjDescID=6241
[71] *Procurement Support Services*. The Global Fund. http://www.theglobalfund.org/EN/procurement/vpp/
[72] *In Focus: AccessRH shares results.* Reproductive Health Supplies Coalition. http://www.rhsupplies.org/
[73] *RHInterchange: A website for coordination of contraceptive orders and shipments.* Reproductive Health Supplies Coalition. http://rhi.rhsupplies.org/docs/RHI_brochure_en.pdf
[74] Hasselberg E, Byington J. *Supply Chain Models and Considerations for Community-Based Distribution Programs: A Program Manager's Guide.* Reproductive Health Supplies Coalition. John Snow, Inc., August 2010.

essential duties and simplifies the link between the medical store and the health facility. In Zimbabwe, where this approach was tested, stock-out rates for nevirapine decreased from 33 % to 2%.[75]

The meet-up and resupply system is the most commonly-used system for CBD, and is often considered the preferred method. In this system, health workers acting as CBD workers meet at regularly scheduled intervals. These meet-ups provide an opportunity for program staff to conduct supervision and training as well as to collect data and resupply the health workers.

[75] *Getting Products to People: The JSI Framework for Integrated Supply Chain Management in Public Health.* John Snow, Inc. January 2012. http://www.jsi.com/JSIInternet/Resources/Publications/healthlogistics.cfm

III. Recommendations and Next Steps

Several clear recommendations have emerged from the initial assessment of three maternal health commodities in six countries. Primarily, the desk review and key informant interviews revealed a number of areas that, given more time, warrant more in-depth research and evaluation. While there are country-specific recommendations provided for each country study, the researchers collectively identified the following key recommendations across all of the countries reviewed.

Evaluate and apply mHealth technologies to management of the supply chain and other key health delivery functions.

Continue evaluation of mobile technologies for applications in supply chain management, training, and diagnostic assistance for health workers; providing information and guidance to mothers; and geographically locating patients in emergency transfer situations. Specifically, it will be important to conduct further research into best practices across the spectrum of commodities, in the use of mHealth technologies for task-shifting and community distribution, in order to identify solutions that can be successfully applied and scaled for maternal health commodities.

Pursue opportunities for bulk purchasing and pooled procurement arrangements at the regional level.

Pooling procurement of essential maternal health commodities can lower prices and help create stable demand for essential commodities, encouraging more manufacturers to enter the market. However, integrating dissimilar purchasing and supply chain practices may present many technical challenges. Additional research into best practices in global or regional pooled procurement is critical to facilitate purchasing mechanisms that successfully lower costs, attract donor investment, and establish consistent supply of essential medicines.

Continue research to inform task-shifting to lower cadres of health workers.

In much of the world, particularly in remote settings, women deliver at home without the presence of a skilled attendant. In settings with limited access to skilled attendants, task-shifting to lower-level health workers is one of the best available options to expand access to essential maternal health commodities, particularly misoprostol. Continued research and field -testing should inform best practices for training, human resource capacity-building, policies and procedures, and community distribution.

Map current initiatives and organizations addressing maternal health commodities

A mapping of current initiatives, programs, and actors addressing maternal health commodities at the country level is essential to fully understand the current landscape; to gauge the level of prioritization among global and national stakeholders; to inform and coordinate efforts going forward; and to develop meaningful partnerships among the players committed to increasing demand, access, and supply of these life-saving commodities.

Develop greater understanding of the role of the private sector

In many countries, the private sector significantly impacts the availability of essential medicines. While the private sector can often increase accessibility, the higher cost of medicines in private clinics often makes these services unattainable for the poor, creating distinct disparities in access to essential medicines within the same country. While understanding the role of the private sector in each of the six countries evaluated in this study is clearly important, there was minimal information readily available on the role of the private sector in supplying oxytocin, misoprostol, and magnesium sulfate and very little robust data on the private sector prices in the respective countries.

Evaluate factors influencing provider demand of maternal health commodities

Given that oxytocin, misoprostol, and magnesium sulfate are primarily administered by skilled birth attendants, these providers play a central role in shaping both demand and supply of these life-saving commodities. Insufficient research has been conducted to date on the factors influencing provider preference and demand for maternal health commodities in the six countries evaluated in this study. Provider demand can be shaped by a range of factors, including outdated or unclear national guidelines, lack of training in administration, inability to reliably access supplies, and personal attitudes about safety and efficacy of a medicine.

Leverage existing research endeavors and models to include maternal health commodities

Generally, many country-level research studies on availability and use of commodities at the country level have not included maternal health commodities. Research conducted during this study revealed that information on prices and availability of other commodities, such as contraceptives and ARVs, is more consistently tracked and documented than for maternal health commodities. There are ample opportunities to integrate tracking of MH commodities into existing research initiatives and a clear need to increase prioritization of MH commodities among institutions conducting the research.

IV. Bangladesh

The Burden of Maternal Mortality in Bangladesh

The rate of maternal death in Bangladesh has fallen dramatically in recent years. In 1990, the maternal mortality ratio (MMR) was 593 deaths per 100,000 live births, and by late 2011 it had fallen to 247 deaths per 100,000 live births.[76] Though it is not quite on track to achieve the Millennium Development Goal 5 target of a 75% reduction in MMR by 2015, it is likely to achieve this goal within a decade.[77] There is evidence to suggest that the enormous expansion of contraceptive use in the past generation, which has led to a steady decline in total fertility,[78] has been a major factor in reducing maternal deaths.

According to preliminary results of Bangladesh's 2011 Demographic and Health Survey (DHS),[79] institutional delivery and skilled care during pregnancy and in the postpartum period have all increased in recent years. Approximately 30% of women delivered with the assistance of a skilled health provider in 2011,[80] double that of 2004.

Increased use of skilled birth attendants has been accompanied by an increase in the number of births taking place in health facilities.[81] In 2011, 29% of births in Bangladesh took place in a health facility, with 12% occurring in a public facility, 15% in a private facility, and 2% at an NGO facility. However, inequities in access to health services are significant: just 10% of women in the poorest quintile gave birth in a facility, compared to 60% among the wealthiest quintile.[82]

The burden of postpartum hemorrhage (PPH) and pre-eclampsia/eclampsia (PE/E) has lessened in recent years: PPH-related deaths decreased by 35% and PE/E-related deaths decreased by 50% between 2001 and 2010.[83] However, PPH and PE/E remain the leading causes of maternal deaths, still accounting for 31% and 21% of maternal deaths in the country, respectively.

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[76] Institute for Health Metrics and Evaluation data cited in *Lozano, R. et al.* (2011), "Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis" *Lancet*; 378: 1139–65. 1153

[77] *Ibid*, 1161

[78] USAID, et al. (2010). Bangladesh Maternal Mortality and Health Care Survey: Summary of Key Findings, 10. And Bergeson-Lockwood, J., et al. (2010). *Maternal Health Supplies in Bangladesh*. Washington, DC: Population Action International.

[79] National Institute of Population Research and Training (NIPORT), Mitra and Associates and MEASURE DHS, ICF International (2012). *Bangladesh Demographic and Health Survey 2011: Preliminary Report*. Dhaka and Calverton, MD: National Institute of Population Research and Training, Mitra and Associates and MEASURE DHS, ICF International.

[80] This includes a qualified doctor, nurse, midwife, family welfare visitor (FWV), or community skilled birth attendant (CSBA).

[81] NIPORT et al., Bangladesh (2012) *DHS 2011 Preliminary Report*, 21.

[82] *Ibid*.

[83] USAID, et al. (2010). *BMMS*, 4-5.

Policy and Regulatory Environment

Most assessments of policy and programming agree that "maternal and child health (MCH) have been given the highest priority in the health system"[84] in Bangladesh. The government's commitment to maternal health is evident in a number of policies that explicitly commit to and lay out strategies for improving maternal health. Further, major donors, such as the World Bank and USAID have also signaled to in-country policymakers that expanding access to essential services and medicines, including maternal health, is a high priority.[85]

However, while policies are generally supportive, they often lack specific, quantifiable targets for improving maternal health, including in such areas as supply chain management.[86] The policy environment is also in flux and revisions may take years to be completed. As of May 2012, the National Health Policy, which was started in 2010, remains under development. The National Maternal Health Strategy has been under revision to reflect changes in priorities since 2001.

Key Policies Supporting Maternal Health

- *The Health Population and Nutrition Sector Development Program (HPNSDP),* the current health sector-wide approach (SWAp) (2011-2016),[87] guides health initiatives and has a strong emphasis on improving quality of and access to maternal health services. The HPNSDP is managed by the World Bank, and explicitly mentions the need to provide essential medicines, including maternal health medicines, for free. In addition, it sets targets for increasing skilled care at all levels of care and seeks to address health worker shortages in order to institute universal, 24-hour access to emergency obstetric care (EmOC).[88]

- *The National Population Policy* mentions the need to address major causes of maternal mortality, to ensure an adequate supply of essential commodities, and to use a comprehensive, client-centered approach to providing reproductive health and family planning services. However, it is neither specific nor targeted, and there is no explicit mention of maternal health commodities. [89]

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[84] SekanderHayat Khan, M., et al., (2010). *Inventory of Emergency MNH Drugs and Monitoring the Regularity of Supply*. Dhaka: Associates for Community and Population Research, 14.; and Bergeson-Lockwood., J. et al., (2010). *Maternal Health Supplies in Bangladesh*

[85] USAID (2011). *Action Plan for USAID/Bangladesh 2011-2016: Best Practices at Scale in the Home, Community, and Facilities for Improved Family Planning, Maternal and Child Health, and Nutrition;* and World Bank (2010). Bangladesh Health Facility Survey: 2009. (Presentation Slides). Human Development Sector South Asia Region, World Bank.

[86] Bergeson-Lockwood et al., (2010) *Maternal Health Supplies in Bangladesh,* 4.

[87] Ministry of Health and Family Welfare (MOH&FW). Health , Population and Nutrition Sector Development Program (2011-2016) (HPNDSP), Available: http://www.mohfw.gov.bd/index.php?option=com_content&view=article&id=75&Itemid=93&lang=en

[88] Ministry of Health and Family Welfare (2010), *Health, Population and Nutrition Sector Development Program (2011-2016), Booklet.* MOH&FW [Bangladesh], 7.

[89] Website of the Ministry of Health and Family Welfare: National Population Policy: www.mohfw.gov.bd/index.php?option=com_content&view=article&id=75&Itemid=93&lang=en

- *The 2009 National Neonatal Health Strategy* discusses the potential scale-up of community-based distribution of misoprostol, the need to ensure proper use of oxytocin, and the authorization of community-based skilled birth attendants (CSBAs) to administer the loading dose of magnesium sulfate and refer patients to EmOC facilities.[90]

Informants[91] noted two important policy developments in the past year that have strong bearing on maternal health commodities. These include a policy supporting the scale-up of community-based distribution of misoprostol and the establishment of pilot studies on the administration of loading dose of magnesium sulfate by low-level paramedic providers, (though details on the latter policy were not available).

Though access to current, national clinical guidance on key maternal health commodities is limited, informants and assessments of efforts to address PPH and PE/E[92] suggested the following:

Status of Maternal Health Commodities in Bangladesh			
	Oxytocin	**Misoprostol**	**Magnesium Sulfate**
Registered for use for maternal indications?	Y	Y	Y
On Essential Medicines List?	Y	Y	Y
In Standard Treatment Guidelines?	Y	Y	Y
Manufactured locally?	Y	Y	Y

Key Maternal Health Commodity Guidance

Oxytocin: Doctors, midwives, nurses and CSBAs are authorized to administer AMTSL, including oxytocin.[93] However, dosage guidelines are not available.

Magnesium Sulfate: Guidance states that "in case of eclampsia, the first dose of magnesium sulfate can be given by CSBA at the community level and the patient referred to an EmOC facility."[94] Though official dosage guidelines could not be located, one clinical review noted that the low dose "Dhaka regimen" is the standard in Bangladesh: an initial loading dose of 4 g delivered intravenously, followed by a 6g intramuscular dose.[95]

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[90] Ministry of Health and Family Welfare (2009). *National Neonatal Health Strategy And Guidelines For Bangladesh*. 35.
[91] Informants from both EngenderHealth (Interview: April 30, 2012) and UNICEF (Interview, May 3, 2012).
[92] Fujioka, A. and Smith, J. (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* USAID/MCHIP Status Report, 24 – 25; and Ministry of ealth and Family Welfare (2008). List of Essential Drugs. Bangladesh Gazette: First Part. Ministry of Health and Family Welfare [Bangladesh]. As well as informants from EngenderHealth and UNICEF.
[93] Fujioka, A. and Smith, J. (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries,* 24 and National Neonatal Health Strategy, 2009.
[94] MOH&FW (2009) National Neonatal Health Strategy, . 63 and Banu, M. et al., (2011). *Stakeholders Knowledge of Obstetric Stakeholders' Knowledge in Obstetric Complications and Role of Health Providers in Accessing Emergency Obstetric Care: Experiences from Nilphamari District.* Working Paper No. 18. Dhaka: BRAC.
[95] Soni, B. (2011). Alternative Magnesium Sulfate Regimens For Women With Pre-Eclampsia and Eclampsia: *RHL commentary.* The WHO Reproductive Health Library, World Health Organization.

Misoprostol: Misoprostol is currently being scaled up at the community level in areas where oxytocin is not readily available. Existing documents do not specify whether the three-tablet blister packs developed for the Mayer Hashi Project, which is the basis for this policy change, will be scaled up nationwide.[96]

Health System Structure

The public health system includes providers such as doctors, nurses, midwives and CSBAs, working in facilities, and at the household and community level. In addition, there is a cadre of health workers with minimal training, operating at the community level.

The DGHS and DGFP each sponsor a separate infrastructure of facilities that may provide maternal health services. Each directorate manages a set of primary, secondary and tertiary facilities, at the union, upazila (sub-district), and district levels.[97] In theory, providers trained to administer each of the three medicines should be on site at nearly every facility.

There are also a number of NGO-managed facilities. Some clinics, such as ICDDR,B's Matlab hospital,[98] are free, while others[99] may carry fees, often for medicines. However, "despite their obvious importance, information on non-public health facilities, human-power, and services is largely unavailable."[100]

In addition, it is worth mentioning that the line between public and private sector services is often blurred. As one informant[101] pointed out: providers may work in public facilities during the day, and then at private clinics by night. But, the impact of "moonlighting" practices on access to services or supplies has not been explored in depth.

Registration and Manufacturing

Multiple local manufacturers are registered to produce each of the three medicines, and all of the medicines procured in the public sector are produced in Bangladesh. In fact, Bangladeshi pharmaceutical firms dominate the market as a whole, accounting for 82% of available medicines. Locally based, multinational corporations account for an additional 13%, and just 5% of medicines are imported.[102]

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[96] RESPOND Project (2010). Mayer Hashi Project Preventing Postpartum Hemorrhage: Community-Based Distribution of Misoprostol in Tangail District, Bangladesh. Project Brief #2.

[97] Bergeson-Lockwood, J. (2010). *Maternal Health Supplies in Bangladesh.*17-18, and SekanderHayat Khan, M., et al., (2010). *Inventory of Emergency MNH Drugs and Monitoring the Regularity of Supply*, 10.

[98] ICDDR, B. Matlab Hospital. http://www.icddrb.org/what-we-do/hospitals/matlab-hospital

[99] See, for example: Pathfinder International. Sustainable Health Services for Isolated Populations in Bangladesh. http://www.pathfind.org/site/PageServer?pagename=Programs_Bangladesh_Projects_Sustainable_Health_Services

[100] Anwar, et al. (2009). Quality of Obstetric Care in Public-sector Facilities and Constraints to Implementing Emergency Obstetric Care Services: Evidence from High- and Low-performing Districts of Bangladesh. *Journal of Health Population and Nutrition*;27(2):139-155.

[101] Interview, EngenderHealth (April 30, 2012)

[102] World Bank (2008). *Public and private sector approaches to improving pharmaceutical quality in Bangladesh*, 5.

There is little official information available with regard to the brand names or dosages of medicines registered by the Directorate of Drug Administration (DDA), but, based on information provided by one informant,[103] the following are registered:

Commodity	Manufacturer
Misoprostol	Square pharma
Misoprostol	Incepta
Misoprostol	Gonosaystha kendro (GK)[104]
Magnesium Sulfate	Beximco pharma
Magnesium Sulfate	Gonosaystha kendro (GK)
Oxytocin	Opsonin pharma
Oxytocin	Chemist pharma

Quality Assurance

According to the World Bank, the pharmaceutical industry in Bangladesh is under-regulated,[105] and the competition among companies to sell generics based on brand names "provides ample opportunity for the sale of low-quality drugs at higher prices."[106] In addition, there seems to be little government monitoring of quality. However, UNICEF testing has found several examples of low quality medicines.[107] However, on the whole the issue of medicine quality assurance currently attracts little scrutiny, and shortfalls in funding for the DDA, lack of trained staff and absence of a testing facility that meets international standards are recognized as barriers to effective oversight.[108]

Marketing

Pharmaceutical companies conduct extensive direct outreach to providers, and the materials they produce include job aids that are often the primary source of education on updated protocols and medicine administration to providers at all levels. While these aids fill a major gap in a system where updated protocols and training in the use of new supplies are difficult to come by, they also represent aggressive marketing practices. This raises a number of ethical questions, and, coupled with the weak regulatory structure, it is clear that this practice should be explored in more depth.

Pharmacies and Unregistered Drug Stores

The DDA is charged with regulating private sector pharmacies, yet fewer than half of the 200,000 drug stores are legally registered pharmacies.[109] Pharmacies unregistered drug stores and often provide

[103] Interview, UNICEF (May 2, 2012)
[104] GK provided misoprostol under the Mayer Hashi project in customized 3-pill blister packs. See: RESPOND Project (2010). Mayer Hashi Project Preventing Postpartum Hemorrhage: Community-Based Distribution of Misoprostol in Tangail District, Bangladesh. Project Brief #2.
[105] World Bank (2008), *Public and Private Approaches to Pharma Quality in Bangladesh*, 7.
[106] *Ibid*.
[107] *Ibid.* 5 and 26.
[108] MOH&FW (2010), *HPNSDP Strategy,* 45.
[109] World Bank (2008). *Public and Private Approaches to Pharmaceutical Quality in Bangladesh*, 7.

medical counsel on a range of health issues, including maternal health,[110] even though staff members are neither skilled to administer drugs, nor, in many cases, qualified to sell them.[111] The Bangladesh Maternal Mortality and Morbidity Survey (BMMS) found that in the past several years, an increasing number of women experiencing complications sought care by purchasing medicines, but did not seek the care of a skilled provider.[112] Given the substantial role that pharmacies play as sources of advice, as well as medicines, this is an important area for further investigation.

Rational Use

There are few restrictions on access to medicines in Bangladesh, and no prescription or other authorization is required to obtain any supplies available in private shops.[113] A study by BRAC found that in urban slum areas of Bangladesh nearly one-third of women used oxytocin in order to accelerate delivery, often at the advice of providers who lack training in proper protocols[114] suggesting that off-label and inappropriate use of some maternal health medicines may be common. One informant[115] noted some wariness among health providers regarding the potential widespread distribution of misoprostol, due to concerns that the medicine can be used as an abortifacient and that compliance – which requires taking three tablets immediately postpartum – may be difficult to monitor at a large scale.

Supply Chain Management

Bangladesh's public sector supply chains are prone to procurement delays, shortages, and stock-outs at all levels of warehouses and facilities.[116] One study, which monitored stock levels of supplies at facilities, found that in the face of stock-outs, many facilities send patients to other facilities to request the necessary medicines.[117] The common need to compensate for gaps in stock confirms a point raised in a number of studies on maternal health services, essential commodities, and maternal health commodities in particular: public sector supply chains have major weaknesses, from the human resources capacity issues that are common throughout the health sector, to more specific issues related to procurement, storage and transportation at all levels.

Most often, when a particular medicine is not available in public sector facilities, providers advise patients to purchase it from private drug stores. There is little specific evidence available regarding the prices that people pay for maternal health commodities, or the potency of the medicines they purchase.

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[110] Moran, A. et al., (2010). Oxytocin To Augment Labour During Home Births: An Exploratory Study In The Urban Slums Of Dhaka, Bangladesh. *BJOG* 117:1608–1615, 1608.
[111] Ahmed, S. and Islam, Q. (2012). Availability and Rational Use of Drugs in Primary Healthcare Facilities Following the National Drug Policy of 1982: Is Bangladesh on Right Track? *Journal of Health, Population and Development.* ICDDR,B. 0;30(0):0000, 1-10, 2.
[112] USAID, et al. (2010). *Bangladesh Maternal Mortality and Health Care Survey: Summary of Key Findings*, 7.
[113] MOH&FW (2010) *HPNSDP Strategy,* 45.
[114] Moran, A. et al. (2010). *Oxytocin to Augment Labour During Home Births*, *BJOG* 117, 1608.
[115] Interview and email, UNICEF, (May 2, 2012)
[116] Ahmed, S. and Islam, Q. (2012). *Availability and Rational Use of Drugs in Primary Healthcare Facilities Following the National Drug Policy of 1982: Is Bangladesh on Right Track?* 2.
[117] SekanderHayat Khan, M., et al., (2010). *Inventory of Emergency MNH Drugs and Monitoring the Regularity of Supply*, 45.

However, medicines from these stores are not price-controlled and price gouging is common.[118] Further, there is a general lack of evidence regarding supply chain mechanisms and the warehouse conditions of the medicines sold at private stores, so it is not clear whether products are appropriately handled, stored or labeled.

Budgeting and Financing

Most public sector health services are financed through the Health Population Nutrition Sector Development Program (HPNSDP), a sector-wide approach (SWAp) to health funded primarily through donor contributions. While an exact budget on maternal health commodities is not available, responsibility for maternal health services is split between the Directorate General of Health Services (DGHS) and the Directorate General of Family Planning (DGFP), and some budget information is available for these bodies. The DGHS has a budget line for maternal, newborn child and adolescent health: 3,019.25 Tk crore (around US$370 million) and the DGFP has a budget line for Maternal, Child, Reproductive and Adolescent Health 879.04 Tk crore (around US$108 million), over the period from 2011-2016. Assessments of inventory and procurement practices[119] suggest that funds for reproductive health overall have been chronically underspent in recent years,[120] and it seems likely that this had an impact on supplies of maternal health commodities in particular.

Supplies are procured by the central government, with facilities required to provide a tender to make purchases, and central authorities responsible for distributing supplies once they are procured. The DGHS and the DGFP order and manage supplies in parallel systems. In addition, some DGFP facilities may receive maternal health supplies directly from the government, without requiring a tender; and, in the past, donors such as UNICEF have occasionally donated supplies directly, rather than providing funds.

Under current policy,[121] all supplies for use in public sector facilities are free at the point of service, and expected to be stocked using government supply chains. However, in practice, both facilities and patients routinely purchase medicines directly from private drug stores.[122] This practice has been recognized as a factor that discourages women from using facilities, and a voucher system was developed to cover costs for some women,[123] but there is no current data on either the burden of this reliance on patients to buy their own medicines or the impact of the voucher program in reducing this burden.

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[118] For general pricing information on essential commodities, see: Ahmed, S. and Islam, Q. (2012). Availability and Rational Use of Drugs in Primary Healthcare Facilities Following the National Drug Policy of 1982: Is Bangladesh on Right Track? and World Bank Public and Private Approaches to Pharmaceutical Quality in Bangladesh

[119] Ahmed, S. and Islam, Q. (2012). *Availability and Rational Use of Drugs in Primary Healthcare Facilities Following the National Drug Policy of 1982: Is Bangladesh on Right Track*? 11 and 37.

[120] Reproductive Health Supplies Coalition. Bangladesh. Country Profile. http://www.rhsupplies.org/index.php?id=3221

[121] MOH&FW.(2010) *HPNSDP Strategy,* 10.

[122] Ahmed, S. and Islam, Q. (2012). *Availability and Rational Use of Drugs in Primary Healthcare Facilities Following the National Drug Policy of 1982: Is Bangladesh on Right Track?,* 2; and SekanderHayat Khan, M., et al., (2010). *Inventory of Emergency MNH Drugs and Monitoring the Regularity of Supply,* 2.

[123] MOH&FW. (2010) *HPNSDP Strategy,* 2.

Procurement, Distribution, and Storage

The World Bank, as the manager of the HNPSDP, has assumed considerable responsibility regarding the procurement of essential medicines in Bangladesh. It sets and maintains the standards that govern the majority of procurement activities in the country. The procurement system has been described as prone to "inevitable" delays and shortages,[124] relating to bidding processes and timing of release of funds and supplies from central authorities. Additional problems have been documented at all levels, including frequent turnover in high level management of the directorates responsible for managing supplies, a general lack of skilled logistical planners and managers, inadequate storage space, slow, complicated distribution processes, and inadequate supervision of supplies, and measures to address these issues are included in the HPNSDP.[125]

Additional medicine purchases are made by health managers at the local level. Facilities seem to rely on very rough estimates of medicine need, such as number of hospital beds,[126] rather than careful tracking of usage. Overall, maternal health medicine supplies at all facility levels were reported as being inadequate and unreliable, although there is some variation in recorded stocks, as well as perception of shortfalls. Plans to improve procurement and logistical management are included in the HPNSDP,[127] but it is too early to determine whether this will translate into steadier supplies of maternal health commodities for providers and consumers.

Studies[128] have noted that storage capacity at all facility levels may lack in both space and temperature control. This is particularly critical with regards to oxytocin, which requires cold chain storage for viability. A recent survey found that just 4% of facilities were able to store oxytocin at the appropriate temperature.[129]

- **Oxytocin:** There are varying reports on the availability of oxytocin across facilities. A 2009 report found that among secondary facilities, 55% of District Hospitals and 38% of Upazila Health Centers reported the medicine as in stock. Lower levels facilities were much less likely to stock oxytocin and, as a result, just 13% of all facilities reported stock.[130] Elsewhere, stock-outs have been reported as occurring on a "quarterly" basis, likely due to delays related to the procurement process.[131].

[124] SekanderHayat Khan, M., et al., (2010). *Inventory of Emergency MNH Drugs and Monitoring the Regularity of Supply,* 9.
[125] MOH&FW (2010). *HPNSDP Strategy,* 45.
[126] Bergeson-Lockwood, J. et al., (2010). *Maternal Health Supplies in Bangladesh,* 28.
[127] MOH&FW. (2010) *HPNSDP Strategy,* 45.
[128] See Bergeson-Lockwood, J. (2010). *Maternal Health Supplies in Bangladesh*
[129] Mayer Hashi Project. (2010) Community-based distribution of misoprostol for the prevention of postpartum hemorrhage: Evaluation of a pilot intervention in Tangail District, Bangladesh, 2.
[130] World Bank Health Facility Survey 2009 (unavailable), cited in Bergeson-Lockwood, J. et al., (2010). *Maternal Health Supplies in Bangladesh* , 21; and SekanderHayat Khan, M., et al., (2010). *Inventory of Emergency MNH Drugs and Monitoring the Regularity of Supply,* 30.
[131] Fujioka, A. and Smith, J. (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries*: *Status Report 2011*, 24.

- **Magnesium Sulfate:** Stock-outs for this medicine at facilities were reported as common, though the question of *how* common appears to vary by report. One national survey conducted in 2009, found that just 3% of public facilities had the medicine in stock, while a 2010 survey with a more limited found that 19% of facilities in its study area did.[132] Another study emphasized that stock-outs of magnesium sulfate occur every few months.[133]

- **Misoprostol:** Though misoprostol has been on the EDL since 2008, there is little evidence that it is reliably stocked, perhaps because government responsibility for procuring misoprostol for community-based distribution is new: it was approved and budgeted for both the DGHS and DGFP in 2011, but both supplies for prior pilot projects and initial scale-up were donated.[134] One informant[135] reported that the procurement process is underway, but supplies are not yet available at facility levels.

Bangladesh's commitment to extending health care to the community level means that, in theory, supply of medicines should be extended to that level as well. Policy has long dictated that CSBAs be equipped with a range of supplies, including magnesium sulfate (loading dose only), and oxytocin, but there is little evidence that anyone is aware that this was implemented, and no clear efforts to ensure that CSBAs had ready access to a reliable supply of key maternal health medicines.[136]

There is evidence to suggest that many local and international stakeholders are working to improve the supply of these three maternal health commodities. USAID has named addressing stock-outs as a priority in its efforts to strengthen maternal health services, with a particular emphasis on ensuring a steady supply of magnesium sulfate.[137] It also supported the establishment of an electronic logistics management system to monitor the contraceptive commodities managed by the DGFP, which may offer an opportunity to address challenges in monitoring stocks of maternal health supplies along with contraceptives, although it is not clear whether or when this might happen.[138]

Demand for Maternal Health Commodities

Demand by Providers

The strongest message regarding supplies and provider demand is around provider preferences for medicine formulations. One informant [139] reported that providers are often dissatisfied with the formulations available through public sector supply chains. For example, oxytocin procured through the

[132] SekanderHayat Khan,M., et al. (2010). *Inventory of Emergency MNH Drugs and Monitoring the Regularity of Supply*. 3.
[133] Fujioka, A. and Smith, J. (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries*, 24.
[134] Mayer Hashi Project and RESPOND Project/EngenderHealth (2011). *Community-Based Misoprostol Distribution to Prevent Postpartum Hemorrhage in Bangladesh: From Pilot to Scale.* Research Summary.
[135] Interview, UNICEF (May 2, 2012)
[136] Bergeson-Lockwood, J., et al. (2010). *Maternal Health Supplies in Bangladesh*, 19.
[137] USAID (2011). *Action Plan for USAID/Bangladesh 2011-2016: Best Practices at Scale in the Home, Community, and Facilities for Improved Family Planning, Maternal and Child Health, and Nutrition*, 5.
[138] Bergeson-Lockwood, J., et al. (2010). *Maternal Health Supplies in Bangladesh*, 31.
[139] Interview, UNICEF (May 2, 2012)

public sector must be diluted. Similarly, the magnesium sulfate preparation that is currently available is not readymade, presenting an inconvenience that may act as a barrier for efforts to ensure that loading doses are widely available. However, there is only anecdotal evidence on provider demand at present, and in-depth research is urgently needed.

Demand by Consumers

A greater proportion of women now give birth in private than public facilities, and the fees associated with "free" public services are widely seen as discouraging poor women from using public facilities. Indeed, that recognition now guides a voucher scheme, which covers the costs associated with obtaining skilled care for many women.[140] In contrast to the hidden costs of "free" public clinics and hospitals, fees associated with services in private facilities are expected to be "all inclusive," covering cost of assistance, necessary equipment and medicines.[141] The sense that essential medicines are more likely to be in-stock may contribute to patients' decisions to seek care in private facilities if they can afford it. However, more evidence is needed with regard to not only quality and cost in private facilities, but what role expectations about fees play in shaping women's decisions about delivery care.

In a study undertaken by BRAC on increasing uptake of maternal healthcare in the Manoshi project (see section below for more about the project), women were wary of being referred to a higher level facility, which many associated with increased likelihood of C-section and higher costs. Women also reported widespread expectation that oxytocin would be available to *induce* labor.[142] This suggests that ensuring that low-level facilities that are equipped to provide EmOC may meet critical community demand. But, at the same time, the finding on uterotonics and induction suggests that much still needs to be done to educate communities in order to build demand in a constructive way.

Projects to pilot misoprostol at the community level have included a strong community-education or mobilization component, working to raise awareness among women of misoprostol's use and availability. Assessments of such pilot programs have generally found an increased demand for misoprostol as a result, as well as increased awareness of labor complications, and, in at least one study, intention to reuse misoprostol at future deliveries.[143]. This suggests that programs that emphasize education and awareness building among patients, of maternal health commodity use and indications, can be very effective.

Civil Society

In Bangladesh, local and international NGOs are involved in all aspects of maternal health, from direct service delivery to policy and advocacy efforts. Civil society also works with government and donor agencies like USAID and the World Bank to implement maternal health projects and policies.

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[140] See Schmidt , J.et al., "Vouchers As Demand Side Financing Instruments For Health Care: A Review of the Bangladesh Maternal Voucher Scheme," Health Policy 96(2):98-107; and MOH&FW (2010), *HSNDP*, 10.
[141] Bergeson-Lockwood, J., et al. (2010). *Maternal Health Supplies in Bangladesh,* 5.
[142] Banu, M. et al., (2011). *Stakeholders' Knowledge in Obstetric Complications and Role of Health Providers in Accessing Emergency Obstetric Care: Experiences from Nilphamari District.* Working Paper No. 18. Dhaka: BRAC, 20.
[143] Quaiyum, M., et al. (2011). *Scaling up of misoprostol for prevention of PP hemorrhage in 29 upazillas of Bangladesh.* Final Report in Brief.

In 2006, the Prevention of Postpartum Hemorrhage Task Force (PPH Task Force) was established as part of USAID's Prevention of Postpartum Hemorrhage Initiative (POPPHI).[144] The PPH Task Force convened experts from organizations such as EngenderHealth, BRAC, and the national OB/GYN Society, with USAID and the Government of Bangladesh. Though POPPHI ended in 2009, the task force remains active and represents a key civil society effort to address maternal mortality. Technical experts continue to advise the government on the development of supportive maternal health policies, specifically around the treatment and prevention of PPH, and to provide technical guidance, such as developing national training manuals to ensure that providers are prepared to implement those policies.

Most projects, regardless of funding source or the institution responsible for implementing them, incorporate some effort to ensure that women have access to life saving supplies. However, there is little discussion of how these projects – apart from those involving misoprostol – respond to breakdowns in supply chains or commodity access barriers. The following maternal health projects include specific emphasis on essential maternal health commodities:

- *The Maternal and Neonatal Health (MNH) Project,* supported by DFID, the European Commission, UNICEF, Government of Bangladesh, UNFPA and WHO, was launched in 2009 in four districts.[145] In addition to efforts to improve service delivery, the project supported a local organization, Associates for Community and Population Research, to conduct a thorough inventory of MNH supplies in 2010. The inventory, which is referenced in this paper, mapped supply chains, stock-outs, procurement practices and other critical issues related to access to 12 commodities, including the three studied here, to facilities.[146]

- *The Manoshi Project*, funded by the Bill & Melinda Gates Foundation and implemented by BRAC, seeks to improve maternal health care in slums of Dhaka. It links unskilled, traditional birth attendants, and community health volunteers with skilled providers (e.g., midwives) at local delivery centers. The project incorporates input of women and health workers into its plans, and as a result, has also provided valuable insight about demand for services and supplies at the community level.[147]

- *ICDDR,B* is a health research institution and through its large-scale research operations, also acts as a service provider. It trains and deploys various cadres of health workers, including CSBAs. ICDDR,B's interventions to improve maternal health span the continuum from community to facility, and it has participated in piloting misoprostol distribution, as well as working to improve services in order to increase facility-based deliveries.[148]

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[144] POPPHI (2009). *Tackling the Biggest Maternal Killer: How the Prevention of Postpartum Hemorrhage Initiative Strengthened Efforts Around the World.* and Mayer Hashi Project and RESPOND Project/EngenderHealth (2011). *Community-Based Misoprostol Distribution to Prevent Postpartum Hemorrhage in Bangladesh: From Pilot to Scale*. Research Summary.
[145] UNICEF Bangladesh (2009). Maternal and Neonatal Health Fact Sheet. UNICEF, 3.
[146] *SekanderHayat Khan, M., et al., (2010). Inventory of Emergency MNH Drugs and Monitoring the Regularity of Supply.*
[147] BRAC. Maternal and Child Health: Manoshi Project. Available: http://www.brac.net/content/bangladesh-health-maternal-and-child-health
[148] See, for example, ICDDR, B (2012). Shahjadpur Integrated MNH Project: Newsletter Issue 7. ICDDR, B.

- *Community-based distribution of misoprostol* was piloted in various parts of the country[149] with the involvement of several NGOs, including BRAC, Pathfinder, ICDDR,B, and EngenderHealth, and informed the development of a policy to take misoprostol to scale.[150]

Recommendations

Document private sector practices and their impact on access to maternal health commodities

Bangladesh's pharmaceutical industry is well developed and supplies the vast majority of medicines to both the public and private sectors, but it is poorly regulated. In addition improving oversight of the industry over the long term, there is a pressing need to document the impact of practices such as the aggressive, personal marketing of medicines to providers on women's access to essential medicines. Though more births take place in private sector facilities than public ones, there is little data on the cost or quality of services and supplies in these facilities; or on the impact of practices like "moonlighting" by public sector providers in private clinics on poor women's access to essential maternity services. Collecting this data can help to guide the definition of a clear role for the private sector in providing equitable access to key supplies.

Investigate training, practice and supply practices for community and field workers

Evidence regarding providers' skill levels, comfort and overall ability to administer critical supplies should be collected and used to improve both training and supply chain practices. For example, a policy permitting CSBAs to administer a loading dose for magnesium sulfate exists, but it is not clear whether CSBAs actually have access to the medicine, or to what extent the policy is even known.

Build on success in good packaging practice

The government, civil society and a pharmaceutical company all contributed to the development and distribution of custom three-tablet blister packs for community-based distribution of misoprostol. Now, it will be important to ensure that sufficient numbers of these packs are procured to support the scale-up of misoprostol. The lessons that this carries may also be expanded to other areas, such as developing and distributing readymade preparations of magnesium sulfate.

Incorporate explicit emphasis on maternal health commodities in efforts to improve supply chains

Maternal health commodities should be included in the DGFP's electronic system for monitoring stocks of reproductive health commodities, and both the DGHS and the DGFP should implement specific plans for ensuring sustainable supplies of maternal health commodities.

[149] USAID (2011). *Action Plan for USAID/Bangladesh 2011-2016: Best Practices at Scale in the Home, Community, and Facilities for Improved Family Planning, Maternal and Child Health, and Nutrition*, 25.
[150] Mayer Hashi Project and RESPOND Project/EngenderHealth (2011). *Community-Based Misoprostol Distribution to Prevent Postpartum Hemorrhage in Bangladesh: From Pilot to Scale.* Research Summary.

Undertake further studies on provider demand

There is anecdotal evidence that providers are dissatisfied with formulations supplied through the public sector, particularly for magnesium sulfate, but there is no comprehensive documentation of providers' demand for particular supplies. Provider preferences should be recorded and addressed in procurement plans and pre- and in-service trainings. This will ensure that providers have access to a supply of medicines that they are both capable and confident in administering.

Map existing programs that involve improvements in supplies

The PPH Task Force has been a critical force in influencing plans to expand access to misoprostol, but information on the full set of programs that involve expanding access to all three supplies is fragmented and difficult to find. In order to document lessons learned and to strengthen coordination, it will be important to map existing efforts to improve maternal health supplies, while also identifying opportunities to build on successes in improving supply of commodities for related health issues, such as child and reproductive health.

V. Ethiopia

The Burden of Maternal Mortality in Ethiopia

With a population of roughly 84 million, Ethiopia is the second most populous country in Africa and among the world's poorest countries.[151] While Ethiopia has made significant progress in reducing maternal mortality over the past two decades, it is consistently ranked among the nations with the highest Maternal Mortality Ratios (MMR) in the world.

It is estimated that more than two girls and women die every hour due to pregnancy related complications in Ethiopia.[152] Currently, the MMR in Ethiopia is 528 per 100,000 live births (2011),[153] with a lifetime risk of maternal death estimated at 1 in 40.[154] More than 85% of maternal deaths in Ethiopia are a result of direct obstetric complications; hemorrhage (10%) and hypertension (9%) are among the five leading causes.[155] Ethiopia is not on track to meet the Millennium Development Goal (MDG) 5 target of reducing its MMR by three quarters by 2015. Reaching the nation's goal of reducing the MMR to 350 per 100,000 live births by 2015, at the current rate of decline (3.8%), is not achievable.[156]

Health service utilization remains extremely low in Ethiopia, particularly in rural areas, where more than 80% of Ethiopians live.[157] There are especially distinct disparities in accessibility and utilization of maternal health (MH) services between urban and rural populations and across the diverse regions of Ethiopia. Of the births that do take place in facilities, the vast majority occur in urban areas, particularly in Addis Ababa, the capital. According to the 2011 Ethiopian Demographic and Health Survey (EDHS), 51% of urban mothers were attended by a health professional during birth and 50% delivered in a health facility. By comparison, only 5% of rural Ethiopian women were attended to by a skilled health professional during delivery with only 4 % of those deliveries occurring in a health facility.[158]

Among the most pressing challenges to healthcare service delivery in Ethiopia and one of the most sizable barriers to Ethiopia achieving the MDGs, is the acute shortage of health personnel, particularly in remote settings. Further, the high attrition of health workers is undercutting the Government of Ethiopia's (GoE) substantial efforts to rapidly train and deploy a health workforce sufficient to meet the

[151] World Bank estimate 2012
[152] Department for International Development (2011) Increasing Access to Reproductive health commodities in Ethiopia: Business Case and Intervention Summary. Available: http:// projects.dfid.gov.uk/IATI/document/3297940
[153] Lozano, Raphael et al. (2011). Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis. The Lancet 378: 1139–65.
[154] *Trend in Maternal Mortality 1990-2008.* Estimates developed by WHO, UNICEF, UNFPA and The World Bank Maternal Mortality Estimation Inter-Agency Group.
[155] Federal Democratic Republic of Ethiopia Ministry of Health (2006). *National Reproductive Health Strategy 2006-2015.*
[156] Lozano, Raphael et al. (2011). Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis. *The Lancet* 2011; 378: 1139–65.
[157] World bank estimate 2012
[158] The Ethiopia Demographic and Health Survey 2011. Central Statistical Agency, Ethiopia. MEASURE DHS, ICF Macro Calverton, Maryland, USA.

population's needs.[159] The most recent physician-to-population ratio in Ethiopia was one physician per 37,996 people.[160] Remarkably, though Ethiopia's population is almost twice that of its neighbor Kenya, the number of health personnel is only one third of Kenya's.[161]

The shortage of skilled healthcare workers and physicians is one of the primary factors contributing to Ethiopia's high MMR. Despite the impressive steps Ethiopia has taken in recent years to dramatically expand the health workforce and increase access to health services across even the most remote regions, one of the greatest challenges to reducing the number of maternal deaths in Ethiopia continues to be the lack of access to and infrequent utilization of skilled birth attendants and the low levels of facility based births. Compounding this challenge is the lack of access to and information about specific life-saving maternal health interventions. With an estimated 94% of births occurring at home, most women do not have access to necessary interventions, including MH commodities, when complications arise.[162]

Status of Maternal Health Commodities in Ethiopia			
	Oxytocin (for PPH)	**Misoprostol (for PPH)**	**Magnesium Sulfate (for PE/E)**
Registered for use for maternal indications?	Y	Y	Y
On Essential Medicines List?	Y	Y	Y
In Standard Treatment Guidelines?	N	N	Y
Manufactured locally?	N	N	N

[159] The Global Health Initiative: Ethiopia Strategy. http://www.ghi.gov/country/ethiopia/documents/159724.htm
[160] Ethiopia's Fourth National Health Accounts 2007/2008. Federal Democratic Republic of Ethiopia Ministry of Health. Addis Ababa, April 2010
[161] Wamai, Richard G. Reviewing Ethiopia's Health System Development. JMAJ 52(4): 279-286, 2009.
[162] Ethiopian Health and Research Institute (2012). *An Evidence-Based Policy Brief: Prevention of Postpartum Hemorrhage in Rural Ethiopia, Full Report, Draft*. Available: http://www.who.int/evidence/assessing/sure/EthiopiaPPHpreventionpolicybrief2012.pdf

Policy and Regulatory Environment

Policies Affecting Maternal Health

An initial desk review of key strategies and policies shaping maternal health in Ethiopia revealed that very few documents include MH commodities as a core component of Ethiopia's efforts to address maternal health. The primary strategies that influence the availability and accessibility of oxytocin, misoprostol and magnesium sulfate but do not explicitly highlight these commodities are:

The National Reproductive Health Strategy

In 1997, the Government of Ethiopia (GoE) conducted a national reproductive health (RH) assessment to identify the country's most pressing RH needs and developed *The National Reproductive Health Strategy* to address them, including a costed implementation plan for the Maternal Newborn Health (MNH) component of the strategy.[163][164]

While the importance of RH commodities, specifically contraceptives, is addressed in the strategy, MH commodities are not specifically mentioned or included as a priority issue.[165] That said, there are several key goals outlined in the strategy, which, if achieved, would ultimately increase availability of the three MH commodities. For example, the strategy outlines key actions to increase the proportion of births attended by skilled health personnel by 60% (at home or in facility) by expanding pre- and in-service training to include the management of obstetric complications.[166] Given that only skilled birth attendants are qualified to administer the three MH commodities, the GoE's prioritization of increasing the number of trained attendants is essential to expanding access and utilization.

The Plan of Accelerated and Sustainable Development for the Eradication of Poverty (PASDEP)

The Plan of Accelerated and Sustainable Development for the Eradication of Poverty (PASDEP), Ethiopia's five-year (2005/06-2009/10) comprehensive poverty reduction strategy, prioritizes scaling up resources to achieve the MDGs. The inclusion of reproductive health commodity security (RHCS) in the national poverty reduction strategy papers and health sector wide approaches (SWAps) is essential to the prioritization, planning, and budgeting for lifesaving RH commodities, including MH commodities. Ethiopia includes RH/MH commodity security into both the PASDEP and health SWAps, which is an important indication of Ethiopia's commitment to and prioritization of RH and MH commodity security.[167] However, it is not clear how this inclusion specifically translates into action on the commodities and further research is warranted.

Health Sector Development Program (HSDP)

Initiated in 1997, the HSDP is a sequence of four phases, each in five-year increments, aimed at addressing the most urgent health issues confronting Ethiopia and specifically at creating access to primary healthcare throughout the country.[168] Currently, HSDP IV (2010/11-2014/15) prioritizes maternal and child health (MCH) and the attainment of the MDGs, particularly MDG 5. While the MH initiatives

[163] Federal Democratic Republic of Ethiopia Ministry of Health (2006). *National Reproductive Health Strategy 2006-2015.*
[164] Countdown to 2015 Maternal, Newborn & Child Survival, Ethiopia.
[165] Federal Democratic Republic of Ethiopia Ministry of Health (2006). *National Reproductive Health Strategy 2006-2015.*
[166] Federal Democratic Republic of Ethiopia Ministry of Health (2006). *National Reproductive Health Strategy 2006-2015.*
[167] UNFPA Global Program to Enhance Reproductive Health Commodity Security Annual Report 2010.

under HSDP IV do not specifically address MH commodities, the initiatives do include scale up of Basic Emergency Obstetric Newborn Care (BEmONC) and Comprehensive Emergency Obstetric Newborn Care (CEmONC), which ideally would include administration of uterotonics for postpartum hemorrhage (PPH) and magnesium sulfate for pre-eclampsia/eclampsia (PE/E). Two other relevant initiatives are 1) the scale-up of midwife training and 2) maternal death audits, which can play an important role in making the case for investment in commodities that prevent the leading causes of maternal deaths, including PPH and PE/E.

Health Extension Program (HEP)

One of the core components of HSDP II was the launch of the Health Extension Program (HEP) in 2003, aimed at increasing access to preventative essential health services. The HEP operates at the *kebele* level, with two Health Extension Workers (HEWs) trained and appointed to deliver a package of preventative and curative primary health services targeting households and women in particular.[169]

The HEP is central to Ethiopia's efforts to rapidly train and expand the health workforce and to improve access and utilization of health services; including antenatal care, skilled attendants at delivery, and postpartum care.[170] By 2010, more than 30,000 HEWs had been trained and deployed to health posts throughout the country, in both rural and urban areas.[171] Additional training for clean and safe delivery is currently being rolled out. This is an exceptional opportunity to increase the availability and accessibility of commodities for women giving birth. Additional research is needed to understand the level of training around the key commodities that is being given.

Regulatory Guidelines

The Pharmaceutical Fund and Supply Agency (PFSA), established by the FMOH in 2007, is the agency responsible for procurement forecasting, quantification, distribution, and management of essential medicines, contraceptives, and other health commodities throughout the country. Prior to PFSA, several agencies have had responsibility, to varying degrees, for the registration, quality control, and procurement of medicines over the last 10 years. The Food, Medicine, and Health Care Administration and Control Authority (FMHACA) was established in 2009 to set regulatory standards, manage inspection and licensing, register products and assess quality, and regulate information delivery. FMHACA's predecessor was the Drug Control Administration and Authority (DACA), which produced the Essential Medicines List (EML) and the Ethiopian Standard Treatment Guidelines (STGs).

Clinical Guidance, Drug Formularies, and Treatment Guidelines

As the health system in Ethiopia has rapidly expanded and become increasingly decentralized it has been a significant challenge to keep healthcare workers informed with up-to-date information on drug formularies and treatment guidelines. The FMOH has, in cooperation with the World Health Organization, created several authoritative documents to guide commodities procurement, availability,

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[168] Strategy to Increase Access to Treatment of Childhood Diarrhea, Malaria and Pneumonia in Ethiopia. Management Sciences for Healthy. April 2012.
[169] The Last Ten Kilometers Project
[170] Ethiopia's Fourth National Health Accounts 2007/2008. Federal Democratic Republic of Ethiopia Ministry of Health. Addis Ababa, April 2010.
[171] Management Sciences for Health (2012). *Strategy to Increase Access to Treatment of Childhood Diarrhea, Malaria and Pneumonia in Ethiopia*.

and in-country use. In addition, the Ethiopian medicines regulatory agency, FMHACA (previously DACA), has attempted to address the unmet need for information by also developing drug information materials, leaflets, and bulletins/brochures.[172] Additional research is warranted to evaluate the content of the health information produced in bulletins/brochures, particularly those providing indications for use of the three MH commodities, and how this method of information sharing complements or diverges from more formal guidelines and training.

Formularies and Treatment Indications Guiding MH Commodities

For the three MH commodities addressed in this study, the formularies and treatment indications guiding use varies greatly across multiple documents, no doubt leading to confusion among health workers and likely to misuse. Interviews with key in-country informants confirmed that there is a lack of clarity around which documents health workers at each level use and how discrepancies in protocols between the various documents are being addressed. Clear guidance is urgently needed to reconcile the disparities between the multiple documents. Reaching healthcare workers at all levels and in all settings, with critical information on MH commodities, and training them to appropriately dispense these medicines, is an urgent challenge for Ethiopia to address.

The formulations and guidelines listed in the key documents are detailed in the following chart and text:

Guidelines for MH Commodities in Ethiopia (for PPH and Pre-eclampsia /Eclampsia)				
	Oxytocin (for PPH)	**Misoprostol (for PPH)**	**Magnesium Sulfate (for PE/E)**	**Clear Guidance provided?**
Essential Medicines List, 4th Ed. (2010)[173]	Y	Y	Y	Formulations only
Ethiopian National Drug Formulary, 1st Ed. (2008)[174]	Y	N	Y	Misoprostol not noted for any indications. Though it was listed in 2007 version for gastric ulcers. Page numbers are incorrect in index.
Standard Treatment Guidelines 2nd Ed. (2010)[175]	N	N	Y	Oxytocin is only indicated for prolonged pregnancy and labor, not PPH.
STG for General Hospitals[176]	N	N	Y	PPH not mentioned in STG. AMTSL not referenced. Page numbering is dramatically off and index does not show magnesium sulfate for PE/E. despite its presence.

[172] Drug Administration and Control Authority (2008). *Ethiopian National Drug Formulary, First Edition*.
[173] Food, Medicine and Healthcare Administration and Control Authority (FMHACA) (2010). *List of Essential Medicines for Ethiopia; Fourth Edition*.
[174] Drug Administration and Control Authority (2008). *Ethiopian National Drug Formulary, First Edition*.
[175] Drug Administration and Control Authority (2010). *Standard Treatment Guidelines for Primary Hospitals, Second Edition* . Available: http://apps.who.int/medicinedocs/en/m/abstract/Js17822en/
[176] *Ibid*.

STG for Primary Hospitals[177]	N	N	Y	None are indexed. PPH not mentioned in STG. AMTSL not referenced. Page numbering is dramatically off and index does not show magnesium sulfate for PE/E. despite its presence.
STG for Health Centers[178]	N	N	N	Index is ailment-based not medicine-based like others. PE/E is only noted for referral only, PPH not listed. AMTSL not referenced.
FMOH Management Protocol on Selected Obstetric Topics[179]	Y	Y	Y	Oxytocin is the preferred medicine for AMTSL and is the 1st line medicine for PPH. Misoprostol is recommended as 3rd line medicine for PPH.

The following further outlines the specific guidelines laid out in the above documents, related to the three maternal health commodities.

National Essential Medicines List (EML), Fourth Edition, 2010[180]

This document is the primary guide for procurement. The EML notes the following requirements for obstetric and gynecological indications:

Magnesium Sulfate for injection, 2%, 5%, 10%, 20%, 50% concentrations in 20ml vials.

Misoprostol in tablet form at 100mcg, 200mcg, 400mcg, 800mcg (Double aluminum blister packs are required for room temperature storage).

Oxytocin for injection, 1unit/ml, 5unit/ml, 10unit/ml.

Ethiopian National Drug Formulary, First Edition, 2008[181]

The National Drug Formulary is designed as a digest for rapid reference for all healthcare workers that provides standard information on all medicines, but does not include comprehensive information on prescribing and dispensing. The document is largely intended to support healthcare workers in remote settings who lack access to current information; it does not replace the standard treatment guidelines.[182]

[177] Drug Administration and Control Authority (2010). *Standard Treatment Guidelines for Primary Hospitals, Second Edition.*
[178] *Ibid*.
[179] Federal Ministry of Health (2010). *Management Protocol on Selected Obstetric Topics, First Edition*.
[180] Food, Medicine and Healthcare Administration and Control Authority (2010). *List of Essential Medicines for Ethiopia; Fourth Edition*.
[181] Federal Ministry of Health (2010). *Management Protocol on Selected Obstetric Topics, First Edition*.
[182] Drug Administration and Control Authority (2008). *Ethiopian National Drug Formulary, First Edition*.

Magnesium Sulfate
Injection, 10%, 20%, 50% concentrations in 20 ml
Indications: prevention of recurrent seizures in eclampsia.
Dose and Administration: IV injection: initially 4 g over 5 - 10 minutes followed by IV infusion at a rate of 1 g every hour for at least 24 hours after the last seizure; recurrence of seizures may require additional IV bolus of 2 g.
Storage: store at room temperature.

Misoprostol
Only indications are for gastric ulceration and medical termination of pregnancy (not for PPH).

Oxytocin
Injection, 10units/ml in 0.5 and 1ml ampoules, 1unit/ml, 5units/ml in 1ml
Indications: *(in addition to other uses)* oxytocin is also indicated to control postpartum bleeding or hemorrhage.
Dose and Administration: *Control of postpartum uterine bleeding: IV infusion:* 10 units at a rate of 20 to 40 milliunits per minute following delivery of the infant(s) and preferably placenta(s).
Storage: store oxytocin at 2 to 8oC, protect from freezing. 10units/mL (1mL) may also be stored at 15 to 25°C for up to 30 days.

Standard Treatment Guidelines (STGs)

In addition to the main Standard Treatment Guidelines (STG) document, another version exists for each facility level (General Hospital, Primary Hospital, and Health Centers). The Standard Treatment Guidelines (STGs) for the three MH commodities are:

Magnesium Sulfate
Injection, 2%, 5%, 10%, 20%, 50% in 20ml.[183]
Dose and Administration: *for both severe pre-eclampsia and eclampsia (PE/E)*: "A loading dose of 4gm as 20% solution IV over 10-15 minutes followed by 10gm as 50% IM injection divided on two sides of the buttock, followed by maintenance dose of 5gm every 4 hours as 50% concentration over 2 minutes, 2 gm IV as 50% solution over 2 minutes if convulsion recurs. Reduce the maintenance dose by half if there are signs of renal derangement during labor and for the first 24 hours postpartum".[184]

Misoprostol
Misoprostol is registered for PPH in Ethiopia but it is not included in the STGs.[185]

[183] Food, Medicine and Healthcare Administration and Control Authority (FMHACA) (2010). *List of Essential Medicines for Ethiopia; Fourth Edition*.
[184] Drug Administration and Control Authority of Ethiopia (2010). *Standard Treatment Guidelines for Primary Hospitals.*
[185] Venture Strategies Innovations (2012). Global Misoprostol Registration by Indication. Map available: http://www.vsinnovations.org/assets/files/Resources/VSI%20Global%20Miso%20Reg%20Map%202012%203%2026F.pdf

Oxytocin
In Ethiopia's Standard Treatment Guideline (STG) for Primary Hospitals, oxytocin is indicated for the treatment of prolonged pregnancy and prolonged labor, but drug treatment for postpartum hemorrhage is not included in the STG.[186]
Dosage: 10 units IM
Storage: 15-30°C, protect from freezing

Management Protocol on Selected Obstetric Topics

The Management Protocol on Selected Obstetric Topics (the Protocol) is intended to serve as a guide to practitioners alongside the STGs, drug formulary, and other official documents. There is limited information available on the intended use of the Protocol as the preface and forward of the document are unavailable. The Protocol is clearly a valuable document, demonstrating FMOH's effort to provide specific guidelines to address obstetric complications and thus to reduce maternal deaths. However, it is unclear how widely distributed this document is, if there is awareness of it among health workers, and if it is included in pre- and in-service training.

Magnesium Sulfate
Not included in the Protocol.

Misoprostol
The Protocol recommends misoprostol be used for Active Management of the Third Stage of Labor (AMTSL) only as the third line medicine (after oxytocin and ergometrine). The Management Protocol indicates that for AMSTL, misoprostol should be dispensed as 400-600mcg orally when oxytocin is unavailable.[187]

Oxytocin
The Protocol indicates that oxytocin is the preferred medicine for AMTSL and is the first line medicine for PPH caused by uterine atony. The Protocol indicates "oxytocin is preferred over other uterotonic medicines because it is effective 2-3 minutes after injection, has minimal side effects, and can be used by all women."[188]

Registration and Manufacturing

Oxytocin, misoprostol, and magnesium sulfate are all registered for emergency obstetric use in Ethiopia. Misoprostol was approved in June 2010 for use as a third line medicine for AMTSL and is reflected as such in The Management Protocol on Selected Obstetric Topics document but is not included in the STGs.[189]

[186] Drug Administration and Control Authority of Ethiopia (2010). *Standard Treatment Guidelines for Primary Hospitals*.
[187] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Management Protocol on Selected Obstetric Topics, First Edition*.
[188] Federal Ministry of Health (2010). *Management Protocol on Selected Obstetric Topics, First Edition*.
[189] Venture Strategies Innovations (2011). WHO takes important step, adds misoprostol to its model list of essential medicines for PPH. Available: http://www.vsinnovations.org/who-adds-misoprostol-to-eml.

While the creation of FMHACA is intended to result in increased efficiency for regulatory management, the organization's mandate is broad and its capacity is extremely limited.[190] FMHACA's bureaucracy can serve as a bottleneck to new procurement options and can cause significant delays through lack of clear information and guidance on topics such as import requirements and it can reportedly take years to get registrations through the system.[191] None of the manufacturers for the three MH commodities have WHO pre-qualification and it can reportedly take years for products from new suppliers to be fully registered in country.[192] It is also unclear as to what, if any, capacity exists at the PFSA to manage re-registration for products undergoing re-packaging or labeling changes. Key informants indicated that Ethiopia does not currently repackage any of the three MH commodities.

As of 2010, there were 87 wholesalers, 53 importers, and 13 local manufacturers for various EML medicines in Ethiopia.[193] However, there are no local manufacturers currently producing magnesium sulfate, misoprostol, or oxytocin; all three are purchased from different sources overseas, though very little information is available on which countries and specific manufacturers Ethiopia sources from.[194] Additional research is required to identify which countries and specific manufacturers Ethiopia is primarily sourcing these three MH commodities from.

Quality Assurance and Storage

FMHACA currently only conducts laboratory analysis of commodities prior to registration in its efforts to ensure that these products meet quality and safety standards. However, the agency does not conduct ongoing in-country testing for procured products after initial registration.[195] While the testing facilities exist, capacity is extremely limited.[196]

In addition to registering products, FMHACA is also responsible for regulating the market. Once the product is in the field, the PFSA, also the main distribution authority, has no means of ensuring proper storage and quality maintenance. However, PFSA, with support from USAID/DELIVER is conducting trainings for all logistics personnel on proper storage and inventory management to diminish concerns of product degradation.[197]

Procurement

As of 2010, PFSA managed commercial purchase and donation imports for 87% of all pharmaceuticals.[198] Procurement is conducted through international and local open tenders/bids; restricted tender, direct purchasing or negotiation from both international and local sources.[199] Due to bulk purchasing and

[190] Interview, Sharmila Raj, USAID, 5.3.12
[191] *Ibid*.
[192] World Health Organization (2010). Prequalification of Medicines by WHO: Fact sheet N°278. Available: http://www.who.int/mediacentre/factsheets/fs278/en/index.html
[193] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Ethiopia's Fourth National Health Accounts 2007/2008*.
[194] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12
[195] Pharmaceuticals Administration and Supplies Service (PASS) of the Federal Ministry of Health (FMOH) and the World Health Organization (WHO) (2005). *Survey on Prices of Medicines in Ethiopia*.
[196] Ethiopia Country Pharmaceutical Profile and NPO. 2008.
[197] USAID/DELIVER PROJECT (2011). *Supply Chain Integration: Case studies from Nicaragua, Ethiopia, and Tanzania*. Available: http://deliver.jsi.com/dlvr_content/resources/allpubs/logisticsbriefs/SCIntegCaseStudies.pdf
[198] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Ethiopia's Fourth National Health Accounts 2007/2008*.
[199] *Ibid*.

competitive bidding, PFSA is able to leverage international reference pricing with roughly 15% discounts.[200]

Supply Chain Integration

In 2006, the FMOH developed the Pharmaceutical Logistics Master Plan (PLMP), aimed at coordinating the actors, levels, and functions of the supply chain to facilitate a reliable and sufficient stream of medicines and supplies, at the lowest cost, to the public sector health facilities[201]. More recently, in an effort to increase efficiency and performance outcomes, the FMOH implemented the Business Process Review (BPR) reform, restructuring medicines regulatory and procurement agencies into a single national commodity supply chain, solely under the management of the PFSA.[202]

Under the new system, procurements and donations are to be needs-based and coordinated through a central PFSA warehouse, then transferred to 1 of 13 PFSA regional hubs/warehouses (with planned expansion of 10 additional hubs). The hubs will manage distribution to the hospitals and health centers within a 160 km radius and the health centers, in turn, will distribute to the health posts.[203]

The new system is designed with a shorter pipeline that improves efficiency through consolidation of logistics functions through the Integrated Pharmaceutical Logistics System (IPLS). The IPLS, which is directly supported by the USAID/DELIVER Project, is a comprehensive computerized financial, inventory control, and management information system that links regional hubs to the central level and the FMOH. The automated, user-friendly, IPLS "specifies the codes, commodities, and reporting frequency that are used by the Health Commodity Management Information System, the Patient Information Management System, and the Health Commodity Tracking System that is supported by a paper based system for Health Centers and HEWs."[204]

Training and implementation of these systems is occurring in a phased approach utilizing successful in-service training from health center storekeepers and tools including job aides, posters, and storage guidelines for HEWs.[205] This new on-the-job training is part of the Health Post Resupply program, which began scale-up to 1000 health posts in March 2012. The training will enable HEWs to effectively manage over 50 medicines and medical supplies, including MH commodities.[206] Impact evaluation has yet to be conducted on this initiative.

With clear ownership for commodity management at each health facility, ongoing and robust training, and clear processes for information flow, these changes should help to ensure more efficient logistics decision-making and better supply chain performance down to the last mile in years to come. However, there will likely continue to be systemic issues such as high staff turnover and transportation challenges

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[200] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Ethiopia's Fourth National Health Accounts 2007/2008*.
[201] Supply Chain Integration: Case studies from Nicaragua, Ethiopia, and Tanzania. USAID/DELIVER PROJECT. http://deliver.jsi.com/dlvr_content/resources/allpubs/logisticsbriefs/SCIntegCaseStudies.pdf
[202] *Ibid*.
[203] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Ethiopia's Fourth National Health Accounts 2007/2008*.
[204] USAID/DELIVER PROJECT (2011). *Supply Chain Integration: Case studies from Nicaragua, Ethiopia, and Tanzania*. Available: http://deliver.jsi.com/dlvr_content/resources/allpubs/logisticsbriefs/SCIntegCaseStudies.pdf
[205] USAID/DELIVER PROJECT (2012). *Health Logistics Quarterly, A Quarterly Newsletter*, Volume 4, NO. 1, 2.
[206] *Ibid*, 8

in hard to reach rural areas.[207]

A key in-country informant identified the largest supply chain challenge to be effectively linking with the health posts, the lowest level of the chain, where HEWs are working. With more than 15,000 health posts, it is very challenging to consistently obtain commodity consumption data at this level, making it extremely difficult to forecast and meet the needs of health posts in a timely manner. In an effort to address this issue, under the new three-tier health service delivery system, there are Primary Healthcare Units (PHCUs); each health center will coordinate four health posts. It will be important to monitor if and how the new PHCU structure improves the timely forecasting and delivery of MH commodities to the health post level.

Oxytocin, presents particular distribution challenges given the requirements for cold chain storage. The central warehousing and hub facilities are all outfitted with cold chain management, though key informants indicate that hubs often do not meet required standards. Health centers generally have adequate electricity, back-up generators, and refrigerators in delivery rooms where oxytocin and other commodities are kept cold.[208] However, electricity is a problem in rural areas and thus, use of misoprostol is often a more feasible option for health posts.[209]

Budget and Financing

In Ethiopia, drug expenditure is financed by the federal and regional governments (10%); non-governmental organizations (NGOs) (16%); bilateral and multilateral donors (27%); and household out-of-pocket spending (47%).[210] There was no information readily available on MH commodity expenditures; this information does not appear to be tracked. Ethiopia's Fourth National Health Account has information on general health expenditures and a subaccount for reproductive health with minimal information on MH services generally and no information on RH or MH commodities. There are significant gaps in research and data on financing of MH commodities specifically and there is a clear need for additional assessment.

Revolving Drug Fund

While there are a number of financing mechanisms available for use in drug procurement, the three MH commodities addressed here are primarily financed through the PFSA and a US$ 21.5 million Revolving Drug Fund (RDF) system financed by the GAVI Alliance, Global Fund, and Protection of Basic Services (PBS).[211] Ultimately, the health centers buy the commodities from the PFSA to replenish the fund, which requires the health centers to charge for services.[212]

MDG Pool Fund

Magnesium sulfate is procured by PFSA through the MDG Pool Fund,[213] which is managed by the FMOH

[207] Interview, Michael Tekie, National Program Officer, UNFPA Global Program on Reproductive Health Commodities, 5.3.12
[208] Interview, Anteneh Tsige, Senior SIAPS Technical Advisor, 5.3.12
[209] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12
[210] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Drug Financing in Ethiopia.*
[211] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Ethiopia's Fourth National Health Accounts 2007/2008*.
[212] Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12
[213] *Ibid*.

and provides specific grants for public goods and health system strengthening in line with the HSDP.[214][215] The MDG Pool Fund was created in 2008 as a joint financing mechanism to pool funds from multiple donors including the Global Fund, GAVI, PEPFAR, and other multilateral and bilateral donors.[216] Additionally, international agencies, such as UNICEF, have purchased these commodities in the past and donated them for use through the PFSA.[217]

User Fees and Waivers

The FMOH Healthcare Financing Proclamation requires maternity services to be provided free of charge, however, in public and private health centers providing delivery services, 66% charged a fee for normal delivery or required women to buy supplies for their delivery, including essential medicines. Of 751 facilities, two-thirds charged for extra supplies including lifesaving obstetric medicines, such as oxytocin, penicillin, and gentamicin.[218]

There is also a waiver policy in place at the national level that should allow health clinics and hospitals to provide free "curative" health services for those unable to afford treatment. While some families are pre-identified and do not have to pay for services for three years; there is no enforcement of the policy.[219][220] Both the waiver and exemption policies would need to be widely implemented and enforced to significantly increase consumer demand for services.

Private Sector

While all three commodities are available in the private sector, there are no data documenting cost, availability, and use; thus it is difficult to determine the impact.[221] The private sector is an extremely important supplement to public sector efforts, yet it only accounts for 3% of the national health expenditure on pharmaceuticals and other medical supplies.[222]

Household out-of-pocket spending accounts for the largest source of medicine financing in Ethiopia; the high proportion of household spending on medicines implies that a significant portion of the population is purchasing medicines from private retail outlets where prices tend to be significantly higher than in the public sector.[223] Clearly, out-of-pocket medicine purchasing is financially unfeasible for the majority of the population.

Availability and Use

Availability of maternal health medicines varies by type of facility, region, urban/rural residence, health

[214] Anteneh Tsige, Senior SIAPS Technical Advisor, 5.3.12
[215] Joint Financing Arrangement between The Federal Democratic Republic of Ethiopia and Development Partners on Support to the MDG Fund. August 2008.
[216] *Ibid*.
[217] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12
[218] Pearson L *et al*. (2011). User fees and maternity services in Ethiopia. *International Journal of Gynecology and Obstetrics* 115:310–315.
[219] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12
[220] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Ethiopia's Fourth National Health Accounts 2007/2008*.
[221] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12
[222] Federal Democratic Republic of Ethiopia Ministry of Health (2007). *Ethiopia's Fourth National Health Accounts 2007/2008*.
[223] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Drug Financing in Ethiopia.*

facility ownership/management, and distance from the source of supply/warehouse. Despite significant supply chain management systems improvements, the challenge of ensuring availability of magnesium sulfate, misoprostol, and oxytocin is immense.

While magnesium sulfate is indicated as the first line anticonvulsant for severe PE/E in Ethiopia, several recent assessments indicate that it is not widely available. Oxytocin is largely available in facilities in urban areas and has been in use for some time. The availability and use of misoprostol has not been as widely assessed as the other two commodities and warrants further research.

In the last two years, there have been three important assessments conducted on the availability of these three MH commodities:

1. The National Assessment of Emergency Obstetric and Newborn Care (EmONC) Services (2008);[224]
2. The United Nations Population Fund (UNFPA) commissioned national survey assessing availability of life-saving MH/RH medicines (including oxytocin and magnesium sulfate but not misoprostol) at Service Delivery Points (SDPs) across nine regional states and two city administrations in Ethiopia (2010);[225] and
3. The USAID/MCHIP assessment of prevention and management of postpartum hemorrhage and pre-eclampsia/eclampsia in selected countries (2011).[226]

   Magnesium Sulfate: The UNFPA survey found that fewer than 1 in 10 (8.6%) surveyed health centers and health posts reported having magnesium sulfate on hand.[227] Similarly, the National Baseline Assessment for Emergency Obstetric Care reported "no or very few" facilities utilized magnesium sulfate for PE/E.[228] The USAID survey (2011), also found very low availability of magnesium sulfate.

   As of 2011, when the USAID survey was conducted, midwives were not authorized to diagnose PE/E or to dispense magnesium sulfate, and it was not regularly available in facilities.[229] However, reports indicate that the authorization of midwives administering magnesium sulfate is included in government plans to scale-up training for administration.[230] The national baseline assessment of EmONC revealed that health workers administer magnesium sulfate without

[224] Federal Ministry of Health, UNICEF, UNFPA, WHO and AMDD (2008). National Baseline Assessment for Emergency Obstetric and Newborn Care in Ethiopia.
[225] Federal Ministry of Health and UNFPA (2010). *National survey on the availability of contraceptives and Essential Life Saving Maternal/RH Medicines in Service Delivery Points in Ethiopia*.
[226] Fujioka, A and Smith, J (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* USAID/MCHIP Status Report.
[227] Federal Ministry of Health and UNFPA (2010). *National survey on the availability of contraceptives and Essential Life Saving Maternal/RH Medicines in Service Delivery Points in Ethiopia*.
[228] *Ibid*.
[229] Fujioka, A and Smith, J (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* USAID/MCHIP Status Report.
[230] Wilson, R *et al*. (2012) *Medicines for Maternal Health Working Paper*. Prepared for the United Nations Commission on Life-Saving Commodities for Women and Children.

national policy authorization.[231] A recent interview with a key in-country informant indicated that the practice of unauthorized health workers administering magnesium sulfate continues to be widespread and task shifting is quite common.

Misoprostol: Ethiopia has approved misoprostol for the prevention and treatment of PPH in its indications for use; is in the process of scaling up use of misoprostol for home births; and has been providing training and distributing misoprostol to Health Extension Workers (HEWs), who assist women who deliver at home and at community health posts.[232] Misoprostol was not included in the UNFPA survey or the national assessment on EmONC.

Oxytocin: The UNFPA survey found that oxytocin was available in 75.7% of the 193 facilities surveyed; it was available in all secondary and tertiary level hospitals while only 70.4% of health posts and health centers reported having this medicine.[233] The national assessment for EmONC found only 43% of the health centers reporting oxytocin in stock while 31% were either out of stock at the time or had reported a stock-out in the previous 12 months and roughly a quarter of health centers reported never having had oxytocin in stock.[234] In practice, all levels of skilled birth attendants administer oxytocin, despite policies that preclude its use by untrained personnel.[235]

Demand for Maternal Health Commodities

Demand by Providers

There is very little information available on provider demand for the three MH commodities; additional research and interviews with key in-country informants is warranted. One interviewee indicated that because magnesium sulfate and misoprostol are still relatively new in Ethiopia, it is difficult to obtain accurate consumption data.[236]

However, there has been some documentation of key barriers to demand for magnesium sulfate among providers. Health workers have attributed low-utilization of magnesium sulfate to a fear of side effects, safety, and a lack of available counteragents.[237] The National Assessment on EmOC showed only 23% of facilities had actually used magnesium sulfate in the preceding year. Since then, provider awareness and demand of magnesium sulfate is growing and that awareness is believed to correlate to increased use where available.[238]

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[231] Federal Ministry of Health, UNICEF, UNFPA, WHO and AMDD (2008). *National Baseline Assessment for Emergency Obstetric and Newborn Care in Ethiopia*.
[232] Fujioka, A and Smith, J (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* USAID/MCHIP Status Report.
[233] Federal Ministry of Health and UNFPA (2010). *National survey on the availability of contraceptives and Essential Life Saving Maternal/RH Medicines in Service Delivery Points in Ethiopia*.
[234] *Ibid*.
[235] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12
[236] Interview, Anteneh Tsige, Senior SIAPS Technical Advisor, 5.3.12
[237] UN Commission on Life-Saving Commodities for Women and Children (2012). Magnesium Sulfate product profile. Available: http://www.everywomaneverychild.org/component/content/article/1-about/304-magnesium-sulfate-mgso4--product-profile-
[238] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12

The USAID survey on prevention and management of PPH and PE/E indicates that another key barrier to provider demand is posed by the fact that there are only stand-alone training in the usage of magnesium sulfate, likely limiting the number of providers who receive specific training. As identified in the survey, one of the key opportunities to expand demand and use of magnesium sulfate is integration into all in-service training, rather than limiting to stand-alone training.[239]

A key in-country informant indicated that the initiation stages of rolling out misoprostol for HEW has been successful and those HEW who have been trained in administration have begun using the product at the community level. However, the vast majority has yet to be trained in managing obstetric complications and their only option is to refer women to health centers through a weak referral network.[240] It will be important to evaluate the impact of introducing misoprostol at the community level, including increases in knowledge and use among HEW who have conducted the training as the program is scaled up. Further, additional research is warranted to monitor whether the increase in HEW training leads to an actual increase in utilization of MH commodities.

Demand by Consumers

One of the biggest challenges to reducing maternal deaths in Ethiopia is the lack of demand seeking behaviors from mothers.[241] Health service utilization in Ethiopia is only 0.24% per person per year, which is consistent with the low facility delivery rates.[242] As expected, the critical barriers to demand among consumers are knowledge and awareness of the risks of pregnancy and childbirth and the clearest pathway to increasing demand for MH services generally, and for MH commodities specifically, is to increase awareness and knowledge of both the risks of PPH and PE/E and the potential life-saving benefits of utilizing skilled attendants at delivery and having access to essential commodities.

Recommendations

Evaluation of Health Extension Worker (HEW) Initiatives

Reportedly, HEWs generally have low skill levels in attending deliveries. In order to address this issue, in 2009, the Health Extension Program (HEP) trained 5,000 HEWs in clean and safe delivery.[243] Given that 94% of births occur at home in Ethiopia, the rapid rollout of HEWs and the distribution of misoprostol to HEW attending home births are two initiatives underway which have the potential to make a sizable impact on Ethiopia's MMR, though the impact of these initiatives will need to evaluated.

Currently, information is not readily available on the content of the HEW training. Specifically, if this training includes management of obstetric complications and training in administration of misoprostol in the event of PPH. Additional research is warranted to evaluate how many HEWs have been trained to date in AMTSL; to what extent they are being trained in administration of misoprostol; and to what extent an increase in training leads to an actual increase in utilization of misoprostol.

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[239] Fujioka, A and Smith, J (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* USAID/MCHIP Status Report.
[240] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12
[241] Interview, Anteneh Tsige, Senior SIAPS Technical Advisor , 5.3.12
[242] Federal Democratic Republic of Ethiopia Ministry of Health (2010). *Ethiopia's Fourth National Health Accounts 2007/2008*.
[243] Bilal, Nejmudin *et al*. Health Extension Workers in Ethiopia: Improved Access and Coverage for the Rural Poor.

Standardization of Guiding Documents

The FMOH has identified a "gap in the unavailability of reference materials for prescribers and dispensers."[244] This gap should be filled by the Standard Treatment Guidelines (STGs). However, the latest STG edition is severely incomplete in relation to MH commodities; misoprostol is not included and oxytocin is not indicated for PPH. Further, there are significant formatting errors challenging ease of use. While AMSTL is included in national policies, education, and training, it is not currently included in the STGs.

A new, updated third edition is warranted ahead of schedule, to incorporate national policies and protocols on AMSTL; including national policy indicating oxytocin as the first line treatment for PPH and misoprostol as the third line treatment. This new and updated version of the STGs should be aggressively rolled out on a national scale. Further, with multiple documents on MH drug formularies in circulation, it is essential to clarify which of the many authoritative documents should guide healthcare workers at each level and there is an urgent need to standardize drug formularies and treatment indications across all documents in circulation.

Packaging of Misoprostol

Very few manufacturers produce the three-pill blister pack equaling 600mcg (WHO recommended dose to treat PPH), and Ethiopia is one of many countries that currently do not have the three-pill pack, which would facilitate ease of use for home births.[245] Misoprostol is available from 50 plus manufacturers globally (35 of which are in developing countries). However, the three-pill blister pack is only produced by a few manufacturers; procurement options in this packaging are extremely limited.[246]

Given that the three-pill blister packaging facilitates ease of use, correct dosage for treating PPH, and provides a barrier against degradation during storage, this packaging has clear advantages particularly when being used for home births.[247] With Ethiopia in the process of scaling up misoprostol for home births, tender of misoprostol in the three-pill blister packaging is recommended if possible. Further, key stakeholders in MH commodities should consider opportunities to encourage misoprostol manufacturers to increase availability of the three-pill blister packaging and potential for global tenders.

Private Sector

All three MH commodities are available in the private sector in Ethiopia, however, there is very little information on cost, availability and use making it difficult to determine the impact.[248] As the Working Paper on Medicines for Maternal Health suggests, it is critical to track private sector financing for MH

[244] Drug Administration and Control Authority (2010). *Standard Treatment Guidelines for General Hospitals, Second Edition, 31*. Available: http://apps.who.int/medicinedocs/en/m/abstract/Js17822en/

[245] Wilson, R *et al*. (2012) *Medicines for Maternal Health Working Paper*. Prepared for the United Nations Commission on Life-Saving Commodities for Women and Children.

[246] UN Commission on Life-Saving Commodities for Women and Children (2012). Misoprostol Product Profile. Available at: http://www.everywomaneverychild.org/component/content/article/1-about/303-misoprostol--product-profile-

[247] Key Data and Findings: Medicines for Maternal Health. Prepared for The United Nations Commission on Commodities for Women's and Children's Health. February 2012.

[248] Interview, Dr. Luwei Pearson: Section Chief, Health, UNICEF, 4.25.12

medicines and to capture the role the private sector plays in increasing accessibility to essential medicines.[249] In Ethiopia, additional research is urgently needed to track the role of the private sector in financing and supplying the three MH commodities. Further, identifying best practices in the private sector can provide valuable modeling for the public sector, and additional research can lay the groundwork for public-private partnerships.

Role of NGOs

Understanding the important role, impact, and valuable programming contributions being made by NGOs in Ethiopia is essential to capturing a comprehensive picture of MH services, including life-saving commodities, and efforts to improve access, availability, and financing for these commodities. Specifically, additional research is warranted to map current NGO programming and initiatives in: capacity building for PFSA and the commodity supply chain; training of HEW and midwives in skilled delivery and use of misoprostol in community settings; and increasing availability of the three MH commodities.

MH Commodity Tracking

There is a clear evidence gap in the area of financing, procurement, and availability of the three MH commodities addressed in this study. In Ethiopia, far more data are readily available on RH commodities (particularly contraceptives) and HIV commodities; developing similar mechanisms to specifically track MH commodities is essential going forward. Additional research to identify what mechanisms are in place for tracking RH and HIV commodities could provide valuable guidance on developing similar tracking mechanisms for MH commodities in Ethiopia.

Barriers to Provider Demand

Health workers have attributed low-utilization of magnesium sulfate to a fear of side effects, safety, and a lack of available counteragents.[250] The counteragent, calcium gluconate (used to counteract an overdose of magnesium sulfate), is currently not readily available in Ethiopia.[251] Procuring and supplying the counteragent to facilities providing magnesium sulfate could go a long way to alleviate provider fears and increase provider demand and utilization.

Single Commodity Supply Chain

The new supply chain mechanism implemented by the FMOH under the Business Process Review reform presents a critical opportunity to develop a more efficient and effective delivery mechanism of the three MH commodities. In the future, additional research should be conducted to evaluate the impact of the reform on streamlining the flow of MH commodities and to identify opportunities to increase efficiency in the procurement and delivery of MH commodities specifically.

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[249] Wilson, R *et al*. (2012) *Medicines for Maternal Health Working Paper*. Prepared for the United Nations Commission on Life-Saving Commodities for Women and Children.
[250] UN Commission on Life-Saving Commodities for Women and Children (2012). Magnesium Sulfate product profile. Available: http://www.everywomaneverychild.org/component/content/article/1-about/304-magnesium-sulfate-mgso4--product-profile-
[251] Fujioka, A and Smith, J (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* USAID/MCHIP Status Report.

VI. India (Bihar)

The Burden of Maternal Mortality in Bihar, India

The Government of India has shown increasing political will to address maternal health issues countrywide. Although maternal deaths have decreased, the country's maternal mortality ratio (MMR) is still 187/100,000.[252] With approximately 50,600 maternal deaths a year, India has the second-highest MMR in the world.[253] Postpartum hemorrhage (PPH) accounts for between 31% and 38% of these maternal deaths and pre-eclampsia/eclampsia (PE/E) accounts for 9%.[254] [255]

In Bihar, despite the state's recent attempts to improve maternal health in the region, the state still has the fourth-highest MMR in India, with approximately 300 deaths for every 100,000 live births. PPH accounts for 16% of these deaths.[256][257] Chief Minister, Nitish Kumar has led Bihar in rolling out national maternal health policies at the state level to address the challenges to reducing maternal deaths. His leadership has resulted in some drastic improvements for women. For example, two years ago facility deliveries made up only about approximately 20% of all deliveries, but are presently closer to 50%.[258]

Bihar is poised for significant improvements in the health system with an influx of investments such as the Bill & Melinda Gates Foundation's USD $80 million grant to the state government in partnership with leading national and international NGOs.[259] However, the state's maternal health indicators are still far below the national average with the root causes attributed to illiteracy, inadequate antenatal care services, and delays in the initiation of treatment when complications arise.[260] Despite significant financial support under the federal government's National Rural Health Mission (NRHM), national policy and programming whose mandate is to reduce maternal deaths, there are still persistent issues such as

[252] Institute for Health Metrics and Evaluation (IHME). (2011) Maternal Mortality Estimates and MDG 5 Attainment by Country 1990-2011. Seattle, United States: *Institute for Health Metrics and Evaluation*.
[253] Ibid.
[254] S.E. Geller et al. (2008) Averting Maternal Death and Disability Factors associated with acute postpartum hemorrhage in low-risk women delivering in rural India. International Journal of Gynecology and Obstetrics. 101, 94–99
[255] Fujioka A, Smith J. (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.* Maternal and Child Health Integrated Program (MCHIP). Available: http://www.k4health.org/system/files/PPH_PEE%20Program%20Status%20Report.pdf.
[256] Singh R, et al. (2009) Pattern of maternal mortality in a tertiary care hospital of Patna, Bihar. *Indian Journal of Community Medicine* .34:73-4
[257] Hota, P.K. (2009). *Norway India Partnership Initiative (NIPI) Baseline Survey Report for the State of Bihar*. P.100
[258] Interview with Dr. Shukla Intrahealth. May 4, 2012.
[259] Bill & Melinda Gates Foundation (March 21, 2011). Bill & Melinda Gates Visit Health & Development Partners in India. Available: http://www.gatesfoundation.org/press-releases/pages/gates-india-partner-visit-110321.aspx
[260] This momentum could position Bihar for becoming a model for improvement in maternal health and access to life saving commodities. However, data representing real-time improvements is not available. Therefore, although improvements are being made in Bihar every day, this case study is limited to using data that sometimes represents a prior stage in an evolving process and a continual need for improvement, as is still the case.

- lack of infrastructure, including health facilities and adequate roads, particularly in rural areas, where 90% of the population lives; [261] [262]
- insufficient staffing, with just 351 of the 583 auxiliary nurse midwife designated posts filled; and
- cultural barriers, such as illiteracy and taboos around sexual and reproductive health that prohibit male rural health practitioners from checking to make sure the cervix is appropriately dilated for administering oxytocin[263] [264]

As the state of Bihar is essentially rebuilding its entire health system, the NRHM is still broadly focused on restructuring maternal health services and has yet to focus specifically on access to maternal health commodities. Only a few district level NRHM Project Implementation Plans are available for Bihar. In Muzaffarpur District, for example, the Plan only lists magnesium sulfate, misoprostol, and oxytocin in the appendix.[265]

Status of Maternal Health Commodities in India[266]			
	Oxytocin	Misoprostol	Magnesium sulfate
Registered for use for maternal indications?	Y	Y	Y
On Essential Medicines List?	Y	Y	Y
In Standard Treatment Guidelines?	Y	Y	Y
Manufactured locally?	Y	Y	Y

Policy and Regulatory Environment

Initial research shows that India's national policies support maternal health, but state implementation of these policies and the focus on maternal health commodities within these policies needs to be strengthened.

At the national level, India recognizes the "reproductive rights of the mother" as "inalienable survival rights", protected under the "right to life" provision in Article 21 of the Constitution.[267] In an effort to secure these rights, the government initiated several national maternal health schemes, primarily

[261] Sinha, T. (2008) Why Mothers Die? A Survey of Maternal Mortality in a District Hospital in Bihar. *Health and Population: Perspectives and Issues*. 31:4, P. 280
[262] This study analyzed 52 maternal deaths in one district hospital in Bihar over a one year period. Results showed that women living in rural Bihar were almost five times more likely to suffer a maternal death than women in urban areas.
[263] Center for Reproductive Rights, Human Rights Law Network. (2011). *Charm v. Bihar*. Available: http://reproductiverights.org/sites/crr.civicactions.net/files/documents/CHARM%20factsheet%20FINAL%2010.7.11.pdf
[264] The Centre for International Public Health Policy (July, 2007). Qualitative Research on Fluoxytine and Oxytocin in India. Working paper 2.
[265] Government of Bihar, National Rural Health Mission. (2012) *Project Implementation Plan 2012-2013*.
[266] Fujioka A, Smith J. (2011) *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries*. Maternal and Child Health Integrated Program (MCHIP).
[267] Press Release from Prime Minister's office February 22, 2012. Wall Street Journal. February 29, 2012.

directed by the Ministry of Health Family Welfare's (MOHFW) Maternal Health Division, to facilitate more equal distribution of public health services.[268]

The Maternal Health Division was created in the 1990s to look after all technical and administrative aspects of maternal health activities, but has no decision-making authority. This division is responsible for addressing the high rates of maternal mortality in the country by providing advice to the Minister and Secretary of Health and by designing maternal health programs for the country, which trickle down to the state level. Unfortunately, it is not compulsory for its officers to have a public health or maternal health background and as the division is highly understaffed (with only four officers), a majority of the time is spent on administrative issues, not technical ones. The division clearly has limited capacity to design appropriate maternal health programs that address the needs for the most vulnerable states in India, such as Bihar.

Key Policies Supporting Maternal Health

A few key programs are highlighted that focus on improving the rates of institutional births, incentivizing women to utilize current programs, and expanding the reach of health care workers. At this stage in Bihar's development, each of these policies has the opportunity to include maternal health commodities as a core component in its design and implementation, but thus far commodities have not been highlighted in the available documents. There are a number of specific strategies and policies shaping maternal health in Bihar, though commodities have not been highlighted in these either.

National

The National Maternity Benefit Scheme was the first of the maternal health schemes, created in 1995. It provides US$ 9 (Rs. 500) in cash for nutritious food to pregnant women over 19 years of age and below the poverty line (BPL),[269] several weeks before the delivery of each of their first two children.

In 2005, *the National Rural Health Mission (NRHM)* was created to focus on increasing access to health care, with an emphasis on women and children in rural areas. The goal of this initiative is to reduce maternal mortality by utilizing both Accredited Social Health Activists (ASHAs), who are community members trained in safe pregnancies, and more formally trained Auxiliary Nurse Midwives (ANMs), to expand the reach and scope of health care workers.[270] Furthermore, the NRHM decentralizes the health care system and assigns responsibility to districts through District Health Action Plans (DHAP).[271] This decentralized model could be a potential opportunity for each district to prioritize its health needs, including more steady supplies of misoprostol, magnesium sulfate, and oxytocin, as well as health care workers trained for administering these medicines appropriately.

In 2005, the NRHM and the MOHFW created the *Janani Suraksha Yojana (JSY),* a program to provide additional cash incentives to pregnant BPL women to promote pre- and post- natal care and institutional

[268] This division was created in the 1990s to design maternal health programs, but lacks decision making power.
[269] A citizen in India is considered below the poverty line if s/he is living on Rs32 or less a day, which is equivalent to $0.60 a day.
[270] Center for Reproductive Rights. (2008) *Maternal Mortality in India. Using International and Constitutional Law to Promote Accountability and Change.* P.22
[271] Government of Bihar, National Rural Health Mission. (2012) *Project Implementation Plan 2012-2013*..

deliveries. Pregnant BPL women older than 19 also receive Rs 500 for at-home deliveries for their first two births; ASHAS who register these women are considered instrumental in this care, and also receive a small sum of money as a link worker, who is able to connect clients to services. An evaluation of the JSY in 2011 revealed that in the twenty-four districts observed in India, over half of the women who previously chose to deliver at home, were opting for institutional deliveries.[272] More specifically, in Bihar, three districts were sampled to evaluate the state. In those three districts, institutional deliveries were at 27.6% (Samastipur), 17.1% (Madhepura), and 39.3% (Nalanda). These figures can be compared to the average of the twenty-four districts in the study, 30.31%,[273] showing that Bihar's JSY program seems to be on par with other states.

12th Five Year Plan (2012 – 2017) Free Medicines for All

In India's recently developed 12th Five Year Plan, there is a proposal to address universal access to medicines. The national government seeks to follow the highly effective state procurement, storage, and distribution model developed for Tamil Nadu, which has centralized all these processes within the state.[274] According to the proposal, the federal government would cover 85% of the cost of generic medicines listed in the National List of Essential Medicines (NLEM) to aid state governments in providing 'free medicines for all' at public health facilities. This would also encourage state governments to spend more on essential medicines in order to reduce inter-state and inter-district disparities. As of 2011, magnesium sulfate, misoprostol, and oxytocin are all listed as essential medicines in India as they are recognized for being cost efficient, safe, and effective, but none are price controlled.[275]

While it is clear from the development of these national maternal health programs, departments, and plans that program objectives have expanded since 1995, and the country is attempting to meet the broader needs of pregnant women, the fact that these programs lack focus on the commodities shows both their limitations, as well as their potential for expansion.

Bihar

Policies and departments are created at the national level, but are implemented at the state level. Their potential for success is determined by the status of the existing health system and leadership within the state. Even though Bihar's Chief Minister has been impressive in improving access to maternal health services, these policies do not take into account the significant barriers to both physical and human resource capacity in Bihar that make implementing the policies difficult. Additional in-country research would provide a better understanding of the ability of the state government to adapt the NRHM programs to the needs of their state, and how these commodities are prioritized and linked with the federal maternal health policies being implemented at the state level.

[272] National Rural Health Mission (2011) *Programme Evaluation of the Janani Suraksha Yojana*.
[273] Ibid.
[274] Tamil Nadu is an economically developed state with investments in pharmaceuticals. Its state drug procurement and distribution is therefore more advanced and serves as a guide for Bihar.
[275] National List of Essential Medicines India (2011) Available: http://www.who.int/selection_medicines/country_lists/India_NLME_2011.pdf

In Bihar, the main program focused on reducing MMR is the NRHM. As with the other programs, the NRHM does not specifically address increasing access to magnesium sulfate, misoprostol, and oxytocin. Instead, the NRHM's District Healthcare Action Plans (DHAPs) have encouraged Bihar to address its specific needs for maternal health with a focus on:

- improving community participation for gathering data;
- monitoring and feedback on health care sites;[276]
- identifying performance gaps in staff quantity and quality;
- training more ASHAs and testing for the quality and retention of training;
- upgrading health facilities with equipment and maintenance;
- implementing 'mobile medical units' to reach communities in remote areas; and
- prioritizing services on a need basis[277]

The result has been an encouraging start, especially as it is a transparent process, requiring state-level data to be documented. The DHAPs also provide an opportunity to include the monitoring of knowledge and access to MH commodities.

Tamil Nadu Medical Services Corporation Limited (TNMSC)

In 1995, the state of Tamil Nadu effectively developed its own medicine procurement and distribution system. The organization is completely run by government officials and they purchase medicines only from manufacturers and not from agents. Over the years TNMSC has been able to procure the lowest prices for all of their essential medicines. This is the model that the state of Bihar is in the process of replicating and the national government is utilizing for the 'Free Medicines for All' component of the 12th Five Year Plan. Given that this includes all essential medicines, it can be assumed that Bihar's replication of the model will include MH commodities. It remains to be seen how this model will develop and be implemented in Bihar and how it will explicitly address barriers to MH commodities.

Regulatory Environment

India has a regulatory structure for pharmaceuticals at both the national and state levels. Both levels impact Bihar's regulatory environment for maternal health commodities since national policies dictate regulation at the state level, and some regulation is managed at the state level.[278] The national government is responsible for regulating the import, manufacturing, distribution, and sale of all medicines through laws and administrative bodies. Additional departments approve licenses to manufacture certain categories of medicines, establish regulatory rules, screen medicine formulations in the Indian market, regulate manufacturing of new medicine, conduct training programs for regulatory officials, and publish information on Indian pharmaceuticals. [279][280]

[276] Government of Bihar, National Rural Health Mission. (2012) *Project Implementation Plan 2012-2013*.
[277] Ibid
[278] Chitra, S. and Venkatraman, S.. (2010) Pharmaceutical Registration in India. Available: http://www.slideshare.net/chitrasp/Pharmaceuticals-Registration-in-India
[279] The departments are supported by an additional tier of regulating bodies, including; Directorate General of Foreign Trade, Department of Biotechnology, Genetic Engineering Approval Committee, Recombinant DNA Advisory Committee, Institutional Biological Safety Committee, and Review Committee on Genetic Manipulation.

The regulatory departments and systems are significant when examining the barriers to, and potential for, expanding access to life saving MH commodities. The fact that a formal structure exists is a promising framework for using the laws to secure regulation for the commodities, but the degree to which the framework is upheld and utilized at the state level is not always strong.

Regulation at the State Level

States are in charge of evaluating medicine labs, determining when medicine formulas become manufactured, monitoring the quality of medicines and manufacturers, and recalling substandard medicines.[281] While information on the impact of these policies was not readily available during this initial research, some isolated pieces of evidence were discovered showing that gaps exist between policy and ground-level realities in state regulation. For example, a WHO regulation workshop was held to address the "clandestine" manufacturing of oxytocin in Bihar and subsequent arrests were made.[282] Also, despite numerous layers of regulatory departments, studies have found that high standards and strict timelines for safety tests are more flexible in practice.[283]

Unregulated Sector

A key informant indicated the financial barriers to medicines have given rise to a strong and pervasive unregulated informal sector, which meets the pharmaceutical needs for those with limited resources.[284] Rural medical practitioners (RMPs) play a vital role in this sector. In the mid-1990s, the number of RMPs was said to be 1.25 million nationwide, which at that point was double the number of licensed doctors. The pharmaceutical companies have utilized these RMPs to increase their medicine distribution at a much faster rate than is possible with formal medical care. [285]

RMPs are also known to be a source of MH commodities, with studies stating that these practitioners provide and administer these commodities. [286] Various studies noted that most undertrained, unqualified private practitioners in both rural and urban centers were widely using oxytocin injections in home deliveries and rural medical practitioners seemed to be the most popular medium in administering these injections. [287]

More research is needed to understand where both formal and informal health care providers and birth attendants are obtaining knowledge on administering these commodities at the state and district level in

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[280] Chitra, S. and Venkatraman, S.. (2010) Pharmaceutical Registration in India. Available: http://www.slideshare.net/chitrasp/Pharmaceuticals-Registration-in-India
[281] Ibid
[282] Government of India. (June 2009) Minutes of the WHO Workshop on Dissemination of Information on Regulatory Affairs and 40th Meeting of the Drugs Consultative Committee. Available: http://cdsco.nic.in/DCC%2040TH%20%20Minutes1.pdf
[283] PharmaTutor(http://www.pharmatutor.org/articles/assests-of-pharmacovigilance-in-india?page=0,1)
[284] Brhlikova, P. et. al. (2009) Intrapartum Oxytocin (Mis)use in South Asia. *Journal of Health Studies* 2(1,2,3): 33-50.
[285] Lalwani, H. et. al. (2011) Study of Incentives being provided by Medical companies to retailers. IIT Bombay.
[286] Jeffery, P. et. al. (2007) Unmonitored Intrapartum Oxytocin Use in Home Deliveries: Evidence from Uttar Pradesh, India. *Reproductive Health Matters*. 15(30): 172-8.
[287] Jeffery, R. et al. (2009) Architecture of Drug Regulation in India: What are the Barriers to Regulatory Reform? *Journal of Health Studies* 2(1,2,3): 13-32.

Bihar. In addition, there is also a need to explore the unregulated incentives given to both licensed doctors as well as RMPs for pushing specific medicines as well as the parallel black market in which a key informant explained that government health workers sold state provided medicines.[288]

Clinical Guidance and Training

The National List of Essential Medicines (NLEM) and Standard Treatment Guidelines (STGs) govern the access and use of the three commodities in Bihar for maternal health administrators and health workers. No state level management guidelines exist beyond the STGs. The text below outlines indications for the three commodities and also provides examples on how they are recognized in health worker trainings.

National List of Essential Medicines

India's NLEM was updated in 2011, and is the first version of the list to include all three commodities discussed in this report. Oxytocin is recommended at the secondary and tertiary health facilities in injectable form in 5 IU/ml and 10 IU/ml and misoprostol was listed for the first time at the tertiary level health center in tablet form at 100ug. Magnesium sulfate was recommended at both secondary and the tertiary levels as an injectable at 500 mg/ml.[289]

Standard Treatment Guidelines and Administering Bodies

Postpartum Hemorrhage: India's STGs promote the active management of the third stage of labor (AMTSL) and recommend using an uterotonic medicine to prevent PPH. The STGs indicate oxytocin (in a dose of 10 U IM) as the first-line medicine to address this condition.

While oxytocin is a widely accepted medical treatment for PPH, given that approximately 50% of births in Bihar occur at home, studies have noted the need for rural health workers to have supplies of oral misoprostol tablets available for patients.[290] One study showed that even minimally trained midwives were able to administer misoprostol when other uterotonics were unavailable.[291] In these cases, the STG encourages the use of three tablets of misoprostol at 200 mcg each, for a total dose of 600 mcg, immediately after delivery.[292] According to a key informant, misoprostol is widely available and has recently been used much more frequently by Skilled Birth Attendants (SBAs) in India although its cost (much higher than oxytocin) continues to be a barrier.[293]

Pre-Eclampsia/Eclampsia: The national STGs recommend two medicines for addressing seizures during PE/E. Magnesium sulfate is the primary choice, followed by Diazepam if magnesium sulfate is unavailable. For PE/E, the first dose of magnesium sulfate should be given by injection (4 g (20 ml of 20%

[288] Anonymous Informant working with Bihar state health workers.
[289] National List of Essential Medicines of India 2011 Available: http://www.who.int/selection_medicines/country_lists/India_NLME_2011.pdf
[290] Kodkany, BS. et al.(2004) Initiating a Novel Therapy in Preventing Postpartum Hemorrhage in India: A Joint Collaboration Between the United States and India. *Human Reproduction Research Collaboration Center, JN Medical College*. P.1
[291] Ibid P.1
[292] Government of India (2005). Guidelines for Pregnancy Care and Management of Common Obstetric Complications by Medical Officers. *Maternal Health Division, Ministry of Health and Family Welfare, Government of India.* http://whoindia.org/LinkFiles/Making_Pregnancy_Safer_Normal_delivery_and_management_of_obstetric_complications_.pdf
[293] Interview with Dr. Manju Shukla, Intrahealth India, March 4, 2012.

solution), slow IV, at the rate of 1 ml every minute). This is followed by 5g of magnesium sulfate injected into each gluteus muscle (10 ml of 50% solution), deep IM, with 1 ml of 2% Lignocaine in the same syringe. The STG recommend that if the health workers are not trained in utilizing the medicine, then it should only be given through the IM route. If convulsions recur after 15 minutes then another 2g of magnesium sulfate is given (10 ml of 20% solution).[294]

National Formulary India, Fourth Edition, 2010 (pre-print version)

India's National Drug Formulary has been updated after 30 years and is currently still in pre-print version, but is expected to be published this year. The draft was not available for review and therefore analysis is based on published assessments of the formulary draft. There is heavy criticism that the document has large gaps in information, as well as misinformation.[295] It has not listed all of the national health programs, missing the Reproductive and Child Health Programs amongst others, and it also lists incorrect compositions of drugs and dosages. The assessment did not mention MH commodities and unless there are major revisions in place, this formulary is not bound to be a proper accompaniment to the STGs or a source of information for healthcare workers at the state and district levels.

Training

In the national government's guidelines for operationalizing training for SBAs at the state and district level, all three commodities were listed in the checklists for the training. Under the checklist for training site readiness and field level monitoring, an assessment was conducted to test if all three commodities were available on the emergency drug tray at the health facility, and if misoprostol and oxytocin were listed as key steps to management of actively managed third stage labor (AMTSL). There was also an evaluation of whether the SBAs knew when to administer both misoprostol and oxytocin and how to do so. There was no other mention of magnesium sulfate beyond its presence on the emergency drug tray.[296]

Even though the assessment appears to be a productive step in evaluating the capacity of health facility managers and SBAs in relation to administering the commodities, this training guideline made no references to the STGs for addressing PPH and PE/E and therefore it is unclear to what extent these guidelines are being taken up and advocated on the ground. Additional research is needed to evaluate the content of trainings for maternal health workers at the state and district level in Bihar and to assess the level of provider knowledge for treatment of PPH and PE/E.

[294] India Standard Treatment Guidelines (2007) Available at: http://whoindia.org/en/Section2/Section428.htm
[295] Batman, G. (2011) The National Formulary of India 2010: Thorough and extensive revision of the preprint version needed. *Journal of Pharmacology and Pharmacotherapeutics.* 2:4: 219-220.
[296] Maternal Health Division, Ministry of Health and Family Welfare, National Rural Health Mission. (2008) *Guidelines for Operationalizing SBA Training in RCH II.*

Registration and Manufacturing

India's US$4.5 billion pharmaceutical industry is the third-largest in the world in terms of volume, and fourteenth in terms of value, with a current annual growth rate of 8-9%.[297] [298] The extensive list of manufacturers (tens of thousands) makes it challenging to evaluate the capacity of specific manufacturers, their level of formal registration, their pricing, and the commodities they produce. Additional research is necessary to further disaggregate manufacturers, as well as their potential for maternal health commodity production in Bihar. Because this is a unique situation among the case studies, two tables are presented below. The first table shows India's top ten pharmaceutical manufacturers in terms of sales in USD. The second table focuses on commodity production as it relates to this report. The asterisk on both tables indicates which companies, based on this research, were producing at least one of the three MH commodities.

Leading Indian Pharmaceutical Companies

Company	Sales in US$ million	Year End
Cipla*	6,368.06	March 2011
Ranbaxy Lab	5,687.33	December 2010
Dr. Reddy's Labs	5,285.80	March 2011
Sun Pharma	1,985.78	March 2011
Lupin Ltd*	4,527.12	March 2011
Aurobindo Pharma	4,229.99	March 2011
Piramal Health*	1,619.74	March 2011
Cadila Health*	2,213.70	March 2011
Matrix Labs	1,894.30	March 2010
Wockhardt	651.72	December 2011

**Producers of MH commodities*

The box below illustrates that most of the manufacturers of MH commodities are domestically produced in India. The national distribution system should, theoretically, make these commodities accessible in Bihar. Limitations on research made it difficult to identify specific manufacturers in Bihar and their product lists.

Just seven states in India make up a top tier of pharmaceutical manufacturing and hold more than 75 % of the drug manufacturing licenses. Bihar, although not in this top tier, is in a second group of ten states, which accounts for approximately 20% of drug manufacturing licenses.[299] Further research is needed to

[297] Veena, R., et al. (2010). Emerging trends in medicine procurement in government sector in India - A critical study. *International Journal of Research in Pharmaceutical Sciences*, *1*(3), 372-381.p373
[298] CCI. (March 2012) Brief Report of the Pharmaceutical Industry in India.. Available: http://www.cci.in/pdf/surveys_reports/indian-pharmaceuticals-industry.pdf
[299] Government of India (November, 2003). Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues,. Available at: http://cdsco.nic.in/html/Final%20Report%20mashelkar.pdf

uncover the names and products associated with these licenses in Bihar, and therefore possible maternal health production., Research revealed only oxytocin and misoprostol on manufacturing lists; even though magnesium sulfate is produced domestically, information on the specific Indian manufacturers was unavailable.

Registered Maternal Health commodities in Bihar, India. [300][301]					
Commodity	**Dosage**	**Manufacturer**	**Country**	**Pack (Volume)**	**Price**
Oxytocin	5IU	Neon Labs	India	10x1 ml	Rs 162[302]
Oxytocin	5IU	Svizera	India	1ml	Rs15
Oxytocin	5IU	Ind-Swift	India	1ml	Rs 14.3
Oxytocin	5IU	Mercury Labs	India	10x1ml	Rs180
Oxytocin	5IU	Jpee LS	India	1ml	Rs18
Oxytocin	5IU/5ml	Cedila (Vibra)	India	1ml	Rs 15
Oxytocin	5IU/ml	Systacare	India	1ml	Rs16
Oxytocin	5 units	Cadila* (Genstar)	India	1ml	Rs 17
Oxytocin	55IU/ml	Inga	India	1ml	Rs 13.5
Oxytocin	5IU	Unique	India	N/A	N/A
Oxytocin	5IU/.5ml	Pfizer	Intl	1ml	Rs 22.1
Oxytocin	5IU/ml	Novartis Pharma	Intl	1ml	Rs 57.2
Oxytocin	5IU/ml	Zee Lab	India	1ml	Rs 13
Misoprostol	200 mcg	Zy Alidac	India	4	Rs 68.74
Misoprostol	200 mcg	Piramal HC*	India	4	Rs 61
Misoprostol	200 mcg	FDC	India	4	Rs54.9
Misoprostol	200 mcg	Lupin*	India	40	Rs 720
Misoprostol	200 mcg	Cipla*	India	4	Rs61
Misoprostol	200 mcg	FDC (Spectra)	India	4	Rs 54.9
Misoprostol	200 mcg	DKT India	India	4	Rs 100
Misoprostol	200 mcg	Alkem	India	4	Rs 72
Misoprostol	200 mcg	Mankind	India	4	Rs 66

Quality Assurance

The Drug Controller of India (DCGI) is responsible for registering nearly all types of medicines nationally. It is also responsible for assuring the quality of medical devices and clinical trials. The Food and Drug Administration registers all other products, accredits manufacturing plants, and conducts the bulk of quality monitoring and inspections.[303] This national quality assurance umbrella is designed to support

[300] Drugs Update: http://www.drugsupdate.com/brand/showavailablebrands/381
[301] Jeffery, R. et al. (2009) Architecture of Drug Regulation in India: What are the Barriers to Regulatory Reform? *Journal of Health Studies* 2(1,2,3): 13-32.
[302] Current exchange rate of US$ to INR is 1 to 53.5 (May 4, 2012).
[303] Naralkar, S. et al. (2010). The Indian Pharmaceutical Environment. *Regulatory Rapporteur.* 7:2. P.9

facilities and systems to maintain high quality at the state manufacturing level as well. However, the most recent data found that "…the central government, in various five year plans and through WHO funds, has provided assistance to states for setting up/upgrading their testing facilities, but the progress has been far from satisfactory. For example, Bihar…had a …testing lab built approximately 20 years back, but the funds provided by the state for its maintenance and upkeep have been woefully inadequate."[304] As Bihar's reputation is improving due to ongoing adjustments in the state health system, Interviews with producers, product testers, and other stakeholders should be conducted for a more current perspective.

Budgeting and Financing

The national budget allocates 1.4% of the national Gross Domestic Product (GDP) to the health budget, with plans to increase this to 2.5% in the near future.[305] Currently, the public expenditure on medicines is very low, at approximately US$1 per capita, but there is no mention on how much is specifically being spent at the state level in Bihar or on the three maternal health commodities.[306] However, because a section of the 12th Five Year Plan addresses pharmaceutical price control, if this policy is approved then all of the 348 medicines on the NLEM, including the three MH commodities, will come under price control. This could be a significant change because in the past fifteen years, the cost of medicines that have not been on the NLEM or under price control have risen by approximately 137%.[307] The new plan would increase the percentage of the domestic pharmaceutical industry that is price controlled from its current level of 20% to 60%.[308]

The government is also increasing health spending in other realms. For example, the NRHM budget, which allocates resources to maternal health and focuses on decreasing maternal mortality, increased from US$3.7 million (Rs.19,534 crores) in the years 2009-2010 to US$ 4.2 million (Rs 22,300 crores) for 2010-2011. If these government funds are utilized legitimately according to the NRHM mandate, this hike in funding should increase access to MH commodities for women by increasing the supply of medicines and health workers at the state level and promote knowledge on the commodities by improving advocacy and behavior change communication methods.[309] Unfortunately, the budget increase does not mandate how much money should be allocated to maternal health commodities and leaves it up to the state to appropriate the funding that is given without effective monitoring and assessment bodies in place. The details on utilization of these funds are not available.

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[304] Government of India (November, 2003). "Report on the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs Ministry of Health and Family Welfare Government of India. ." P.91 http://cdsco.nic.in/html/Final%20Report%20mashelkar.pdf

[305] Press Release from Prime Minister's office February 22, 2012. Wall Street Journal February 29, 2012.

[306] Ibid.

[307] *Times of India*. (November.28, 2011)"Prices of 348 Essential Drugs to be Controlled." http://articles.timesofindia.indiatimes.com/2011-11-18/india/30414539_1_nlem-essential-medicines-dpco

[308] Sinha, K. . (January .6, 2012) Pharma industry opposing inclusion of 348 drugs in essential medicines list." *Times of India*)." Available: Articles.timesofindia.indiatimes.com/2012-01-06/delhi/30597275_1_nlem-essential-medicines-drug-price-control-order

[309] Veena, R et al. (2010). Emerging trends in medicine procurement in government sector in India - A critical study. *International Journal of Research in Pharmaceutical Sciences*, *1*(3), 372-381.

Budgeting and Use of Funds at the State Level

"In Bihar, the share of state expenditure on primary health care services in 2008-09 was 55%, secondary health care 14%, and tertiary health care 26%."[310] Moreover, "as per the budget tracking study done by NHSRC in 2007-08, the increase in states' own share of health budget over the previous year for Bihar was 10%."[311] Research did not reveal how much of this expenditure was spent on providing misoprostol, magnesium sulfate, and oxytocin to women in need of maternal health medicines, but additional investigation to disaggregate this spending could be useful to evaluate potential adjustment of resources for these commodities.

The national government's insufficient monitoring and evaluation of state level execution of the national budget has led to mismanagement of spending in Bihar. The 2008-2009 NRHM budget evaluation states that Bihar spent only 66% of its funds while other comparable states utilized 90% of their budgets.[312]. The lack of state level accountability and follow-through is also highlighted in a current lawsuit against Bihar in its mismanagement of NRHM funds.[313] In March 2012, the High Court issued an interim order to the Health Secretary of Bihar requesting a detailed expense report of the entire NRHM program within the state, which totaled to $680 million dollars of funding.[314] There is hope that with this civil movement for transparency and efficiency in Bihar's health system, current loopholes in funding and efforts can be closed.

Procurement, Distribution, and Storage

Procurement challenges are a serious barrier to accessing magnesium sulfate, misoprostol, and oxytocin in Bihar, as well as in India, generally. Government hospitals spend approximately 25-35% of their budgets on medicines and other pharmaceuticals, but continue to have procedural issues related to bulk procurement.[315] [316] The Director General of Supplies and Disposals (DG&S) is the central purchasing organization for the government, and is responsible for buying medicines and other necessary medical supplies. DG&S procures medicines for hospitals through several methods, including direct purchase from manufacturers, competitive bids, contracts (fixed, running, or rate based), and emergency local purchases in the event suppliers fail to provide proper services.[317]

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[310] Government of India-Ministry of Health and Family Welfare. (November 2011) Report of the 5th Common Review Mission-Bihar. Available : http://www.mohfw.nic.in/NRHM/CRM/CRM_files/5th_CRM/Statewise/Bihar.pdf
[311] Kapur, A. et al. (2011) NRHM Government of India Accountability Initiative Budget Briefs 2010-2011. P.2 http://xa.yimg.com/kq/groups/2076232/1733327169/name/NRHM+Budget+Brief+2011.pdf
[312] Ibid
[313] Center for Reproductive Rights, Human Rights Law Network. (2011). *Charm v. Bihar*. Available at: http://reproductiverights.org/sites/crr.civicactions.net/files/documents/CHARM%20factsheet%20FINAL%2010.7.11.pdf
[314] Ibid
[315] Veena, R. et al. (2010). Emerging trends in medicine procurement in government sector in India - A critical study. *International Journal of Research in Pharmaceutical Sciences*, *1*(3), 372-381.
[316] Interview with Dr. Manju Shukla, Intrahealth India. May 4, 2012
[317] Veena, R., Revikumar, K. G., Manna, P. K., & Mohanta, G. P. (2010). Emerging trends in medicine procurement in government sector in India - A critical study. *International Journal of Research in Pharmaceutical Sciences*, *1*(3), 372-381.

A case study on the district of Dharbanga in Bihar demonstrated the weakness in local-level procurement by examining the logistics and supply management system of medicines at different levels of care. Results indicated that the health centers were understaffed and the pharmacies and drugstores were managed by unqualified professionals. In addition, the drug list available did not meet the needs of the population and the health centers were in short supply of essential medicines, which were also unavailable at local pharmacies.

In another example, an NRHM evaluation was conducted in the district of Muzaffarpur. The evaluation found that out of the sixteen blocks reviewed not one had all three MH commodities available when data was being collected. [318] Although this is not representative of all districts in Bihar, it raises an alarm on the probable lack of procurement in similar districts in the state.

These inefficiencies, which hinder other states in addition to Bihar, have led to the development of independent, emergency systems for procurement in states such as Delhi, Jharkhand and Tamil Nadu.

In 1994, the state of Delhi established a central procurement, distribution and storage center for all of the hospitals in the state. An NGO called the Delhi Society for the Promotion of Rational Use of Drugs ran the program and the model focused on several key issues such as: a pooled procurement system, preparation of a formulary for the state, introduction of a quality assurance program, medicine information, training to health care professionals to ensure rational drug use, development of standard treatment guideline as protocols for treatment, and drug usage monitoring and research.[319] This model not only improved access to quality medicines at all Delhi government health facilities, but it also kept down the cost related to the procurement of medicines.[320]

On a smaller scale, the state of Jharkhand has developed a stopgap strategy through the creation of an emergency fund for auxiliary nurses midwives (ANMs) to be utilized during a stock-out. The program makes an emergency fund of US$185 (Rs.10, 000 a year) accessible to each district for the ANMs to buy the medicines themselves in cases of PPH or PE/E when it is not available at the sub center or primary health center.[321]

Additional interviews with administrators and recipients of these initiatives could improve understanding of how the policies affected the access and procurement of magnesium sulfate, misoprostol, and oxytocin and how Bihar can continue to improve by replicating successful models from other states.

Distribution and Storage

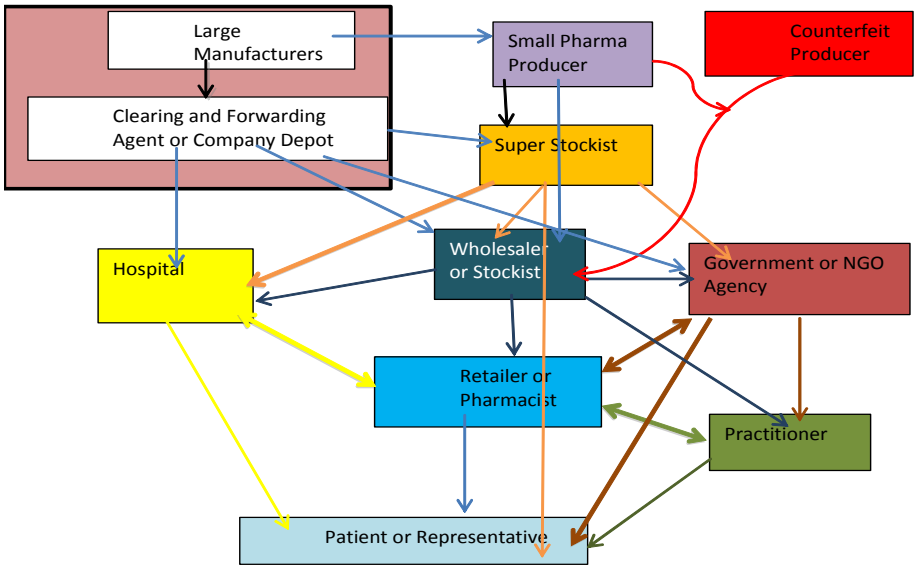
India's pharmaceutical industry has grown enormously, reaching upwards of 13% growth annually between 2002 and 2008. In 2006, the country's pharmaceutical distribution was valued at US$200

[318] National Rural Health Mission (September 2011) *Programme Evaluation of the Janani Suraksha Yojana*.
[319] Veena, R. et. al. (2010). Emerging trends in medicine procurement in government sector in India - A critical study. *International Journal of Research in Pharmaceutical Sciences*, *1*(3), 372-381.
[320] Ibid
[321] Interview with Dr. Manju Shukla, Intrahealth India, May 4, 2012.

million, with the logistics/distribution industry growing at an average rate of 4% per year.[322] According to the Indian Retail Druggists and Chemists Association, there are approximately 65,000 stockists and 550,000 pharmacies in India[323] and approximately 1-3 clearing and forwarding agents (CFAs) in each Indian state, supported by pharmaceutical companies to manage storage and fill stock requests.[324]

However, medicine distribution in Bihar is a complex and often uncoordinated system that is based on the national structure described through Diagram A. This fractured system puts distributors and medicine producers' products, especially those that require cold storage, at risk for expiration and degradation.[325] Although this study was unable to address how the distribution and storage system's limitations and complexities impact the effectiveness of oxytocin, misoprostol, and magnesium sulfate specifically, the system is bound to affect these medicines and additional research is recommended.

Diagram A: The Complex Drug Distribution Relationship in India[326]



The previous diagram shows that distribution is a process that works through many levels and is not just conducted by stockists and wholesalers. National level programs have been designed to help deepen and broaden the scope of distribution so that medicines could reach more patients, and more equal access could be achieved by utilizing the level of retailers, practitioners, and hospitals or similar care facilities. Current data indicates that Bihar does not achieve this goal at the state level. For example, ASHAs in most high-focus states are equipped with drug kits to assist them in their work, but in Bihar these distribution is lagging. A 2011 evaluation report indicated that out of the three levels of health centers

[322] Langer, E. et al. (September 2008). "Pharmaceutical Distribution in India." *India Today*. BioPharmInternational.2
[323] Ibid
[324] Ibid
[325] Ibid
[326] Jefferey, R. (June 2007) Pharmaceuticals Distribution Systems in India. Manuscript. Available: http://www.csas.ed.ac.uk/__data/assets/pdf_file/0003/38829/PharmaDistributionIndia.pdf

that needed to be constructed in the state, only the primary health centers were completed. This left a gap in the construction of sub-centers and referral hospitals, key locations where magnesium sulfate, misoprostol and oxytocin could potentially be distributed.[327]

Although precise contents in these drug kits is not known, and construction for health centers where distribution takes place did not mention maternal health commodities as a priority, interviews with ASHAs and other grass root- level distributors could reveal opportunities for both including these three commodities in the kits and centers, and for strengthening distribution systems in Bihar that are designed to reach isolated populations and support important, but less formal systems.

Demand for Maternal Health Care Commodities

Demand by Providers

There is a very high demand by health care providers for all three MH commodities. In a recent training, health workers stated how these commodities had made them feel proud that they could save mothers lives and they were no longer scared of PPH or PE/E.[328] Providers have demonstrated a demand for the commodities because they are confident consumers will benefit from treatments and be willing to pay for them to administer the medicine. In fact, "retailers commonly act as unlicensed prescribers themselves, who learn about common treatments and then readily sell prescription medicines to customers who seek their advice."[329]

Demand by Consumers

Presently, all three commodities require prescriptions and none of the three are under price control. With the exception of oxytocin, the commodities are too expensive for the masses as is illustrated in the box above on registered MH commodities in Bihar. In fact, approximately one-third of the out of pocket costs for women to have institutional deliveries, or about US$ 6.60 (Rs.357), is associated with payments for medicines.[330] Although these costs are not solely attributed to the three commodities in this report, it shows that cost has become a barrier to access.[331] A key informant has indicated that although this financial barrier exists, there is still a high demand by the consumers for whichever commodity is encouraged by their doctor or RMP, leaving many of them borrowing for health spending and in debt.[332] Consequently, 71% of health spending is out of pocket, and, every year, such expenditure forces 4% of the population into poverty.[333]

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[327] Government of India (November, 2003). Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues. P.1

[328] Interview with Dr. Manju Shukla, Intrahealth India. May 4, 2012

[329] The Centre for International Public Health Policy (July, 2007). Qualitative Research on Fluoxytine and Oxytocin in India. Working paper 2..P. 6

[330] Government of India-Ministry of Health and Family Welfare. (November 2011) Report of the 5th Common Review Mission-Bihar Available: http://www.mohfw.nic.in/NRHM/CRM/CRM_files/5th_CRM/Statewise/Bihar.pdf

[331] Interview with Dr. Manju Shukla. Intrahealth India. May 4, 2012.

[332] Ibid.

[333] Roa, M. et al. (February 2011). India: Towards Universal Health Coverage 5: Human Resources for Health in India. *Lancet* 377.P.587

Interviews with stakeholders on the ground would provide a more detailed account of the current demand by both consumers and providers and the respective barriers and incentives for all three MH commodities.

Private Sector Involvement

The private sector plays an active role in the health care system. One study revealed that, "although the public sector is the main provider of preventive care services, 80% of outpatient visits and 60% of hospital admissions are in the private sector.[334] Many of the national policies described promote the involvement of the private sector, although integration has only been achieved successfully in a handful of cases.[335] [336] Bihar's utilization of the private sector mirrors the percentages represented by national figures. These figures are especially high for rural private healthcare in Bihar as 90% of the population lives in villages where public infrastructure is limited. [337] Further research is needed to understand the private sector's role in specifically supplying the MH commodities.

Recommendations

Expand research and documentation on the landscape of Bihar's MH Programming

The government of Bihar has made a concerted effort to increase community participation, feedback, monitoring and evaluation, and access to services in the state. Although these practices are far from sufficient, they embrace a contextualized, decentralized, and holistic vision of data gathering and maternal health program design. Further research is needed in order to understand the landscape of the maternal health system in Bihar and determine which regions are collecting data and to what extent. There needs to be a more thorough understanding of the discrepancies between regions in Bihar, and where data is being collected and which districts are more efficient in maintaining adequate supplies of MH commodities. These districts can serve as starting points for scaling the use and impact of magnesium sulfate, misoprostol and oxytocin. In addition, NHRM district implementation reviews should be conducted annually in the other 37 districts, as was done in Muzaffarpur District and made available for a comprehensive evaluation of the state maternal health programs accessibility of the MH commodities.

Strike a balance between a regulated and informal system

India's regulatory and market systems shows a wavering between regulating all medical practices and pharmaceuticals, and a system flexible enough to reach remote communities with affordable drugs. For example, it is currently "…still illegal to practice as a RMP (rural medical practitioner) in India because

[334] Kumar, C. et al. (2011) Public-Private Dichotomy in the Utilization of Health Care Services in India. *Consilience: The Journal of Sustainable Development Vol 5 Issue 1. P26.*

[335] Gujarat and the Chiranjeevi scheme is one of these rare cases The government created clear and transparent agreements with private OBGYNs and contracted out services. This alliance worked particularly well because of the trust developed through personal relationships developed through visits between public and private representatives and the appointment of managers to lead training initiatives and the result has been an increase in access to maternal health services.

[336] Vora, Krabti S., Dileep V. KV Ramani, Mudita Upadhyaya, Bharti Sharma, Sharad Iyengar, Vikram Gupta, Kirti Iyengar. (Apr. 2009). "Maternal Health Situation in India: A Case Study" *Journal of Health, Population, and Nutrition*. 27:2.P.199.

[337] Kumar, C and Prakash, R. (2011) " Public-Private Dichotomy in the Utilization of Health Care Services in India." *Consilience: The Journal of Sustainable Development Vol 5 Issue 1.* P26.

they do not have formal medical qualifications." RMPs have been making demands for the government to acknowledge their grass roots healthcare work and incorporate them into the national healthcare system. RMPs claim to be as qualified and as well trained as many licensed doctors. Therefore, it is recommended that further research be conducted on the extensive role that the RMPs play in providing access to these commodities in Bihar and the opportunity to integrate them into the state maternal health programs. The research needs to look at how RMPs are a large source of demand generation for the three maternal health commodities and how their role as an informative and trained health worker could increase access to these commodities for those with limited access to formal health systems.

Training

Training is mandatory at every level of the health system in Bihar. Presently, there is lack of documentation on the training mechanisms in place and how effective they have been. As the gap in capacity at all three levels of health care remain a persistent problem in the state, formal SBA training needs to be developed that is far more advanced and integrative then the current guidelines by MOHFW from 2008. An updated training requires the incorporation of the STGs for PPH and PE/E, information from the upcoming National Formulary on India, and should take into account the social and physical contexts and limitations for each district.

Balance development with structural support

Overall, policies that push for maternal health advancements, such as the use of misoprostol, magnesium sulfate, and oxytocin, need to be balanced with a structure that is able to support the initiatives. One study indicates that the demand for oxytocin can be cause for concern because although policies are pushing for more institutional deliveries, there is still a lack of sufficiently trained medical professionals. This imbalance can result in health care workers compensating for the overwhelming number of women who need attention and facilities for delivering by using oxytocin to speed up the delivery process and freeing bed space and staff availability for the next patient.[338] Since there is a lack of capacity in the government to carry out institutional deliveries, even though each of their programs encourages it the government needs to complement the effort of supplying the commodities with an initiative to provide more access for institutional deliveries and more formally trained health care workers.

Mapping of NGOs, programs, and initiatives in the state and nationally

Civil society and NGOs play a key and active role in Bihar and their insights are critical to gaining a comprehensive understanding of the accessibility and barriers related to the three maternal health commodities. Further research is needed so that the programs that are being implemented can be mapped and stronger linkages need to be made to the state and district level maternal health implementation plans in Bihar in order to increase the effectiveness in how these commodities are being represented, accessed and administered.

[338]The Centre for International Public Health Policy (July, 2007). Qualitative Research on Fluoxytine and Oxytocin in India. Working paper 2.

VII. Nigeria

The Burden of Maternal Mortality in Nigeria

Although maternal deaths have decreased in the past decade, Nigeria has one of the world's highest burdens of maternal mortality, with 487 maternal deaths for every 100,000 live births, according to the most recent available estimates.[339] It is not on track to achieve the MDG 5 target of a 75 percent reduction in its MMR[340]. According to the most recent Demographic and Health Survey (DHS), completed in 2008,[341] the total fertility rate remains high, with an average of 5.7 births per woman.

As of 2008, only 39% of births were attended by a skilled provider, most often a nurse or midwife.[342] While many women give birth with assistance from traditional birth attendants (TBAs), nearly 20% of women deliver with assistance from only a family member or friend, while another 19% give birth alone, with no assistance at all. Further, these national averages vary dramatically among regions: just 10% of births in the North West region are assisted by a skilled attendant in contrast to 82% of births in the South East.[343]

Health service utilization remains extremely low in Nigeria, particularly in rural areas. There are distinct disparities in accessibility and utilization of maternal health (MH) services between urban and rural populations and across different regions of Nigeria. In rural areas, 73% of births take place at home, while in urban areas, 36% do. Similarly the variation by region is immense. Nearly all women in the North West region give birth at home, while in the South East, 74% of women deliver in a facility.

In the face of these staggering statistics, the Nigerian government has prioritized maternal health since the change in government in 1999. However, despite an increased prioritization of maternal health both in public statements and on paper, this commitment has yet to yield significant impact on the ground. A number of critical barriers impede progress:

1. **Funding:** Low levels of funding for maternal health constrain implementation.[344]
2. **Federal system:** Nigeria's federal system places considerable power over health systems in the hands of both state and local government area (LGA) authorities, limiting the ability of the federal government to implement policies. "Federal-level officials can only encourage and provide incentives; they cannot commandeer."[345]

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[339] Lozano, R. et al. (2011). Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis, *The Lancet; 378: 1139–65 September 2011 (11)61337-8,* 1160.
[340] *Ibid*., 1161.
[341] National Population Commission and ICF Macro (2009). *Nigeria Demographic and Health Survey 2008: Key Findings*.
[342] *Ibid*, 134.
[343] *Ibid*.
[344] Bankole, A. et al. (2009). *Barriers to Safe Motherhood in Nigeria*. Guttmacher Institute.18
[345] Shiffman, J. and Okonofua, F. The state of political priority for safe motherhood in Nigeria, *BJOG* 114 (2):127-33, 130.

3. **Donor-control of commodities:** Commodities are funded strictly through global donor funds. This has created multiple parallel vertical systems for supplying health commodities, none of which include maternal health interventions.
4. **Lack of emphasis on commodities:** National policies rarely include a specific emphasis on commodities, so even if state governments do attempt to align actions with national policies, there is little guidance on what investments are needed to improve access to these essential medicines.
5. **Lack of data:** National data on maternal health in Nigeria are weak, making it difficult to assess the situation and determine if access to services and commodities is available. PPH and PE/E are undoubtedly responsible for a large proportion of deaths,[346] but because there is weak record-keeping on causes of death,[347] estimates of the toll exacted by these complications are rough, and there have been no efforts to collect the data necessary to quantify the need for maternal health medicines.

As a result, there are not only substantial gaps between stated commitments and the realities on the ground, but also an almost total lack of evidence on what commodities are available where, how they are procured, how much they cost, or who pays for them. Significant in-country research is needed to more fully understand the landscape of these commodities in Nigeria.

Status of Maternal Health Commodities in Nigeria			
	Oxytocin (PPH)	Misoprostol (PPH)	Magnesium Sulfate (PE/E)
Registered for use for maternal indications?	Y	Y	Y
On Essential Medicines List?	Y	Y	Y
In Standard Treatment Guidelines?	Y	Y	Y
Manufactured locally?	Not Available (N/A)	N/A	N/A

[346] Estimates on PPH burden range from 23% to 55% ; and PE/E from 11% to 46%: See: Federal Ministry of Health (2011). *Saving newborn lives in Nigeria: Newborn health in the context of the Integrated Maternal, Newborn and Child Health Strategy*. Second edition. Abuja: Federal Ministry of Health [Nigeria], Save the Children and Jhpiego; Jhpiego et al.(2012). Strengthening Emergency Obstetric And Newborn Care And Family Planning Services In Northwest Nigeria. (Presentation Slides);. Ia,U., et al. (2005). Factors Contributing To Maternal Mortality In North-Central Nigeria: A Seventeen-Year Review. *African Journal Of Reproductive Health.* 9(3):27-40.

[347] Bankole, A. et al., (2009). *Barriers to Safe Motherhood in Nigeria*, 21.

Policy and Regulatory Environment

An initial review of policies impacting maternal health in Nigeria shows that, since the 1999 move to democratic rule in Nigeria,[348] several policies have been adopted in an effort to increase the priority of maternal health. That said, this stated commitment has not translated into effective implementation.

Key Policies and Departments Supporting Maternal Health

Federal Ministry of Health (FMOH)

In 2004, the FMOH established a multi-sectoral National Commission on Safe Motherhood, demonstrating a commitment to improving maternal health and it has explicitly maternal health in a succession of policies and guidelines on reproductive and child health.[349] In addition, in 2003, the FMOH (with support from UNFPA) produced the only national study[350] to date on the status of maternal health services, and its alarming findings continue to be widely cited in discussions of the continued poor state of maternal health in the country. It is also responsible for several studies on the status of commodity prices and supply chains. However, recent research and policy guidance by the FMOH lack the explicit emphasis on maternal health commodities that is needed to strengthen supplies of these commodities.

State and Local Policies

Among Nigeria's 36 states, there is substantial variation in health policies, and the situation at the local level is even more complex. Some state policies, such as those declaring maternal and child health services to be free could be important tools for improving poor women's access to services. However, as one informant pointed out, even these apply only to those facilities that are the responsibility of the state – i.e. central hospitals— so women who seek care in lower level facilities are likely to still be required to pay. That said, there is little information available on policies at the local level, so it is impossible to gain a full understanding of what impact these policies have on access to essential commodities.

State Ministries of Health (SMoH) and Local Government Areas (LGAs)

Previous studies note the overall lack of priority given to maternal health at the state level and local levels. State policies have also been criticized for their lack of transparency,[351] and lack of sufficient funds to implement, monitor and evaluate the impact of policies such as those that establish "free" services.[352] A 2007 assessment found that state authorities face little political pressure to develop or support policies that would specifically impact women's health, and that the states that have successfully instituted maternal health policies have done so almost exclusively as a result of interest from individual state level

[348] Shiffman, J. and Okonofua, F. (2007). The state of political priority for safe motherhood in Nigeria, *BJOG* 114 (2):127-33, 128.
[349] *Ibid*.
[350] Fatusi, A. and Ijadunola, K. (2003). *National Study on Essential Obstetric Care Facilities in Nigeria*. Federal Ministry of Health [Nigeria] and UNFPA, at vii, 11.
[351] Center for Reproductive Rights (2008) *Broken Promises: Human Rights, Accountability, and Maternal Death in Nigeria.* Center for Reproductive Rights and Women Advocates Research and Documentation Centre, 8.
[352] Okonfua, F. (2010). Reducing Maternal Mortality in Nigeria: An Approach through Policy Research and Capacity Building. *African Journal of Reproductive Health 14[3]:* 9-13 [Special Edition], 10.

officials. There has been an increase recently in the number of such policies across the country,[353] suggesting that there are growing political incentives.

National Strategic Health Development Plan (NSHDP) (2010- 2015)

This is the guiding document for health interventions, and includes a costed framework for action, as well as an Essential Package of Care[354] for reproductive, maternal and infant health. This Essential Package if Care includes diagnosis and treatment of PE/E, including the administration of magnesium sulfate; and a less specific provision for both basic and comprehensive emergency obstetric care (EmOC) that likely includes either oxytocin, misoprostol or both. The NSHDP also includes provisions to monitor stock levels of "key tracer health commodities,"[355] and to dramatically reduce stock-outs by 2015, but it is not specified which commodities will be monitored, or whether magnesium sulfate, oxytocin or misoprostol will be included. Further, the costs noted in the framework for action do not include any specific information on funding for maternal health commodities. The government's plan to make necessary investments in the NSHDP was stated as part of its commitment to the UN Secretary-General's *Every Woman Every Child* strategy: "Nigeria is committed to fully funding its health program at US$31.63 per capita through increasing budgetary allocation to as much as 15% from an average of 5% by the Federal, States and Local Government Areas by 2015."[356]

Integrated Maternal, Newborn, and Child Health Strategy

This Federal Ministry of Health policy, adopted in 2007 with assistance from UNICEF, aims to take an integrated approach across all levels of government and across the continuum of care for women and children, from pregnancy through early childhood. At least one UNICEF-produced overview of the strategy notes that it will promote administration of magnesium sulfate for PE/E and EmOC, including administration of oxytocin among the essential services that must be accessible to all women. However, this document's provisions related to essential services appear to be nearly identical to those in the NSHDP,[357] and it is not clear whether the explicit mention of oxytocin here is at all significant in terms of access to this medicine.

Essential Childhood Medicines Scale-up Plan

The strategy, currently in draft form,[358] identifies four short-term interventions to transform child health. Though the plan does not address maternal health, it holds potential to this area because it is aimed toward reinforcing the IMNCH strategy and because it highlights certain investment priorities, including the need to ensure that essential supplies reach primary health centers (PHCs). This may strengthen systems that deliver key maternal health commodities. However, for this plan to have an impact on supplies of maternal health medicines, it must not only be finalized, but it must be linked to more explicit directions regarding these commodities.

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[353] Okonofua, F. et al., (2010). Advocacy for free maternal and child health care in Nigeria--Results and outcomes. *Healh Policy.* 99(2):131-8
[354] FMOH (2010) *NSHDP*, 58-59.
[355] FMOH (2010) *NSHDP,* 96
[356] Every Woman Every Child (2012). Summary of Commitments for Women's and Children's Health. United Nations.
[357] UNICEFIntegrated Maternal, Newborn and Child Health Strategy. (Brochure). and FMOH (2010), *NSHDP,* 59.
[358] Federal Ministry of Health (2011). *Draft Essential Childhood Medicines Scale-up Plan*.

Midwives Service Scheme

Although the policy environment is generally not supportive of specific investments in maternal health commodities, the Midwives Service Scheme (MSS) serves as one example of a national policy that reflects a relatively high level of harmonization among tiers of government, including clear roles and responsibilities for federal, state and local authorities. The MSS seeks to address the particular issue of the shortage of skilled care in rural areas by deploying a cadre of midwives to primary health centers (PHCs) throughout the country and supporting efforts to upgrade the equipment and improve supplies at PHCs, [359] including magnesium sulfate and misoprostol.[360]

National Health Bill (Pending)

Perhaps the most promising policy development in recent years has been a proposed national health bill that would transfer a substantial amount of funds from the country's oil revenues to improve health services. If approved, the bill would not only have a national reach, but it would also direct funds specifically to maternal health supplies, including medicines.[361] However, the bill's passage has never been assured; it lingered in Parliament for several years before being passed in 2011,[362] but has not been signed into law by the President. This leaves the prospect of a major, national level injection of needed funds in serious doubt. Efforts to harmonize policy and coordinate implementation among the federal, 36 states and 774 local governments is therefore seen as essential, particularly if the bill does not become law. Whether any progress can be made toward aligning the priorities of these bodies is not clear, but without much better data on the problem at hand, it seems unlikely that even successful efforts will translate into real improvements in maternal health.

Clinical Guidance on Maternal Health Commodities

The 2010 Essential Medicines List (EML)[363] and the 2008 Standard Treatment Guidelines (STG) provide very limited guidance on the three maternal health commodities focusing on dosage without specifying where or by whom these commodities can be administered. The guidance is as follows:

Oxytocin

- EML: Includes injection 5 units or 10 units / mL in ampoules
- STG: Oxytocin is not mentioned.

[359] Federal Ministry of Health (2011). *Saving newborn lives in Nigeria: Newborn health in the context of the Integrated Maternal, Newborn and Child Health Strategy*. Second edition. Federal Ministry of Health [Nigeria], Save the Children and Jhpiego, 40.
[360] Okoli, U. et al., (2011). Prenatal care and basic emergency obstetric care services provided at primary healthcare facilities in rural Nigeria. *International Journal of Gynecology and Obstetrics,* 1-5, 4.
[361] Federal Ministry of Health (FMOH) (2010). *National Strategic Health Development Plan (NSHDP*) 2010 – 2015. Federal Government of Nigeria, 73.
[362] The Lancet (2011). Hope for Health in Nigeria. Editorial *The Lancet*, Vol 377, 1891.
[363] Revisions to Nigeria's Essential Medicines List (EML) were undertaken following the convening of a technical committee in February 2012 but the new version as not yet been made public. (see: FMOH (2012). FG Inaugurates Expert Committee on Essential Drugs List. (Press Release). Federal Ministry of Health [Nigeria].

Misoprostol

- EML: Includes approval of Tablet: 200 micrograms, Vaginal tablet: 25 micrograms [364]
- STG: Misoprostol is not mentioned in the most recent available guidelines.

Magnesium Sulfate

- EML: Includes injection 50% in 2-mL ampoule
- STG: Specifies use of the Pritchard regimen, which includes loading dose of 4 g by slow intravenous injection over a period not less than 5 minutes (preferably over 10 – 15 minutes); and maintenance dose: 10 g in 1litre of sodium chloride 0.9%, given by intravenous infusion at a rate of 1g per hour.

The STG also notes that magnesium sulfate treatment packs are contained in cardboard boxes containing magnesium sulfate for the loading dose, 24-hour maintenance therapy and treatment of one (recurrent) convulsion. Syringes, swabs, drip sets, and fluids are also contained in the approved treatment packs.

Authorizations

It is difficult to identify what cadre of providers is authorized to provide care and administer medicines based on currently available policy documents:[365] Primary facilities are expected to provide skilled care at delivery, and to diagnose PE/E and administer magnesium sulfate; first referral facilities are expected to provide basic EmOC; and second referral facilities are expected to provide comprehensive obstetric care.

Secondary documents, note that Active Management of Third Stage of Labor (AMTSL) is a national policy, and that it is part of training for midwives and doctors.[366] Although official information on what cadre of health providers is authorized and expected to be trained in the administration of each medicine is difficult to find, the EML includes some specific requirements[367] for dispensing these medicines: However, only the guidance on misoprostol is clear. That commodity is listed as "restricted," and is supposed to be available only in pharmacies, and accessible only to pharmacists and skilled health providers. Guidance on stock requirements for magnesium sulfate and oxytocin for maternal health is not included. In fact, ergometrine is the only uterotonic listed for inclusion in primary health centers and appropriate preparations of magnesium sulfate are not included. The consequences of these designations for actual practice are not documented, so it is impossible to ascertain whether they expand or restrict access in any meaningful way.

[364] This may be because guidance has suggested marketing of the low dose of misoprostol in order to avoid overdose in women whose labor is induced. See: Jadesimi, A. and Okonofua, F. (2006). Tackling the unacceptable: Nigeria approves misoprostol for postpartum hemorrhage. *Journal of Family Planning and Reproductive Health Care*; 32(4): 213–214.
[365] UNICEF. Integrated Maternal, Newborn and Child Health Strategy. (Brochure). and FMOH (2010) *NSHDP, 59.*
[366] Fujioka, A. and Smith, J. (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries,* USAID/MCHIP Status Report. 83
[367] EML – fifth revision, 2010, 36-48

Registration and Manufacturing

Specific information on domestic manufacturing of maternal health commodities is scarce. For example, only one national manufacturer was listed as providing obstetric medicines in a recent UNIDO study.[368] However, that study, like so many assessments related to essential commodities, did not gather any specific information on magnesium sulfate, oxytocin or misoprostol, so it is not possible to determine whether any of these commodities are produced in Nigeria.

Although one report states that the registration system for the main regulatory agency, the National Agency for Food and Drug Administration and Control (NAFDAC) is well-organized and searchable in an electronic database,[369] attempts to access this system through NAFDAC's website were unsuccessful. As specific registration information for these commodities could not be accessed, secondary sources were the only source of information on current registration. Among these, limited information was found on magnesium sulfate and misoprostol and no information could be found regarding guidance on oxytocin.

The following information on magnesium sulfate and misoprostol was drawn from research and program reports:

Misoprostol: Registered in at least one formulation, and has recently been approved for community-based distribution.[370] Venture Strategies Innovations , an NGO that has been instrumental in promoting access to misoprostol in Nigeria, notes that it has worked to register multiple misoprostol products in the country, "including the socially marketed product, Mistol®, by the Society for Family Health, and an additional product, Misoclear®."[371] However, it is not clear whether these are registered for both post-abortion care and prevention and treatment of PPH, or for post-abortion care alone.

Magnesium sulfate: According to a 2009 report, at least one formulation of magnesium sulfate is registered – and there has recently been a dramatic improvement in supplies, particularly in urban areas, although it was still far from universally available.[372] Another 2009 study noted that magnesium sulfate was "initially produced by the drug-manufacturing unit of the University College Hospital, Ibadan, but this was not enough for the country. However, in the last year [2008-2009], a pharmaceutical company has started importing the drug at an affordable rate."[373] However, no further information was accessible regarding which pharmaceutical company this refers to, or whether additional suppliers have emerged since 2009.

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[368] United Nations Industrial Development Organization (UNIDO) (2011), *Pharmaceutical Sector Profile: Nigeria*, UNIDO, Vienna, 79.
[369] Federal Ministry of Health (2010). *Access to and Rational Use of Medicines at the Facility Level.* Federal Ministry of Health [Nigeria], 30.
[370] Gynuity (2011). The Products Problem. (Meeting Report), 22.
[371] Venture Strategies Innovations. Where We Work: Nigeria. Available: http://vsinnovations.org/nigeria.html
[372] Ekele, B. (2009) Use of Magnesium Sulfate to Manage Eclampsia and Pre-Eclampsia in Nigeria, *Annals of African Medicine,* volume 8 Issue 2, 73-75. 74.
[373] Tukur J. (2009). The Use of Magnesium Sulfate for the Treatment of Severe Pre-Eclampsia and Eclampsia *Annals of African Medicine* [serial online]; 8: 76-80, 77.

Budgeting and Financing

Federal Funding

Despite commitments by the federal government in support of maternal health, public spending on health is quite low and most efforts remain vastly underfunded.[374] On the whole, efforts to improve access to maternal health services rely heavily on donor contributions. However, these investments are fragmented, and essential commodities do not appear to be priorities in either broader commodities-related efforts or maternal health-specific programming. Most funds for essential commodities are applied to vertical, disease specific programs: as of 2010, there were at least 12 different donors[375] involved in procuring supplies such as vaccines, contraceptives, HIV/AIDS treatments in Nigeria. Additionally, funding from donors to advance maternal health efforts are often components of broader health systems strengthening efforts rather than specifically targeted for interventions such as commodities.[376] Maternal health funds also go to specific projects managed by non-governmental organizations (NGOs)[377] but there is no comprehensive information on how much money is allocated here or how much of it goes to purchase maternal health commodities through these organizations. This arrangement creates a gap in knowledge – and likely a gap in investment – around maternal health commodities.

Some funds for commodities appear to be folded into budget lines for broader health initiatives. For example, a draft budget summary for the Federal Ministry of Health includes a budget line for maternal health of N800,000,000 (around US$ 5,100,000) to support: "MDG-IMNCH:[378] Procurement and distribution of emergency obstetrics care on contraceptive commodities; capacity building for service providers; awareness creation and supportive supervision." This likely includes maternal health commodities, but the lack of information and explicit attention to MH commodities in research or policy documents makes it difficult to confirm.[379]

State and Local Budgets

State and local budgets are also significant in determining levels of funds available for commodities, but given the time constraints of the research, it was not possible to access this information. That said, it seems clear that state level financing for commodities—whether included as explicit budget lines or folded in to other areas—varies enormously in amount, and, without a national procurement plan or other strong guidance, even the highest-spending states likely fall short of what is needed. As one in-country informant noted, some state governors have been willing to purchase medicines, but this is still "unreliable, episodic, and frequently makes little sense," [380] with little effort to determine what medicines are needed and in what quantity.

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[374] Bankole, A. et al. (2009). *Barriers to Safe Motherhood in Nigeria*, 19.
[375] Federal Ministry of Health (2010). *Mapping Of Partners' Procurement and Supply Management Systems For Medical Products*. Federal Ministry of Health, [Nigeria], 12.
[376] Shiffman, J. and Okonofua, F. (2007). The State Of Political Priority For Safe Motherhood in Nigeria, 129.
[377] Bankole, A. et al. (2009). *Barriers to Safe Motherhood in Nigeria*, New York: Guttmacher Institute, 17.
[378] "MDG-IMNCH" refers to Millennium Development Goal/Integrated Maternal, Newborn and Child Health strategy developed by the government in partnership with UNICEF.
[379] Federal Government of Nigeria, *2012 Budget Summary, Federal Ministry of Health*.
[380] Interview, USAID (May 3, 2012)

Out-of-Pocket Spending

As a result of low levels of public financing, most of the cost of maternal health commodities, as well as health services in general, is covered by out-of-pocket spending,[381] posing a major barrier to access. There is some evidence suggesting that such practices are very common in maternal health services in particular. For example, it has been reported that in receive care, patients must first purchase a very specific list of supplies.[382] Additional research is warranted to understand the burden this may impose on the women who are expected to pay them and the impact on restricting access to services and commodities.

Access to maternal health supplies in the public sector is often funded through revolving drug funds (DRF) schemes. In these arrangements, facilities buy supplies from the private market and sell medicines to patients, often with substantial markup for "administrative"[383] fees, a practice described as "a purely profit-making venture."[384] DRFs are officially sanctioned by the National Drug Policy, which includes provisions for reimbursing some patients who cannot afford to pay for medicines.[385] The policy notes that in the past, mismanagement has plagued DRFs in the past, and that many patients who are entitled to reimbursements have not received them. However, there is not enough evidence available to determine whether this situation has been improved.

Private sector

Currently, 15% of total births take place in private facilities.[386] Private facilities are generally concentrated in urban areas, and they are staffed by a majority of the country's doctors. Yet there are high levels of staff turnover in nursing and midwifery,[387] suggesting that working conditions are not ideal, a fact which may compromise quality of care. Overall, however, very little is known about the quality of maternal health care in private facilities, or the price that patients must pay to access them. There is also a serious lack of on whether these fees cover the full set of services and supplies that are needed to ensure safe delivery, or if women and their families are expected to purchase those independently, so it is not clear whether these commodities are available in private facilities or administered appropriately when they are needed.

The NSHDP includes a full chapter on the need to develop public-private partnerships, including the role of for-profit, non-profit, religious groups, and "traditional" health providers in working together to

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[381] Bankole, A. et al (2009). *Barriers to Safe Motherhood in Nigeria*, 18.
[382] Center for Reproductive Rights (2008) *Broken Promises: Human Rights, Accountability, and Maternal Death in Nigeria.* New York: Center for Reproductive Rights and Women Advocates Research and Documentation Centre.
[383] Federal Ministry of Health (2010). *In Depth Assessment Of Procurement And Supply Management Systems For Medical Products*, 19.
[384] .Federal Ministry of Health (2006). *Medicine Prices in Nigeria*: *Prices People Pay for Medicines.* Federal Ministry of Health [Nigeria], World Health Organization, DFID, European Union and Health Action International, 35.
[385] Federal Ministry of Health (2005), National Drug Policy. Federal Ministry of Health [Nigeria] and WHO, 14-15.
[386] FMOH (2010), *NSHDP,* 132
[387] Dutta, A. et al. (2009). *The Private Health Sector in Nigeria – An Assessment of Its Workforce and Service Provision.* Bethesda, MD: Health Systems 20/20 project, Abt Associates Inc.,XIII.

improve health at all levels. One informant described the private sector as "eager"[388] to play a more constructive role in extending access to health. However, there are few signs that any specific plans are being developed to encourage such collaboration around the provision of maternal health medicines. Given their role in providing a significant share of MH services, a deeper understanding of their contribution, especially the access to and use of commodities, will be essential to fully understanding the landscape.

Procurement, Distribution, and Storage

Procurement and management of health supplies commodities is almost exclusively funded through international donor initiatives related to specific diseases and health areas. As a result, supply chains are managed more or less independently and access to a particular commodity appears to be determined by very specific investments by very specific donors, rather than as part of an integrated or coordinated approach that spans health issues or institutions[389]. The government appears to be aware of the problems that accompany this arrangement, as the NSHDP acknowledges that supply chains managed by the government are weak. It states, "Poor commitment to the establishment of systemic procurement systems for health commodities resulting in loss of confidence and decreased utilization of public sector health facilities due to medicine stock-outs."[390] Yet there is little evidence regarding what efforts are being made to remedy this situation across commodities, and there appear to be no plans by donors or government agencies to improve logistics and procurement processes for maternal health commodities specifically.

Nigeria's National Drug Policy, which was last updated in 2005, lays out a number of good practices for the procurement of essential medicines. However, it appears that this policy has little impact on actual practice. For example, legally, the Federal Medical Store (FMS) has primary responsibility for managing procurement of all commodities included on the EML.[391] However, there is little evidence that this policy is followed by either donors or the federal government. Instead, the FMS does not handle essential medicines,[392] and, rather than taking part in managing procurement processes, acts only as a storage "depot" for donors' supplies.[393] Perhaps more importantly, there appears to be *no* national procurement plan, so not only do various donors procure supplies based on their own timeframes, but various government bodies do too, and there is little to suggest that these groups communicate regarding storage needs or distribution schedules for a given storage facility at a given time.[394]

Based on what can be inferred from information on other items on the EML that are not managed by donors, procurement practices for essential maternal health commodities are decentralized. The State Medical Stores (SMS) act as the most central sites in the supply chain. It appears that most facilities are

[388] Interview, UNICEF (April 25, 2012)
[389] FMOH (2010). *Partner Procurement,* 12.
[390] FMOH, (2010) *NSHDP*, 33.
[391] Federal Ministry of Health (2005). National Drug Policy, 16.
[392] FMOH (2010). *In Depth Assessment of Procurement Practices,* 19
[393] *Ibid*, 8.
[394] *Ibid*, 9.

expected to place orders for supplies as they are required, rather than according to a set schedule.[395] Stock-outs at SMS appear to be common, and distribution is frequently delayed,[396] a fact which compromises the as-needed system of ordering supplies. There is also some doubt as to whether even these stores even function as integral parts of supply chains. Informants seemed to agree that state governments are rarely involved in procurement, and there is evidence to suggest that facilities are most often left to fend for themselves,[397]even though many lack copies of critical guidance, such as the EML[398] and rarely use stock cards or other record-keeping systems to monitor supplies.[399]

There is little specific information on supply shortages or stock-outs, and it does not appear that this information is monitored closely: the NSHDP notes that there is not even baseline data on status of stock-outs across essential commodities in general, and it appears that the government assumes that the vast majority of facilities lack sufficient supplies. In fact, the NSHDP names *achieving* stock-outs at *80% of facilities* as a first target for efforts to reduce stock-outs.[400]

There is some, limited, information on stocks of maternal health supplies at primary health centers (PHCs) due to recent baseline research that seeks to guide activities under the Midwives Service Scheme (MSS) A survey of PHCs where the MSS is being piloted found that magnesium sulfate was available in just 27% of the facilities in question and misoprostol was available in 30% (oxytocin was not included in the survey).[401] However, it is difficult to get any sense of the stock levels of these commodities across facilities and responses to stock-outs are not well documented. As one informant said of responses to stock-outs, "whether they say to women 'go to the drug shop across the street' or 'you're out of luck,' I couldn't tell you."[402]

Although management of supply chains is widely considered inadequate, some reports do suggest that the physical infrastructure that houses these supplies is in place and, with some upgrades, could accommodate all needed essential supplies. This suggests that in the event that upgrading supply chains for maternal health commodities becomes a priority, relatively small investments will be needed to upgrade physical infrastructure. For example, one study reported that across the country, SMS have sufficient space and ventilation, and cold chain storage is generally possible, although they often lack tools to monitor fluctuations in temperature[403] that can compromise products such as oxytocin. Similarly, storage at higher-level health facilities has been reported to be sufficient in terms of space, but often goes without needed maintenance, such as timely repair of leaky roofs.[404] It is important to note that

[395] *Ibid*, 23.
[396] *Ibid*, 21.
[397] *Ibid*,14.
[398] FMOH, *Access to and Rational Use of Medicines at the Facility Level,* 41.
[399] *Ibid,* 35
[400] FMOH, *NSHDP,* 96
[401] Okoli, U. et al., (2011). Prenatal care and basic emergency obstetric care services provided at primary healthcare facilities in rural Nigeria *International Journal of Gynecology and Obstetrics,* 1-5, 4.
[402] Interview, USAID (May 3, 2012)
[403] FMOH (2010). *In Depth Assessment of Procurement and Supply Management Systems*, 20.
[404] FMOH (2010). *Access to and Rational Use of Medicines in Facilities,* (44).

much more effort would be required to fully equip PHCs, as these seem to lack both sufficient storage space and the ability to control temperature.[405]

Quality Assurance

One informant[406] noted that though the regulatory agency NAFDAC is seen by many as relatively strong and well-organized, its scope is limited to the registration of new medicines, and its laboratories have not been certified by international standards.[407] Thus, the government lacks the critical capacity to monitor the quality of medicines, including maternal health medicines.

In the private sector, where the majority of medicines are sold, there is little to no oversight. One FMOH report noted: "The reality regarding supplies of medicines in Nigeria is that those who are not trained and registered as pharmacists are actively involved in supplying pharmaceuticals, using unregistered premises. Rural and poor communities, which have no health facilities, receive medicines from patent stores[408] and vendors in open market places." [409] It is believed that some 17% of the essential medicines in circulation are counterfeit.[410] New tools, such as Truscan[411] have been demonstrated to be effective in removing counterfeit drugs from the market in Nigeria, and also hold possibility for assuring quality of maternal health medicines. However, Truscane has not been used in relation to these medicines thus far.

Demand for Maternal Health Commodities

Training

AMTSL and EmOC are supported by national policy, and one survey reported that they are included in the protocols for pre-service training for a range of providers, from community health extension workers to nurses, midwives and doctors.[412] However, there is little data on whether this offers sufficient preparation for providers to administer drugs appropriately, and anecdotal evidence suggests that it is not. One informant observed that providers tend to use uterotonics, including either misoprostol or oxytocin, to *treat* PPH, rather than to prevent it, and that many providers are unfamiliar with AMTSL.[413]

Nigeria has received acclaim as the first country to approve the use of misoprostol for PPH. That said, this approval came with a number of limits. Distribution is restricted to skilled providers and pharmacists

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[405] Pathfinder International (2009). *COMPASS: End of Project Report*. 8-9.
[406] Interview,UNICEF(April 25, 2012).
[407] FMOH(2010). *In Depth Assessment Of Procurement And Supply Management Systems For Medical Products,* 19.
[408] Patent stores are stores that are authorized only to sell over-the-counter medicines, but there is little evidence to suggest that this restriction is followed. See: FMOH (2010), *Access and Rational Use in Facilities,* 12.
[409] UNIDO (2011). *Pharmaceutical Sector Profile: Nigeria*, UNIDO, Vienna, 23.
[410] *Ibid*., 25
[411] See Ahura Scientific (2007). *TruScan Rapid Material Verification with Handheld Raman Spectroscopy*. Ahura Scientific, Inc. BTSRMv1.0 Copyright 2007. Available: http://www.antech.ie/media/file/Handheld/TruScan%20Antech%20Brochure.pdf and Antech (2012). *TruScan & the Pharmaceutical Counterfeiting Problem*. Antech, Inc.
Avialable: http://www.antech.ie/truscan2.shtml
[412] Fujioka, A. and Smith, J. (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries*: *Status Report 2011,* 61.
[413] Interview, USAID (May 3, 2012)

and it was not included on the EML until 2010,[414] so public sector procurement is quite new. Additionally, the government declined to approve community-based distribution without local evidence that it is safe, effective and feasible, and the first results affirming this finding have only recently been published.[415] And while these findings are encouraging, there is not yet strong national guidance on community-based distribution.[416] It appears that such distribution is still limited to pilot sites managed by NGOs. If this policy changes as expected, it will be critical to educate providers of various skill levels about both the option to access misoprostol through government supply chains and to provide adequate information and training to ensure that women and providers alike know how and when to use it.

Demand by Providers

Though there have been no efforts to map demand for maternal health commodities among health providers, findings collected over the course of interventions sheds important light on the role that provider demand may play in efforts to enhance access.

Despite the fact that magnesium sulfate has long been included in essential medicines lists, there is evidence suggesting that demand remains low. One 2011 study assessing the impact of the introduction of magnesium sulfate in Kano State by a Population Council/MacArthur Foundation-supported project, found that:

> In Nigeria, the drug was not widely available as of five years ago but that has now changed. It is imported into the country by some pharmaceutical companies and is available in several pharmacy shops. However, it could be that there are still health workers who do not know how to use the drug or are resistant to change. Other possible reasons for its poor universal appeal include: the lack of guidelines on its use; non-inclusion in many national essential drug lists; the wrong perception that the drug is meant for use only at the highest level of facilities (such as those with intensive care facilities); a lack of training in its use for health workers; little incentive for pharmaceutical companies to commercialize the drug; and ready availability of pre-packaged forms of less effective drugs.[417]

While low demand by providers poses a significant barrier to access and use of maternal health medicines, it is not an insurmountable barrier. Linking efforts to train health providers with community mobilization and advocacy may be effective in creating sustainable supply and demand from providers. For example, one USAID-supported intervention had an impact on providers' use of EmOC and AMTSL, and helped influence the state ministry of health (SMOH) to procure oxytocin, magnesium sulfate and misoprostol without relying on a donor to do so.[418]

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[414] See FMOH (2010) *EML* foreword.
[415] Prata, N. Et al. (2012). Community Mobilization to reduce postpartum hemorrhage in home births in northern Nigeria. *Social Science and Medicine* 74, 1288-1296, 1289.
[416] *Ibid*, 1295.
[417] Tukur, J., Ogedengbe et al. (2011) Introduction of an innovation for the reduction of maternal mortality in Kano State, Northern Nigeria, a case study of magnesium sulfate, *Tropical Doctor*: 41, 197-200, 197.
[418] Jhpiego (2010). Nigeria. *ACCESS End of Project Report*. Available: http://www.mchip.net/sites/default/files/r_Nigeria_Country_Brief.pdf

In another case, provider advocacy played an important role in improving supply. The Population Council/MacArthur Foundation project on magnesium sulfate initially provided funds to cover necessary supplies for the introduction of the medicine in 10 general hospitals in Kano State. However, thanks in part to health workers in those hospitals who shared their positive experiences with providers in facilities that were not included in the study, several additional facilities moved to increase allocations and improve monitoring of stocks.[419]

Demand by Consumers

Several studies suggest that there is a high demand among consumers for these three maternal health commodities, including a willingness to purchase them in the future. One study of a community-based misoprostol distribution pilot project found that 95% of women reported willingness to pay for the medicine, and the average they were willing to pay, across five sites surveyed, was approximately US$3.50.[420]

While women may be hypothetically willing to pay for essential maternal health medicines, there is also growing acknowledgment [421] of the role that user fees and other costs have played in discouraging people from using health services overall. Additionally, the actual prices that people pay for medicines are much too high: patients pay between 2 and 64 times the international reference prices for medicines.[422] This, coupled with reports that single out magnesium sulfate as being particularly likely to be inaccessible due to high cost,[423] makes clear that any effort to identify, build, or meet demand for these commodities among consumers must involve some effort to address the issue of cost. However, there are critical gaps in evidence in this area in particular, so it is not clear how much women may pay for these medicines, and how many women fail to get the care they need because medicine is too expensive.

Some policies and programs, which are supported by government and donor funding, seek to reduce the price that women pay for commodities, with the aim of increasing demand for their use in public facilities. These include state-level policies establishing “free” services for mothers and children. However, as one informant noted, such policies often fall short of their promise, either because they do not include the cost of medicines,[424] because they only cover services in the secondary facilities managed by the state, [425] or because necessary funds are simply not allocated as intended. Another informant noted that while state governments are eager to declare maternal and child services cost-free, “they fail

[419] Tukur, J., Ogedengbe et al. (2011) Introduction of an innovation for the reduction of maternal mortality in Kano State, Northern Nigeria, a case study of magnesium sulfate, *Tropical Doctor*: 41, 197-200, 199.
[420] The Population & Reproductive Health Partnership and Venture Strategies Innovations (2010). Prevention of Postpartum Hemorrhage at Home Births in Five Communities around Zaria, Kaduna State, (Brief). PRHP and VSI. .
[421] FMOH (201), *NSHDP,* 37.
[422] UNIDO (2011), *Pharmaceutical Sector Profile: Nigeria*, 28.
[423] Fujioka, A. and Smith, J. (2011). *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries*: *Status Report 2011. USAID/MCHIP*, 64.
[424] Kassim Safiatu, S.,et al. (2009). *CIDA Trust Fund Project 2005 – 2009: Contraceptives and Safe Motherhood Kits Supply.* UNFPA. 101
[425] *Ibid*., 71

to recognize that this might cost money."[426] Another measure that seeks to reduce cost is distribution of "Mama Kits" to low-income pregnant women, which contain essential supplies that women would otherwise have to purchase if they were to seek care in a facility. However, it is not clear whether these kits contain essential maternal health medicines. Further, in states where there is no policy on free services, women may still be required to purchase the kits, although likely at a reduced cost.[427]

The National Health Insurance Scheme that now covers health costs for primarily federal employees may eventually be expanded to cover the cost of health care for low-income women and is supposed to cover 90% of the cost of medicines[428] for those enrolled. Though widely cited as a potential source of improved financing, one informant's[429] classification of the current program, which primarily covers federal employees, seems typical: the program is still "in a pilot stage,"[430] despite the fact that it launched several years ago, and, in practice, does not cover the full promised cost of medicines.

Civil Society

One 2007 analysis[431] found that though there are many maternal health champions in Nigeria, local and national maternal health advocates lack the coordination necessary to push for maternal health as a high political priority, and this seems to still be the case, particularly with regards to maternal health supplies. However, there have been important evidence-based advocacy successes in recent years, such as the inclusion of misoprostol in the EML, and there are several other projects that have successfully generated priority for maternal health supplies.

In one limited example of direct support for government purchase of a maternal health commodity, the MacArthur Foundation supported the FMOH in promoting and purchasing magnesium sulfate[432] between 2008 and 2010. Much more common are programs with a much smaller scope such as the Targeted States High Impact Project (TSHIP), a program funded by USAID and managed by JSI and other partners, which provided "emergency trolleys"[433] that included an initial supply of critical commodities, including magnesium sulfate, and was followed up by training for health providers in their use, and planning to ensure that supplies would be restocked without project support. Similar efforts have been implemented by a range of donors, such as UNFPA/CIDA,[434] and often include partnerships with local organizations. Yet it is difficult to find information on these programs' immediate and long-term impact on access to supplies. Further, there is little evidence that these organizations are communicating or coordinating to

[426] Interview, USAID (May 3, 2012)
[427] Kassim Safiatu, S., et al. (2009). *CIDA Trust Fund Project 2005 – 2009: Contraceptives and Safe Motherhood Kits Supply.* UNFPA, 11.
[428] Federal Ministry of Health (2010). *Access to and Rational Use of Medicines at the Facility Level.* Abuja: Federal Ministry of Health [Nigeria],10.
[429] Interview, UNICEF(April 25, 2012)
[430] Interview, UNICEF(April 25, 2012)
[431] Shiffman, J. and Okonofua, F. (2007). The state of political priority for safe motherhood in Nigeria, *BJOG* 114 (2):127-33. 130
[432] John D. and Catherine T. MacArthur Foundation (2010). *Reducing Maternal Mortality.* MacArthur Foundation.
[433] JSI. TSHIP. Project Description. Available: http://www.jsi.com/JSIInternetProjects/InternetProjectFactSheet.cfm?dblProjDescID=4041
[434] Kassim Safiatu, S. et al. (2009). *CIDA Trust Fund Project 2005 – 2009: Contraceptives and Safe Motherhood Kits Supply.*

advance good practice at a large scale, or promoting common goals related to policy change or implementation.

Recommendations

Make maternal health commodities a priority

There is little evidence that the policies Nigeria has enacted in recent years are having any impact on access to maternal health commodities. In order to be effective, measures such as the NSHDP's strategy for reducing stock-outs must be fully funded and must explicitly include magnesium sulfate, misoprostol and oxytocin as essential "tracer" commodities. Further, baseline data on the unmet need for these commodities is critical to fully understand the landscape, and efforts must be made to gather this information. Finally, an explicit focus on maternal health commodities must be incorporated into efforts to harmonize policy and implementation among local, state and federal governments and to develop more efficient procurement and supply chain management by donors and government bodies alike.

Identify opportunities and challenges in involving the private sector

As more evidence is gathered on the status of maternal health supplies, it will be important to consider the role of the private sector. Both private sector facilities and Nigeria's expansive pharmaceutical sector could play a role in ensuring equitable access to essential commodities. There is no comprehensive, national level data on the quality of care or cost of the services and supplies provided these providers. Given their important role, additional information is necessary and investments are needed to identify challenges and opportunities to support appropriate partnerships.

Assess training and practice of AMTSL and EmOC

There is at least anecdotal evidence that many providers do not routinely use AMTSL to prevent PPH, and instead administer medicines only after women appear to hemorrhage, but there is no national-level data on such practices. More information is needed regarding pre-service and in-service training, as well as providers' skills and confidence in administering medicines in practice in order to ensure that efforts to increase supplies support safe and effective treatment.

Inventory commodities and packaging

Without a national procurement plan, it appears that states and other bodies responsible for procuring medicines have no reason to purchase particular supplies in specific dosages or preparations. It is essential to identify what products are procured, how they are packaged, and where they are produced as a preliminary step to ensure that the supply of medicines is of high quality. At the same time, it is essential to develop a plan, along with guidelines for preferred packaging, such as three-pill blister packs for misoprostol. From there, it may be useful to explore possibilities for contracting with Nigerian or other West African manufacturers.

Identify opportunities to incorporate maternal health commodities within current efforts to improve procurement and supply chains

Given the lack of national procurement plans for commodities in general and the lack of investment in maternal health commodities in particular, it is critical for Nigeria and its partners to identify opportunities to integrate commodity purchasing and supply across all essential commodities. In order to reduce the chances of further duplication of systems and inefficiencies, it is critical to conduct an in-depth analysis of the structures that exist for complementary health areas, such as HIV/AIDS, child

health, or family planning and to identify what opportunities to introduce maternal health commodities into these programs might exist.

Undertake further research on provider demand of maternal health commodities

Along with identifying the training and skill level of health providers in administering medicines, it will be important to treat them as potential advocates for new investments. Providers can help educate patients about signs of complications, as well as the benefits of a particular medicine or dosing regimen, and can help persuade facility managers to treat investments in particular medicines as high priorities.

Map existing maternal health programs and improve coordination at the grassroots

Given that many efforts to improve maternal health are managed by NGOs, it is important to identify examples of work that has netted sustainable change so that other groups can build on these findings. This will be a critical first step toward enabling civil society to mobilize the political will that is necessary to generate the funding needed to improve access to maternal health commodities. Coordination among local civil society groups and international NGOs that work on maternal health will enable these groups to compile high quality evidence, and identify priorities for investments and potential policy change. This coordination will also strengthen the voices of champions of maternal health as they articulate the need to treat these commodities as priorities within routine efforts to improve health services.

VIII. Tanzania

The Burden of Maternal Mortality in Tanzania

The United Republic of Tanzania has one of the highest maternal mortality ratios (MMR) in the world and is unlikely to achieve the Millennium Development Goal 5 target of reducing MMR by three-quarters by 2015. However, Tanzania has seen progress in the last 15 years. In 2011, Tanzania's MMR stood at 418 deaths per 100,000 live births, nearly half the ratio of maternal deaths occurring in 1997.[435] However, in 2011, still nearly 8,000 women died as a result of maternal complications, including postpartum hemorrhage (PPH) and pre-eclampsia/eclampsia (PE/E).

Although national data on causes of maternal deaths for Tanzania do not exist, regional data for Africa suggest that PPH and PE/E are among the leading causes of maternal death, responsible for approximately 34% and 9% percent of deaths, respectively.[436] Although these complications contribute to a large proportion of maternal deaths, they are treatable using relatively straightforward interventions. However, the barriers to prevention and treatment are often systemic problems (such as a lack of human resources, disrupted supply chains, lack of quality data, etc.) that cannot be easily overcome.

Policy and Regulatory Environment

Prioritizing Maternal Health Commodities

Maternal health supplies are specifically mentioned in a number of national policy documents, including the National Roadmap Strategic Plan to Accelerate Reduction of Maternal, Newborn and Child Deaths in Tanzania, and UNICEF staff based in Tanzania reported that maternal health supplies are a priority for the government.[437] The UK Department for International Development (DFID) is working with the Government of Tanzania to implement a project on reproductive and maternal health supplies that will spend roughly US$ 24 million over three years to "ensure that family planning and maternal health commodities are available in Tanzania throughout the health system."[438]

The National Roadmap Strategic Plan

In 2008, the Tanzanian Ministry of Health and Social Welfare (MOHSW) adopted the National Strategic Plan to Accelerate Reduction of Maternal, Newborn and Child Deaths in Tanzania[439] ("The Strategic

[435] Institute for Health Metrics and Evaluation (IHME). Maternal Mortality Estimates and MDG 5 Attainment by Country 1990-2011. Seattle, United States: Institute for Health Metrics and Evaluation, 2011.
[436] WHO analysis of causes of maternal death: a systematic review. Khalid S Khan, Daniel Wojdyla, Lale Say, A Metin Gülmezoglu, Paul FA Van Look. *The Lancet* 1 April 2006 (Volume 367 Issue 9516 Pages 1066-1074 DOI: 10.1016/S0140-6736(06)68397-9).
[437] Email correspondence with UNICEF informant #1, 27 April 2012 and Email correspondence with UNICEF informant #2, 27 April 2012.
[438] Department for International Development (2011). Reproductive and maternal health supplies in Tanzania: Business case and intervention summary. Available: http://projects.dfid.gov.uk/iati/Document//3447450.
[439] Available: http://www.who.int/pmnch/countries/tanzaniamapstrategic.pdf

Plan"). The Strategic Plan provides a situational analysis of maternal, newborn, and child health in Tanzania and discusses a framework for moving forward to reduce deaths and improve health, which includes specific strategies, interventions and a plan for implementation.

The Strategic Plan includes a specific objective to strengthen "mechanisms for availability of essential commodities," with an emphasis on "essential obstetric supplies and medicines for ANC [antenatal care], delivery, and postpartum." The Strategic Plan estimates that US$ 400 million is required to meet the objective that essential maternal, newborn and child health commodities always be available at every health facility.

Oxytocin and magnesium sulfate appear on the Essential Medicines, Equipment and Supplies list in the Strategic Plan. Misoprostol is not included, but is on the more recently updated National Essential Medicines List.

Status of Maternal Health Commodities in Tanzania			
	Oxytocin	**Misoprostol**	**Magnesium Sulfate**
Registered for use for maternal indications?	Y	Y	Y
On Essential Medicines List?	Y	Y	Y
In Standard Treatment Guidelines?	Y	Y	Y
Manufactured locally?	N	N	N

Private Sector Involvement

The Strategic Plan discusses partnerships with the private sector and private hospitals including the roles and responsibilities of the private sector to "invest in commodities and supplies for MNCH [maternal, newborn, and child health] interventions." The private sector is also listed as a responsible party for achieving the aforementioned objective, that essential maternal, newborn and child health commodities always be available at every health facility.

Clinical Guidance and Standard Treatment Guidelines

Postpartum Hemorrhage: The Standard Treatment Guidelines for Tanzania mandate the active management of the third stage of labor (AMSTL) including the injection of an oxytocic after delivery. However, the guidelines do not fully outline the appropriate timing for AMSTL steps. Oxytocin (10 IU) is the preferred medicine to treat PPH, followed by ergometrine (0.25-0.5 mg) and misoprostol (600 microgram).[440] Midwives at all levels of the health systems are authorized to perform AMSTL with oxytocin.[441]

[440] The United Republic of Tanzania Ministry of Health and Social Welfare (Third Edition, 2007). Standard Treatment Guidelines (STG) and The National Essential Medicines List (NEMLT) for Mainland Tanzania. pp. 50-51.
[441] Fujioka A, Smith J. (2011) *Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries*. Maternal and Child Health Integrated Program (MCHIP); 2011.

Pre-Eclampsia/Eclampsia: Magnesium sulfate is also included in the Standard Treatment Guidelines to treat PE/E with dosages of 4g in 100mls every eight hours for pre-eclampsia and 4g in 20mls for stabilization followed by 4g in 1000mls every eight hours for eclampsia.[442] Midwives have authorization to diagnose PE/E and treat it with magnesium sulfate.[443]

Essential Medicines List

The National Essential Medicines List for Mainland Tanzania (NEMLT) includes oxytocin (injection 10 IU in 1ml ampoule), misoprostol (tablet 200mcg), and magnesium sulfate (injection 50%). The list indicates that misoprostol and magnesium sulfate may only be available at regional and referral hospitals, while oxytocin may be available at district hospitals. Ergometrine is the only uterotonic that is available through local dispensaries, according to the NEMLT.[444]

Registration and Manufacturing

The Tanzania Food and Drug Authority (TFDA) is a semi-autonomous organization within the MOHSW that is responsible for registration and quality assurance of medicines.

Registration of Medicines

The TFDA oversees quality control, safety and effectiveness of medicines and medical commodities in Tanzania,[445] including oxytocin, misoprostol, and magnesium sulfate, which are all registered for use in the country. Tanzania was an early adopter of misoprostol, registering its use for the prevention and treatment of PPH in 2007.[446]

Only a limited number of manufacturers of maternal health commodities are registered in Tanzania. Misoprostol is the only medicine of the three that come from multiple suppliers, but these come in different dosages. However, additional registered manufacturers may not have any impact on the availability of these medicines at the district and facility level since, according to key informants, these medicines are generally available at the Central Medical Store.[447]

Registered Maternal Health Commodities in Tanzania[448]

Commodity	Dosage	Manufacturer	Country	Pack*
Misoprostol IH	100mcg	Cipla Ltd.	India	N/A
Misoprostol	200mcg	Cipla Ltd.	India	N/A

[442] The United Republic of Tanzania Ministry of Health and Social Welfare (2007). pp. 48-49
[443] Fujioka (2011).
[444] The United Republic of Tanzania Ministry of Health and Social Welfare (2007). 208
[445] Tanzania Food and Drugs Authority. Functions of TFDA. Available : http://www.tfda.or.tz/function.php. Accessed 2 May 2012.
[446] Nigeria was the first country to approve misoprostol for the prevention and treatment of PPH in 2006.
[447] Email correspondence with UNICEF informant #1, 27 April 2012 and Email correspondence with UNICEF informant #2, 27 April 2012.
[448] Tanzania Food and Drugs Authority (2011). List of registered products (Government Gazette). Available: http://www.tfda.or.tz/downloads/registered_products/report_registered_human_drugs.pdf.

IH				
Misoprostol IH	25mcg	Egyptian Co. for Chemicals and Pharmaceuticals S.A.E.	Egypt	N/A
Magnesium Sulfate BP	10% w/v	Pharmaceutical Solution Industry	Saudi Arabia	N/A
Magnesium Sulfate BP	50% w/v	Pharmaceutical Solution Industry	Saudi Arabia	N/A
Oxytocin BP	10 IU/ml	Gland Pharma Ltd.	India	N/A
*No information on packaging is available through the List of Registered Products.				

Regional Registration

In March 2012, the East African Community (EAC) and the New Partnership for Africa's Development (NEPAD) launched the EAC Medicines Registration Harmonization (MRH) Project in Arusha, Tanzania. Efforts at regional registration have been in existence for over a decade as noted in the EAC's founding treaty: "Partner states will undertake to…harmonize drug registration procedures so as to achieve good control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the Community."[449] The MRH Project receives support from a number of donors, including technical support from the U.S. Food and Drug Administration and the European Medicines Agency. Within this framework, EAC countries should be able to increase access to essential medicines and build capacity within national medicine registration bodies.

Quality Assurance

The TFDA conducts laboratory analyses to ensure that medicines meet national quality and safety standards. The Medicines and Cosmetics Analysis Department is responsible for setting guidelines and procedures as well as analyzing medicines for compliance with those guidelines. According to a 2008 MOHSW report, of the medicines that were procured and sent for analysis by the Medicines Stores Department, 90% were tested by the TFDA, with the remainder analyzed by the Government Chemistry Agency and the Tanzania Bureau of Standards.[450] There is a lack of oversight regarding medicine quality assurance, as the report noted that no other procurement agency "systematically take samples from batches procured and send for quality analysis."

Further, Choudhuri *et al.* argued that the TFDA's resources and capacity are limited to ensure that locally manufactured or imported medicines meet national standards:

> The critical issue is not just specification of standards, but capacity to monitor whether the manufacturers are following the procedure and abiding by the safeguards, to produce drugs that are safe and effective, and if not to take corrective action. Here Tanzania lags behind…

[449] Treaty Establishing the East African Community (2000). Article 118d.
[450] Ministry of Health and Social Welfare (2008). Mapping of the medicines procurement and supply management system in Tanzania. 35.

> There are manufacturers…who knowingly or unknowingly produce drugs that do not satisfy the quality requirements, and the drug control authorities…have yet been able to prevent this.[451]

Local Manufacturing

A total of 19 manufacturers based in Tanzania are named on the List of Registered Human Medicinal Products published by the TFDA.[452] However, none of these local manufacturers make oxytocin, misoprostol, or magnesium sulfate. However, according to a UNICEF staff person, at least one local manufacturer, Shelys Pharmaceutical, is at a point where it has the capacity to produce misoprostol and magnesium sulfate.

Registered Tanzanian Manufacturers[453]	
A.A. Pharmaceuticals Ltd.	Oscar Ernest Mgimbe
A1-Store	Salama Pharmaceuticals
Astra Phara (T) Ltd.	Shelys Pharmaceuticals
Eagle Multrade Ltd	Sokoine University of Agriculture
Farmchem Ltd.	Tanzania Pharmaceuticals Industries Ltd.
Kejo Super Sembe	Tanzansino United Pharmaceuticals Ltd.
Mansoor Daya Chemicals	Twiga Chemical Industries
Mek One General Traders Ltd.	University of Dar es Salaam
Murzah Oil Mills (T) Ltd.	Zenufa Laboratories (T) Ltd.
Nile Perch Fisheries Limited.	

Regional Manufacturing

The EAC estimates that only 20-30% of the US$ 3.8 billion pharmaceuticals market in Sub-Saharan Africa is manufactured in the region, and the majority of that is in South Africa. In order to promote local manufacturing, the EAC has developed the Regional Pharmaceutical Manufacturing Plan of Action 2012-2016. The document lays out strategies for the:

> Promotion of competitive and efficient regional pharmaceutical production; facilitation of increased investment in pharmaceutical production in the region; strengthening of pharmaceutical regulatory capacity; development of appropriate skills and knowledge on pharmaceutical production; utilization of World Trade Organization - Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS) flexibilities towards improved local production of pharmaceuticals; and mainstreaming innovation, research and development within regional pharmaceutical industry.[454]

Budgeting and Financing

[451] Chaudhuri *et al*. (2010). Indian generics producers, access to essential medicines and local production in Africa: An argument with reference to Tanzania. *European Journal of Development Research.* 459
[452] Tanzania Food and Drugs Authority (2011). List of Registered Product: Human Medicinal Products. Available: http://www.tfda.or.tz/downloads/registered_products/report_registered_human_drugs.pdf
[453] *Ibid.*
[454] East African Community Regional Pharmaceutical Manufacturing Plan of Action 2012-2016. 3-4.

Maternal health supplies in Tanzania are generally financed by the government through the Ministry of Health and development partners. The MOHSW's budget contained two line items for 2009-2010 expenditures and 2010-2011 estimates that address "drugs and medicines" under the Curative Services Delivery and Preventative Services Delivery programs. The 2009-2010 actual expenditures were equal to TZS 25,022,599,828 and the approved estimates for 2010-2011 amount to TZS 25,002,144,236 (US$ 15-16 million in both cases). However, in both cases, there is no specific reference to maternal health medicines.

The Citizens' Budget, which provides easily digestible budget information to Tanzanian citizens, explains that a total of TZS 22.6 billion (approximately US$ 14.4 million) have been allocated in 2011-2012 to reduce child and maternal mortality, but it does not include specific information on medicines or supplies.

DFID estimates the costs of producing and shipping the necessary quantities of oxytocin, misoprostol and magnesium sulfate are approximately US$ 1.2 million for 2012. The estimates "are based on a modeling exercise using estimates of numbers of deliveries and proportions of women suffering from various birth complications."[455] Although the US$ 1.2 million is only for three commodities, the difference between this number and the US$ 400 million estimate in the Strategic Plan underscores the complexity and systemic nature of addressing commodities. The costs associated with ensuring access to commodities include more than the cost of the commodities and the shipping costs, e.g. storage costs, training of providers on proper use, creation and implementation of systems to monitor stocks and reorder supplies, and numerous other factors.

Total Estimated Annual Cost of Maternal Health Commodities (US$)

Commodity	2012	2013	2014
Oxytocin	$518,588	$576,720	$644,613
Misoprostol	$140,850	$150,300	$158,937
Magnesium sulfate	$593,307	$647,400	$702,770
Total	$1,252,745	$1,374,420	$1,506,320

Source: DFID[456]

Maternal Health Fees

According to the Strategic Plan, maternal, child and newborn health services are exempt from cost-sharing, but mothers often face costs associated with pregnancy: "the exemption policy faces difficulties in its implementation at lower level due to lack of clarity on how to effect the exemption mechanisms."[457] The free delivery services offered in Tanzania do not cover many of the costs

[455] Department for International Development (2011). Reproductive and maternal health supplies in Tanzania: Business case and intervention summary. Available: http://projects.dfid.gov.uk/iati/Document//3447450.
[456] *Ibid.*
[457] Strategic plan, 25.

associated with delivery or the complementary services that may be required. Two studies from 2008 and 2009 both estimate the out-of-pocket costs for mothers to average US$ 5.[458,459] A 2009 study by Family Care International, suggested that maternal health supplies accounted for roughly one-third of out-of-pocket costs associate with delivery for women in Tanzania. The authors estimated that the cost of supplies for both typical and complicated births in 2006 amounted to approximately TZS 2350 or US$ 2.20.[460]

Women in Tanzania are willing to pay for maternal health medicines they believe to be effective. Prata *et al*. found that 99% of women who took misoprostol would take it again for PPH, would recommend its use to a friend, and would be willing to pay up to US$ 1.15.[461]

Procurement, Distribution, and Storage

The Medicine Stores Department (MSD), which is "internationally recognized as relatively effective among African public purchasing organizations," oversees procurement, storage, and distribution of medicines in the public sector in Tanzania.[462] MSD is an autonomous body within the MOHSW. Due to its bulk purchasing and competitive bidding capacity, MSD is generally able to procure medicines at low costs, and procures approximately 50% of medicines in Tanzania.[463]

MSD distributes medicines throughout the country every two weeks using a fleet of trucks based in Dar es Salaam and is able to maintain cold chain storage. This is critical for the procurement and distribution of oxytocin, which requires such temperature-controlled storage. While a 2008 MOHSW report indicated that cold chain storage was followed at the MSD central and all five zonal medical stores, such storage once the commodity reaches the health facility is a challenge. The report found that approximately two-thirds of health facilities in the sample, ranging from referral hospitals to dispensaries, did not or could not adhere to proper cold chain storage.[464]

In addition, according to one key informant, MSD has lengthy processes for procurement, ordering, and resupplying that impede distribution nation-wide. Although health facilities order medicines from MSD through an integrated logistics system, in practice, many facilities, particularly lower level facilities, operate on the kit system, whereby the supplies sent to facilities are determined at the central level and are uniform for all facilities at a given level. This is cited by key informants as one of the main contributors of stock-outs, since the kits received are not necessarily tailored to the needs of the community, based on demographics or other characteristics that may influence the types and amounts needed for individual medicines.

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[458] Kruk ME *et al.* (2008). User fee exemptions are not enough: out-of-pocket payments for 'free' delivery services in rural Tanzania. *Topical Medicine and International Health* 13[12].
[459] Perkins, *et al.* (2009). Out-of-pocket costs for facility-based maternity care in three African countries. *Health Policy and Planning* 24.
[460] *Ibid.* 297.
[461] Prata et al. (2009) Community based availability of misoprostol. *African Journal of Reproductive Health* 13[2]: 125.
[462] Chaudhuri *et al*. (2010). 460
[463] *Ibid.* 456.
[464] Ministry of Health and Social Welfare. (2008) In-depth assessment of the medicines supply system in Tanzania. pp. 23-24.

As early as 2003, misoprostol was used in Tanzania for treatment and prevention of PPH in home births. In these less formal settings, community distribution of misoprostol has been found to be acceptable, safe and effective. Prata *et al.* wrote:

> Our results indicate misoprostol is a safe and effective means to control PPH at the community level and, in the absence of continued monitoring and training, TBAs [traditional birth attendants] continued to diagnose excessive bleeding and safely administer misoprostol in home births.[465]

Although misoprostol has been used in Tanzania, there have not yet been steps to scale up it use for PPH prevention in home births.[466]

Inventory Management

With support from DANIDA, the Danish development agency, MSD was able to create a computerized system for inventory management that tracks orders, shipments, deliveries, and expiration dates. However, according to a report by MCHIP and input from key informants, stock-outs of oxytocin, misoprostol, and magnesium sulfate frequently occur and may last for months at a time.[467]

MSD operates a Central Medical Store (CMS) located in Dar es Salaam and five Zonal Medical Stores (ZMS) throughout the country. The 2008 MOHSW report outlined the main causes of stock-outs at the Central and Zonal Medical Stores and health facilities. For the CMS and ZMS, delays in delivery were the most common cause of stock-outs, while a lack of funds and inconsistency between the quantity ordered and the quantity delivered were most common cause for stock-outs at health facilities.[468] At the CMS, a reported 3.7% of medicines were expired, primarily due to a failure to follow the "first expired, first out" rule, changes to the Standard Treatment Guidelines after procurements were made, and errors in supply forecasting.[469]

A 2012 study of infrastructure and access to emergency and surgical care in Sub-Saharan Africa included data on medicines storage and monitoring in Tanzania. The study found that more than 70% of hospitals and health centers met physical storage standards. However, when it came to monitoring inventory, both hospitals and health centers performed significantly worse, with less than 20% having systems to inspect stock for expired medicines.[470]

Stock-outs at the facility level seem to be more likely to be caused by poor inventory management rather than country-level procurement. Two key informants suggested that there are problems with

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[465] Prata *et al*. (2009). 126.
[466] Fujioka (2011). 80.
[467] *Ibid.* 80.
[468] Ministry of Health and Social Welfare. (2008) In-depth assessment of the medicines supply system in Tanzania. 25
[469] *Ibid*. 26
[470] Hsia RY, Mbembati NA, Macfalane S, and Kruk ME. Access to emergency and surgical care in sub-Saharan Africa: the infrastructure gap. *Health Policy and Planning* 27 239. Storage is defined as a "system for storing medicines away from water, sun, pests and rodents."

inventory management that contribute to stock-outs at lower level facilities even while there remain plenty of supplies in the CMS. This was noted as particularly common for magnesium sulfate.[471]

A recent study from the USAID Deliver Project reviewed the Report and Request forms [R&R] submitted by health facilities and the availability of select commodities at facilities. However, while the study found "significant stock-outs of malaria commodities, essential medicines, and reproductive health commodities across the country" and that "family planning commodities did not fare well," it is important to note that maternal health commodities were not considered in the study.[472]

Demand for Maternal Health Commodities

Demand by Providers

A study published in 2009 indicated that maternal health commodities are in demand from providers at the hospital level. The study found that a uterotonic (either ergometrine or oxytocin) was administered in 97% of the 251 observed deliveries. However, in many cases, the medicine was not administered at the correct time, resulting in correct management of the third stage of labor in just 7% of cases. Among women who received oxytocin in the observed births, only 35% received oxytocin at the correct time.[473] However, in many cases, posters, wall charts, flyers and other materials are readily available in facilities and delivery rooms outlining proper administration of medicines and treatment guidelines.[474]

A key challenge to generating demand by health providers is that providers, at dispensaries and health centers, may not be knowledgeable enough of the medicine needs of their community or the process of the integrated logistics system to be able to properly maintain stocks. According to a DFID Business Case and Intervention Summary for maternal, newborn, and child health in Tanzania:

> A 'pull' systems means that health facilities a) need to understand what they are ordering; b) must make trade-offs and do not always make the best choices; and c) don't know what is not in stock and often expect medicines when they [are] not available. Many DMOs [district medical offices] do not understand or don't care about the Report & Request [R&R] form and simply copy out last month's form.[475]

During the pilot phase of Tanzania's Integrated Logistics System (ILS), a national system for reporting on use of medicines and resupplying providers, participants found they needed more training than was initially offered. Of the survey respondents, 41% said that the course was not sufficient to allow them to complete their ILS duties. They noted specifically that they needed more reinforcement for completing the R&R (72.5%) and for dealing with mathematics and calculations (47.5 percent). The trainers, anecdotally, reported that their courses went until the evening hours (for some courses).

[471] Email correspondence with UNICEF informant #1, 27 April 2012 and Email correspondence with UNICEF informant #2, 27 April 2012.
[472] USAID Deliver Project (2010). *Tanzania: Review of the Health Facility Report and Request Forms at MSD Zonal Stores*. 11.
[473] Mfinanga, et al.(2009) Health facility-based active management of the third stage of labor: findings from a national survey in Tanzania. *Health Research Policy and Systems.* 7:6.
[474] Email correspondence with UNICEF informant #1, 27 April 2012.
[475] Department for International Aid (2011). p 24.

Simply extending the length of a training course will not necessarily result in a better outcome; however, the curriculum appears to have overestimated participants' ability to absorb the material quickly.[476]

The USAID-funded Deliver Project is active in Tanzania and provides logistical and technical assistance to the MOHSW and other partners. Contraceptive security is a major component of the project, as is the strengthening of the ILS. In the past, Deliver has offered training in logistics and supply chain management to increase knowledge and uptake of the ILS and to ensure proper inventory management and the availability of supplies.

Demand by Consumers

In Tanzania, only 50.1% of births occur in facilities,[477] and national guidelines dictate that oxytocin and magnesium sulfate may only be administered by skilled attendants in facilities. Increasing the number of births taking place in facilities would generate an increased need for maternal supplies at the facility level, and could potentially leverage greater prioritization of these medicines.

Recommendations

Support efforts at regional registration and manufacturing

Support of and research on the East African Community's steps toward regional registration of commodities and its promotion of local manufacturing is needed to see if it will increase access to life-saving commodities and build capacity of national registration bodies and local manufacturers.

Include maternal health commodities in studies assessing availability and pricing

A number of studies, from the USAID Deliver Project and Health Action International, for example, have looked at pricing and availability of medicines at country levels. Models and research methodologies already exist, and have been carried out in Tanzania, for determining country level prices and availability, meaning that it may be possible to for institutions carrying out these assessments to include maternal health commodities in their work.

Evaluate and sytematically review new innovations

A number of innovative approaches are being taken in Tanzania and other developing countries to improve access to maternal and other life-saving commodities. However, rigorous research is needed to determine whether or not the innovations and new technologies are effective and efficient at getting commodities in the right place at the right time. Systematic reviews of interventions may be necessary to provide a broader perspective.

Determine the efficacy of the ILS

The Integrated Logistics System is relatively new in Tanzania. Neighboring Uganda developed a hybrid system after introducing an ILS that reinstated the kit system for lower level facilities that lacked capacity

[476] United States Agency for International Development (2005) Tazania: Integrated logistics system pilot-test evaluation. 26.
[477] National Bureau of Statistics (NBS) [Tanzania] and ICF Macro. 2011. Tanzania Demographic and Health Survey 2010. Dar es Salaam, Tanzania: NBS and ICF Macro. 135.

to effectively manage stocks. Decision makers should keep an eye on developments in Uganda as a possible third way if there continue to be stock-outs at facilities when supplies are available in the Central Medical Store.

Identify champions in at the national and local level

Political will is required to improve access to maternal health and other life-saving commodities. Strong advocates for maternal health and commodities should be identified and supported.

IX. Uganda

The Burden of Maternal Mortality in Uganda

In recent decades, Uganda has seen steady progress in reducing maternal mortality, with a more than 50% reduction in its maternal mortality ratio (MMR) from 1990 and 2011. Yet its MMR is still high, sitting at 274 maternal deaths per 100,000 live births and Uganda is not on pace to meet Millennium Development Goal 5, to reduce MMR by three-quarters. In 2011, more than 4,000 Ugandan women died due to pregnancy- and childbirth-related causes, including postpartum hemorrhage (PPH) and pre-eclampsia/eclampsia (PE/E).[478]

Regional data for Africa suggest that PPH and PE/E are among the leading causes of maternal death, responsible for approximately 34% and 9% percent of deaths, respectively.[479] In a review of deliveries at three levels of health units in Uganda, covering nearly 200,000 deliveries and approximately 1,300 maternal deaths in 2003, Mbonye *et al.* found that PPH was the cause of 42.3% of deaths but did not calculate those attributed to PE/E.[480] However, according to the most recent Uganda Demographic and Health Survey (DHS), only 41.1% of births occur in health facilities,[481] and the causes of the maternal deaths occurring outside facilities are not well documented.

Status of Maternal Health Commodities in Uganda			
	Oxytocin	**Misoprostol**	**Magnesium Sulfate**
Registered for use for maternal indications?	Y	Y	Y
On Essential Medicines List?	Y	N	Y
In Standard Treatment Guidelines?	Y	N[482]	Y
Manufactured locally?	N	N	N

[478] Institute for Health Metrics and Evaluation (IHME). Maternal Mortality Estimates and MDG 5 Attainment by Country 1990-2011. Seattle, United States: Institute for Health Metrics and Evaluation, 2011.
[479] WHO analysis of causes of maternal death: a systematic review. Khalid S Khan, Daniel Wojdyla, Lale Say, A Metin Gülmezoglu, Paul FA Van Look. *The Lancet* 1 April 2006 (Volume 367 Issue 9516 Pages 1066-1074 DOI: 10.1016/S0140-6736(06)68397-9).
[480] Mbonye *et al.* (2007). Declining maternal mortality ratio in Uganda: Priority interventions to achieve the Millennium Development Goals. *International Journal of Gynecology and Obstetrics* 98 288.
[481] Uganda Bureau of Statistics (UBOS) and Macro International Inc. 2007. Uganda Demographic and Health Survey 2006. Calverton, Maryland, USA: UBOS and Macro International Inc. 126.
[482] Although misoprostol is not in the Uganda Clinical Guidelines, Venture Strategies Innovations, an American NGO, and the Ministry of Health have developed separate clinical guidelines for the use of misoprostol.

Although these two complications account for a large number of maternal deaths, they are often preventable or treatable using relatively straightforward interventions. However, the barriers to prevention and treatment are often systemic problems (such as a lack of human resources, disrupted supply chains, lack of quality data, etc.) that cannot be easily overcome. According to a UK Department for International Development (DFID) project summary, "Inadequate supplies are cited by the Ugandan public as their greatest problem to accessing effective healthcare."[483] A 2002 World Bank study references a 1997 report that notes "resale of drugs represented the greatest single source of income for health workers in most units."[484]

A number of organizations working in Uganda have identified essential medicines as a priority to improve health outcomes in Uganda. However, the extent to which maternal health medicines are prioritized by these organizations is not clear. The Medicines Transparency Alliance (MeTA), Securing Uganda's Right to Essential Medicines (SURE), and Stop the Stock-Outs are just three examples of organizations or initiatives that specifically work to address access and affordability of essential medicines in Uganda.

Policy and Regulatory Environment

Health Sector Strategic Plan

The Health Sector Strategic Plan III (HSSP III) emphasizes the need for increased access to medicines and other health commodities. HSSP III outlines a number of specific strategies and interventions that will "consolidate, strengthen and ensure an effective and harmonized procurement and supplies management system is in place" and strengthen the National Medical Stores.[485] The document includes medicines and supplies as one of the key areas impeding full coverage of maternal health services: "Slow progress in addressing maternal health problems in Uganda is due to lack of human resources, medicines and supplies and appropriate buildings and equipment including transport and communication equipment for referral."[486] However, beyond this, there is little discussion specifically of maternal health supplies in HSSP III.

National Health Policy

Uganda's second National Health Policy was adopted in 2010 and was informed by the National Development Plan. The creation of the National Policy was inclusive, using a participatory process involving technical working groups, various government ministries, private sector actors, non-governmental organizations, and local governments.

The document outlines a number of challenges that prevent full coverage of health commodities:

[483] Department for International Development (2011). Project Summary: Increasing Access to Antimalarial Drugs in Uganda. 4.
[484] Ferrinho P, Van Lerberghe W (2002). *Managing Health Professionals in the Context of Limited Resources: A Fine Line Between Corruption and the Need for Moonlighting*. World Bank , 1-28. Referencing Asiimwe D, McPake B, Mwesigye F, Ofoumbi M, Oertenblad L, Streefland P, Turinde A. The private sector activities of public-sector health workers in Uganda. in: Bennet S, McPake B, Mills A (editors). *Private Health Providers in Developing Countries. Serving the Public Interest?* London and New Jersey: Zed Books, 1997,140-157.
[485] Ministry of Health (2010a). Health sector strategic plan. Kampala: Government of Uganda. 102.
[486] *Ibid.* 11.

> Weaknesses in supply chain management such as poor quantification, delays in procurement, inappropriate and late deliveries, late orders from facilities and poor record keeping contribute to shortage and wastage of medicines in the public sector…The private sector in this area is fragmented and comprises of dispensing hospitals and clinics, retail pharmacies and both legal and illegal drug stores. There is an emerging pharmaceutical industry in the country but with limited production. As a result approximately 90% of all medicines are imported and close to 95% of these are generic products. The challenge of counterfeit products on the market is becoming an increasing concern.[487]

While the plan does not specifically address maternal health commodities, many of these barriers are applicable to them.

Uganda National Drug Policy

In 2002, Uganda published a National Drug Policy that outlines objectives and strategies around 10 policy areas, including selection, supply and rational use of medicines, monitoring and evaluation, and financing and pricing. Although this document does not specifically address maternal health commodities, the strategies outlined address many of the barriers and opportunities for innovation surrounding oxytocin, misoprostol and magnesium sulfate.

Private Sector Involvement and Partnerships

The Health Sector Strategic Plan discusses instances where the private sector can and should be involved in health commodities, though it does not describe this is detail and does not mention maternal health commodities specifically. According to HSSP III, the "private sector plays an important role in the delivery of health services in Uganda covering about 50% of the reported outputs."

Additionally, the private sector is involved in increasing access to affordable medicines through the public-private partnership of the Medicines Transparency Alliance (MeTA). DFID supports MeTA, which is attempting to increase "information sharing among various stake holders in the pharmaceutical sector in selected developing countries."[488] MeTA Council Members include individuals from Ugandan pharmaceutical companies, the Pharmaceutical Society of Uganda, as well as ministries, non-governmental organizations, and multilateral organizations.

Finally, the National Drug Policy includes the private sector as a major component of ensuring the proper use and distribution of medicines.

Clinical Guidance and Standard Treatment Guidelines

The Uganda Clinical Guidelines (UGC) were most recently revised in 2010 to "provide updated, practical and useful information for both upper and lower level health facilities on the diagnosis and management of common conditions presenting in Uganda," including treatment of PPH and PE/E.

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[487] Ministry of Health (2010b). The second national health policy: Promoting people health to enhance socio-economic development. Kampala: Government of Uganda. 8

[488] Medicines Transparency Alliance (2009). MeTA Uganda Workplan. Available: http://www.medicinestransparency.org/fileadmin/uploads/Documents/MeTA-Uganda-workplan.pdf

Postpartum Hemorrhage

The UCG recommend ergometrine and oxytocin for the management of PPH. Although misoprostol is not included in the UCG, the Ministry of Health, in conjunction with Venture Strategies Innovations, developed clinical guidelines specifically for the use of misoprostol for treatment and prevention of PPH. In this document, misoprostol is recommended as "an alternative uterotonic drug in settings where parenteral uterotonic drugs are not available or cannot be properly administered."[489]

Pre-Eclampsia/Eclampsia

The UCG recommend magnesium sulfate as the first line treatment in the management of PE/E. Diazepam is listed as an alternative treatment, only when magnesium sulfate is not available.

Essential Medicines List

The Essential Medicines List for Uganda (EMLU) was updated most recently in 2007 and contains recommendations on medicines "which satisfy the needs of the majority of the population and should therefore always be available in adequate quantities and appropriate dose forms." Oxytocin (injection 10IU/ml) and magnesium sulfate (injection 500mg/ml) are both listed in the EMLU, but misoprostol is not. According to the EMLU, oxytocin may only be administered at a hospital, while magnesium sulfate may be administered at "health centre 3" or sub-district level facility. The EMLU is in the process of being updated and revisions will likely be published in 2012.

Registration and Manufacturing

Registration of Medicines

The National Drug Authority (NDA) is responsible for inspecting and registering medicines and medical commodities in Uganda. Prior to 1996, imported medicines were not subject to registration. Currently, oxytocin, misoprostol, and magnesium sulfate are all registered for use in Uganda. However, according to a Population Action International report on maternal health supplies in Uganda, on low margin supplies, such as oxytocin, companies may find the process of registration too burdensome: "the Ministry of Health had to lobby Parliament for an exception to the bidding process in order to locate a supplier willing to provide oxytocin in Uganda."[490]

Registered Maternal Health Commodities in Uganda[491]				
Commodity	**Dosage**	**Manufacturer**	**Country**	**Pack**
Magnesium Sulfate	50mg/ml	Gland Pharma Ltd.	India	1*5*5ML AMPOULES
Magnesium Sulfate	50%W/V	Marck Biosciences	India	1*50*10ML

[489] Population Action International (2010). *Maternal Health Supplies in Uganda*.
[490] *Ibid.*
[491] National Drug Authority (2012). List of registered human drugs. Available: http://www.nda.or.ug/hmn_list.php. Accessed 3 May 2012.

		Ltd.		
Misoprostol	200mcg	Acme Formulation Pvt. Ltd.	India	1*10 BLISTER
Misoprostol	200mcg	Fourrts Laboratories Pvt LTD.	India	1*1*2 STRIP, 1*10*10
Misoprostol	200mcg	Piramal Healthcare, Ltd.	UK	1*2*14 BLISTERS
Oxytocin	10IU/ML	Geofman Pharmaceuticals	Pakistan	1ML AMPPOULE
Oxytocin	10IU	Gland Pharma Ltd.	India	1*10*1ML AMPOULE
Oxytocin	10IU/ML	Gland Pharma Ltd.	India	1ML AMPOULES
Oxytocin	10IU/ML	Ningbo Dahongying	China	1*10*1ML AMPOULES
Oxytocin	10IU/ML	Norvartis Pharma Stein Ltd.	Switzerland	1*10*1ML AMPOULES
Oxytocin	51U/ML	Win-Medicare Pvt Ltd.	India	5 * 10 ML AMPS
Oxytocin	10IU/ML	Zheijang Ruixin Pharmaceutical Co.	China	1X100X1ML & 1*10*1 ML Ampoule

Regional Registration

In March 2012, the East African Community (EAC) and the New Partnership for Africa's Development (NEPAD) launched the EAC Medicines Registration Harmonization (MRH) Project in Arusha, Tanzania as part of the 2000 treaty establishing the EAC. Within this framework, EAC countries should be able to increase access to essential medicines, including oxytocin, misoprostol and magnesium sulfate, and build capacity within national medicine registration bodies. The MRH Project receives support from a number of donors, including technical support from the U.S. Food and Drug Administration and the European Medicines Agency.

Quality Assurance and Inspection

Within Uganda's NDA, the Drug Inspectorate Department is responsible for ensuring the quality of medicines in the country. In addition to inspecting hospitals, clinics, and retailers, NDA inspectors "examine imported drug consignments to ensure that they comply with requirements prior to granting NDA clearance of the shipment."[492]

The Head of Drug Inspectorate Services at the NDA recently estimated that 20-30% of medicines in the Ugandan market are counterfeit, but there is no indication regarding the percentages of counterfeit

[492] National Drug Authority. Drug Inspectorate Department. Available: http://www.nda.or.ug/drug-insp.php. Accessed 3 May 2012.

medicines marketed as oxytocin, misoprostol or magnesium sulfate.[493] Reports suggest that anti-malarials and "lifestyle products" (such as Viagra and Cialis) are the most commonly counterfeited medicines.

In 2012, in order to address counterfeit medicines in Uganda, Pfizer and SURE, a USAID-funded program, donated Truscan devices that allow rapid testing of medicines to ensure their validity, and producing results in less than a minute. However, given the low costs for these maternal health commodities, expired medicines seem to be generally of more concern than counterfeits.

Local Manufacturing

As of April 2012, approximately six Ugandan manufacturers were reported as part of the Human Drug List published by the NDA.[494] However, none of these local manufacturers make oxytocin, misoprostol, or magnesium sulfate because they cannot compete with the prices of international manufacturers. According to Nazeem Mohamed, CEO of Kampala Pharmaceuticals Industries, local manufacturers face a number of challenges, including the high cost of operations, unreliable energy supply, unfair competition from international manufacturers, inadequate research and development of products, and lack of a functioning market. The Government of Uganda had not, as of 2009, taken steps to implement a policy that supports local pharmaceutical manufacturing: "The Government's policy is to promote local manufacturing of pharmaceutical products, but proper legislative framework within which the policy can be implemented in not yet in place."[495]

Local Manufacturers in Uganda[496]
Abacus Parenteral Drugs Ltd
Kampala Pharmaceuticals Industries
Medipharm Industries (EA) Ltd
Quality Chemicals Industries, Ltd
Rene Industries Ltd
SEV Pharmaceuticals Ltd

Quality Chemical Industries Limited recently received the WHO Good Manufacturing Practices (GMP) certification and has achieved prequalification for antiretrovirals (ARVs) and artemisinin-based combination therapies (ACTs), a step that many local manufacturers believe is necessary:

> Manufacturers argue that, given the increasing volume of funding of essential medicines by donors and international agencies who require manufacturers to have WHO GMP certification in order to prequalify for procurement exercises, they are slowly being pushed out of the local

[493] Onyango E (2012). Uganda: Malaria Medicines Most Counterfeited. *East African Business Week*. Available: http://allafrica.com/stories/201204170444.html.
[494] This number varies between different sources and we have not been able to verify the final current number of local manufacturers.
[495] Mohamed, N. (2009). The role of local manufacturers in improving access to essential medicines. *Africa Health*. 42.
[496] National Drug Authority (2012).

> essential medicines market. This, according to some manufacturers and the chairman of the UPMA [Uganda Pharmaceutical Manufacturers' Association], might be the single biggest threat to the survival of local pharmaceutical manufacture.[497]

Regional Manufacturing

The EAC estimates that only 20-30% of the US$ 3.8 billion pharmaceuticals market in Sub-Saharan Africa is manufactured in the region, and the majority of that is in South Africa. In order to promote local manufacturing, the EAC has developed the Regional Pharmaceutical Manufacturing Plan of Action 2012-2016. The document lays out strategies for the:

> Promotion of competitive and efficient regional pharmaceutical production; facilitation of increased investment in pharmaceutical production in the region; strengthening of pharmaceutical regulatory capacity; development of appropriate skills and knowledge on pharmaceutical production; utilization of World Trade Organization - Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS) flexibilities towards improved local production of pharmaceuticals; and mainstreaming innovation, research and development within regional pharmaceutical industry.[498]

Budgeting and Financing

In the 2011 Budget Speech from the Minister of Finance, there is a request for UGX 96 billion (approximately US$ 39 million)[499] for medicines and UGX 24 billion (approximately US$ 9.8 million) for maternal and child health.[500] However, from this and other readily available documents, there is little information on the budget specifically for maternal health commodities. According to a 2009 Ministry of Health report, the actual per capita spending on essential medicines and health supplies for FY 2007-08 was UGX 13,949 (US$ 5.67), a decline from 17,437 (US$ 7.09) in FY 2004-05.[501]

Maternal Health Fees

In 2001, the Government of Uganda abolished user fees in public health facilities. Public hospitals, however, were also allowed to operate private, fee-based wards. The purpose of the decision "was not to discourage payment for services, as prepayment mechanisms are not abolished, but rather to limit the financial barriers clients face in accessing health services by removing charges placed by government."[502]

Levin et al. observed the range of maternal health costs to end-users in 1998 to be US$ 1.00 and US$ 2.80 for antenatal services and US$ 2.30 and US$ 22.80 for vaginal deliveries.[503] These figures include "user fees, travel costs and other costs such as food." Unfortunately, the data was collected prior

[497] UNIDO (2010). *Pharmaceutical Sector Profile: Uganda*. 28
[498] East African Community Regional Pharmaceutical Manufacturing Plan of Action 2012-2016. 3-4.
[499] All conversions are based on May 2012 exchange rates.
[500] Kiwanuka M (2011). Republic of Uganda Budget Speech: Financial Year 2011/12.
[501] Ministry of Health (2009) Final Report: Essential Medicines and Health Supplies Tracking Study. 61.
[502] Nabyonga-Orem J *et al.* (2008). Maintaining quality of health services after abolition of user fees: A Uganda case study. *BMC Health Services Research* 8:102.
[503] Levin A *et al.* (2003). Cost of maternal heath care services in three Anglophone African countries. *International Journal of Health Planning and Management* 18 13.

to the elimination of user fees. Subtracting the explicit user fees reduces average total antenatal care costs to patients by US$ 0.84 at public hospitals and US$ 0.35 at public health centers. Out-of-pockets costs for vaginal deliveries are reduced by US$ 4.35 in public hospitals and US$ 0.70 in public health centers.

Procurement, Distribution, and Storage

The National Medical Stores (NMS), an autonomous government corporation established in 1993, handles procurement and distribution of medicines in the public sector. NMS divides Uganda into five zones and provides monthly supplies, quarterly supplies, emergency supplies, and flexible demand-based supplies in each zone.

The NMS uses a combination of push and pull systems[504] in order to keep supplies in stock throughout the country. In 2002, Uganda adopted a pull system where facilities would order supplies from the NMS. However, for some low-level facilities lacking the capacity to properly manage and order supplies, this system was dysfunctional. As a result, the kit system[505] was reintroduced by the Ministry of Health and the NMS for "lower-level health facilities found to have the weakest supply management skills."[506] Magnesium sulfate is included as a vital medicine in the kit for Level III Health Centers and ergometrine is listed as an essential medicine. But none of the four medicines: magnesium sulfate, ergometrine, oxytocin, or misoprostol are included in the Level II Health Center kit. While this hybrid system has not solved commodities supply issues in Uganda, it has reportedly improved availability of supplies in low-level facilities.

The Joint Medical Store (JMS) also plays a role in the procurement, storage, and distribution process for medicine supplies in Uganda. The JMS is a non-profit NGO, originally formed as a joint venture of the Uganda Catholic Medical Bureau and the Uganda Protestant Medical Bureau. The JMS sells oxytocin and magnesium sulfate, though not misoprostol, possibly due to its association with abortion. Oxytocin is available in 10- and 100-unit packages of 10IU/ml 1ml ampoules for UGX 1,665 (US$ 0.66) and 20,372 (US$ 8.10), respectively. One 50% 10ml vial of magnesium sulfate costs UGX 4,027 (US$ 1.63).[507] After being approved by JMS, hospitals, health centers, dispensaries and other providers are able to place order online via the JMS website.

A 2012 study of infrastructure and access to emergency and surgical care in Sub-Saharan Africa included data on medicines storage and monitoring in Uganda. The study found that nearly 60% of hospitals and about 45% of health centers met physical storage standards. However, only 40% of

[504] A push system is one where "quantities of supplies and the schedule for their delivery to facilities are determined at a higher (usually central) level with little to no input from lower levels" and a pull systems is one where "facilities provide information on actual consumption and needs estimates to higher levels." See: Islam (2007).
[505] Kits are standardized packages of essential medicines and supplies that are delivered to the facility. Type and quantities of contents are determined by expected utilization rates for predefined services. Kits are generally part of a *push* distribution system that does not use requisitions. See Islam (2007).
[506] Ministry of Health and SURE (2011). *Assessment of the Essential Medicines Kit-Based Supply System in Uganda.* 1
[507] Joint Medical Stores (2012). *Catalogue Users Guide*.p. 21. Available: http://www.jms.co.ug/uploads/catalogue.pdf

hospitals and just one-third of health centers had systems in place to monitor stock for expired medicines.[508]

Demand for Maternal Health Commodities

Demand by Providers

A 2010 report from the Regional Centre for Quality of Health Care suggested a high level of demand for uterotonics among hospital-based health providers, as oxytocin or ergometrine were administered in 97.3% of observed births in the active management of the third stage of labor (AMTSL).[509] The study also found that 86.7% of observed hospitals in Ethiopia, Tanzania, and Uganda had appropriate storage conditions, although many of the hospitals did not have a three-month supply on hand.[510] The report suggested that follow-up training for providers could increase the rates of proper administration of AMTSL, including the administration of an uterotonic such as oxytocin.

Demand by Consumers

A 2011 DFID assessment found considerable demand among the Ugandan public for essential medicines and supplies: "Inadequate supplies are cited by the Ugandan public as their greatest problem to accessing effective healthcare."[511] Yet a key informant from the Ministry of Health noted that the *need* for maternal health supplies is obvious, but *demand* for maternal health commodities, compared to other commodities, is lacking.

A 2009 report from the Ministry of Health indicated that availability of supplies is a factor in care-seeking behavior for Ugandans. Over 61% of clients in the survey "sought treatment because they heard that medicines had been delivered at the heath unit" even if they were not sick.[512] The report suggests that, unless there has been a recent delivery of medicines, people expect the medicines not to be available at health facilities:

> The reason, people all of a sudden flocked the HU [health unit] once supplies arrived, was that many people in the communities were sick but had kept away because they knew there was no medicine and waited until the medicines arrived. In addition, because of the erratic availability of medicines at HUs, some people turned up to collect medicines to keep at home for [future use] when they fell sick.[513]

While the report does not specifically mentioned maternal commodities, the unfortunate reality for mothers is that they cannot decide when they go into labor and need to seek treatment, but may be more likely to go to a facility for delivery if they know the needed supplies will be there.

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[508] Hsia RY, Mbembati NA, Macfalane S, and Kruk ME. Access to emergency and surgical care in sub-Saharan Africa: the infrastructure gap. *Health Policy and Planning* 27 239. Storage is defined as a "system for storing medicines away from water, sun, pests and rodents."
[509] Murokora, D (2010) Report on follow up of AMTSL Training in Tanzania, Ethiopia and Uganda. Regional Centre for Quality of Health Care. 6.
[510] *Ibid.* 24.
[511] Department for International Development (2011). Project Summary: Increasing Access to Antimalarial Drugs in Uganda. 4.
[512] Ministry of Health (2009) Final Report: Essential Medicines and Health Supplies Tracking Study. 55-56.
[513] *Ibid*. 55.

Marie Stopes Uganda has instituted a project to improve maternal health in Uganda by increasing demand for institutional maternal health services directly and, indirectly, maternal health commodities through the use of vouchers. The vouchers were redeemable for antenatal care visits, delivery and postnatal care. Of the women who participated in the survey, women from the poorest and second-poorest quintile were more likely to use the vouchers than wealthier women. The evaluation, undertaken by Population Council, found that mothers who used vouchers were significantly more likely to deliver in a private facility compared to a public facility, and this decreased the likelihood of out-of-pocket payments in private facilities.[514]

Recommendations

Support efforts at regional registration and manufacturing

Support of and research on the East African Community's steps toward regional registration of commodities and its promotion of local manufacturing is needed to see if it will increase access to maternal health commodities and build capacity of national registration bodies and local manufacturers.

Identify champions in at the national and local level

Political will is required to improve access to maternal health and other life-saving commodities. People who are strong advocates for maternal health and commodities should be identified and supported.

Improve packaging of maternal health commodities

The packaging for maternal health supplies should be in a manner that is conducive to their use. In many cases, simply repackaging the medicines may make them easier for providers to correctly administer. None of the registered manufacturers of misoprostol in Uganda package it in the exact dose (three 200mcg tablets) or in packages that are multiples of three. It makes sense to package misoprostol in 1x3 blister packs or multiples thereof, instead of packages of ten as is common, as multiples of three will facilitate ease of use and correct dosages for treating and preventing PPH.

Consider community-based distribution of misoprostol

Presently, Uganda does not distribute misoprostol at the community level. However, community based distribution has been piloted and found to be acceptable to mothers and health care providers in neighboring Tanzania. The approach provides an opportunity to get a life-saving commodity to women who do not give birth in facilities and where oxytocin may not be available.

Test and modify the national distribution system

Uganda's commodity distribution system is a hybrid of 'push' and 'pull' systems that provides kits to lower level facilities that may not have the capacity to monitor and maintain stocks of life-saving commodities. The system should continuously be monitored and modified as chances to improved coverage arise.

[514] Bellows B and Obare F. (2012) Population level impact of vouchers on access in Uganda. Presentation at Dissemination if Impact Evaluation Findings Workshop: Kampala, Uganda.

XI. Conclusion

The inaccessibility of oxytocin, misoprostol and magnesium sulfate to treat PPH and PE/E in some developing countries contributes to high levels of high maternal mortality and morbidity. This report is meant to serve as an aggregation and review of readily available information regarding these three key maternal health commodities in six target countries with high burdens of maternal mortality. While findings differ across countries, one aspect is clear – significantly more research is needed to fully capture the state of maternal health commodities in these countries, and probably others.

Building on this initial review, a well-planned series of consultations with in-country stakeholders is a critical next step. A comprehensive understanding of the status and accessibility of these commodities is a necessary component of ensuring access to high quality maternal health services for millions of women around the world.

The Maternal Health Task Force and Global Health Visions are pleased to be a part of the work to inform the UN Commission on Lifesaving Commodities for Women and Children's efforts on maternal health commodities. Despite the short timeline of this project (20 days of desk-research and key informant interviews), we believe this working paper represents a critical, initial milestone in larger efforts to fully understand the landscape. We look forward to furthering this research in-country and continuing to support the Commission's goals.

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Introduction

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