

Availability and Management of Medicines for Emergency Obstetric Conditions in Kenya

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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ACRONYMS

AMTSL	active management of the third stage of labor
DHS	Demographic and Health Survey
DHMT	District Health Management Teams
DRH	Division of Reproductive Health
EML	Essential medicines list
FEFO	First Expiry First Out
HCSM	Health Commodities and Services Management program
KEMSA	Kenya Medical Supplies Agency
KEPH	Kenya Essential Package for Health
KNPP	Kenya National Pharmaceutical Policy
mcg	microgram
MCHIP	Maternal and Child Health Integrated Program
MDG	Millennium Development Goals
MEDS	Mission for Essential Drugs and Supplies
MgSO ₄	magnesium sulfate
MH	maternal health
MoH	Ministry of Health
MNCH	Maternal, newborn, and child health
MNH	Maternal and newborn health
MOMS	Ministry of Medical Services
MOPHS	Ministry of Public Health and Sanitation
MSH	Management Sciences for Health
NEML	National Essential Medicines List
NHSSP	National Health Sector Strategic Plans
PE/E	pre-eclampsia and eclampsia
PHMT	Provincial Health Management Team
PMSMT	Provincial Medical Services Management Team
PPB	Pharmacy and Poisons Board
PPH	Post-partum hemorrhage
RA	research assistant
SCG	standard clinical guidelines
SPS	Strengthening Pharmaceuticals Systems program
SSA	sub-Saharan Africa
USAID	United States Agency for International Development
WHO	World Health Organization

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EXECUTIVE SUMMARY

Every year, more than 300,000 women die from pregnancy-related complications, with 99 percent of deaths occurring in developing countries, mostly in sub-Saharan Africa (SSA). The maternal health status in Kenya is similar to that of many SSA countries. According to the latest Demographic and Health Survey (DHS), while children under five mortality rates have decreased, maternal mortality increased from 414 deaths per 100,000 live births in 2003 to 488 deaths per 100,000 live births in 2008¹ and there has been little progress in reducing neonatal mortality (33 to 31 per 1,000 live births). The most common causes of maternal deaths in Kenya include post-partum hemorrhage (PPH), hypertensive disorders such as pre-eclampsia and eclampsia (PE/E), ruptured uterus/obstructed labor, and severe anemia. While medicines for these conditions exist, access to quality maternal health medicines remains a challenge.

The Strengthening Pharmaceutical Systems (SPS) and Health Commodities and Services Management (HCSM) programs have been providing support for improving the pharmaceutical supply systems for HIV/AIDS, malaria, reproductive health, and other disease conditions. However, there has not been a focus on improving access to pharmaceuticals for maternal and child health conditions to date and recent data on the barriers to access, availability, management and use of medicines for PPH and eclampsia are unavailable for Kenya. As a result, SPS and HCSM conducted a rapid assessment to determine the availability, management and use of the maternal health (MH) pharmaceuticals as a basis for future programming. The assessment collected information on knowledge and practices of storage and inventory management of MH medicines, availability of the medicines at the different health care levels and sectors, and management support to health care professionals.

Overall, this assessment has found that there are challenges and gaps in the pharmaceutical management cycle that impede the availability of quality maternal health medicines in Kenya at various levels of the health care system in both the public and private sectors. A review of the National Essential Medicines List (NEML) and standard clinical guidelines (SCG) found that both national documents are not aligned. The Ministries of Health have recently updated the SCGs to be in line with the World Health Organization recommended guidelines for PPH and PE/E, but there is an urgent need to update the NEML as medicines are being procured and used at health facility levels that are not authorized to use them or where personnel may not be trained properly to use these medicines. Additionally, these facilities do not have the storage capacity to store the medicines under the recommended conditions. This assessment found that many of the facilities surveyed do not have the infrastructure or systems (operational refrigerator or temperature monitoring mechanisms) in place to maintain cold chain storage which is recommended for oxytocin and ergometrine. Similarly, there is little knowledge on storage guidelines for oxytocin despite this medicine being available at all the health facilities with little or no stock-outs. This may be partially due to two types of oxytocin being procured depending on the health care level.

¹ Kenya National Bureau of Statistics (KNBS) and ICF Macro, *Kenya Demographic and Health Survey 2008-09*. Calverton, Maryland: KNBS and ICF Macro. 2010.

There are also issues with the availability of maternal health commodities. While oxytocin is widely available, other key maternal health commodities continue to face challenges. For example the assessment found that misoprostol is not usually available as well as magnesium sulfate (MgSO₄) and diazepam. Similarly, medicines for neonatal sepsis and asphyxia were essentially not available throughout the sectors and health facility levels. All the health centers and hospitals surveyed experience stock-outs of caffeine citrate for the six months prior to the survey. Why this happened is unclear but other findings in this assessment indicate that it may be attributed to challenges in the quantification of needs, poor inventory management, and possible central level stock-outs. Additionally, there is confusion regarding the ordering process at each of the health care levels which may be due to the government transitioning to the pull system where health needs are determined locally and sent up to the central levels.

As the government continues to transition to the pull system and expand access to maternal and newborn health medicines to reduce maternal and neonatal mortality, the following recommendations are given to strengthen the national pharmaceutical management system.

1. Align and harmonize policies regarding essential obstetric care
2. Standardizing methods for estimating needs and ordering process
3. Developing standard operating procedures for sub-national procurements
4. Ensure that facilities only have medications that staff are trained to use.
5. Reassessing the need to procure two types of oxytocin
6. Enhancing training and supervision
7. Increasing access to management tools

INTRODUCTION

The United States Agency for International Development (USAID)-funded SPS program (2007–2012), aimed to improve governance and policies in the pharmaceutical sector, strengthen pharmaceutical systems and financing mechanisms, contain antimicrobial resistance, and enhance access to and appropriate use of medicines. SPS Maternal, Newborn, and Child Health (MNCH) activities specifically focus on increasing the availability of medicines for the prevention and treatment of PE/E and PPH by improving pharmaceutical management systems to support the scale-up of active management of the third stage of labor (AMTSL) and eclampsia interventions.

Kenya is one of the focal Global Health Initiative countries and a focal country for the USAID MNCH portfolio. In April 2011, the Health Commodities and Services Management (HCSM) program was awarded to Management Sciences for Health, by USAID/Kenya with the goal of improving systems that support the overall management of health commodities and related services in Kenya. While both SPS and HCSM have been providing support for improving the pharmaceutical supply systems for HIV/AIDS, malaria, reproductive health and other disease conditions, there has not been a focus on improving access to the pharmaceuticals for maternal and child health conditions to date. In addition, data on the barriers to access, availability, management and use of medicines for PPH and eclampsia are unavailable for Kenya.

As a result, SPS and HCSM conducted a rapid assessment to determine the availability, management and use of maternal health (MH) pharmaceuticals as a basis for future programming. The survey is part of the broader objective of MSH to support the Kenyan Ministries of Health (MoH) to achieve the objectives of the Kenya Maternal and Neonatal Health (MNH) National Plan by providing evidence to support four key priority areas.²

- Strengthening data management and utilization at all levels for MNH
- Contributing towards strengthening operations research in MNH by promoting the documentation, dissemination and utilization of evidence based practices
- Strengthening national, provincial and district capacity for health planning and management of MNH care
- Generating evidence for mechanisms to improve availability of, access to, and utilization of quality MNH care

Assuring the quality and availability of these pharmaceuticals at all levels of the health system requires effective pharmaceutical management for each of the following functions: product selection, procurement, distribution, and use. Each function must be supported by a policy and regulatory environment that promotes the equitable supply of high-quality products. This report summarizes key findings from an assessment conducted in 2011 on the management and

² MOPHS, *Road Map for accelerating the attainment of the MDGs related to Maternal and Newborn health in Kenya*, DRH, 2010.

availability of essential maternal health pharmaceuticals for the management of emergency obstetric conditions such as PPH and PE/E. The assessment collected information on knowledge and practices of storage and inventory management of MH medicines, availability of the medicines at the different health care levels and sectors, and management support to health care professionals.

Background

Every year, more than 300,000 women die from pregnancy-related complications, with 99 percent of these deaths occurring in developing countries. SSA bears the largest burden with an estimated 1 in every 22 women dying from maternal causes compared to 1 in every 7,300 in developed countries.^{3,4} PPH and eclampsia are the leading cause of maternal mortality worldwide with a prevalence of approximately 6 percent; Africa has the highest prevalence of about 10.5 percent.^{5,6} In Africa and Asia, where most maternal deaths occur, PPH accounts for more than 30 percent of all maternal deaths.⁷

The maternal health status in Kenya is similar to that of many SSA countries. In addition to PPH, the most common causes of maternal deaths in Kenya include hypertensive disorders such as PE/E, ruptured uterus/obstructed labor and severe anemia. According to the latest Demographic and Health Survey, while children under five mortality rates have decreased, maternal mortality increased from 414 deaths per 100,000 live births in 2003 to 488 deaths per 100,000 live births in 2008 and there was little progress in reducing neonatal mortality (33 to 31 per 1,000 live births).⁸ Only 48 percent of births occur in health facilities and 58 percent of births are not attended by a skilled health provider.⁹ Additionally, in spite of the critical role of emergency obstetric care, very few facilities in Kenya are adequately equipped to offer this service.¹⁰

Maternal health medicines used to prevent and treat the two leading causes of maternal death worldwide such as excessive bleeding after childbirth and high blood pressure during pregnancy include oxytocin, misoprostol, and MgSO₄. AMTSL has been promoted in developing countries to reduce PPH. The principal components of AMTSL include–

³ Lozano, R., H. Wang, K.J. Foreman, J.K. Rajaratnam, M. Naghavi, J.R. Marcus, L. Dwyer-Lindgren, K.T. Lofgren, D. Phillips, C. Atkinson, A.D. Lopez, and C.J. Murray, *Progress towards Millennium Development Goals 4 and 5 on maternal and child mortality: an updated systematic analysis*. *Lancet*. **378**(9797): p. 1139-65.

⁴ Friberg, I.K., M.V. Kinney, J.E. Lawn, K.J. Kerber, M.O. Odubanjo, A.M. Bergh, N. Walker, E. Weissman, M. Chopra, R.E. Black, H. Axelson, B. Cohen, H. Coovadia, R. Diab, and F. Nkrumah, *Sub-Saharan Africa's mothers, newborns, and children: how many lives could be saved with targeted health interventions?* *PLoS Med*. **7**(6): p. e1000295.

⁵ Khan, K.S., D. Wojdyla, L. Say, A.M. Gulmezoglu, and P.F. Van Look, *WHO analysis of causes of maternal death: a systematic review*. *Lancet*, 2006. **367**(9516): p. 1066-74.

⁶ Carroli, G., C. Cuesta, E. Abalos, and A.M. Gulmezoglu, *Epidemiology of postpartum haemorrhage: a systematic review*. *Best Pract Res Clin Obstet Gynaecol*, 2008. **22**(6): p. 999-1012.

⁷ Khan, K.S. 2006. WHO analysis.

⁸ Kenya National Bureau of Statistics (KNBS) and ICF Macro, *Kenya Demographic and Health Survey 2008-09*. Calverton, Maryland: KNBS and ICF Macro. 2010.

⁹ Kagama, F., J. Ricca, B. Rawlins, et al. *Quality of Care for Prevention and Management of Common Maternal and Newborn Complications: Findings from a National Health Facility Survey in Kenya*. MCHIP. 2012.

¹⁰ Ziraba, A.K., S. Mills, N. Madise, T. Saliku, and J.C. Fotso, *The state of emergency obstetric care services in Nairobi informal settlements and environs: results from a maternity health facility survey*. *BMC Health Serv Res*, 2009. **9**: p. 46.

- Administration of a uterotonic (preferably oxytocin) one minute after delivery
- Controlled cord traction
- Uterine massage following delivery of the placenta

WHO recommends oxytocin as the drug of choice for prevention and management of PPH with an alternative being misoprostol where storage conditions or skilled birth attendants are not available. WHO also recommends MgSO₄ as the drug of choice for the management of PE/E. Despite the recognition of the importance of oxytocin, misoprostol and MgSO₄ there is a lack of knowledge of treatment and clinical guidance and poor supply chain management of these medicines which can negatively impact interventions to reduce maternal deaths at the facility level.

Supply Chain Management System for Medicines and Supplies

Health Policy Landscape

Kenya's current health care system is anchored on the Health Sector Policy Framework of 1994 and the subsequent National Health Sector Strategic Plans (NHSSP) 1999–2004 and 2005–2010. The KHPF aims to ensure equitable allocation of government of Kenya's resources to reduce disparities in health status; increase cost-effectiveness and efficiency of resource allocation and use; manage population growth; enhance the regulatory role of the government in health care provision; create an enabling environment for increased private sector and community involvement in service provision and financing; and increase and diversify per capita financial flows to the health sector.¹¹ The framework is being put into operation by the NHSSP. While NHSSP I (1999–2004) focused on decreasing the burden of disease, NHSSP II (2005–2010) shifted focus to promoting healthy lifestyles of individuals and community health. Specifically, NHSSP II introduced the Kenya Essential Package for Health (KEPH) which aims to provide comprehensive, integrated curative and preventive health services in each of the life phases.

In recent years, the Government of Kenya has made reproductive, maternal, neonatal and child health priority and has developed and implemented policies and strategic plans to meet the MDGs 4 and 5 which aim to reduce child mortality and improve maternal health. In 2010, the ministries of health launched the National MNH Road Map to accelerate the reduction of maternal and newborn morbidity and mortality to achieve the MDGs 4 and 5.¹² Key strategies of the Road Map include improving availability of, access to, and utilization of quality maternal and newborn health care and family planning options, increasing commitment to MNH resources, strengthening community based approaches for MNH, and strengthening the referral system, monitoring and evaluation system and operations research. These strategies have also incorporated in the National Reproductive Health Strategy (2010–2015).

The Health Policy & Financing Strategy, which advocates for a health care financing strategy, that provides free health care for pregnant women and children less than five years old, is being finalized. In addition, performance-based financing is also being considered as an option in the

¹¹ MOH, *National Health Policy Framework 2011 – 2030 Creating Wealth Through Health*. 2011: Nairobi.

¹² MOPHS. 2010. Road map.

draft financing strategy as well as a referral mechanism for the community to be included as part of health care financing. Overall the reproductive health policy environment in Kenya is firmly grounded on the new constitution. All these policies are intended to guide the implementation of strategic interventions related to the achievement of MDGs 4 and 5.

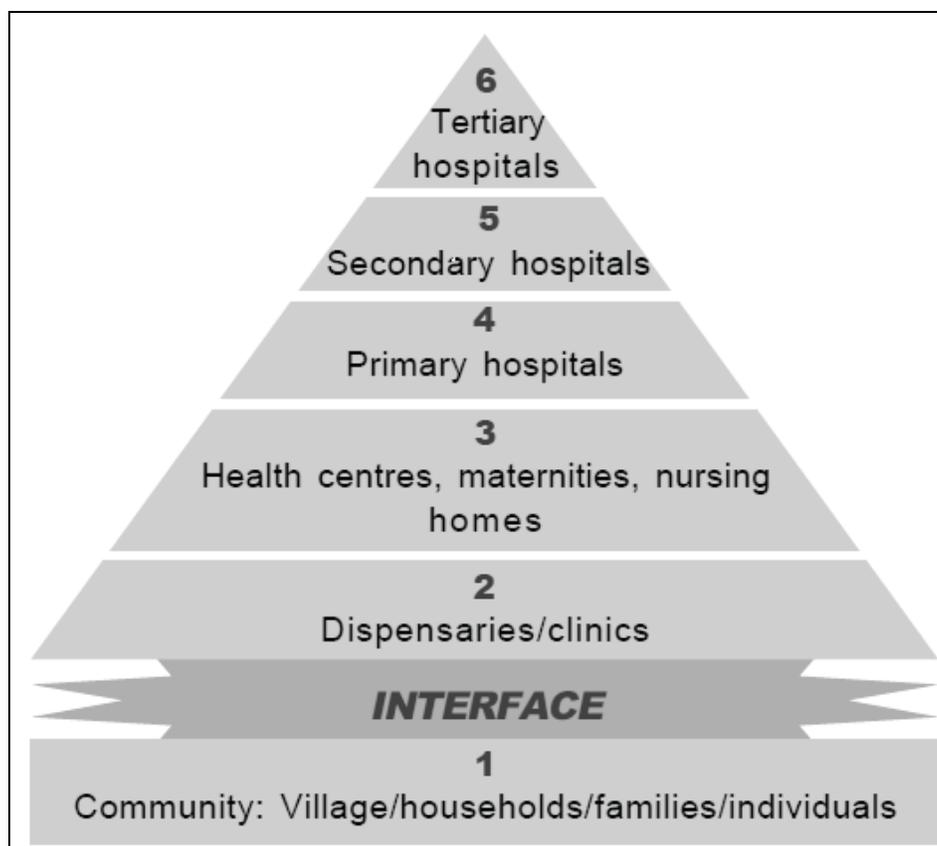
Currently, Kenya is in the process of reviewing the drug policy in the Kenya National Pharmaceutical Policy (KNPP), the official National Medicines Policy document updated in 2010.¹³ This Policy has been developed in the context of Kenya's Vision 2030, the Health Policy Framework and the relevant health sector strategic plans. The policy provides for broad restructuring of pharmaceutical governance structures, including the necessary de-linking, upgrading and decentralization, for better responsiveness to current and future demands. It further outlines the health and development goals; objectives and targets; and key strategies to guide its implementation.¹⁴

Health System in Kenya

The KEPH classifies health facilities into six levels of service delivery and delineates the health services to be provided at each level of care and at each life-cycle cohort: pregnancy, delivery and newborn (two weeks), early childhood (0–5 years), late childhood (6–12 years), adolescence and youth (13–24 years), adulthood (25–59 years), and elderly (60+ years). As shown in Figure 1, the six levels of care are hospitals (levels 4–6), health centers, maternity homes, nursing homes (level 3), dispensaries, clinics (level 2) and community, such as villages, households and individuals (level 1). Tertiary or national hospitals provide highly specialized services, while provincial hospitals provide specialized care and receive referrals from district hospitals. The district hospitals concentrate on delivery of health care services at the district level and the health centers provide mainly preventive and curative services. The dispensaries are the first line of contact with patients and provide preventive health measures.

¹³ Republic of Kenya, *Sessional Paper on National Pharmaceutical Policy: Reforming the pharmaceutical sector to ensure equitable access to Essential Medicines and essential health technologies for all Kenyans*. 2010.

¹⁴ Republic of Kenya. 2010. Sessional paper.



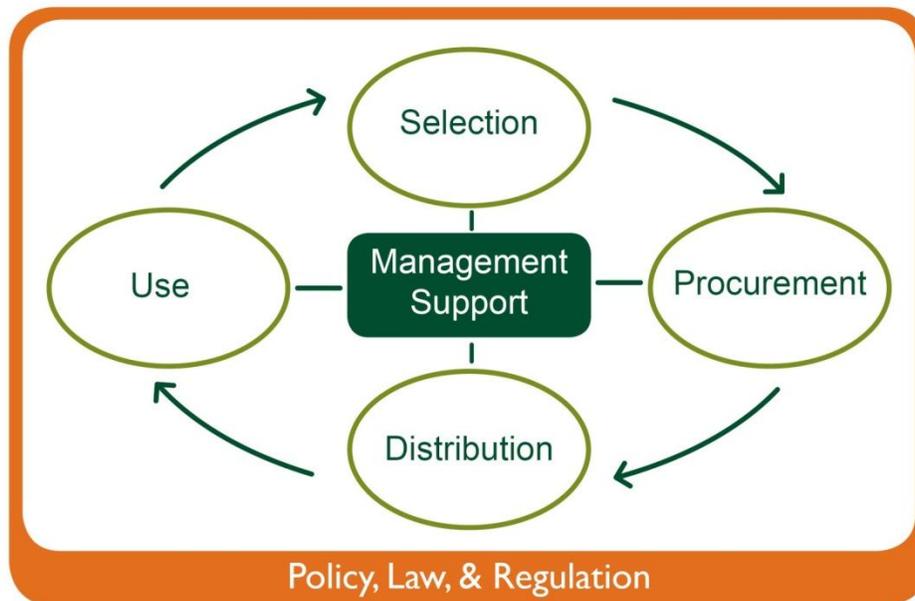
(Source MoH, Kenya)

Figure 1. Levels of service delivery within the KEPH

In 2008, the MoH was split into two separate ministries— the Ministry of Medical Services (MOMS) and the Ministry of Public Health and Sanitation (MOPHS). Under this structure, MOMS is responsible for service delivery levels 4–6 and MOPHS is responsible for primary health care facilities (levels 1–3). MOPHS’s major function is to provide primary health care services and for maternal health these include antenatal care, delivery care, postnatal care and family planning. Due to the separation of services between the two ministries, there are separate management teams at different levels of care. At the provincial level (district and sub-districts), management of MOPHS services is done by the Provincial Health Management Team while MOMS services are managed by the Provincial Medical Services Management Team. Additionally, as part of Kenya’s decentralization strategy, districts are also responsible for providing health services. As a result there are separate management teams at the district level; district hospitals are managed by District Medical Service Teams while District Health Management Teams provides management and supervision support to rural health facilities (sub-district hospitals, health centers, and dispensaries).

Pharmaceutical Management System

Figure 2 below outlines the components of the pharmaceutical management cycle. This cycle begins with product selection. Once products are selected, they are then procured and distributed throughout the system. Finally, products are dispensed and used. Each step in the cycle requires management support and occurs in a policy and regulatory environment that promotes the equitable supply of quality products.



(Source MSH)

Figure 2. Components of the Pharmaceutical Management Cycle (Source MSH)

Selection

Three elements are important in understanding the selection of pharmaceutical products including MNH supplies. This includes the availability and use of essential medicines list(s) (EML); procedures for updating the EML; and the EML content. Kenya has developed and printed four EMLs since in 1989; and the latest in 2010. The EML is based on national standard clinical guidelines (SCGs) and identifies medicines by level of care as defined in the KEPH.¹⁵ In terms of production, Kenya is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa region, supplying about 50 percent of the regions' market. It is approximated that about 9,000 pharmaceutical products are registered for sale in Kenya.

¹⁵ Luoma, M., J. Doherty, S. Muchiri, et al. *Kenya Health System Assessment 2010*. Bethesda, MD: Health Systems 20/20 project, Abt Associates Inc. 2010.

Procurement

Medicines procurement for the public sector is undertaken by Kenya Medical Supplies Agency (KEMSA). KEMSA was established in 2001 as a state corporation to improve availability of medicines and supplies. Previously, the MoH procured medical supplies and equipment. But, following recommendations from the KEMSA Task Force in October 2008, procurement of both medicines and supplies (pharmaceuticals) was handed over to KEMSA to improve both efficiency and coordinate supply chain activities. The agency is mandated to manage procurement, warehousing and distribution for the public sector healthcare supply chain. It is the largest purchaser of medicines in the country and distributes them to public medical institutions. The tendering system for medicines is open to both local and foreign manufacturers and distributors. KEMSA gets its funding through an annual budget from the MoH treasury for medicines and medical supplies based on an estimate of public sector health delivery requirements. KEMSA procurement is through both the open national tender and the open international tender; the choice of the tender methods depends on the estimated value of the procurement. Procurement is done annually and is based on the annual budgets, limiting on how much each facilities can procure from KEMSA.

Quantification of needs is largely determined by the pharmacy departments and is based on historical procurement and issues data. It may also take into account the targets from the Department of Reproductive Health (DRH) and Department of Obstetrics and Gynecology. MNH commodities are quantified along with the other essential medicines. If facilities require more than what is included in their budget it is not uncommon for the facilities to procure medicines from other sources such as the Mission for Essential Drugs and Supplies (MEDS) and private wholesalers. MEDS procures medicines and sells them to not-for-profit facilities, mainly faith-based organizations while private wholesalers sell mainly to private, for-profit facilities. While it is a challenge to quantify what effect MEDS has on the pharmaceutical market, MEDS has led to other suppliers offering medicines at more reasonable prices.

Procurement of medicines is strictly regulated by the Pharmacy and Poisons Board (PPB) to ensure the quality of the medicines. PPB is also responsible for the registration of all drugs in the country and MEDS can only procure drugs approved by the Board. Only registered products can be sold in both the public and private sectors and samples are sent to the national quality labs to ensure the quality of the medicines. MEDS is further regulated by the PPB and must adhere to the rules and regulations that govern the pharmaceutical sector. For example, while MEDS has its own quality assurance mechanism, this system must be approved by the government. Routine checks are conducted in both the public and private sectors to ensure that rules, regulations, and quality assurance mechanisms are being followed.

Distribution

Until 2005, distribution of pharmaceuticals in Kenya was largely managed through a push system where a central authority orders medicines from suppliers and determines the quantities that will be shipped to the health facilities. In 2005, after a pilot pull system (health facilities order from a warehouse or supplier according to local determination of needs) was successfully introduced in two provinces (Coast and North Eastern), with support from the Danish Agency for

Development Assistance, the ministries began to roll-out the pull system to all the hospitals (KEPH levels 4 and 5).¹⁶ Currently, there are two distribution systems operating however Kenya is in the process of phasing out the push system and transitioning into the pull system where districts and lower level facilities quantify their needs and obtain medicines from the central level. While most of the facilities at each level have officially transitioned, a few still operate under the push system. KEMSA outsources transportation of deliveries in about 90 percent of cases. In addition it has also entered into some arrangements with development partners (like UNICEF) to ensure distribution of goods procured by development partners.¹⁷ Over the years, KEMSA has implemented a centralized supply chain network and established scheduled deliveries to all of its 4,001 customers through this transport system. Hospitals are resupplied very two months while rural health facilities are resupplied every three months. However, the frequency of resupply is likely to be revised in due course so as to have all health facilities resupplied at the same frequency.

Managing stock during transportation as well as storage of the medicines in warehouses and at the facility levels are still challenging. For example, a study conducted in 2009 showed that all KEMSA warehouses and depots have functional temperature-controlled storage with sufficient capacity, but there were many of the lower level facilities (KEPH levels 2 and 3) that do not have sufficient cold storage. Most of these facilities store medicines in refrigerators intended for vaccines. Additionally, the outsourced transportation vehicles are not fitted with equipment to maintain the cold chain, so products that require cold chain are transported in cold boxes by courier.¹⁸ This is a concern as some maternal health medicines, such as oxytocin and ergometrine, require cold chain storage to maintain their potency.

Use

Appropriate use of medicines can be assessed using indicators such as functioning mechanisms and tools for improving medicines in health facilities and availability of SCGs and their use. The three-volume National Clinical Guidelines were developed in line with the KEPH. Volume I is for use at the community level, Volume II targets levels 2 and 3 facilities, while Volume III is for hospitals (levels 4 to 6). These guidelines also guide the development of the NEML. However, availability and use of these essential tools is poor. Studies have found that although the SCG has been produced, their use by health care workers has been limited due to inadequate dissemination and supply of the SCGs.¹⁹ Additionally, limited human resources also affect the availability and use of essential medicines. Although the number of pharmaceutical personnel (pharmacists and pharmaceutical technologists) has increased with time, they are still insufficient relative to the population in need.²⁰ In addition, these personnel are inequitably distributed across the country with the majority concentrated in the private sector and in urban areas.

In 2010, USAID's MCHIP conducted a quality of care assessment in eight provinces in Kenya. The study found that 57 percent of facilities had all the essential supplies for delivery and only 20 percent had all the elements to support high quality of care during delivery which includes

¹⁶ Louma, 2010. Kenya health system assessment.

¹⁷ Louma, 2010. Kenya health system assessment.

¹⁸ Louma, 2010. Kenya health system assessment.

¹⁹ Louma, 2010. Kenya health system assessment.

²⁰ MOMS. 2008. *Kenya National Pharmaceutical Policy*.

guidelines, standards, partograph, and 24-hour staff. Only 50 percent of women received AMTSL according to standards and only some mothers with severe PE/E received MgSO₄ and/or diazepam.²¹ Improving the quality of facility-based health care and expanding access to essential maternal health medicines to prevent and treat maternal complications is crucial for the reduction of maternal deaths.²²

Objectives

This assessment sought to answer three main questions.

- What is the current availability of MH pharmaceuticals in the medical stores and at the health facilities?
- What are the problems, in terms of the organization and function of the pharmaceutical supply system, in assuring the availability of MH pharmaceuticals?
- What interventions can be implemented to help address the problems identified during the assessment and improve the availability and management of the MH pharmaceuticals?

To address these questions the study sought specifically to–

- Identify the supply sources of MH pharmaceuticals in health facilities
- Determine the availability of MH pharmaceuticals during the interviewer’s visit and for the year prior to the visit
- Describe the storage conditions of MH pharmaceuticals
- Identify obstacles to the application of standards and procedures for managing medicines
- Make suggestions for improving the practices of availability and use of emergency obstetric medicines in maternity hospitals

²¹ MCHIP. 2012. Quality of care survey, Kenya.

²² Wagstaff, A. and M. Claeson. 2004. *The Millennium Development Goals for Health: Rising to the Challenges*, World Bank.

METHODOLOGY

This was a cross-sectional, descriptive study aimed at determining the availability, management and use of the MH pharmaceuticals in selected sites in Kenya. A rapid assessment was conducted by the SPS and HCSM programs of health facilities, health care providers and pharmaceutical managers. Methods used included direct observation, record reviews and structured questionnaires.

Sampling

The study was conducted in five counties that were selected by the DRH of the MoH of Kenya: Kakamega, Kirinyaga, Kwale, Nairobi, and Turkana. Selection was based on maternal mortality rates with a focus on counties with high maternal mortality. The selection also took into consideration varying geographical areas, poverty levels, and demographic profiles of the various parts of the country. A mix of rural and urban settings was also inbuilt into the assessment. All counties, except Nairobi, have a largely rural population and all counties, except Kirinyaga, have high maternal and neonatal mortality rates.

In each county, it was initially planned that samples would be taken of at least 10 health facilities to reflect the types and level of providers offering MNH services. The sampling of facilities was designed to reflect care given at various levels (dispensary, health center, and hospital) and a mix of public and faith-based (private sector) health facilities. Because of the limited timeframe for this assessment (5 days), rough terrain and vast distances that needed to be covered between facilities within Turkana County, data collectors were able to sample only eight facilities (table 1).

Table 1. Key Demographics of Study Sites

County	Total population	Rural population, %	Health expenditure per person (Ksh)	Health facilities sampled
Kakamega	1,660,651	84.8	524	11
Kirinyaga	528,054	84.2	835	10
Kwale	649,931	81.9	1620	10
Nairobi	3,138,369	0	655	10
Turkana	855,399	85.8	17625	8

(Source MoH, Kenya)

Private sector facilities sampled in this assessment have been categorized based on the Kenya's master health facility list. While faith-based health facilities (Mission) are considered to be private sector facilities, they tend to be private in terms of ownership but are largely dependent on the government for a number of pharmaceuticals. This assessment will refer to faith-based or mission facilities as private sector facilities.

Pharmaceutical managers (medical officers, clinical officers in charge, and pharmacist/medical store managers) were interviewed at each facility to assess knowledge and implementation of

pharmaceutical management practices for maternal health medicines such as storage and inventory management and supervision and training. In additions, delivery room managers (physicians, nurse, or clinical officer) working in the health facilities' maternity units were interviewed.

Selection of Tracer Medicines

A short list of tracer medicines and supplies essential for maternal (specifically for PE/E and PPH) and newborn health was developed to focus the data collection on availability and management. While the focus of the assessment was specifically on maternal health commodities, DRH also requested that medicines to treat neonatal sepsis and asphyxia be included to roughly assess the availability of these essential neonatal medicines.

The table below provides the comprehensive list of the tracer medicines for this assessment. The tracer medicines were selected from the 2010 national clinical guidelines and the 2002 Standards for Maternal Care and all are included in the NEML.

Table 2. Tracer Drugs Selected for the Assessment

Condition	Drug group	Tracer drug/dosage forms
Maternal health		
PE/E	Anticonvulsant (parenteral)	<ul style="list-style-type: none"> • MgSO₄: injection 500 mg/ml in a 10-ml ampoule • Calcium gluconate: injection (for treatment of magnesium toxicity): 100 mg/ml in a 10 ml ampoule • Diazepam 5 mg • Diazepam 5 mg/ in 2 ml
	Anti-hypertensives	<ul style="list-style-type: none"> • Methyldopa 250 mg • Methyldopa 500 mg • Hydralazine (HCl) 20 mg in 2 ml • Nifedipine 10 mg
PPH	Oxytocics	<ul style="list-style-type: none"> • Oxytocin 10 IU/ ml in 1 ml • Ergometrine (hydrogen maleate) 200 micrograms/ml • Misoprostol 200 micrograms • Misoprostol 25 micrograms
	Supplies	<ul style="list-style-type: none"> • Dipstix (urine tests) for PE/E
Newborn health		
Neonatal sepsis	Antibiotics (broad spectrum) for IV/IM and oral administration	<ul style="list-style-type: none"> • Ampicillin powder for injection 500 mg; 1 g (as a sodium salt) in vial • Gentamicin injection 10 mg/ ml in 2 ml • Gentamicin 40 mg /ml in a 2 ml vial • Metronidazole injection 500 mg in a 100-ml vial • Tetracycline eye ointment 1 percent (eye infection) • Chlorhexidine 5 percent for dilution (liters; cord care)
Asphyxia/ apnea		<ul style="list-style-type: none"> • Caffeine citrate, liquid 20 mg/ml

Data Collection Methods and Tools

Six forms were developed to collect data on storage and inventory management, knowledge and practices of health care providers, and availability of MNH medicines through direct observation, record reviews and questionnaires.

Direct Observation Form: Storage and Inventory Management

The direct observation form was used to record the observations of the conditions within the storage area for medicines at a medical store, warehouse or health facility. The direct observation form was essentially a check list to determine whether proper storage practices were being followed, such as sufficient storage space in the storage area; products protected from direct light; identification labels and expiry dates facing forward; first expiry, first out (FEFO) procedures being followed; and cold chain being maintenance, among others.

Inventory Data Form

The inventory data form collects information on the inventory management of the selected tracer medicines. The physical inventory and review of stock records serve as a “single point in time” and was carried out by examining the bin card and the stock card records of each tracer medicine item in stock. Information on existing inventory control systems (computerized or a manual system) was also recorded for each facility. Stock on hand was manually counted to check that the stock balance records were correct. The goal was to assess whether the facilities have been managing the supply of MNH medicines effectively by examining the differences between medicines received, entered into the system and those that have been used as well as amount of non-expired stock.

Stock-Out Data Form

This form provides information on the availability of the tracer medicines. The number of days of stock-out for each tracer medicine was recorded for each month in the 12-month period prior to the assessment. This information was recorded from the individual facility’s existing inventory-recording system (computer, ledger, or bin cards) and the number of days each tracer drug was recorded out of stock.

Structured Questionnaires

Medical Stores and Health Facility Pharmacies

Pharmacy store managers are defined as providers who are in charge of the pharmacy. They include pharmacists and pharmacy technicians. Facility managers are those charged with managing facilities on a daily basis. They include medical officers, clinical officers and nurses. Managers of medical stores and health facilities were interviewed to assess their knowledge and practices regarding storage, ordering, distribution and stock management, and report submission. Additionally, information on access to and needs for supervision, training and tools was also collected.

Delivery Room Managers

Delivery room managers, which include physicians, midwives, obstetric nurses and matrons and who normally provide services in the delivery rooms, were interviewed. The aim was to assess their knowledge and practices regarding MNH medicines and their use, how they manage stocks of MNH medicines as well as supervision, training and management aspects. Additionally, the questionnaire for delivery room managers collected some information on financing (i.e. costs to women for delivery and treatment). Additionally, information of supervisory visits and access to training and management tools was also collected.

Data Collectors' Training

Fifteen research assistants (RA) were involved in the study. These formed five data collection teams consisting of a team leader and four data collectors. The team leaders were mainly pharmacists who have experience working in the country and prior experience conducting similar surveys in Kenya. The other four members of the team were selected on basis of their previous experience in similar surveys. The research team participated in a four-day in-house training, which involved plenary sessions in which the content of the tool and the rationale behind each question were discussed. On the last day of the training there was a pilot data collection exercise in facilities that were not involved in the survey. The pilot exercise provided a chance for the data collectors and research teams to learn vital lessons ahead of the actual data collection exercise. The training was conducted by two SPS/HCSM staff with prior experience in facility surveys and maternal health. At the end of the training, the team was taken through the logistics of the exercise including the sampling procedures, the number of interviews to be conducted by each RA and who was supposed to be interviewed at each level (annex 1).

Data Analysis

Questionnaires and check lists were used to capture quantitative data. Data from the data collection tools were entered into Epidata 3.1 then transferred to Excel for analysis. Cleaning of data entailed running frequencies and correcting inconsistencies during the analysis. The data was analyzed at two levels— public versus private and between three health care levels (dispensary, health center, and hospital).

Ethical Issues

The study was approved by both the DRH and the directors of both MOMS and MOPHS. No ethical clearance was needed as since this was an operation research that examined facilities that are within the mandate of both ministries at various levels. Additionally, in each district, consent was given by the District Medical Officer of Health to work in their respective jurisdiction. All interviews were undertaken with the consent of participants and were carried out in locations and times that were convenient for them. The study team made every effort to protect the privacy and maintained the confidentiality of all the information provided. No respondents' name or other identifiers were included in reports from this study.

RESULTS

Characteristics of Respondents

A total of 49 facilities were sampled (annex 2). Of these facilities, 31 (63 percent) were from the public sector and 18 (37 percent) were in the private sector. Private sector facilities included Mission or Faith Based and non-profit health facilities. The majority of the health facilities (55 percent) are level 3 health facilities or health centers while 33 percent and 12 percent are hospitals and dispensaries (levels 4 and 2). The table below provides the breakdown of the facilities sampled by sector and health care level.

Table 3. Sampled Health Facilities

Public	Private	Dispensary	Health center	Hospital	Total
31	18	6	27	16	49
63 percent	37 percent	12 percent	55 percent	33 percent	

At each facility, the pharmacy store manager and the delivery room manager were interviewed to assess their knowledge and reported practices for pharmaceutical management of maternal health commodities. Pharmacy store managers were mostly pharmacy technicians/ nurses (69 percent) and pharmacists (27 percent). Overall, 51 percent of the respondents had between 1 and 5 years of experience in their position; 16 percent had more than 5 years of experience in their current position and 31 percent had been in their position for 0–6 months. Public sector pharmacy store managers are mostly pharmacy technicians (68 percent) and 29 percent are pharmacists compared to 22 percent and 72 percent of the respondents from private sector.

Delivery room managers were mostly midwives and matrons (57 percent and 18 percent). The majority of the respondents from the public sector are midwives (65 percent) versus 44 percent of private sector respondents. The other respondents were either nurses or matrons; only three respondents were clinical officers.

As shown in table 4, below, the majority of pharmacy store and delivery room respondents were pharmacy technicians and midwives at each health facility level. While there was more of an equal distribution at the hospital level, respondents from the health center level were predominantly pharmacy technicians (67 percent) and midwives (70 percent).

Table 4. Profile of Pharmacy Store Managers and Delivery Room Managers

Position	Overall, % (n=49)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=18)
Pharmacy store managers				
Pharmacist	27	0	26	38
Physician	2	0	4	0
Pharmacy technician	69	100	67	63
Procurement manager	2	0	4	0
Delivery room managers				
Midwife	57	67	70	31
Matron	18	0	19	25
Clinical officer	6	0	0	19
Nurse	18	33	11	25

Education Levels

Education levels assessed during the assessment include secondary, certificate, diploma, degree and higher. Secondary level education, the next level after primary school education continues to grade four and right before university. Certificates and diplomas are awarded to two to three-year college graduates who are given specific, vocational training; diplomas require more training and are higher than the certificate level. Those given certificates include enrolled nurses while registered nurses or clinical officers usually have diplomas. Those possessing a degree or higher have the highest level of training such as physicians and pharmacists. In terms of qualification, those with at least a diploma or degree would be more suited to be managers.

Overall, more than 60 percent of pharmacy store managers and delivery room managers had a diploma and 16 percent and 6 percent, respectively, had a degree or higher. There is a slight difference in education level between the public and private sector among the pharmacy store managers— 81 percent in the public sector compared to 78 percent in private sector had at least a diploma. However, there is a larger difference in education level between the sectors for delivery room managers. Slightly over 80 percent of delivery room managers sampled have at least a diploma while only 67 percent in the private sector have a diploma or higher. Figure 3 shows the differences in education levels of respondents from health centers and hospitals.

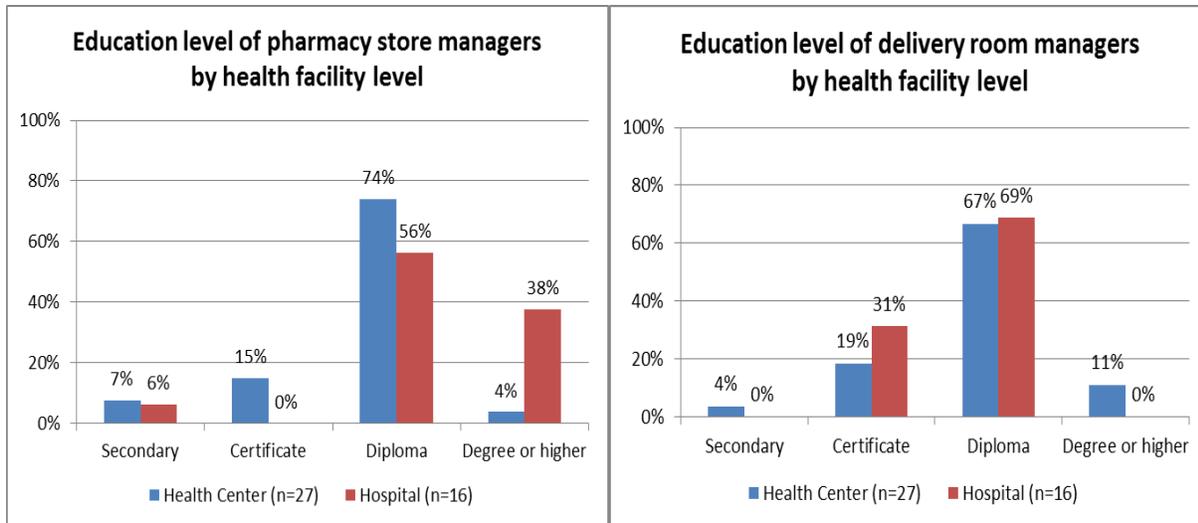


Figure 3. Education levels of pharmacy store and delivery room managers sampled

Training

Inventory management skills are needed to manage stores but these skills are sometimes not imparted during pre-service training for physicians, pharmacists, nurses and clinical officers. Only 29 percent of pharmaceutical managers had been trained on general pharmaceutical management in the last 12 months. For maternal health commodities, only 8 percent of pharmaceutical managers and 29 percent of delivery room managers were trained on the management and use of medicines for obstetric emergencies in the last 12 months prior to the assessment. Training was extremely low in both the public and private sector and all health facility levels. None of the six delivery room managers (midwives and nurses) from the dispensaries received training on the management and use of medicines used for obstetric emergencies.

Selection

Appropriate selection of medicines for use in the health system involves “reviewing the prevalent health problems, identifying treatments of choice, choosing individual drugs and dosage forms, and deciding which drugs will be available at each level of care”.²³ This assessment focused on essential maternal health commodities and selected tracer medicines and supplies in close coordination with the DRH for the prevention and treatment of PPH and PE/E, the two leading causes of maternal deaths (table 2). All medicines are included in the NEML and registered in the country. Neonatal medicines for the treatment of neonatal sepsis and asphyxia were included to gauge information on the availability of these essential neonatal medicines.

²³ Management Sciences for Health. 2012. *MDS 3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health.

With the support of WHO, MOMS and MOPHS updated the 2002 clinical guidelines in 2009 to be more aligned with the changes introduced in the second NHSSP-II (2005-2010) and the KEPH, which emphasizes district levels of care. Likewise, the national EML was also updated to be in line with the SCG. In regards to maternal health services, table 5 shows the maternal health services that should be available at each level of care as delineated by the KEPH. While all deliveries must be referred to hospitals, health centers should be equipped to provide basic obstetric and newborn care.

Table 5. Maternal Health Services at the Different Health Care Levels

Level of care	Health services
1 Community	Community health workers and community health extension workers Equip targeted communities with current knowledge and facilitate appropriate practices and attitudes leading to safe pregnancy and delivery of a healthy newborn
2 Dispensary/ clinic	<ul style="list-style-type: none"> • Basic prenatal care • Refer all hypertensive disorder cases to the hospital • Refer all deliveries (regardless of risk) to the hospital
3 Health center	<ul style="list-style-type: none"> • Basic essential obstetric care • Delivery of quality obstetric and newborn care • Functional supportive supervision system • Outreach programs to serve “hard to reach” populations
4-6 Primary/district/sub-district hospital	Essential comprehensive obstetric care
Secondary/ provincial hospital	<ul style="list-style-type: none"> • Administer IV antibiotics, MgSO₄, and parental oxytocics • Perform manual removal of the placenta, removal of retained products and assisted vaginal delivery (e.g. by vacuum extraction)
Tertiary/ national hospital	<ul style="list-style-type: none"> • Perform newborn resuscitation • Perform surgery (cesarean section) and blood transfusion
	Ensure facilities are adequately equipped to manage mothers and newborns referred from lower levels (Level 6)

The 2009 SCGs and the 2010 NEML were reviewed to determine the treatment guidelines for maternal and neonatal health and determine at which health care levels the medicines should be available. The SCG and NEML are often contradictory and are not aligned with the WHO recommendations and WHO EML, especially for PPH. Specifically, the review found the following–

1. **PE/E.** The 2009 SCGs indicate that all cases of PE should be referred to higher level facilities (hospitals). Eclampsia (as well as convulsions) should be treated at both the health center and hospital levels; MgSO₄ is the first medicine of choice and diazepam is the second-line treatment. At hospitals, hydralazine is the first medicine of choice for controlling blood pressure and nifedipine should be given if the patient is allergic. The NEML indicates that MgSO₄ should be available at health centers and hospitals while diazepam, used as an anticonvulsant, should be available at all three health facility levels.

Calcium gluconate, however, should only be available at hospitals as well as the recommended antihypertensive medicines (hydralazine, methyldopa, and nifedipine).

2. **PPH.** The 2009 SCGs indicate that all cases of PPH should be referred to the hospital. Oxytocin is the first-line treatment for the prevention and treatment of PPH; if not available, the second-line treatment is either ergometrine or misoprostol. Despite the SCGs, the NEML indicates that while oxytocin should be available at all three health care levels, ergometrine and misoprostol should only be available at hospitals. Additionally, the NEML indicates that misoprostol (200 micrograms [mcg] and 25 mcg) is restricted for specialist use in incomplete abortion and miscarriage. As the government continues to phase out the use of ergometrine for PPH, the use of misoprostol for the prevention and treatment of PPH as the second-line treatment should be clarified.
3. **Neonatal sepsis.** All cases of neonatal sepsis must be referred to the hospital level and treated with penicillin and gentamicin. Tetracycline eye ointment is given to prevent eye infection, which is common during the first month, and application of chlorhexidine to the cord to prevent infection is recommended. Since ampicillin is used more often than penicillin for neonatal sepsis, it was included on the tracer list instead. All recommended medicines for neonatal sepsis except for ampicillin should be available at all three health care levels while ampicillin should only be available at hospitals. Chlorhexidine should be available at all levels. Also, tetracycline is not included in the 2010 NEML.
4. **Asphyxia/apnea (preterm births).** For resuscitation of premature newborns, caffeine citrate is the recommended treatment. All cases must be referred to hospitals and the medicine should only be available at hospitals, specifically district hospitals (level 5) or higher.

Table 6. Availability of Tracer Medicines at the Different Health Facility Levels

Medicine	Health facility level		
	Dispensary	Health center	Hospital
PE/E			
MgSO ₄ 500 mg/ml in a 10 ml ampoule		x	x
Calcium gluconate 100 mg/ml in a 10 ml ampoule			x
Diazepam 5mg/ in 2 ml (anticonvulsant)	x	x	x
Antihypertensives			
Methyldopa 250 mg			x
Methyldopa 500 mg			
Hydralazine (HCl) 20 mg in 2 ml			x
Nifedipine 10 mg			x
PPH			
Oxytocin 10 IU/ml in 1 ml	x	x	x
Ergometrine (hydrogen maleate, 200 mcg/ml)			x
Misoprostol 200 mcg			x
Misoprostol 25 mcg			x
Neonatal sepsis			
Ampicillin powder for injection, 500 mg; 1 g (as a sodium salt) in vial			x
Metronidazole injection 500 mg in a 100 ml vial	x	x	x

Medicine	Health facility level		
	Dispensary	Health center	Hospital
Gentamicin injection 10 mg/ml in 2 ml	x	x	x
Gentamicin injection 40 mg/ml in 2 ml	x	x	x
Tetracycline eye ointment 1 percent			
Chlorhexidine 5 percent for dilution (count in liters) (cord care)	x	x	x
Asphyxia/apnea			
Caffeine citrate, liquid 20 mg/ml			x (level 5)

In 2012, the Ministries of Health and DRH recently released the National Guidelines for Quality Obstetric and Perinatal Care (2012) to include updated and evidence-based interventions. These guidelines give further guidance on the prevention and treatment of obstetric and neonatal emergencies. The 2012 guidelines indicate that medicines for the prevention and treatment of PE/E, PPH, and neonatal emergencies (sepsis and asphyxia) should be available at all levels of care (dispensary, health center and hospital). Since this assessment was conducted before the change in the guidelines, availability of tracer drugs will be assessed based on the 2009 guidelines.

Procurement

Procurement of medicines and supplies involves “quantifying drug requirements, selecting procurement methods, managing tenders, establishing contract terms, assuring drug quality and ensuring adherence to contract terms”.²⁴ Through the questionnaire for pharmacy store managers, the assessment sought information on estimating needs for MH commodities and the major sources of supply for essential medicines, assumed to include medicines for PPH and PE/E. Multiple sources of suppliers for essential medicines may indicate challenges in estimating needs or breaks in the distribution cycle, which force facilities to order medicines from other suppliers.

Quantification Methods

The ideal method for estimating the requirements for uterotonics and PE/E medicines is a combination of stock on hand, average monthly consumption, and safety stock. Overall, only 12 percent of pharmacy store managers stated that they take all three into consideration when estimating requirements for PPH and PE/E medicines. Slightly over 30 percent stated they consider stock on hand and average monthly consumption, 14 percent mentioned they consider safety stock, and 37 percent said that they rely on general experience; 10 percent surveyed said that the requirements are determined by the national program.

²⁴ Management Sciences for Health. 2012. MDS 3.

Source of Maternal Health Commodities

For pharmacy store managers, 67 percent indicated that the source of the facility’s essential medicines is KEMSA and 27 percent indicated their source as MEDS. Comparing between sectors (figure 4) shows the differences in the source of supplies between the public and private sector. As expected, the primary source of essential medicines for public health facilities is KEMSA (stated by 90 percent of managers); other sources included MEDS, private wholesalers, private pharmacies and donations. While over 50 percent of the private sector facilities stated MEDS as the primary source of medicines, about 28 percent of private sector managers, all from health centers, indicated KEMSA was their source as well. This is surprising as the process for private sector facilities to procure from KEMSA is long since authorization is required by relevant officials at the ministerial level.

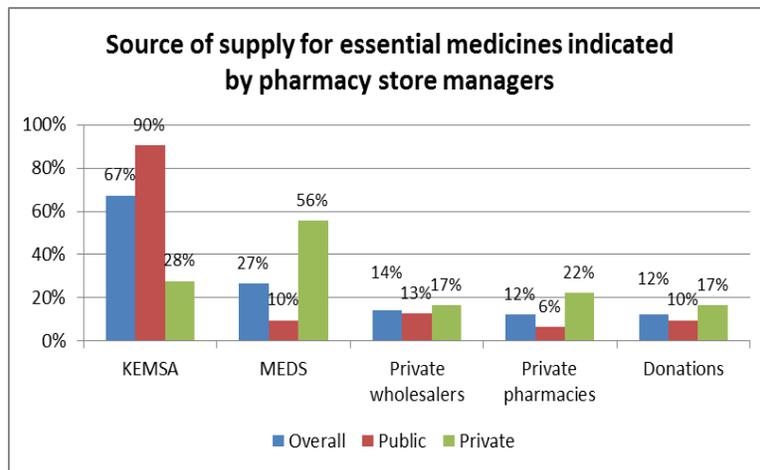


Figure 4. Source of supply for essential medicines by sector

Additionally, comparing the different sources for supply of essential medicines by health facility level (figure 5) the assessment found that multiple sources of essential medicines are common at all levels of the health system. As mentioned earlier, at the time of the survey all hospitals were transitioned to the pull system while the push system continued to operate at the health center and dispensary levels in some of the counties. This may explain the multiple supplies sources identified at the lower two levels; but the fact that hospitals also are relying on multiple sources of supply may indicate challenges in the supply chain.

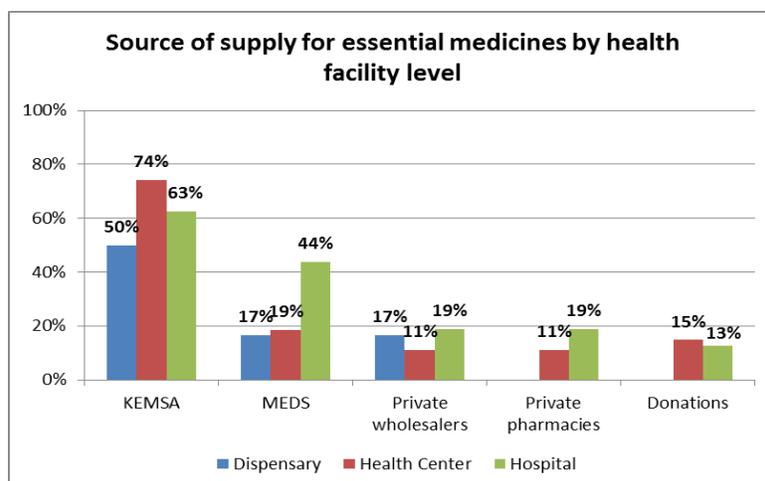


Figure 5. Source of supply for essential medicines by health facility level

Distribution

The goal of the distribution component is to maintain a steady supply of pharmaceuticals and supplies to health facilities. This has four key elements— system type, information system, storage and delivery. To assess the distribution system in Kenya, the assessment focused on the ordering process, inventory management, storage conditions, and the availability of the tracer medicines.

Order Process

Among the pharmacy store managers interviewed, 73 percent stated that they personally manage uterotonics and PE/E medicines. It is assumed that all those interviewed should know the ordering process of medicines.

Responses related to the frequency medicines are ordered were spontaneous responses and many respondents provided multiple answers. Pharmacy store managers reported that uterotonics are ordered either quarterly (33 percent), monthly (29 percent) or when necessary (61 percent). Similarly, 65 percent of pharmacy store managers stated they order PE/E medicines when necessary and 24 percent said they order them quarterly. Eight pharmacy store managers (16 percent) stated that they do not order any PE/E medicines as PE/E is not treated at their facility. Of these, seven of the facilities were health centers (88 percent) where PE/E is supposed to be. Slightly over 30 percent of pharmacy store managers said that orders for uterotonics were incomplete and did not arrive on time. Main reasons for this were central level stock-outs (47 percent) and not issuing the orders on time (33 percent). Table 7 summarizes the reasons cited for orders not being filled on time for both uterotonics and PE/E medicines and compares responses between sector and health facility level.

Table 7. Reasons Cited by Pharmacy Store Managers for Incomplete Orders of PPH and PE/E Medicines

	Overall, % (n=49)	Public, % (n=31)	Private, % (n=18)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=16)
Order filled on time for uterotonics						
Yes	49	42	61	33	41	69
No	31	35	22	17	33	31
NA	12	10	17	33	15	0
Reasons for notfilling orders in time						
Central level stock-outs	47	36	75	100	33	60
Order not issued on time	33	45	0	0	33	40
Other	20	18	25	0	33	0
Order filled on time for PE/E medicines						
Yes	53	42	72	33	44	75
No	20	29	6	17	22	19
Reasons for notfilling orders in time						
Long delivery time	0	0	0	0	0	0
Insufficient quantity received	40	44	0	0	17	100
Central level stock-outs	40	33	100	100	50	0
Order not issued on time	10	11	0	0	50	0
Other	10	11	0	0	17	0

Knowledge of Storage Conditions

Maintaining appropriate storage conditions is essential to assuring the effectiveness of medicines, especially for those medicines that have specific storage conditions such as PPH medicines, oxytocin and ergometrine. When these medicines are not stored properly they lose their effectiveness as the active pharmaceutical ingredient begins to degrade.

Generally, it is recommended that all medicines be kept in secure locations and in a closed box, protected from water, moisture, light and freezing temperatures. The temperature in the storage facility should be monitored and recorded regularly and managers should follow the FEFO rule in which the commodities with the earliest expiry date are issued first, regardless of the order in which they were received. This procedure reduces the risk of having expired products and should especially be used with short-dated products. The majority of the tracer medicines has general storage recommendations, such as store at room temperature, protect from light, and store in a secure place. Some PPH medicines however have specific storage guidelines that are essential to maintaining the potency of the medicine.

In Kenya, it was found that two types of oxytocin requiring different storage conditions are procured based on the level of the health system for which it is being procured. The oxytocin that

does not need refrigeration and requires storage at a temperature not exceeding 30°C is considered more suited for rural health facilities, dispensaries and health centers because in these sites, availability of electricity is not always guaranteed and gas refrigerators are not universally available. The oxytocin procured at the hospital levels requires cold chain storage between 2–8°C. Ergometrine requires cold chain at 2–8°C and must be stored in a box protected from light while misoprostol does not need cold chain but must be protected from moisture, depending on manufacturer packaging. PE/E medicines (MgSO₄, diazepam, and calcium gluconate) can be stored at room temperature (15–30°C) and must follow general storage recommendations.

Pharmacy Store Managers

Over 80 percent of respondents stated that they are familiar with medicines for preventing and treating PPH and PE/E. Of those respondents, 72 percent are familiar with MgSO₄ but only 33 percent stated they are familiar with diazepam, the second-line treatment for PE/E.

Knowledge of general storage guidelines was poor among pharmacy store managers overall. Only 41 percent knew to check manufacturer recommendations and 45 percent were familiar with the FEFO rule. Knowledge on temperature monitoring was poor with only 31 percent of managers aware of it while 57 percent of managers knew to store injectable uterotonics between 2–8°C. When comparing sectors, a larger proportion of private sector pharmacy store managers had knowledge on storage conditions for ergometrine and syntometrine. However, more public sector managers knew of the FEFO rule (48 percent compared to 39 percent among private sector managers). Pharmacy store managers from hospitals had slightly better knowledge of recommended storage conditions except regarding ergometrine and syntometrine. Only 13 percent of hospital pharmacy store managers spontaneously indicated correct storage conditions for these two uterotonics.

Knowledge of maintaining temperatures at 30° C or below when transferring medicines for a short period of time was poor overall (35 percent) however 57 percent of managers knew to maintain cold chain at 2–8° C when transferring medicines. This was higher among the private sector pharmacy store managers (67 percent) compared to the public sector (52 percent) and was lowest among pharmacy store managers from the health centers (48 percent) compared to almost 70 percent of hospital managers (table 9).

Table 8. Pharmacy Store Managers Familiar with General Storage Recommendations for Medicines

Recommended storage guidelines	Overall, % (n=49)	Public, % (n=31)	Private, % (n=18)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=16)
Check manufacturer's recommendations	41	39	44	50	37	44
FEFO Rule	45	48	39	50	41	50
Use temperature monitoring system, regularly	31	29	33	50	26	31
Keep injectable uterotonics between 2-8 °C	57	52	67	50	56	63
Store ergometrine and syntometrine in box	20	16	28	33	22	13

Recommended storage guidelines	Overall, % (n=49)	Public, % (n=31)	Private, % (n=18)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=16)
protected from light and freezing temp.						
Keep cold chain between 2-8 °C when transferring medicines	57	52	67	67	48	69
Place medicines in a cooler with ice packs when transferring	59	55	67	50	52	75
Medicines can be transported at 30 °C or lower for a short period	35	29	44	33	37	31

Respondents were also asked specifically about their knowledge of storage guidelines for oxytocin, misoprostol and MgSO₄. As shown in the graphs below, knowledge of storage guidelines for oxytocin (cold chain or storage temperature of 30°C or below) was the poorest overall with only 51 percent aware of the storage guidelines for misoprostol. With the exception of oxytocin, knowledge of storage guidelines for misoprostol and MgSO₄ was poorer in the public sector. Knowledge was also found to be poorest within the health centers for PPH medicines. Only 7 percent and 26 percent of health center managers were aware of the storage guidelines for oxytocin and misoprostol.

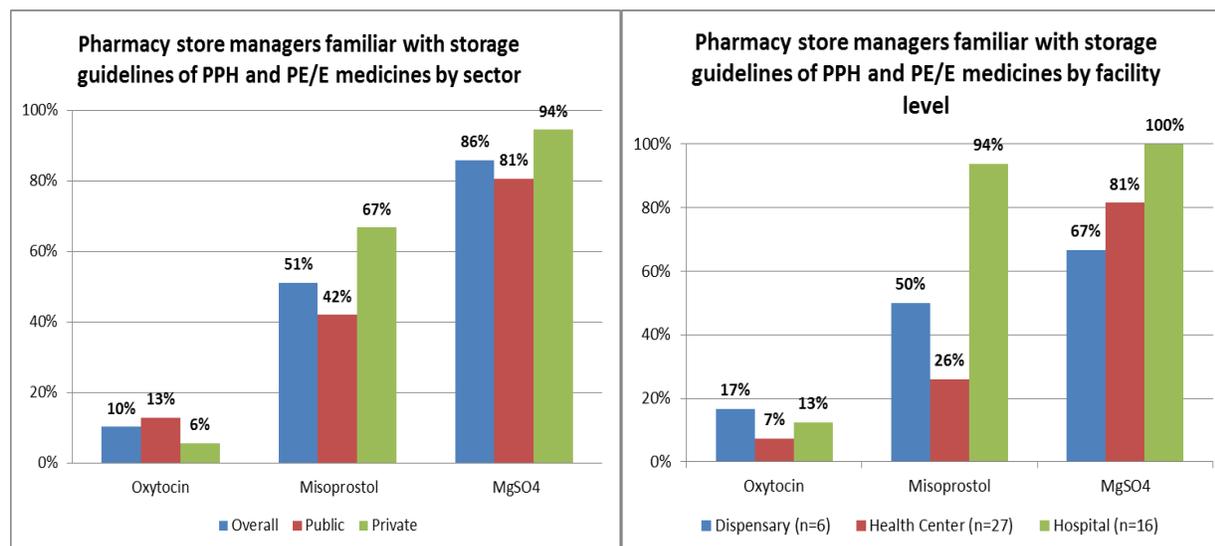


Figure 6. Pharmacy store managers' knowledge of storage guidelines

Delivery Room Managers

Delivery room managers were asked about their familiarity with PPH and PE/E medicines in the NEML. While most delivery room managers are aware of first-line treatments, knowledge of second-line treatments is poor, especially for PPH. While all delivery room managers stated they are aware of oxytocin, only 31 percent, and 51 percent overall, were aware of misoprostol and ergometrine. Staff knowledge of misoprostol was only 17 percent in the private sector and

slightly over 30 percent in each of the health facility levels. In the health centers, was 63 percent of staff knew what ergometrine was, but only 47 percent of hospitals staff were aware. Over 90 percent of respondents stated they were aware of PE/E medicines in the NEML with 91 percent aware of MgSO₄ and only 46 percent aware of diazepam.

Overall, 73 percent of delivery room managers stated that oxytocin should be stored at temperatures between 2–8°C and 20 percent stated that it can be stored unrefrigerated at 30°C or lower. The oxytocin procured at the dispensary and health center levels requires storage at 30°C or below, but knowledge of these guidelines was exceptionally low with only 11 percent of managers at health centers aware of these storage guidelines. Knowledge of storage guidelines for ergometrine and syntometrine is low (31 percent and 27 percent) and 47 percent of delivery room managers were aware of the storage guidelines for misoprostol (table 9).

Table 9. Knowledge of Recommended Storage Guidelines for PPH Medicines

Recommended storage guidelines	Overall, % (n=49)	Public, % (n=31)	Private, % (n=18)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=16)
Oxytocin:						
Keep between 2–8 °C	73	71	78	17	89	69
Could be kept unrefrigerated for some time at 30 °C or lower	20	23	17	17	11	38
Room temperature	35	29	44	50	33	31
Ergometrine:						
Keep in box protected from light and freezing temps.	31	32	28	33	26	38
Short periods without refrigeration are tolerable in shade (do not exceed 4 weeks at 30 °C or 2 weeks at 40 °C)	16	13	22	0	26	6
Other: Cold chain	47	60	29	0	56	43
Other: Room temperature	53	40	71	100	44	57
Syntometrine:						
Keep in box protected from light and freezing temps.	27	23	33	17	22	38
If kept in shade, short periods w/o refrigeration are tolerable (do not exceed 4 weeks at 30 °C or 2 weeks at 40 °C)	12	13	11	0	19	6
Misoprostol:						
Store at room temp in a closed container	47	55	33	67	48	38

Direct Observation of Storage Management Practices

Direct observation found that general recommendations for medicines storage are being practiced. It was observed that FEFO procedures are done in almost 90 percent of the facilities visited and over 90 percent of facilities have organized their stock where the expiration dates are visible and the stock is protected from direct light (table 10)

Table 10. Direct Observation of General Recommended Storage Guidelines

Recommended storage guidelines	Overall, %	Public, %	Private, %	Dispensary, %	Health center, %	Hospital, %
Visible expiration dates	92	94	89	100	96	81
FEFO procedures observed	86	87	83	83	89	81
Protection from water and moisture	86	87	89	100	81	93
Protection from direct light	94	97	89	100	96	88
Self-reported maintaining cold chain between 2-8 °C	67	68	67	50	63	81

Although 67 percent of health facilities reported that cold chain is maintained between 2–8°C, only 35 percent of the health facilities sampled regularly monitored and recorded temperatures. Moreover, only 47 percent of facilities have an operational refrigerator and 59 percent of facilities have vaccine couriers with coolers to transport medicines. The two graphs below show the percent of facilities between sectors and facility levels that have the means to maintain the recommended storage temperatures for cold chain. Interestingly, 81 percent of respondents from hospitals said that they maintain cold chain however only 69 percent of the hospitals surveyed actually have operational refrigerators. This indicates that the recommended storage guidelines for oxytocin are not being maintained at the hospital levels. Similar discrepancies are found at the dispensary and health center levels.

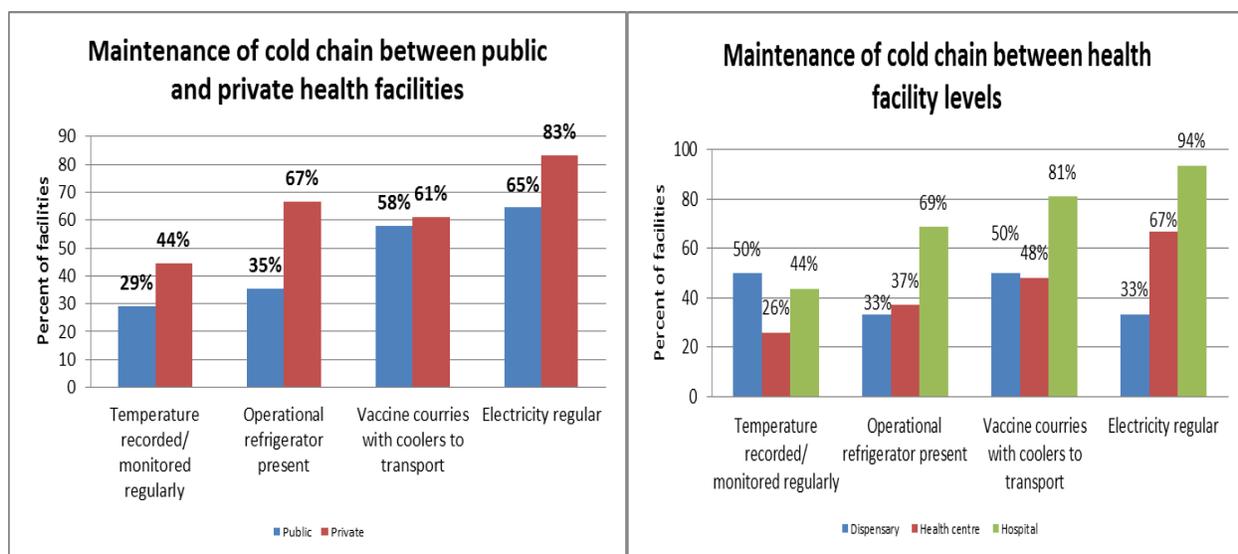


Figure 7. Storage practices for maintaining cold chain requirements

Inventory Management

Pharmacy store managers were also asked about their stock management practices. Overall, 90 percent of respondents stated the facility had stock registers or stock cards and 73 percent and stated they had stock registers/ cards specifically for uterotonics and 67 percent had them for PE/E medicines. While there was no difference between sectors for stock registers/cards for PE/E medicines, 81 percent of respondents from public sector facilities had stock registers/ cards for uterotonics compared to 61 percent of the private sector respondents. Overall, the vast majority of private sector pharmacy store managers who had stock registers/ cards stated that they are up to date for uterotonics (82 percent) and PE/E medicines (75 percent) compared to the public sector (68 percent and 71 percent respectively).

Table 11. Respondents with Stock Registers or Stock Cards that are Up to Date

	Overall, %	Public, %	Private, %	Dispensary, %	Health center, %	Hospital, %
Facilities with stock registers/ cards	90	90	89	83	89	94
Stock registers/cards for uterotonics	73	81	61	83	67	81
Up-to-date	(72)	(68)	(82)	(40)	(78)	(77)
Stock registers /cards for PE/E meds	67	68	67	67	56	88
Up-to-date	(73)	(71)	(75)	(25)	(67)	(93)

Over 70 percent of the respondents reported on how often they update facility stock registers/ cards. Slightly over 40 percent of pharmacy store managers stated that they update their stock registers on a daily basis and 30 percent stated they are updated when necessary. For those facilities using stock cards, 42 percent stated that they are updated when necessary and 32 percent stated they are updated daily. The majority of the pharmacy store managers from the public sector (52 percent) and health centers (75 percent) update their stock cards when necessary compared to 23 percent of managers in the private sector and 42 percent from the hospitals. Similar results were found for updating stock registers when comparing between facility levels—the majority of the private sector managers update stock registers daily (54 percent) compared to those in the public sector (35 percent).

Overall, the majority of facilities have a system for recording the transfer of uterotonics (89 percent) and PE/E (79 percent) medicines between the pharmacy and delivery room. Comparing between sectors and among facility levels found that a higher proportion of private sector facilities and hospitals have a system for PE/E medicines (92 percent and 100 percent) compared to the public sector facilities and health centers (72 percent and 68 percent).

Inventory Records Review

Existing inventory control systems were present in 45 of the 49 sampled facilities (92 percent). Of these, 87 percent had a manual system (manual ledger or tally/ bin/ stock record cards), 9 percent had a computerized inventory control system, and 4 percent stated other methods, such as physically counting the stock. All of the dispensaries and 96 percent of health centers had a manual inventory control system compared to 73 percent of hospitals.

All facilities completed an inventory data form. This form collected information from inventory records and other paperwork on each of the tracer drugs for this assessment, which include—

- Record count: amount of stock recorded in the inventory record
- Unposted receipts: paperwork that showed that the stock was received but not yet put in the records
- Unposted issues: paperwork that shows that stock was dispensed but not yet put in the records
- Physical count: actual stock count present
- Expired stock: amount of expired stock

The adjusted total for each product was determined by taking into consideration the unposted receipts and unposted issues. This was then compared to the physical count of the product to determine the total number of products per facility for which the adjusted total was equal to the physical count. Products for which the record count was not available were not considered in calculating the percent of records corresponding with physical counts per facility. Facilities should properly maintain inventory records for all products that are available in the facility. The assessment found that the majority of these tracer products are being available at health facilities despite what is indicated in the NEML. Therefore it is expected that most of the facilities should not only have available records for the tracer product but also these records should correspond to the physical count of these products.

Figure 6 shows the percent of facilities with available inventory records for the tracer products. Only 4 facilities (8 percent) had available inventory records for all 20 tracer drugs and 35 percent and 31 percent of facilities had records available for 5–9 products and 10–14 products that are on the tracer list. Only one facility had no records for any of the tracer products. On average, 56 percent of health facilities sampled had records available.

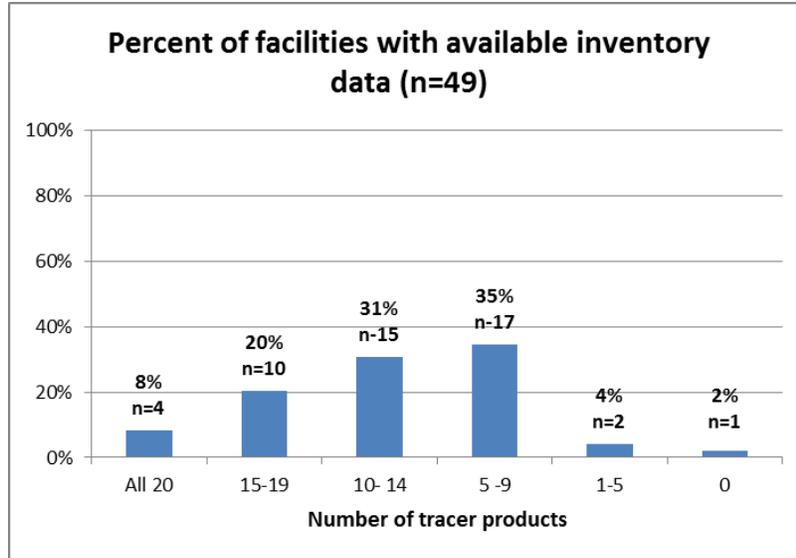


Figure 8. Availability of inventory records

Figure 9 shows the percentage of facilities that had matching inventory records (when adjusted record count equals the physical count) for all tracer products and 75–99 percent, 50–74 percent, 25–49 percent and 1–24 percent of the tracer products. While the public sector is performing slightly better than the private sector, inventory management is weak across the both sectors. Less than 20 percent of facilities had matching records for all 20 tracer products and 23 percent and 17 percent of public and private sector facilities had matching inventory records for 75–99 percent of facilities.

Of the 48 facilities with available inventory records, the average percentage of products with matching inventory records is 78 percent. Specifically, only 29 percent of these facilities had matching inventory records for all the products for which they had available records and 69 percent of facilities had matching records for at least 75 percent of the tracer products for which records were available. When comparing between health care levels, availability of inventory records was poorest among dispensaries and health centers. The average percentage of tracer products with available records was only 35 percent (n=7) and 52 percent (n=10) at the dispensary and health center levels while hospitals on average had available records for 70 percent (n=14) of the tracer products. Of these records, over 60 percent of the available inventory records matched with the physical count.

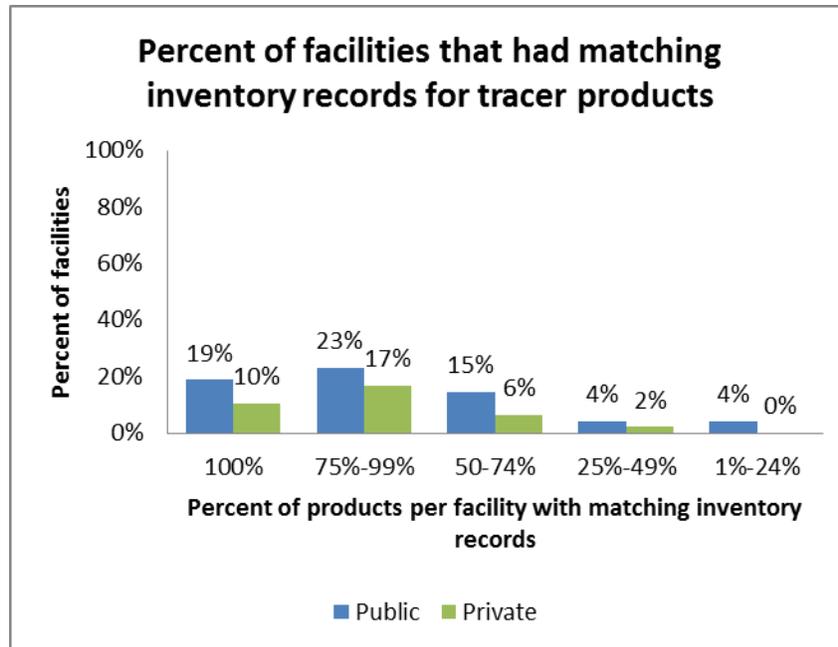


Figure 9. Inventory management of tracer products

Availability

The availability of tracer medicines was evaluated in all the sampled facilities using record reviews and direct observation. When oxytocin is not available, misoprostol or ergometrine are the recommended second line treatments. The ministries of health are currently phasing out the use of ergometrine because of its adverse reactions, instability and stringent cold chain storage requirements however the status of this is unclear. While oxytocin should be available at all levels of care, only hospitals should have misoprostol and ergometrine. Medicines to control severe hypertension (methyldopa, hydralazine and nifedipine) are recommended for the prevention of pre-eclampsia and should only be available at hospitals. MgSO₄ is the first line treatment for preventing and treating eclampsia, should be available at health centers and hospitals while diazepam, the recommended second line treatment, should be available at all health care levels.

At the request of the DRH, the assessment collected availability data for medicines for newborn health. For newborn health, antibiotics are recommended for the treatment and prevention of neonatal sepsis. The preferred antibiotics are penicillin and gentamicin; however, metronidazole is also included in the tracer list as some providers prefer to use this drug. For newborn resuscitation and cord care caffeine citrate and chlorhexidine are recommended. All medicines for neonatal sepsis, except ampicillin, should be available at all three health facility levels and ampicillin should only be available at hospitals. Caffeine citrate, used for asphyxia, should only be available at hospitals, specifically level 5– facilities and higher.

Data collectors recorded the physical count of each of the tracer medicines on the inventory data form. As shown in the table below, first line treatments for PPH (oxytocin) and PE/E (MgSO₄)

was present in 90 percent and 80 percent of the facilities on the day of the visit and 94 percent of facilities had the second-line treatment for PE/E available (diazepam 5 mg/ ml in 2 ml).

Ergometrine and misoprostol were available in only 55 percent and 57 percent of the facilities visited. Most of the tracer medicines were less available in the public sector compared to the private sector. For example, ergometrine and misoprostol were available in only 48 percent and 45 percent of the public health facilities compared to 67 percent and 78 percent of the private health facilities.

Comparison among health-facility levels found that there is clearly a disconnect between what is dictated by the NEML and what is actually being procured and made available at the different facility levels. Although the majority of the dispensaries surveyed had ergometrine and misoprostol, the availability of these medicines was poor at the hospital level where they should be available. Similarly, there was poor availability of antibiotics for neonatal sepsis among health centers visited compared to hospitals. While ampicillin was available in 78 percent of health centers and 88 percent of hospitals, gentamicin was available in 67 percent and 69 percent of health centers and hospitals.

Chlorhexidine was present in most of the facilities (86 percent) and caffeine citrate was available in only 49 percent of the sampled facilities. Table 12 shows that caffeine citrate is more available in the private sector. Caffeine citrate was available in only 31 percent of hospitals where it is supposed to be available, but was found to be in all of the six dispensaries surveyed and 48 percent of the health centers where obstetric and neonatal emergencies should be referred.

Table 12. Availability of Tracer Products

Product	Percent of facilities with the product available					
	Overall, % (n=49)	Public, % (n=31)	Private, % (n=18)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=16)
Oxytocin	90	87	94	100	81	100
Ergometrine	55	48	67	67	59	44
Misoprostol 200 mcg	57	45	78	83	52	56
MgSO ₄	80	84	72	67	81	81
Diazepam 5 mg	63	58	72	50	48	94
Diazepam 5 mg/ ml in 2 ml	94	97	89	67	96	100
Methyldopa 250 mg	63	55	78	83	44	88
Methyldopa 500 mg	45	32	67	83	41	38
Hydralazine	65	52	89	83	48	88
Nifedipine	43	32	61	83	41	31
Tetracycline	94	97	89	100	93	94
Ampicillin	82	71	100	83	78	88
Gentamicin 10 mg/ ml in 2 ml	37	26	56	33	33	44
Gentamicin 40 mg/ ml in 2 ml	63	58	72	33	67	69
Metronidazole	69	65	78	67	56	94

Product	Percent of facilities with the product available					
	Overall, % (n=49)	Public, % (n=31)	Private, % (n=18)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=16)
Caffeine citrate	49	45	56	100	48	31
Chlorhexidine	86	90	78	67	81	100
Dipstix	69	65	78	83	67	69
Calcium gluconate	59	52	72	83	56	56

Presence of Expired Products in Facility Stores

There was no expired stock of PPH and newborn health commodities found in any of the facilities surveyed. However, some facilities (n=4) did have expired stock of PE/E medicines and anti-hypertensive medicines, specifically methyldopa. Of these facilities, three health centers had some expired stock of MgSO₄, diazepam 5 mg/ ml and methyldopa 250 mg (one facility each) and one dispensary had some expired stock of diazepam 5 mg.

Stock-Outs in Health Facilities

Data from the one year prior to the assessment was collected from the stock records of each of the facilities visited. Unfortunately, most of the facilities did not have data available for the first six months of the year so data was analyzed for only the six months prior to the assessment. Sample sizes for each medicine differ based on whether the facility had available records for that specific medicine. For example, while 42 facilities had data available for oxytocin, only 29 facilities had data for misoprostol 200 mcg and 24 facilities had data available for caffeine citrate. The average percentage of time in the six months prior to the survey (184 days) was calculated overall for all the facilities that had data available. The average time out of stock for each medicine was further calculated for facilities that experienced stock-outs.

The below table shows the percent of facilities surveyed that had records available for each tracer medicines. For most of the medicines, records were available for more than 60 percent of the facilities surveyed and for misoprostol, methyldopa 500 mg and nifedipine, over 50 percent of the facilities had available records.

Table 13. Percent of Facilities That Had Available Records for Tracer Medicines

	Overall, % (n=49)	Public, % (n=31)	Private, % (n=18)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=16)
Oxytocin	86	94	72	67	85	94
Ergometrine	63	68	56	50	59	75
Misoprostol (200 mcg)	59	58	61	33	56	75
MgSO ₄	76	81	67	67	67	94
Diazepam (5 mg)	78	81	72	50	78	88
Diazepam (5 mg/ml)	88	90	83	67	89	94
Methyldopa (250 mg)	69	74	61	33	63	94

Results

	Overall, % (n=49)	Public, % (n=31)	Private, % (n=18)	Dispensary, % (n=6)	Health center, % (n=27)	Hospital, % (n=16)
Methyldopa (500 mg)	53	58	44	33	52	63
Hydralazine	67	71	61	33	67	81
Nifedipine	57	61	50	33	48	81
Tetracycline	90	94	83	83	89	94
Ampicillin	84	84	83	67	89	81
Gentamicin 10 mg/ml in 2 ml	71	74	67	67	67	81
Gentamicin 40 mg/ml in 2 ml	86	90	78	83	85	88
Metronidazole	84	77	94	67	78	100
Caffeine citrate	49	58	33	33	44	63
Chlorhexidine	67	71	61	67	63	75
Dipstix	37	39	33	33	37	38
Calcium gluconate	67	65	72	33	59	94

Maternal Health Medicines

Review of stock records from the six months prior to the assessment found that while only 7 percent of facilities with available records had stock-outs of oxytocin (n = 42), over 70 percent of facilities had stock-outs of ergometrine (n = 31) and misoprostol (n = 29), respectively. The three facilities that had stock-outs of oxytocin were all public sector facilities of which two were health centers and one was a hospital. Among the facilities that had stock-outs of ergometrine (n = 21), 83 percent were from the public sector and 57 percent and 33 percent were health centers and hospitals. For ergometrine, this represents 90 percent of the public health facilities sampled and 81 percent and 67 percent of the health centers and hospitals sampled. The situation is similar for facilities having stock-outs of misoprostol. The stock-outs mostly occur in the public sector and at the health center level with some stock-outs at public hospitals.

Unlike ergometrine and misoprostol, PE/E medicines had fewer stock-outs with the exception of calcium gluconate. Among all the facilities that had available records, 24 percent and 37 percent of facilities had stock-outs of MgSO₄ (n = 37) and diazepam 5 mg (n = 38) and 61 percent of facilities had stock-outs of calcium gluconate (n = 33). Only 7 percent of facilities had stock-outs of diazepam 5 mg/ml (in 2 ml, n = 43). The majority of the facilities that had stock-outs of PE/E medicines were from the public sector. Over 50 percent of the facilities that had stock-outs of MgSO₄ are public sector facilities as well as 79 percent of the facilities that had stock-outs of diazepam (5 mg). Analysis between health facility levels found that stock-outs of PE/E medicines largely occur among the health centers. None of the dispensaries experienced stock-outs of MgSO₄ and only 22 percent of hospitals had stock-outs of MgSO₄. However, over 65 percent of health centers experienced stock-outs of MgSO₄ and diazepam 5 mg for over 70 percent of the time in the last six months.

Medicines for severe hypertension include methyldopa (250 mg and 500 mg doses), hydralazine and nifedipine. Over 40 percent of facilities experienced stock-outs of anti-hypertensive medicine in the six months prior to the survey. In particular, over 80 percent of facilities experienced stock-outs of methyldopa (500 mg) and nifedipine and 52 percent of facilities had

stock-outs of hydralazine. Comparing between sectors and health facility level, the assessment found that the majority of the facilities experiencing stock-outs of anti-hypertensives were public sector health facilities (over 70 percent) and at the health center level (52–82 percent). Table 14 shows the breakdown of facilities experiencing stock-outs of tracer medicines for PPH, PE/E and hypertension by sector and health facility level.

Table 14. Percentage of Facilities with Available Records that Experienced Stock-Outs of Maternal Health Medicines

Product	Overall, %	Public, %	Private, %	Dispensary, %	Health center, %	Hospital, %
Oxytocin	7	10	0	0	9	7
Ergometrine	74	90	40	67	81	67
Misoprostol (200 mcg)	72	89	45	50	87	58
MgSO ₄	24	20	33	0	39	13
Diazepam (5 mg)	37	44	23	33	57	7
Diazepam (5 mg/ml)	7	11	0	25	4	7
Methyldopa (250 mg)	44	52	27	50	71	13
Methyldopa (500 mg)	88	94	75	50	86	100
Hydralazine	52	59	36	50	78	15
Nifedipine	82	89	67	50	92	77
Dipstix	39	50	17	50	40	33
Calcium gluconate	61	75	38	0	81	47

The average percent of time out of stock within the six months (184 days) prior to the survey was calculated for each of the tracer medicines. Overall, on average, oxytocin was out of stock for only 1.84 days (1 percent of the 184-day period) while the average time ergometrine and misoprostol were unavailable was 69 percent and 70 percent for all facilities that had available records. For PE/E medicines, MgSO₄ was out of stock for 16 percent of the time in the last six months while diazepam (5 mg) and calcium gluconate was not available for 35 percent and 51 percent of the time.

Table 15. Average Percentage of Time Out of Stock for Maternal Health Medicines in Facilities with Available Records in the Six Months Prior to the Survey

Product	Overall, %	Public, %	Private, %	Dispensary, %	Health center, %	Hospital, %
Oxytocin	1	1	0	0	1	0
Ergometrine	69	82	40	35	76	67
Misoprostol 200 micrograms	70	86	45	50	83	58
MgSO ₄	16	12	25	0	27	7
Diazepam 5 mg	35	43	20	33	55	4
Diazepam 5	4	6	0	12	4	1

Results

Product	Overall, %	Public, %	Private, %	Dispensary, %	Health center, %	Hospital, %
mg/ml in 2 ml						
Methyldopa 250 mg	38	46	20	50	66	4
Methyldopa 500 mg	88	94	75	50	86	100
Hydralazine	45	53	28	50	70	9
Nifedipine	79	85	67	50	92	71
Dipstix	39	50	17	49	40	33
Calcium gluconate	51	63	32	0	67	41

With the exception of oxytocin, when facilities have stock-outs of maternal health medicines the amount of time ranges from 53 to 97 percent of the 184 days prior to the survey. Of the facilities that experienced stock-outs, the average percent of time out of stock was 8 percent (15 days) for oxytocin and over 90 percent for ergometrine and misoprostol (over 166 days). In other words, when ergometrine and misoprostol were out of stock, it was for almost every month in the last six months. Similarly, when facilities had stock-outs of PE/E medicines, the average percentage of time MgSO₄, calcium gluconate, and diazepam (5 mg) were out of stock was 65 percent, 84 percent and 94 percent in the last six months.

Figure 10 shows the average percentage of time PPH and PE/E medicines were out of stock among facilities experiencing stock-outs and compares it between sectors. All of the private sector facilities that had stock-outs of ergometrine experienced them for all six months prior to the survey and public facilities had stock-outs of ergometrine for almost all six months. It should be noted that while ergometrine is not expected to be in stock as it is currently being phased out the 2010 national SCGs and NEML has not been updated to reflect this change. As shown earlier, on the day of the visit, 55 percent of the surveyed facilities had ergometrine available in their facility. Additionally, with regards to misoprostol and MgSO₄, both medicines have not been commonly used for long and the NEML does not indicate using misoprostol for prevention and treatment of PPH.

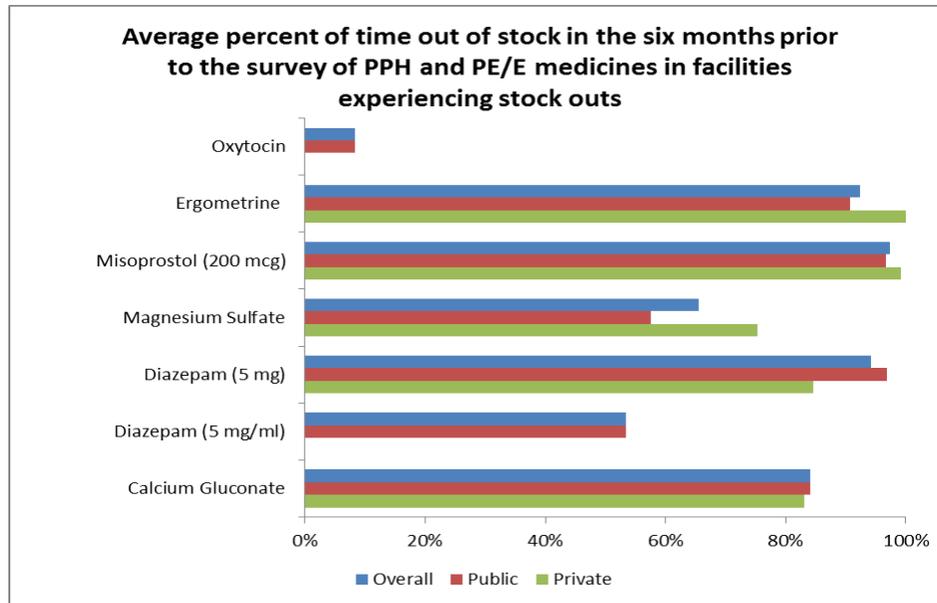


Figure 10. Average amount of time out of stock for maternal health medicines when stock-outs occur

Newborn Health Medicines

As shown in the table below, stock-outs of newborn health medicines for sepsis and asphyxia were most common for gentamicin (10 mg/m l in 2 ml), caffeine citrate and metronidazole. Specifically, 66 percent and 41 percent of facilities had stock-outs of gentamicin (10 mg) and metronidazole and 96 percent had stock-outs caffeine citrate within the six months prior to the survey. Over 70 percent of the facilities experiencing stock-outs of antibiotics were from the public sector representing between 50-94 percent of the public health facilities surveyed (except for tetracycline, gentamicin 40 mg and chlorhexidine which were found to be mostly available). When comparing between health facility levels, 100 percent of health centers and hospitals surveyed experienced stock-outs of caffeine citrate and 83 percent and 62 percent of health centers experienced stock-outs of gentamicin 10 mg and metronidazole.

The average time out of stock for facilities that experienced stock-outs of neonatal medicines in the six months prior to the survey is shown below. Overall, tetracycline, gentamicin, metronidazole and caffeine citrate were out of stock for over 65 percent of the time. Ampicillin was out of stock for an average of 94 days (51 percent) out of the 184 days that were analyzed.

Table 16. Percentage of Facilities with Available Records That Experienced Stock-Outs of Newborn Health Medicines

Product	Overall, %	Public, %	Private, %	Dispensary, %	Health Center, %	Hospital, %
Tetracycline	9	7	13	0	8	13
Ampicillin	37	50	13	75	33	31
Gentamicin 10 mg/ml in 2 ml	66	78	42	25	83	54
Gentamicin 40 mg/ml in 2 ml	24	29	14	20	26	2
Metronidazole	41	54	24	75	62	6
Caffeine citrate	96	94	100	50	100	100
Chlorhexidine	21	18	27	0	29	17

Table 17. Average Percent of Time Out of Stock for Newborn Health Tracer Medicines in Facilities Experiencing Stock-Outs in the Six Months Prior to the Survey

Product	Overall, %	Public, %	Private, %	Dispensary, %	Health Center, %	Hospital, %
Tetracycline (eye ointment)	68	35	100	0	83	52
Ampicillin	51	57	15	53	47	58
Gentamicin 10 mg/ml in 2 ml	79	75	93	100	74	86
Gentamicin 40 mg/ml in 2 ml	47	53	22	100	58	6
Metronidazole	85	86	82	44	94	100
Caffeine citrate	100	100	100	99	100	100
Chlorhexidine	56	45	69	0	76	5

Use

The assessment did not analyze the use of the tracer medicines by health care providers. It was learnt that MCHIP was conducting an extensive quality of care study in Kenya that included more robust methods of collecting data on use such as direct observation. As such, we decided not to examine use as part of this assessment.

Management Support

Submission of Reports

The distribution systems are different depending on the health care level. As discussed earlier, at the time of the survey all hospitals has fully transitioned to the pull system whereas the majority of the health centers and dispensaries continued to operate under the push system. Accordingly, reports on consumption and inventory data of essential medicines are to be sent to KEMSA every two months from hospitals and quarterly by health centers and dispensaries for facilities to be resupplied. The assessment found that there is confusion among pharmacy store managers across sectors and health facility levels regarding the ordering and resupply of essential medicines.

Overall, 76 percent of the pharmacy store managers prepare consumption and inventory reports which contain information on the quantity received (70 percent), quantity distributed (89 percent), quantity expired (57 percent) and quantity in stock (86 percent). Only 65 percent stated that this report includes information on uterotonics and PE/E medicines— 75 percent of the public facilities and only 46 percent of private facilities. Additionally, only 44 percent of the health centers that submit reports stated that uterotonics and PE/E medicines are included. These reports are submitted mostly on a monthly basis (65 percent) but some managers submit them on a bi-monthly or quarterly basis. While no stark differences were found between sectors, 31 percent of hospitals stated they send the reports monthly and only 54 percent stated reports are sent bi-monthly.

Supervision, Training, and Tools

Pharmacy Store Managers

Over 80 percent of the pharmacy store managers interviewed have a direct supervisor of which 63 percent stated they were visited within the same month of the survey and 24 percent indicated the last supervisory visit was the month before. While there are differences between sectors, the differences are greater when comparing between health facility levels. As shown in the graphs below, supervisory visits that check stock cards are lower within the private sector facilities and at the hospital level while visits that check storage conditions are lower in the private sector and at the health center level.

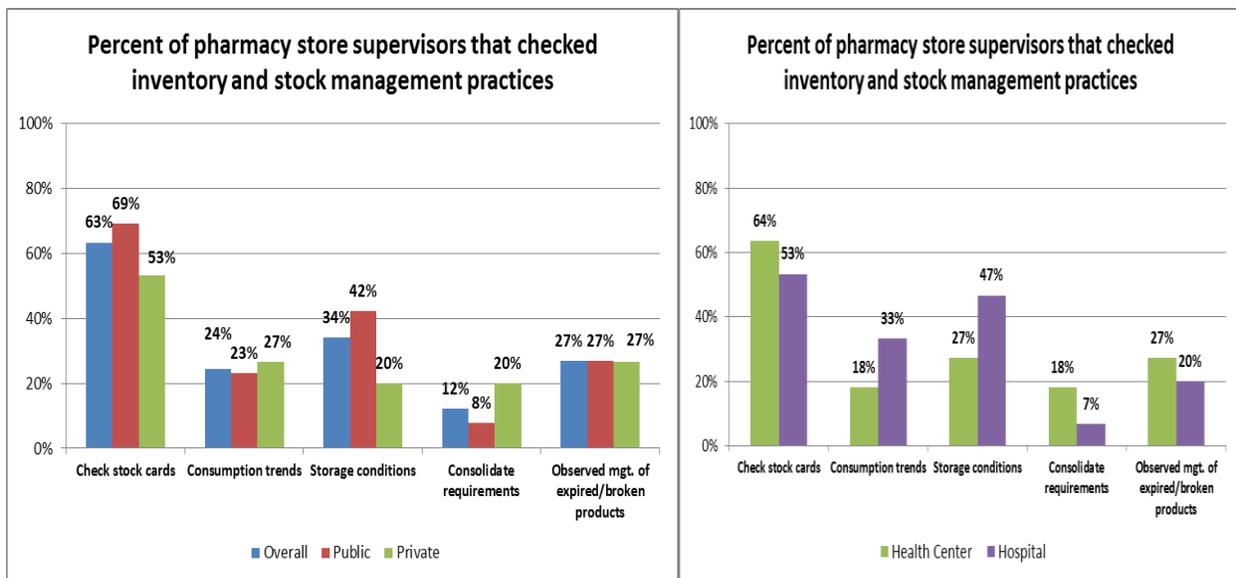


Figure 11. Actions conducted during supervisory visits by pharmacy store supervisors

In general, pharmacy store managers are trained on general inventory management but this does not include specific training on the management of uterotonics or PE/E medicines. Accordingly,

the results of this assessment found that the majority of the managers have not had training on PPH and PE/E medicines. Specifically, only 29 percent of the pharmacy store managers interviewed stated that they have received training on the management of uterotonics in the last 12 months prior to the survey and almost all (96 percent) feel that there is a need for more training.

Availability of tools such as the NEML and job aids was found to be extremely low for pharmacy store managers. Only 31 percent of all respondents had a copy of the NEML, representing 35 percent and 22 percent of the public and private health facilities and 35 percent of facilities had worksheets such as job aids on the management of medicines (table 18).

Table 18. Percent of Pharmacy Store Managers with Access to Pharmaceutical Management Tools

Tool	Overall, %	Public, %	Private, %	Dispensary, %	Health Center, %	Hospital, %
NEML	31	35	22	33	26	38
Worksheets (i.e. job aids) on the management of medicines	35	42	22	33	30	44

Delivery Room Managers

Over 90 percent of the delivery room managers interviewed stated that they have a direct supervisor of which 43 percent said visited them three months ago and 24-26 percent said their supervisor visits them daily or the last visit was sometime during the month the survey was conducted. Similar results were found when comparing health facilities, however 69 percent of respondents from the private sector stated their supervisor last visited three months ago and 25 percent stated they visited the last month prior to the survey. None of the supervisors of the private sector pharmacy store managers conducted daily or monthly supervisory visits. When supervisory visits are conducted, 52 percent of respondents stated their supervisor observed deliveries and checked partographs. Other actions included reviewing inventory of medicines and storage conditions (39 percent), reviewing medical records (33 percent), inspecting the facility and quality of care (patient satisfaction, 26 percent) and discussing concerns and challenges (13 percent). Slight differences were found between sectors and health facility levels, particularly with the private sector having a much higher proportion of supervisors observing deliveries and checking partographs– 69 percent compared to 43 percent of the public sector supervisors.

Only 29 percent of delivery room managers received training on the management and use of medicines used for obstetric emergencies and uterotonics in the 12 months prior to the survey. Over 50 percent of delivery room managers from the public sector and 75 percent of delivery room managers working in the health centers stated they completed the training. None of the delivery room managers from the hospitals stated that he or she completed the training. All of the

respondents felt that more training is needed on the aspects of the management of uterotonics and other medicines for obstetric emergencies.

The availability of NEML and worksheets/ job aids was found to be poor. Only 8 percent of delivery room managers had access to the NEML and 39 percent stated that they had worksheets/ job aids. Comparing sectors found that 67 percent of dispensaries and 48 percent of health centers surveyed had job aids and only 13 percent of the managers from hospitals stated they had job aids available.

The questionnaire further assessed the availability of management tools such as delivery registers and books to record the transfer of uterotonics and PE/E medicines to delivery rooms and operating suites. Table 19 shows both the availability of these tools and whether they are up-to-date. All delivery room managers have up to date delivery registries but availability of tools used to manage the transfer of uterotonics and PE/E medicines is poor overall with slight differences across sectors. When available, however, these books are usually kept up to date.

Table 19. Availability and Updating of Management Tools for Delivery Room Managers

Management Tools	Overall, %		Public, %		Private, %	
	Available	Up-to-date	Available	Up-to-date	Available	Up-to-date
Delivery registers	100	100	100	100	100	100
Book to record the transfer of uterotonics to the delivery room	39	95	39	92	39	100
Book to record the transfer of uterotonics to the operating suite	12	83	13	75	11	100
Book to record the transfer of medicines for eclampsia to the delivery room	33	81	32	80	33	83
Book to record the transfer of medicines for eclampsia to the operating suite	12	83	13	100	11	50

Financing

Information regarding fees associated with deliveries was obtained from the questionnaire for the delivery room managers. The survey found that overall, 84 percent of facilities charge women for normal deliveries, most of which include the cost of medicines. In regards to complicated deliveries, only 47 percent of facilities charged women. As shown in table 20, a higher proportion (90 percent) of public health facilities charge women for deliveries compared to 72 percent of the private health facilities surveyed.

Table 20. Percent of Delivery Room Managers/Facilities Charging User Fees for Deliveries

	Overall, %	Public, %	Private, %	Dispensary, %	Health Center, %	Hospital, %
Women charged for normal deliveries	84	90	72	83	85	81
Cost for normal deliveries includes medicines	73	71	77	80	74	69
Women charged for complicated deliveries	47	52	39	67	48	38

Delivery room managers were also asked about the average cost for normal deliveries, PPH treatment and PE/E treatment. Overall, the average cost charged for normal deliveries was 2,121.25 Kenya shillings (KES) with a wide range from facilities charging as low as 500 KES to 6,000 KES and some charging 10,000 KES (n=2). The average cost for PPH and PE/E treatment was 3,533.33 KES and 4,772.22 KES respectively. Table 21 shows the average costs for normal deliveries, PPH treatment and PE/E treatment. Health centers and public sector facilities charge a much higher amount for PPH and PE/E treatment.

Table 21. Average Costs (KES) for Normal Deliveries and Treatments for PPH and PE/E

	Overall	Public	Private	Dispensary	Health Center	Hospital
Average cost of normal deliveries	2121.25	2303.57	1695.83	1700.00	2490.91	1657.69
(N)	(40)	(28)	(12)	(5)	(22)	(13)
Average cost of PPH treatment	3533.33	4150.00	2300.00	2166.67	4793.33	1066.67
(N)	(22)	(15)	(7)	(3)	(14)	(5)
Average cost of PE/E treatment	4772.22	5323.08	3340.00	2500.00	6291.67	966.67
(N)	(17)	(13)	(4)	(3)	(11)	(3)

SUMMARY OF KEY FINDINGS

While the government of Kenya has made significant progress in improving the health status of children in the last decade, progress towards maternal health has been inadequate. Increasing access to quality maternal health commodities for key conditions such as PPH and PE/E can significantly decrease the maternal mortality in Kenya but proper management of all aspects of the pharmaceutical management cycle is essential. This assessment found that there are challenges and gaps in the pharmaceutical management cycle that impede the availability of quality maternal health medicines in Kenya at various levels of the health care system and in both the public and private sectors.

In early 2012 Kenya's Ministries of Health updated the national SCGs for maternal and child health which is now aligned with WHO's recommendations. Yet, there is a need to also update the NEML. Since this assessment was conducted prior to the 2012 update, it was found that there is a disconnect between the 2009 Kenya SCGs and the 2010 NEML guidelines as well as the availability and use of these medicines at the different health care levels. For example, while the SCGs indicate that all cases of PPH and PE/E be referred to the hospitals, the NEML indicates that oxytocin be available at all health facility levels and MgSO₄ be available at health centers and hospitals while the second line treatment for PPH (misoprostol and ergometrine) be available at the hospital level only and PE/E be available at all health care levels. Additionally, misoprostol is only indicated for restricted for specialist use in incomplete abortion and miscarriage despite the SCGs stating that it is a second-line medicine for the prevention and treatment of PPH. Similarly, while the government has been phasing out the use of ergometrine since 2007 because of its storage requirements and side effects, this has not been reflected in either the SCGs or the NEML. The 2012 SCGs have now indicated that PPH and PE/E prevention and treatment occur at all health care levels in line with international evidence and WHO guidelines. The NEML must be aligned with these new guidelines and be clear as to the use of misoprostol and ergometrine.

In regards to procurement the assessment found that health facilities are ordering medicines from multiple places. While most public health facilities procure from KEMSA, some pharmacy store managers are procuring medicines from MEDS and private wholesalers. Similarly, while most private health facilities procure from MEDS, they are also procuring from KEMSA and other private wholesalers. Multiple sources of suppliers for essential medicines may indicate challenges in estimating needs or breaks in the distribution cycle, which force facilities to order medicines from other suppliers. We found that there is no standard method used by facilities to estimate need for maternal health medicines. Most facilities use stock on hand or average monthly consumption to estimate needs and some indicated that they take into consideration safety stock (14 percent). Many managers (37 percent) indicated that they rely on "general experience." Overall, it is not clear how facilities are estimating their need which increases the risk of ordering insufficient quantities leading to stock-outs of essential maternal health commodities.

Currently the government is transitioning from the push system to the pull system where needs are determined at the local level and sent up to KEMSA. This may also affect the distribution cycle at some of the sampled facilities, especially at the health center and dispensary level which may continue to operate under a push system. Key findings when assessing aspects of the distribution

cycle includes confusion regarding the ordering cycle at all health facility levels, poor inventory management, including weaknesses of knowledge and practices for maintaining storage conditions, and availability of maternal and newborn health medicines.

Pharmacy store managers indicated that they frequently ordered uterotonics and PE/E medicines. While 33 percent and 24 percent indicated they are ordering uterotonics and PE/E medicines on quarterly basis, most indicated (over 60 percent) that both uterotonics and PE/E medicines are ordered when necessary. Additionally, some facilities stated that their orders for uterotonics and PE/E medicines are not filled on time or completely. Reasons cited for this included central level stock-outs, orders not issued on time and long delivery times. It is unclear if central level stock-outs did occur during the reporting period, yet the assessment shows that facilities are facing challenges with receiving medicines in adequate amounts and on time.

Maintaining storage requirements for maternal health medicines is essential for maintaining the quality and potency of the medicine. The assessment found that while most pharmacy store managers are aware of the storage guidelines for misoprostol and MgSO₄, very few are aware of the storage guidelines for oxytocin. Additionally, many facilities do not have the means for temperature monitoring or maintaining cold chain. After the assessment was conducted it was found that two types of oxytocin, specifying different storage guidelines, are procured for the hospital level and the dispensary and health center level. While the oxytocin procured by hospitals specifies cold chain storage, the oxytocin procured at the dispensaries and health centers indicates storage at 30°C and below. Consequentially, only 69 percent of the hospitals surveyed had operational refrigerators and only 50 percent and 26 percent of dispensaries and health centers monitored and recorded temperatures regularly.

An inventory record review found weak inventory management. It is expected that inventory records be up-to-date for all medicines availed at the health facility. The assessment found that the majority of the tracer medicines are available in both sectors and across health care levels. However, less than 20 percent of the facilities in both the public and private sectors surveyed had matching inventory records for all 20 tracer products and 23 percent and 17 percent of public and private health facilities had matching records for 75 percent of the tracer products. This shows that inventory management is a challenge at all health facility levels which affects the availability of these medicines.

When the availability of these medicines was assessed, it was found that some of these medicines are available at health care levels that are not mandated to address PPH and PE/E. Although misoprostol is indicated to be used only at the hospital level it was found to be available in the majority of the dispensaries and slightly over 50 percent of the health centers surveyed. In regards to newborn medicines, caffeine citrate that should only be available at the hospitals was found at all of the dispensaries surveyed.

Oxytocin is widely available at all health care levels with essentially no stock-outs while other key maternal health commodities continue to face challenges. For example the assessment found that misoprostol is widely unavailable as well as MgSO₄ and diazepam. Similarly, medicines for neonatal sepsis and asphyxia were essentially not available throughout the sectors and health facility levels. All the health centers and hospitals surveyed experienced stock-outs of caffeine

citrate for 100 percent of the six months prior to the survey. It is unclear as to exactly what the reasons are but this finding indicates challenges in supply chain and distribution cycle that include quantification of needs and inventory management.

In regards to training and supervision of health care managers, the assessment found that while the majority of the pharmacy store and delivery room managers have adequate education (most have diplomas or higher), there is a need to include or enhance training in stock management such as maintaining storage conditions, for maternal health commodities, especially for pharmacy store managers. Only 29 percent of pharmaceutical managers had been trained on pharmaceutical management in the last 12 months and only 8 percent of pharmaceutical managers and 29 percent of delivery room managers were trained on the management and use of medicines for obstetric emergencies in the 12 months prior to the assessment. Additionally, health facility managers do not have the tools necessary to properly manage medicines. Only 31 percent and 35 percent of the pharmacy store managers has access to the NEML and job aids and less than 30 percent of delivery room managers had tools to record the transfer of uterotronics and PE/E medicines to the delivery room. Providing managers with the tools and resources necessary for managing medicines is essential to improving inventory management and thereby increasing the availability of the products

Finally, some data was collected regarding the costs for deliveries and PPH and PE/E treatment. It was found that the average cost for normal deliveries is 2121.25 KES and the average costs for treatment of PPH and PE/E is 3533.33 KES and 4772.22 KES.

RECOMMENDATIONS

1. **Align and harmonize policies regarding essential obstetric care.** Specifically, the SCGs and the NEML must be coordinated. It is also important to clarify recommendations for the use of misoprostol and ergometrine for PPH. There needs to be clear guidance and communication to health care providers regarding misoprostol use and whether or not ergometrine is still a recommended second-line treatment as facilities continue to procure and receive this medicine.
2. **Standardize methods for estimating needs and for the ordering process.** Pharmacy managers need more training as well as a simple tool that could assist in improving current practices for estimating needs for pharmaceuticals. Many respondents reported that orders are not arriving on time. This also warrants further exploration as it may be that facility personnel are not placing orders as soon as they should. A simple tool or job aide that reminds managers when to order medicines may alleviate this problem.
3. **Develop standard operating procedures for sub-national procurements.** Local or sub-national procurement practices merit further investigation as these will affect both the quality and cost of essential medicines. The presence of substandard essential medicines in the private sector has been well documented for other health conditions. If facilities are able to procure their own medicines and supplies, the personnel carrying out these functions should be trained in how to incorporate quality assurance components in the process. Standard operating procedures could be developed and shared with personnel in charge of these processes.
4. **Ensure that facilities only have medications that staff are trained to use.** The presence of medicines in facilities where, according to MoH policies, they should not be should be investigated further. If personnel who have not been adequately trained in their use are in fact administering them, patient safety is at risk.
5. **Reassess the need to procure two types of oxytocin.** The presence of two types of oxytocin (one that requires storage between 2–8° C and another that requires storage below 30°C) may be causing confusion as to the storage of this medicine. It is recommended that the government reassess whether or not it is necessary to procure two different types of oxytocin.

If, however, the MoH decides to continue to procure oxytocin requiring cold storage, cold storage conditions need to be improved in the majority of health facilities, especially at the hospitals where it is supposed to be available. Additionally, the MoH needs to ensure that cold storage oxytocin is being procured that are able to maintain cold chain conditions.

6. **Enhance training and supervision.** Training and supervision of pharmacy managers need to be enhanced, specifically for the management and use of maternal health medicines. Currently, the nursing council is working to enhance training of certificate holders (enrolled nurses) so that they can have diplomas. This is expected to enhance the quality of maternal

health services at the different health service levels. To complement these efforts, inventory management and storage of medicines in general need to be more closely supervised, and specific attention given to the storage of maternal health medicines.

7. **Increase access to management tools.** In order to improve the performance of the necessary pharmaceutical management tasks, facility personnel, specifically pharmacy managers should have tools for inventory and stock management such as the NEML and job aids that serve as reminders of appropriate practices.

ANNEX 1. LIST OF SAMPLED HEALTH FACILITIES

Facility Name	County	Sector	Level
Kakamega Central Private	Kakamega	Private	Health Center
Kambiri Health Centre	Kakamega	Public	Health Center
Khalaba	Kakamega	Public	Health Center
Makunga Health Centre	Kakamega	Public	Health Center
Malava District Hospital	Kakamega	Public	Hospital
Matungu Sub - District Hospital	Kakamega	Public	Hospital
Nala Private Hospital	Kakamega	Private	Hospital
Namasoli Mission Health Centre	Kakamega	Private	Health Center
Shibwe Sub-District Hospital	Kakamega	Public	Hospital
Shikusa Health Centre	Kakamega	Public	Health Center
St. Mary's Mumias Mission Hospital	Kakamega	Private	Hospital
Baricho Catholic Health Centre	Kirinyaga	Private	Health Center
Difathas Health Centre	Kirinyaga	Public	Health Center
Kabare Health Centre	Kirinyaga	Public	Health Center
Kagio Nursing Home	Kirinyaga	Private	Health Center
Kianyaga Sub-District Hospital	Kirinyaga	Public	Hospital
Kimbimbi Sub-District	Kirinyaga	Public	Hospital
Mt Kenya (Ack) Hospital	Kirinyaga	Private	Hospital
Murinduko	Kirinyaga	Public	Health Center
Our Lady Of Lourdes Mwea Hospital	Kirinyaga	Private	Hospital
Sagana Health Centre	Kirinyaga	Public	Health Center
Diani Health Centre	Kwale	Public	Health Center
Kinango Dh	Kwale	Public	Hospital
Kwale District Hospital	Kwale	Public	Hospital
Magodzoni Dispensary	Kwale	Public	Dispensary
Matunga Dispensary	Kwale	Public	Dispensary
Msambweni Dh	Kwale	Public	Hospital
Samburu Health Centre	Kwale	Public	Health Center
Shimba Hills Health Centre	Kwale	Public	Health Center
Star Of Good Hope	Kwale	Private	Dispensary
Vigurungani	Kwale	Public	Dispensary
Eastleigh Marie Stopes	Nairobi	Private	Hospital
Kangemi Health Centre	Nairobi	Public	Health Center
Langata Health Centre	Nairobi	Public	Health Center
Makadara Health Centre	Nairobi	Public	Health Center
Mariakani Health Centre	Nairobi	Public	Health Center
Mary Immaculate	Nairobi	Private	Health Center
Mathare North Health Centre	Nairobi	Public	Health Center
Melchizedeck Hospital	Nairobi	Private	Health Center
Pumwani Health Centre	Nairobi	Public	Health Center
St Marys Mission Hospital	Nairobi	Private	Hospital
Kakuma	Turkana	Private	Hospital
Kalokol Health Centre	Turkana	Private	Health Center
Lodwar District Hospital	Turkana	Public	Hospital
Logurumu	Turkana	Private	Health Center
Lokichar Health Centre	Turkana	Private	Health Center
Makutano Health Centre	Turkana	Public	Health Center
Namukuse Dispensary	Turkana	Public	Dispensary
Namuruputh Pag	Turkana	Private	Dispensary

ANNEX 2. LIST OF TEAM LEADERS AND DATA COLLECTORS

Assessment Coordinators

1. Dr. Joseph Mwangi
2. Alex Muturi

Team Leaders

1. Alice Karani
2. Dr. George Walukana
3. Dr. Howard Mugambi
4. Dr. Jonah Mwangi
5. Dr. Winfred Mugure Murage

Data Collectors

1. Mable Lumonya
2. Getrude Okiko
3. John Mutiso
4. David Kisiang'ani
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6. Millicent MKiruki
7. Rosemary Ndinda Mbithi
8. Elizabeth Makali
9. Cosmas Mutunga
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1. Kirui Kiplangat Elvis
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