

MSH/Health Commodities and Services Management Program Annual Report: April 1, 2011–September 30, 2012

October 2012



MSH/Health Commodities and Services Management

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About MSH/HCSM

The MSH/HCSM Program strives to build capacity within Kenya to effectively manage all aspects of health commodity management systems, including pharmaceutical and laboratory services. MSH/HCSM focuses on improving governance in the pharmaceutical and laboratory sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines and related supplies.

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ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
ADR	adverse drug reaction
ADT	ARV Dispensing Tool
AIDS	acquired immunodeficiency syndrome
AL	artemether-lumefantrine
AMU	appropriate medicine use
APHIA	AIDS Population and Health Integrated Assistance
ART	antiretroviral therapy
ARV	antiretroviral (medicine)
CDC	US Centers for Disease Control and Prevention
CPD	continuous professional development
DHMT	District Health Management Team
DLTLD	Division of Leprosy, Tuberculosis and Lung Diseases
DOMC	Division of Malaria Control
DOP	Department of Pharmacy
DRH	Division of Reproductive Health
EMMS	essential medicines and medical supplies
FBO	faith-based organization
FP	family planning
F&Q	forecasting and quantification
FY	fiscal year
GOK	Government of Kenya
HIV	human immunodeficiency virus
HCSM	Health Commodities and Services Management
ICC	Interagency Coordinating Committee
KEML	Kenya Essential Medicines List
KEMSA	Kenya Medical Supplies Agency
KHSSP	Kenya Health Sector Strategic Plan
KMTC	Kenya Medical Training College
KNPP	Kenya National Pharmaceutical Policy
KPA	Kenya Pharmaceutical Association
LMIS	Logistics Management Information system
LMU	Logistics Management Unit
M&E	monitoring and evaluation
MEDS	Mission for Essential Drugs and Supplies
MOH	Ministry of Health
MOMS	Ministry of Medical Services
MOPHS	Ministry of Public Health and Sanitation
MSH	Management Sciences for Health
MTC	medicines and therapeutics committee
NASCOP	National AIDS & STI Control Program
NCMG	National Clinical Management and Referral Guidelines
NMS	National Malaria Strategy

NPHLS	National Public Health Laboratory Service
OJT	on-the-job training
PGH	Provincial General Hospital
PMS	post-marketing surveillance
PPB	Pharmacy and Poisons Board
PSK	Pharmaceutical Society of Kenya
QOC	Quality of Care
RDT	rapid diagnostic test
SCMS	Supply Chain Management System
SDP	service delivery point
SWAp	sector-wide approach
TB	tuberculosis
TORs	terms of reference
TOT	training of trainers
TWG	Technical Working Group
UON	University of Nairobi
USAID	United States Agency for International Development
USD	US dollar
USG	US Government
USP	United States Pharmacopoeia
WHO	World Health Organization

EXECUTIVE SUMMARY

The availability of health commodities of good quality and their safe and appropriate use are important prerequisites for the provision of quality health services. Therefore, in addition to ensuring access, it is important to address issues related to quality assurance of these products and implement programs that will support health care workers and consumers in using these commodities rationally, minimizing adverse and unwanted effects while deriving the required therapeutic outcomes. Reaching these goals requires a holistic approach to address commodity management, including selection, procurement, distribution, and use. These processes must be supported by an enabling policy and legal framework and proper management support, including adequate financing, appropriate human resources, and functional information management systems for evidence-based decision making.

Health Commodities and Services Management (HCSM) is a five-year (April 1, 2011–March 31, 2016) USAID Kenya program, implemented by Management Sciences for Health (MSH). The goal of the program is to improve health outcomes and impact through sustainable, country-led programs and partnerships. Specifically, this is a systems strengthening program, supporting systems that deliver essential health commodities and services for the country's health sector, with a focus on key public health priorities—HIV/AIDS, malaria, TB, and reproductive health. Anchored on the USAID Kenya objective of strengthening health systems for sustainable delivery of quality services, the program has three outcome areas: strengthened Ministry of Health (MOH) commodity management, strengthened pharmaceutical services, and strengthened laboratory services.

The program was officially launched by Prof. Peter A. Nyong'o, Minister for Medical Services, on June 10, 2011, at a ceremony attended by senior officials from the Ministry of Medical Services (MOMS) and the Ministry of Public Health and Sanitation (MOPHS), USAID Kenya, and other stakeholder organizations. During the setup period, the program developed an 18-month work plan (covering April 1, 2011, through September 30, 2012) in collaboration with the ministries of health (MOH) as well as national- and regional-level counterparts and stakeholders. Additionally, a national baseline survey conducted during the initial months of the program informed activity design and prioritization as well as the development of the program's monitoring and evaluation (M&E) framework.

Overall, the program has adopted a systems strengthening approach based on an implementation model that seeks to improve local capacity to lead and manage service delivery and health commodity management. In doing this, the program seeks to adapt and implement proven pharmaceutical and laboratory management approaches and tools and bring them to scale, and to integrate them across all public health programs. The program is also cognizant of the need to build on existing collaborations and linkages as well as create new ones with stakeholders, donors, and implementing partners to scale up interventions and to develop strategic partnerships that promote harmonization of technical strategies and coordination of donor inputs.

In the implementation of work plan I, HCSM worked collaboratively with both the MOMS and the MOPHS, as well as other stakeholders, to ensure that their priorities were addressed and that implementation was in accordance with approved health sector plans. To achieve this, the

program adapted a two-pronged approach, which involved working with MOH at the central (national) level and the peripheral (regional) level in implementing activities.

At the central level, MSH/HCSM worked closely with the ministries of health to strengthen structures and systems for commodity security, appropriate use, and medicine safety, and also supported initiatives to review and develop an appropriate policy and legal framework to guide and facilitate commodity management and service delivery at all levels of the health system. Specifically, the program has provided technical leadership to national-level commodity Interagency Coordinating Committees (ICCs) and Technical Working Groups (TWGs) for improved commodity security. A key activity has been support for forecasting and quantification exercises across all programs to inform commodity procurement and supply planning. In addition, HCSM has supported compilation of national monthly stock-status reports for the priority health programs, which have been used to inform national-level decision making.

Also at the national level, HCSM has supported the MOH in the development, finalization, dissemination, and implementation of policy guidelines such as the Kenya National Pharmaceutical Policy (KNPP) and clinical governance tools, including the National Clinical Management and Referral Guidelines (NCMG) and program-specific treatment guidelines. In addition, the program contributed to health sector policy reviews to support the implementation of the 2010 constitution of Kenya. The program also contributed to the finalization of the National Health Policy Framework 2012–2030 and the Kenya Health Sector Strategic Plan (KHSSP) July 2012–June 2017, which provides medium-term direction for health services in the country.

The program has also supported the Pharmacy and Poisons Board (PPB) in promoting patient safety through better documentation and reporting of poor-quality medicinal products and adverse drug reactions, and improved use of pharmacovigilance data for decision making. Specific decisions taken by the PPB have included medicine withdrawals, recalls, label changes, and closure of pharmaceutical manufacturing companies. Recognizing that provision of quality and appropriate health care requires a functional laboratory service, the program also worked with the ministries of health, the National Public Health Laboratory Service (NPHLS), and other stakeholders to strengthen laboratory systems at both the central and peripheral levels. The focus has been on ensuring an uninterrupted flow of laboratory commodities and their appropriate management and use; this has included development and implementation of laboratory commodity management curricula to improve inventory management and commodity usage reporting.

At the peripheral level, the program focused on providing technical support to regional health management teams and facilities in establishing and strengthening oversight structures for commodity management and use, including the establishment of provincial and district health commodity security committees and the strengthening of Medicines and Therapeutics Committees (MTCs) at hospitals. Eight provincial and more than 50 district commodity security committees have been operationalized, with the mandate to improve commodity management, accountability, and usage reporting. Working with these committees, HCSM has implemented a package of targeted interventions, including orientation on commodity management for district managers and facility staff; on-the-job training (OJT) and mentorship on the use of various

commodity management tools and approaches; and supportive supervision in the program's priority districts.

This period has been marked by an enhanced rollout of the ARV Dispensing Tool (ADT), an electronic dispensing tool for ARVs, which helps facilities to better manage these medicines, report usage, and follow up patients. MTCs have been formed or reactivated in more than 50 level 4–5 hospitals, with HCSM supporting capacity building for these committees as well as implementation of activities and interventions to improve medicine use, quality of service delivery, and ultimately, health outcomes.

Overall and to ensure sustainability, HCSM has been deliberate in the design and implementation of activities, in order to ensure skills transfer, integration, and mainstreaming of approaches and tools. To this end, the program has worked to develop skills in commodity management and pharmaceutical care at both the pre- and in-service levels. Working with middle-level colleges such as the Kenya Medical Training College (KMTC) and the University of Nairobi (UON), the program has been instrumental in curricula reforms and in the restructuring and the introduction of courses that address specific health sector needs. For example, the program supported the development of a master's-level course in Pharmacoepidemiology and Pharmacovigilance currently being implemented at the UON, and the incorporation of commodity management in courses into the curriculum at KMTC. At the in-service level, the program continues to work with the MOH and professional associations in developing and implementing targeted workplace and continuous professional development (CPD) courses to address specific needs and identified gaps.

In implementing the HCSM work plan I, the program experienced a number of challenges, such as competing priorities among MOH counterparts and additional needs beyond the scope of the program at the peripheral level, for example, weak commodity storage infrastructure and staffing issues.

During the implementation of work plan I, the program learned a number of key lessons, including the importance of leveraging with other partners and the need for tailored, region-specific interventions as well as greater MOH engagement for enhanced sustainability of interventions.

These lessons learned have played a critical role in the development of the program's work plan II (covering October 2012 to September 2013), which was carried out through a participatory process led by MOH and involving all stakeholders, in line with the program's approach of promoting country-led, country-owned initiatives.

INTRODUCTION

The MSH Health Commodities and Supplies Management (MSH/HCSM) program goal is to build capacity within the Kenya health system for effective management of health commodities and delivery of quality pharmaceutical and laboratory services at all levels. Awarded in April 2011 and running through March 2016, the program is designed to contribute to strengthening health systems for the sustainable quality services component of the USAID Kenya implementation framework for the health sector. Overall, the program has adopted a systems strengthening model that seeks to improve local capacity to lead and manage service delivery and health commodity management. This is augmented by a systematic approach that emphasizes capacity building in the design and implementation of interventions for enhanced sustainability.

The program has three focus areas:

- Commodity management support for the Ministry of Medical Services (MOMS)/Ministry of Public Health and Sanitation (MOPHS) and health facilities
- Support to pharmaceutical policy and service delivery
- Support to laboratory governance, commodity security, and service delivery (implemented in collaboration with the US Centers for Disease Control and Prevention [CDC]–funded Strengthening Public Health Laboratory Systems (SPHSL) program implemented through MSH)

Figure 1 on the next page illustrates the three focus areas.

In implementing work plan I, the program sought to build on and strengthen existing systems using the following core principles and approaches:

- Promoting country-led and country-owned initiatives
- Using of innovative approaches to and building local capacity for improved management of health commodities
- Adapting and implementing proven pharmaceutical and laboratory management approaches and tools and bringing them to scale
- Promoting integration of approaches and tools for pharmaceutical and laboratory subsectors across public health programs
- Engaging the private sector and professional bodies to strengthen both pharmaceutical and laboratory management systems in support of public health goals

- Promoting new concepts in pharmaceutical management and services (such as pharmaceutical care and pharmacovigilance) and laboratory management and services (e.g., integrated laboratory networking and local quality assurance) to complement commodity security and supply chain strengthening activities
- Facilitating the adoption of new health technologies and innovative strategies to support the scale-up and expansion of treatment services
- Building on existing as well as new collaboration and linkages with stakeholders, donors, and implementing partners to scale up interventions; developing strategic partnerships that promote harmonization of technical strategies and coordination of donor inputs
- Focusing on health sector-wide systems strengthening for commodity management and services to include both faith-based organizations (FBOs) and the private sector

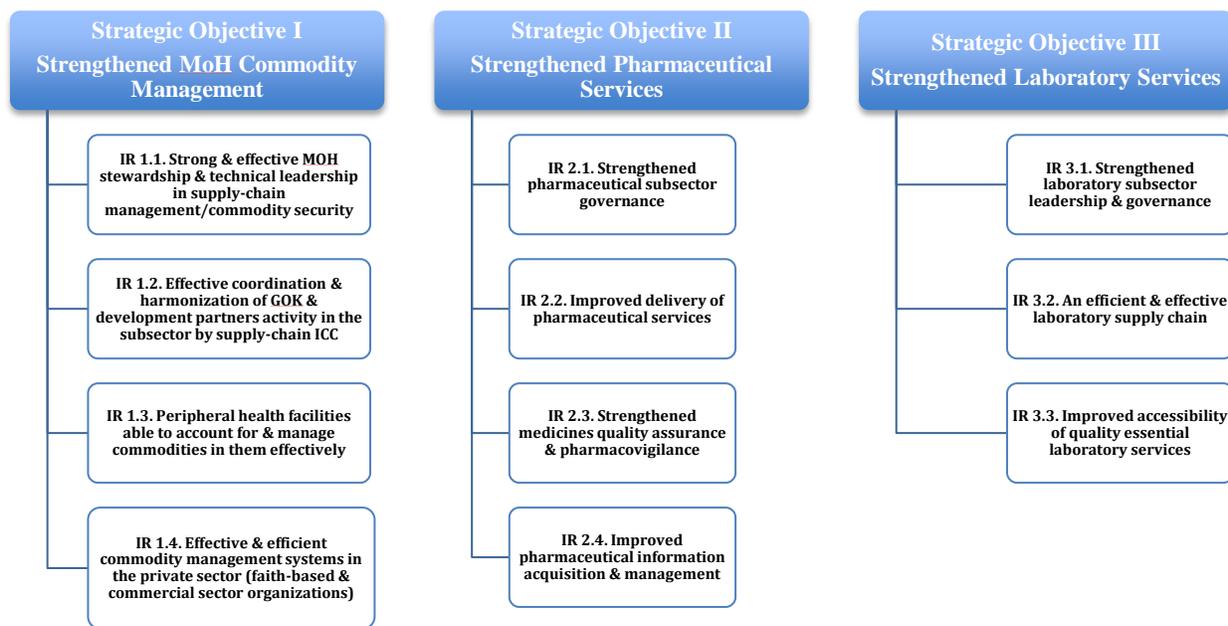


Figure 1. HCSM results framework

COMMODITY MANAGEMENT AND SECURITY

During the reporting period, HCSM implemented various interventions with the aim of ensuring uninterrupted access to health commodities at the health facility level. The program focused on improving management and accountability at the peripheral level as well as improving oversight and planning at the central level.

Central-Level Commodity Management and Security

HCSM supported the MOH in playing a greater and more effective leadership role in supply chain management and commodity security. In implementing its activities, HCSM adopted a mix of approaches, including providing technical assistance and active participation in high-level stakeholder meetings, technical working groups, and targeted training workshops, and also provided active support to specific initiatives. These interventions ensured that stock-outs of health commodities for priority health programs—HIV/AIDS, malaria, TB, and reproductive health—were largely avoided at the national level. Major collaborators in these activities included both ministries of health, priority health programs (National AIDS & STI Control Program [NASCOP], Division of Malaria Control [DOMC], Division of Reproductive Health [DRH], Division of Leprosy, Tuberculosis and Lung Diseases [DLTLD]), Kenya Medical Supplies Agency (KEMSA), US Government (USG) partners (e.g., Kenya Pharma, the Supply Chain Management System [SCMS], KEMSA’s technical assistance partner), and other donor agencies (Danish International Development Agency, German International Development Agency, and the Clinton Foundation).

Other key national-level activities and achievements in commodity security over the reporting period include capacity building and skills transfer for forecasting and quantification (F&Q) and pipeline monitoring; systems strengthening and capacity building for supply chain audits; supporting the generation of monthly stock-status reports; supporting national quantifications; supporting a malaria Quality of Care Survey; and participating in national policy reform activities.

Capacity Building and Skills Transfer for F&Q and Pipeline Monitoring

Using a systematic capacity building approach that addressed all levels of capacity development, the program engaged in strengthening the capacity of MOMS/MOPHS and priority health programs for commodity management and security. Besides supporting active participation of senior MOMS/MOPHS and priority program staff in commodity security–related activities, HCSM conducted quantification and pipeline monitoring training courses, during which a total of 25 key officers were trained. Those trained include 23 MOH officers drawn from various divisions and programs and two staff from the Mission for Essential Drugs and Supplies (MEDS). Additionally, six senior DRH staff were trained in quantification and pipeline monitoring, including the use of various tools (Reality Check, Pipeline®). These officers have continued to apply the skills learned during the trainings to provide leadership in national quantification activities.

In addition, three staff from NASCOP and DOMC successfully supported the review of the Global Fund Round 10 procurement plans on behalf of the country in Geneva in 2011. Their work contributed to ensuring that Kenya received a grant of 345 million US dollars (USD) for HIV and AIDS programs, as well as a USD 136.9 million grant for malaria programs from the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Supply Chain Audits

Supply chain audits are important in assessing the efficiency and effectiveness of supply chain systems. Undertaking supply chain audits on a regular basis can help identify potential areas of weakness and hence provide opportunities for targeted interventions.

To build systems and capacity for health commodity supply chain audits, the program initiated and supported various initiatives. This included supporting the MOH to in developing an integrated tracer list of health commodities—a key tool for these audits. The list consists of pharmaceuticals, laboratory commodities, and nonpharmaceuticals (medical supplies and dental, X-ray, and rehabilitative care products).

The program also supported the review of the supply chain audit checklist specific to HIV laboratory commodities and in collaboration with NPHLS, conducted a supply chain audit at four sites in Nyanza province (New Nyanza Provincial General Hospital [PGH], Kisii level 5 Hospital, Siaya District Hospital and Bondo District Hospital). Measures to address the gaps identified at the four sites in Nyanza are being implemented with support from the Provincial Health Management Team and Hospital Management Teams. As a result of the audit at New Nyanza PGH, the supply of HIV rapid test kits to the hospital, which had been suspended due to concerns about accountability, was reestablished. HCSM intends to continue supporting MOH to scale up implementation of similar supply chain audits within the health system.

Pipeline Monitoring of National Health Commodity Stocks

HCSM supported the generation of national monthly stock-status reports for priority health commodities, which have been used to provide strategic information to MOH as well as to programs, donors, and partners supporting the public health sector (box on next page). The information contained in these strategic information reports has continued to be used by all key stakeholders to keep informed about national stock status as well as make supply chain decisions, such as procurement planning and forestalling potential stock-outs.

Key Features of the National Stock Status Reports

The national stock status reports are produced on a monthly basis.

They summarize the national commodity stock status in simple charts, showing how long the in-country stocks and pending stocks on order from suppliers will last.

Comments summarizing the key highlights for the month as well as the stock situation and key action points are included.

They have proven to be popular and user-friendly, as they provide a quick snapshot of commodity security for the key program commodities.

They provide strategic information to support MOH decision-making, thereby facilitating management of commodity availability, allocation of resources, and better coordination of the various donors and partners involved in the commodity supply chains.

National Quantifications

Quantification informs planning and resource mobilization for timely commodity procurement. When done properly, it minimizes the need for emergency procurement and ensures uninterrupted availability of commodities within the pipeline. During the last work plan period, HCSM provided technical support to the MOH in the national quantification of commodities for HIV/AIDS, malaria, TB, and family planning (FP), as well as essential medicines and medical supplies (EMMS). The national quantification process was led by key MOH departments and incorporated inputs from all key stakeholders, including supply chain agencies (KEMSA, Kenya Pharma, and SCMS) and donor agencies.

Quantification reports produced include FP F&Q report for fiscal year (FY) 2011/2012–2013/2014; F&Q and procurement plan for FY 2011/2012 for the malaria program; F&Q for FY 2011/12 for the TB program; F&Q for FY 2011/12 and 2012/13 for HIV commodities and F&Q for FY 2012/13 for EMMS commodities. The above reports have informed development of commodity procurement plans for the various programs, supported commodity management, and guided procurement. The outputs of the quantification process were used to lobby for financial commitment from the Government of Kenya (GOK) and development partners, as in the following examples:

- The 2012/13 F&Q for HIV and supply planning report was used in the preparation of Global Fund Round 10 Year 2 work plan as well as GOK commodity procurements.
- The FP quantification for FY 2011/2012–2013/2014 informed donor commitments of over USD 18 million for procurement of family planning commodities.
- As a result of the malaria quantification, timely call down of pending procurement of AL under the Global Fund as well as the second procurement of Global Fund Affordable Medicines Facility–malaria subsidy was initiated.

- Quantification of malaria rapid diagnostic tests (RDTs) for FY 2012/2013 and FY 2014/2015 informed additional support for purchase of 4.2 million extra doses of AL, which was made necessary by reduced Global Fund funding for procurement.

Quality of Care Survey

The 2009–2017 Kenya National Malaria Strategy (NMS) recommends that malaria case-management should be based on confirmed parasitological diagnosis and artemisinin-based combination therapy (ACT). The NMS sets targets to ensure the universal availability of ACTs and diagnostics; universal coverage of health facilities and health workers with health systems support activities; and universal health worker adherence to malaria case-management guidelines.

HCSM has provided technical support to DOMC on case and drug management at the central and peripheral levels in implementation of the NMS. To monitor the progress of these activities, HCSM in collaboration with DOMC has undertaken biannual national health facility surveys. Two surveys—round 3 (July–August 2011) and round 4 (March–April 2012)—were conducted during the reporting period. Key findings showed improvements in the availability of malaria diagnostic services, with an increase from 55 percent to 65 percent, mainly due to an increase in the availability of RDTs (7.5 percent vs. 16.9 percent), among other positive findings.

Participation in National Policy Reform Activities for Commodity Security

The promulgation of the new constitution in 2011 has made it necessary to review all health laws and ensure that they are consistent with the new structures established. The importance of commodity security as an element of service delivery must be clearly articulated in the revised policy documents and strategic plans now under development by the MOH. HCSM has continued to participate actively in these initiatives, including the formulation of the Kenya Health Sector Strategic Plan III. The program has participated specifically under the health technologies thematic group, one of the pillars of the health systems strengthening approach adopted by MOH. This health systems strengthening process is ongoing in preparation for the merging of MOMS and MOPHS and the devolution of the central government after elections in March 2013. The health sector’s coordinating mechanism under the sector-wide approach (SWAp) secretariat is being restructured to align with the Comprehensive Health Sector Framework 2012–2030. Finalization of this process will clarify and harmonize the roles and responsibilities of state and the non-state actors.

HCSM has also supported MOH priority programs in reviewing and developing policies and guidelines to promote commodity security and assist health care workers at all levels in effectively managing the commodities placed in their custody. For example, DRH was able to review their National Reproductive Health Commodity Security Strategy for 2012–2017, as well as develop a booklet for standard operating procedures and job aids for reproductive health commodity management.

Peripheral-Level Commodity Management and Security

During work plan I, MSH/HCSM worked to initiate and establish its decentralized regional-level (peripheral) activities, with a presence in all five USAID Kenya defined health zones. To support the rollout of regional-level work, the program deployed staff to each of the regions to work alongside MOH provincial, district, and hospital management teams as well as regional-level implementing partners such as APHIA (AIDS Population and Health Integrated Assistance) Plus teams. The strategy for the program at this level has been to support the establishment of provincial and district health commodity security committees to provide oversight for commodity management and security and the implementation of targeted intervention packages for various levels. Using a systematic, phased scale-up approach, the program targeted rollout of district-level interventions to cover 50 districts during the first phase, in the initial 18 months. This standardized package of interventions has entailed strengthening the capacity of local health management teams in commodity security, overall commodity management and reporting, and in providing supportive supervision to staff.

Commodity Security

HCSM worked toward strengthening the capacity of Provincial and District Health Management Teams (P/DHMTs) to plan, manage, and supervise health commodities and services for improved service delivery. This was achieved through support for formation and operation of provincial and district-level health commodity security committees. Eight provincial and 52 district commodity security committees have been formed and are operational. Members include provincial and district health management team members as well as representatives of key stakeholders such as KEMSA, Kenya Pharma, and APHIA Plus. In addition and in recognition of the need for broad-based multisectoral representation in health commodity management and coordination forums, especially at the provincial level, the program advocated for inclusion of FBOs (e.g., Christian Health Association of Kenya and the Kenya Episcopal Conference) in these committees. The committees were oriented in commodity management, appropriate medicine use (AMU), and pharmacovigilance and were supported in developing their terms of reference and action plans. HCSM has subsequently supported these committees in the development and implementation of these action plans, with an aim of strengthening their capacity to plan, manage, and supervise health commodities and pharmaceutical and laboratory services for improved service delivery.

Commodity Management and Reporting

Commodity management and reporting activities were implemented through strengthening the capacity of facility staff to manage commodities appropriately through capacity building, mentorship, and OJT using training of trainers (TOT) and champions to improve quantification, inventory management, and the use of logistics management information systems (LMIS) tools and reporting. A total of 603 DHMT members drawn from 59 districts were oriented on commodity management; additionally, 412 out of these underwent a two-day intensive training on inventory management, pharmacovigilance, and AMU to better position them as champions for commodity management in their respective districts. The program has worked with other stakeholders and actively engaged in the distribution of LMIS tools and provision of OJT to

health facility staff on how to use the tools appropriately, since availability and use of tools has been singled out as a main factor contributing to low rates of commodity usage reporting.

In addition, the rollout of electronic LMIS tools—the ARV Dispensing Tool (ADT) (figure 2) and the Inventory Tracking Tool—is one of the program’s key areas of support to facilities to improve commodity management and reporting. The program supported review of the ADT to incorporate new regimens per the revised NASCOP guidelines and user feedback from users. The revised version was approved by NASCOP and regional orientations on the tool conducted. A total of 394 regional trainers of trainers were trained in the upgraded ADT. As a result, there has been increased use of ADT in managing the data of patients on antiretroviral therapy (ART). A total of 306 of the 350 targeted sites are using the tool, and approximately 83 percent of patients on ART in the country are being managed using this tool. In addition, 36 of the targeted district-level hospitals and district stores are using the Inventory Tracking Tool.

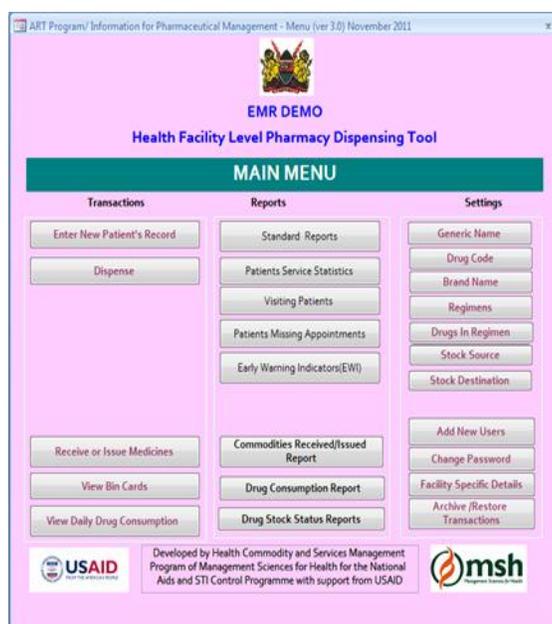


Figure 2. Main menu of the ARV dispensing tool

Supportive Supervision

Strengthening the technical and operational capacity of P/DHMTs for supportive supervision, including provision of integrated tools and support for quarterly missions, was one of the program’s strategies during the reporting period for improving commodity management in the priority districts. Specifically, the program used champions from the P/DMTs to conduct these visits. Jointly with MOH counterparts, the program has been employing a continuous quality improvement process, which entailed gap analysis, problem identification and prioritization, root cause analysis, and intervention design and implementation at the site level using a standardized tool. Subsequently, supported facilities have developed action plans to guide activity

implementation as well as M&E. Overall, the achievements realized at the peripheral level using this approach during work plan I are summarized in table 1.

Table 1. Cumulative Achievements in Priority Districts

Indicator	Target	Achievement	Percentage achievement
DHMT teams oriented on commodity management and commodity security committees established	50	64	128
DHMT members oriented on commodity management	—	603	—
District champions oriented on commodity management	—	412	—
Districts with commodity management champions	50	59	118
Health workers trained on commodity management	—	2521	—
Districts supported to undertake support supervision	50	50	100
Facilities reached under supportive supervision	500	1,060	212

STRENGTHENED PHARMACEUTICAL POLICY AND SERVICE DELIVERY

The focus of the program in this area is to strengthen health systems to deliver quality pharmaceutical services in all sectors (public, private, and FBO) and all levels (national and peripheral). The overall objectives include strengthening pharmaceutical sector governance, improving pharmaceutical services and pharmaceutical care, strengthening medicines quality assurance and pharmacovigilance, and improving pharmaceutical information acquisition and management for decision making.

During the first 18 months of the program, HCSM used a health systems strengthening approach to strengthen pharmaceutical policy implementation and service delivery at the national/central and peripheral levels. At the national level, the focus was on development of governance-related policies and guidelines, whereas at the peripheral level the focus was on the dissemination and support of implementation of policies to improve both pharmaceutical service delivery and the appropriate use of medicines. In addition, the program continued to support the implementation of the national pharmacovigilance system to promote medicine quality and safety, thus enhancing patient safety.

Central-Level Pharmaceutical Policy and Services Delivery

Support to Policy and Legislative Reform

A functional policy and legal framework is key to the proper regulation and provision of pharmaceutical services. The program worked with the MOH and other stakeholders in conducting health sector policy reviews in support of the implementation of the constitution of Kenya; particularly in developing the MOH position paper on implementation of the new constitution. The program also supported the development of the health bill, National Health Policy Framework 2011–2030, and the associated first five-year medium-term implementation plan (KHSSP III July 2012–June 2017).

To improve governance, HCSM provided technical assistance to MOH in the development, finalization, dissemination and implementation of policy guidelines, such as the KNPP. In addition, the program played a key role in supporting the development of clinical governance tools, including the NCMG and program-specific treatment guidelines. In collaboration with other pharmaceutical sector stakeholders, HCSM supported the MOH—specifically the Department of Pharmacy (DOP) and the PPB—in the ongoing review of laws applicable to the regulation of medicines (health products and technologies) and pharmacy practice in the country.

Support to Improved Medicine Quality Assurance and Pharmacovigilance

HCSM supported the PPB to implement an integrated national pharmacovigilance system in collaboration with the MOH, priority health programs, and other stakeholders. The goal has been to promote patient safety through improved documentation and reporting of adverse drug reactions, poor-quality medicinal products, and use of pharmacovigilance data for decision making.

At the national level, HCSM supported the development of guidelines, training materials, job aids, and biannual medicine information and pharmacovigilance newsletters. HCSM provided technical and operational support for pharmacovigilance data acquisition and transmission to the PPB. This support, coupled with the trainings and sensitization of health care workers on pharmacovigilance, has resulted in improved reporting of adverse drug reactions (ADRs) and poor-quality medicinal products by health facilities to the PPB.

Cumulatively, the number of ADR reports received at the PPB has increased from 1,459 (in September 2011) to more than 5,000 (by September 2012); similarly, the number of reports received of poor-quality medicinal products has increased from 175 (in June 2011) to more than 250 (by September 2012)—representing an increase of more than 240 percent and 42 percent, respectively, in one year. To boost reporting and increase the reach of the pharmacovigilance system, HCSM is currently supporting the PPB in the development of an electronic reporting system on multiple platforms, including the Web, mobile technology, and desktop applications. This initiative is expected to make reporting easier and faster and to facilitate data collation and analysis at the PPB.

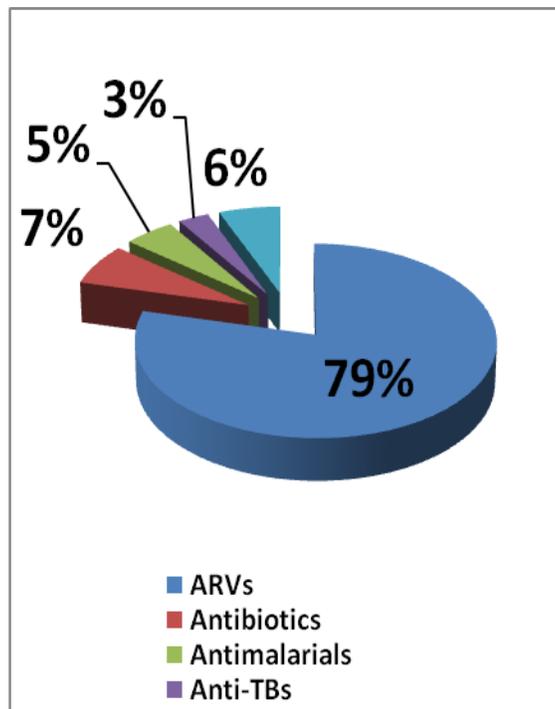


Figure 3. Proportion of ADR reports by class of medicine, as of September 2011

To augment the above mentioned spontaneous reporting of poor-quality medicinal products, the PPB, with support from HCSM and other stakeholders, has been proactively monitoring the quality of medicines in the Kenyan market through post-marketing surveillance (PMS) activities. During the reporting period, the program provided the PPB with technical and operational support for analysis, documentation, and dissemination of PMS survey reports for ARVs, as well

as TB and malaria medicines. This was done in collaboration with the World Health Organization (WHO), the CDC, and the United States Pharmacopoeia (USP). These PMS reports were disseminated to central-, regional-, and facility-level MOH staff, priority health program staff, health care workers in all sectors, and other stakeholders in various meetings, events, and fora.

Pharmacovigilance data analysis and PMS survey findings have led to several regulatory actions, including drug withdrawals, recalls, label changes, and closure of pharmaceutical manufacturing companies. Examples include the following:

- Withdrawal of market authorization of two pharmaceutical companies due to poor-quality products
- Recall of certain brands of paracetamol tablets, metronidazole suspension, herbal preparations, and TB medicines
- More stringent restrictions or rescheduling of some antibiotics and injectable medicines

More than 70 percent of ADR reports have been related to ARVs, with this information used to guide selection of recommended ART regimens during the recent review of national ART guidelines. Currently, there is heightened vigilance on tenofovir, one of the recommended first-line agents, following growing reports of renal toxicity.

The program continues to support the compilation and dissemination to all stakeholders, policy makers, and health care workers of a quarterly newsletter highlighting pharmacovigilance-related activities and the resultant outcomes, including regulatory decisions, thus promoting patient safety. For example, in the first quarter of 2012, 10,000 copies were printed and disseminated.

Curriculum Development and Implementation

Several health sector assessments have shown pervasive challenges in human resources for health, particularly highlighting staff shortages and lack of requisite skills for the appropriate management and use of health commodities. This gap has been a major constraint in the management of health commodities, the delivery of quality pharmaceutical services, and the appropriate use of medicines.

To strengthen human resources capacity, HCSM has continued to work with the MOH and selected training institutions in curriculum review and restructuring to include commodity management and pharmaceutical care–related topics. At this preservice level, HCSM has supported the following:

- Incorporation of commodity management topics into the pharmaceutical supply management course at the KMTC and sensitization of 67 KMTC professional practice experience tutors on mentorship skills for pharmaceutical management and care as well as their orientation in the course content and training skills.

- Development and implementation of a KMTC-led accredited international course on effective management and appropriate use of medicines and medical supplies. The course is administered by KMTC staff, and participants are expected to pay only a nominal fee, to promote uptake while still ensuring sustainability in its implementation.
- Development and implementation of a master's-level degree course in pharmacoepidemiology and pharmacovigilance by the UON in response to the increasing demands for skilled professionals in this area. The first intake of more than 20 postgraduate students has already enrolled for this course and classes are ongoing.

The focus of the program at the in-service level has been to build the skills of health care workers across all cadres for effective management of health commodities, and their appropriate use to promote better treatment outcomes. Specifically, HCSM supported the following:

- Development of an integrated course on Effective Management of Health Commodities that incorporates essential medicines and supplies plus program-related health commodities
- Development of a curriculum on implementation of MTCs to promote AMU at the facility level

Continuous Professional Development

The program supported implementation of needs-based continuous professional development (CPD) programs and scale-up of trainings in partnership with professional associations such as the Pharmaceutical Society of Kenya (PSK) and the Kenya Pharmaceutical Association (KPA). To inform review of guidelines and implementation of CPD programs for pharmaceutical cadres, the program supported a countrywide survey to determine the status, needs, constraints, and enablers for CPD programs. The survey findings were disseminated to 325 and over 500 participants, respectively, during the June 2012 PSK symposium and the July 2012 KPA conference. Collaboratively with PSK, HCSM identified priority CPD topics, developed a CPD logbook for documenting participation in CPD activities, and supported implementation of CPD sessions countrywide. To date, a total of 7 PSK regional CPD sessions have been held, reaching 244 health care providers. In addition, the CPD logbook has been disseminated to 320 pharmacists.

Peripheral-Level Pharmaceutical Policy and Services Delivery

Medicines and Therapeutic Committees and Appropriate Medicine Use

MTCs are institutional committees responsible for promoting appropriate use of medicines and delivery of quality pharmaceutical and related services. However, these committees are nonexistent, moribund, or nonfunctional in many facilities in the country. This problem has often been attributed to health care workers' lack of knowledge and skills to conduct MTC activities. To support MTCs at the facility level, the program, in collaboration with the DOP, developed and implemented a set of interventions over the last 18 months, including:

- Developing an MTC assessment tool for use in assessing status and identifying areas for capacity building and support. The tool was used in assessing more than 30 level 4–6 facilities in the country.
- Developing MTC training curricula and implementing training and related capacity building activities in more than 40 level 4–6 facilities. More than 180 health care workers have been trained.
- Supporting facilities to develop and implement MTC action plans addressing gaps in rational medicine use and pharmaceutical service delivery.

For example, HCSM worked with the Kenyatta National Hospital to revitalize its MTC, which subsequently implemented a number of initiatives in the hospital to improve patient care. This included setting up systems for ADR monitoring and reporting, as well as medication error reporting and prevention, in addition to embarking on a review of the institutional formulary list and manual.

Medicine Quality Assurance and Pharmacovigilance

In collaboration with the PPB and regional partners, HCSM supported implementation of pharmacovigilance at the peripheral level through capacity building of health care workers and dissemination of guidelines, tools, job aids, and newsletters. The program supported the dissemination of 6,000 pharmacovigilance job aids and more than 10,000 copies of the *Medicines Information and Pharmacovigilance* newsletter to health care workers in the public, private, and FBO sectors. These materials are aimed at promoting medication safety through strengthening advocacy for pharmacovigilance and updating health care workers on activities and regulatory actions taken by the PPB. Additionally, the program provided technical and operational support in sensitizing health care workers in all sectors on pharmacovigilance using the revised national training curricula, job aids, and manuals. The training curriculum has been used to train more than 300 health care workers; additionally, more than 600 DHMT members and 2,500 facility staff have been sensitized in pharmacovigilance.

In collaboration with the PPB and NASCOP, HCSM also supported mini-PMS for ARVs and medicines to treat and prevent opportunistic infections, which was undertaken in 32 facilities in Nyanza and Nairobi provinces in response to reports of counterfeit ARVs circulating within the country. As a result of this exercise, a number of regulatory actions were taken, including the following:

- Counterfeit zidolam N batches E100766 and A9366 were withdrawn, retrieved from the market and quarantined.
- The program assisted NASCOP in developing recommendations that would mitigate recurrence of the same problem. These included expedited merging of the existing multiple procurement and supply chains for the public sector for ARVs, and limiting these functions to KEMSA and Kenya Pharma.

Overall, pharmacovigilance-related activities at the peripheral level have contributed to increased reporting of ADRs and poor-quality medicines, and these reports have been used for decision making, resulting in several regulatory decisions including product recalls and withdrawals by the PPB, as stated above.

Policy Dissemination and Implementation

In collaboration with the MOH, regional- and facility-level health management teams, and other stakeholders, the program worked to support the dissemination and implementation of pharmaceutical and related policies to strengthen service delivery at the peripheral level. Following the approval of the revised KNPP by the Cabinet, HCSM supported the DOP in reviewing the policy and identifying implementation requirements that will call for legislative, regulatory, and administrative changes. Furthermore, the program is supporting the development of a pharmaceutical services governance framework aligned to the stipulated devolved system under the new constitution and in line with the policy directions of the KNPP.

For improved pharmaceutical service delivery and care, besides strengthening MTCs, the program supported dissemination of clinical governance tools, including the NCMG, the Kenya Essential Medicines List (KEML) and AMU guidelines nationwide. In addition, the program conducted regional dissemination workshops in several provinces, including Nairobi, Nyanza and North Eastern provinces, to sensitize health care workers and promote their use.

SUPPORT TO LABORATORY GOVERNANCE, COMMODITY SECURITY, AND SERVICES

Laboratory diagnosis and monitoring are integral to quality health service delivery. The provision of quality laboratory services is dependent on an uninterrupted supply of laboratory commodities. For the program, laboratory commodity management and security have been key focus areas over the reporting period. Implementation of other areas, such as governance and quality of laboratory services, has been led by the CDC-funded Strengthening Public Health Laboratory Services project implemented by MSH.

Interventions to address laboratory commodity security have been targeted at both the central and peripheral levels. At the national level, the major stakeholders in implementing the activities included the various departments at the MOH (NPHLS, DDFS, National HIV Reference Laboratory, and National Blood Transfusion Services), donor agencies (e.g., USG, the Japan International Cooperation Agency [JICA]), supply chain agencies (KEMSA, SCMS), other implementing partners, and facility staff. These stakeholders have also been engaged during implementation at the peripheral level, with a focus on resource leveraging and collaboration to maximize the impact of the desired interventions. Program achievements toward improving laboratory commodity security include supporting national quantification; providing support to pipeline monitoring; strengthening coordination and oversight; strengthening commodity overall management; and supporting the rollout of malaria RDTs.

National Quantification for Laboratory Commodities

The program supported the MOH during the last work plan period to determine national laboratory commodity requirements, with a focus on priority programs (HIV/AIDS, TB, and malaria). Quantification of these laboratory commodities was incorporated into the overall commodity quantifications undertaken by NASCOP, DLTLD and DOMC for their commodity requirements.

Pipeline Monitoring of National Stock Status

HCSM has continued to support key priority programs to monitor their commodity pipelines. On a monthly basis, the program has supported NASCOP to generate the national stock-status report for HIV laboratory commodities. This information has been used to inform procurement planning and delivery of required laboratory commodities from suppliers, among other supply chain decisions. This routine monitoring has also ensured that national stock-outs of key HIV laboratory commodities are avoided. Moreover, the stock-status reports have been useful tools for sharing strategic commodity information with key stakeholders to inform decision making on commodity security. This approach has also been applied in other priority programs for tracking of key laboratory commodities on a regular basis, such as malaria RDTs.

Coordination and Oversight for Laboratory Commodity Management and Security

Effective coordination and oversight for laboratory commodity management is an important prerequisite for ensuring commodity security. In previous years, there has been a very fragmented approach in rolling out interventions addressing laboratory commodity management, at both the national and peripheral levels. As a result, issues of laboratory commodity management have not been tackled effectively, compared to other aspects of health service delivery.

At the national level, HCSM has worked to strengthen planning and oversight of laboratory commodity management activities by giving technical support to commodity security TWGs in the priority divisions of NASCOP, DLTLTD, and DOMC, building their capacity to provide stewardship and oversight for commodity management interventions targeting laboratory commodity challenges. Additionally, the program has been supporting interventions aimed at addressing laboratory commodity management gaps and usage reporting. For example, recognizing the importance of the availability of reagents in ensuring patient care, the program, in collaboration with NASCOP and NPHLS, convened a consultative meeting in August 2012 to chart the way forward in addressing the supply chain issues affecting availability of CD4 reagents. During the meeting it was agreed that reporting on laboratory ART commodities would be a key performance indicator for laboratories. The stakeholders also agreed that issues of service, placement, and maintenance of equipment would be handled from the national-level, unlike previously, when individual facilities were dealing directly with suppliers.

At the peripheral level, weak coordinating structures have been highlighted as one problem area that must be addressed to improve laboratory commodity security. Therefore, the program began an initiative to support provincial and district laboratory managers to take the lead in addressing laboratory commodity-related issues. By September 2012, all provincial laboratory managers had developed into crucial members of the provincial commodity security teams. The program also supported regional review meetings that brought together Provincial Medical Laboratory Technicians, Provincial Medical Laboratory Scientific Officers, District Medical Laboratory Technicians, and laboratory in-charges. During these meetings, teams identified gaps and challenges in laboratory commodity management, developed action plans, and set targets. The program is supporting the implementation of these action plans and tracking achievements against the set targets.

Capacity Building for Laboratory Commodity Management

Strengthening the laboratory commodity management system has required a mix of approaches to address the complex, multifaceted nature of the challenges it faces. The program adopted a comprehensive approach aimed at building both human and institutional capacity to manage laboratory commodities.

To address the knowledge gaps in commodity management, the program developed a laboratory commodity management curriculum in collaboration with NPHLS, DDFS, National Blood Transfusion Service, and others. The curriculum has been piloted and used to train 46 laboratory

TOT staff, and has now been finalized in readiness for countrywide rollout. HCSM has also developed commodity management job aids, which have been disseminated to sites. These address key aspects of commodity management such as quantification and inventory management of laboratory commodities.

Table 2 shows the various tools that have been printed and disseminated by HCSM to service delivery points (SDPs).

Table 2. Tools and Other Material Disseminated by HCSM to SDPs

Description
<ul style="list-style-type: none">• Job aids (quantification, storage practices, inventory management)• Laboratory stock cards• Commodity top-up forms• Instruction forms• Daily activity register (MOH 642)• Facility consumption request and reporting forms (MOH 643)• Expiry tracking charts• Temperature monitoring charts

These job aids and commodity management tools have been distributed to sites across the country, with specific focus on the priority districts targeted by HCSM under the first-year work plan. For example, 4,402 job aids, 9,462 stock cards, 11,084 commodity top-up forms, 4,303 instruction forms, 4,420 DAR (MOH 642), 4,325 F-CDRR (MOH 643), 4,396 expiry tracking charts, and 4,388 temperature monitoring charts were distributed between April 2012 and June 2012.

Other approaches used by the program to address commodity management include supporting one-day orientation sessions on the use of laboratory inventory and LMIS tools; provision of OJT on good inventory management; supportive supervision on data quality and continuing medical education sessions on laboratory commodity management. These strategies have improved the management of laboratory commodities; for example, Malaria Quality of Care (QOC) round 4 survey findings indicated an improvement in the availability of laboratory stock cards from 52 percent (at HCSM baseline survey) to 79 percent in the sampled facilities.

Support to Rollout of Malaria RDTs

HCSM worked closely with the DOMC to develop a national system to scale up the use of malaria RDTs. Under work plan I, the program supported the piloting of malaria RDTs in five districts: Msambweni, Manga, Machakos, Ijara, and Vihiga. The program's support entailed development of training materials on the use of malaria RDTs, implementing training sessions,

and supportive supervision in the pilot districts. To date, 491 front-line workers from the five pilot districts and 33 epidemic preparedness and response districts have been oriented. The lessons learned from the pilot will be used in rolling out the use of malaria RDTs nationally under work plan II, a priority area for the DOMC, the President’s Malaria Initiative, and the Global Fund. Figure 4 shows a job aid on the use of malaria RDT kits.

HOW TO DO THE RAPID TEST FOR MALARIA

REQUIREMENTS FOR TEST PERFORMANCE

<p>New unopened test kit*</p> <p><small>*These are not an unopened test kit</small></p>	<p>Gloves</p>	<p>Timer</p>	<p>Sharps box</p>	<p>Sterile gauze/ cotton wool</p>
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PROCEDURE	TEST RESULTS
<p>1 Open & label the test cassette.</p>	<p>POSITIVE A line near letter "C" and a line near letter "T" means the patient is POSITIVE for malaria in single species detecting tests.</p>
<p>2 Open the alcohol swabs. Clean the skin finger on the patient's left hand with the alcohol swabs. Allow the finger to dry before pricking. Open the lancet. Pick patient's finger to get a drop of blood.</p>	<p>POSITIVE The test is positive even if the line near "T" is faint.</p>
<p>3 Wipe the first drop with the sterile gauze/cotton wool. Use the Pipette/Collecting Device to collect the drop of blood.</p>	<p>NEGATIVE A line near letter "C" and NO LINE near letter "T" means the patient DOES NOT have malaria.</p>
<p>4 Transfer the collected blood into the sample well marked "S".</p>	<p>INVALID NO LINE near letter "C" and one or no line near letter "T" means the test is INVALID.</p>
<p>5 Add the required buffer solution into the buffer well marked "B".</p>	<p>INVALID NO LINE near letter "C" and one or no line near letter "T" means the test is INVALID.</p>
<p>6 Time the test as per manufacturer's instruction after adding the buffer. Read test results. <i>(NOTE: Do not read the test sooner than the recommended time after adding the buffer. You may get FALSE results.)</i></p>	

WASTE DISPOSAL	RECORD
<p>Discard the used lancet, pipette, blood collecting device in the Sharps box immediately after use.</p>	<p>Record the test results in your registers. <i>NOTE: Each test can be used ONLY ONE TIME. Do not try to use the test more than once.</i></p>
<p>Dispose the gloves, alcohol swabs, cassette and packaging in a non-sharps waste container immediately after use.</p>	

Figure 4. Malaria RDT kit job aid

Increasing Universal Access to Malaria Diagnosis in Kenya

Mbale Provincial Rural Health Training Centre in Western Kenya receives about 120 outpatients per day, 41 percent of whom are treated for malaria. The center provides various medical services at a subsidized rate; however, malaria treatment is free. According to Dr. Jacob Odipo, who is in charge of the facility, all children below five years receive free mosquito nets, but there is still a high rate of children with malaria. He attributes this to mosquito bites received before children go to bed.

At 11 a.m., mothers start streaming into the center, most carrying children. Victor is one-year old and his mother, Mama Victor, has brought him in for routine immunization, but she is also concerned about his lack of appetite and a high fever. The nurses recommend that Victor get a malaria test. In half an hour, his mother received his test results and he is receiving first-line treatment for malaria.

Three months ago, Victor's mother would have had to wait three to four hours for treatment. Thanks to malaria RDTs, Victor received treatment faster.

“Previously, we used to rely on microscopy for malaria tests and with the limited number of lab technicians, patients would have to wait for three to four hours for their results. Some left before receiving test results because of the long distances they have to travel back home. We suspect an unknown number were self-medicating for malaria to avoid the long lines,” explains Dr. Odipo. The center only has one lab technician performing an average of 200 lab tests per day.

“Malaria RDT kits have helped ease congestion in the labs and helped patients receive treatment faster, with only those who test positive for malaria receiving medication,” Dr. Odipo adds.

RDTs are a much-needed intervention that represents benefits across all areas of the health care delivery system. Correct diagnosis saves the government or the patient USD 4 in unnecessary treatment costs for a malaria-negative case. The kit costs USD 1, whereas the unsubsidized retail cost for artemether/lumefantrine 24s used to treat malaria is approximately USD 5.

The management of malaria was previously based on the clinical symptoms for patients under-five years in malaria-endemic zones. However, the Kenyan Government recently adopted a diagnostic policy to successfully provide universal malaria treatment. This led to the procurement of approximately 80 million RDTs for distribution and use in 2012 through the help of development partners.

HCSM, in collaboration with DOMC, has provided technical assistance through quantification, developing and rolling out the RDT implementation plan, and supportive supervision to ensure that the procured RDTs and other malaria commodities are managed appropriately at the facility level. The program is currently orients about 3,200 front-line health workers on the use of RDTs in lower-level facilities countrywide. Mbale Provincial Rural Health Training Centre was a pilot site on the use of RDTs for improving service delivery to patients like Victor.



Mama Victor administering malaria first-line treatment to Victor in Mbale, Vihiga.

NEXT STEPS

The program has since developed work plan II (covering October 2012 through September 2013), building on the achievements of the previous work plan and drawing on lessons learned in its implementation. The program will continue implementing interventions at both the central and peripheral levels. At the central level, the program will continue supporting MOPHS/MOPHS, priority health programs, and government agencies to strengthen health systems for commodity management and security. The program will also support the ongoing initiatives to review policy and legal frameworks for the health and pharmaceutical sectors. In providing technical assistance at this level, HCSM will leverage with the MOH, donor organizations, implementing partners, and other stakeholders in prioritizing and implementing interventions. The program will also take into account the evolving priorities, restructuring, and reorganization occasioned by the implementation of the country's new constitution and devolution and the new national health policy framework.

HCSM is also providing guidance to the ministries of health (MOMS/MOPHS) on a conceptual framework for the implementation of a national LMIS. This LMIS is intended to institutionalize a framework for the optimal management of health commodities at all levels and provide critical information to improve the health commodities supply chain in Kenya.

At the peripheral level, HCSM will continue collaborating with regional stakeholders and implementing partners to scale up implementation of interventions initiated in the first cohort of priority districts. The program will build on already-established relationships with these regional stakeholders to fast-track and sustain activity implementation. The focus of activities at this level will be to improve management, use, and accountability for health commodities through establishment and support for appropriate oversight mechanisms and capacity building of facility-level staff. The program will continue to use mentorship, OJT, and the monitoring-training-planning quality improvement approaches for institutional and individual capacity building and skills transfer.

INDICATOR PERFORMANCE TABLES

Table 3. Result Area 1: Strengthened MOH Commodity Management

Indicator (those not due yet have been omitted) and data source	Baseline	Target (Sept. 2012)	Achievement as of Sept. 2012	Deviation from target	Comments
IR 1: Peripheral Health Care Facilities Able to Account for and Manage Commodities Within Them Effectively					
<p>Indicator 1: Percentage of health facilities submitting commodity usage reports to the central level for priority program commodities (ART, malaria, TB, FP)</p> <p>Data source: LMU^a workbooks</p>	<ul style="list-style-type: none"> • ART: 84% (ordering points) • Malaria: 62% (SDPs) • TB: 49% (ordering points) • FP: 51% (stores) 	<ul style="list-style-type: none"> • ART: 90% (ordering points) • Malaria: 70% (SDPs) • TB: 70% (ordering points) • FP: 70% (stores) 	<ul style="list-style-type: none"> • ART: 91% (ordering points) • Malaria: 43% (SDPs) • TB: 73% (ordering points) • FP: 58% (stores) <p style="text-align: center;">All as of July 2012</p>	<ul style="list-style-type: none"> • ART: +1% (ordering points) • Malaria: 27% (SDPs) • TB: +3% (ordering points) • FP: -12% (stores) <p style="text-align: center;">All as of July 2012</p>	<p>Reporting rates have been fluctuating and in the last 3 months they have averaged as follows:</p> <ul style="list-style-type: none"> • ART: 92% (ordering points) • Malaria: 48% (SDPs) • TB: 56% (ordering points) • FP: 52% (stores) <p>This fluctuation has been influenced by diverse determinants such as availability of tools, capacity gaps in use of LMIS tools, and challenges with data transmission systems to the LMU.</p> <p>The program has been addressing these challenges in LMIS and has prioritized them in work plan II.</p>
<p>Indicator 2: Total number of health workers trained in commodity management (desegregated by cadre and ownership [FBO or public])</p> <p>Data source: HCSM progress reports</p>	—	Built capacity of regional and facility staff in commodity management in 50 districts	More than 2,500 health care workers trained from 59 districts	+9	Training of health care staff in commodity management was part of intensive rollout of HCSM Commodity and Services Management Package at the peripheral level.
<p>Indicator 3: Percentage of facilities reporting stock-out for a set of tracer health commodities on the day of the assessment</p> <p>Data source: Malaria QoC survey round 4</p>	<ul style="list-style-type: none"> • DMPA: 26.4% • TB patient pack: 22.9% • AL all sizes (malaria): 25% • AZT/3TC/NVP 300/150/200 tab (ART): 4.8% 	<ul style="list-style-type: none"> • DMPA: 20% • TB patient pack: 15% • AL all sizes (malaria): 15% • — 	<ul style="list-style-type: none"> • DMPA: 18% • TB patient pack: 42% • AL all sizes (malaria): 7% • — 	<ul style="list-style-type: none"> • DMPA: +2% • TB patient pack: -27% • AL all sizes (malaria): +8% • — 	The program leverages the QoC survey to collect data on this indicator. At the time of the assessment, the country was experiencing a shortage in TB patient packs occasioned by procurement delays by the World Bank.

Indicator Performance Tables

Indicator (those not due yet have been omitted) and data source	Baseline	Target (Sept. 2012)	Achievement as of Sept. 2012	Deviation from target	Comments
<p>Indicator 6: Percentage of health facilities having expiries of at least one commodity from the tracer commodities list</p> <p>Data source: Malaria QoC survey round 4</p>	36%	< 20	14.0% for one expired AL pack	+6	<p>Expired antimalarial medicines were uncommon, though an increase trend in the availability of at least one expired AL pack was observed (from 2.9% at baseline to 14.0% at the last survey).</p> <p>This is a proxy indicator for existence of expiries in the facility pending a comprehensive facility assessment, scheduled for work plan II.</p>
<p>Indicator 7: Percentage of health facilities receiving integrated supportive supervision visits in the last 3 months</p> <p>Data source: Malaria QoC survey round 4</p>	78% reported, but no supporting documentation (actual estimated to be <40%)	No target for 2012 but at least 50% by 2013	60.5%	+10.5 for 2013 target	<p>There was a significant increase, from 41.5% of health workers receiving at least one supervisory visit in 3 months prior to the baseline to 60.5% prior to the last follow-up survey.</p> <p>This is a proxy indicator for facilities receiving integrated supportive supervision visits pending a comprehensive facility assessment scheduled for work plan II; however, 50 districts were supported to conduct integrated supportive supervision visits during work plan I.</p>
<p>Indicator 8: Number of functional regional commodity security committees established (disaggregated by administration units)</p> <p>Data source: HCSM progress reports</p>	Nonexistent	Functional (8 provincial and 50 district-level) commodity security committees set up in all the regions with TORs ^a and minutes of quarterly meetings	8 provincial health commodity committees formed 52 district health commodity committees formed	— +2	<p>The program supported formation of provincial- and district-level health commodity management committees. The committees are chaired by MOH staff and members include P/DHMTs and representatives of key stakeholders (e.g., KEMSA, Kenya Pharma, APHIA plus, CDC partners).</p>
IR 2: Strong and Effective MOMS/MOPHS Stewardship and Technical Leadership in Supply Chain Management/Commodity Security					
<p>Indicator 1: Functional MOMS/MOPHS supply chain oversight committee (SCOC) at the national level</p> <p>Data source: HCSM progress reports</p>	SCOC nonfunctional	<ul style="list-style-type: none"> • TORs reviewed and adopted • Work plan developed • Supply chain audit toolkit reviewed • Two level-4 hospital audits 	<ul style="list-style-type: none"> • TORs drafted but not adopted • Not done • Supply chain audit toolkit reviewed • Supply chain audits conducted in 		<p>The health sector's coordinating mechanism under the SWAp secretariat is being restructured to align with the Comprehensive Health Sector Framework 2012–2030. Finalization of this process will guide formation of this committee.</p>

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Indicator (those not due yet have been omitted) and data source	Baseline	Target (Sept. 2012)	Achievement as of Sept. 2012	Deviation from target	Comments
		conducted	Nyanza province (New Nyanza PGH and Kisii level-5, Siaya, and Bondo DHs)		
Indicator 2: Percentage of priority programs and key MOH departments (including NASCOP, DLTLD, DOMC, DRH, NPHLS) able to independently generate monthly commodity stock-status reports	None	DOMC, DRH, DLTLD, and NPHLS able to generate monthly commodity stock-status reports	Monthly stock status reports routinely generated for all priority program		Staff from priority programs has been actively involved in generation of monthly stock-status reports.
Indicator 3: Percentage of priority programs (including NASCOP, DLTLD, DOMC, DRH, NPHLS) and key MOH departments mentored by HCSM that are able to independently undertake commodity quantification Data source: HCSM progress reports	NASCOP's ART program (1 staff), and DRH/FP (1 staff) able to independently undertake commodity quantification	Key officers from DOMC (2), DRH (2), DLTLD (1), NASCOP ART (1), and NPHLS (1) trained in quantification	23 key officers from DoP, NPHLS, & priority MOH programs & 2 MEDS officers trained in quantification; 6 senior DRH staff trained in quantification & pipeline monitoring concepts & tools (Reality-FP, Pipeline®).		Staff from priority programs has been actively involved in development and review of the quantification reports and as a result FY 2012/13 quantification reports have been developed for all priority programs and EMMS, including supply plans.
IR 3: Effective Coordination and Harmonization of GOK and Development Partners' Activity in the Subsector by the Procurement and Supply Chain ICC					
Indicator 1: Functional and expanded PSC-ICC ^a Data source: HCSM progress reports	PSC-ICC partially functional; nonexistent harmonized procurement planning and F&Q guidelines & procurement plan	TORs reviewed and adopted	None		The health sector's coordinating mechanism under the SWAp secretariat is being restructured to align with the Comprehensive Health Sector Framework 2012–2030. Finalization of this process will guide formation of this committee.

^aLMU, Logistics Management Unit; PSC-ICC, Procurement and Supply Chain Inter-agency Coordinating Committee; ^aTORs, terms of reference

Table 4. SO 2: Strengthened Pharmaceutical Services

Indicator (those not due yet have been omitted) and data source	Baseline	Target (Sept. 2012)	Achievement as of Sept. 2012	Deviation from target	Comments
IR 1: Improved Delivery of Pharmaceutical Services					
<p>Indicator 2: Percentage of health facilities with the most current edition of Kenya National Standard Treatment Guidelines and Essential Medicines List</p> <p>Data sources: HCSM progress reports and malaria QoC survey round 4</p>	<p>47.1%</p> <p>5.7% new malaria guidelines</p>	<p>70% for all guidelines</p>	<p>NCMG disseminated</p> <ul style="list-style-type: none"> • 8,646 copies vol. I • 10,784 copies vol. II • Also 2,914 copies of KEML <p>45.3% new malaria guidelines</p>	—	<p>The program has supported dissemination of NCMG and the KEML to all level 2 and 3 facilities countrywide.</p> <p>This is a proxy indicator on trends in availability of key treatment guidelines. Health facility surveys have been scheduled to be undertaken in work plan II.</p>
<p>Indicator 3: Percentage of tracer conditions treated according to treatment guidelines at health facilities</p> <p>Data source: Malaria QoC survey round 4</p>	<p>Diarrhea: 6.9%</p> <p>Malaria: 22%</p>	<p>Diarrhea: 15%</p> <p>Malaria: 40%</p>	<p>—</p> <p>Malaria: 44%</p>	+6	<p>The performance of the composite malaria case-management indicator improved from 28.1% at the baseline to 44.3% during the last follow-up survey:</p> <ul style="list-style-type: none"> • Testing rates increased from 42.5% to 57.8%. • In children below 5 years of age, composite performance improved from 19.3% to 37.9% while testing rates increased from 33.3% to 50.6%. • In patients 5 years and older, composite performance improved from 36.1% to 49.3% while testing rates increased from 50.8% to 63.6%.
IR 2: Strengthened Medicines Quality Assurance and Pharmacovigilance					
<p>Indicator 1: Availability of pharmacovigilance guidelines at facilities</p> <p>Data source: HCSM progress reports</p>	28.8%	40%	46%	+6	The program has supported dissemination of pharmacovigilance guidelines to health facilities.
<p>Indicator 2: Availability of suspected ADR and poor-quality medicinal products reporting forms at facilities</p> <p>Data source: HCSM progress reports</p>	<p>ADR forms: 57.6%</p> <p>Poor-quality medicine forms: 53.4%</p>	70% for both	<p>ADR forms: 47%</p> <p>Poor-quality medicine forms: 46%</p>	<p>ADR forms: -23%</p> <p>Poor-quality medicine forms: -23%</p>	
<p>Indicator 3: Number of ADR reports received at the central level</p> <p>Data source: PPB</p>	1,400 (Sept. 2011)	3,500	More than 5,000 reports received at PPB as of Sept. 2012	>+1,500	The program provided ongoing support in pharmacovigilance data acquisition from health facilities through national courier services for submission of reports to PPB.

Indicator (those not due yet have been omitted) and data source	Baseline	Target (Sept. 2012)	Achievement as of Sept. 2012	Deviation from target	Comments
Indicator 4: Number of poor-quality medicinal products reports received at central level. Data source: PPB	175 (Sept. 2011)	200	More than 250 reports received at PPB as of Sept. 2012	>+50	
Indicator 5: Number of regulatory actions taken during the reporting period consequent to pharmacovigilance activities Data sources: PPB, NASCOP	No data available	1	20	+19	Key decisions made: <ul style="list-style-type: none"> • Counterfeit zidolam N batch numbers E100766 and A9366 quarantined • Supply chain for ARVs merged into only two suppliers: KEMSA and Kenya PHARMA • Market authorization of a pharmaceutical company withdrawn due to poor-quality products, including brands of azithromycin, paracetamol, itraconazole, and cefixime • More than 10 products withdrawn and 8 products recalled from the market, including counterfeit quinine sulfate and Enzoy[®], claimed to be a vitality drink
IR 3: Strengthened Pharmaceutical Subsector Governance					
Indicator 1: Updated National Pharmaceutical Policy approved by the Government, including corresponding implementation and M&E plans Data source: HCSM progress report	Draft revised KNPP available and awaiting Cabinet approval	Draft KNPP implementation plan (KNPP IP) and M&E plan	KNPP adopted by the Cabinet Draft KNPP implementation plan developed		The program has been providing technical and operational support to KNPP development process and to its implementation.
Indicator 2: Updated strategic plans for KPA and PSK Data sources: KPA and PSK	KPA: 2009–2012 strategic plan	KPA strategic plan revised and implementation plan developed		—	
	PSK: Strategic plan exists (2009–2014); no implementation plans	PSK implementation plan developed	Development of PSK implementation plan ongoing		

Table 5. SO 3: Strengthened Laboratory Systems

Indicator (those not due yet have been omitted) and data source	Baseline	Target (Sept. 2012)	Achievement as of Sept. 2012	Deviation from target	Comments
IR 1: Efficient and Effective Laboratory Supply Chain					
<p>Indicator 5: Percentage of health facilities submitting monthly commodity usage reports to the central level for priority programs (HIV, malaria)</p> <p>Data source: LMU workbook</p>	<p>HIV test kits: 50%</p> <p>CD4: None</p>	<p>HIV test kits: 70%</p> <p>CD4: 70%</p>	<p>HIV test kits: 57%</p> <p>CD4: 58%</p> <p>As of July 2012</p>	<p>HIV test kits: -13%</p> <p>CD4: -12%</p>	<p>Reporting rates have been fluctuating and in the last 3 months, they have averaged as follows:</p> <p>RDTs: 56% (SDPs)</p> <p>CD4: 58% (SDPs)</p>
<p>Indicator 6: Number of functional regional commodity security committees established (disaggregated by administration units)</p> <p>Data source: HCSM progress reports</p>	<p>Nonexistent</p>	<p>Functional (8 provincial- and 50 district-level) commodity security committees set up in all the regions with TORS and minutes of quarterly meetings</p>	<p>8 provincial health commodity committees formed</p> <p>52 district health commodity committees formed</p>	<p>—</p> <p>+2</p>	<p>The program supported formation of provincial- and district-level health commodity management committees. The committees are chaired by MOH staff and members include P/DHMT staff and representatives of key stakeholders (e.g., KEMSA, Kenya Pharma, APHIAplus, CDC partners).</p> <p>Lab commodity issues form part of the key agenda at the provincial and district commodity security committee meetings.</p>

ENVIRONMENTAL MITIGATION AND MONITORING REPORT

In compliance with USAID’s environmental procedures—22 CFR 216 (“Reg 216”)—HCSM completed and submitted an Environmental Mitigation and Monitoring Report (EMMR) to USAID/Kenya Mission.

The program activities as captured in the report were considered to be low risk to the environment as summarized in table 6.

Table 6. Environmental Assessment of Program Activities

Program activities	Screening Result		
	Very low risk	High risk	Moderate or unknown risk
1. Strengthen MOMS/MOPHS stewardship and technical leadership in supply chain management/commodity security	√		
2. Support effective coordination and harmonization of government and development partners’ activity in the subsector	√		
3. Strengthen peripheral health care facilities to able to account for and manage commodities effectively	√		
4. Support effective and efficient commodity management systems in the private sector (faith-based and commercial-sector organizations).	√		
5. Strengthen pharmaceutical sector governance	√		
6. Improve delivery of pharmaceutical services	√		
7. Strengthen medicines quality assurance and pharmacovigilance	√		
8. Improve pharmaceutical information acquisition and management	√		
9. Strengthen laboratory sector leadership and governance	√		
10. Support an efficient and effective laboratory supply chain	√		
11. Improve accessibility of quality essential laboratory services	√		

SUMMARY OF FINANCE REPORT

FEDERAL FINANCIAL REPORT

(Follow form Instructions)

1. Federal Agency and Organizational Element to Which Report is Submitted USAID/OFM		2. Federal Grant or Other Identifying Number Assigned by Federal Agency (To report multiple grants, use FFR Attachment) AID-623-LA-11-000008		Page 1	of pages		
3. Recipient Organization (Name and complete address including Zip code) Management Sciences for Health, Inc. 784 Memorial Drive, Cambridge, MA 02139							
4a. DUNS Number 071713085	4b. EIN 04-2482188	5. Recipient Account Number or Identifying Number (To report multiple grants, use FFR Attachment) FRLC 72 00 1329		6. Report Type <input checked="" type="checkbox"/> Quarterly <input type="checkbox"/> Semi-Annual	7. Basis of Accounting <input checked="" type="checkbox"/> Cash <input type="checkbox"/> Accrual		
8. Project/Grant Period From: (Month, Day, Year) 04/01/2011		To: (Month, Day, Year) 03/31/2016		9. Reporting Period End Date (Month, Day, Year) 09/30/2012			
10. Transactions <i>(Use lines a-c for single or multiple grant reporting)</i>					Cumulative		
Federal Cash (To report multiple grants, also use FFR Attachment):							
a. Cash Receipts					\$6,396,250.00		
b. Cash Disbursements					\$6,896,148.96		
c. Cash on Hand (line a minus b)					(\$499,898.96)		
<i>(Use lines d-o for single grant reporting)</i>							
Federal Expenditures and Unobligated Balance:							
d. Total Federal funds authorized					\$10,111,574.00		
e. Federal share of expenditures					\$6,896,148.96		
f. Federal share of unliquidated obligations					\$0.00		
g. Total Federal share (sum of lines e and f)					\$6,896,148.96		
h. Unobligated balance of Federal funds (line d minus g)					\$3,215,425.04		
Recipient Share:							
i. Total recipient share required					\$1,249,845.00		
j. Recipient share of expenditures					\$41,775.23		
k. Remaining recipient share to be provided (line i minus j)					\$1,208,069.77		
Program Income:							
l. Total Federal program income earned							
m. Program income expended in accordance with the deduction alternative							
n. Program income expended in accordance with the addition alternative							
o. Unexpended program income (line l minus line m or line n)							
11a. Indirect Expense	a. Type	b. Rate	c. Period From	Period To	d. Base	e. Amount Charged	f. Federal Share
	Salaries	81%	07/01/2012	09/30/2012	50,594.39	40,981.46	100%
	Local Prof	40%	07/01/2012	09/30/2012	414,283.66	165,713.46	100%
	Consultants	40%	07/01/2012	09/30/2012	9,200.43	3,680.17	100%
					g. Totals: \$	684,453.57	
12. Remarks: Attach any explanations deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation:							
13. Certification: By signing this report, I certify that it is true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent information may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 218, Section 1001)							
a. Typed or Printed Name and Title of Authorized Certifying Official Patricia Barros-Smith, Manager Corporate Accounting			c. Telephone (Area code, number and extension) 617-250-9214				
b. Signature of Authorized Certifying Official 			d. Email address pbarrossmith@msh.org				
			e. Date Report Submitted (Month, Day, Year) 10/22/2012				
14. Agency use only:							

Standard Form 425
OMB Approval Number: 0348-0061
Expiration Date: 10/31/2011

Paperwork Burden Statement
According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is 0348-0061. Public reporting burden for this collection of information is estimated to average 1.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the