SIAPS Activity and Product Status Report

A report on quarterly progress achieved towards activities, products, and results

Project Year 1 Quarter 1

October - December 2011

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Systems for Improved Access to Pharmaceuticals and Services
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Website: www.siapsprogram.org

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ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
ADDO	accredited drug dispensing outlet
ADR	adverse drug reaction
ADT	ARV Dispensing Tool [MSH]
AHSEP	Afghanistan Health Services Enhancement Project
AIDS	acquired immunodeficiency syndrome
ALCO	Abidjan to Lagos Corridor Organizations
APR	annual progress report
AQ	amodiaquine
APR	annual progress report
ART	antiretroviral therapy
AS	artesunate
CAMERWA	Centrale d'Achat des Médicaments Essentiels du Rwanda (CMS of Rwanda)
CBO	community-based organization
CMS	Central Medical Store
COP	chief of party
CPDS	Coordinated Procurement and Distribution System
DTC	Drug and Therapeutics Committee
EML	essential medicines list
EU	European Union
FDC	fixed-dose combination
FEFO	first expiry, first out
FHI	Family Health International
FY	fiscal year
GDF	Global Drug Facility
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GoB	Government of Bangladesh
GoK	Government of Kenya
HBC	home-based care
HIV	human immunodeficiency virus
HMM	home management of malaria
HSSP	Health Systems and Services Strengthening system
IC	infection control
ICAT	Infection Control Assessment Tool
IEC	information, education, and communication
INRUD	International Network for Rational Use of Drugs
IPT	intermittent prevention treatment
IRS	indoor residual spraying
JSI	John Snow, Inc.
M&E	monitoring and evaluation
MDR	multidrug resistant
MIS	management information system
MoH	Ministry of Health
MoHSW	Ministry of Health and Social Welfare (Swaziland)

MoPH	Ministry of Public Health
MOU	Memorandum of Understanding
MSH	Management Sciences for Health
MTP	Monitoring, training, planning (methodology)
NASCOP	National AIDS and STD Control Program
NDTC	National Drug and Therapeutics Committee
NGO	nongovernmental organization
NMCP	National Malaria Control Program (Senegal)
NSP	National Strategic Plan (South Africa)
PCI	Pharmaceutical Control and Inspection [Namibia]
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLWHA	People Living With HIV/AIDS
PM	pharmaceutical management
PMI	President's Malaria Initiative
PMIS	pharmaceutical management information system
PMTCT	prevention of mother-to-child transmission
PSI	Population Services, International
PV	pharmacovigilance
QA	quality assurance
RBM	Roll Back Malaria
RDT	rapid diagnostic test
REACH	Rural Expansion of Afghanistan's Community-based Healthcare
RH	reproductive health
RMU	rational medicine use
RPM Plus	Rational Pharmaceutical Management Plus
SCMS	Supply Chain Management System
SOW	statement of work
SPS	Strengthening Pharmaceutical Systems (Program)
STG	standard treatment guideline
STI	sexually transmitted infections
TA	technical assistance
TB	tuberculosis
TBCAP	TB Control Assistance Program
TOR	terms of reference
TOT	training of trainers
TWG	technical working group
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNION	International Union Against |Tuberculosis and Lung Disease
URC	University Research Co.
USAID	U.S. Agency for International Development
USG	United States Government
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

HIGHLIGHTS FROM SIAPS-ARLINGTON

SIAPS – PY1 (FY12) – Quarter 1 (October to December 2011)

Overview

The Award - The Systems for Improved Access for Pharmaceuticals and Services (SIAPS) was awarded to Management Sciences for Health on September 23, 2011. It is a five year cooperative agreement ending September 22nd, 2016

In its first year (FY12), SIAPS will receive funding from several disease elements of the Global Health Bureau including Malaria, TB, and MCH in addition to Common Agenda funding. SIAPS is also funded by the US Food and Drug Administration (USFDA) through a USFDA/USAID inter-agency agreement. A regional office, Latin American and the Caribbean (LAC), is also providing funding to SIAPS. Field support funding is committed from 21 USAID Missions in Africa, Asia, and LAC.

Organization and Staffing – All key Program positions were filled or transitioned into during the first quarter. The Project Director, Technical Deputy Director, and Deputy Director for Finance and Operations all transitioned into their SIAPS roles, from first day of the program. The Deputy Director for Country Programs also started during the course of the quarter. The M&E Advisor was hired under CPM prior to program start and hence was available from the start. Meanwhile, CPM has also identified a candidate for the Knowledge Management position who will be starting early in the year. The Country Director for the new Guinea program was identified and will soon take on his new post.

Work planning – SIAPS developed a new template to guide the work planning process for all program portfolios. The template focuses on emphasizing the relation between activities and SIAPS intermediate results, highlights M&E as a key section, while also captures portfolio specific knowledge management activities.

By the end of the quarter, all workplans for which SIAPS had received obligations were completed and submitted to the respective Missions and to USAID/Washington.

Program Communication – As specified in the award, SIAPS developed and submitted the proposed program logo to USAID. This was approved prior end of the quarter. In order to communicate SIAPS mandate, a program brochure was developed and made available in print form. It includes a series of technical inserts that explain the different technical functions and strategies that SIAPS aim to address

US Launch – On December 14th, SIAPS held its official launch. The one-day meeting was attended by USAID, MSH leadership, SIAPS core and resource partners as well as all SIAPS US based staff. This was an opportunity to present and share a common vision for SIAPS. All SIAPS partners had the opportunity to present during the meeting, highlighting their areas of expertise and their potential roles and contributions to SIAPS. Taking advantage of the launch, individual meeting were also held with partners to discuss specific areas of collaboration.

Regional Launches – In order to introduce the mandate of the new program, its organization, and in order to better define roles and responsibilities, SIAPS will be holding three regional launches in January/February 2012 in Rwanda, Ethiopia, and South Africa. These will primarily target country programs' leadership as well as country M&E representatives. Preparations for the launches have been taking place during this quarter.

Setting up Program Management Systems – SIAPS explored options for procuring and/or adapting new software solutions to help better manage specific aspects of the program. These include work planning and reporting; managing technical assistance and training needs; and managing program documentation and reports. Several tools were identified and examined. A web-based tool, Central Desktop, was identified as a suitable platform for managing technical assistance and training resources. The tool is expected to be procured next quarter when it will be customized and tailored to SIAPS needs and for potential use during the third quarter. Meantime, analysis continues to a number of tools for potential use in work planning and reporting.

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GLOBAL PROGRAMS

Maternal and Child Health

Beth Yeager

Despite progress made in reducing both maternal and child mortality rates over the past few decades, the rates still remain high and very few countries are on track to meet the Millennium Development Goal targets of reducing the maternal mortality ratio by three-quarters and the under-five child mortality by two-thirds, by 2015. What is most alarming about the situation is that most of these deaths could have been avoided if women and children had access to adequate health services, where the necessary medicines and supplies were available and skilled health providers were present. The preventative and curative measures for the major causes of maternal and child deaths are well-known, but access to them remains elusive for many. As part of the global effort to improve maternal and child health (MCH), the United States Global Health Initiative (GHI) has included targets for maternal and child health in its strategic plan, specifically to reduce maternal mortality by 30 percent and to reduce under-five mortality rates by 35 percent across USG assisted countries. Under the GHI, USAID is focusing on effective interventions addressing key high-mortality complications along the continuum of care from pregnancy to childhood, such as postpartum hemorrhage, hypertension (pre-eclampsia/eclampsia), and infections (diarrheal disease, pneumonia and malaria).

Beginning under the Rational Pharmaceutical Management Plus program, and continuing under the Strengthening Pharmaceutical Systems program, MSH has supported USG efforts to improve maternal and child health through activities designed to improve access to and appropriate use of the medicines and supplies necessary to prevent and treat the leading causes of morbidity and mortality. In terms of maternal health, MSH worked with other USG-funded initiatives, such as the Prevention of Postpartum Hemorrhage Initiative (POPPHI) to document the pharmaceutical management issues related to active management of the third stage of labor (AMTSL). MSH also worked with national stakeholders in several countries to identify and address weaknesses in their pharmaceutical systems and thereby improve access to the medicines and supplies necessary for AMTSL. With respect to child health, MSH focused on pharmaceutical management for integrated management of childhood illness, both within health facilities and at the community level. MSH developed assessment tools and training materials to help ensure availability of medicines and supplies. MSH also worked with national stakeholders to adopt new recommendations of treatment for common childhood illnesses, such as zinc and low osmolarity ORS for diarrhea. Lastly, MSH developed innovative strategies to incorporate the private sector in community case management.

Building on this wealth of experience, SIAPS will contribute to GHI objectives and achievement of the MDGs by working with international organizations to increase global awareness of the barriers to access to essential maternal and child health medicines and supplies, and assisting national stakeholders in developing innovative approaches to addressing these barriers in their countries. The goal of the MCH portfolio is to assure availability and appropriate use of quality medicines and supplies and effective pharmaceutical services to reduce maternal and child mortality. SIAPS will work towards this goal through increasing global awareness of the

importance of good pharmaceutical management of maternal and child health supplies, and coordinating efforts with other USAID implementing partners, and with regional and country-level initiatives. Since access to quality maternal, newborn and child health services demands a strong health system, SIAPS will focus on systems-strengthening approaches that increase the capacity of health workers to appropriately manage maternal and child health supplies, increase availability and use of information for decision-making and improve availability and use of medicines and supplies for maternal and child health.

Quarter Overview

During this quarter, the work plan was developed. Several meetings were held with USAID to discuss proposed activities and countries to support. Also, Sheena Patel was hired as a Technical Associate to support the MCH portfolio.

Key activities for next quarter

Two key activities for next quarter will be to finalize the work plan based on feedback from USAID and continue to assist in preparing background documentation for the soon-to-be launched UN Commission on Commodities for Women and Children's Health.

Objective 1

Capacity for supply management of maternal and child health pharmaceuticals and services increased and enhanced

Objective 1: Quarterly progress

None.

Sub-Objective 1.1

Capacity of individuals, institutions, organizations to manage maternal health medicines and supplies strengthened

Progress toward sub-objective 1.1

Some pre-work was done in December 2011 to provide information on SPS experiences in DRC, Ghana and Mali related to maternal health commodities. This information was shared with partners from UNFPA, USAID, PATH and other key partners.

Sub-Objective 1.2

Capacity of individuals, institutions, organizations, and to manage child health medicines and supplies strengthened

Progress toward sub-objective 1.2

None.

Tuberculosis Core

Andre Zagorski

Portfolio Background

According to the WHO 2011 Global TB Report, tuberculosis remains a major public health challenge. Despite the availability of highly efficacious treatment for decades, TB remains a major global health problem. In 2010, there were 8.8 million (range, 8.5–9.2 million) incident cases of TB, 1.1 million (range, 0.9–1.2 million) deaths from TB among HIV-negative people and an additional 0.35 million (range, 0.32–0.39 million) deaths from HIV-associated TB . Although the absolute number of cases, incidence and mortality rates have been slowly dropping in the past years, the rapid emergence of drug-resistant forms of tuberculosis and their weak management becomes a major challenge.

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is a follow on to the Strengthening Pharmaceutical Systems (SPS) program. SPS has been a major USAID mechanism for providing technical leadership in pharmaceutical management for tuberculosis to Global TB initiatives, donors, Stop TB partners, and national TB programs. In the past years the focus of the response to the Global Plan to Stop TB 2006 – 2015 had been mainly on addressing its strategic components related to increasing the availability of, and ensuring access to quality assured first- and second-line TB medicines; this was done through the ongoing technical leadership to the Global Drug Facility, the Green Light Committee and STOP TB partners, capacity building exercises, and development and promotion of frameworks and approaches for strengthening pharmaceutical systems in the anticipation of new TB tools and technologies. SPS also responded to the threat of MDR/XDR TB and TB/HIV co-infection. SIAPS will build upon successes and results of its predecessor projects, adapting them to rapidly changing dynamics and challenges of global TB control.

Quarter Overview

This quarter, the only progress to report is completion of the 2011-12 SIAPS work plan. In the coming year, the portfolio will work on achieving the portfolio goal: to strengthen pharmaceutical management systems to achieve global TB goals. Through the implementation of existing proven pharmaceutical management for TB tools and adaptation of other methodologies, SIAPS TB Core portfolio will develop evidence and experiences in addressing the challenges and gaps described above, and will assist Stop TB partners, donors, and national TB programs in selected priority countries to adopt and implement these tools and interventions and monitor and evaluate their impact.

Key activities for next quarter

Begin implementation of the SIAPS work plan and progress toward quarter and annual objectives and targets.

Technical Activity Coordination

TB Core and technical lead staff at headquarters worked with staff in the field to develop and finalize the 2011-12 SIAPS work plan.

Objective 1

Strengthen DOTS

Objective 1: Quarterly progress
Because the first quarter focused on developing and finalizing the work plan, there is no progress to report on this objective.

Sub-Objective 1.1
Improved access to quality assured TB medicines.

Progress toward sub-objective 1.1
As written above, because the first quarter focused on developing and finalizing the work plan, there is no progress to report on this objective.

COUNTRY PROGRAMS

Angola

Dinah Tjipura

Portfolio Background

Malaria is a major cause of morbidity and mortality in Angola, accounting for an estimated 60% of hospital admission, 35% of the overall mortality in children under five, and 25% of maternal mortality. In 2004, Angola's Ministry of Health introduced Artemesinin-based combination therapies (ACT) to improve malaria case management. The first-line treatment of malaria is Artemether-lumefantrine (AL–Coartem®). The prevalence of HIV in Angola is estimated at 2% in a total population of 18 million. TB/HIV co-infection is a major concern. HIV/AIDS prevention, treatment and care activities under the National Strategy Plan on HIV/AIDS 2011-2014 are implemented under the MOH's National HIV/AIDS Control Program (Instituto Nacional de Luta Contra o Sida-INLS). USAID provides funding and logistic support for procurement and distribution of condoms and rapid test kits for HIV/AIDS prevention. The INLS has also received support in its treatment and care efforts by the USAID-supported Essential Health Services program that has now become the Strengthening Angolan Systems for Health Systems (SASH) program. The total fertility rate of Angola averages 5.8 births per woman. The high fertility is associated with high infant mortality rates and a high maternal mortality ratio of 1,400 per 100,000 live births. Access to contraceptives is low, with frequent stock-outs of RH/FP commodities at health facilities. The Government of Angola considers FP an important strategy to improve the health of women and children, under the National Road Map to accelerate the reduction of maternal, newborn and child mortality.

USAID's PEPFAR support for HIV/AIDS activities is channeled through the INLS. USAID-funded condoms are distributed via the INLS and USAID implementing partners. PMI support is channeled through the National Malaria Control Program, and population (POP) support goes through the National RH/FP Program. The MOH's National Directorate of Medicines and Equipment (Direcção Nacional de Medicamentos e Equipamentos –DNME) and the National Essential Medicines Program (Programa Nacional de Medicamentos Essenciais–PNME) oversee and coordinate all pharmaceutical supply management activities in Angola. The annual DNME/PNME Plans of Activities generally follow the 5-year strategic plans, currently for 2009-2014. With USAID/ PMI support, MSH/SPS program and its predecessor RPM Plus have collaborated with other USAID Implementing Partners and NGOs and other local partners to assist the Angolan MOH to implement pharmaceutical management strengthening interventions at central and lower levels of the health care delivery system since 2005.

USAID/Angola has provided SIAPS/Angola with $1,450,000 in FY11 funding (PMI-$650,000, PEPFAR-$500,000 and POP-$300,000). SIAPS/Angola will use this funding to implement the pharmaceutical management-strengthening activities from October 2011 to September 2012. SIAPS will work to strengthen Angola's health system by assuring the availability and safe use of quality pharmaceutical products, in line with USAID/Angola's goal to improve health service delivery through systems strengthening, integration and creating partnerships with local organizations. The program will ensure a seamless transition between SPS and SIAPs. Remaining

SPS pipeline will be used to continue implementing activities from the SPS FY10 work plan that remained unaccomplished due to challenges associated with delayed MSH in-country registration

Quarter Overview

There was not much progress (using SIAPS funding) during this quarter. Remaining SPS activities continued while the SIAPS work plan was developed. This included:

- Coordinating and collaborating with local counterparts to finalize priority areas for SIAPS work plan intervention. Staff then drafted the FY 11 work plan, and communicated and met with key USAID Mission representatives to discuss Mission feedback and obtain work plan approval.
- Assisting the USAID Mission with initial preparations for upcoming meetings between the MOH and key local development partners to form an inter-agency coordination committee (ICC) to harmonize partners' support for the MOH's municipal revitalization program.
- Initiating preparations for SIAPS/Angola staff travel to the SIAPS regional launch in South Africa.

Key challenges of quarter

As was the case under SPS, there was continued delay in approval of MSH's application for in-country registration, continued lack of corporate bank account, and inability to hire permanent Portuguese-speaking project staff.

Key activities for next quarter

Initiate preparations for the activities to: strengthen the DNME's capacity to regulate medicines, support local coordination and collaboration among MOH and partners for improved pharmaceutical management pharmaceutical supply chain, support MOH supportive supervision, support the DNME and CECOMA to improve the national LMIS, and assist strengthen public sector procurement and supply management system and CECOMA. Staff will continue to provide TA to the MOH to implement strategic monitoring tools and to receive, store and distribute USAID-funded commodities. SIAPS will also continue to provide TA to the MOH to strengthen national PV system.

Technical Activity Coordination

Activities focused on work plan development and activity progress reporting.

Evaluation plans for next quarter

Initiate preparations for the following: a rapid situation analysis of medicines regulation, an analysis of the existing public sector LMIS, an analysis of the public sector supply chain management system, and an analysis of the existing PV system.

Objective 1

Medicines policy governance strengthened

Objective 1: Quarterly progress

There was no significant progress towards this objective this quarter. The work plan was developed, including this activity, and submitted to USAID for review and feedback in December 2011

Sub-Objective 1.1
DNME capacity to regulate medicines strengthened.

Progress toward sub-objective 1.1
There was no progress towards this sub-objective this quarter. Following a DNME request in October for TA support to help strengthen the medicines regulatory system, the activity was included in the proposed FY11 work plan and submitted to USAID for review and feedback.

Sub-Objective 1.2
Coordination and collaboration among local pharmaceutical management stakeholders improved to promote knowledge exchange.

Progress toward sub-objective 1.2
No SIAPS-funded progress this quarter.

Main challenges for sub-objective 1.2
As part of the Angola MOH's Municipal Revitalization Program, there are ongoing efforts to create a coordinating mechanism to harmonize local development agencies' and their implementing partners' activities and thereby maximize effectiveness and efficiency of TA. There is therefore need to first coordinate with the DNME, key MOH departments and key local partners to share work plan information on planned areas of support to the MOH, interventions, budgets and expected results and plan out implementation of the work plan activities. A framework should then be developed to guide and coordinate the actions and timelines of stakeholders' support to the MOH.

Steps to address challenges for sub-objective 1.2
Before initiating work plan activities, there is need to first coordinate with the DNME, key MOH departments and key local partners to share work plan information on planned areas of support to the MOH, interventions, budgets and expected results and plan out implementation of the work plan activities. A framework should then be developed to guide and coordinate the actions and timelines of stakeholders' support to the MOH.

Sub-Objective 3.2
Strategic monitoring tools implemented to improve pharmaceutical management decision-making.

Progress toward sub-objective 3.2
SIAPS collaborated with the NMCP and PNME in implementing the PPMRm and ACT needs estimation tools. Technical staff initiated compilation of quarterly and annual ACT needs estimate reports for Angola in collaboration with the INLS.

Bangladesh

Mavere Tukai

Portfolio Background

Despite several advances made in supply chain management for reproductive health commodities in Bangladesh, procurement continues to be a challenge, particularly in supporting adequate and timely program implementation for the health sector. There have been noted variances in procurement performance. Overall, the procurement unit of the Directorate General of Family Planning (DGFP) under the Ministry of Health and Family Welfare (MOHFW) of the Government of Bangladesh, handles a more uniform set of items and has generally performed better than the Central Medical Store Depot (CMSD), the main procurement unit of the Directorate General of Health Services (DGHS), which handles a wide range of pharmaceuticals, supplies and equipment. Since fall of 2009, the SPS Bangladesh Program has been providing technical assistance to the DGFP and other national stakeholders, to improve procurement management systems for reproductive health commodities, strengthen existing distribution and Management Information Systems (MIS), and increase local capacity to reinforce health systems.

SIAPS will use the information gathered from the past two year assessments in supply chain management to analyze successful approaches in capacity building of the MOHFW and its key directorates in an effort to improve availability and access to pharmaceuticals. After the successful introduction of the web-based procurement and logistics management tool "DGFP Supply Chain Information Portal – SCIP" which includes an online procurement tracking system, logistics management information system (LMIS), and interventions to support the procurement management systems of the DGFP, the MOHFW had requested the SPS Bangladesh program to provide support to strengthen its capacity for procurement and supply chain for the entire DGHS. Following a meeting on October 13, 2010 with the Secretary of the MOHFW, USAID, and Health Secretary and Joint Secretary, several priority areas were identified for support including building the capacity of the MOHFW and component procuring entities to better manage the procurement and supply chain management systems. Following the recent assessment of the procurement and supply chain management systems of the MOHFW and the CMSD, one of the main recommendations was to transform the CMSD into a strategic procurement organization. In addition, as part of the new 5 year (2012-2016) 'Health, Population and Nutrition Sector Development Program (HPNSDP)' one of the main goals is to set up a Procurement and Logistics Management Cell (PLMC) within the MOHFW to oversee the procurement functions of all procuring entities under the Ministry.

The goal of the expanded support to the MOHFW and DGHS includes the strengthening of policy decisions and increasing the capacity for commodity management by health care providers and institutions with an emphasis on good governance, procurement, institutional capacity building and other system strengthening initiatives aimed at ensuring continuous availability of goods required to support health care delivery and the timely availability of reliable data to support evidence based decision making. In addition SIAPS will collaborate with other stakeholders to implement selected options to ensure that the capacity of the MOHFW and other indigenous institutions are developed to carry out the required procurement and supply chain management functions in a sustainable manner. Based on lessons learned working with DGFP, a general consensus among key stakeholders was made that there is a need to strengthen the medicine

registration process under the Drug Administration. The development of a simple and effective medicine registration process is a substantial contribution to the successful completion of procurement processes of any procurement package. Considering the that the Drug Administration plays a key role in the procurement process SIAPS will provide technical support to the Directorate General of Drug Administration (DGDA) to strengthen the medicine registration process. Based on the success of the SPS program interventions in DGFP, the USAID Bangladesh Mission has also requested the assistance of SIAPS to strengthen the pharmaceutical management system of the National TB Program (NTP) in Bangladesh.

Quarter Overview

SIAPS has managed to get approval to embed a consultant at the MOHFW to lead the procurement processes improvement and coordinate the PLMC establishment. The strategic planning process was defined, buying-in by all procuring entities was done, the catalogue was completed, and the procurement tracker used (74% of packages are on course). Program managed to facilitate the quarterly logistics management meeting, supply manual revision process has started, field visit to upazila stores and service delivery points were made by SIAPS staff, and SIAPS performed joint monitoring visit for providing on-the-job training. Maintenance of the SCIP, roll-out UIMS installation, and the SIAPS Quarterly newsletter were completed this quarter. In addition, the monthly commodity tracking/monitoring meeting was attended. SIAPS facilitated a TB commodity management planning for all partners.

Key challenges of quarter

- Delays in project commencement
- Increase demand, workload and expectation, especially after starting to work with DGHS
- Delays in hiring new staffs
- Lack of proper M&E staff and framework
- Delays in procurement
- Bureaucracies that lead to delay in achieving key milestones e.g. publication of the procurement procedure manual
- Transition from SPS to SIAPS

Key activities for next quarter

- Support the development of tools to help effectively plan, forecast, procure and manage the procurement processes of health commodities.
- Support the establishment and functioning of the procurement and logistics management cell (PLMC) within the Ministry of Health and Family Welfare, by supporting to review and agree the proposed structure, function and mandate of PLMC, and providing technical and logistics support in establishing PLMC by facilitating planning sessions, mentorship, and placement of a consultant within the MOHFW.
- Provide support to conduct a feasibility and options analysis for selection of a suitable electronic warehouse and inventory management solution for DGHS warehouses. Review and update the current DGFP supply manual.
- Establish a coordinated mechanism to introduce national level forecasting, quantification and supply planning for TB commodities.
- Introduce pipeline monitoring system using appropriate tools based on DGFP experience.

Evaluations of SIAPS: Description
Quality assessment tools are still pending; however preliminary qualitative evaluations have shown decreased stock-outs in over half Upzaillas. Warehouse field studies have shown significant improvement in availability of pharmaceuticals, however further investigations need to address warehouse storage and waste (expired pharmaceutical) management.

Evaluation plans for next quarter
Development of specific monitoring and evaluation tools with M&E Coordinator, Michael Cohen, after Q2 site visit.

Objective 1
Provide TA to strengthen procurement management system of the MOHFW and its procuring entities.

Objective 1: Quarterly progress
As part of strengthening procurement management systems, the focus of SIAPS support was to provide technical assistance to the MOHFW, DGFP, DGHS, and HED including the health wing of PWD to effectively manage the procurement processes. SIAPS supported the MOHFW to develop an on-line procurement tracking/monitoring system for all procurement packages. In order to ensure accurate forecasting, quantification, and supply planning of health commodities, SIAPS introduced a centrally coordinated mechanism for national level forecasting and quantification with a Forecasting Working Group (FWG) to lead the 5-year national forecast and 3-year supply plan for DGFP contraceptives. Q1 saw approval of the roadmap towards development of the MOHFW procurement management strategic planning, approval/acceptance to establish the PLMC within MOHFW, and initial discussions on options analysis for more innovative procurement processes. A decision made to embed a consultant at the MOHFW to lead the procurement processes improvement and coordinate the PLMC establishment. The strategic planning process was defined and catalogue created.

Sub-Objective 1.1
Provide TA to strengthen MOHFW and its procuring entities to effectively plan, forecast, procure and manage the procurement processes of health commodities.

Progress toward sub-objective 1.1
As part of strengthening procurement management systems, the focus of SIAPS support includes providing technical assistance to the MOHFW, DGFP, DGHS, and HED including the health wing of PWD to effectively manage the procurement processes. Below is a summary of activities. In collaboration with the World Bank, SIAPS supported the review of all procurement packages to ensure that they meet set standards and timely completion of the family planning commodities procurement process. Staff also facilitated monthly procurement meeting with DGFP and DGHS/CMSD to monitor the procurement progress.

Sub-Objective 1.2
Support the establishment and functioning of the procurement and logistics management cell (PLMC) within the Ministry of Health and Family Welfare.

Progress toward sub-objective 1.2
During quarter one of SIAPS FY11 implementation, the following were achieved:

- The team (in collaboration with the Joint Secretary, and STTA) facilitated a workshop to develop the strategic plan for MOHFW procurement management system.
- SIAPS agreed with the MOHFW on the proposed PLMC establishment, reviewed the structure, and also managed to obtain approval from USAID to recruit and embed the procurement consultant into the MOHFW to lead the PLMC establishment.
- The consultant has also been given a long term assignment to ensure the continuity of the activity. In addition, SIAPS started process of recruiting a procurement technical advisor who will work with the DGHS on all procurement issues at the DGHS

Deliverables for sub-objective 1.2
The FY12 work plan.

Objective 2
Strengthen warehousing, distribution, and logistics management systems of DGHS and DGFP to improve availability and access.

Objective 2: Quarterly progress
SIAPS has initiated the review of the supply manual and worked with the MOHFW to propose a steering committee for the process, and managed to organize a manual review scheduled for the second quarter. In addition, the team continued to provide scheduled on site TA visit and troubleshooting. The STA logistics, DCD logistics and the 5 TA logistics continued to provide o site TA on inventory management, LMIS and family planning commodity management. The program managed to facilitate the quarterly logistics management meeting. The supply manual revision process has started, a field visit to Upazila stores and service delivery points was made by SIAPS staff, and a joint monitoring visit for providing on-the-job training were completed.

Sub-Objective 2.1
Provide TA to DGHS/CMSD and DGFP on efficient storage, warehousing, and logistics management system.

Progress toward sub-objective 2.1
Scheduled TA visits to address reporting, inventory management, and LMIS were conducted. SIAPS continued SCIP updating and monitoring.

Main challenges for sub-objective 2.1

- Protection of computers at the Upazila.

Steps to address challenges for sub-objective 2.1

- Antivirus software
- On-site TA

Sub-Objective 2.2
Develop Standard Operating Procedures/Guidelines to support a comprehensive and sustainable Warehousing, Distribution, and Logistics management system under MOHFW.

Progress toward sub-objective 2.2
SIAPS has initiated the review of the supply manual and worked with the MOHFW to propose a steering committee for the process, and managed to organize a manual review scheduled for the second quarter. In addition, the team continued to provide scheduled on site TA visit and troubleshooting

Main challenges for sub-objective 2.2
- Late commencement of the program
- Specific procedures to dispose expired/unwanted product
- Some warehouses are in poor structural shape and specific funds may need to be allocated to facilitate renovation to improve inventory management control

Steps to address challenges for sub-objective 2.2
- Direct communication with the MOHFW

Objective 3
Support evidence based decision making by strengthening commodity management information systems.

Objective 3: Quarterly progress
SIAPS continued to improve the information management and sharing for decision making by:
- Continued updating the SCIP
- Roll-out of the UIMS to 18 more sites
- Production of quarterly newsletter and monthly reports on procurement, stock status and commodity distribution information
- Any anticipated challenges were also communicated to DGFP and MOHFW

Sub-Objective 3.1
Improve availability of data and information by providing support for the maintenance and optimal functions of electronic logistics management information tools (e.g.: SCIP, procurement tracker, LMIS, UIMS, WIMS, Pipeline, Quantimed, etc).

Progress toward sub-objective 3.1
On site TA for data collection, reporting, uploading of supply chain data to the DGFP SCIP continued during this quarter. The scaling up of these training programs enabled the further use of the UIMS and allowed for accurate and timely inventory reporting, in Q1 18 news sites were installed with UIMS.

Sub-Objective 3.2
Improve transparency by establishing the procurement management portal.

Progress toward sub-objective 3.2
SIAPS started working with MOHFW and its key directorates to develop and strengthen effective procurement management systems for the MOHFW. During FY 11-12, SIAPS has provided necessary technical support to finalize the development of the MOHFW Procurement

Management Portal in a participatory manner. During Q1, SIAPS planned for the facilitation of a Technical Working Group (TWG) meeting to review the Procurement Management Portal.

Sub-Objective 3.3
Generate and disseminate supply chain information to stakeholders.

Progress toward sub-objective 3.3
In FY 2011-12 SIAPS will continue to work with staff of the DGFP's Logistics and Supply Unit and MIS Unit to analyze and generate routine logistics reports (Supply Planning and Scenario analysis, monthly contraceptive commodity status report, procurement planning and monitoring report, DGFP procurement and action status matrix, monthly family planning logistics report) to ensure regular updates on the web-based procurement tracking system. During Q1 SIAPS continued to develop and circulate the quarterly SIAPS newsletter and share updates on program development.

Deliverables for sub-objective 3.3
- SIAPS quarterly newsletter.
- Monthly reports on procurement, stock status and distribution information, scenario analysis and supply planning.

Objective 4
Promote commodity security by building capacity of MOHFW and its directorates including national institutions and networks to coordinate and manage information relation to health commodity management.

Objective 4: Quarterly progress
- Updating the SCIP
- Monthly commodity tracking/monitoring meeting

Sub-Objective 4.1
Support for the development and implementation of capacity building framework and strategy under the leadership of PLMC to build the capacity of relevant personnel of the MOHFW and its key directorates to sustainability manage their supply chains and also of indigenous institutions to provide supply chain technical assistance and training.

Progress toward sub-objective 4.1
Monthly commodity tracking/monitoring meeting has been established.

Sub-Objective 4.2
Provide technical leadership and coordination in procurement and supply chain management of health commodities.

Progress toward sub-objective 4.2
As part of strengthening procurement management systems, the focus of SIAPS support includes providing technical assistance to the MOHFW, DGFP, DGHS, and HED including the health wing of PWD to effectively manage the procurement processes. During this quarter SIAPS has

reviewed and developed a strategic plan on how to consolidate 32 operational plans and create a leadership group to facilitate TA planning.

Objective 6
Strengthen pharmaceutical management systems for TB.

Objective 6: Quarterly progress
SIAPS will support TB program performance through the design of a web-based logistics management information system capable of timely collection and reporting of logistics data. A comprehensive assessment of TB commodity management system will be utilized to develop user-friendly guidelines/frameworks to ensure proper functioning and usage of e-TB Manager.

- There have been several TB technical meetings focusing on commodity management facilitated by SIAPS and NTP. SIAPS has also managed to have URC, TNP, WHO and other partners onboard to support TB commodity management.
- The eTB manager has been revived, and the first national training is scheduled for February 2012.
- SIAPS is now leading the TB commodity management forecasting and quantification and scheduled the first national training on TB forecasting and quantification on March 2012, with the help of consultants.

Sub-Objective 6.1
Improve TB program performance through strengthening management information systems in collaboration with WHO, URC, and other key stakeholders.

Progress toward sub-objective 6.1

- Technical forum established
- Several technical meetings done and recommended SIAPS to lead the commodity management for TB.
- The eTB sites have been visited, assessed, provided TA, the tool upgraded and a roadmap towards roll out of eTB Manager agreed (which will include TB case management and logistics management.

Deliverables for sub-objective 6.1
Assessment of current logistics management of NTP, to introduce TB-LMIS.

Brazil

Joel Keravec

Portfolio Background

With 72,000 new cases and 4,800 deaths reported in the 2011 World Health Organization (WHO) Tuberculosis (TB) Report, Brazil continues to be ranked as one of the 22 highest TB burden countries in the world. Although Brazil was acknowledged as one of the countries to have reached the target of halving the 1990 mortality rate by 2010 (contributing with China to a significant decrease in the global TB burden), the TB treatment success rate in Brazil is still estimated at 72%, below the 85% United Nations (UN) Millennium Development Goal targets for TB control. Considerable progress has been achieved over the last several years and innovative strategies have been introduced for better TB and drug resistant TB (DR-TB) control, but to-date only 80% of government health primary care facilities are offering DOTS, some with severe quality discrepancies in DOT implementation. Brazil still reports a high rate of defaulters (9.2%), and the number of cases cured with smear microscopy control is still much lower than it should be. TB/HIV control is considered at macro-level but yet few initiatives have been incorporated at routine service delivery points. DR-TB case detection and treatment success rates are consistently improving over the years, with the support of a web-based system for managing patients and second line drugs which is implemented nationwide. However, the national health system is still detecting less than half of its estimated DR-TB burden. Health System organization for patients referrals from primary care to secondary or tertiary care levels for DR-TB control is also far from satisfactory in many of those states yet to address DR-TB challenges. Quality laboratory, diagnostic (culture and drug sensibility test (DST)) and drug management capacity are still weak and need to be strengthened at many service delivery locations to offer optimum conditions for patient treatment.

Since 2004, USAID/Brazil has funded MSH's RPM Plus and SPS Programs to strengthen pharmaceutical management in Brazil's TB program. Initial work entailed working with key TB partners, including: the National Tuberculosis Program (NTP) of the Secretary of Health Surveillance, Oswaldo Cruz Foundation (Fiocruz/MoH), the TB Reference Center Professor Hélio Fraga (CRPHF/Fiocruz), the National Institute of Quality Control (INCQS/Fiocruz), Farmanguinhos/Fiocruz, the Network of Public Pharmaceutical Manufacturers, the National Coordination of Laboratory Network, the Public Health Laboratory Network (Lacens), TB State and Municipal Coordinators; Penitentiary System treatment units, NGOs, and the Brazilian Academy (Rede-TB Network). Since 2007, SPS has helped strengthen the nationwide diagnosis and treatment of multidrug resistant (MDR)-TB patients, management of second-line medicines, and overall drug-resistant (DR)-TB surveillance. For example, the number of DR-TB treatment centers has expanded from 62 to 167, which has increased geographic accessibility. Also, an innovative tool was developed, the web-based e-TB Manager© information management tool, which was implemented in all DR-TB centers. SPS supported the adoption of new evidence-based guidelines for TB and DR-TB control and developed MDR-TB guidelines and training-of-trainers materials. In addition, SPS conducted nationwide capacity building programs in all 167 reference centers focusing on case management, diagnostic capacity, monitoring of MDR-TB cases, and information sharing at all levels. These interventions contributed to a 12 percent increase in DR-TB cure rate between 2004 and 2010, and more than doubled the number of DR-TB case notifications between 2004 and 2011. SPS strengthened DOTS and overall TB drug management

by institutionalizing a permanent product quality assurance-testing program for first- and second-line drugs. As a result, Brazil has been recognized by international organizations, including the Green Light Committee/Global Drug Facility at Stop TB Department/WHO, for promoting the use of quality assured medicines. SPS also has supported the transition to fixed dose combination (FDC) products for TB by training providers in all 27 states in rational use of FDCs and by providing technical assistance in the development and manufacture of the new FDC dosage forms. In addition, SPS supported the national public health laboratory network to achieve international standards, implement quality systems according to ISO norms, and promote accreditation processes through innovative methodologies in ten public health laboratories.

As a result of these achievements, SPS is recognized for its expertise among local TB partners and has been nominated for a second mandate to the new MoH TB advisory committee created in 2011 to provide input into national TB policies. During all these years, MSH has been able to leverage substantial human and financial resources. Using the same collaborative model that was used by the Government of Brazil, MoH is committed to continue its support for all proposed activities in this work plan on a cost-share basis of approximately 50 percent.

Quarter Overview

Several activities were conducted during this quarter within the three main objectives designed for this fiscal year. The highlights included trainings conducted at the TB reference centers, progress in SITETB's incorporation, and the support to CRPHF's laboratory. However, many issues still need to be addressed, since the major goal for FY11 will not only be to transmit, but to ensure the activity's internalization for long-term sustainability within the Brazilian health system.

Key activities for next quarter

- Conduct training in SLD management for the CRPHF's pharmacy employees.
- Internalization of activities by CRPHF's pharmacy staff previously performed by MSH staff.
- Support the MoH in the establishment of the terms of reference for the SLD medicine acquisition.
- Complete the medicines acquisition and prepare the terms of reference for ensuring the quality of drugs to be acquired.
- Finalize the reference guide for the pharmacy supervision.
- Customize SITETB according to the outcomes from the piloting reference centers.
- SITETB implementation in 12 new reference centers within the 4 states involved in the piloting phase.
- SITETB's piloting phase finalization.
- Define and formalize the contract with the company responsible for managing the five consultants in charge of performing the proposed activities.
- Culture decentralization plan approved. NRL quality-related documentation reviewed and updated.
- Standardized forms reviewed and data collected to produce the performance indicators aligned with WHO. Reports of QC for culture media received from LACENs completed and distributed.
- New NRL organization chart approved.
- Assist on establishing a cooperative agreement between INCQS and the SVS and the

Secretariat of Science and Technology and Strategic Commodities (SCTIE) to routinely test (orientation analysis) drugs procured for all diseases under the management of SVS, not only for TB.

- Explore the need to train other Lacens to be included in the FLDs QC activities countrywide. Explore with NTP, CGLAB, SVS and SCTIE development of a QC plan including the Lacens recently trained and other Lacens with proven expertise on this matter (i.e., Rio de Janeiro, São Paulo, Minas Gerais and Goiás).
- Organize and conduct one Labmost TOT workshop with participation of NTP, INCQS and CGLAB representatives.
- Explore incorporation of Labmost methodology by CGLAB and GGLAS/ANVISA to support the funding through FinLacen mechanism. Train a pool of consultants or potential TOTs replicators to disseminate Labmost methodology within the public health network.

Objective 1
Strengthen TB pharmaceutical management and information systems

Objective 1: Quarterly progress
Several activities were performed to strengthen the pharmaceutical management and information system. Overall, 90% of the planned deliverables and outputs were accomplished. Trainings for the reference centers on clinical management and SITETB's internalization in-country (finalization of the piloting phase is planned for Q2) and the adoption of several procedures and monitoring reports by the reference centers, generating a more accurate medicine consumption forecast at the health unit level, making the central-level distribution more rational.

Sub-Objective 1.1
Sub-Objective 1.1: Support incorporation of key drug management achievements and policies within the public health system

Progress toward sub-objective 1.1

- 5 Clinical Management trainings held (83.3% of the scheduled trainings) at the following states: Pernambuco (78 participants - 45 men and 33 women), Paraná (70 participants - 8 men and 62 women), Piaui (113 participants - 18 men and 95 women), Sao Paulo (120 participants - 20 men and 100 women) and Sao Paulo (120 participants - 24 men and 96 women).
- 6 Trainings for TB references: Alagoas and Sergipe: 41 professionals (8 men and 33 women), Rio Grande do Norte and Piauí: 46 professionals (12 men and 34 women) Paraíba: 38 professionals (34 men and 4 women); Amapá, Rondônia and Tocantins: 55 professionals (13 men and 42 women), Goiás: 48 professionals (6 men and 42 women) and Mato Grosso do Sul: 28 professionals (6 men and 22 women). Total: 256 professionals (49 men and 207 women).
- Medicine quantification calculated for 81 different TB/DR-TB treatment units in order to avoid stock-outs, overstocks and losses due to expiration.
- Implementation of the inventory model in 1 Reference Center.

Deliverables for sub-objective 1.1

- 3 worksheets with the medicine movement report elaborated.

- 3 worksheets with the monthly distribution elaborated.
- 2 medicine procurement process monitoring report for 2012 elaborated.
- 1 training material for the Reference Centers Medicine Management elaborated.
- 1 training schedule elaborated

Sub-Objective 1.2
Sub-Objective 1.2: Support SITETB (Brazilian e-TB Manager specific version) long term sustainability, management and use countrywide.

Progress toward sub-objective 1.2
- Reference units using SITETB for case management and medicine management: 13 (28.2% of the 46 total planned).
- States using SITETB: 4 (25% of the 16 total planned).
- Pilot phase assessment tool developed to be applied in all states involved in pilot phase (Bahia, Espírito Santo, Santa Catarina and Pará).
- SITETB's manual chapters developed and published on the system's webpage (www.sitetb.org through the link download) - 1) Summary of the chapters, 2) How to access SITETB, 3) Reporting a case in SITETB, 4) How to dispense medicines using SITETB, 5) How to manage medicines in SITETB; 6) How to follow-up a case in SITETB.
- SITETB training performed in Santa Catarina - Total of participants: 33 (7 men and 26 women).
- SITETB pilot phase monitor performed through the analysis of the information registered in the system's database.
- Cases from Bahia, Santa Catarina, Espiríto Santo and Pará reported from January 1994 to December 2011 migrated from the previous system (TBMR) to SITETB (1163 of 5849 cases, representing 20% of country's total).
- 4 pharmacists trained for the SITETB medicine module use (total of 4 women - 3 from Santa Catarina and 1 from CRPHF).

Main challenges for sub-objective 1.2
Due to staff unavailability, two meetings scheduled were not yet done, one with the Secretariat for Health Surveillance/MoH (SVS) and the other with the National Health System IT Department. This delayed the establishment of the directives to be followed.

Sub-Objective 2.3
Support the SP State TB program in implementing specific TB control activities

Progress toward sub-objective 2.3
Work plan with the activities finalized by the São Paulo State TB Program. The company that will manage the five consultants in charge of performing the proposed activities is still under process of definition and further formalization.

Main challenges for sub-objective 2.3
Formalization of the contracts pending.

Objective 3

Strengthen Hélio Fraga National TB Reference Center Activities and the Public Health TB Laboratory Network

Objective 3: Quarterly progress
MSH has provided technical support for strengthening CRPHF‘s activities through participation in meetings, staff training, transfer of technical knowledge, establishment of SOPs, adaptation of laboratory forms with standards adopted by WHO, provision of logistic support for the organization, and conduction of a Biosafety Workshop for lab staff.

Sub-Objective 3.1
Support Hélio Fraga Center in delivering its key mandate as National TB Reference Center.

Progress toward sub-objective 3.1
- Analysis of remaining batches collected was completed and analytical reports disseminated by INCQS to stakeholders according to NTP/SVS definitions.
- Provided technical support for preparation of training materials regarding TB smear microscopy diagnostic to be distributed by NRL to Lacens network.
- Participation in meeting with CGLAB representatives for update and review of the culture decentralization plan and submission to NTP/CGLAB coordination for approval.
- SOPs, standardized forms, work instructions and other quality-related documentation partially reviewed jointly with lab staff and submitted to lab coordination for approval (required review identified during the quality monitoring conducted in September 2011 at the NRL).
- Adaptation of lab standardized forms to fit data collection of performance indicators aligned with WHO (draft); meetings to improve integration between labs and TB coordination to enable regular collection of these indicators, preparation of particular forms to record these indicators (draft), partial data collection to calculate indicators of smear microscopy and culture, and identification of potential inconsistencies regarding culture and DST requests to the NRL.
- Evaluation of results of the QC for culture media received from LACENs and preparation of QC analysis report.
- Proposal for a new NRL organization chart presented to coordination for approval.
- Abstracts regarding ISO17025 norm and quality control for culture media implementations in the NRL accepted for poster presentation in the Society of Quality Assurance 2012 Conference.
- Provided logistics support for organization and conduction of Biosafety Workshop for lab staff following the lab capacity building plan.
- Training conducted for CRPHF's pharmacy staff.

Main challenges for sub-objective 3.1
Due to required review and adaptation the culture decentralization plan was not approved.
- Quality-related documentation review and adaptation not completed due to lack of lab staff for final revision and approval.
- Data collection to calculate indicators of smear microscopy and culture not completed due to several source of information to be checked.
- Due to NTP logistical issues, sample collection of 4 in 1 tablets in target states were not

performed by NTP.
- Due to internal logistic issues, Lacen Bahia did not start analyses of 4 in 1 FDC samples received from INCQS.
- Ambulatory accreditation process not started--still waiting for the guidance from Hélio Fraga Center (CRPHF). Fiocruz Biosafety Department did not send to date the evaluation report from the visit performed on the beginning of November 2011, this is the only item pending for accomplishing all requirements towards CRPHF's Pharmacy Accreditation at Level 1.

Deliverables for sub-objective 3.1
- 3 planned meetings with the CRPHF's Quality Committee
- 4 SOPs elaborated and implemented in CRPHF's Pharmacy (medicine Inventory, storage and discard of expired medicines, medicine side effects control and Medicine Acquisition Planning for MoH).

Sub-Objective 3.2
Support public health laboratory network in using Labmost methodology to strengthen laboratory quality management systems and accreditation process.

Progress toward sub-objective 3.2
Abstract regarding Labmost methodology and its implementation experience in Brazil was accepted for poster presentation in the Society of Quality Assurance 2012 Conference.

Main challenges for sub-objective 3.2
Due to logistics and staff availability issues the planned workshop was not conducted.

Cameroon

Christine Onyango

Portfolio Background

SIAPS has been provided with $1.5 million in field support from the USAID Regional Office in Accra to implement a package of interventions aimed at strengthening the pharmaceutical sector in Cameroon at the central level of the health system as well as in four USAID-focus regions (Admawa, East, North West and South West). SIAPS did not have an office in Cameroon, but plans to establish one with three technical staff and one administrative staff by the second quarter of Year 1. An assessment of Cameroon's public pharmaceutical sector conducted by MSH's Strengthening Pharmaceutical Systems (SPS) program in October 2011 identified key weaknesses and priority interventions to address them. The SIAPS Year 1 work plan is based in part on the recommendations of this assessment. Additionally, PEPFAR's FY11 operational plan has identified capacity building of key public sector actors in the pharmaceutical system in procurement, distribution and pharmaceutical management information systems are priority activities. Under SIAPS's first year of activity in Cameroon, interventions will be implemented to both address immediate supply chain bottlenecks in four USAID selected regions, and build the foundation for sustainable nationwide improvements in the functioning of Cameroon's public pharmaceutical sector.

JUSTIFICATION. The assessment conducted by MSH/SPS in October 2011 identified a number of weaknesses and variations in the quality of pharmaceutical management within the public pharmaceutical sector which could generally be summarized as:

- Poor coordination existing between the central level of Ministry of Health (MoH) and Cameroon's regions to ensure implementation of the national pharmaceutical policy. For instance, there is absence of a functional national coordinated mechanism for collecting, transmitting and analyzing consumption data on pharmaceuticals across various disease programs.
- Paucity of pharmaceutical management data for quantification, forecasting and supply planning.
- Lack of national standards, guidelines and standard operating procedures to govern various areas of pharmaceutical management in the public and private sector.
- Poor inventory management and storage practices existing at pharmaceutical warehouses and dispensing points.
- Inadequate training and supervision of dispensing staff in health facilities.
- Varying financing and governance arrangements exist at the regional level with respect to funding and payment for pharmaceuticals, with resulting variation in the availability of products.

The FY 11 PEPFAR Country Operational Plan identifies capacity building of Cameroon's Central Medical Stores, CENAME (Centrale Nationale d'Approvisionnement en Médicaments Essentiels), regional pharmaceutical supply centers (Centre d'Approvisionnement Pharmaceutique Régional, or CAPRs) as well as district hospitals in procurement and distribution of HIV/AIDS, STI and family planning supplies and in management of logistics information as priority activities. Additionally PEPFAR expressed interest that funds be used to build capacity of these actors of the pharmaceutical sector in recording, transmitting and

using pharmaceutical management information. SIAPS is proposing phased implementation of interventions to incrementally address these issues. This will start with a focus on rendering functional the national coordination mechanism for quantification/forecasting/procurement planning and redesigning the existing pharmaceutical management information system in Year 1. In subsequent years, SIAPS will increasingly focus on strengthening pharmaceutical services such as prescribing and dispensing.

Quarter Overview

The key achievements of Q1 were the development and submission (to USAID) of a concept paper to articulate proposed SIAPS activities for Year 1 of activity in Cameroon and the initiation of recruitment of what will eventually be a staff of four Cameroon-based persons to implement SIAPS activities. Data and recommendations from an assessment conducted in October 2011 by the predecessor project to SIAPS, the Strengthening Pharmaceutical Systems (SPS) Program, focused on the management of pharmaceuticals used for Neglected Tropical Diseases was used to inform development of the concept paper.

Key challenges of quarter

- The identification of a Senior Technical Advisor focused on Supply Chain strengthening who will start working on SIAPS Cameroon activities during Q2.
- Recruitment of a SIAPS Country Project Director for Cameroon initiated.
- No technical or administrative staff hired yet in country, particularly Country Project Director.
- SIAPS HQ awaiting response from USAID/Accra on concept paper submitted in December before developing detailed work plan.

Key activities for next quarter

- Finalize hiring of Country Project Director (CPD) – have CPD officially start working before the end of Q2.
- Submit 3-year country strategy and 1-year detailed work plan to USAID West Africa Regional Office by February 24, 2012.
- Identify suitable office space.
- Submit application to obtain registration for Management Sciences for Health.
- Advertise for Office Manager (local hire).

Objective 1

Pharmaceutical Sector Governance Strengthened

Objective 1: Quarterly progress

During Q1, a concept paper was submitted to USAID. SIAPS received a response in February 2012 and was asked to submit a detailed work plan by February 24, 2012.

Sub-Objective 1.1

Improved medicines policies, legislation, regulations, norms and standards

Progress toward sub-objective 1.1

During Q1, a concept paper was submitted to USAID. SIAPS received a response in February

2012 and was asked to submit a detailed work plan by February 24, 2012.

Sub-Objective 1.2
Transparent and accountable pharmaceutical management systems.

Progress toward sub-objective 1.2
During Q1, a concept paper was submitted to USAID. SIAPS received a response in February 2012 and was asked to submit a detailed work plan by February 24, 2012.

Objective 2
Capacity for Pharmaceutical Management and Services Increased and Enhanced

Objective 2: Quarterly progress
During Q1, a concept paper was submitted to USAID. SIAPS received a response in February 2012 and was asked to submit a detailed work plan by February 24, 2012.

Objective 3
Utilization of Information for Decision Making

Objective 3: Quarterly progress
During Q1, a concept paper was submitted to USAID. SIAPS received a response in February 2012 and was asked to submit a detailed work plan by February 24, 2012.

Sub-Objective 3.1
Pharmaceutical management information available and used for decision making at different levels of the health system

Objective 4
Financing Strategies and Mechanisms to Improve Access to Medicines Strengthened

Objective 4: Quarterly progress
During Q1, a concept paper was submitted to USAID. SIAPS received a response in February 2012 and was asked to submit a detailed work plan by February 24, 2012.

Sub-Objective 4.1
Financial resources available to the pharmaceutical sector increased

Objective 5
Pharmaceutical Services to Achieve Desired Health Outcomes Improved

Objective 5: Quarterly progress
During Q1, a concept paper was submitted to USAID. SIAPS received a response in February 2012 and was asked to submit a detailed work plan by February 24, 2012.

Sub-Objective 5.1
Pharmaceutical services standards defined, adopted and implemented

Democratic Republic of the Congo

Philippe TSHITETA

Portfolio Background

The Democratic Republic of the Congo (DRC) is a country characterized by numerous public health challenges. This situation follows decades of civil war and unrest, which, coupled with inadequate allocation of human and financial resources to the health sector resulted in a fragmented public health delivery system throughout the country, with an inconsistent availability of essential medicines. In the past, the absence of an inadequate regulatory framework in the form of up-to-date legislation and policy documents for the pharmaceutical sector coupled with a weak Drug Regulatory Authority (DRA), and the absence of a national system for planning pharmaceutical procurements created an environment that allowed multiple donors and technical assistance partners to create parallel systems for procurement and distribution of pharmaceuticals. Additionally, the long distances involved in transporting pharmaceuticals across a large country like the DRC combined with lack of transportation infrastructure, renders distribution of health products difficult, and contributes to the stocks frequently found at health facilities. To address the challenges mentioned above, the United States Agency for International Development has progressively increased its assistance to activities that strengthen the DRC's pharmaceutical sector by funding successive projects aimed at improving the availability and the appropriate use of essential medicines and key health commodities in the DRC. Prior to the start of the recently-awarded Systems for Improved Access to Pharmaceuticals and Services project (SIAPS), the most recent of these projects was the Strengthening Pharmaceutical Systems (SPS) Program also managed by MSH. Under SPS, the following major achievements were realized on which SIAPS is going to build:

- The National Drug Regulatory Authority is functional.
- The production of norms and guidelines for Maternal, Neonatal and Child Health, achieved in collaboration with partners such as the World Health Organization (WHO), United Nations Population Fund (UNFPA), United Nations Children's Fund (UNICEF), Maternal and Child Health Integrated Program (MCHIP), the International Rescue Committee (IRC), and the Integrated Health Project (IHP), among others.
- A mechanism now exists at the provincial level, which serves as the main mechanism for planning and coordinating pharmaceutical activities and resolving supply chain bottlenecks.
- Drugs and Therapeutics Committees (DTC) have been introduced to the DRC for the first time.
- The DRC has become the 99th country to join the WHO Uppsala Monitoring Centre (UMC) following SPS financial support to members of the National Pharmacovigilance Center (NPVC) to attend the International Pharmacovigilance Conference in Nairobi in 2009. As a result, the DRC has submitted over 500 adverse drug event notifications to the WHO Vigiflow database to date.
- Because of SPS assistance, the National HIV/AIDS Program (PNLS) is now able to report patient and commodity-related data on patients on antiretroviral treatment (ART) for 6 provinces. These data have made it possible for the PNLS to conduct quantification based on consumption data, rather than on morbidity data, as was done in the past.

The following amounts have been provided in FY11 funding for the first year of SIAPS activities:

FP/RH: $200,000
PEPFAR: $500,000
PMI: $550,000
TB: $300,000
Total: $1,550,000

Quarter Overview

During this quarter we mainly addressed the preparations for the SIAPS Y1 work plan, and supported the National Drugs Regulatory Authority to hold their quarterly medicines registration session.

Key challenges of quarter

None specifically linked to SIAPS.

Key activities for next quarter

Provide financial and technical support to national and provincial mechanisms for coordinating pharmaceutical activities. Provide technical support to the FEDECAME and ASRAMES to meet USAID standards to serve as a procurement agent for pharmaceutical products. Training of health practitioners using updated training modules on pharmaceutical management for HIV/AIDS. Provide technical support to PEPFAR implementing sites to improve their system for managing PMTCT commodity data. Identify weaknesses in storage conditions and practices at selected CDRs and ART sites in Kisangani (Province Orientale) and develop an action plan to address them.

Technical Activity Coordination

Quarterly activity consisted of coordination and monitoring, work planning, budgeting, reporting, meetings, and communications with partners and collaborators.

Office Management

Local office rental and all associated costs (security, communication systems, etc.), staff salaries, as well as finance and administrative support functions. These costs are shared with the Integrated Health Project (IHP), with which SIAPS shares an office in Kinshasa and in some of the provinces.

Objective 1

Pharmaceutical sector governance strengthened

Objective 1: Quarterly progress

The National Drugs Regulatory Authority is functional now and meeting regularly every quarter. The number of medicines registered in the country has reached more than 600 from almost zero in less than two years.

Sub-Objective 1.1

Increased efficiency and transparency of the drug registration system

Progress toward sub-objective 1.1

SIAPS provided financial support to the Registration Committee of the National Drugs Regulatory

Authority to organize the first quarterly meeting (November 1-23, 2011). A total of 245 dossiers were analyzed.

Main challenges for sub-objective 1.1

The high number of medicines of sub-standard quality still circulating in the country.

Guinea

Christine Onyango

Portfolio Background

More than 90% of the clinical cases of malaria each year occur in Africa, with much of the burden in children under five years of age. Strategies to address these challenges must be implemented in collaboration with programs aimed at integrated approaches to childhood illness and reproductive health and assuring that quality medicines are available and used appropriately. Guinea is a West African country where malaria is endemic to the whole territory. In 2005, Guinea changed its malaria treatment policy to include an artemisinin–based combination therapy (ACT), artesunate-amodiaquine (ASAQ) as first-line treatment for uncomplicated malaria. To date, funding for procurement of ASAQ has been through the Global Fund Round 6 grant in 2009 and more recently the President's Malaria Initiative (PMI). The first consignment of approximately three million treatments of ASAQ arrived in country in 2009 with subsequent PMI-procured treatments in 2011. ASAQ has been distributed to almost 1300 public sector health facilities in Conakry and in all 38 prefectures. Treatments have been provided to beneficiaries at no-cost. Prior to the arrival of PMI-procured ACTs in late 2011, health facilities experienced stock-outs of ASAQ for about 6 months. In addition to political instability in Guinea, there were delays in implementing Global Fund Round 6 planned activities and subsequently delays in fund disbursement for phase 2 of the Round 6 grant, which led to the stock-outs. Furthermore, an inefficient information system which prevented appropriate decision making and limitations of the central medical store (PCG) to provide essential medicines to the health facilities' in a timely and effective manner contributed to the stock-outs.

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health (MSH)'s Center for Pharmaceutical Management, has received funds from PMI to provide technical assistance to improve supply chain management and logistics management information systems alongside other partners. In addition, PMI expects SIAPS to support the improved performance of the pharmaceutical system and create conditions for PCG and other key health systems structures to ensure that malaria commodities are distributed to health facilities in a timely manner to avoid recurrent stock-outs. This support is intended to facilitate the implementation of Guinea's national malaria policies. While this is the first support from USAID Guinea directly to SIAPS for assistance in strengthening pharmaceutical systems, SIAPS will build on appropriate lessons and work conducted under its predecessor program Strengthening Pharmaceutical Systems (SPS) in other PMI beneficiary countries, as well as other MSH programs in Guinea, such as Pour Renforcer les Interventions en Sante Reproductive et MST/SIDA (PRISM) and Extending Service Delivery (ESD). PMI has provided $1,000,000 to SIAPS for fiscal year 2011.

Quarter Overview

An exploratory visit throughout the country was held in November 2011, in order to assess the situation of the pharmaceutical system before developing the work plan for FY 11. The SIAPS program also worked with the MoH (NMCP and PCG as well as USAID/Guinea) to assure the best and fastest approach to a transparent distribution of the emergency ASAQ stock.

Key activities for next quarter

SIAPS will organize a roundtable of stakeholders in the pharmaceutical sector, develop an action plan, and begin implementing recommendations from the plan focused on improving coordination. SIAPS will also continue to participate in different workshops organized by the MoH dealing with pharmaceuticals (training sessions, revision of guidelines, etc.).

Evaluations BY SIAPS: Description
SIAPS did an exploratory mission in Guinea last November to assess the pharmaceutical system, in order to discuss and the pharmaceutical management priorities and then develop a work plan for SIAPS FY 11.

Objective 1
Pharmaceutical sector governance strengthened

Objective 1: Quarterly progress
SIAPS has a clear vision of the major priorities in the pharmaceutical management area after the exploratory visit. During the visit, staff met with the DNPL, the PNLP, and the central medical store. ASAQ tablets are available everywhere in the country after the emergency distribution coordinated by SIAPS with PNLP, PCG, and other partners.

Sub-Objective 1.1
Improved ability of the "Direction Nationale de la Pharmacie et des Laboratoires (DNPL)" to regulate the pharmaceutical system

Progress toward sub-objective 1.1
A job aid and a model of a monthly report in pharmaceutical management were developed in preparation of the emergency distribution of ASAQ throughout the country.

Jordan

Gladys Tetteh

Portfolio Background

The public health sector in Jordan is well established, and includes a strong structure to support an appropriate formulary process. Drug and Therapeutics Committees (DTC) exist in nearly all MOH and RMS hospitals in addition to a central DTC. Procurement is performed centrally through the Joint Procurement Department (JPD). However, formulary decisions are not always made using the latest medical evidence, standard treatment guidelines (STGs) are not produced or utilized to a good extent, and the inter and intra-departmental set up within a hospital is not always optimal for implementing guidelines and procedures. Suboptimal use of antibiotics for surgical prophylaxis is also a common problem, including that for CS, and was shown in a study conducted in three sectors in Jordan, and published by the Jordan Food and Drug Administration (JFDA).

Consistent with the overall mission of MSH's Center for Pharmaceutical Management (CPM), the USAID-supported SIAPS Jordan Country Program's vision is to bring positive patient and health outcomes through improved availability and use of pharmaceuticals. The pivotal approach taken to achieve this end will be to work closely with in-country partners to strengthen their capacity and health systems, leading to sustainable health improvements. The overall goal for SIAPS Jordan is to strengthen in-country capacity and systems to improve selection, availability, and use of medicines of assured quality to help save lives and improve health outcomes. Specifically, SIAPS Jordan's objective is to strengthen national and institutional capacity for effective, safe, and cost-efficient use of antimicrobials to help contain antimicrobial resistance and improve patient outcomes. In FY10, SPS/SIAPS Jordan began a pilot program engaging four Jordanian public-sector hospitals: 3 Ministry of Health and one Royal Medical Services. The program aimed to improve the prophylactic use of antibiotics for cesarean section (CS) procedures by engaging stakeholders, using evidence based medicine, and monitoring and evaluation through continuous quality improvement (CQI) processes. The process began by creating a baseline-practice profile for each of the hospitals, and continued with helping each hospital develop their own Protocol and Procedure (P&P) for prophylactic use of antibiotics in CS. In the meantime, involvement from relevant and complimentary Ministry of Health departments and directorates helps establish sustainability and strengthen the mandates of the hospital DTCs.

Quarter Overview

SIAPS Jordan worked this quarter to implement CQI activities and increase antibiotic prophylaxis in cesarean sections.

Key challenges of quarter

Coordination with tangent MoH departments in order to make the antibiotic of choice available.

Key activities for next quarter

Complete and submit new work plan to USAID and follow-up with the hospital teams in both their implementation through completion of CS Log and in monitoring program indicators through Excel Monitoring Tool.

Objective 1

Consolidating on-going work in the currently participating MOH and RMS hospitals, strengthening involvement of all relevant MOH directorates and departments

Objective 1: Quarterly progress
The hospital teams continue protocol implementation, monitoring and evaluation through a continuous quality improvement process. One hospital has not only succeeded in establishing a new DTC, but has also conducted a first meeting for the committee and in it discussed implementation progress and indicator data. The other hospitals are also taking steps toward establishing sustainability, and are continuing to implement the protocol and aggregate indicator data.

Sub-Objective 1.1
Continuous quality improvement (CQI) system strengthened in the hospitals participating in the pilot initiative to improve antibiotic prophylaxis in cesarean sections

Progress toward sub-objective 1.1
Prince Faisal Hospital:

- The feedback on the training done for 33 staff nurses and mid-wives at the end of the previous reporting quarter (Sept. 2011) was positive, and the quality of information recorded on the CS Log started improving after the training (shown in table below).
- The training was performed in coordination with the MOH, such that the staff attending obtained continuing education certificates from the MOH.
- The nursing staff was given an opportunity to discuss the terminology and set-up of the CS Logs, and their feedback was incorporated into a new draft of the CS Log.
- The improvements in the CS Log were also disseminated to the other hospital teams, and introduced in their training sessions.
- Improvement in the CS Log capture is: August- 31%, September- 45%, October- 61% (CS Log Capture Rate: percent of total OBGY CS cases for which a CS Log was completed).
- The hospital team continues to implement the protocol, to monitor through the use of the CS Log, and to measure indicators are measured through Excel Monitoring Tool (EMT).
- Illustrating one example from the EMT with indicator 2: percent of patients who received the prophylactic antibiotic (PAB) at appropriate time (within 60 min prior to incision) - Percent of CS cases (given capture rate from above) receiving PAB at appropriate time: August- 75%, September- 81%, October- 56%.
- The results for indicator 2 declined after the training, but this is attributed to more accurate and honest completion of the CS Logs and not to poorer performance.
- SPS (Salah) met with the physician head of OBGY, Dr. Ishaq Hasoneh, and discussed the training and the continued monitoring of protocol implementation. Also discussed was the need to create a continuous monitoring vector through the activation of the hospital's Pharmacy and Therapeutics Committee (PTC).

Prince Hussein Hospital:

- The hospital team continues to implement the protocol and to monitor its use with the CS Log and the EMT. However, the recent data has not been completely entered for analysis.
- The hospital director gave the PTC the responsibility of monitoring progress of protocol implementation through its meetings, to evaluate the resulting indicators, and to improve results.
- The hospital administration asked SPS/SIAPS (Salah) to take part in the committee's first

meeting, and a discussion of the program was included in the meeting agenda.

- In support of the program, and to ensure further progress and a wider technical application, the hospital administration appointed the head of OBGY to also head the PTC.
- The PTC was appropriately made up of physicians from different specialties, the departments of pharmacy and nursing, and the quality and infection control committees, among others.
- During the meeting, the physician representing General Surgery was interested in applying a similar effort to hernia-repair surgeries.

Dr. Jameel Al Totanji Hospital:

- Efforts at mandating the protocol and procedures, the CS Log, and the EMT did not come to completion.
- The physicians are continuing to administer the protocol, but no record keeping is available to evaluate prescribing and administration habits.
- A new hospital director was assigned to Al Totanji Hospital in October.
- SPS/SIAPS (Salah) met with the new director, Dr. Khaled Al Khreisha, and discussed the program work accomplished, the obstacles and gaps, and agreed on a new plan of action to re-establish implementation, monitoring, and continuous quality improvement (CQI).
- The new administration will be mandating the protocol, the CS Log, and the EMT through official hospital memos, and will disseminate to all the relevant hospital departments.
- SPS/SIAPS (Salah) is preparing for OBGY nursing training sessions once the protocol and the monitoring tools are mandated.
- After the meeting with the new director, SPS/SIAPS (Salah) met with the infection control department and reviewed the EMT and its proper use. In order to speed up progress, the improvements and editing resulting from work in the other two hospitals were introduced to the Totanji team and incorporated into their CS Log and EMT.

RMS, Al Hussein Hospital:

- A meeting with the office of information and planning (I&P) resulted in the creation of a work plan outlined by the three main points:
    - Creating a committee composed of four senior-level providers: head physician of OBGY, head of RMS nursing, head of infection control, and pharmacy.
    - This team will be held responsible for the tasks required, and will report progress to the office of information and planning.
    - The senior-level team will then assign a person from his/her department to specifically overlook the protocol work required from each department. This secondary team will work closely with the SPS consultant, and will report to the senior-level team on monthly basis.
- Based on the work plan, a second meeting was held at the Office of I&P with Dr. Issa Hazza. The four heads of department, as outlined above, were to participate. However, the head physician of OBGY did not attend.
- The subsequent meeting was to include the heads of each department, in addition to a technical person from those departments. But the internal information flow and coordination and attendance by the various department heads and staff at the meeting was less than adequate.
- As a result, the meeting did not end positively, as the RMS team insisted on having just "one" person assigned and completely devoted to working on the protocol implementation, monitoring, and continuous quality improvement. This is in opposition to the idea of

system-building and process improvement.
- Outcome of this meeting was reported to the Office of I&P through email and through the representative present.

Main challenges for sub-objective 1.1
One of the hospitals has a change of director, and renewed efforts were needed in re-establishing the process. However, the new administration is on board and has shown to be more aggressive toward implementation of the protocol.

Steps to address challenges for sub-objective 1.1
SIAPS has worked with the new director and has established a new "plan of work" which gained his immediate approval. This plan is now being followed and the team is adjusting well.

Objective 2
Replicating the process of improving antibiotic prophylaxis in CS at Al Basheer Hospital, a key MOH hospital.

Objective 2: Quarterly progress
Plans for expanding work into this main MoH hospital, Al Basheer, has been placed on hold by the local MoH administrator until after the workshop and results.

Lesotho

Dinah Tjipura

Portfolio Background

AIDS constitutes an alarming threat to Lesotho and its people. Findings of the 2009 Lesotho Demographic and Health Survey, carried out by the Ministry of Health and Social Welfare (MOHSW) and the Bureau of Statistics, confirmed that Lesotho has a severe, generalized HIV epidemic. According to the DHS 2009 report, overall adult prevalence is estimated to be 23%. GOL's current HIV/AIDS National Strategic Plan (NSP) recognizes the need to provide treatment, care and support services to cater for the large number of individuals testing for HIV and AIDS. The plan makes provision for the scale-up of care and treatment by increasing access to ART services, ensuring quality and expanding capacity and efficiency of service provision in both the public and the private sectors. One of the interventions to achieve this is decentralization of services to the health center level. The government aimed to provide access for ART to more than 80% of individuals who are in need of therapy by 2010. By the end of 2009, 52% of adults and 51% of children in need of treatment were receiving antiretroviral therapy at hospitals, health centers and private practitioners' clinics across the country. The GOL and its multi-sectoral partners regard this progress as one of the most significant achievements to date within the national HIV and AIDS response.

One of the key challenges of the scale-up of HIV and AIDS prevention, care, treatment and support services is the need to ensure that adequate human, technical, infrastructural resources and effective commodity procurement and distribution systems are put in place. Inadequate information management systems to support decision making in supply chain has also been one of the critical challenges, and without reliable information, the country is unable to account for the financial resources invested in purchasing medicines and laboratory commodities. This has resulted in a condition precedent being set for Round 8, Phase 2 of the Global Fund for the fight against AIDS, Tuberculosis and Malaria (GFATM). The condition precedent requires the Principal Recipient (PR) to show in a manner acceptable to the GFATM that a robust management information system for the ART program is in place. The United States Government (USG) has been providing support to the Government of Lesotho for its HIV and AIDS prevention, care and treatment efforts through its USAID Mission in Lesotho. Since FY08, technical support has been provided to the MOHSW through the MSH Strengthening Pharmaceutical Systems (SPS) program. As a follow on to SPS, the USG will continue to support the MOHSW through the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program of MSH.

The strategic focus of SIAPS is on assuring the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. To achieve this goal, SIAPS will promote and use a systems-strengthening approach consistent with the Global Health Initiative that will result in positive and sustainable health impact. The focus of activities will be on health system strengthening, laboratory supply chain strengthening, and policy and strategic information support. Work initiated and successes realized under SPS will be leveraged, with the approach being to move from first generation HSS to second generation approaches. The focus with SIAPS will be to adopt interventions that are more integrated, looking at the five building blocks of health systems, with medical products as an overlay. This ensures increased efficiency in

implementing interventions, broader reach and a more sustainable impact. One of the critical activities of SIAPS under this work plan will be to provide technical assistance to the MOHSW towards meeting the condition precedent set by GFATM. The MOHSW has requested SIAPS to provide TA to the PR to meet this condition precedent set by the GFATM.

Quarter Overview

In Lesotho, the 2011-12 work plan had not been approved yet in quarter 1, therefore was no progress made in reaching the portfolio goal or objectives.

Key activities for next quarter

Provide technical support for the finalization and implementation of STGs and an EML. Provide TA for implementation of the in-service training and supportive supervision and mentoring program for pharmacists and pharmacy technicians at 3 district hospitals. Enhance implementation of the ePMIS and RxSolution at all district hospital ART sites. Provide TA for strengthening implementation of LMIS. Support the development of the Medicines Bill. Implement quality assurance mechanisms for ARVs and other HIV-related commodities at NDSO. Provide technical support for the development and piloting of ART pharmaceutical standards of care. Coordination of SCM activities through the SCM TWG. Provide TA to the MOHSW for development of a robust plan of action to help PR meet the condition precedent set by the GFATM. Mentor the laboratory logistics officer. Help revitalize and capacitate the national and hospital therapeutics committees. Implement public education campaigns on appropriate use of antibiotics and ARVs.

Technical Activity Coordination

Expenditures included salaries (LOE for SIAPS launch bookings).

Office Management

Administrative costs included office supplies, project vehicle costs, and rentals.

Objective 1

Strengthen pharmaceutical sector governance

Objective 1: Quarterly progress

No progress on activity because the work plan was not approved until quarter 2.

Sub-Objective 1.1

Improve medicines policies, legislation, regulations, norms, and standards

Progress toward sub-objective 1.1

No progress on activity because work plan was not approved.

Mali

Christine Onyango

Portfolio Background

SIAPS has been provided with a total of $950,000 in funds from the USAID/Mali mission to implement activities to improve functioning of the pharmaceutical system over a one-year period. It should be noted that $100,000 of this was provided to the Strengthening Pharmaceutical Systems program (SPS) to allow program operations to continue while the start of SIAPS got underway. SIAPS will build on the work conducted by the SPS program to address the following key weaknesses in the pharmaceutical sector:

- Availability of regular, reliable pharmaceutical management information for decision-making.
- Inadequate capacity and organization within key institutions responsible for developing, overseeing and regulating the pharmaceutical sector.
- Inadequate collaboration and communication among key actors in the pharmaceutical sector

As one of the countries participating in the US President's Malaria Initiative (PMI), and now the Global Health Initiative (GHI), Mali has the opportunity to accelerate its progress toward achieving the Millennium Development Goals (MDGs). SIAPS will use resources being made available through the US government whose priorities include significantly improving health-related Millennium Development Goals (MDGs) 4, 5 and 6 which focus on reduction of child mortality, reduction of maternal mortality and prevention and treatment of malaria, HIV and other diseases including NTDs) in Mali through integrated programmatic interventions. The funding breakdown for Year 1 of SIAPS activity is as follows:

- $500,000 PMI funds
- $300,000 POP funds
- $50,000 MCH funds

In Mali, key health commodities such as anti-malarials, family planning commodities, and other essential pharmaceuticals are frequently unavailable at various different levels of the health system when they are needed by patients and information on pharmaceuticals that are needed for planning by the government, donors and technical partners are not readily available when required. Additionally, imbalances in stock levels of key commodities are a challenge to address rapidly because of poor coordination and information sharing among various actors in Mali's public health system that manage pharmaceuticals. Lastly, the key institution with responsibility for overseeing the pharmaceutical sector, the Direction de la Pharmacie et du medicament, is unable to full carry out the functions conferred through its mandate.

Quarter Overview

Technical assistance was provided to the National Malaria Control Program (NMCP) to update the malaria commodity procurement plan for 2012, and to carry out a performance review of the NMCP strategic plan for 2006-2011. SIAPS helped in preparation and submission of a Procurement Planning and Monitoring Report for malaria and contraceptives (PPMR) in October 2011. An End Use verification survey was conducted in November and December 2011. The EUV collected data from 75 sites (health facilities, central medical stores warehouse, and district pharmaceutical warehouses known as depots repartiteurs de cercles).

Key challenges of quarter
The most significant challenge to implementation was the length of time it is taking to obtain clarification on which work plan activities will be retained in the final version of the SIAPS Year 1 work plan, which in turn has had an impact on approval of the work plan and start of certain activities. This problem has been partially alleviated by the USAID/Mali agreeing to provide provisional approval for some work plan activities.

Key activities for next quarter
Dissemination of the End User Verification Survey conducted in December 2011. Submission of the PPMRm report in January 2011 and the PPMRc report during Q2. Assistance to the DPM to conduct a national inventory of contraceptive products ahead of conducting the six-monthly workshop where contraceptive procurement tables are generated. Workshop to generate contraceptive procurement tables where the supply plan for contraceptives will be updated. Planning for the second End User Verification Survey. Finalize hiring of Country Project Director (CPD) – with CPD to officially start working before the end of Q2.

Technical Activity Coordination
A considerable amount of time spent on technical activity coordination focused on developing the SIAPS Y1 work plan which SIAPS was asked to develop based on terms of reference provided by USAID/Mali. These terms of reference were received by SIAPS in November 2011. The first draft of the work plan was shared with USAID/Mali in December 2011 and was subsequently revised and sent to USAID during the same month. In addition to work plan development, the SIAPS/Mali team participated in discussions concerning USAID Mali Mission indicators alongside other USAID implementing partners, and made suggestions on how indicators that SIAPS/Mali is required to report on could be strengthened or clarified. The SIAPS/Mali team also held coordination meetings with the technical departments of the Ministry of Health (such as the Direction National de la Santé and the Direction de la Pharmacie et du Médicament) in the context of thematic groups formed to write the new 10 year strategy for the Ministry of Health which included a section on the situation of the pharmaceutical sector. SIAPS participated in working sessions with implementing partners such as the ATN Plus bilateral project (funded by USAID) and Solthis in the context of the dissemination workshop on procurement and stock management. SIAPS also participated with PSI on quantification and procurement and supply management for the consolidation of Round 6 and Round 10 Global Fund grants.

Office Management
Procedures for the renewal of MSH's registration on Mali were initiated.

Objective 1
Pharmaceutical sector governance strengthened

Objective 1: Quarterly progress
The committee for coordinating supply chain issues for malaria commodities led by the National Malaria Control Program held meetings to coordinate planning on procurement and distribution of malaria commodities, as well as to coordinate actions aimed at increasing availability of malaria commodities and reducing stock outs. The committee achieved this with technical support from

SIAPS. For example, members of the committee contributed to the PPMRm report (normally submitted to USAID, but which is shared with malaria partners as well), which made specific recommendations on actions to take to ensure continuous available to malaria commodities in Mali. Committee members also contributed to providing updated ACT needs estimation data which was submitted to WHO for the purposes of global-level planning.

Sub-Objective 1.1
Improved capacity of the DPM to promote and instill good governance in the Malian pharmaceutical sector.

Progress toward sub-objective 1.1
There was no activity on this sub-objective during Q1. The Mission is undergoing internal discussions on whether to retain one of the activities under this sub-objective (institutional self assessment of the DPM and implementation of assessment recommendations). The activity focused on distribution of the Schema Directeur is on hold pending final approval of the SIAPS Year 1 work plan.

Sub-Objective 1.2
Mechanisms for national forecasting, quantification and supply planning of key pharmaceuticals consolidated and made more efficient and transparent

Progress toward sub-objective 1.2
Monthly meetings are now held between the NMCP and its partners to discuss issues related to malaria commodities, include stock levels, quantification of needs, forecasting, procurement planning, and distribution planning and monitoring and evaluation. SIAPS provides technical assistance to the National Malaria Control Program in the use of PipeLine procurement planning software on an ongoing basis.

Objective 3
Pharmaceutical management information available and used for decision making at different levels of the Malian health system

Objective 3: Quarterly progress
During this quarter, data concerning the stock status, storage conditions and overall management of a range of health commodities were collected through the PPMRm and PPMRc mechanisms, as well as through an End User Verification Survey. These reports used to summarize these data contain recommendations which were transmitted to various decision makers and actors, in particular, the National Malaria Control Program, Mali's National Drug Regulatory Authority (the DPM) and USAID. SIAPS continues to follow up to ensure that these recommendations are implemented.

Sub-Objective 3.1
Pharmaceutical management systems (PMIS) support both products and patients

Progress toward sub-objective 3.1
The SIAPS team collaborated with the NMCP to provide updated information on ACT needs to the

World Health Organization. In October 2011, SIAPS submitted a PPMRc report to USAID/Washington in October 2011. The following were the key recommendations made in the report:

- IUD Implant: USAID/Mission to make available to the PPM 36700 IUDs in bulk packs. Request PSI to repackage 10,000 IUDS I (5,000 for PSI and 5,000 for the PPM).
- Duofem/Pilplan D: The recommendation is to move up the delivery of this commodity by KfW from December 2011 to November 2011.
- Jadelle Implant: The DPM to make available to the PPM 51,200 in stock of Jadelle Implant.
- Ovrette cycle/Microlut: The recommendation is to delay the shipment by USAID of 82,000 cycles of this product planned for November 2011 whilst awaiting the update of contraceptive procurement tables.

An End User Verification survey was carried out in November/December, 2011. The survey was conducted in 75 facilities, which included hospitals, health centers and pharmaceutical warehouses, among others. Although the EUVS primarily collects data on malaria commodities, SIAPS used the opportunity to collect data on reproductive health commodities such as contraceptives and oxytocin, as well as on a list of tracer medicines. The survey was planned and executed in close collaboration with the National Malaria control program and a draft report was produced from the survey. A discussion and dissemination meeting of survey results is planned for February 2012, which is the timeframe when the PNLP will be available to hold this meeting.

Main challenges for sub-objective 3.1

The small number of technical staff 1 senior technical staff and 3 junior technical staff) creates difficulties in carrying-out major activities simultaneously.

Deliverables for sub-objective 3.1

- PPMRm report submitted to USAID.
- PPMRc report submitted to USAID.
- Draft End User Verification Survey report on availability of malaria commodities in 75 health structures, December, 2011.
- Draft report on the availability of contraceptives in 75 health structures, December 2011.
- Draft report on the availability of Oxytocin in 75 structures, December 2011.
- Draft report on the availability of tracer drugs in 75 health structures, December 2011.

Objective 4

Pharmaceutical services improved to achieve desired health outcomes

Objective 4: Quarterly progress

A number of corrective actions were recommended by SIAPS through the PPMRm, PPMRc processes as well as through Mali's last EUVS which was conducted in December 2011. SIAPS will follow up in Q2 to verify whether all recommendations.

Mozambique

Dinah Tjipura

Portfolio Background

Significant gaps exist in pharmaceutical policies and the delivery of pharmaceutical services in Mozambique. They have received limited technical support and need to be addressed through strengthening the pharmaceutical sector of the Ministry of Health to ensure the quality, safety and efficacy of medicines, particularly for priority health program like HIV/AIDS. The Mozambique pharmaceutical sector has been undergoing substantial reform in recent years. Establishing an effective and sustainable regulatory system is a high priority for the pharmaceutical sector as well as improving the quality and effectiveness of pharmaceutical services. In recognition of the importance of the pharmaceutical sector to the overall functioning of an integrated health system and the quality of services-- in particular, for priority health conditions, such as HIV/AIDS-- USAID/Mozambique has enlisted SIAPS to strengthen the sector's institutional and technical capacity with PEPFAR funds for FY11. Based on the gaps that have been identified in the pharmaceutical system, SIAPS will focus on supporting the Mozambique pharmaceutical sector in the areas of policy, regulation, pharmacovigilance, rational use and the overall delivery of pharmaceutical services.

Quarter Overview

During Quarter 1, SIAPS initiated planning and implementation of key operational and technical activities. Work plan activities and next steps across all technical objectives were defined, aligned and coordinated with key partners, namely the Pharmaceutical Department and the Pharmaceutical Unit at Direccao Nacional de Asistencia Medica (National Directorate of Medical Assistance, or DNAM). Notable progress was made in strengthening both governance and capacity-building for improved registration of pharmaceutical products through training in the evaluation of pharmaceuticals and development of tools to establish and standardize criteria and guidelines for registration. Additional meetings were held in-country to discuss management information systems and tools, pharmacy curriculum revision and dissemination of the national pharmacovigilance system framework. SIAPS also made progress in the recruitment of in-country staff, which is expected to result in the installation of key staff next quarter.

Key challenges of quarter

The primary challenged faced during Quarter 1 has been recruiting full-time in-country staff. The absence of in-country technical staff to represent the SIAPS program and ensure regular follow-up of activities has made it difficult to establish SIAPS as a key technical partner in the pharmaceutical sector and sustain progress on activities. To address the challenge, a US-based staff member remained in-country for two months of the quarter.

Key activities for next quarter

The following activities will be addressed in the next quarter:

- Provide technical support for the development of the National Medicines Policy (pending progress and availability of lead partners).
- Provide technical support for the development of processes, procedures and criteria for the registration of pharmaceutical products and conduct follow-up training in the evaluation of medicine dossiers for product registration.

- Conduct a stakeholder meeting to build consensus on the framework for the national pharmacovigilance system and agree on roles and responsibilities and assist the Pharmacy Department (PD) with pharmacovigilance training for provincial level staff.
- Conduct an options analysis to identify an appropriate information system in support of the regulatory system for pharmaceuticals (pending availability of key SIAPS staff).
- Collaborate with DNAM and other stakeholders to develop plans for the pilot of drug and therapeutic committees at two to three hospitals.

Technical Activity Coordination
The SIAPS country portfolio manager spent two months in-country to ensure timely and effective technical activity coordination. Meetings were held with key partners across the pharmaceutical sector-- including the PD, DNAM, USAID, CDC, WB, CMAM, SCMS/DELIVER, VillageReach, I-TECH, Jhpiego, ICISA, Department of Human Resources and JICA-- to align and coordinate activities and define plans for implementation.

Office Management
MSH is in the process of preparing its application to register as a foreign NGO with the Ministry of Foreign Affairs so that a field office can be set up to facilitate implementation of SIAPS activities. A Mozambique-based law firm has been contracted to manage the registration process. In the meantime, SIAPS is planning to embed in-country technical staff within the Ministry of Health (PD and DNAM) and will consider alternative office arrangements, including subletting office space from another partner, as needed.

Objective 1
Governance in the Pharmaceutical Sector Strengthened

Objective 1: Quarterly progress
Key areas of governance in need of strengthening-- including the development, documentation and dissemination of policies, frameworks and guidelines-- were identified, agreed upon and incorporated into the FY11 work plan in collaboration with partners. Progress was made in developing tools specifically for product registration.

Sub-Objective 1.1
Improved medicines policies, legislations, regulations, norms and standards

Progress toward sub-objective 1.1
Tools needed to establish and standardize improved criteria and procedures for registering pharmaceutical products, were identified and drafts of two of the tools were developed in Quarter 1. Plans were also discussed and agreed upon with the lead partners for the revision of the National Medicines Policy to be initiated in Quarter 2 (pending progress and availability of lead partners).

Deliverables for sub-objective 1.1
Drafts of two tools for improved product registration-- a receiving checklist and an evaluation report-- were developed, which will be reviewed and finalized in the next quarter.

Sub-Objective 1.2
Transparent and accountable pharmaceutical management systems

Progress toward sub-objective 1.2
The Pharmacovigilance Unit at the PD and SIAPS scheduled the national stakeholder consensus meeting for February 22-24, agreed upon technical and operational preparations to be completed in advance of the meeting and initiated logistical planning.

Main challenges for sub-objective 1.2
The head of the Pharmacovigilance Unit was on leave for two months and thus progress on preparations for the PV stakeholder meeting and provincial training was limited.

Deliverables for sub-objective 1.2
The PV unit completed a draft of their SOPs and submitted it to SIAPS for review.

Sub-Objective 1.3
National pharmaceutical sector development plans are strategic and evidence-based

Progress toward sub-objective 1.3
Additional information/data on the current status of the regulatory system was collected, which will contribute to the baseline assessment of the system using the RSAT (analysis planned for Quarter 2). In addition, meetings were held with the lead partner responsible for developing the strategic plan for the pharmaceutical sector to discuss the timeline and terms of collaboration with SIAPS. Development of the strategic plan specifically for the Pharmacy Department will follow the development/revision of a draft of the National Medicines Policy (Sub-Objective 1.1).

Main challenges for sub-objective 1.3
The availability of technical staff to begin analyzing the data for the regulatory system baseline assessment impeded additional progress in the current quarter.

Objective 2
Capacity in Pharmaceutical Management Increased and Enhanced

Objective 2: Quarterly progress
Efforts to improve the capacity of the registration team at the PD to effectively evaluate and register pharmaceutical products was initiated and plans were made to improve the capacity of key partners/stakeholders and provincial staff in pharmacovigilance based on the national framework.

Sub-Objective 2.1
Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened

Progress toward sub-objective 2.1
SIAPS conducted a 7-day training on the evaluation of medicine dossiers for pharmaceutical product registration, which was attended by all 10 members of the PD registration team as well as a member of the PV unit and the head of FARMAC (public retail pharmacies). Discussions were

also held with the PV unit about preparations for the training for provincial PV staff, which will be conducted immediately following the stakeholder consensus meeting, February 23-24. Progress was made on the logistical arrangements.

Main challenges for sub-objective 2.1
The availability of PV unit staff impeded additional progress on preparations for the PV training scheduled for Quarter 2.

Steps to address challenges for sub-objective 2.1
In-country support will be provided to the PV unit staff in the weeks leading up to the PV meeting/training to assist them with the necessary technical preparations.

Deliverables for sub-objective 2.1
Training materials for the evaluation of medicine dossiers were completed, photocopied and disseminated to training participants to use as reference materials.

Sub-Objective 2.2
Innovative and proven approaches for human resource capacity building adopted and implemented.

Progress toward sub-objective 2.2
SIAPS attended several meetings with key in-country partners-- including ICISA, the Department of Human Resources/MOH, CMAM, the PD, DNAM, SCMS and JICA-- to discuss the status of the existing curriculum for pharmacy technicians and the need for revision. Consensus among partners was not reached on the urgency of the need or the specific deficiencies in the current curriculum and thus requires further discussion in the next quarter. In Quarter 1, meetings were also held with I-TECH and Jhpiego, which have been involved with curriculum revision for other cadres in Mozambique, namely medical technicians and nurses, in order to better understand the methodology and process they have followed. SIAPS will aim to employ a similar methodology and process in an effort to promote standardization. Pending consensus among partners for the revision, SIAPS will draw upon existing tools from I-TECH and Jhpiego for the task analysis proposed.

Main challenges for sub-objective 2.2
Partners have not been able to reach consensus on the need for a revision of the pharmacy technician curriculum. Further discussion is required.

Objective 3
Utilization of Strategic Information for Decision-Making Increased

Objective 3: Quarterly progress
Discussions were initiated with the PD, SCMS and CMAM, as well as other partners involved in information systems for the pharmaceutical sector, about gaps in the existing information systems, plans for implementation of improved information systems and the need for compatibility, coordination and integration across the sector in this area.

Sub-Objective 3.1
Pharmaceutical Management Information Systems (PMIS) support for both products and patients

Progress toward sub-objective 3.1
SIAPS conducted internal discussions about the information system tools available for regulatory functions at the PD as well as pharmaceutical services at hospitals. The need to upgrade the SIAMED system currently in use at the PD and to strengthen overall IT support at the department was agreed upon with the head of the PD. Addressing these needs is considered a top priority.

Main challenges for sub-objective 3.1
General IT support and capacity at the PD is weak and will need to be addressed as part of the implementation of a new electronic information system.

Sub-Objective 3.2
Innovative and proven tools broadly available and used

Objective 4
Pharmaceutical Services to Achieve Desired Health Outcomes Improved

Objective 4: Quarterly progress
SIAPS held several meetings with the pharmaceutical unit at DNAM to identify needs and to define and align work plan activities to strengthen pharmaceutical services. SIAPS worked with DNAM to package and integrate related activities into a more strategic approach.

Sub-Objective 4.2
Patient safety and therapeutic effectiveness assured

Sub-Objective 4.3
Medication use improved

Sub-Objective 4.4
Pharmaceutical services standards defined, adopted and implemented

Progress toward sub-objective 4.4
SIAPS shared supervision tools developed for integrated supportive supervision in Angola with the DNAM team to use as an example for revising their existing supervision tools.

Namibia

Gladys Tetteh

Portfolio Background

SIAPS builds the capacity of the Ministry of Health and Social Services (MOHSS) of the Government of Namibia (GRN) and other local institutions to manage pharmaceutical systems and service delivery of HIV/AIDS commodities in all regions of Namibia. The project contributes to three strategic areas of the Partnership Framework (PF) in all regions of the country: governance, systems strengthening, and care and treatment, specifically addressing antimicrobial resistance, access to medicines, and the appropriate use of medicines. In Namibia, SIAPS focuses on achieving the following objectives:

- Strengthened capacity of key actors in pharmaceutical sector governance
- Building individual, organizational, and institutional capacity for pharmaceutical supply management and services
- Strengthened strategic information systems to ensure availability of reliable information for effective decision making in the pharmaceutical sector
- Strengthened financing strategies and mechanisms for improving access to medicines
- Improving pharmaceutical services to achieve desired health outcomes

In FY2012, SIAPS will advocate for the absorption of technical staff seconded to MoHSS to reduce costs. In addition, the project will share operational costs, leverage synergies of other mechanisms managed by MSH in Namibia, and encourage MoHSS to co-fund selected interventions to be more cost-effective. SIAPS will strengthen institutional leadership to strengthen local ownership and mentor relevant staff. These steps will be strategies for transition. In this regard, SIAPS is in line with USAID's GHI strategic focus of transition as well as improving access. In order to strengthen monitoring and evaluation systems SIAPS has developed measurable indicators which have been used to track the progress of the project. SIAPS will monitor data quality assurance and outcomes and document case studies and success stories which will be disseminated. An end-of-project evaluation will also be conducted.

Quarter Overview

SIAPS drafted a post-marketing surveillance strategy and completed a tool for enhancing the documentation of complementary medicines. Staff provided HR support for critical positions in the MoHSS and UNAM. An EDT user satisfaction survey was completed and a workshop to pilot eTB manager was conducted. PMIS was expanded to include more indicators on medical stores and pharmaceutical regulation.

Key challenges of quarter

Delays in getting approvals from MoHSS on policy documents (NPMP, NMP and NMRC SOPs) continue to affect the implementation of activities. Staffing constraints in the MoHSS (NMPC) Unit and delays in the absorption of MoHSS seconded staff have also caused constraints. Despite the data quality training which was provided to the facility health staff, most facilities have not been able to report on the data quality issues in their facilities, to enable effective targeting of data quality support to the facilities.

Key activities for next quarter

Continue providing technical assistance to the Namibia Medicines Regulatory Council towards the development of a post-marketing surveillance strategy. Continue providing technical assistance to the Quality Surveillance Laboratory towards the development of a Quality Management Manual. Support NMPC in monitoring of implementation of the National Pharmaceutical Master Plan (NPMP) through support supervision visits. Engage UNAM in the development of a strategic plan for the School of Pharmacy. Support NMPC with data analysis, compilation, production and dissemination of the ART quarterly report. Provide technical assistance for the PMIS task-force meeting.

Technical Activity Coordination
MSH activities were implemented by Senior Program Associates and overseen by the Associate Directors and the Senior Program Associate for Strategic Information. Technical activities were implemented using the USAID approved work plan, and closely monitored for budget, progress monitoring, reporting, meetings, reports and products, and communications with partners and collaborators.

Office Management
The Country Operations Management Unit (COMU) continued to provide administration and operations support to technical staff and were supported by administrative support staff from the home office.

Evaluation plans for next quarter
Continue with the evaluation of ART adherence interventions study that was temporarily halted due to availability of the lead consultant.

Objective 1
Enhance access to pharmaceutical products and services through improved medicine policies, regulation, quality assurance and governance

Objective 1: Quarterly progress
During the reporting period (October 2011- December 2011), the post marketing surveillance strategy was drafted, and an electronic tool to enhance the documentation of complementary medicines was also developed. In addition, support was provided to QSL for self-assessment of its quality management systems, in readiness for a planned WHO prequalification assessment. The tool for the implementation of support supervision visits to assess the implementation of various activities in the current NPMP and also provide technical assistance was revised.

Sub-Objective 1.1
Support implementation of strategies and best practices to improve regulatory capacity and processes for a sustainable NMRC (Technical assistance, training)

Progress toward sub-objective 1.1
During the reporting period (October 2011- December 2011), the post marketing surveillance strategy was drafted, and an electronic tool to enhance the documentation of complementary medicines was also developed. In addition, support was provided to QSL for self-assessment of its quality management systems, in readiness for a planned WHO prequalification assessment.

Main challenges for sub-objective 1.1
Resignation of the SIAPS-supported medicines registration pharmacist from the Namibia Medicines Regulatory Council (NMRC).

Steps to address challenges for sub-objective 1.1
Redeployment of a Senior Technical Advisor to support medicines registration activities at the NMRC.

Deliverables for sub-objective 1.1
An electronic tool to enhance the documentation of complementary medicines.

Sub-Objective 1.2
Support monitoring of implementation of the National Pharmaceutical Master Plan (NPMP) (Technical assistance, advocacy activities, support visits) using the revised PMIS

Progress toward sub-objective 1.2
Approval of the revised NPMP and NMP by Ministry of Health and Social Services (MoHSS) was still being awaited at the end of the quarter. The tool for the implementation of support supervision visits to assess the implementation of various activities in the current NPMP and also provide technical assistance was revised. The visits are scheduled to take place in the second quarter. The revision of the tool included reviewing, improving and refining the tool by including relevant matrix to enable objective measurements and comparison of different facilities. A total of 50 facilities will be visited during the support supervision.

Main challenges for sub-objective 1.2
Delays in the approval of the revised NPMP and NMP by Ministry of Health and Social Services (MoHSS).

Steps to address challenges for sub-objective 1.2
Continued advocacy for the approval of the NPMP and NMP.

Deliverables for sub-objective 1.2
Revised tool for the implementation of Support supervision visits to assess the implementation of various activities in the current NPMP

Objective 2
Strengthen human resources capacity for pharmaceutical management functions and services; increasing the capacity of local institutions and networks to provide pharmaceutical management technical assistance

Objective 2: Quarterly progress
During the reporting period, HR support (lecturers) continued to be provided to the University of Namibia (UNAM) and the National Health Training Center (NHTC). This enabled UNAM and NHTC to enroll 35 pharmacist assistants and 25 pharmacy students, respectively. Other HR support included salary support for 8 positions seconded to the Ministry of Health and Social

Services (MoHSS).

Sub-Objective 2.1
Technical support to implement the Ministry's Human Resources Strategic Plan and training plan

Progress toward sub-objective 2.1
During the reporting period, HR support (lecturers/tutors) continued to be provided to the University of Namibia (UNAM) and the National Health Training Center (NHTC). This enabled UNAM and NHTC to enroll 25 pharmacy students and 35 pharmacist assistants, respectively. It is projected that in 2012, an estimated 109 students will be pursuing the two pharmacy courses supported by SIAPS and a total of 25 PAs will graduate from the Pharmacist' Assistant Course provided at NHTC. Other HR support included salary support for 8 positions seconded to the Ministry of Health and Social Services (MoHSS).

Main challenges for sub-objective 2.1
Delays in the transitioning of the 2 lecturers from SIAPS to UNAM budget, and the 2 NHTC tutors and other seconded positions to MoHSS budget.

Steps to address challenges for sub-objective 2.1
Continued advocacy for the absorption of the lecturers by UNAM and the tutors and other seconded positions by MoHSS.

Sub-Objective 2.2
Strengthen the institutional capacity of NHTC for sustainable training of pharmacist's assistants

Progress toward sub-objective 2.2
During the reporting period, SIAPS provided HR support (2 tutors) to the National Health Training Center (NHTC). This enabled NHTC to enroll 35 pharmacist assistants. It is projected that in 2012, about 25 PAs will graduate from the Pharmacist Assistant Course provided at NHTC (also reported under 2.1). Other activities for strengthening NHTC capacity included providing technical assistance for the planned renovation of the pharmacy training premises and supporting linkages with UNAM. Technical assistance was provided to strengthen the teaching of pharmacology, which is one of the critical courses of the PA curriculum.

Main challenges for sub-objective 2.2
Delays in the implementation of planned classroom renovation for training of pharmacist assistants due to budgetary constraints. Accumulated teaching backlog after contract for one of the SIAPS-supported NHTC tutors was terminated for absenteeism.

Steps to address challenges for sub-objective 2.2
Review budget to explore possibility of securing funding for the planned renovation of NHTC PA classrooms. Arrangements were made for one of the UNAM pharmacy lecturers to assist with the teaching of the affected sections of the syllabus and examine the students.

Deliverables for sub-objective 2.2
Technical report on improving pharmacology training for PA students. Pharmacology study guide

and course materials.

Objective 3

Strengthen pharmaceutical services to enhance achievement of planned TB and HIV Program goals and objectives for both adults and pediatrics

Objective 3: Quarterly progress

During the reporting period, an EDT user satisfaction survey was completed. Issues identified in the satisfaction survey were addressed and an updated EDT version developed. Among the modules updated was the adherence module. The updated EDT was piloted in three sites- Katutura health center, Gobabis Hospital and Rehoboth Hospital. Through technical assistance from SIAPS, a total of 10 motivations for the Namibia Essential Medicines List (NemList) were reviewed. A total 113 Adverse Medicine Reaction reports were received and processed by the TIPC. An e-TB workshop was conducted during the reporting period, to commence piloting of the tool.

Sub-Objective 3.1

Support and strengthen financing strategies and mechanisms that will enhance public private partnership in improving access to medicines

Progress toward sub-objective 3.1

As part of ensuring pharmaceutical related continuous professional development amongst the private sector, a mapping exercise of current Continuing Professional Development (CPD) providers was previously carried out in collaboration with the University of Namibia (UNAM). During the reporting period, UNAM continued to engage private sector pharmacists, through evening professional education lecture sessions and collection of their views and suggestions to enable effective implementation of this initiative. During the reporting period, an EDT user satisfaction survey was completed. Issues identified in the satisfaction survey were addressed and an updated EDT version developed. Among the modules updated was the adherence module. The updated EDT was piloted in three sites- Katutura health center, Gobabis Hospital and Rehoboth Hospital. Following the successful piloting in these sites, a national roll out to all the facilities has been planned for the second quarter. Use of the adherence module will enable facilities to effectively collect, use and report objective information on patient adherence. Other components of the EDT that were improved have been reported under the relevant activities. SIAPS provided support for the development of the NemList which was previously submitted to MoHSS for approval. During the reporting period, support was provided to the MoHSS (NMPC) in the review of motivations in preparation for the EML committee meeting. A total of 10 motivations were reviewed. Support was provided for the preparation of TC functionality report that documents the performance of TCs, specifying the type of activities and impact of these activities on the organization and delivery of therapeutic services, following the development and circulation of the MoHSS TC Terms of Reference in 2011. The report will be finalized in the second quarter. A total of 10 Technical Assistance positions were supported during the reporting period. The support enabled MoHSS and other stakeholders to accomplish pharmaceutical control and inspection activities like evaluation of dossiers for the registration of medicines, management of the quality surveillance laboratory and perform essential pharmaceutical quality control laboratory tests, conduct patient safety surveillance and evaluation activities, manage the pharmaceutical supply

chain strategic information, delivery of lectures, assessment and examination of pharmacy/pharmacy assistant students, and management of training activities, including the recruitment of new UNAM and NHTC pharmacy students.

During the reporting period, the development of an updated EDT version with dispensing module was completed and, piloted in three sites. Use of the revised dispensing module will enable facilities to effectively collect, use and report objective information on pediatric patients formulations, dosages and adherence. A report on pediatric ART coverage which was prepared by MSH was presented and discussed during a series of meetings that were conducted. Support continued to be provided to the TIPC to carry-out patient safety monitoring activities. A total 113 Adverse Medicine Reaction reports were received and processed by the TIPC. Additional support was provided to the TIPC on the public health evaluation of compliance to switching guidelines, investigation of risk of nevirapine associated skin and liver reactions, and the risk of renal failure associated with tenofovir. It is anticipated that once implemented, the evaluations will lead to better patient (clinical) management actions that will be shared with clinical staff to ensure improvement of patient outcomes. An e-TB workshop was conducted during the reporting period. The workshop follows a series of technical meetings held during the reporting period to discuss the implementation of the e-TB manager, which was introduced to MoHSS with USAID funding, to enable the National Tuberculosis and Leprosy Program to comprehensively manage MDR and XDR TB cases. During the workshop, MSH/SIAPS technical staff presented the medicines management module. The hands-on workshop enabled all the participants to use the e-TB manager. As a way forward, TB treatment facilities are working on ensuring that all the relevant patient data is entered into the electronic tool.

Main challenges for sub-objective 3.1
Delays were experienced in getting MoHSS in-put and feedback on PHE protocols developed to carry-out planned Public Health Evaluations. Staffing constraints at the MoHSS (NMPC) Unit. Delays in the absorption of MoHSS seconded staff.

Steps to address challenges for sub-objective 3.1
- Follow-up on the necessary approvals of the TIPC PHE on compliance to ART guidelines.
- Continue to advocate for the absorption of the seconded staff by the MoHSS.

Deliverables for sub-objective 3.1
- Report EDT user satisfaction survey.
- Enhanced EDT.
- Report of NemList motivations review.
- eTB manager workshop.

Objective 4
Strengthen pharmaceutical information systems to provide evidence-based analyses that enhance evidence-based decision-making in the pharmaceutical sector in Namibia

Objective 4: Quarterly progress
During the reporting period, technical support was provided for the expansion of the PMIS to cover the performance measurement of the public pharmaceutical sector.

Sub-Objective 4.1
Support the PMIS Taskforce to finalize the PMIS review process (including the e-PMS) and roll-out PMIS to PHC level.

Progress toward sub-objective 4.1
During the reporting period, technical support was provided for the expansion of the PMIS to cover the performance measurement of the public pharmaceutical sector. PMIS indicators for the Central Medical Stores (CMS) and Pharmaceutical Control and Inspection (PCI) were completed. Additional PMIS indicators were added to the health facility section. As a way forward, a workshop will be organized in the second quarter during which key staff will be trained in the expanded PMIS so that they can lead in the implementation process.

Sub-Objective 4.2
Support program monitoring and data quality.

Progress toward sub-objective 4.2
This activity focuses on quality of the data produced by the PMIS Tools that have been implemented with MSH support, as well ensuring that overall program monitoring data is of good quality. During the reporting period, the data quality protocols developed in FY 2011 were finalized. Arrangements were made to have them integrated into the forthcoming national-level support supervision visits. This will help to follow-up on the progress that facilities have made in ensuring that regular data quality checks between the ART subsystems, as well as reporting the data quality risks to RME to enable mobilization of targeted data quality support to the facilities in need.

Main challenges for sub-objective 4.2
Despite the data quality training which was provided to the facility health staff, most facilities have not been able to report on the data quality issues in their facilities, to enable effective targeting of data quality support to the facilities. Despite the need for comprehensive data quality checks, and the advances made by Pharmaceutical Services Division in standardizing data quality assessment tools, the Response, Monitoring and Evaluation (RME) sub-division of the Directorate of Special Programs (DSP) has yet to approve the integration of data quality procedures into the main ART data quality assessment framework, preferring to continue with ad hoc checks, which are not adequately documented to ensure systematic tracking of improvements.

Steps to address challenges for sub-objective 4.2
Continue supporting and advocating for the use of data quality tools and approaches at Response Monitoring and Evaluation sub-division/MoHSS.

Rwanda

Kwesi Eghan

Portfolio Background

While Rwanda, like most developing countries, benefits from increased accessibility of new medicines and fix-dosed combination formulations to treat HIV/AIDS and malaria, the country's lack of experience with these products creates concerns about medicine safety and highlights the need to identify and evaluate Adverse Drug Reactions (ADR) to better understand possible risks and improve treatment protocols. Rwanda can address these issues through a pharmacovigilance —or medicine safety—system. In many countries, the national drug authority is responsible for ensuring the quality, safety, and efficacy of the medicines available in the country through activities such as medicine registration, quality control testing, and pharmacovigilance. In Rwanda, regulatory functions are administered by the Ministry of Health (MoH). Over the last few years, the Pharmacy Task Force (PTF) has increased its presence as the authority to regulate pharmaceutical management in both public and private sectors. However, the decisions related to medicines are quite fragmented. Long-term sustainability of PEPFAR and PMI interventions requires that the political and legal frameworks of the pharmaceutical system become better coordinated, and cover all aspects of the pharmaceutical sector, including rational medicine use, drug quality and pharmacovigilance. In line with the Government of Rwanda's (GOR) objectives, several assessments have confirmed the need for Rwanda to work towards establishing a national medicine regulatory authority to enforce laws and build capacity in core functions of medicines regulation. The SIAPS Program has developed a one-year plan to provide technical assistance to improve health system development in Rwanda and contribute to USAID/Rwanda's strategic objective of a better educated and healthier population. This program is designed to improve governance, build capacity for pharmaceutical management and services, and improve pharmaceutical services to achieve desired health outcomes in the pharmaceutical sector. SIAPS Rwanda FY11 work plan will build on the SPS work in fiscal year (FY) 09 and FY 10, particularly in improving pharmaceutical, policies, laws, and regulations, as well as in establishing an ADR reporting system.

Quarter Overview

During the first quarter, SIAPS Rwanda has been involved in the development of its FY11 work plan. For this purpose, SIAPS conducted several interactive meetings with Rwanda Biomedical Center (RBC) counterparts, the Ministry of Health (MoH), the Pharmacy Task Force (PTF), the Community Health desk (CHD) and the Medical Procurement and Production Division (MPPD RBC) to get clear sense about GOR focus and priorities for FY11 that guided the design of FY11 work plan. Also during this period, SIAPS staff took the opportunities to wrap up with some SPS technical reports and finalize them. As continuous support in strengthening pharmaceutical sector governance, during the first quarter, SIAPS supported the MoH/PTF to start the process of reviewing and evaluating the MoH/PTF 2009-2012 strategic plan. The MoH/PTF in collaboration with SIAPS, developed the Rwanda Pharmaceutical sector situation analysis as an initial step to review the strategic plan. The first draft is available. In order to ensure that Rwanda pharmaceutical sector has all necessary legal documents, SIAPS assisted MoH/PTF to create a list of necessary pharmacy regulations remained to be developed or completed based on recommendations of adopted laws and from recommendations of the parliament.

During the reporting period, SIAPS supported the MPPD/RBC to develop a scope of work and identify consultant prior to the development of the MPPD strategic plan. In relation to strengthening supply chain management of community case management, during the reporting period, SIAPS assisted the CHD in the distribution of medicines in the district pharmacies (DPs). SIAPS continued to follow up with CAMERWA on the next procurement plan of medicines especially amoxicillin and zinc. In addition, SIAPS had assisted the community health desk in developing pharmaceutical management SOPs at the health center level to improve management of CCM commodities.

SIAPS provided support towards preparation of Maternal and Child Health (MCH) survey, which will funded through SPS Global Core funds and will basically be a survey on supply chain management of commodities used in Obstetric emergency. The protocol and questionnaires were finalized and validated by the MCH Technical Working Group (TWG) and submitted at the end of December 2011to the Rwanda National Ethic Committee (RNEC) for approval prior to conduct the survey. To improve Pharmaceutical services to achieve desired health outcomes, SIAPS continued to promote rational medicine use by providing Drug Therapeutics Committee (DTC) support to King Faysal Hospital (KFH) to improve pharmaceutical management. During the reporting period, SIAPS mainly assisted KFH to improve internal requisition procedures. The new requisition procedure and SOPs were introduced in order to directly request products from the main store and to easily document stocks movements. A draft list of medicines and other health commodities specific to different sub-pharmacies was developed to avoid having unnecessary products in different departments and to improve pharmaceutical management. In the same line, SIAPS assisted KFH to conduct a physical inventory in the main store, main pharmacy and sub-pharmacies to know the products and quantities available within the hospital. During the process, reporting tool such as new stock cards to record stock movements were developed and implemented to have accurate data in both electronic and physical inventory. One staff was trained in the use of stock cards and in conducting physical inventory. In terms of staffing and structure, SIAPS also assisted KFH to restructure staff to facilitate stock management and to better utilize available human resources. SIAPS is currently finalizing documents that will serve as guidelines to conduct DTC activities (DTC concise practical guidelines and MoH strategies to strengthen DTCs). These documents will be handed over to MoH/PTF as part of the transferring capacity to PTF to assume full technical responsibility for supervising existing DTCs and expanding them to all districts. In relation to pharmacovigilance, SIAPs assisted TBC/HIV division, MoH/PTF and RBC/CAMERWA to manage the report on abnormal bitterness of TDF-3TC provided by Hetero Industry. Protocol to conduct the assessment was developed and the assessment was conducted. The findings will be disseminated in the next quarter. To transfer capacity to MoH/PTF in the area of pharmacovigilance, SIAPs developed a progress report and strategic approach to establish pharmacovigilance in Rwanda. SIAPS assisted PTF to develop SOPs for management of Adverse Event report (including databases and hard copies of reports). Terms of reference and functionality of the National Medicine Safety Committee (NMSC) were developed and submit to the Minister for approval. This committee will assist the National Pharmacovigilance & Medicine Information Center (NPMIC) to conduct causality assessment and analysis of the adverse events reports. SIAPS worked closely with the MSH Integrated Health System Strengthening Project (IHSSP) and the MoH Clinical Services to conduct an internal review of the Clinical Protocols/Treatment Guidelines (CPs/TGs). The draft was shared with professional bodies such as ARPHA, Medical association for their final inputs. SIAPs also assisted the MoH/PTF to identify key people local

expert consultant for the final review of the CPs/TGs.

Key activities for next quarter

- Review and evaluation of the MoH/PTF 2009-2012 strategic plan.
- Desktop review on various assessments on the regulation of pharmaceuticals.
- Review and update processes needed to put in place a pharmaceutical registration system in Rwanda.
- Develop necessary SOPs needed to manage and process ADR and MPQ report.
- Develop risk communication strategy for medicine safety.
- Continue to support the finalization of the STGs.

Objective 1

Strengthening pharmaceutical regulatory systems for improved access

Objective 1: Quarterly progress

In strengthening pharmaceutical regulatory systems for improved access, SIAPS continued to support the Ministry of Health in strengthening pharmaceutical sector governance. During the first quarter, SIAPS supported the MOH/PTF to start the process of reviewing and evaluating the MoH/PTF 2009-2012 strategic plan. The MoH/PTF in collaboration with SIAPS developed the Rwanda Pharmaceutical sector situation analysis as an initial step to review the strategic plan. The first draft is available.

In order to ensure that Rwanda pharmaceutical sector has all necessary legal documents, SIAPS assisted MoH/PTF to draw list of necessary pharmacy regulations remained to be developed or completed based on recommendations of adopted laws and from recommendations of the parliament. During the reporting period, SIAPS has supported the MPPD/RBC to develop a scope of work and identify consultant prior to the development of the MPPD strategic plan.

Sub-Objective 1.1

Improved medicines policies, legislation, regulations, norms, and standards

Progress toward sub-objective 1.1

During this quarter, a list of necessary pharmacy regulations have been completed and the ones that still need to be developed was drawn to ensure that Rwanda pharmaceutical sector has all necessary legal documents.

Main challenges for sub-objective 1.1

Delays in the process of approval of the regulations: The processes to comment and approve those regulations documents do not depend on SIAPS, but rather the MoH Senior management team, Prime Minister cabinet or Parliament.

Steps to address challenges for sub-objective 1.1

Continue to follow up with PTF and MoH on the status of the regulations and support the integration of various stakeholders' inputs.

Deliverables for sub-objective 1.1

List of completed and incomplete legal documents.

Sub-Objective 1.2
Transparent and accountable pharmaceutical management systems

Progress toward sub-objective 1.2
During the reporting period, SIAPS supported the MPPD/RBC to develop a scope of work and identify consultant prior to the development of the MPPD strategic plan.

Main challenges for sub-objective 1.2
This activity will only happen once the RBC will develop its overall strategic plan.

Steps to address challenges for sub-objective 1.2
Follow up on the planning of the RBC strategic exercise to plan ahead the MPPD exercise.

Sub-Objective 1.3
National pharmaceutical sector development plans are strategic and evidence-based

Progress toward sub-objective 1.3
As continuous support in strengthening Pharmaceutical sector governance, during the first quarter, SIAPS supported the MoH/PTF to start the process of reviewing and evaluating the MoH/PTF 2009-2012 strategic plan. The MoH/PTF in collaboration with SIAPS developed the Rwanda Pharmaceutical sector situation analysis as an initial step to review the strategic plan. The first draft is available.

Main challenges for sub-objective 1.3
None.

Deliverables for sub-objective 1.3
Draft of the Rwanda Pharmaceutical sector situation analysis.

Objective 2
Support MoH institutions to improve pharmaceutical management capacity and pharmaceutical services

Objective 2: Quarterly progress
During the reporting period, SIAPS assisted the CHD in the distribution of medicines in the district pharmacies (DPs). SIAPS continued to follow up with CAMERWA on the next procurement plan of medicines especially Amoxicillin and Zinc. In addition, SIAPS had assisted the community health desk in developing pharmaceutical management SOPs at the health center level to improve management of CCM commodities.

Sub-Objective 2.1
Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened

Progress toward sub-objective 2.1
Assisted CHD in the distribution of CCM medicines to district pharmacies. Follow up on the procurement plan for Zinc and Amoxicillin with the Medical Production Division.

Main challenges for sub-objective 2.1
The CHD plan to recruit personnel that will be in charge management of medicines at district level is delaying. Currently, SIAPS is performing pharmaceutical management activities alone for the CHD. The capacity building part for CHD could only be covered by SIAPS once the staff is on board.

Steps to address challenges for sub-objective 2.1
SIAPS regularly reminds CHD about the need to have a staff to perform pharmaceutical management activities

Deliverables for sub-objective 2.1
Introductory plan of the new formulation of Zinc and Amoxicillin to the district pharmacies.

Objective 3
Improve pharmaceutical services to achieve desired health outcomes

Objective 3: Quarterly progress
SIAPS continue to promote rational medicine use by providing Drug Therapeutics Committee (DTC) support to King Faysal Hospital (KFH) to improve pharmaceutical management. During the reporting period, SIAPS mainly assisted KFH to improve internal requisition procedures. The new requisition procedure and SOPs were introduced in order to directly request products from the main store and to easily document stocks movements. A draft list of medicines and other health commodities specific to different sub-pharmacies was developed to avoid having unnecessary products in different departments and to improve pharmaceutical management. In the same line, SIAPS assisted KFH to conduct a physical inventory in the main store, main pharmacy and sub-pharmacies to know the products and quantities available within the hospital. During the process, reporting tools were developed and implemented to have accurate data in both electronic and physical inventory. One staff was trained in the use of stock cards and in conducting physical inventory. In terms of staffing and structure, SIAPS also assisted KFH to restructure staff to facilitate stock management and to better utilize available human resources.

SIAPS is currently finalizing documents that will serve as guidelines to conduct DTC activities (DTC concise practical guidelines and MoH Strategies to strengthen DTCs). These documents will be handed over to MOH/PTF as part of the transferring capacity to PTF to assume full technical responsibility for supervising existing DTCs and expanding them to all districts. In relation to pharmacovigilance, SIAPs assisted TBC/HIV division, MoH/PTF and RBC/CAMERWA to manage the report on abnormal bitterness of TDF-3TC provided by Hetero Industry. A protocol to conduct the assessment was developed and the assessment was conducted. The findings will be disseminated in the next quarter. To transfer capacity to MOH/PTF in the area of pharmacovigilance, SIAPs developed a progress report and strategic approach to establish pharmacovigilance in Rwanda. SIAPS assisted PTF to develop SOPs for management of Adverse Event report (including databases and hard copies of reports). Terms of reference and functionality

of the National Medicine Safety Committee (NMSC) were developed and submit to the Minister for approval. This committee will assist the National Pharmacovigilance & Medicine Information Center (NPMIC) to conduct causality assessment and analysis of the adverse events reports. During the same reporting period, SIAPS worked closely with the MSH Integrated Health System Strengthening Project (IHSSP) and the MOH Clinical Services to conduct an internal review of the Clinical Protocols/Treatment Guidelines (CPs/TGs). The draft was shared with professional bodies such as ARPHA, Medical association for their final inputs. SIAPs also assisted the MOH/PTF to identify key people local expert consultant for the final review of the CPs/TGs.

Sub-Objective 3.1
Patient safety and therapeutic effectiveness assured

Progress toward sub-objective 3.1
SIAPS continued to promote rational medicine use by providing Drug Therapeutics Committee (DTC) support to King Faysal Hospital (KFH) to improve pharmaceutical management. During the reporting period, SIAPS mainly assisted KFH to improve internal requisition procedures. The new requisition procedure and SOPs were introduced in order to directly request products from the main store and to easily document stocks movements. A draft list of medicines and other health commodities specific to different sub-pharmacies was developed to avoid having unnecessary products in different departments and to improve pharmaceutical management. In the same line, SIAPS assisted KFH to conduct a physical inventory in the main store, main pharmacy and sub-pharmacies to know the products and quantities available within the hospital. During the process, reporting tool such as new stock cards to record stock movements were developed and implemented to have accurate data in both electronic and physical inventory. One staff was trained in the use of stock cards and in conducting physical inventory. In terms of staffing and structure, SIAPS also assisted KFH to restructure staff to facilitate stock management and to better utilize available human resources. SIAPS is currently finalizing documents that will serve as guidelines to conduct DTC activities (DTC concise practical guidelines and MoH Strategies to strengthen DTCs) .These documents will be handed over to MOH/PTF as part of the transferring capacity to PTF to assume full technical responsibility for supervising existing DTCs and expanding them to all districts.

Main challenges for sub-objective 3.1
None.

Deliverables for sub-objective 3.1
King Faysal hospital pharmaceutical management system assessment report.

Sub-Objective 3.2
Medication use improved

Progress toward sub-objective 3.2
In relation to pharmacovigilance, SIAPs assisted TBC/HIV division, MoH/PTF and RBC/CAMERWA to manage the report on abnormal bitterness of TDF-3TC provided by Hetero Industry. Protocol to conduct the assessment was developed and the assessment was conducted. The findings will be disseminated in the next quarter. To transfer capacity to MOH/PTF in the area

of pharmacovigilance, SIAPs developed a progress report and strategic approach to establish pharmacovigilance in Rwanda. SIAPS assisted PTF to develop SOPs for management of Adverse Event report (including databases and hard copies of reports). Terms of reference and functionality of the National Medicine Safety Committee (NMSC) were developed and submit to the Minister for approval. This committee will assist the National Pharmacovigilance & Medicine Information Center (NPMIC) to conduct causality assessment and analysis of the adverse events reports. During the same reporting period, SIAPS worked closely with the MSH Integrated Health System Strengthening Project (IHSSP) and the MOH Clinical Services to conduct an internal review of the Clinical Protocols/Treatment Guidelines (CPs/TGs). The draft was shared with professional bodies such as ARPHA, Medical association for their final inputs. SIAPs also assisted the MOH/PTF to identify key people local expert consultant for the final review of the CPs/TGs.

Main challenges for sub-objective 3.2
Match the MOH Clinical services deadlines and MOH priorities with the development process required for a quality STGs

Steps to address challenges for sub-objective 3.2
Continue to advocate for a process for the development of STGs that ensure quality.

Deliverables for sub-objective 3.2
- Protocol to conduct the assessment abnormal bitterness of TDF-3TC.
- Progress report and strategic approach to establish pharmacovigilance in Rwanda.
- Terms of reference and functionality of the National Medicine Safety Committee (NMSC).
- Draft of STGs monographs by health conditions.

USFDA

Jude Nwokike

Portfolio Background

Studies have reported the huge impact that poor product quality, adverse drug reactions (ADRs), and medication errors have on health system in general and on patients' health in particular. Few developing countries, however, have the structures, systems, or resources in place to support medicine safety activities, and countries often lack unbiased, evidence-based information to help guide regulatory and patient safety decisions. Pharmacovigilance activities in many developing countries are fragmented and often do not include all components of a comprehensive pharmacovigilance and medicine safety system. Medicines safety monitoring or post-marketing surveillance (PMS) is crucial to quantify previously recognized ADRs, identify unrecognized ADRs, and evaluate the effectiveness of medicines in real-world situations to decrease mortality and morbidity associated with medicine-use-related adverse events. There is a need to develop a comprehensive pharmacovigilance system that includes not only adverse event data collection but also risk evaluation, minimization, and communication, thereby serving as safety net to prevent the majority of adverse events. To build this safety net, there is also a need to strengthen regulatory capacity, develop strong mechanisms for communication and information sharing, and target for improvement those areas of the safety net with the largest vulnerabilities.

The SIAPS program continues and expands upon the work of SPS in the areas of pharmacovigilance and regulatory systems. The USAID-funded SPS program implemented by MSH recently published the seminal paper, Supporting Pharmacovigilance in Developing Countries: The Systems Perspective. The systems approach provides a conceptual framework and operational approach for strengthening pharmacovigilance systems and stresses the intersection of people, functions, and structures to arrive at local decisions that prevent medicine-related problems and reduce associated morbidity and mortality. This approach highlights the need for building capacity to undertake both passive and active surveillance activities and the complementary role of the two approaches in ensuring a robust pharmacovigilance system. The SPS program also developed the Indicator-based pharmacovigilance assessment tool (IPAT) for the systematic and longitudinal monitoring of country's capacity and performance in ensuring the safety and effectiveness of health products registered in the country. The SIAPS program applies a broad regulatory systems framework and systems perspective to strengthen regulation of pharmaceutical personnel, premises, practices, and products and ensure timely access to quality, safe, and effective health products and technologies in developing countries.

In 2010, the U.S. Food and Drug Administration (FDA) and USAID signed an Interagency Agreement, implemented through the SPS program. The objective of the agreement was to foster collaboration between the two agencies on the task of strengthening those systems that ensure the quality and safety of FDA-regulated products. The FY10 funding of the agreement was used for the conduct of the assessment of pharmacovigilance systems and their performance in sub-Saharan Africa. FY11 funding will produce deliverables to: 1) Assess of pharmacovigilance systems and their performance in Asia and dissemination of findings; 2) Hold conference to disseminate findings of the Sub-Saharan Africa Study and workshop to identify needs related to the development of pharmacovigilance tools; and 3) Develop and disseminate framework and tools for pharmacovigilance systems.

Quarter Overview

Quarter one was comprised primarily of start-up activities related to the USFDA FY11 work plan and completion of deliverables related to the USFDA FY11 work plan, namely the assessment of the pharmacovigilance systems and performance in Sub-Saharan Africa. In addition to submission of the work plan, draft plans were submitted for design and conduct of the pharmacovigilance and post-market surveillance systems performance in Asia and the 2012 Africa Pharmacovigilance Meeting to be held in Nairobi, Kenya from April 18-20, 2012. The 2012 Africa Pharmacovigilance Meeting will include both the launch of the sub-Saharan Africa study through a one-day dissemination conference and conducting an intensive two-day workshop where countries will share their current practices related to pharmacovigilance and, collectively, identify operational tools needed to support the implementation of the pharmacovigilance systems perspective.

Key challenges of quarter

The key challenge experienced during the quarter was to identify ways to complete the FY10 activities including the finalization, publication, and launch of the sub-Saharan Africa report while initiating the implementation of the FY11 activities. With no funding remaining for the FY10 activities, efforts were made to leverage the workshop for the development of the tool to support the launch of the sub-Saharan Africa report. The implication of this on the availability of funds for the completion of the FY11 activities is closely being monitored and all efforts will be made to ensure that sufficient funds are allocated to complete the deliverables as outlined in the FY11 work plan.

Key activities for next quarter

Activities planned for Q2 include: Develop methodology and data collection tools for the assessment of the Asia pharmacovigilance systems and their performances. Inform and engage national regulatory authorities (NRAs) and other stakeholders in selected countries on the assessment. Conduct the assessment in the selected countries (through Q3). Present findings of the SSA study at related conferences and through publications (including receipt of approval, editing, printing, and distribution of the publication in Q2, prior to the April 2012 meeting). Develop protocol detailing the approach to analyze feedback from the tools workshop and develop operational tools for the implementation of pharmacovigilance and post-marketing surveillance systems in selected countries.

Evaluation plans for next quarter

No plans for evaluations related to the USFDA FY11 Interagency Agreement exist for Q2.

Objective 1

Assess and disseminate findings on the pharmacovigilance and post-market surveillance systems performance in the Asia/Pacific region

Objective 1: Quarterly progress

The FY11 work plan was developed by SIAPS and submitted to USAID. It was agreed that the methodology used for the sub-Saharan Africa assessment will be adapted and refined for the purpose of the Asia assessment, with extensive review of the adapted assessment tools by selected consultants and regulatory specialists from the region. An initial list of suggested assessment

countries was provided to USFDA and USAID for consideration in Q1. Final determination on country selection for the assessment will be made in Q2 by USFDA and USAID.

Sub-Objective 1.1
Assess pharmacovigilance systems and performance in selected Asia/Pacific countries

Progress toward sub-objective 1.1
The FY11 work plan was developed by SIAPS and submitted to USAID. SIAPS developed and submitted the following for discussions with USFDA and USAID: criteria for the selection of countries for the Asia study and a detailed project plan (providing further details to the work plan and submitted in MS Project) for the implementation of all the FY11 activities.

Main challenges for sub-objective 1.1
All anticipated progress towards planning for the Asia assessment was achieved in Q1.

Steps to address challenges for sub-objective 1.1
No challenges were experienced related to conduct of the Asia assessment in Q1.

Deliverables for sub-objective 1.1
The FY11 Work Plan was submitted to USFDA and USAID in Q1. The activities implementation plans including detailed task list were submitted to USFDA and USAID in Q1.

Sub-Objective 1.2
Document and disseminate results of the Asia study

Progress toward sub-objective 1.2
Documentation and dissemination of results of the pharmacovigilance systems and performance assessment in selected Asian countries is planned for Q4 of FY11. The related Sub-Saharan Africa assessment has been completed and approved by USFDA and USAID, and will be available for distribution and dissemination in Q2 (Feb 2012) in print and electronic copy.

Main challenges for sub-objective 1.2
All anticipated progress towards planning for the Asia assessment was achieved in Q1.

Steps to address challenges for sub-objective 1.2
No challenges were experienced related to conduct of the Asia assessment in Q1.

Objective 2
Conduct a workshop for the development of pharmacovigilance tools and conduct a conference for the dissemination of findings of the SSA study

Objective 2: Quarterly progress
Initial planning for the 2012 Africa Pharmacovigilance Meeting took place in Q1. A detailed plan for the sub-Saharan Africa study findings dissemination conference and pharmacovigilance tools development workshop was submitted to USAID and USFDA for review and agreement in early Q2. The conference dates of April 17 – 18, 2012 were proposed as well as suggested conference

locations (including Nairobi, Kenya) and key stakeholder participants and roles. The development of the protocol for the design and deployment of the tools was initiated.

Sub-Objective 2.1
Conduct workshop for the development of pharmacovigilance tools

Progress toward sub-objective 2.1
Included in the plan for the 2012 Africa Pharmacovigilance Meeting submitted to USFDA and USAID in Q1 were details on the proposed approach for mapping of current practices to inform the development of the pharmacovigilance framework and pharmacovigilance tools that will assist countries to implement the pharmacovigilance systems perspective. This systems approach was published in the seminal paper, Supporting Pharmacovigilance in Developing Countries: The Systems Perspective, produced by SPS through MSH with funding from USAID. The workshop will be conducted in Q3 in conjunction with the sub-Saharan Africa assessment dissemination conference.

Main challenges for sub-objective 2.1
All anticipated progress towards planning for the workshop was achieved in Q1.

Steps to address challenges for sub-objective 2.1
No challenges were experienced related to planning for the workshop in Q1.

Deliverables for sub-objective 2.1
The FY11 Work Plan was submitted to USFDA and USAID in Q1. The 2012 Africa Pharmacovigilance Meeting plan and detailed timeline was submitted to USFDA and USAID in Q1.

Sub-Objective 2.2
Disseminate findings of the SSA study

Progress toward sub-objective 2.2
Included in the plan for the 2012 Africa Pharmacovigilance Meeting submitted to USFDA and USAID in Q1 were details on the proposed approach for conducting the sub-Saharan Africa assessment dissemination conference in Q3. This included illustrative stakeholders and speakers, such as the host country MOH; Medicines Regulatory Authorities from focus countries; the World Health Organization; regional regulatory organizations; and global stakeholders such as the Bill and Melinda Gates Foundation. The dissemination conference will be held in Q3 in conjunction with the pharmacovigilance tools workshop.

Main challenges for sub-objective 2.2
All anticipated progress towards planning for the dissemination conference was achieved in Q1.

Steps to address challenges for sub-objective 2.2
No challenges were experienced related to planning for the dissemination conference in Q1.

Deliverables for sub-objective 2.2

The FY11 Work Plan was submitted to USFDA and USAID in Q1. The 2012 Africa Pharmacovigilance Meeting plan and detailed timeline was submitted to USFDA and USAID in Q1.

Objective 3
Develop and disseminate framework and tools for pharmacovigilance system

Objective 3: Quarterly progress
The FY11 Work Plan was prepared and submitted to USFDA and USAID, including details on FY11 activities related to development and dissemination of operational tools for the implementation of pharmacovigilance and post-marketing surveillance systems in selected countries.

Sub-Objective 3.1
Develop pharmacovigilance framework and tools

Progress toward sub-objective 3.1
Included in the plan for the 2012 Africa Pharmacovigilance Meeting submitted to USFDA and USAID in Q1 were details on the proposed approach for mapping of current practices to inform the development of the pharmacovigilance framework and operational tools that will assist countries to implement the pharmacovigilance systems perspective. SIAPS initiated efforts at the development of protocol for the design, development, and validation of the tools. Feedback from the pharmacovigilance tools workshop outline in

Sub-Objective 2.1 and information gathered from in-depth literature review will be analyzed in Q3 to inform the development of operational tools related to pharmacovigilance, which may include checklists, flow diagrams, policy guidance, and any other tools that help to improve transparency and accountability, strengthen the supply chain, improve surveillance, improve enforcement practices, enable effective risk management, and improve communication and information sharing between relevant stakeholders and regulatory authorities.

Main challenges for sub-objective 3.1
All anticipated progress towards planning for the development of the pharmacovigilance framework and operational tools was achieved in Q1.

Steps to address challenges for sub-objective 3.1
No challenges were experienced related to planning for the development of the pharmacovigilance framework and operational tools in Q1.

Deliverables for sub-objective 3.1
The FY11 Work Plan was submitted to USFDA and USAID in Q1.

Sub-Objective 3.2
Disseminate pharmacovigilance framework and tools

Progress toward sub-objective 3.2
The activities in this

Sub-Objective including the development of the dissemination plan were introduced during the quarter under review. Concrete works on the tools dissemination activity will only commence after the identification, design, and development of the tools. A concept note will be developed in Q3 and Q4 to discuss the dissemination of the tools.

Main challenges for sub-objective 3.2
All anticipated progress towards planning for the dissemination of the pharmacovigilance framework and operational tools was achieved in Q1.

Steps to address challenges for sub-objective 3.2
No challenges were experienced related to planning for the dissemination of the pharmacovigilance framework and operational tools in Q1.

Deliverables for sub-objective 3.2
The FY11 Work Plan was submitted to USFDA and USAID in Q1.