SIAPS Activity and Product Status Report

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

Project Year 1 Quarter 3

April - June 2012

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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.

Recommended Citation

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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

FINANCIAL INFORMATION

Systems for Improved Access to Pharmaceutical Services
Fiscal Data: April 1- June 31, 2012
AID-OOA-A-11-00021

On September 23, 2011, Management Sciences for Health was awarded the Systems for Improved Access to Pharmaceutical Services (SIAPS) agreement. The cumulative obligation for SIAPS currently stands at US $39,595,872.

MSH tracks and reports program expenditures by source of funding (Global or Core and Field Support, by Bureau, Region, and Country). MSH further subdivides Global or Core expenditures based on the various Program Elements designated by USAID when funding is received (e.g., Maternal Child Health (MCH) [and sub-elements Antimicrobial Resistance (AMR), Child Survival and Reproductive Health], HIV/AIDS, Tuberculosis (TB), Malaria and Other Public Health Threats (OPHT)).

The Fiscal Data chart shows the Year 1 obligations, cumulative funds obligated, quarter three (April to June 2012) expenditures, in addition to the cumulative to-date (September 23, 2011 to June 31, 2012) expenditures of US $14,638,501 by funding source.

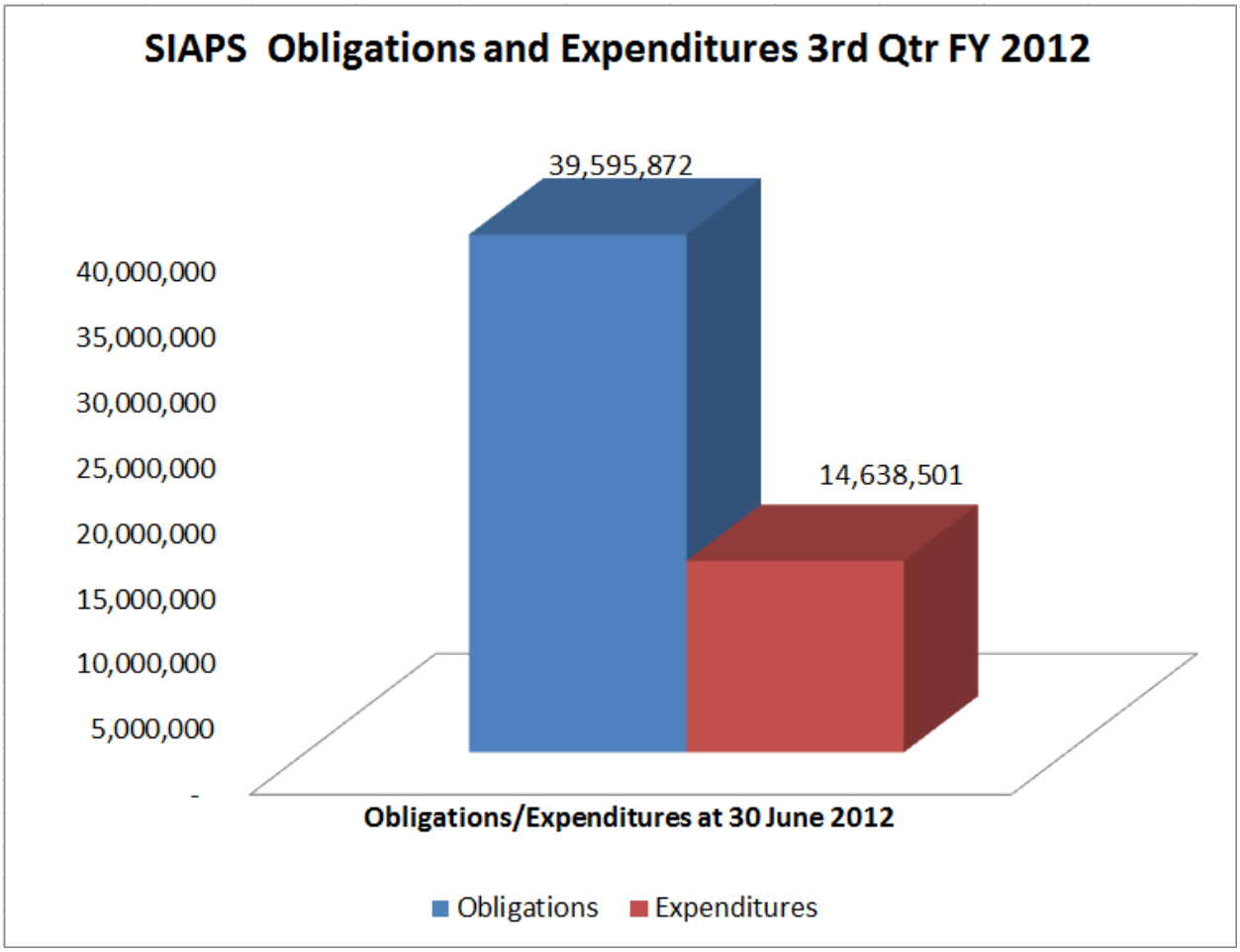
The SIAPS cooperative agreement stipulates that MSH should cost-share an amount not less than US$14,844,484 over the life of the program (7.5% of actual total activity costs). As of June 31, 2012, SIAPS had generated US $1,644,432.43 in non-Federal funding, within the technical scope of work for SIAPS.

Strengthening Pharmaceutical Systems Program | AID-OAA-A-11-00021
Fiscal Data: April-June 2012.

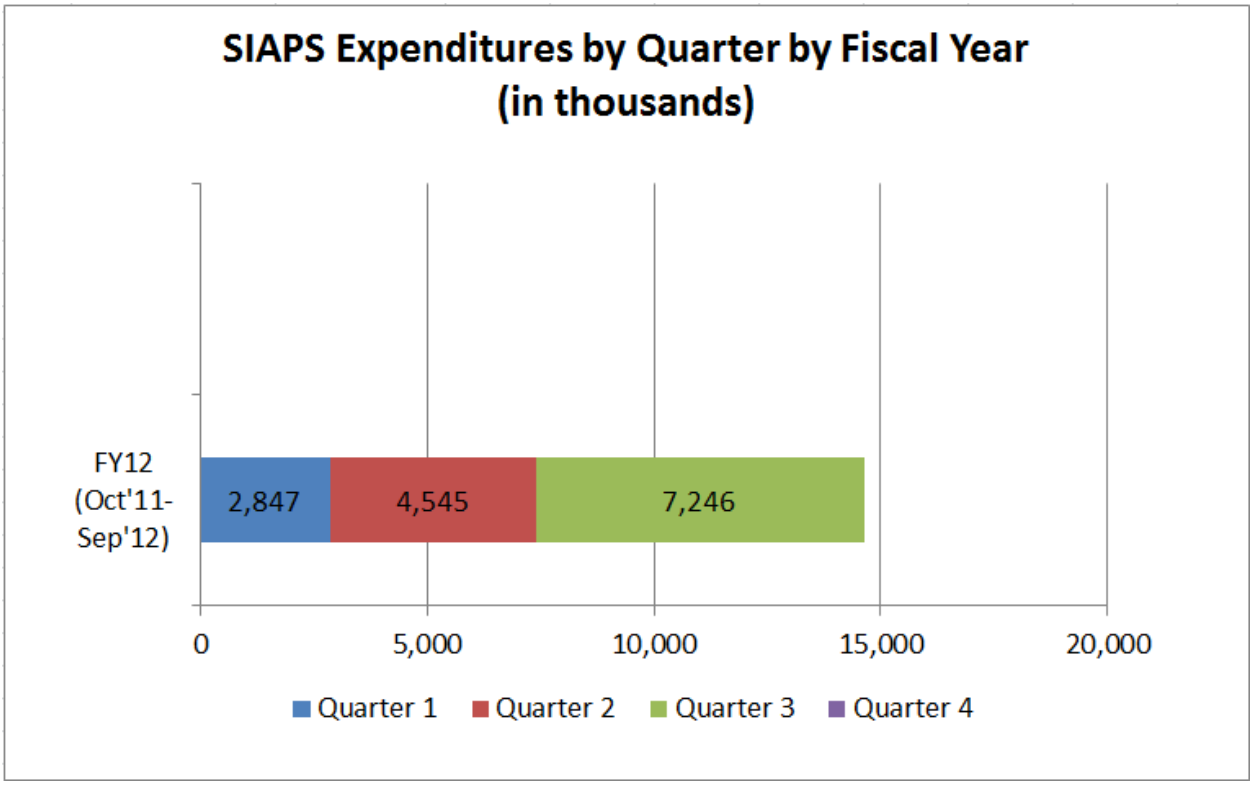
Funding Source	Funding Type		Grand Total Funded	Q3 Expenditures Apr-Jun 2012	Grand Total Spent	Grand Total Remaining
Core Funding:						
Directed	Malaria		300,000	81,361	142,936	157,064
	MCH		1,100,000	163,098	315,101	784,899
	TB		2,300,000	424,087	621,976	1,678,024
Common Agenda	MCH,NUT,TB		679,609	79,130	95,912	583,697
USFDA	USFDA		800,000	332,665	489,473	310,527
Core Total			**5,179,609**	**1,080,341**	**1,665,399**	**3,514,210**
Angola	FPRH		300,000	18,472	19,658	280,342
	PEPFAR		500,000	525	525	499,475
	PMI		650,000	17,524	42,657	607,343
Angola Total			**1,450,000**	**36,520**	**62,840**	**1,387,160**
Bangladesh	FPRH		1,700,000	351,819	814,431	885,569
	MCH/CSMH		1,000,000	107,308	198,792	801,208
	TB		1,600,000	96,987	230,043	1,369,957
Bangladesh Total			**4,300,000**	**556,114**	**1,243,267**	**3,056,733**
Brazil	TB		2,100,000	382,960	859,955	1,240,045
Brazil Total			**2,100,000**	**382,960**	**859,955**	**1,240,045**
Burundi	Malaria		805,000	181,547	261,408	543,592
Burundi Total			**805,000**	**181,547**	**261,408**	**543,592**
Cameroon	PEPFAR		1,499,999	221,885	322,033	1,177,966
Cameroon Total			**1,499,999**	**221,885**	**322,033**	**1,177,966**
Dominican Republic	TB		197,000	18,741	18,741	178,259
	PEPFAR		403,000	135,651	147,473	255,527
Dominican Republic Total			**600,000**	**154,392**	**166,214**	**433,786**
DRC (Dem Rep of Congo)	FPRH		200,000	92,884	94,630	105,370
	PEPFAR		500,000	83,947	117,050	382,950
	PMI		550,000	226,664	669,069	(119,069)
	TB		300,000	19,725	23,986	276,014
DRC (Dem Rep of Congo) Total			**1,550,000**	**423,220**	**904,735**	**645,265**
Ethiopia	PEPFAR		3,500,000	881,865	1,726,700	1,773,300
	PMI		950,000	171,183	347,340	602,660
Ethiopia Total			**4,450,000**	**1,053,048**	**2,074,040**	**2,375,960**
Guinea	PMI		1,000,000	157,677	358,086	641,914
Guinea Total			**1,000,000**	**157,677**	**358,086**	**641,914**
Haiti	**PEPFAR**		**-**	**104,711**	**136,569**	**(136,569)**
Haiti Total			**-**	**104,711**	**136,569**	**(136,569)**
Jordan	MCH/CSMH		200,000	27,221	39,842	160,158
Jordan Total			**200,000**	**27,221**	**39,842**	**160,158**
LAC RSD	TB		90,000	2,693	2,693	87,307
	Malaria		900,000	136,542	153,600	746,400
LAC RSD Total			**990,000**	**139,235**	**156,293**	**833,707**
Lesotho	PEPFAR		550,000	175,971	270,892	279,108
Lesotho Total			**550,000**	**175,971**	**270,892**	**279,108**
Liberia	PMI		664,500	178,401	420,845	243,655
Liberia Total			**664,500**	**178,401**	**420,845**	**243,655**
Mali	FPRH		300,000	74,625	85,812	214,188
	MCH/CSMH		50,000	6,260	14,279	35,721
	PMI		500,000	157,310	418,117	81,883
Mali Total			**850,000**	**238,195**	**518,209**	**331,791**
Mozambique	PEPFAR		1,200,000	191,901	337,213	862,787
Mozambique Total			**1,200,000**	**191,901**	**337,213**	**862,787**
Namibia	PEPFAR		2,394,442	692,682	1,852,403	542,039
Namibia Total			**2,394,442**	**692,682**	**1,852,403**	**542,039**
Philippines	TB		300,000	5,563	18,763	281,237
Philippines Total			**300,000**	**5,563**	**18,763**	**281,237**
Rwanda	FPRH		150,000	12,864	260,911	(110,911)
	MCH/CSMH		150,000	21,164	34,118	115,882
	PEPFAR		544,405	57,616	137,767	406,638
	PMI		220,000	6,447	64,596	155,404
Rwanda Total			**1,064,405**	**98,091**	**497,391**	**567,014**
South Africa, Republic Of	PEPFAR		4,942,917	86,015	310,926	4,631,991
	TB		500,000	7,441	7,441	492,559
South Africa, Republic Of Total			**5,442,917**	**93,456**	**318,367**	**5,124,550**
Southern Sudan	FPRH		100,000	14,103	14,103	85,897
	Malaria		500,000	429,076	692,235	(192,235)
	MCH/CSMH		**1,105,000**	**279,435**	**359,574**	**745,426**
Sudan Total			1,705,000	722,614	1,065,912	639,088
Swaziland	PEPFAR		1,300,000	308,739	478,157	821,843
Swaziland Total			1,300,000	308,739	478,157	821,843
Ukraine	**HIV**		**-**	**-**	**-**	**-**
Ukraine Total			-	-	-	-
Vietnam	**PEPFAR**		**-**	**29,632**	**32,567**	**(32,567)**
Vietnam Total			-	29,632	32,567	(32,567)
Subtotal			**34,416,263**	**6,173,774**	**12,396,000**	**22,020,263**
ACF Surplus/Deficit				**7,853**	**(577,102)**	**(577,102)**
Grand Total			**39,595,872**	**7,246,261**	**14,638,501**	**24,957,371**

Systems for Improved Access to Pharmaceuticals and Services
Financial Status Overview
Cumulative Expenditure activity through June 31, 2012

Total Funding Received to Date:	$39,595,872
Total Amount Spent to Date:	$14,638,501
Pipeline	$24,957,371
Percent of Funds Spent	36.97%



SIAPS Program Expenditures by Quarter through June, 2012 (in 1,000s $)



HIGHLIGHTS FROM SIAPS HEADQUARTERS

SIAPS – PY1 (FY12) Quarter 3 (April to June 2012)

Portfolio Management Summary for Q3

SIAPS continued to bolster its capacity to achieve program results and continuous improvement by hiring more staff at country and headquarter levels, conducting on-going reviews of the performance of our portfolios and training staff in MSH standards for compliance, operational and financial management. We conducted our quarterly review meeting with USAID to assure ongoing engagement with USAID in reviewing SIAPS performance, discussing program implementation issues and sharing feedback and ideas for program improvement.

During this quarter, we supported SIAPS country programs in the continued development of strategic plans to guide the next three to four years of the SIAPS program. The planning process provided an opportunity for partners and staff to establish common language and involvement in SIAPS global and country programs and assure that proposed goals, strategies, activities, outputs and outcomes are responding to expressed Country and USAID priorities in the corresponding years. This was also a precursor to the work planning process which kicked off towards the end of the quarter in June.

In preparation for the work planning, the team revised the work planning process to allow more time, rigor and participation of the various SIAPS teams, facilitate enduring collaboration and linkages among country and headquarter based teams and programs, and ensure alignment between the strategic plans and work plans. A revised Work Planning Guidance Document was developed, peer-reviewed and disseminated to all SIAPS teams.

Following the guidance, the work planning process kicked off with the development of initial drafts by country teams, presentation and discussion with Arlington-based SIAPS teams, and clear feedback and plans for the development of full first drafts.

During the quarter, we also had several activities to strengthen collaboration with SIAPS partners and other stakeholders in pharmaceutical management. We met with the Deputy Director for United States Pharmacopeia (USP) Promoting the Quality of Medicines Program to discuss partnership and areas of collaboration. From the meeting, SAIPS and USP agreed to always work together in countries where SIAPS and USP have concurrent programs.

Monitoring and Evaluation

This quarter, the SIAPS M&E team dedicated significant resources to finding and evaluating a new monitoring, reporting, and evaluation software for the SIAPS Program. To replace the Strategic Monitoring System (SMS) used during SPS, staff researched and evaluated several M&E and project management tools. After detailed reviews and demonstrations from 3 different software companies, SIAPS determined that the Newdea software (www.newdea.com) best met the program's requirements. Once this decision was made, an on-site customization meeting was held with a Newdea representative; the software representative travelled to Arlington and spent 3

days with SIAPS staff, customizing the tool and developing a detailed implementation plan. SIAPS plans to roll-out the tool and conduct trainings during Quarter 4 in order to use Newdea for the Q4 progress report.

The M&E team was also focused on finalizing the SIAPS Performance Monitoring Plan (PMP). The goal is to develop a list of indicators, based on the SIAPS results framework, to be used by every SIAPS portfolio and to be aggregated across portfolios to evaluate the program's performance. After several iterations, the team agreed to begin at the SIAPS Intermediate Results level, with a general set of indicators to measure overall progress. A list of more specific outcome indicators for use in-country will also accompany the more general output indicators.

Next quarter, the team will focus on assisting headquarter and in-country staff with the work planning process, as well as with collecting baseline data for SIAPS and country PMP indicators.

Capacity Building and Performance Management

In late March 2012, SIAPS headquarters held a SIAPS Organizational Meeting where all SIAPS Technical staff and Portfolio Managers attended a day-long meeting to learn about new processes and provide SIAPS technical staff at HQ with the same guidance that field staff received during the Regional Launch Meetings held in January/February 2012. This meeting was accompanied by a two day CPM Frameworks Orientation, facilitated by David Lee, which allowed SIAPS technical staff the opportunity to strengthen their knowledge of CPM's technical frameworks and approaches.

The CB&PI Unit has supported staff by providing several successful and informative brown bags, including presentations from SIAPS partners like the University of Washington and ACPE, other special guests from Riders for Health and the Center for Pharmaceutical Care Development at the Taiwan Pharmacist Association. The Unit also helps manage the SIAPS Technical Discussion Series, a monthly forum where SIAPS and other CPM technical staff can share and collaborate on timely and innovative technical work.

With funding from the SPS Afghanistan program, the Capacity Building and Performance Improvement (CB&PI) Unit launched the pilot phase of the *Literature Search Skills Course* in Summer 2012 to participants in these SIAPS and SPS Associate Award countries: Afghanistan, Ethiopia, Kenya, Rwanda, and South Africa. This initiative is in an effort to explore the potential of eLearning and other innovative technologies in our training interventions. Further eLearning courses have also been developed on USAID's Global Health eLearning Center.

The CB&PI Unit has also assisted in the management and assurance of TraiNet compliance for the SIAPS project. The USAID Mission in Swaziland recognized MSH as a one of the few compliant TraiNet implementing partners.

Communication and Knowledge Management

The MSH CPM Communications and Knowledge Management team supported SIAPS with information services, editorial support, communications and knowledge management. Most

notably, the team contributed significantly to the FDA pharmacovigilance report and Kenya workshop through editing, layout and design of the report, development of conference materials and "branding", and through an After Action Review to capture lessons learned. The team also completed the Swaziland Standard Treatment Guidelines and began work on the pharmaceutical care concept paper and SIAPS country profiles. The Senior Librarian continued submission of SIAPS documents to the USAID Development Experience Clearinghouse, coordinated online journal access for Kimberley Hospital in South Africa and provided ongoing research support. The team implemented the new Wordpress platform for the SIAPS website including site design, content mapping and plug-in development. USAID has reviewed and approved the beta version allowing SIAPS to move forward in completing the first version for launch. Content development and feature refinement will be completed and the site launched in the fourth quarter. In support of the WHO KM collaboration on the essential medicines portal, SIAPS hosted a meeting with Richard Laing and Gilles Forte in Arlington to develop a shared work plan and to review key elements of the KM platform.

Requests for Technical Assistance – During the quarter, the technical team received 22 additional technical assistance requests from 9 different SIAPS country portfolios. These have been reviewed by the cluster leads and members to assure quality of the requested scopes. The requests cut across several functional areas such as supply chain, pharmaceutical management information systems, medicine safety, and pharmaceutical services.

Conferences and Meetings attended - In collaboration with the ministry of health in Kenya, SIAPS hosted a pharmacovigilance meeting held in Nairobi from April 18-20, 2012. The new report on: "Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance" published by SPS was launched during the meeting. Many partners from the African Regulatory Authorities, The World Health Organization (WHO), The Bill & Melinda Gates Foundation, European Medicines Agency, Centers for Disease Control and Prevention (CDC), FDA, USAID, and other key stakeholders attended the meeting. This was followed by a two-day workshop to discuss experiences and priority for regulatory system tools. SIAPS staff also participated in the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 17th Annual International Meeting held in Washington, DC (June 2-6, 2012)

USAID/Washington and SIAPS held discussions with WHO Geneva regarding the WHO draft tool on "Country Situation Analysis on Antimicrobial Resistance (AMR)". As a next step, SIAPS will review the draft of the tool and forward comments/suggestions to USAID and to colleagues at WHO Geneva. On the other hand, SIAPS delivered a 2-hour lecture at the West Virginia University in Morgantown, WV, on June 12th, 2012 on the topic of "Essential Medicines List". This was targeted to the participants of the Global Health Program "Annual Summer Tropical Medicine Course" held by the University.

The Program Director attended the Regional Conference "Engaging with the Private Sector in Health in Africa" held in Dar es Salaam, Tanzania, May 14-16, 2012. He presented on the Access to Medicines and the Private Sector engagement in supply and distribution.

SIAPS also attended the USAID Supply Chain Advisors workshop held in Johannesburg May 21-25, 2012. The workshop was instrumental in sharing practices and lessons learned amongst the

supply chain community. USG staff and partners met to share supply chain updates, challenges, innovations and various ways to improve SCM. The program also participated at the AMDS annual meeting held in Geneva 18-19 June 2012. This meeting was an opportunity to share pharmaceutical management tools developed by the different partners.

SIAPS participated in the technical working group meeting organized by WHO in Geneva (June 21-22) for the review of the laboratory procurement specifications tool. The tool is expected to guide country programs and decision makers in planning and quantifying laboratory commodities (equipment and supplies). The meeting was attended by many partners, including UNICEF, GFATM, CHAI, and JSI.

Representatives from the program continued to participate and contribute to the meetings of the People that Deliver ("PtD") initiative which aims at improving supply chain management through "professionalization" of health logistics.

Key Documentation Developed - During the quarter, the program developed a draft concept paper on SIAPS Support for Strengthening Regulatory Systems and Governance in Developing Countries. It also published an article on "Pharmacovigilance and global HIV/AIDS" in the Journal of *Current Opinion in HIV and AIDS.* A flyer on "Using Continuous Quality Improvement to Strengthen Pharmaceutical Management: The SIAPS Approach" was drafted and reviewed internally. This is expected to be finalized in the next quarter

Staffing – a Senior Technical Advisor joined the technical assistance team this quarter in support to the Pharmaceutical Systems Cluster. She will be working to provide support to core and country portfolios primarily in the area of medicine safety. Also a Technical Associate joined the team working primarily on TB activities.

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GLOBAL PROGRAMS

Malaria

Portfolio Background

Every year, malaria causes 300 to 500 million cases of acute illness resulting in more than a million deaths worldwide of which 90% occur in Sub Saharan Africa. Most affected populations are children under five, pregnant women and people living with HIV/AIDS. The economic burden of the disease is significant with a GDP reduction estimated at 1.3% per person per year in high transmission areas. Funds for the procurement of malaria medicines and commodities are increasingly becoming available through the Global Fund, the World Bank Booster Program, the President's Malaria Initiative, UNITAID, and other interventions such as the Affordable Medicines Facility for Malaria Mechanism. With this comes the growing challenge to ensure coordination among partners, dissemination and application of best practices for appropriate use, medication safety, adequate procurement, distribution and supply chain management. Improving health outcomes through reduced malaria mortality and morbidity can only be achieved through improving access to and appropriate and safe use of quality malaria medicines.

SIAPS will build on the successes of its predecessor programs, and will redouble emphasis on GHI principles, especially in improving metrics, monitoring, and evaluation, capacitating local governments and organizations, and increasing country ownership. SIAPS will collaborate with national malaria control programs and central medical stores to develop and implement strategies to strengthen pharmaceutical management for malaria prevention and case management. SIAPS will also support the Roll Back Malaria (RBM) Partnership Secretariat and the regional RBM networks. In addition, SIAPS will support to the Global Fund in proposal design, the development of Procurement and Supply Management Plans and in addressing grant implementation bottlenecks.

Quarter Overview

At the global level, SIAPS continued to enforce good governance principles through leadership and support to the Roll Back Malaria Secretariat, working groups and partners. PMI was able to make key procurement decisions based on stock status reports and supply plans for malaria commodities information provided by SIAPS. Similarly, three countries (Angola, Liberia and DRC) were able to address different challenges that were identified through EUV surveys. In an effort to strengthen financing mechanisms and improve access to medicines, SIAPS is working towards identifying distribution costs for ACTs, RDTs, and nets from CMS to facilities.

Objective 1

Strengthen pharmaceutical sector governance

Objective 1: Quarterly progress

SIAPS continued to enforce good governance principle through leadership and support to the Roll Back Malaria Secretariat, working groups and partners.

Objective 2

Increase capacity for pharmaceutical supply management and services

Sub-Objective 2.1
Strengthen capacity of networks, organizations, and institutions in pharmaceutical management

Progress toward sub-objective 2.1
SIAPS was originally going to develop a guide to introduce ACT and RDTs in the private sector. However, USAID did not feel this was a priority activity, so development of the guide was suspended. Instead, SIAPS will conduct operational research in preparation of the introduction of RDTs in the private sector. The research will be done next year; SIAPS is currently developing a concept paper for the work.

Objective 3
Increase utilization for information for decision-making

Sub-Objective 3.1
Strengthen the use PMI tools

Progress toward sub-objective 3.1
PMI was able to make key procurement decisions based on stock status and supply plan for malaria commodities information provided by SIAPS. Similarly, three countries (Angola, Liberia and DRC) were able to address different challenges that were identified through EUV surveys. This was the first EUV exercise in the DRC. The DRC data showed a very high percentage (83%) of children under the age of 5 not treated with ACTs and considerable stock-outs of these medicines.

Maternal and Child Health

Portfolio Background

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 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

Significant progress was made this quarter on one key maternal health activity and one key child health activity. Data analysis was completed for the Rwanda maternal health assessment and the draft report of findings was circulated for internal review at the end of the quarter. Also, the revised introduction and first three chapters of the intervention guide for increasing access to medicines for childhood illnesses were completed and are under review. Both activities are expected to be finalized next quarter.

In addition, SIAPS continued to participate in maternal and child health partners meetings, such as the CCM task force, the Diarrhea and Pneumonia Working Group led by UNICEF, and the Maternal Health Supplies Working Group. SIAPS also participated in international technical meetings this quarter. Beth Yeager presented on the pharmaceutical management of maternal health commodities at the Asia Regional Meeting on Interventions for Impact in Essential Obstetric and Newborn Care organized by MCHIP and the Ministry of Health and Family Welfare of Bangladesh, held in Dhaka on May 3–6, 2012.

Key challenges of quarter

Two activities under objectives 2 and 3 proposed in the SIAPS work plan were discussed with Deb Armbruster from USAID in Dhaka, Bangladesh. Based on this conversation, an updated description of the activities were re-submitted to USAID. At the end of the quarter, however, the activities had still not been approved. A meeting has been scheduled for early July to again discuss these activities with USAID. Other challenges for implementation of activities include the political situation in Mali, which has brought all activities to a standstill and slow responses from the Guinea Ministry of Health regarding CCM.

Key activities for next quarter

Key maternal health activities for next quarter include:

- Finalization of the Rwanda assessment report and preparation of an action plan with stakeholders.
- Participation in the next Maternal Health Supplies Working Group meeting.
- Working with USAID to obtain approval for pending maternal health activities.

Key child health activities for next quarter are:

- Participation in the UNICEF child health working group.
- Working with the CCM task force to review indicators and tools on the CCM Central website.
- Coordination with MCHIP on CCM in Guinea.
- Proceed with activities in Mali as soon as approval is granted.

Objective 1
Capacity for maternal and child health pharmaceutical supply management increased and enhanced

Objective 1: Quarterly progress
Overall, SIAPS made significant progress in contributing to building capacity for maternal and child health pharmaceutical supply management in Rwanda. While there were slight delays in the data analysis for the Rwanda assessment on pharmaceutical management for emergency obstetric and newborn conditions, the analysis was completed with guidance from the SIAPS Rwanda team and a draft report was circulated for review and feedback. The report is expected to be completed prior to the dissemination and policy options workshop next quarter in August.

In addition, Beth Yeager and Sheena Patel represented SIAPS at the Asia Regional Meeting on Interventions for Impact in Essential Obstetric and Newborn Care organized by MCHIP and the Ministry of Health and Family Welfare of Bangladesh, held in Dhaka on May 3–6, 2012. B. Yeager presented on the panel for maternal health medicines and supplies, specifically on issues related to pharmaceutical management of maternal health commodities.

SIAPS also participated in the Maternal Health Supplies Working Group quarterly meeting; a policy dialogue co-hosted by PATH and the Woodrow Wilson International Center for Scholars regarding the draft UN Commission on Life-saving Commodities for Women and Children recommendations; the Diarrhea and Pneumonia Working Group; and the CCM task force (including the CCM indicators review meeting).

Sub-Objective 1.1
Capacity of individuals, institutions, organizations to manage maternal health medicines and supplies strengthened

Progress toward sub-objective 1.1
During this quarter, the analysis of the data from the survey on pharmaceutical management for emergency obstetric and newborn conditions in Rwanda was conducted. A draft report was sent for comment to the local team and initial plans were made for the dissemination and policy options workshop in August.

SIAPS participated in the Asia Regional Meeting on Interventions for Impact in Essential Obstetric and Newborn Care organized by MCHIP and the Ministry of Health and Family Welfare of Bangladesh, held in Dhaka on May 3–6, 2012. Beth Yeager and Sheena Patel attended the nutrition symposium organized by the USAID-funded SPRING program and MCHIP prior to the maternal health meeting. On day one of the meeting, Beth Yeager presented in a panel on maternal health medicines and supplies. Also, over the course of the meeting, B. Yeager and S. Patel attended several auxiliary meetings including the PPH and PE/E drugs and devices task force meetings, a stakeholder consultation on policy recommendations for improved access to maternal health supplies coordinated by PATH, and a regional consultation meeting for Women Deliver. Also during this quarter, SIAPS participated in the Maternal Health Supplies Working Group quarterly meeting held on May 17th.

On June 7, SIAPS participated in a policy dialogue co-hosted by PATH and the Woodrow Wilson International Center for Scholars to identify and prioritize global and national policies to improve access to maternal health supplies in light of the draft recommendations of the UN Commission on Life-saving Commodities for Women and Children.

Main challenges for sub-objective 1.1
The data analyst needed considerable guidance on how to analyze some key aspects of the data, which has delayed progress somewhat. The dissemination workshop had been proposed for June, but the MoH was not available due to end of financial year activities; therefore, it will be held in the following quarter.

Steps to address challenges for sub-objective 1.1
Clear guidance was provided to the analyst and the final analysis of the Rwanda assessment is underway.

Deliverables for sub-objective 1.1
Survey instruments and survey protocol for the Rwanda assessment.

Sub-Objective 1.2
Capacity of individuals, institutions, organizations, and to manage child health medicines and supplies strengthened

Progress toward sub-objective 1.2
This quarter SIAPS continued to participate in the Diarrhea and Pneumonia Working Group led under the auspices of the Essential Medicines Initiative of UNICEF in support of the UN Commission. Jane Briggs represented SIAPS via telephone at the working group meeting on May 10, 2012. Also during this quarter, SIAPS participated in a CCM task force meeting on April 30th. Finally, SIAPS participated in a meeting to review the CCM indicators developed by the CCM task force. The meeting was held on June 18 at the MCHIP office. Representatives from several organizations that participate in the task force were present, including Save the Children, JSI, UNICEF, Johns Hopkins University, URC and USAID. The current status of the indicator reference sheets and guidance document were discussed. Breakout sessions to allow more in-depth discussion of specific indicators were also conducted. SIAPS offered to provide written comments on the medicines and supplies related indicators following the meeting.

The regional consultative workshop on the CCM indicators that had been initially proposed to SIAPS by Emmanuel Wansi was also discussed. UNICEF and WHO feel that the workshop should not be a separate event, but should be planned around another child health event to maximize time and resources. Since no such meeting is planned for the last quarter of this fiscal year, the meeting is likely to occur at the end of 2012 or the beginning of 2013.

Objective 2
Utilization of information for decision-making increased

Objective 2: Quarterly progress

This quarter, Harvard submitted the drafts for chapters 1-3 of the intervention guide which are being reviewed by SIAPS. The guide is expected to be finalized next quarter. The second activity is still pending USAID approval.

Sub-Objective 2.1
Innovative and proven tools broadly available and used

Progress toward sub-objective 2.1
The activity to develop a handbook for district level managers, proposed in the SIAPS work plan, was discussed with Deb Armbruster from USAID in Dhaka, Bangladesh. Based on this conversation, an updated description of the activities (including Activity 3.1.1, roadmap for national program managers) were re-submitted to USAID. At the end of the quarter however, the activities had still not been approved. A meeting has been scheduled for early July to again discuss these activities with USAID. The team at Harvard continued to work on the revision of the guide. By the end of the quarter, the introduction and chapters 1 through 3 had been sent for review. As SIAPS continues to participate in the weekly conference calls when possible, the review process can move ahead smoothly. The use of the web-based storage site Zotero has facilitated the review by SIAPS staff, as it is possible to access all the resources documents.

Main challenges for sub-objective 2.1
Minimal delays in the submission of the first draft due to the partners other activities and travel.

Objective 3
Pharmaceutical services for maternal and child health improved

Objective 3: Quarterly progress
This quarter progress on this objective has been limited. Work on the road map for national program managers' activity has not begun due to pending USAID approval. SIAPS activities in Mali continue to be stalled due to political instability in the country and USAID ban to work with the Mali government. USAID partners met this quarter to discuss and agree on creative ways of working given the ban on interaction with Ministry of Health staff. The SIAPS Mali team's presentation focused on proposing intervention areas for SIAPS activities in case we need to work on a humanitarian basis due to the political crisis.

Little progress was made in Guinea, as the Ministry of Health has made slow advances for CCM. Jane Briggs met with MCHIP to discuss the importance of a steering committee, which was finally was authorized at the end of May. It was agreed that SIAPS will participate in the first meeting of the steering committee to define the scope of TA technically and geographically.

Sub-Objective 3.1
Availability of pharmaceuticals for maternal health improved

Progress toward sub-objective 3.1
The roadmap activity is still under discussion with USAID and awaiting approval. A meeting has been scheduled next quarter to discuss approvals for the remaining activities in the work plan.

Sub-Objective 3.2
Availability of pharmaceuticals for child health improved

Progress toward sub-objective 3.2
Due to political instability and USAID's ban on interaction with government institutions, no programmatic activities were implemented this quarter in Mali. However, Core MCH, in collaboration with the Mali portfolio manager supported the SIAPS Mali team to prepare a presentation for USAID Mali partners' meeting. The objective of that meeting was to discuss the importance of keeping key USAID-funded activities going in order to achieve intended health objectives and agree on creative ways of working given the ban on interaction with Ministry of Health staff. The SIAPS Mali team's presentation focused on proposing intervention areas for SIAPS activities in case we need to work on a humanitarian basis due to the political crisis. The proposed interventions for SIAPS on a humanitarian basis focused on the community level of the system (FENASCOM, FERASCOM, FELASCOM, ASACO which are the national, regional, local federations and health associations at the community level) and NGOs to provide technical assistance to: (a) Assess the supply chain including CCM (needs estimation for medicines and other medical products, storage capacity) and propose a plan of action; (b) Provide technical assistance for the management of medicine donations; and (c) Monitor the distribution of medicine supplies.

There has been little progress in Guinea this quarter. Jane Briggs met with Serge Raharison of MCHIP to discuss the issues and determine a course of action for moving forward. Serge stressed the importance of the formation of a national steering committee, which MCHIP in country has been trying to form for some time. This group was finally officially formed at the end of May. SIAPS will participate in the first meeting of the steering committee to define the scope of TA technically and geographically.

Main challenges for sub-objective 3.2
The political instability has been the major challenge to progress in Mali this quarter. In Guinea, progress has been slow because of the delayed response of Ministry of Health. Now that the national steering committee has been formed, activities will be able to move forward in the next quarter.

Steps to address challenges for sub-objective 3.2
SIAPS will be proactive to discuss with MCHIP on aspects of CCM implementation and will participate in all planning meetings.

Tuberculosis Core

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 numbers 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

In the third quarter SIAPS worked with the Stop TB Secretariat and GDF staff on strategies for strengthening the GDF performance and expediting the supply of TB medicines to countries. SIAPS developed TOR for the GDF interim manager, and identified a consultant and budget. SIAPS also contributed to the development of the GDF Letter of Intent in response to the UNITAID RFA TB monitoring Missions.

With regards to strengthening DOTS, SIAPS conducted missions which identified common gaps in the pharmaceutical management of childhood TB. Furthermore, SIAPS supported the scale up of prevention and treatment of Drug-Resistant TB by providing technical expertise to Second-Line Drug Access Improvement Initiative (SLDAII) in preparation for a workshop in Geneva in April 23-26.

Key challenges of quarter

Several planned activities – those related to the revision of SIAPS Pharmaceutical Management for TB Guidelines and training materials - were not started due to increased demand in the activities related to support of the GDF.

The regional data collection for the Global Early Warning Information System, and TA activities to selected priority countries in Africa region were delayed because of slow WHO and Stop TB

communication with National TB programs.

Key activities for next quarter

Activities for next quarter will proceed as previously outlined in the FY11 funds work plan, and will include:

- TB drug management course on the TB/DR
- TB training for TB program managers in Riga, Latvia organized by WHO EURO/KNCV will be facilitated.
- Information obtained by GDF monitoring missions on pharmaceutical management of childhood TB will be analyzed and supplemented with a literature review.
- Kenya specific DUR guidelines will be finalized and its implementation in Kenya will be planned.
- Lab module of eTB Manager will be finalized and tested in Uzbekistan.

Objective 1

Strengthen DOTS

Objective 1: Quarterly progress

SIAPS efforts this quarter were primarily aimed at strengthening the GDF as a global supplier of first- and second-line TB medicines. This assistance to the GDF is a top priority for USAID and other donors, including CIDA and UNITAID. The GDF has been without proper management for a number of years now, and is also lacking the technical capacity necessary to streamline its functions and expedite the delivery of TB medicines.

SIAPS and USAID TB team have developed a strategy for the GDF strengthening that includes both short-term specific technical assistance, and long-term – through a seconded technical specialist and manager.

Focus on the GDF has slowed down other activities. Also, some funding will have to be reallocated within the current work plan to address the need of this technical support.

Sub-Objective 1.1

Improved access to quality assured TB medicines.

Progress toward sub-objective 1.1

In April 2012, UNITAID issued a call for a Letter of Intent to submit a proposal. This call followed the decision of the UNITAID Board to hold at least one open call per year in recognition of the need to consider a range of innovative approaches to increasing access to preventive, diagnostic and treatment commodities for HIV, TB and malaria. Proposed approaches should target the needs of people living in low income (LICs) or low-middle income (LMICs) high burden countries.

SIAPS was requested to provide direct assistance to the GDF and the Multi-Drug Resistant Tuberculosis Second-Line Drug Access Improvement Initiative (SLDAII) in the development of UNITAID LOI. SIAPS consultants travelled to Geneva to contribute to the GDF LOI. The scope of work included:

- Prioritize and identify the core and supporting intervention(s) for a UNITAID LOI

- Leverage group expertise of a UNITAID LOI with existing work and anticipated scale-up in MDR-TB treatment
- Identify opportunities for collaboration with GDF as the prime recipient
- SIAPS advised USAID and Stop TB Partnership Secretariat on a strategy for strengthening the GDF. TOR and SOW for an Interim GDF Manager have been developed and a specialist to take this position has been identified and contracted (start date is July 15).

SIAPS Principal Technical Advisor for TB Andre Zagorski traveled to Sondalo, Italy to facilitate the sessions on pharmaceutical management for TB sessions at the WHO Course "Implementing New Stop TB Strategy: Skills for Managers and Consultants (TB MDR-/XDR-TB TB/HIV)". The sessions covered technical areas including: good governance for medicines; best practices and challenges in medicines selection procurement distribution and utilization; challenges of medicines quality assurance including WHO-prequalification the Global Fund and GDF quality assurance requirements and practices; monitoring and evaluation of supply program performance and outcomes. The participants were a mix of TB program managers and international consultants; a total of 21 participants representing 12 countries were trained (6 female and 15 male).

Main challenges for sub-objective 1.1
Assistance to the GDF required significantly more resources than was planned or anticipated, which slowed down the progress of other planned activities.

Steps to address challenges for sub-objective 1.1
SIAPS discussed support to the GDF with USAID TB team, and the activity was given top priority.

Deliverables for sub-objective 1.1
- Trip Report: Geneva, April 23-26, 2012
- The GDF final version of UNITAID Letter of Interest (LOI)
- Trip report: Sondalo TB Course, May 2012
- Trip Reports: GDF monitoring missions to Armenia and Georgia
- TOR and SOW for the GDF Interim Manager (supported through SIAPS TB Core)

Sub-Objective 1.3
Improved management of childhood TB

Progress toward sub-objective 1.3
Childhood TB was part of the GDF monitoring missions to Georgia and Armenia. Missions discovered common gaps in pharmaceutical management of childhood TB.

Sub-objective 1.4
Improved safety of TB/HIV and other co-morbidities co-medication

Progress toward sub-objective 1.4
During this quarter, the strategy for the risk management activity was conceptualized; literature review of documents have commenced and the process of identification of risk factors for each second line TB medicine on the WHO treatment guidelines based on package insert information

and information from regulatory authorities and other online resources has been completed. Next Steps for this activity are to categorize risk levels of all 2nd line TB medicines, and to develop appropriate tools for medicines with high risk that countries can use to minimize the risk and finalize the risk management protocol.

Development of the active surveillance protocol for TB medicines will commence in Quarter 3. Preliminary discussions have already been held to conceptualize the framework for the activity.

Deliverables for sub-objective 1.4

- Risk management protocol for TB medicines with accompanying tools
- Protocol for active TB active surveillance

Objective 2

Scale up prevention and treatment of Drug-Resistant TB

Quarter progress: Objective 2

This quarter, SIAPS efforts towards scaling up prevention and treatment of drug resistant TB focused primarily on improving and adapting tools for data collection. As part of efforts to improve access to second line TB medicines, SIAPS modified the forecasting component of e-TB Manager to allow for its use in regular data collection.

Additionally, SIAPS developed draft TOR for an advisory group that will guide the Stop TB Partnership Board on issues such as strengthening the GDF and developing new TB tools. Lastly, under the scope of Objective 2, SIAPS crafted a number of tools to strengthen public private mixes by enhancing data collection and creating training materials for pharmacists.

Sub-objective 2.1

Improved access to second-line TB medicines

Progress toward sub-objective 2.1

SIAPS continued to provide technical expertise to Second-Line Drug Access Improvement Initiative (SLDAII) in preparation for a workshop in Geneva in April 23-26 (development of the GDF UNITAID LOI).

On the request from USAID, SIAPS developed draft TOR for a permanent Advisory Group on Pharmaceutical Management for TB to advise Stop TB Partnership Board on issues related to strengthening the GDF, and improving access to second-line TB medicines and new TB tools.

Deliverables for sub-objective 2.1

Draft TOR for Stop TB Board Advisory Group on Pharmaceutical management for TB.

Sub-Objective 2.3

Public Private Mix for Prevention and Control of Drug Resistant TB

Progress towards sub-objective 2.3

Pakistan:

- Broader consultation with key stakeholders [NTP, Punjab Pharmacy Council, Punjabi University/ Faculty of Pharmacy, Pakistan Academy of Family Physician, Drug Regulatory Authority of Pakistan, Pakistan Planning Commission, Interactive Resource Center (IRC)] achieved and received good feedback and input on the proposed pilot.
- Data collection tool developed, successfully field-tested (both English and Urdu version), and revised; developed data collection plan with University of Punjab Faculty of Pharmacy.
- Revised the work plan with new timeline and budget.

Tanzania

- Finalization of the reports on the baseline assessment on the knowledge and practices in TB case management among pharmacies and ADDOs.
- Workshop for dissemination of key findings from the baseline assessment (conducted at pharmacies and ADDOs in Morogoro and Dar es Salaam in August 2011) for "understanding the private retail pharmaceutical sector knowledge and practice in regards to TB case management in Tanzania" on May 23, 2012.
- Workshop for development/adaptation of training materials and various tools (recording tools: reporting and referral forms, cough register and TB symptoms checklist) to improve knowledge and skills of pharmacists and ADDOs attendants with the goal to increase TB case detection, on May 24 – 25, 2012.
- Delivery of training of trainers on June 20 – 22, 2012.

Kenya:

- A Memorandum of Understanding between KAPTLD and MSH as signed.
- Activities were prioritized with KAPTLD.
- Draft MDR-TB baseline assessment tool was shared with KAPTLD for review.
- Identification and selection of assessment sites (private hospitals and chest physicians) pending.

Deliverables for sub-objective 2.3

Pakistan:

- Data collection tool
- Revised work plan

Tanzania:

- Training materials for pharmacists and ADDOs
- Various tools including recording and referral forms
- Cough register

Kenya:

- Draft MDR-TB baseline assessment tool
- MoU

Objective 3

Expedite adoption and implementation of new TB tools

Quarter progress: Objective 3

As part of efforts to expedite the adoption of implementation of new TB tools, SIAPS has made progress both in terms of developing financing tools as well as disseminating information on pharmaceutical management. With regards to financing tools, the NTPs of both Rwanda and Uganda have agreed to participate in the piloting of a novel tool. As for the dissemination of innovative approaches to pharmaceutical management, SIAPS developed interview guides and

began pre-assessments for select countries in preparation for the conference in December. Additional efforts focused on securing initial logistics including the identification of location and venue.

Sub-objective 3.1
Efficient use of financial resources for new TB tools

Progress toward sub-objective 3.1
Tool development is in progress. A tool will be piloted in Rwanda and Uganda between July and August. Rwanda and Uganda NTPs agreed to participate in the assessment. The assessment will be carried out from July to August 2012. An approval for conducting an assessment from Uganda MoH and NTP has been received. An assessment may be subject to an ethics review in Rwanda. A document to support a request for not seeking ethics approval has been submitted.

Sub-objective 3.2
Evidence and information on innovative approaches to pharmaceutical mismanagement for tuberculosis disseminated

Progress toward sub-objective 3.2
Initial planning for the conference started this quarter. Concept papers and conference strategy has been developed. Interview guides were developed and a rapid pre-assessment for selected countries (15) has commenced. Conference content will be determined based on identified gaps and strengths of the countries in their TB pharmaceutical system. SIAPS has contacted WHO as a potential partner for the conference. The conference logo and branding is still under development. Conference announcement and save the date have been drafted. All activities are ongoing. Initial logistics arrangement has begun; location and venue have been identified and SIAPS is in the process of finalizing contract terms with the venue.

Deliverables for sub-objective 3.2
Country action plans to strengthen TB pharmaceutical systems.

Objective 4
Improve health systems

Sub-objective 4.2
Improved MIS for TB

Progress toward sub-objective 4.2
Work continues on updating the User's Guide for e-TBM Generic Version 2.0. Once the document is finalized, it will be disseminated, and then work on updating user's guides for the Russian and Ukrainian language versions of e-TBM Generic Version 2.0 will begin. After completing the Ukrainian language Generic Version 2.0 of the guide, the e-TBM Customized for Ukraine User's Guide will be updated in Ukrainian and English.

Namibia: As mentioned above, the e-TBM implementation is moving in Namibia. Had sporadic contacts with local partners to follow-up pilot activities and, during this quarter, the MSH e-TBM

focal point in Namibia resigned and other staff is acting. He had a meeting with the NTLP to discuss the review of the pilot phase and agreed to keep implementing the tool. They also decided to have standing meetings at least once a month to discuss e-TB manager implementation progress. The acting focal point also contacted MSH Arlington and Brazil for updates and clarifications. The pilot report is expected for August 2012 to guide further customizations and set the countrywide roll-out implementation plan.

Kenya: The implementation process was interrupted due to withdrawal of funding from the country project (Kenya SPS). Last quarter, NTP expressed interest in use the tool but concerned to stop again without getting to full implementation for the country to realize benefit from new investment.

Bangladesh: The e-TB implementation is moving in Bangladesh. It was slow for last couple of quarters but with the involvement of the local SIAPS office the activity has jump started. A training of trainers was performed. e-TBM will be implemented in an additional 20 sites starting July 2012. Also, e-TBM is being considered for use with the DR-TB patients in the country as well.

As mentioned above there were not many activities carried out in development of the desktop application. The activities have now started again and the first prototype is planned for September and will be piloted in Bangladesh in October.

Main challenges for sub-objective 4.2

- Authors discovered bugs and labels that correcting prior to releasing Version 2.0 of the User's Guide the

Namibia:

- Regular close monitoring of pilot activities.
- To replace MSH local e-TBM focal point.
- Establish funding resource to budget the countrywide rollout phase.

Kenya:

- Funding gap to resume implementation process.

Bangladesh:

- Changes in NTP in the country.
- NTP not taking responsibility.

Steps to address challenges to sub-objective 4.2

- The e-TBM team is working on procedures to ensure that system maintenance, documentation, and implementation activities are carried out in an efficient and timely manner.

Namibia:

- The acting focal point staff is improving communication with the NTLP and MSH Inc. and high level discussions about budgeting will be performed.

Kenya:

- Contacts with Senior TB Technical Advisor- Africa (CHS/MSH) to updates and clarifications.
- Advocacy efforts and coordination to bridge the funding gap.

Bangladesh:

- The local office is involved in the process of implementation.
- Close monitoring is being done by the local office and initiating activities.

Deliverables for sub-objective 4.2

Basic SOPs for eTB Manager Use in Namibia (5 documents).

USFDA

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 3 objectives focused on initial implementation of the Asia Pharmacovigilance Assessment in Bangladesh, Cambodia, Nepal, the Philippines, and Vietnam (Objective 1), planning for and conducting the 2012 Africa Pharmacovigilance Meeting held in Nairobi, Kenya from April 18-20, 2012 (Objective 2), and gathering of data for identification of priority pharmacovigilance tools for development (Objective 3).

Key challenges of quarter

The key challenges that was encountered during the quarter under review with the implementation of the activity include: delays in the approval of the assessment in Vietnam and Cambodia, challenges with managing the recruitment of the consultants and data collectors particularly in countries without SIAPS presence (for instance Cambodia, Nepal, and Thailand), and budgetary challenges due to higher costs of implementing the assessment in the selected Asia countries compared to the Africa study.

Key activities for next quarter

Activities planned for Q4 include implementation of the Asia Pharmacovigilance Assessment in Bangladesh, Cambodia, Nepal, the Philippines, and Vietnam and drafting and dissemination of individual country reports and a combined regional report (Objective 1). A report on the 2012 Africa Pharmacovigilance Meeting held in Nairobi, Kenya from April 18-20, 2012 will be published (Objective 2). Priority PV tools including the existing tools that were enhanced to include important PV features will be developed and piloted.

Objective 1

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

Objective 1: Quarterly progress

Implementation for the Asia Pharmacovigilance assessment commenced in Q3 in the six study countries, Bangladesh, Cambodia, Nepal, the Philippines, Thailand, and Vietnam. In all countries, local consultants have been appointed by the national regulatory authorities and engaged. The data collection and documentation review phase is underway in Q3 and will be completed in Q4, along with report preparation and publication.

Sub-Objective 1.1

Assess pharmacovigilance systems and performance in selected Asia/Pacific countries

Progress toward sub-objective 1.1

Planning for and implementation of the Asia Pharmacovigilance Assessment commenced in Bangladesh, Cambodia, Nepal, the Philippines, and Vietnam. Local consultants and a team of data collectors were engaged in each country through the respective National Regulatory Authorities. The assessment includes review of key documentation and semi-structured interviews based on the Indicator Based Pharmacovigilance Assessment Tool (IPAT) with key informants representing the Ministry of Health, National Regulatory Authority, national public health programs, health facilities, industry, pharmacies, academia, professional associations, and clinical research organizations.

Main challenges for sub-objective 1.1
There were delays in the approval of the assessment in some countries, however the planning and implementation for the Asia Pharmacovigilance Assessment has gone well. There have been challenges particularly related to timing and budget due to the complexities of working in Asian countries where SIAPS has little or no presence.

Steps to address challenges for sub-objective 1.1
In order to maximize use the use of funds, cost leveraging has been utilized whenever possible with existing SIAPS programs. This has been successful particularly in Bangladesh and the Philippines.

Deliverables for sub-objective 1.1
Assessment implementation instruments have been designed and distributed to the study countries, including stakeholder workshop presentation materials, data collection questionnaire, data analysis tool, and individual country report template.

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. During this quarter the data analysis spreadsheet and report template for the country specific reports was developed and shared with the local consultants to ensure consistent quality in the reports to be generated from the assessment. Also literature review to support the report was initiated.

Main challenges for sub-objective 1.2
Anticipated progress towards planning for the Asia assessment report writing and documentation was achieved in Q3.

Steps to address challenges for sub-objective 1.2
No challenges were experienced related to conduct of the Asia assessment in Q3.

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
The Africa Pharmacovigilance Meeting 2012 was held in Nairobi, Kenya from April 18-20, 2012. The meeting included a dissemination conference and workshop for the development of pharmacovigilance tools, which identified a priority package of tools and guidance documents that could be developed and deployed to address some of the assessment findings and for overall strengthening of pharmacovigilance and regulatory systems. The meeting also included training conducted by the US FDA Center for Biologics Evaluation & Research on active surveillance for vaccine pharmacovigilance.

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

Progress toward sub-objective 2.1
The two-day workshop was conducted in Q3 April 19 – 20, in conjunction with the sub-Saharan Africa assessment dissemination conference held on April 18, 2012. The workshop approach included mapping of current pharmacovigilance practices through administration of a pre-meeting survey and guided workshop discussion groups, 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 five key pharmacovigilance tools identified were:

- Template of a local pharmacovigilance database to collate data from all sources
- Templates for protocols, SOPs, and model software for conducting active surveillance
- Protocol and operational guide for requesting and monitoring risk management plans to prevent or minimize known serious risks
- Website for real-time sharing of global medicine safety alerts, local safety and quality issues, and regulatory decisions
- Model of comprehensive pharmacovigilance guidelines

Main challenges for sub-objective 2.1
All anticipated progress towards conducting the workshop was achieved in Q3.

Steps to address challenges for sub-objective 2.1
No challenges were experienced related to conducting the workshop in Q3.

Deliverables for sub-objective 2.1
The Africa Pharmacovigilance Meeting 2012 conference materials and survey analysis was completed in Q3. The workshop report was drafted in Q3 and will be submitted in Q4, including a summary of the various sessions and technical conclusions.

Sub-Objective 2.2
Disseminate findings of the SSA study

Progress toward sub-objective 2.2
In Q2, the assessment report Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance, was published. The publication was launched at the Q3 2012 Africa Pharmacovigilance Meeting held in Nairobi, Kenya from April 18-20, 2012. The meeting included 110 participants from 32 countries and brought together partners from the global regulatory and pharmacovigilance community, including the World Health Organization, Bill and Melinda Gates Foundation, European Medicines Agency, U.S. Centers for Disease Control and Prevention, U.S. Food and Drug Administration, U.S. Agency for International Development, and national regulatory authorities and public health programs.

Main challenges for sub-objective 2.2
All anticipated progress towards conducting the dissemination conference was achieved in Q3.

Steps to address challenges for sub-objective 2.2
No challenges were experienced related to conducting the dissemination conference in Q3.

Deliverables for sub-objective 2.2
The Africa Pharmacovigilance Meeting 2012 conference and workshop report was drafted in Q3, including a summary of the various sessions and technical conclusions. It will be published in Q4.

Objective 3
Develop and disseminate framework and tools for pharmacovigilance system

Objective 3: Quarterly progress
This quarter, SIAPS progressed in information analysis to inform the development of operational tools related to pharmacovigilance and disseminated the pharmacovigilance framework and operation tool. These activities allowed us to make progress toward the objective.

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 outlined in

Sub-Objective 2.1 and information gathered from in-depth literature review was 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 Q3.

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 Q3.

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 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 Q3.

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 Q3.

REGIONAL PROGRAMS

LAC- Amazon Malaria Initiative

Portfolio Background

The Amazon Malaria Initiative (AMI) was launched in March 2002, through USAID LAC/RSD-PHN, to address malaria in the Amazon countries (Bolivia, Brazil, Colombia, Ecuador, Guyana, Peru, and Suriname). This region began to experience a re-emergence of malaria in the early 1990s, including the appearance of Plasmodium falciparum and resistance to inexpensive, first-line antimalarial drugs. With technical and financial support from AMI, the seven participating countries conducted in vivo efficacy studies of antimalarials and changed their drug policies for malaria to include new, more efficacious combination therapies. Strengthening the core elements of pharmaceutical management—including the policy and legal framework, selection, procurement, distribution, use and management—is essential to the effective implementation of these new policies.

The USAID founded programs, Rational Pharmaceutical Management Plus (RPM Plus), Strengthening Pharmaceutical Systems (SPS), and currently the Improved Access to Pharmaceuticals and Services (SIAPS), have successively been the technical pharmaceutical management partners for AMI since 2002. The other partners in the Initiative include the Pan American Health Organization (PAHO) Infectious Disease Division, the Center for Disease Control and Prevention (CDC), the United States Pharmacopoeia Promoting Quality of Medicines (USP-PQM) Program, National Malaria Control Programs in the Amazon and Central American regions, and the local USAID Missions. Between 2003 and 2011, RPM Plus and SPS collaborated with these partners to develop and implement strategies to strengthen pharmaceutical management for malaria in the region, particularly related to the new treatment policies. Both programs developed training materials; conducted regional workshops on pharmaceutical management issues to professionals representing all the Initiative countries; developed and disseminated tools; provided country-specific technical assistance to assess and improve their pharmaceutical supply systems for malaria; contributed to the Initiative's technical documents and study protocols; participated in annual meetings, regional workshops and dissemination activities; and, served on the Steering Committee. These activities have resulted in a solid foundation upon which SIAPS can further strengthen pharmaceutical management systems in the region. A summary of the activities supported by SPS and technical reports are available at: http://www.msh.org/projects/sps/Global-Focus/Amazon-Malaria-Initiative.cfm.

With FY10 funds SPS supported the elaboration and publication of standard operational procedures for malaria pharmaceutical management; the scale up and monitoring of the supervision system to malaria diagnostic and treatment posts; regional studies on the impact of the introduction of ACTs; regional and national workshops to strengthen good programming and procurement practices in low incidence settings; and support to the pharmaceutical management information systems.

SIAPS has received USD 900,000 in FY11 funds to support pharmaceutical management activities under AMI. These funds will be used to follow up on activities initiated on FY10 with SPS

resources. The FY11 focus will be on the institutionalization of activities promoted by AMI and the development and implementation of strategies to improve pharmaceutical management in low incidence settings. These proposed activities were discussed with AMI partners during the AMI Steering Committee in September 2011, and follow the 2010 - 2015 AMI Strategic Orientations on Drug Access and Use.

Quarter Overview

During the quarter, the LAC portfolio team visited three countries to conduct activities, in addition to work carried out by three consultants in their three respective countries. Among the highlights of the quarter, SIAPS visited Ecuador and agreed with local counterparts that the integration of disease control programs into a unified system (as recently proposed by the Ecuadorian sector reform) requires the elaboration and implementation of standard operational procedures at least in three components: information, procurement programming, and distribution. SIAPS completed the final reports of the following studies: (1) “Adequacy" evaluation of malaria control strategies in Brazil, Nicaragua and Panama; (2) Dissemination and use of malaria pharmaceutical management information; (3) "Bottle neck” analysis in the procurement of malaria medicines. SIAPS carried out an evaluation of the introduction of a malaria pharmaceutical guideline in Madre de Dios. A baseline study for the introduction of a similar guideline was conducted in Bolivia and Guatemala during this quarter.

Key challenges of quarter

The adequacy evaluation for malaria control strategies is being completed slower than originally anticipated. The countries have been slow in responding to the study request and returning key data for the study.

Key activities for next quarter

SIAPS will visit Ecuador to start the elaboration of the SOPs and Bolivia will report on the integration process and the gap to be bridged for a complete fusion. SIAPS will elaborate research protocols for studies proposed in current work plan: (1) competences of personnel for malaria diagnosis and treatment in low incidence areas; (2) monitoring of performance “gap closure” in the implementation of malaria control strategies. SIAPS will present the results to the malaria programs (Peru, Bolivia and Guatemala). Staff will also decide on the scale up of the intervention to the rest of the country (in the case of Peru), and the final design of the guideline (in Bolivia and Guatemala).

Objective 1

Availability of quality data for decision making improved

Sub-Objective 1.1

Regular pharmaceutical management information systems improved

Progress toward sub-objective 1.1

In order to strengthen the regional monitoring system of availability of antimalarials, DIGEMID issued the quarterly bulletin on May 2012, with SIAPS assistance. Eight countries (including some in Central America) provided data. This is the highest number of countries participating since the inception of the regional monitoring plan in 2010.

Main challenges for sub-objective 1.1
The countries are not sending information within the required timeline. Therefore, the report is not being sent out according to the agreed timeline.

Steps to address challenges for sub-objective 1.1
SIAPS consultants are working with each country staff to submit the data in a timely fashion.

Sub-Objective 1.2
Access to strategic pharmaceutical management information improved

Progress toward sub-objective 1.2
During this quarter SIAPS completed the final reports of the following studies: (1) “Adequacy" evaluation of malaria control strategies in Brazil, Nicaragua and Panama; (2) Dissemination and use of malaria pharmaceutical management information; and (3) “Bottle neck” analysis in the procurement of malaria medicines. All studies finalized by SIAPS during this quarter were disseminated (electronically) to AMI partners and selected audiences.

Objective 2
Malaria control program governance improved

Quarter Progress: Objective 2
There are currently two countries writing SOPS for malaria control. SIAPS consultants visited one of the countries and a consultant lives in the other country. Both countries saw progress on SOP development. SIAPS visited Ecuador during this quarter, and agreed with local counterparts that the integration of disease control programs into unified system (as recently proposed by the Ecuadorian sector reform) requires the elaboration and implementation of standard operational procedures at least in three components: information, procurement programming, and distribution. In coordination with local partners (PAHO), SIAPS will support this intervention. SIAPS also supported the integration of the Bolivian malaria program to the unified pharmaceutical system. For the next quarter, SIAPS will visit Ecuador to start the elaboration of these SOPs and Bolivia will report on the situation of the integration process and the gap to be bridged for a complete fusion.

Sub-objective 2.1
Performance of regional/local malaria pharmaceutical management increased

Progress toward sub-objective 2.1
In order to institutionalize supervision to malaria diagnostic and treatment posts, Colombia and Bolivia conducted rapid assessments of their respective supervision systems. The Colombian technical report was submitted to the national malaria program. No response has been provided on the need of additional technical assistance.

Sub-objective 2.2
Integration of malaria into National pharmaceutical services

Progress toward sub-objective 2.2
SIAPS visited Ecuador during this quarter, and agreed with local counterparts that the integration of disease control programs into unified system (as recently proposed by the Ecuadorian sector reform) requires the elaboration and implementation of standard operational procedures at least in three components: information, procurement programming, and distribution. In coordination with local partners (PAHO), SIAPS will support this intervention. SIAPS also supported the integration of the Bolivia malaria program to the unified pharmaceutical system.

Main challenges for sub-objective 2.2
In Bolivia, the malaria program managers have recently changed. This has complicated the integration of the program with the pharmaceutical system.

Steps to address challenges for sub-objective 2.2

The program is training new staff members on the malaria program and pharmaceutical supply of the medications.

Objective 3
Availably of antimalarial is increased

Quarter progress: Objective 3
SIAPS worked with Bolivia, Guatemala and Peru this quarter to improve pharmaceutical management in LAC countries. Each country made steps in development of protocols for their countries.

Sub-objective 3.1
Programming/quantification tools improved

Progress toward sub-objective 3.1
In an effort to institutionalize malaria pharmaceutical management guidelines, SIAPS carried out an evaluation of the introduction of a malaria pharmaceutical guideline in Madre de Dios. A baseline study for the introduction of a similar guideline was conducted in Bolivia and Guatemala during this quarter. For the next quarter, SIAPS will present the results to the malaria programs (Peru, Bolivia and Guatemala), and decide the scale up of the intervention to the rest of the country (in the case of Peru), and the final design of the guideline (in Bolivia and Guatemala.

Sub-objective 3.3
Increased availability of antimalarial in remote areas/groups

Progress toward sub-objective 3.3
During this quarter SIAPS organized a workshop in Peru, to establish the criteria for programming and distributing malaria medicines in low and high incidence areas. During a visit to Guyaquil, Ecuador, SIAPS conducted a rapid study to assess the implications of the implementation of these criteria. For the next quarter, SIAPS will support the elaboration of a Ministerial Decree to support this technical proposal, and will support the implementation of these criteria in Madre de Dios, and Loreto, Peru.

Main challenges for sub-objective 3.3
Low incidence settings are a newer area of technical assistance for SIAPS. The LAC program is developing indicators and study protocols since they have not been designed previously.

Steps to address challenges for sub-objective 2.2
LAC is designing new technical approaches so countries can manage malaria in areas of low incidence.

LAC SAIDI

Portfolio Background

The growing problem of antimicrobial resistance is threatening to undermine the advances achieved through priority health programs including tuberculosis, malaria, acute respiratory infections, sexually transmitted infections and HIV/AIDS, by rendering currently available treatments ineffective. Antimicrobial resistance (AMR) is the result of an increased exposure of microorganisms to antimicrobial medicines and the subsequent development of survival mechanisms in these microorganisms. The consequences of AMR include an increase in mortality, morbidity and in the cost of health care worldwide. An example of AMR of particular concern is multi-drug resistant tuberculosis (MDR-TB). The emergence and spread of MDR-TB has serious implications for a national TB control program: treatment is longer and less effective than treatment of non-resistant tuberculosis and is significantly more costly.

In response to this growing challenge, the USAID Bureau for the Latin America and Caribbean Region (USAID/LAC/SD) has proposed a sub-regional strategy for the Andean countries and Paraguay, called the South American Infectious Disease Initiative or SAIDI. The general objective of this initiative is to contain the emergence and spread of AMR by improving the availability and the use of antimicrobials of assured quality. Thus, the central focus of SAIDI is rational use of antimicrobials and AMR control, with a special emphasis on preventing the emergence of MDR-TB.

Since FY04, the Rational Pharmaceutical Management Plus (RPM Plus), and Strengthening Pharmaceutical Systems (SPS) programs – predecessors to MSH's current Improved Access to Pharmaceutical Services Program (SIAPS) – and the other SAIDI international partners, including the Promoting Quality of Medicines Program from the US Pharmacopeia (PQM USP), Links Media, the US Center for Disease Control and Prevention (CDC), and the Infectious Disease Division of the Pan-American Health Organization (PAHO) have been working with national counterparts in Bolivia, Peru and Paraguay to create a new, evidence-based and stepwise approach to local solutions for containing AMR. This approach considers the factors contributing to AMR within the context of existing systems and not in isolation, and thereby takes advantage of the interaction among stakeholders. Over the past three years, national AMR working groups have been formed in Peru and Paraguay and, in conjunction with SAIDI international partners, have conducted various assessment activities which led to a holistic local view of the factors contributing to AMR in each country.

Based on these results, MSH's USAID sponsored programs and national partners have implemented multiple activities to address the problem areas (check SPS/SAIDI Web site: http://www.msh.org/projects/sps/Global-Focus/SAIDI.cfm). On FY10, SAIDI partners decided to concentrate all the technical assistance and resources in the control of TB and MDR-TB in the jurisdiction of Madre de Dios, Peru. Limited resources were still used to document the impact of previous interventions, and transferring capacities to national institutions.

SIAPS has received USD 90,000 in FY11 funds to support pharmaceutical management activities under SAIDI. These funds will be used to follow up on activities initiated on FY10. The FY11 work plan will focus on the implementation of the SAIDI approach in Madre de Dios, Peru.

Quarter Overview

This quarter, SIAPS reviewed the work plan for developing an alternative model for provision of health services with the partners in SAIDI. SIAPS developed and validated a pharmaceutical guideline for primary health care facilities and agreed on an implementation plan. The counterparts and SIAPS began assessing ad hoc technologies for improving local medicine stores.

Key activities for next quarter

All activities for the next quarter will take place in Madre de Dios, Peru. The first activity will support the introduction of the primary health facility guidelines. A results/impact evaluation will be conducted by the end of 2012 for this intervention. Secondly, SIAPS will begin an impact evaluation of ad hoc technologies in local medicine stores in Madre de Dios, Peru. The study will have particular emphasis on (eventually) lowering of the temperature achieved by this intervention.

Objective 1

Access to treatment and diagnosis of TB increased in population leaving in special circumstances

Objective 1: Quarterly progress

During the quarter, SIAPS concentrated their activities on pharmaceutical guidelines for primary health care facilities and a study on medical stores in Madre de Dios, Peru.

Sub-Objective 1.1

TB morbidity and mortality reduced in Madre de Dios, Peru

Progress toward sub-objective 1.1

The alternative model for the provision of health services to populations living on special circumstances in MDD was completed, discussed and presented to local counterparts during the previous quarter. During this quarter, SIAPS disseminated the results among SAIDI partners to support the implementation work plan. For the next quarter, and considering the limited resources for this activity, SIAPS will monitor the implementation of the work plan, and provide technical assistance to specific pharmaceutical management areas, if required.

Sub-Objective 1.2

Distribution and dispensing practices improved

Progress toward sub-objective 1.2

SIAPS concluded a study on the conditions of the medicine stores in MDD and started the conditioning of selected medicines using affordable technology. For the next quarter, an impact evaluation will be conducted with particular emphasis on the eventual lowering of the temperature achieved by this intervention.

COUNTRY PROGRAMS

Angola

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 (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

DNME continues to lead in the monthly ICC meeting and meeting minutes are shared with all stakeholders. CECOMA has successfully integrated the 5 MOH public health programs (Malaria, HIV/AIDS, Reproductive Health/Family Planning, Tuberculosis, and Essential Medicines and Supplies) from the central warehouse, except for the HIV/AIDS test kits which are stored at NEOFARMA. Weekly inventory of all program medicines is on-going. Bidding for 100,000 RDTs is in progress (coordinated by CECOMA) and CECOMA distributed LLINs to the provinces, in coordination with the NMCP program. Remodeling and improvement work is underway at the CECOMA warehouse (e.g. creation of a new office within the warehouse, securing solar power to prevent power interruption, and installation of shelves). One refrigerated truck is functional and based at CECOMA for storage of sensitive drugs. PNME has finalized the list of essential medicines in the health kits (4 types of health kits) and warehouse forms were distributed to the provinces. Distribution of an additional batch of warehouse forms is in progress. The PV Director attended the Africa PV Meeting in Kenya and a report was produced and disseminated. An EUV survey was completed in 8 provinces covering 36 health facilities and the report was compiled and disseminated in early June. SIAPS collaborated with USAID/DELIVER in providing TA to the DNME/PNME to facilitate receipt of PMI-funded malaria commodities (1,800,840 Coartem and 862,150 RDTs. Once completed, SIAPS collaborated with USAID/DELIVER and NMCP in coordinating distribution of the ACT and RDTs to the country's 18 provinces, following an agreed distribution plan.

Key challenges of quarter

- Difficulties in bringing all 5 public health program coordinators and officers in one setting to review the integrated supervision tool.
- Delays in reproduction of second batch of the warehouse forms.
- Limited access to project funds.
- Challenges capacitating the new PNME logistician to take over role of facilitating receipt of PMI-funded malaria commodities.

Key activities for next quarter

- National logistic management workshop and essential medicines management training at the provincial level. EUV survey.
- PV and rational medicines use awareness training in 4 provincial hospitals and integrated follow up supportive supervision visits.
- Technical assistance to CECOMA to assist them in operationalization of the central warehouse, including the bidding process and procurement abroad.
- Technical assistance to PNME in the establishment of LMIS and strengthening of the supply chain activities from the national down to the community levels.
- Technical assistance to the Pharmacovigilance Department.

Technical Activity Coordination

The Portfolio Manager communicated and coordinated as needed with and in country-based and externally-based technical staff and local counterparts and partners via e-mail, phone, Skype, and STTA.

Office Management

The corporate account was successfully opened for the SIAPS project. The registration process in being supported by UTCAH and the USAID/Angola Mission. A new office space was identified and finalization of the payment is in progress. A new Administrative Assistant was hired. Wireless internet connection for PNME has been renewed until December 2012 and transport support was provided as needed to the PV department.

Objective 1

Medicines policy governance strengthened

Objective 1: Quarterly progress

DNME has authorized/provided licenses to 1,054 private pharmacies, 176 importers and distributors, and 3 herbal stores (Herbanaria) to operate in the country. SIAPS is assisting clinics in obtaining registration to operate laboratory analysis.

Sub-Objective 1.1

DNME capacity to regulate medicines strengthened

Progress toward sub-objective 1.1

DNME has developed SOPs for acquisition of medicines and equipment policies and regulations, approved use of the new form to monitor poor quality of medicines, and continued to follow-up with the MoH in the installation of the Quality Control Laboratory.

Main challenges for sub-objective 1.1

Delayed deployment of technical consultant(s) to conduct the rapid assessment and to determine the organizational or technical challenges for future interventions.

Steps to address challenges for sub-objective 1.1

Continue searching for the technical consultant(s) to be deployed in Angola.

Sub-Objective 1.2

Coordination and collaboration among local pharmaceutical management stakeholders improved to promote knowledge exchange

Progress toward sub-objective 1.2

DNME has continued to lead the ICC meetings and compile and share meeting minutes with all stakeholders. SIAPS continued to compile program reports and share relevant information with MoH partners (e.g. PPMRm, CPP, and ACT/RDT gap analysis). SIAPS also collaborated with MoH program partners and PMI NGOs (SASH, WL, and Pathfinder) in reviewing the integrated supervision tool and collaborated with CUAMM in trying to integrate supervision activities and monitoring of the TB program. Staff conducted the EUV survey, submitted reports, including feedback, and held meetings with NMCP and DNME/PNME on the results of the survey.

Main challenges for sub-objective 1.2

It is difficult to bring all 5 MoH program coordinators/officers together to review the integrated

supervision tool. Poor collaboration was received from NMCP (SIAPS was not invited to attend the malaria forum).

Steps to address challenges for sub-objective 1.2
SIAPS will support PNME in instituting the integrated supervision tool. SIAPS will request the Malaria Administrator to include SIAPS in all malaria meetings or conferences they are undertaking, for better working relationship and coordination.

Deliverables for sub-objective 1.2
- ICC meeting minutes.
- Final draft of the integrated supervision tool.
- Distribution plan for ACT/RDTs.
- Concept paper for the national logistics meeting.
- EUV survey report.

Objective 2
Local capacity for pharmaceutical supply management enhanced

Objective 2: Quarterly progress
The results of EUV survey conducted this quarter showed that 77% of the health staff have been trained on pharmaceutical management, and 25% of the total needed pharmaceutical management forms were reproduced/distributed this quarter giving us 75% for Q2 and Q3 accomplishments. The remaining 25% of the forms are to be completed and distributed to priority provinces following the distribution plan prepared by the MOH/PNME.

Sub-Objective 2.1
Health facility human resource pharmaceutical management capacity improved

Progress toward sub-objective 2.1
There was a significant increase in number of the health staff trained in pharmaceutical management. This is the result of capacity-building trainings and continued follow-up supportive supervision undertaken in the previous quarters. The EUV survey has captured the impact of supervision and other technical support provided in the peripheral health units. Pharmaceutical management forms were distributed to the provinces as follows: Stock records = 142,000; Livro de registo = 2,370; Weekly balance sheets = 100,500; and prescription pads = 96,000. Another reproduction of the same forms in underway. Additional forms were reproduced in the second batch. Collaboration with CUAMM was enhanced in relation to the supervision and training at the provincial level.

Main challenges for sub-objective 2.1
There were limited funds in the pipeline that led the training in Zaire to include the provincial warehouse management training, as well. The HR assessment to determine the Angola MoH capacity-building has not yet materialized. The delayed reproduction of forms affected the distribution to the provinces.

Steps to address challenges for sub-objective 2.1

A corporate account has been opened to facilitate the project fund flow to the country and on-going visa preparation for MSH HR consultant in underway. Intensive follow-up with the supplier of forms have been undertaken.

Sub-Objective 2.2
Capacity of DNME/PNME and key MOH program central-level staff to conduct follow up supportive supervision of peripheral health units improved

Progress toward sub-objective 2.2
The finalization of the integrated supervision tool is in progress. The four programs (essential medicines, HIV/AIDS, TB and reproductive health) have reviewed the tools and provided their comments and inputs.

Main challenges for sub-objective 2.2
There have been major challenges related to cooperation of malaria program staff. Some of the NMCP staff are paid through GF resources, and have been uncooperative and hard to access, due to delayed payment of their salary. We are waiting for their input to have the tool finalized. The integrated supervision is pending until the new tool is finalized.

Steps to address challenges for sub-objective 2.2
Continuous follow-up with NMCP.

Objective 3
Information for pharmaceutical management decision-making improved

Objective 3: Quarterly progress
The EUV survey report is the only monitoring tool that was used to gather information related to LMIS and supply chain management during this quarter. A feedback meeting with MoH program partners was held as a platform to share and disseminate the results of the EUV report, highlighting the issues affecting the supply chain and LMIS from the provincial level down to the health units. The EUV report has given the MoH partners an opportunity to assess and take steps to correct and improve pressing issues and challenges in the field.

Sub-Objective 3.1
LMIS strengthened to enable evidence-based decision-making

Progress toward sub-objective 3.1
SIAPS initiated preparatory planning for the upcoming assessment, and conducted an initial mapping and gathering of information related to the logistics management information system with PNME and CECOMA, including the existing 15 LMIS forms and their use, and existing information and commodity flows from the central down to the health units' levels.

Main challenges for sub-objective 3.1
Delayed deployment of technical consultant(s) to carry-out the rapid supply chain and LMIS assessments.

Steps to address challenges for sub-objective 3.1
Opening of program bank account, new office premises, application for in-country registration were well advanced, and STTA travel planning is in progress.

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

Progress toward sub-objective 3.2
SIAPS conducted the EUV survey in 8 provinces, 23 municipalities and 36 health facilities (8 provincial warehouses and 28 health units). Staff held a feedback meeting with the provincial directors and national program coordinators and submitted the EUV report on time. SIAPS also submitted the second quarter PPMRm report during this quarter.

Objective 4
Pharmaceutical services strengthened to achieve desired health outcomes

Objective 4: Quarterly progress
SIAPS collaborated with USAID/DELIVER in providing TA to the MOH/DNME to process documents to facilitate arrival, receipt and distribution of related to PMI-funded commodities to 18 provinces (ACT=1,800,840 blisters and RDT=862,150 tests).

Sub-Objective 4.1
Public procurement and supply chain management system strengthened to improve availability of pharmaceutical

Progress toward sub-objective 4.1
SIAPS coordinated with USAID/DELIVER in providing TA to the MOH/DNME to process documents to facilitate arrival, receipt and distribution of related to PMI-funded commodities to 18 provinces (ACT=1,800,840 blisters and RDT=862,150 tests).

Main challenges for sub-objective 4.1
Delayed deployment of STTA consultant(s) to assist CECOMA conduct assessment of SCM/LMIS

Steps to address challenges for sub-objective 4.1
Opening of program bank account, new office premises, application for in-country registration and STTA travel planning.

Sub-Objective 4.2
MOH PV system strengthened to improve safety and use of medicines

Progress toward sub-objective 4.2
SIAPS supported the MOH/PV Unit Director to attend the African Regional PV Meeting in Kenya. With SIAPS assistance, the PV department has completed 3 PV awareness training in 3 health units in Luanda City with 33 health personnel (15 doctors, 15 nurses and 3 pharmacy technicians). The PV Unit received 5 ADR reports from the field.

Main challenges for sub-objective 4.2
Delayed deployment of the technical consultant(s) to assist the PV department.

Steps to address challenges for sub-objective 4.2
Processing of visa to travel to Angola.

Bangladesh

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

The SIAPS Program has the lead role in strengthening the procurement management system of DGFP. This has resulted in most of the procurement packages being on course under FY 2012-13 plans, which will help to eventually ensure availability of contraceptive commodities at the field level. As a follow-on of the strategic plan development workshop for the MOHFW procurement management system, SIAPS conducted a workshop for the finalization of the Draft Strategic Plan on MOHFW Procurement Management in the presence of stakeholders and the Senior Secretary. The Implementation Plan will be finalized and submitted to the MOHFW. Additionally, in order to ensure governance and transparency in procurement, SIAPS demonstrated the procurement portal system to the Health Minister and Senior Secretary who decided that all line directors must to prepare their FY 2012-13 procurement plan using the portal during the second week of July 2012.

The Ministry has created the Procurement and Logistics Management Cell (PLMC) to oversee procurement activities and SIAPS is providing logistics and technical support (sessions, mentorship and placement of consultants within the MOHFW) for its smooth operation. The SIAPS technical team is working to revise the DGFP Supply Manual to incorporate the condemnation process. The finalization workshop is planned to be held in July 2012. SIAPS facilitated monthly procurement meetings to share the update on the current procurement and logistics status and challenges. The program also published monthly reports (stock status, PPMRm, etc.) which were all disseminated to the stakeholders. In order to ensure the availability of products at the service delivery points, SIAPS facilitated the preparation of the forecasting exercise of RH commodities for the next ten years, with different scenarios and a funding gap analysis in consultation with the relevant stakeholders. This concept note will be presented by the Health Minister at the FP summit in late 2012. The draft reports on RH and TB quantification have been submitted to the SIAPS team.

SIAPS provided support to the NTP to prepare the PSM plan for the next round under the Global Fund. With NTP, SIAPS developed a roll-out plan for e-TB manager. SIAPS is also planning to conduct an assessment on the existing commodity management system of NTP, in order to develop specific recommendations and action plans. SIAPS has already started working with the DGDA to strengthen its capacity in the promotion of patient safety. The team has facilitated meetings and workshops with DGDA to prepare an action plan. In collaboration with the FDA and University of

Washington, SIAPS is currently assessing the regulatory system and pharmacovigilance system of the DGDA, to strengthen the capacity for regulatory, monitoring of safety, quality, and effectiveness of medicines in Bangladesh.

Key challenges of quarter

The main challenge this quarter to SIAPS is the delay in getting USAID approval for the contract with local IT firm, Softwork. This delay is affecting:

- Rolling-out of eTB manager, UIMS
- Upgrading the MOHFW Supply Chain Management Portal (SCMP) and DGFP Supply Chain Information Portal (SCIP)
- Development of TB-LMIS and Drug registration database

Other challenges include the in-operational status of the Upazila (Sub-district) Inventory Management System at different sites, due to lack of human and technological resources. SIAPS has experienced delays in hiring technical staff: We are often not receiving the high quality of applicants as we would like which is requiring additional time in advertising.

Key activities for next quarter

- Launching of DGFP Procurement Procedures Manual
- Development procurement plans of all line directors of MOHFW using the Supply Chain Management Portal
- Dissemination report and training on quantification exercise of RH and TB commodities
- Publication of revised DGFP Supply Manual
- Support for the smooth functioning of the Procurement and Logistics Management Cell (PLMC) within the MOHFW
- Introducing the pipeline monitoring system at the NTP
- Facilitating a ToT on Upazila Inventory Management System
- Roll-out of e-TB Manager to new sites
- Development of MOHFW Procurement Strategic Plan
- MOHFW Procurement Procedures Manual
- Development of TB-LMIS
- Finalization of RSAT and PV assessment of DGDA

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 developed the MOHFW supply chain management portal for all procurement packages. In order to ensure the availability of products at service delivery points, SIAPS facilitated the forecasting exercise of RH commodities for the next ten years with different scenarios and a funding gap analysis in consultation with the relevant stakeholders. This concept note will be presented by the health minister in the FP summit in late 2012.

SIAPS is working closely with MOHFW for smooth functioning of the PLMC, and is also working with MOHFW and its key stakeholders to introduce e-procurement and a 2 year procurement cycle for ICB. SIAPS is in the process of recruiting a qualified candidate to be embedded in the MOHFW to lead the procurement process and coordinate the PLMC establishment.

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.

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 meetings with DGFP and DGHS/CMSD to monitor the procurement progress.

Main challenges for sub-objective 1.1
DGFP's delay in issuing award of contract to the bidders.

Steps to address challenges for sub-objective 1.1
SIAPS is closely working with MOHFW and DGFP to address this challenge.

Deliverables for sub-objective 1.1
- Quantification Exercise report
- Strategic Planning Workshop Report
- DGFP Procurement Procedures Manual

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
• SIAPS continues to work closely with MOHFW to operationalize the PLMC.
• An external consultant on a long term assignment is working within the MOHFW and PLMC to ensure the continuity of the activity. In addition, SIAPS going to recruit a procurement technical advisor who will work with the PLMC on all procurement issues at the MOHFW.
• A local consultant has been recruited to work on the implementation of the framework contract and two year procurement cycle system.

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

Objective 2: Quarterly progress
SIAPS is in the process of reviewing the DGFP supply manual, with the help of the MOHFW steering committee, and has managed to organize a series of workshops and meetings. In addition, the team continued to provide scheduled on site TA visit to the FP store and regional warehouses as well as troubleshooting visits. The STA Logistics and the 5 TA Logistics continued to provide onsite TA on inventory management, LMIS and family planning commodity management. The program managed to facilitate the quarterly logistics management meeting. Joint monitoring visits for providing on-the-job training continued.

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
The revision of the supply manual is in progress. The revision will include the updated waste removal process, cleaning, work flow analysis, etc. SIAPS will hire an independent consultant to do a feasibility and option analysis for introducing integrated WMS into the DGFP and DGHS.

Deliverables for sub-objective 2.1
Inclusion of chapters on the condemnation process and cleaning in the revised DGFP Supply Manual. Feasibility and options analysis report on WMS.

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

Sub-Objective 2.3
Support to develop a monitoring and supportive supervision framework and system for MOHFW

Progress toward sub-objective 2.3
The SIAPS team is conducting Joint-monitoring visits regularly with the DGFP central and regional level officers.

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

Objective 3: Quarterly progress
The MOHFW SCMP is ready to prepare procurement plans for the 32 Line Directors. The DGFP SCIP, Pipeline, UIMS, WIMS, and e-TB Manager are all functional.

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 Q3 no news sites were installed with UIMS. The roll-out plan for 312 upazilas is developed and SIAPS support continues for UIMS functioning. The TOT manual is developed and a regional based TOT was planned in May 2012 but could not be organized due to the delayed approval of the Softworks contract.

Main challenges for sub-objective 3.1
The delayed contract approval for the Softworks Contract.

Steps to address challenges for sub-objective 3.1
MSH contracts team continues to provide all requested information to USAID/W in a timely fashion.

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

Progress toward sub-objective 3.3
Reports, newsletters, success stories are being produced and shared with clients and stakeholders.

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
In order to strengthen the capacity of Government officials, SIAPS is discussing with a national teaching institution the possibility of a collaboration to provide professional training on supply chain management including procurement, logistics and quantification techniques, etc.

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
Sponsored cross-learning study tour at SMC and EDCL for DGFP staff.

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

Progress toward sub-objective 4.2

SIAPS facilitated the forecasting exercise of RH commodities for the next ten years with different scenarios and a funding gap analysis in consultation with the relevant stakeholders. This concept note will be presented by the health minister in the FP summit 2012.

Objective 6

Strengthen pharmaceutical management systems for TB.

Objective 6: Quarterly progress

- Support for existing sites continued.
- The development of TB-LMIS is underway and a demo version will be shared in next quarter.

Sub-Objective 6.1

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

Main challenges for sub-objective 6.1

The delay in the approval of the Softworks contract has affected the ability of the SIAPS team to roll out the eTBM and start the development of the TB-LMIS.

Deliverables for sub-objective 6.1

- TB-LMIS presentation
- Trip report on e-TBM

Brazil

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

SIAPS continued working on the implementation of all planned activities. Highlights were SITETB's implementation (achieving almost 100% of the activities planned, to date). The pilot phase was finalized and the evaluation of the exercise was very positive. SITETB was not only was approved by key personnel from Brazil's MoH, but was requested to be implemented in all TB reference centers. SIAPS staff is concentrating on sustainability of interventions by focusing on transmitting all technical knowledge and skills to the government's staff.

Key activities for next quarter

- Support clinical management training for Minas Gerais and Mato Grosso states. Conduct training for the secondary and tertiary references from Minas Gerais, the last state to be trained.
- Update the SITETB User's Manual.
- Elaborate SOP for case validation and medicine orders.
- Monitor implementation of the culture decentralization plan in key labs/states.
- Finalize translation of the GLI/WHO Biosafety manual into Portuguese and develop NRL biosafety operational plan (based on GLI/WHO guidelines) to be submitted to NRL for approval.
- Complete smear microscopy proficiency testing report from 2011 to be submitted to NRL for approval.
- Conduct one Labmost workshop for staff of Adolfo Lutz Institute (São Paulo City Public Health Lab) focused on biology area.
- Explore with Adolfo Lutz Institute board of directors and INCQS possibility to conduct workshops for the 5 regional/municipal public health labs of São Paulo State. SIAPS to follow-up implementation of the action plan developed in September 2011 for Pernambuco

State Public Health Lab.

- Explore incorporation of Labmost methodology by CGLAB and GGLAS/ANVISA as an official tool to support lab quality management initiatives and Anvisa financial support to public health lab network

Objective 1

Strengthen TB pharmaceutical management and information systems

Objective 1: Quarterly progress

SITETB's implementation is on track with our goals for this year. Our indicators demonstrate that we have reached almost 65% of all our planned reference centers using the SITETB system. SIAPS is progressively transmitting responsibilities to CRPHF's staff, to ensure the full ownership by the end of the project. The medicine quantification worksheets were fully incorporated by CRPHF's staff. The SIAPS team is only reporting through SITETB.

Sub-Objective 1.1

Support incorporation of key drug management achievements and policies within the public health system

Progress toward sub-objective 1.1

Training was conducted for the secondary and tertiary references from Distrito Federal and Mato Grosso, in Brasília, with PNCT's support (transportation and per diems of participants from Mato Grosso). The total number of participants was 24 (9 men and 15 women). SIAPS conducted a training for second -line medicine management in Brasília (24 participants: 15 women and 9 men). The inventory model was applied in 3 hospitals (Hospital de Referência Santa Maria, Hospital dos Servidores, and Hospital Getúlio Vargas) with SIAPS support.

2 trainings were conducted for CRPHF pharmacists: one on XDR medicine purchase through PAHO (1 female participant) and one on medicine forecasting calculation (1 female participant). Training was also held on good pharmaceutical practices for CRPHF's pharmacy staff (3 participants: 2 women and 1 man). Jointly with NTP, SIAPS conducted the Second National Workshop on Quality Control of TB Drugs for 22 attendees (14 females and 8 males). Participants included individuals from NTP/SVS, NIES/SVS, DAF/MoH, MSH/SIAPS, INCQS and the public health TB labs of São Paulo, Amapá, Bahia, Ceará, Goiás, Minas Gerais and Pernambuco States. During the workshop, attendees defined key proposals and recommendations to support the reactivation of TB quality control program, selected focal point persons for all institutions involved, and nominated a working group to review and update the TB quality control proposal drafted in 2010.

Main challenges for sub-objective 1.1

The reactivation of TB quality control program was delayed (the workshop will happen next quarter), due to the complexity of articulation among different government sectors involved. NTP has not received a response concerning the request for inclusion of TB reference substances in the production portfolio of the Brazilian Pharmacopeia. INCQS did not perform the two remaining sample analyses due to internal issues.

Deliverables for sub-objective 1.1

- Training material for the Reference Centers Medicine Management
- Worksheets of the medicine movement report.
- Worksheets on monthly distribution.

Measureable contributions of partners for sub-objective 1.1

PNCT's collaborated on the training for secondary and tertiary references from Distrito Federal and Mato Grosso in Brasília.

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

A meeting was conducted with PNCT's for presentation of the SITETB system and registration of users. A meeting for SITETB's piloting phase evaluation was conducted with representatives from all 4 states involved, as well as individuals from PNCT, DATASUS, GT SINAN, DAF, CRPHF and SIAPS. During this meeting all SITETB's modules (cases, medicines and management) were evaluated. Several suggestions were given for the system's improvement and information adequacy. Overall, SITETB's evaluation was very positive, leading to approval for the implementation in all remaining states. An implementation schedule was elaborated: 12 states will be trained until December 2012 (Paraíba, Pernambuco, Rio de Janeiro, Ceará, Rio Grande do Norte, são Paulo, Maranhão and Piauí) and 11 states will be trained until the middle of April 2013 (Amazonas, Amapá, Roraima, Rondônia, Acre, Mato Grosso, Mato Grosso do Sul, Distrito Federal, Goiás, Minas Gerais and Tocantins).

Two meetings were conducted with the DATASUS team, GT, SINAN, PNCT and CRPHF for establishing a schedule for SITETB's maintenance/management's full transfer to DATASUS/MS and PNCT. The planned schedule for the system to be hosted at DATASUS is April 2013, after all states have been trained and all cases migrated from TBMR system to SITETB. All respective reports were registered. After SITETB's evaluation meeting and Technical Information Group (CTA/PNCT) meeting, discussions about the interoperability between SITETB and TBWEB were re-initiated. A meeting was scheduled with CVE (PECT/SP), PRODESP and SIAPS for the beginning of Q4. A tool for monitoring and evaluation of DR-TB reference centers was developed; this tool was applied as pilot test in Piauí State reference center, during PNCT's monitoring visit. A monitoring and evaluation plan will be developed by PNCT.

Currently PNCT does not manage SITETB. Professionals from PNCT will participate in all state trainings, and will progressively be part of the team that manages SITETB. 2 SITETB trainings were conducted in PB and PE and 26 medicine orders were attended to, received through the SITETB system.

Objective 2

Support TB state programs in strengthening DOTS and community DOTS implementation

Objective 2: Quarterly progress

Monthly support was initiated for 9 municipalities of Rio de Janeiro's metropolitan region. This support was in the form of a car rental for implementing TB control activities and strengthening DOTS strategy. Activities planned with PECT/SP are still pending USAID approval.

Sub-Objective 2.2
Support DOTS implementation with RJ State TB Program

Progress toward sub-objective 2.2
SIAPS continued supporting 9 municipalities in Rio de Janeiro's metropolitan region, by supporting DOTS strategy through car rental for development of routine program control activities. The municipalities included: Rio de Janeiro, Nova Iguaçu, Duque de Caxias, Belford Roxo, Mesquita, Itaboraí, Queimados, Itaguaí and Magé.

Report containing the activities performed with the car rental:

- Searching for respiratory symptoms within communities: 37
- Searching for respiratory symptoms in health units: 61
- Activities in health education/promotion of TB in the community: 12
- Activities in health education/promotion of TB in schools: 5
- Activities in health education/dissemination of TB to health facilities with: 36
- Integration activities between TB and HIV/AIDS programs: 2
- Delivery of incentives and facilitators for DOT: 35
- Delivery of laboratory test results: 73
- Meetings with PCT's staff: 34
- Meetings with health facility managers: 24
- Meetings with PECT (State Program for TB Control): 5
- Meetings with PMCT (Program Municipal TB Control): 10
- Transporting samples to laboratories: 69
- Medicine transportation: 30
- In-service training (hospitals/emergency units): 3
- In-service training (basic health units/Family Health teams): 96
- Monitoring visits (information recording instruments): 141
- Supervisory visits to health facilities: 145
- Home visits for strengthening adherence: 51
- Home visits to rescue defaulters: 70
- Home visits to patients under DOT: 56
- Delivery of supplies and printed materials: 2

Deliverables for sub-objective 2.2
Report on DOTS implementation.

Objective 3
Strengthen Hélio Fraga National TB Reference Center Activities and the Public Health TB Laboratory Network

Objective 3: Quarterly progress
SIAPS provided technical support for strengthening CRPHF's activities through participation in

meetings, staff training, and transfer of technical knowledge. SIAPS also worked on the establishment of standardized forms (lab exam requisition), approved by NTP, to collect official WHO TB indicators countrywide. A lab supplies spreadsheet, developed by SIAPS and approved by NRL, was distributed to the public health TB lab network for use. The Labmost tool was applied in Adolf Lutz Institute, one of the biggest public health laboratories in Brazil.

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

Progress toward sub-objective 3.1
Training was conducted on pharmaceutical assistance and SOP application for the CRPHF's pharmacist (1 female participant). SIAPS acquired materials for accomplishment of all criteria for accreditation at ONA's level 1. The culture decentralization plan was approved by NTP and database assessment (using GAL and SINAN systems) to evaluate culture and DST coverage in key states began, as the first step for implementation. Teaching material and presentations were prepared. The public health TB lab network management training was conducted at CRPHF for 29 lab and NTP staff (22 females and 7 males). Difficulties and suggestions were presented by the labs during a course delivered by NRL and MSH to NTP and CGLAB.

SIAPS participated in meetings with São Paulo State TB program and NTP. At this meeting, the final revision of standardized forms (lab exam requisition) was approved by NTP and the data collection template now allows collection of official WHO TB indicators countrywide. SIAPS also participated in meetings with CGLAB and provided technical support for GAL system implementation at NRL and public health TB lab network in revising data entry fields for DR-TB automated epidemiological reports. SIAPS participated in meeting with NTP and partners to finalize the Brazilian DR-TB Control Plan draft (lab component), as agreed with PAHO/WHO in 2011.

SIAPS provided technical support for a critical analysis of drug sensitivity test (DST) proficiency program for 17 public health labs (27 labs have been evaluated to date: one lab per state). Recommendations and corrective measures were defined and a final report drafted and submitted to NRL for approval and dissemination.

SIAPS supported NRL in an analysis of remaining DST results (mainly focused on retests for Bahia State samples) for the second national resistance survey. The final report was drafted and submitted to NRL for approval and dissemination. NRL was also supported in proposing new adjustments on performance and quality indicators templates for NRL and public health TB lab network evaluation. Two posters regarding ISO 17025 quality norm and the quality management system's ongoing implementation process at NRL were presented during the 28th Society of Quality Assurance Conference in Miami (USA). The lab supplies spreadsheet developed by SIAPS and approved by NRL was distributed to the public health TB lab network for use. With NRL, SIAPS made a technical supervision visit for Rio Grande do Norte public health lab as part of the NTP's task force for evaluation of TB state programs. The supervision report drafted and disseminated. SIAPS supported the application process for a Customer Satisfaction Survey (developed with NRL) for the public health TB labs network. A report with results analysis and recommendations was drafted, approved by NRL, and delivered to public health TB labs,

NTP/SVS and CGLAB.

SIAPS prepared a checklist to assist the accreditation process for NRL and support strategies to implement the quality management system, based on the ONA guidelines. SIAPS also supported a partial translation of the GLI/WHO biosafety draft manual into Portuguese and drafted the NRL biosafety operational plan (based on GLI/WHO guidelines), including an implementation checklist. SIAPS supported a partial translation of the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) Checklist from WHO/Africa, into Portuguese. The final document will be further adapted for NRL and public health lab network.

Smear microscopy proficiency testing results from 2011 were released by the provider: SIAPS started to draft a final report with recommendations and corrective measures to be further approved by NRL and CGLAB.

Main challenges for sub-objective 3.1
The Fiocruz Biosafety Department did not send the evaluation report from the visit performed in the beginning of November 2011: this is the only item pending CRPHF's Pharmacy Accreditation at Level 1. The New Quality Committee still needs to be designated by CRPHF's new board.

NRL has not had an officially nominated quality manager since October 2011, making the quality management improvements process very difficult. Meetings with NRL and CRPHF Reference Ambulatory to harmonize DR-TB diagnosis procedures were interrupted by request of the new appointed ambulatory coordinator.

The CRPHF quality commission was dissolved in November 2011, by request of the newly elected CRPHF direction board. The bidding process to select the company in charge of providing the smear microscopy proficiency testing program for 2012 was delayed and, therefore, related activities are delayed until October or November 2012.

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
Poster regarding Labmost methodology and its implementation experienced in Brazil presented during the 28th Society of Quality Assurance Conference in Miami (USA). SIAPS conducted two meetings with Adolfo Lutz Institute (São Paulo State) board of directors and INCQS for workshop definitions and arrangements. SIAPS carried out jointly with INCQS one Labmost workshop for 25 staff (23 females and 2 males) of Adolfo Lutz Institute (São Paulo City Public Health Lab) focused on products area (medicines, cosmetics, sanitizers and food).

Main challenges for sub-objective 3.2
Due to the complexity of articulation among different government sectors the incorporation of Labmost methodology by CGLAB and GGLAS/ANVISA was not done.

Burundi

Portfolio Background

Malaria is considered a major public health problem in Burundi and places a heavy burden on the health system. According to Ministry of Public Health (MOPH) statistics, malaria is responsible for up to 60% of all outpatient visits and up to 50% of deaths occurring in health facilities among children under five years of age. Almost the entire population of Burundi lives in areas at risk of malaria. Plasmodium falciparum accounts for more than 90% of all infections.

The malaria control strategy in Burundi includes: Improving accessibility to effective antimalarial drugs; prevention of malaria through the use of insecticide-treated nets (ITNs) and indoor residual spraying and; early detection and control of epidemics. Ensuring prompt, effective, and safe ACT treatment to a high proportion of patients with confirmed or suspected malaria in Burundi continues to represent one of the greatest challenges for the PNILP given the weaknesses in the country's pharmaceutical management system, poor access to health services, and the lack of accurate laboratory diagnostic capabilities.

The Strengthening Pharmaceutical Systems (SPS) Program received field funding from USAID/Burundi in 2009 and 2010 to address pharmaceutical management challenges in malaria control in Burundi, build capacity of the PNILP, provide assistance to develop strategic and policy documents and their implementation as well as play a coordination role for all USAID short-term assisted technical assistance in Burundi.

With FY11 funding, SIAPS will continue to build upon the work carried out with FY09 and FY10 funding to ensure that pharmaceutical sector governance is strengthened, the capacity for pharmaceutical supply management and services is increased and enhanced, information for decision-making challenges in the pharmaceutical sector are addressed and that pharmaceutical services improved to achieve desired health outcomes. All the above objectives will contribute to the SIAPS intermediate results and objectives as well as USAID/Burundi's objective of reducing the mortality and morbidity due to malaria in Burundi.

Quarter Overview

The Burundi team started transitioning from SPS to SIAPS during March 2012. During this quarter, activities were completed under both programs. During the reporting period, SIAPS assisted the PNILP in the coordination of all Roll-Back Malaria (RBM) stakeholders around the implementation of the joint work plan developed in January 2012. On April 16, 2012, a 1-day quarterly evaluation meeting was organized to evaluate and track progress towards the implementation of PNILP's work plan. Achievements during the quarter (Jan-March) were highlighted. PNILP was able to implement 33% of planned activities during Q1 of 2012. The joint work plan was adapted accordingly for the coming quarter (April- June).

SIAPS continued to provide technical assistance to the PNILP to improve its organizational structure and managerial skills. In July 2011, an evaluation of the organizational structure of the PNILP was conducted using the MOST evaluation tool. From the evaluation recommendations were made to strengthen the PNILP structure by revising its legal status to upgrade the institution to an autonomous entity with an updated organogram, capacitating the staff by providing local

trainings: mostly in leadership management, communication, basic computer skills, data management and English, equipping the PNILP with IT equipment, office equipment and communication means (internet, telephone, etc.). On May 14, 2012, the PNILP organized an internal dissemination meeting of findings and recommendations of the MOST assessment with all staff. SIAPS identified a list of "must have" trainings (English, IT and computer skills) for PNILP staff and potential trainers. The training sessions will start in September.

During the reporting period, SIAPS contributed financially to the successful organization of the World Malaria Day on May 4, 2012 under the patronage of His Excellency the President of Burundi. The World Malaria Day events coincided with the official launching of a new insectarium (laboratory of entomology) located in Gihanga. The SIAPS contribution to the opening of the insectarium was to provide the air conditioners upon the request of the PNILP.
To strengthen the supervision system of health facilities, SIAPS assisted the various departments within the Ministry of Health and the PNILP to design the supervision system. From June 12 - 14, 2012, SIAPS leveraged funds with UNICEF to support the Ministry of Health/Directorate of Service Delivery to organize a 3-days retreat on the development of a harmonized supervision guide for district teams while conducting formative supervision at the health center level. The harmonized supervision guide developed for the district level is based on the minimum package of activities of the health center as defined by the Ministry of Health. 32 Participants coming from 14 Institutions (PSI, MSPLS, PRONIANUT, PNLS, PNILP, EIP, PNILT, WHO, UNICEF, IMAD, SIAPS, PATHFINDER, BELGIAN COOPERATION, AMAGARA MEZA) gathered at Gitega to develop the harmonized supervision guide for district management team. The harmonized supervision guide will be validated in a larger group in August. Once validated, the orientation to all health care professionals will follow.

From June 21 -22, 2012, SIAPS assisted the PNILP with stakeholders to develop a harmonized supervision checklist for malaria while the central level is supervising the district and facility levels. This supervision checklist focuses on five areas: case management of malaria, diagnostics/laboratory, pharmaceutical management, prevention, and data management/reporting. The check list will be field-tested in 15 districts during the month of July. The check list was developed in close collaboration with 15 representatives from 10 institutions (PSI, IMAD, PNILP, DPML, SEP/CNLS- Malaria, LNR/INSP, DSNI, AMAGARA MEZA, MSPLS/DODS and SIAPS).

To strengthen the case management of malaria SIAPS assisted the PNILP to finalize the review of the malaria treatment protocol. The new treatment protocol is being edited and will be disseminated to all health care professionals starting July 2012 through trainings. SIAPS assisted the PNILP to develop job aids and algorithms that will be disseminated with the printed version of the new guidelines to all provincial and district teams. A dissemination plan was developed and shared with all involved partners (PNILP, USAID/IMAD, SEP-CNLS/GF sub-recipient). Necessary funds for trainings, review of the training materials, printing of the new protocol brochure, printing of job aids will be leveraged among the partners. SIAPS will fund the printing, the review of the training material and the training of trainers both at central and district level.

SIAPS continues to work closely with the ESD Project managed by PATHFINDER INTERNATIONAL to follow-up on the implementation of a piloting community case

management of malaria in 2 districts. During the reporting period, SIAPS continued to organize supervision visits in 14 health centers (out of 25) to ensure that ACTs, RDTs and other commodities needed by CHWs are available. During the supervision visits, monthly coordination meetings were called for all the CHWs within the health centers catchment areas. 128 CWHs attended the meetings and received refresher training on the management of commodities and reporting tools (mostly on the filling of stock card, requisition form and the case management report). The supervision visits showed that CHWs are capable to diagnose and treat malaria. But the challenge remains on the availability of stock for ACTs and RDTs. Most health centers encounter shortages of stock as the resupply system at community level is not well organized. Based on those findings, SIAPS assisted the PNILP and the 2 district authorities to organize a 1-day meeting with authorities of all 25 health centers in the 2 districts piloting the CCM to discuss and adopt strategies to improve the requisition and re-supply system at the community level as well as the supervision system of CHWs. From the meeting, all 25 health centers were capacitated to calculate the Average monthly consumption (AMC) to be used for future requisitions to avoid stock outs.

As a preliminary step to assist DPML, CAMEBU and PNILP to establish a strong Pharmacovigilance system in Burundi, SIAPS funded counterpart participation in the Africa Pharmacovigilance Meeting 2012, held in Nairobi, Kenya from April 18 - 20, 2012. Three participants from Burundi attended the conference: the Director-adjoint of PNILP, 1 pharmacist from CAMEBU in-charge of the Supply Unit (Chef du Service Approvisionnements) and 1 SIAPS staff. The meeting was co-organized by the Kenya Ministry of Health, the Kenya Pharmacy and Poisons Board; and the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program. As an immediate next step, SIAPS will assist the DPML to organize a dissemination of the trip report to all the Thematic group of medicines members to share best practices and tools needed to support the set-up of the pharmacovigilance system in Burundi. During the next quarter, SIAPS will assist the DPML to conduct an evaluation of the current PV system using the IPAT Indicators Assessment Tool and then present findings during a stakeholder's awareness meeting.

Key challenges of quarter

Some activities that were originally planned for in the SIAPS FY 2011 work plan have been delayed or will not happen this year due to delays or changes in priorities within the Government of Burundi. The IPTp is not yet a priority for the GoB, neither is the development of an improved and costed M&E plan which has been postponed until the development of the PNILP strategic plan for 2012-2015 is complete (planned for early 2013).

During Q3, implementation of many activities was not possible, due to conflicts of agenda. The PNILP cannot accommodate 2 activities at the same time. The other challenge is inaccurate and inconsistent information reported on the management/consumption of malaria commodities at the peripheral level. This situation impacts the distribution of commodities, resulting in shortages and stock-outs.

Key activities for next quarter

- Complete PPMRm for April - June and analyze the stock status of malaria commodities, both at CAMEBU and peripheral level.

- Advocate for the implementation of an EUV survey planned in August.
- Conduct the quantification training at the central level and develop a quantification report for the malaria commodities needed in 2013 (ACTs, RDTs, laboratory reagents, etc.), including the new molecules added in the new STG for malaria.
- Present the quantification report of LLINs distributed through routine ANC and immunization services to all involved stakeholders and fundraise to purchase the needed quantities of LLINs.
- Collaborate with the DPML and Amagara Meza to begin the design of an LMIS to put in place in Burundi for essential medicines including ACTs and RDTs.
- Analyze data on the morbidity/consumption of malaria commodities reported from the peripheral level during January to December 2011 and present analysis to stakeholders within the thematic group of medicines for decision making.
- Assist DPML in the literature review as a preliminary step to develop a strategic plan for 2013-2015.
- Recruit a consultant to develop a procedures manual on administrative and financial management within the PNILP.
- Continue to provide equipment to PNILP whenever a need is identified.
- Assist the PNILP to organize the 2012 Q2 evaluation meeting to track progress towards the joint work plan.
- Organize the leadership and management training for DPML, PNILP and other members of the thematic group of medicines.
- Continue to support the dissemination of the new STG for malaria.
- Leverage funds with the SEP/CNLS-Malaria managing GF money to field- test the supervision check list of malaria in 30 districts and disseminate findings in a stakeholders meeting for adopting strategies to reinforce the coaching/capacity building at the district level.
- Supervise additional HC and CHWs in the 2 districts piloting the CCM of malaria.
- Conduct the evaluation using IPAT indicators to establish a strong PV system.

Technical Activity Coordination

Technical staff meetings were organized on a bi-weekly basis and calls with the portfolio managers were organized on monthly basis to track implementation progress of the FY 11 work plan. A budget was planned for the period of April – September 2012 for the SIAPS pipeline. From April 23 to May 4, SIAPS participated in the development of the Malaria Operational Plan for FY12 in collaboration with the USAID local, USAID Kenya and PMI Washington teams.

Office Management

Included finance and administrative support, local office rental, and associated costs (security, communication systems, etc.).

Objective 1

Organizational and management Capacity of PNILP to develop policies and strategies Strengthened

Objective 1: Quarterly progress

During the reporting period, SIAPS assisted the PNILP in the coordination of all Roll-back malaria (RBM) stakeholders around the implementation of the joint work plan developed in January 2012. On April 16, 2012, a 1-day quarterly evaluation meeting was organized to evaluate and track

progress towards the implementation of PNILP's work plan. Achievements during the quarter (Jan-March) were highlighted. PNILP was able to implement 33% of planned activities during Q1 of 2012. The joint work plan was adapted accordingly for the coming quarter (April- June). SIAPS continued to provide technical assistance to the PNILP to improve its organizational structure and managerial skills. In July 2011, an evaluation of the organizational structure of the PNILP was conducted using the MOST evaluation tool. From the evaluation recommendations were made to strengthen the PNILP structure by revising its legal status to upgrade the institution to an autonomous entity with an updated organogram, capacitating the staff by providing local trainings: mostly in leadership management, communication, basic computer skills, data management and English, equipping the PNILP with IT equipment, office equipment and communication means (internet, telephone, etc.). On May 14, 2012, the PNILP organized an internal dissemination meeting of findings and recommendations of the MOST assessment with all staff. SIAPS identified a list of "must have" trainings (English, IT and computer skills) for PNILP staff and potential trainers. The training sessions will start in September.

Objective 2
Pharmaceutical Management Capacity Strengthened

Objective 2: Quarterly progress
During the month of April SIAPS completed and submitted the PPMRm files with supply chain data from January through March 2012 and analyzed the pipeline to identify and anticipate problems of stock out or expiries. The files were shared with the PNILP, SEP/CNLS- Malaria- GF and the USAID/PMI team Burundi for inputs and comments. From the PPMRm analysis, quantities available at CAMEBU are sufficient for nationwide distributions till December, 2012, but the 6-month security stock is not enough at CAMEBU. During the same period, the SIAPS Burundi team developed and discussed the malaria commodities (ACTs, RDTs) gap analysis for 2012/13/14 with SEP/CNLS- Malaria- GF/PR and USAID/PMI, both the local and Washington teams. The 6-month security stock estimates for ACTs and RDTs for 2012/13 were ordered by USAID/PMI and Global Fund. Products will be delivered starting December 2012.

In the month of June, the USAID local mission requested SIAPS to collaborate with PSI and the PNILP in reviewing the 2012 quantification of long lasting nets (LLINs) distributed during the routine ANC and immunization services for prevention of malaria to pregnant women and children under 1 year. The group identifies gaps in estimated quantities for 2012 and also developed quantifications for 2013. The estimations were presented to the PNILP Director. A meeting with key stakeholders (USAID, UNICEF/GAVI, Global Fund) involved in the procurement of LLINs distributed in routine ANC and immunization services will be organized later to fundraise the required amount.

SIAPS continued to advocate for the establishment of a formal national quantification committee with all stakeholders involved in the pharmaceutical sector through the leadership of DPML (Directorate of Pharmacy, Medicines and Laboratories). During the reporting period, SIAPS assisted the DPML to organize meetings of the "Thematic group of medicines" where all stakeholders involved in pharmaceutical management meet to discuss pharmaceutical management and adopt appropriates decisions. During May, the Thematic group discussed the management of ACTs: currently, malaria commodities (ACTs, RDTs) are available in sufficient

quantity at the central medical stores level (CAMEBU) while the peripheral levels (District pharmacies, health centers) are encountering shortages. The Thematic group analyzed the roots of this situation and made recommendations to all levels in order to improve the supply chain management of ACTs and RDTs. The main recommendation at the central level was to create a quantification committee where all stakeholders (CAMEBU, UNICEF, SEP/CNLS, USAID, AMAGARA MEZA and SIAPS) will quantify needs together and plan for national distribution. The 1st annual quantification exercise will be conducted in September 2012 to review the 2012 quantification and estimated needs for 2013. At the peripheral level, stock managers will be capacitated on the analysis of consumption/morbidity data and on how to calculate/update the Average monthly consumption (AMC) through trainings and close supervision.

During the reporting period, SIAPS used the SPS pipeline funds to build capacity of stock managers in the 45 districts with basic computer skills from May 28 to June 2, 2012. The objective was to provide key basic concepts to allow the stock managers to have better performance using "channel" (the software used at district level to manage pharmaceuticals) and also revisit the requisition and distribution processes of malaria commodities to avoid stock outs at the health facility level. The 45 stock managers received a 3-day training on basic computer concepts. In addition, an opportunity was provided for participants to gather with the managers of the Health information system (SNIS) for 2-days to analyze data reported during the last quarter (January-March 2012). This exercise will continue on monthly basis to strengthen the link between the 2 staff on the analysis of data before submitting it to central level to avoid the inaccuracy/inconsistency currently observed and provide feedback to health centers within their catchment area. Data analyzed will be also used to plan distributions on a quarterly basis. Facilitators during the training were coming from PNILP, DPML, PNSR, SNIS, SEP/CNLS-Malaria and SIAPS.

In September 2011, a HQ based SPS staff conducted an evaluation of the current PMIS for malaria commodities in Burundi. The evaluation showed some needed areas of improvement; data reported by the peripheral level through various reporting channels (PNILP, SNIS, CAMEBU) are not compiled and analyzed for decision making at national level. Based on the recommendations to strengthen the existing PMIS of malaria commodities, SIAPS developed a Scope of Work to recruit a data analyst to assist the PNILP, CAMEBU, DPML, SNIS and key stakeholders to analyze monthly data on morbidity and consumption of malaria commodities generated and submitted from the peripheral level. The recruited consultant will at the same time train a team from the aforementioned institutions with training on data management in order to capacitate them for future analysis. The 1st period to be analyzed will be January to December 2011. The SOW was sent out and the potential candidate will be recruited in July.

Cameroon

Portfolio Background

SIAPS has been provided with $3.5 million in field support from the USAID Regional Office in Accra to implement within 3 years, 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 (Adamawa, 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 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.

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), the National Commission for fighting AIDS (CNLS), 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 NTD 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

During Q3, the SIAPS Cameroon program mainly made progress toward three SIAPS Cameroon work plan objectives. Under Objective 2, SIAPS Cameroon initiated a standardized assessment of the 10 regional pharmaceutical warehouses and of the Central Medical Stores, with the goal of using the data collected to develop an action plan for addressing weaknesses identified in the management of physical capacity of these entities. The assessment was conducted using a standardized tool that was reviewed, tested and adapted in coordination with Cameroon's Central Medical Stores (the CENAME) and the National AIDS Control Program (CNLS). Data collection teams include either CENAME or CNLS staff. This assessment started at the end of Q3 and will be finished in early Q4. In addition to resulting in an action plan, this assessment will also produce information that will make it possible to progress with

The information will make it possible to develop a strategic plan for the implementation of an efficient pharmaceutical management system for ARVs and other HIV AIDS commodities. This strategic plan was initially scheduled to be developed during the first month of Q4, but it has been necessary to postpone the development of this plan to the second month of Q4. Additionally, the assessment will produce information on training needs of staff at the 10 pharmaceutical warehouses plus the CENAME, which will make it possible to develop a training plan for improving the capacity of these staff. The outputs from this assessment will enable SIAPS to fulfill one of the conditions that the CNLS is required to meet in order to access funds for procuring HIV/AIDS commodities through its Round 10 Global Fund HIV/AIDS grant. Accessing these funds would contribute to reaching Objective 4, which aims to strengthen financing strategies and mechanisms to improve access to medicines. A short-term technical assistance visit planned in Q4 will accelerate SIAPS's assistance to the CNLS to meet the remaining conditions precedent to accessing procurement funds from the Global Fund. Prior to beginning technical activities, SIAPS applied for official registration to operate in Cameroon, set up an office in Yaoundé, and initiate recruitment of local administrative and technical staff. SIAPS organized an official launch of it is program which occurred on May 10, 2012. The launch served to introduce the SIAPS program strategy and planned activities for the first year of operation to key stakeholders in Cameroon. Remarks were made by His Excellency Mr. Robert P. Jackson, US Ambassador to Cameroon, and by His Excellency Mr. Andre MAMA FOUDA, Minister of Health of Cameroon. The Minister of Health of Cameroon officially opened the launch. Presentations on the SIAPS program were made by Dr. Gege Buki, Country Project Director for Cameroon, and Dr. Aline Kane, Senior Technical Advisor for Cameroon.

Key challenges of quarter

Key challenges experienced during the quarter included complicated and slow administrative

procedures of Cameroon's government, with respect to issues such as registration and obtaining visas. The small number of technical staff compared to the number of activities to be implemented. Additionally, the time required hiring local administrative and finance staff put pressure on the time of SIAPS technical staff, which had to balance organizing the program launch and starting technical activities with administrative tasks associated with office set up. As technical activities began, the SIAPS team also encountered occasional problems with availability of CENAME and Ministry of Health staff for meetings, which in turn sometimes delayed progress on activities. Availability of consultants and regional staff for short-term technical assistance visits within desired time-frame was also a challenge.

Key activities for next quarter

During the next quarter, the following key activities will be conducted:

- Conduct stakeholder workshop to reach consensus on recommendations of the action plan stemming from the June/July 2012 assessment of Cameroon's pharmaceutical warehouses.
- Assist the National HIV/AIDS Program with meeting conditions precedent to receiving Global Fund funds for procuring HIV/AIDS commodities for the Round 10 Global Fund grant.

Technical Activity Coordination

During Q3, technical activity coordination focused on confirming/updating work plan activities with the Ministry of Health, submitting the Q2 report to USAID/WARO, launching the SIAPS program in Cameroon, planning for implementation of activities contributing to reaching two objectives in the SIAPS Cameroon Y1 work plan, and finalizing the set-up of the SIAPS/Cameroon office.

Office Management

During Q3, a physical office was selected, a lease was signed, and preparations got underway to render the office functional. Because the SIAPS Cameroon staff also needed to launch the SIAPS project and get technical activities underway during this quarter, the decision was made to send operational staff from headquarters to accelerate the set-up of the office and to free up technical staff to focus on technical activities. Dan Brame traveled to Yaounde, Cameroon from May 13-25 to finalize the set-up of the office, to support the Country Project Director with recruitment of finance and administrative staff, and to begin putting administrative infrastructure/elements in place for the new office. The major accomplishments of the TDY were the following:

- Accountant/Office Manager and Administrative Assistant candidates interviewed and staff selections made.
- Local vendors for office equipment and services identified along with prices for goods and services, and database created with this information.
- Office equipment (e.g. photocopiers, printers) and furnishings to be sourced locally were procured, and asset tags attached to all equipment and furniture delivered to the SIAPS Cameroon office.
- Plan developed for ensuring coverage of basic administrative and financial operations until local administrative and financial staff begins work.
- Training plan develop for finance and administrative staff being recruited.
- Identified the support that was required from SIAPS HQ for training of SIAPS Cameroon new hires in MSH financial and administrative operations and propose a timeline for providing this HQ support.

- Internet installed in the SIAPS Cameroon office.
- Follow-up conducted on MSH's registration file, already submitted to the Ministry of External Relations and "accord de siege" submitted to this Minirex.
- Mechanism developed for tracking local legal obligations and agreement deadlines.
- Security set-up for SIAPS/Cameroon office and operations assessed, and recommendations made for improvements.
- Follow-up conducted to obtain exemption for MSH from value-added tax (VAT).
- Post office box obtained for MSH.
- Documentation for opening MSH bank account submitted to bank.

Objective 1
Pharmaceutical Sector Governance Strengthened

Objective 1: Quarterly progress
There was no progress on this objective during Q3. However, an assessment was conducted starting at the end of Q3 to allow SIAPS to obtain a baseline (will be available in Q4) and to lay the ground work for periodically measuring this over time.

Objective 4
Financial resources available to the pharmaceutical sector increased

Objective 4: Quarterly progress
During Q3, SIAPS conducted a major activity which in addition to providing baseline data on the situation and practices at all CAPRs in Cameroon's 10 regions, will also provide the information necessary to develop an action plan for resolving storage-related issues at all of these warehouses. The development of this action plan is a condition precedent to the disbursement of funds to Cameroon from the Global Fund Round 10 HIV/AIDS grant. The assessment results and proposed actions are being presented to stakeholders through a workshop on August 9 in Yaounde, and the action plan will be finalized once this workshop is completed. SIAPS had also planned to provide technical assistance to meeting other conditions precedent to the disbursement of funds for this grant during Q3. This includes the revision of a procurement manual to ensure that it takes into account Global Fund quality assurance procedures, and the development of a strategy that when implemented, will ensure that information on HIV/AIDS patients and commodities is available to the National AIDS Program for quantification, forecasting, monitoring and reporting purposes. A TDY was planned at the beginning of July to fulfill these two latter conditions. However, late approval of the travel made it necessary to postpone the TDY to Q4. The TDY is now scheduled for late August/early September 2012.

Democratic Republic of the Congo

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.

Quarter Overview

The Drug Regulatory Authority (DRA) continued the medicine registration sessions and registered 38 medicines during the quarter. The cumulative number of medicines registered has reached 704 medicines, at end of June 2012, toward the annual target of 1000 medicines to be registered by end of the fiscal year. All stakeholders, including the major partners in health, now go through the registration process before bringing in medicines that are not yet registered with the DRC DRA. The DRA is publishing the list of registered medicines after each registration session. The databank of registered medicines will soon be used by the provinces to assess the percentage of unregistered medicines circulating in the country for further appropriate corresponding measures. The main mandate of the DRC National Medicine Committee (CNM) is for the MOH to be able to coordinate the pharmaceuticals procurement and supply chain in the public sector in the entire country and to solve the problem of multiple, inefficient channels. With SIAPS technical and financial assistance, the CNM has started to meet and held a meeting on May 22, 2012, chaired by the DRA Director. This first meeting was followed by two others chaired by the Secretary General of MOH, and the Minister of Health. USAID Mission representative attended the last two meetings.

The outcomes of these meetings have been:

- For the first time, the DRC government has been able to collect information from the partners in health on the figures of their contributions to medicines procurement in DRC. The total amounted to more than US $83 million per year for a DRC population estimated at 70 million.
- The partners also provided information about the supply chains used.
- All partners providing medicines to the DRC were requested to provide details on medicines categories they procure, the health zones they intervene in, and the details of their supply chains.
- The CNM has to estimate medicines needs for 6 months for one health zone as to be able to calculate the country needs. The MOH has taken leadership in coordinating partners, having information on available stocks, pipeline, and orders. This has been lacking for decades, and was the main cause of medicines stock-outs and expiries in DRC. Based on the information now available, the MOH is able to make the right decisions. With decentralization in the DRC, the provinces have become responsible for health matters at their level.

Building on SPS work, SIAPS has continued strengthening the capacity of the provincial medicine committee (CPM) in pharmaceuticals management. CPMs have become the sole provincial official forum for all discussions and decisions pertaining to pharmaceuticals, such as reallocation of medicines within the health zones of the province when necessary. The Sud Kivu province was assisted by a non-USAID-supported province (Nord Kivu) with TB medicines. The CPM is chaired by the State Provincial Pharmacist (PIP). All partners in the province are members. As at national and provincial level, the MOH has recovered its leadership in the pharmaceutical sector. Other provincial government departments invited officially to CPM meetings attend, participate into the CPM decisions and execute them within their mandate. During Q3, SIAPS continued with technical and financial assistance to the CPM as follows:

- In Kasai Occidental, a meeting of the Provincial Medicine Committee (CPM) was held on May 12, 2012 with technical and financial assistance from SIAPS and the European Union (EU). The meeting developed the performance contract which is to regulate the

relationship between CADIMEK and the provincial health Directorate (DPS). With technical assistance from SIAPS, the CPM Kasai Occidental also held a workshop on June 23, 2012 during which the CPM came up with the draft of proposals to the National Essential Medicines List (NEML) to be submitted to the National NEML Committee in Kinshasa for the upcoming NEML revision expected this year, and with the draft of the provincial Essential Drugs List tailored to the local provincial epidemiological profile. The workshop was jointly funded by International Rescue Committee (IRC), SIAPS and CADIMEK. WHO availed copies of the NEML 2010 and of the National Therapeutic Formulary for the meeting.

- In Sud Kivu, a CPM meeting was organized on June 13, 2012 under the chairmanship of the Provincial Pharmacist Inspector. The meeting was attended by 39 members from the MOH, faith based organizations, local and international NGOs, the private sector, the national intelligence service, the Congolese Quality Control Organization (OCC), the provincial Directorate of Customs and Excise and the Provincial Revenue Authority. During Q3, the Electronic Dispensing Tool (EDT) captured 183 new patients.

With the unavailability of MOH staff during the quarter, it has been difficult to move ahead with the next steps of this activity. The total number of patients registered into the system has reached 1783 AIDS patients since its installation in July 2011 in the 4 pilot sites in Kinshasa. However, extensive problems with electricity at one site made it necessary to close down the site, reducing the total number of EDT sites to 3. SIAPS continues to provide EDT reports to the PNLS for decision making. The information generated from the EDT in the pilot sites has made it possible for the provincial PNLS of Kinshasa to reallocate ARVs with close expiry dates among treatment sites. In collaboration with the National Centre for Pharmacovigilance (CNPV), SIAPS has organized a baseline study on rational use of medicines in 2 general referral hospitals (additional to the previous two), bringing the total of baseline studies conducted to 9 general referral hospitals. The report is being completed. This study will show the findings in hospitals representing 4 provinces of the DRC. It is likely the reflection of what is happening in other hospitals in the rest of the country. The measures to address the challenges found will assist in improving access to improved pharmaceutical services in these hospitals.

Key challenges of quarter

During Q3, activities were affected by the establishment of a new government and a new Minister of Health. The MOH was run by an acting Minister for three months and a new Minister was sworn in May 2012. The new government has set up a result based performance plan and Ministers are expected to produce results in the first 100 days. Therefore, the availability of the MOH staff to work with SIAPS was very limited. We initially started with 4 EDT pilot sites in Kinshasa. Because of frequent power supply failures in one of the sites (Matete), we had to close it down waiting for any improvement of power supply, while we continue with the 3 others. The selection of new sites by the PNLS will have to be negotiated carefully, taking into account the quality of the power supply to the site. The expansion of EDT to new sites was to include EDT in 2 TB treatment sites. With the decision of the national TB control program to embark on the community-based DOT, the implementation of EDT becomes challenging and will need additional consideration.

Key activities for next quarter

Conduct supervision visits in provinces to examine the percent of medicines available in the

market place that are registered with the NDRA. Continue the joint support with WHO to the National Medicines Committee (CNM) in medicines procurement, as it organizes its coordination meetings to bring together partners implementing pharmaceutical activities. Joint support will also continue to improving the procurement and supply chain in DRC. Conduct the second End User Verification Survey (EUV) for malaria commodities. Provide financial support to the NPVC and DPM to hold one meeting to provide a forum for discussing the outcomes of ADE data analysis for decision making. Work with the CNPV to train and install provincial focal points in 5 provinces with DTCs.

Objective 1
Pharmaceutical sector governance strengthened

Sub-Objective 1.1
Increased efficiency and transparency of the drug registration system

Progress toward sub-objective 1.1
To increase efficiency and transparency of the process at the central level, the Provincial Pharmaceutical Committees (CPM) planned to conduct inspection exercises to assess the percentage of medicines available in the market place which are registered with the NDRA. However, they were unable to conduct this activity this quarter because the official updated DRA list of registered medicines was not provided to the provinces. The list will be sent to the provinces by the DRA through the official channels and the activity will be conducted in Q4.

Deliverables for sub-objective 1.1
DRA report for medicines registration for the quarter.

Sub-Objective 1.2
Improved medicines policies, legislation and regulations

Progress toward sub-objective 1.2
The last National Essential Medicines List (NEML) update involved a lot of inputs from the provincial pharmaceuticals committees (CPMs). We planned to consult widely with them again this time and the Kasai Occidental Province had their meeting to discuss their inputs to the NEML, too. We are still awaiting the invitation from the MOH to start with the first official meeting for Q4. All provinces have bought into the process and many hospitals have requested copies of the NEM List.

Sub-Objective 1.3
Improved coordination of supply chain management activities by national and provincial authorities

Progress toward sub-objective 1.3
At the national level, the coordination of supply chain has started improving with CNM meetings held with technical and financial assistance from SIAPS. At the provincial level, the process started earlier with support from the SPS program and CPMs are now the key mechanism and entity coordinating all pharmaceutical management in USAID-focus provinces. Assessments of

three CDRs (Kolwezi, Kamina and Kisangani) were completed and reports are available. Agreement has been obtained between IHP and SIAPS to start with the upgrading of some CDRs/depots in Q4 with IHP funding. The CDRs to be upgraded first will be selected in agreement between IHP and SIAPS. In Kasai Occidental, the performance contract has been finalized between CADIMEK and the Provincial Health Directorate (DPS). A list of essential medicines specific to the epidemiological profile of the province of Kasai Occidental has been created. The CPM finalized the draft of proposals to be submitted to the National NEML Committee in Kinshasa for the upcoming NEML revision. From April 13-16, the Kasai Occidental SIAPS Representative accompanied the SCMS team during their assessment of the Kasai Occidental CDR (CADIMEK), commissioned by USAID. The assessment looked into management procedures (storage, distribution, etc.) and quality assurance of CADIMEK. During the month of April, SIAPS monitored the distribution of medicines to IHP supported health zones on the basis of the distribution plan developed in March 2012. With the Malaria Control Program provincial office and the Provincial Pharmacist, SIAPS assisted in development of a distribution plan to the same IHP supported health zones of the PMI Rapid Diagnostic Tests (TDR) (June 2012). SIAPS facilitated the meeting between the IHP Chief of Party and CADIMEK team.

During this meeting, the following points were addressed: (1) The basis for the calculation of management fees. (2) The amendment to the contract between CADIMEK and IHP (the current management contract expires June 30, 2012). (3) The file depot in Luiza.

In Sud Kivu a CPM meeting was organized on June 13, 2012 under the chairmanship of the Provincial Pharmacist Inspector. The meeting was attended by 39 members from the MOH faith based organizations local and international NGOs the private sector the national intelligence service the Congolese Quality Control Organization (OCC) the provincial Directorate of Customs and Excise and the Provincial Revenue Authority. The meeting recommended/resolved: (1) Project PASS/Malteser Funded by the Government of Switzerland to purchase ACTs for 3 months for health zones about to experience stock outs (while waiting for the ACTs purchased under MSH/IHP Task Order #2). (2) IHP authorized distribution of family planning commodities that were consigned for six months. (3) Presentation of results of qualitative analysis of drugs in the province by the PIP Office. The analysis shows over 40% of drugs circulating in the province are sub-standard. (4) The closure of drugs outlets in the Bukavu Town and Uvira Town. SIAPS supported APAMESK and CEPAC depots in reporting on medicines data management. With IHP, SIAPS assisted the PNLP, PNSR, PNLS and the Blood Transfusion Program with the distribution plan for their commodities by providing them with information to clear the depots that have stored products for more than six months. In collaboration with IHP Kasai Oriental staff, the SIAPS Team developed distribution plans for medicines (health zones were slow to place their orders to CDRs according to their credit lines). The tracking of the implementation of these distribution plans at the CDR showed that all health zones were served with the exception of two (Lusambo and Pania Mutombo: to be served shortly). In addition, with the CDR, the MSH team cleared the balance of credit lines related to the last two deliveries for each general referral hospital. In Katanga, SIAPS assessed the storage conditions in the Kolwezi Depot. As a result, the depot has improved some storage conditions with their own funds, and still had some minor work to complete. The depot has been able to recruit new staff, including a stock manager, a logistician and an accountant.

Main challenges for sub-objective 1.3
Insecurity in the eastern DRC.

Objective 2
Capacity for pharmaceutical supply management and services increased and enhanced

Sub-Objective 2.1
HIV/AIDS Pharmaceutical management capacity of individuals, institutions, organizations strengthened

Quarterly progress toward sub-objective 2.1
A training session on managing PMTCT medicines and commodities was held from April 9-13, 2012 in five health zones, 26 PMTCT sites, CDR and Provincial Inspection, to ensure compliance with Good Distribution Practice (GDP), Good Storage Practice (GSP) in those structures. The full support of this training was provided by USAID with funding through PEPFAR/SIAPS. Thirty four women out of 70 participants took part in this training session. This training helped strengthen the capacity of persons entrusted with the management of medicines in five health zones of the Kisangani Town in Province Orientale. Participants of CS and ZS supervisors were capacitated to use PNAM medicines management tools, quantify their medicines needs and prepare their orders, properly keep the various management tools available, and develop a pharmaceutical management report to be transmitted to health zone management team. Members of the health zones management team are now able to carry-out supervision on the management of medicines, analyze and validate the orders from health centers and general referral hospitals through the "Quantification Committees" of the health zones, and compile reports of pharmaceutical management from health facilities to transmit them to the DPS.

Deliverables for sub-objective 2.1
Training report

Sub-Objective 2.2
TB Pharmaceutical management capacity of individuals, institutions, organizations strengthened

Progress toward sub-objective 2.2
The results of the assessment were officially presented to the MOH, Central Departments and Specialized Programs, Caritas Congo, USAID, MSH, and other partners in the TB sector in the DRC. Findings in the provincial TB offices included inadequate human resources, inadequate storage capacity, poor storage conditions, very low distribution capabilities, limited management and control of stock, weak logistics management information system, lack of involvement of the PNLT in the buying process, lack of a common procurement plan, and the use of outdated laboratory products since 2008. The following recommendations were made

- Develop mapping of the coverage of CPLTs and CDRs throughout the country.
- Analyze the relevance of integrating TB in the SNAME.
- Develop a phased plan of integration taking into account the geographical accessibility to the CDRs.
- Store the TB medicines at CDRs where possible.

- Adapt the manual PATIMED to the Procurement Supply document of the MOH.
- Redefine the responsibilities within the PNLT Kinshasa office, as related to the logistics service.

The assessment findings and report provide the MOH with an official document showing the inadequate of storage of TB medicines in offices and the need to transfer these medicines into CDRs where possible.

Objective 3
Pharmaceutical management information generated through SIAPS activities is used for decision-making

Objective 3: Quarterly progress
On June 25 and 26, 2012, as part of the promotion and development of the SNIS-Med through the national system, SIAPS provided financial and technical assistance to PNAM for a workshop to validate the tools for data collection for SNIS-Med at health facilities. This workshop brought together participants from specialized program of the MOH and some partners IHP and SIAPS. Three main results were obtained at the end of the workshop:

- New data collection tools for SNIS-Med were validated.
- Tracer medicines for specialized programs included in the new SNIS-Med tools.
- A list of indicators for SNIS-Med was adopted.

The next step will involve the extension of the new reporting framework SNIS-Med in the provinces assisted by USAID.

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

Progress toward sub-objective 3.1
SIAPS provided technical and financial assistance to the Ministry of Health to conduct a workshop to update and validate tools used for collecting data on medicines through the ministry mechanism known as the SNIS-Med. Now that these tools are validated by the Ministry of Health, they can be used for data collection at health facilities for submission to the SNIS-Med. This workshop brought together participants from specialized MOH programs, as well as implementing partners, such as IHP and SIAPS. Updating the tools included adding tracer medicines used in specialized programs of the MoH, and adopted a list of SNIS-Med indicators SNIS-Med. SIAPS collaborated with the National Malaria Control Program (PNLP), the National Drug Regulatory Authority of the Ministry of Health (Direction de la Pharmacie et du Médicament) and the National Essential Medicines Procurement Program (PNAM) to successfully conducted the first End User Verification Survey (EUVs) in 2 of the 4 PMI-supported Provinces (Kasai Occidental and Katanga) in May 2012 and submitted the final report to USAID/Washington in July 2012. The purpose of the End User Verification (EUV) survey is to assess the availability and use of malaria commodities at end user level.

Main challenges for sub-objective 3.1
The poor security situation in the 2 provinces is still negatively impacting the transmission of all

health data, including pharmaceuticals management from health centers up to health zones and provinces.

Deliverables for sub-objective 3.1

- Workshop reports
- EUV Report

Objective 4

Financing strategies and mechanisms strengthened to improve access to medicines

Objective 4: Quarterly progress

With the CNM meetings that SIAPS sponsored, the Minister of Health has decided to have a holistic approach of improved access to medicines, beyond medicines procurement alone. Therefore, objective 4 is being readdressed as we move with the CNM meetings. It has also become difficult for SIAPS to predict next steps activities. We have advanced faster than we thought toward improving access to medicines because we now have the basic figures of funds committed to medicines. There was a decision to streamline the procurement and distribution chain and a commitment from the MOH to ensure more availability of medicines at the health center level. The affordability of these medicines to the communities will be looked into in next meetings.

Objective 5

Pharmaceutical services improved to achieve desired health outcomes

Objective 5: Quarterly progress

The April PPMRm reported that from November 2011, all donors and development partners involved in malaria activities in the DRC agreed to set up a commodities procurement coordination mechanism under the NMCP leadership. The national data validation was in progress and validated data will be available for the next quarter.

Using the data available on the previous availability of malaria commodities assessment, PMI held discussions with the NMCP, IHP Project and DRC SIAPS Program to estimate the needs in malaria commodities (RDTs and ACTs) for 4 provinces. PMI subsequently placed an order for approximately 7,000,000 doses of ACTS (both strengths) and 3,500,000 units of RDTs in the fourth quarter of 2011 to cover the DRC's needs for the calendar year of 2012. The report mentioned that apart from the malaria commodity orders currently in process, PMI planned to place an additional order in May 2012 for 4 million doses of ACTs, and 2.5 million tablets of Sulfadoxine-Pyrimethamine.

The report stated that the PMI commodities are stored in CDR/Depots which have contracts with the USAID-funded IHP Project. The process of upgrading storage conditions, which was initiated through the SPS project (through assessments), should continue. PMI will consider that the quantities of commodities will increase significantly and will require extension of the storage space where needed. In March 2012, the shipment from previous PMI orders arrived in the DRC and was undergoing customs clearance. Distribution plans are under way. Meanwhile, the order of 1,1 million tablets of Sulfadoxine-Pyrimethamine that reached the country was partially delivered

to CDRs/Depots in Sud Kivu (250,000 tablets in Bukavu) and Kasai Oriental (329,000 tablets in Mbujimayi).

The baseline study organized in collaboration with the National Centre for Pharmacovigilance (CNPV) has been completed in 8 out of the 9 DTCs. The team is busy compiling results in one document. The document is expected to be used as the baseline data for hospitals in the four USAID-supported provinces to improve the rational use of medicines. Most of these hospitals were briefed on the findings of the study conducted within their own hospitals.

Sub-objective 5.1
Availability of pharmaceuticals improved

Progress toward sub-objective 5.1
All stakeholders in family planning have submitted their data for the quarter. SIAPS submitted a PPMRm report for Q2 in April 2012. All donors and development partners involved in malaria activities in the DRC have agreed to set up a commodities procurement coordination mechanism that will operate under chairmanship of the National Malaria Control Program.

Sub-objective 5.2
Adverse Drug Event reporting is increased

Progress toward sub-objective 5.2
The draft of the 2nd issue of the National Pharmacovigilance Center (CNPV) Newsletter was submitted to SIAPS for editing before publication in French and English. The CNPV and SIAPS agreed to start with only 2 issues of the newsletter per year.

Sub-objective 5.3
Medicines use is improved at hospitals with DTCs

Main challenges for sub-objective 6.1
A baseline study on prescribing and dispensing of medicines in hospitals with a functional DTC, was conducted. Two additional hospitals (Hospital Dibindi and Lodja) have completed the study. This study aims to determine the baseline of WHO drugs use indicators within the identified hospitals and take necessary corrective measures to improve drug use in these hospitals. A summary of the major problems identified was developed with support from CNPV and will be available soon. Relevant solutions will be proposed to these identified problems. The process will assist in improving the prescribing and dispensing behavior in these hospitals, as all prescribers in these hospitals have been exposed to rational use of medicines and a follow up is planned within Drug and Therapeutic Committee of each hospital.

Dominican Republic

Portfolio Background

The Dominican Republic (DR) Ministry of Health (MoH) is currently receiving support from the USAID mission in Santo Domingo to implement a National Pharmaceutical Management System (SUGEMI, by the Spanish acronym). SUGEMI will improve the supply of medicines currently managed by the TB and HIV/AIDS programs.

SPS activities for FY09 and FY10 included the elaboration of standard operational procedures for all the SUGEMI components, the training of personnel in its procedures, and the initial implementation of two components: the pharmaceutical management information systems and the programming of needs for 2012 procurement. A summary of the activities and documents produced during the SPS program are available at:
http://www.msh.org/projects/sps/Global-Focus/Dominican-Republic.cfm.

SIAPS has received USD 600,000 from the USAID mission in Dominican Republic in FY11 funds to provide technical assistance for the implementation of the SUGEMI and document its impact particularly in public health programs such and TB and HIV/AIDS.

Quarter Overview

All the activities in the Dominican Republic are focused on implementing the national pharmaceutical management system. During the quarter SIAPS focused on the implementation of the SUGEMI national pharmaceutical system procedures to health facilities, working with the National Pharmaceutical Unit, and developing the national pharmaceutical management information system. Lastly, SIAPS focused on developing an alternative procurement mechanism for all essential medicines in the country.

Key activities for next quarter

SIAPS activities will continue to focus on the implementation of the SUGEMI pharmaceutical management system in the country and work with the National Pharmaceutical Management Unit. SUGEMI activity will include the estimation of needs for 2013 procurement. SIAPS will continue supporting the information/requisition/dispatch sub-system. SIAPS will support the estimation of needs for 2013 procurement of HIV and TB programs. SIAPS will seek the technical support of a consulting firm programmer, to support the maintenance of the electronic application and develop/adjust an inventory management module for pharmacies and warehouses.

Technical Activity Coordination

Edgar Barillas oversees all technical activity in the Dominican Republic form the SIAPS office in Arlington, VA. Caludia Valdez works more closely in the country as an MSH consultant. She oversees all operations in country and works directly with all short-term consultants.

Objective 1

Increased number of suitable personnel to operate the National Pharmaceutical System

Objective 1: Quarterly progress

SIAPS continues to focus on the SUGEMI system. SIAPS supported the analysis of information

generated by the national inventory. A technical report on the integration of the TB and HIV programs to SUGEMI was issued. SIAPS participated in the supervision of health facilities and regional directorates, to support the first round of information, requisition and dispatch following SUGEMI procedures. For the next quarter, the main SUGEMI activity will be the estimation of needs for the 2013 procurement. SIAPS will continue supporting the information/requisition/dispatch sub-system.

Sub-Objective 1.1

Personnel in National and Regional Pharmaceutical Management Unit with complete knowledge of SUGEMI SOPs and Pharmaceutical Management tools

Progress toward sub-objective 1.1
SIAPS supported the analysis of information generated by the national inventory. A technical report on the integration of the TB and HIV programs to SUGEMI was issued. SIAPS participated on the supervision to health facilities and regional directorates, to support the first round of information, requisition and dispatch following SUGEMI procedures. For the next quarter, the main SUGEMI activity will be the estimation of needs for 2013 procurement. SIAPS will continue supporting the information/requisition/dispatch sub-system. SIAPS provided technical assistance to the National Pharmaceutical Unit (UNGM) to perform routine activities and demands coming from the MoH. SIAPS is still supporting –through three short term consultants- the operations of the UNGM.

Sub-Objective 1.2
MoH personnel supporting the National Pharmaceutical Management increased

Progress toward sub-objective 1.2
Support the institutional development of the national pharmaceutical management unit SIAPS provided technical assistance to the National Pharmaceutical Unit (UNGM) to perform routine activities and extraordinary demands coming from the MoH. SIAPS is still supporting –through three short term consultants- the operations of the UNGM. For the next quarter, SIAPS will restate the importance that the MOH absorb SIAPS consultants, as regular MoH employees.

Objective 2
Increased availability of pharmaceutical information for decision making

Objective 2: Quarterly progress
SIAPS is supporting capacity building for health care workers in the country to learn the reporting requirements for the SUGEMI System. During the quarter, SIAPS participated in the supervision to health facilities and regional directorates, to support the first round of information, requisition and dispatch following SUGEMI procedures. SIAPS will continue supporting the information/requisition/dispatch sub-system

Sub-Objective 2.1
National Pharmaceutical Management System supported by a functional PMIS

Progress toward sub-objective 2.1
During this quarter SIAPS (through a local consulting firm hired by SPS), finalized the electronic application used to consolidate and report on the national inventory and consolidate the information/requisition forms (SUGEMI-1) generated by health facilities. For the next quarter, SIAPS will seek the technical support of a consulting firm/programmer, to support the maintenance of the electronic application and develop/adjust an inventory management module for pharmacies and warehouses.

Objective 3
National pharmaceutical management system fully operational and institutionalized

Sub-Objective 3.1
Distribution and storage conditions improved

Progress toward sub-objective 3.1
Based on a baseline study that SPS carried out last year, SIAPS, national counterparts, and the Global Fund project supported the financing of a model warehouse in La Vega. For the next quarter, a supervisor will be hired and the construction/conditioning will be completed. SIAPS will support, for the fourth quarter, training courses on good storage practices.

Sub-Objective 3.2
Programming procedures improved and institutionalized

Progress toward sub-objective 3.2
After the national inventory (February 2012), SIAPS analyzed the inventory information of both programs and proposed alternatives for the redistribution and procurement of medicines. For the next quarter (July 16-20) SIAPS will support the estimation of needs for 2013 procurement of HIV and TB programs.

Sub-Objective 3.3
Procurement procedures improved and institutionalized

Progress toward sub-objective 3.3
SIAPS prepared a summary of the proposal elaboration process and the next steps for its implementation. Current MoH authorities will present the document to the new MoH administration which should take over around August 2012.

Deliverables for sub-objective 3.3
For the next quarter, and if the new authorities approve the proposal, SIAPS will support the elaboration of the tender invitation documents and will provide technical assistance for the implementation of the first bid process.

Sub-Objective 3.4
Selection and rational use procedures improved and institutionalized

Progress toward sub-objective 3.4

The Global Health Council conference was canceled, so a presentation already accepted was canceled. SIAPS supported the organization of an expert panel on HIV pharmaceutical management during a Latin American conference held in Santo Domingo. The achievements of SUGEMI were shared with the participants.

Deliverables for sub-objective 3.4

For the next quarter (first week, July) SIAPS will support a GDF monitoring mission to the TB program. A report will be issued before the end of July 2012.

Ethiopia

Portfolio Background

Ethiopia is Africa's oldest independent country. It is the tenth largest country in Africa, covering 1,104,300 square kilometers and is the major constituent of the landmass known as the Horn of Africa. The major health problems of the country remain largely preventable communicable diseases and nutritional disorders. Despite major progresses in improving the health status of the population in the last one and half decades, Ethiopia's population still faces a high rate of morbidity and mortality.

Despite tangible accomplishments in ARV drugs management in Ethiopia, there are gaps that need to be addressed to further improve pharmaceutical services. Irrational use of medicines, shortage and high turnover of staff, poor record keeping and reporting, poor quality of consumption data for quantification, poor dispensing practice leading to unfavorable treatment outcomes and development of resistance to antimicrobial agents, inadequate training and a lack of reference materials, a lack of pharmaceutical institutional framework that would guarantee "ownership" of interventions by implementing partners, poor tracking of expiry and delayed disposal of obsolete and expired products are some of the challenges that health facilities still face.

As follow-on to Strengthening Pharmaceutical Systems (SPS), the scope of SIAPS is to provide technical assistance to governmental and non-governmental organizations in developing countries to build their capacity so as to enable them to effectively manage their pharmaceutical systems. The ultimate goal of creating strong pharmaceutical systems is to ensure access to essential medicines and improve quality of pharmaceutical services, thereby improving health outcomes. This will contribute significantly to the successful implementation of USAID priority services, and ultimately save lives and protect the public's health by improving access to and use of medicines of assured quality.

SIAPS/E benefits from the strong and successful partnership and collaboration created between SPS and key government agencies & professional associations during the past four years. SIAPS/E will build on the milestones achieved through SPS and expand its interventions in the areas of access to and rational use of medicines, pharmaceutical good governance (to ensure accountability, transparency and operational efficiency) and strengthening of pharmaceutical services to improve health outcomes.

Under COP11, SIAPS/E will continue to support capacity building of national organizations, such as Pharmaceutical Fund and Supply Agency (PFSA); Food, Medicines and Health Care Administration and Control Authority (FMHACA) and Regional Health Bureaus (RHBs); professional associations, teaching institutions and health facilities using the SIAPS framework. Support will be focused around strengthening pharmaceutical management, improving Pharmaceutical Good Governance, policy and practice reform aimed at strengthening national skills and capacity in various areas of pharmaceutical systems, promotion and implementation of rational use of medicines, containing the emergence and spread of antimicrobial resistance, promotion of treatment adherence and medicines safety with the aim to improve treatment outcomes.

Quarter Overview

In collaboration with PFSA, SIAPS supported hospital DTCs to develop, print and launch facility-specific drug lists. A drug list development workshop was facilitated at Dessie hospital, a drug list was printed and handed over to Gondar University Hospital, and six drug lists are in press. SIAPS has been working to strengthen the establishment and institutionalization of DTCs throughout the country. During quarter, a total of 13 DTCs were established, 26% of the target set for the year. While the setting up of DTCs is a relatively easy task, getting the commitment of health facility leaders and responsible pharmacists to implement the extended role of DTCs to ensure ownership and sustainability requires repeated advocacy and mentoring.

A 4-day DTC/RDU training for the newly established hospitals has been finalized and modalities for the provision of onsite training for those facilities that had received DTC trainings were agreed upon. The on-site training is an MTP training approach that involves: gap assessment using a standard checklist, orientation based on the gap assessment and planning, and support implementation of the plans. This approach is expected to improve the training delivery and subsequent change we desire in regard to the management and use of pharmaceuticals as it will be more practical and brings the support to the where the actual demand is. In this quarter, one DIS training event was organized for SIAPS regional technical advisors (RTAs) and PFSA staffs. The training was successfully conducted and the necessary evaluations were made and a total of 22 trainees successfully trained and certified. In addition, four pre-service ART/AMDM trainings were successfully conducted at Jimma, Addis Ababa, Gondar and Mekele Universities. The trainings were given for graduate class of the four universities. This will help in the institutionalization of ART trainings at schools of pharmacy by building their capacity in the organization and conduction of such training events. The trainers selected for the purpose were senior physicians and TOT trained pharmacists with masters' degrees. SIAPS has trained the pharmacy lecturers for the same purpose.

One round of in-service training on clinical pharmacy/pharmaceutical care to EHRIG-implementing sites was carried out in collaboration with school of pharmacy of Jimma University. The main purpose of this activity was to train pharmacists on clinical pharmacy in an effort to initiate clinical pharmacy services in 21 selected hospitals. The training started in mid-May and finalized in the first week of June, with one week class based and three weeks bed-side training. Immediately after the training, a one day workshop was organized at Jimma University to discuss possible ways for smooth implementation and startup of clinical pharmacy service at the targeted health facilities. Participants of this particular workshop were trainees/pharmacists, CEOs of the selected hospitals and representatives of RHBs. After the workshop, the participants pledged to do all in their capacity to realize the clinical pharmacy services in their respective health facilities.

To help EPA's efforts and achieve the desired degree of ethical practice in the pharmaceutical sector and improve pharmaceutical governance, one round of training was organized to 39 pharmacists on Pharmaceutical Ethics and Ethical Standard of Practice for Pharmacists in Ethiopia was organized in collaboration with EPA. In this quarter, APTS training curriculum was finalized in an effort to standardize and guide the delivery of topics on the trainings and focus on establishing transparent and accountable transaction and service system that will create a means to maximize the use of available resources and reduce wastages. A 3 day curriculum/course outline

has been developed and three round of training organized for 132 participants.

RDV training curriculum was updated under the title: Training course on Drug Supply Management and Rational Use of Drugs for RDV Practitioners with the objective of improving access to and use of pharmaceuticals. The training for RDV practitioners is believed to address gaps in dispensing and counseling, storage of medicines, DSM, regulatory affairs, etc. Two rounds of EDT trainings were conducted and 48 professionals were successfully trained and certified and 55 participants trained on SOPs.

Key challenges of quarter

- Stakeholders not always responsive to the need for timely implementation of joint work plans.
- Shortage of pharmacy professionals at health facilities as a result of high staff turnover.

Key activities for next quarter

Pharmaceutical sector good governance:

- Conduct the second popularization workshop on medicines waste management and disposal and the national framework.
- Support FMHACA to update the Standard Treatment Guidelines (STGs) and national drug list (NDL).
- Assist health bureaus to hold consultative meeting with EHRIG-implementing health facilities on APTS.
- Assist RHBs to organize familiarization workshops for regionally approved APTS proclamations

Strengthening institutional capacity to increase access and improve quality of pharmacy services and achieve improved health outcomes:

- Provide TA to facilities in the preparation of health facility–specific drug lists and support printing of the drug lists.
- Support onsite DTC trainings.
- Provide support to strengthen/establish DTCs with extended roles at health facilities.
- Provide support to conduct joint supportive supervision and mentoring to improve the work of facility DTCs in implementing EHRIG.
- Conduct joint supportive supervision and mentoring to improve the work of facility DTCs at private hospitals.
- Provide onsite training and launch of DIS at selected hospitals.
- Conduct 2nd round in-service training on clinical pharmacy/pharmaceutical care to 27 EHRIG-implementing sites in collaboration with schools of pharmacy.
- Conducting additional APTS trainings.
- Finalize RDV training impact assessment data entry, analysis and report writing.
- Conduct second round journalists training on AMR and RMU.
- Printing of the Medicines Good Prescribing and Dispensing manuals.
- Carry out regional pharmacovigilance framework familiarization workshops.
- Carry-out face-to-face discussions on ADE monitoring/Pharmacovigilance to health providers from public and private hospitals

Strengthen national capacity for safe, accountable management and timely disposal of pharmaceutical waste:

- Organize workshop to popularize the waste disposal framework and directives.

- Provide training to healthcare providers and other relevant stakeholders and develop action plan for the safe disposal of pharmaceutical waste.

Strengthen pharmaceutical management information systems to support evidence-based decision-making:

- Collect, compile and disseminate patient uptake and cumulative regimen breakdown report.
- Distribute PMIS formats.
- Conduct assessment and identify health facilities to roll out EDT.
- Onsite training for dispensers on real-time dispensing.
- Upgrade ADT to EDT for health facilities.
- Provide continuous onsite support until the tool is properly utilized by the dispensing staff.

Promote Access to Essential medicines:

- Produce RDVs training outcome assessment report.
- Provide training to RDVs and regulatory personnel from Eastern Amhara.

Objective 1

Pharmaceutical sector governance strengthened

Objective 1: Quarterly progress

SIAPS-Ethiopia has supported FMHACA to prepare health facility standards for health posts, health centers, primary hospitals, general hospitals and comprehensive specialized hospitals. In the reporting quarter, the board of the Ethiopian Standard Authority (ESA) approved 39 health facility standards. These standards and other legislation will be popularized through workshops and meetings in the coming quarter.

FMHACA was supported to conduct three consultative meetings with medicines manufacturers, importers and wholesalers, as well as with health professional associations. In addition, similar support was given to FMHACA to conduct its nine month performance review meeting with all regulatory key players from the federal to the regional level. The purpose of the consultative meetings with manufacturers was to familiarize FMHACA's effort in promoting local production and discuss the challenges and available opportunities. The meeting also discussed local capacity building, new medicines registration and licensing strategy, and future direction of medicines quality control laboratory. The forum served as a platform to build constructive partnership between FMHACA and local medicines manufacturers. It is expected that this will build a culture of transparency and accountability in the relationship between the two institutions.

With the technical support of SIAPS, FMHACA has finalized the Medicines Waste Management and Disposal Directives and the National Strategic Framework on Medicines Waste Management. One popularization workshop was conducted to familiarize stakeholders drawn from key administrative units of the Amhara Regional State. Meanwhile, a short-term intervention plan was drafted in consultation with FMHACA that will lead to the development of a country plan for medicines waste disposal.

Sub-Objective 1.1

Provide trainings in Leadership, Management, Supervision, and Team Building

Progress toward sub-objective 1.1

It was planned to provide training in leadership, management, supervision and team building to 60 managers at FMHACA, PFSA, RHB Pharmacy Department and EPA to enhance their leadership and management capacity. It was planned that the Leadership Management and Governance Program (LMG) would kick off in Ethiopia at the end of the second quarter and thus SIAPS would use the expertise of LMG staff to conduct the trainings. As the launching of LMG project in Ethiopia was delayed, an assessment has been conducted to identify local institutions that could provide the training. Meanwhile, the scope of work has been developed for the firm that will be selected after advertisement and essential leadership training topics have been identified.

Main challenges for sub-objective 1.1
Unclear progress of CLM and late priority setting in selecting the most appropriate leadership training topics from stakeholders.

Steps to address challenges for sub-objective 1.1
Local training institute was chosen as the most viable option. We have decided to move forward based, on the response collected, even though one stakeholder did not respond.

Deliverables for sub-objective 1.1
Scope of work.

Sub-Objective 1.2
Support FMHACA in implementing Pharmaceutical Good Governance

Progress toward sub-objective 1.2
SPS/SIAPS-Ethiopia has supported FMHACA to prepare health facility standards for health posts, health centers, primary hospitals, general hospitals and comprehensive specialized hospitals. In the reporting quarter, the board of the Ethiopian Standards Authority (ESA) approved 39 health facility standards. These standards and other legislation will be popularized through workshops and meetings in the coming quarter.

FMHACA was supported to conduct three consultative meetings with medicines manufacturers, importers and wholesalers as well as with health professional associations. In addition, similar support was given to FMHACA to conduct its nine month performance review meeting with all regulatory key players from the federal to the regional level. The purpose of the consultative meetings with manufacturers was to familiarize FMHACA's effort in promoting local production and discuss the challenges and available opportunities. The meeting also discussed local production capacity building, new medicines registration and licensing strategy and future direction of medicines quality control laboratory. The forum served as a platform to build constructive partnership between FMHACA and local medicines manufacturers. It is expected that this will build a culture of transparency and accountability in the relationship between the two institutions.

The consultation with medicines importers and wholesalers focused on new medicines registration and licensing and the quality control of medicines. Concerns on counterfeit, poor quality, backlog of product registration applications, limited access to certain medicines and equitable access to information had been raised and discussed. FMHACA is working to establish a database for

medicines information that will be accessible to all concerned. At the end of the meeting, participants agreed to establish Medicines Importers and Wholesalers' Association so that communication and consultation between this sub-sector and FMHACA will be more effective. This will improve pharmaceutical sector good governance by improving the transparency and accountability of different organizations involved in the regulation, importation and wholesale of medicines.

SIAPS supported another consultative meeting that was held between FMHACA and the health professional associations. The use of civil societies, such as professional associations, in promoting good governance is well accepted. During this consultative meeting, professional ethics, continuing education, professional registration and licensing were key issues raised and discussed. At the end of the consultation, a consensus was reached that health professional associations will provide accredited continuing education for registration and licensing. In order to facilitate this transition, a memorandum of understanding between health professional associations and FMHACA was signed. A steering committee comprising of seven members that oversees the implementation of this MOU will be established soon. This MOU will enable the two bodies to discuss policy issues and problems associated with health professionals.

The nine-month performance review meeting of FMHACA gave the organization the opportunity to institutionalize a transparent and accountable organizational culture. During the meeting the strengths and weaknesses of different units of FMHACA and its regional branches were presented and discussed.

With the technical support of SIAPS, FMHACA has finalized the Medicines Waste Management and Disposal Directives and the National Strategic Framework on Medicines Waste Management. In the reporting period, one popularization workshop was conducted to familiarize stakeholders drawn from key administrative units of the Amhara Regional State. Meanwhile, a short-term intervention plan was drafted in consultation with FMHACA that leads to the development of a country plan for medicines waste disposal.

Main challenges for sub-objective 1.2

- FMHACA is not moving to popularize the standards, as expected.
- FMHACA is not adhering to our joint work plan and we are given very short notice when organizing meetings.

Steps to address challenges for sub-objective 1.2

- A dedicated person from FMHACA side is recommended to complete this task.
- We have notified FMHACA of the minimum time required to organize a meeting.

Deliverables for sub-objective 1.2

- Scope of work for leadership training revised as per stakeholders' response.
- Scope of work for STG re-advertised.
- Proceedings of the two consultative meetings

Sub-Objective 1.3

Strengthen the legal framework of APTS to increase transparency and accountability

Progress toward sub-objective 1.3
SIAPS supports implementation of EHRIG/APTS. To help in the implementation of APTS, a training curriculum has been drafted to conduct a training course for pharmacy professionals, CEOs, MDs, cashiers and accountants.

Four Hundred forty copies of EHRIG pharmacy chapter booklet were distributed with the necessary information to 37 hospitals of SNNPR (16 hospitals), Tigray (15 hospitals) and Dire Dawa, Harari and Eastern Oromia regions (6 hospitals).

Trainings on EHRIG-Pharmacy Chapter and APTS were conducted in eight hospitals of the Amhara (six hospitals) and Tigray (two hospitals) regional states and a total of 15 hospitals initiated APTS.

The Ethiopian Health Centers Reform and Implementation Guideline (EHCRIG) were extracted from EHRIG by FMOH's Hospital Services Directorate in collaboration with SIAPS, Ethiopian Pharmacy Association, and Addis Ababa University Schools of Pharmacy. Once approved by the FMOH, the health center reform pharmacy chapter will be printed and distributed to all health centers.

Deliverables for sub-objective 1.3
- Training Manual
- Training PowerPoint presentations for 13 chapters
- Training report

Measureable contributions of partners for sub-objective 1.3
The Amhara Regional Health Bureau shared the cost of the second round training of EHRIG/APTS. The Bureau is determined to start APTS in six hospitals this year.

Strengths of partners in sub-objective 1.3
- APTS implementation is one of the top priorities of the Amhara and Tigray RHB.
- The auditor general of Tigary Region said that APTS is a powerful name with a powerful system.

Objective 2
Capacity for pharmaceutical supply management and services increased and enhanced

Objective 2: Quarterly progress
In collaboration with PFSA, SIAPS supported hospital DTCs to develop, print and launch facility-specific drug lists. In the reporting quarter, a drug list development workshop was facilitated at Dessie hospital, a drug list was printed and handed over to Gondar University Hospital, and six drug lists are in press. SIAPS has been working to strengthen the establishment and institutionalization of DTCs throughout the country. A total of 13 DTCs have been established, 26% of the target set for the year. Whereas the setting up of DTCs is a relatively easy task, getting the commitment of health facility leaders and responsible pharmacists to implement the extended role of DTCs to ensure ownership and sustainability requires repeated advocacy and

mentoring is much harder.

Technical assistance was provided to DTCs in 22 hospitals to conduct ABC/VEN analysis to evaluate their resource utilization, identify gaps, and design intervention through developing systems for proper selection, quantification, procurement, distribution and use of drugs. An SOP for compounding was also drafted to help hospitals strengthen their pharmacy services. Similarly, on-site trainings were provided to service providers (CEOs, DTC Chair, prescribers and dispensers) to establish drug information services at the hospital level. In the reporting quarter, drug information services were initiated in a total of 10 health facilities, 50% of the target set for the year. SIAPS strives for institutionalized training provision at local universities by building the capacity of university's' staff to enable them conduct regional trainings. This year, the capacity building efforts focuses primarily on ART and AMDM areas. Two pre-service ART/AMDM trainings were successfully conducted at Jimma and Addis Ababa universities. A total of 88 students were successfully trained and certified, 44% of the target set for the year. Upon deployment to health facilities, these trained pharmacists will join the work force to deliver appropriate services in ART and anti-malarial drugs management.

One round of in-service training on clinical pharmacy/pharmaceutical care to EHRIG-implementing sites was carried out in collaboration with school of pharmacy at Jimma University. The main purpose of this activity was to train pharmacists on clinical pharmacy, in an effort to initiate clinical pharmacy services in 21 selected hospitals (35% of the annual target). A total of 723 professionals attended different training events in this quarter. Of which, 186 (25.7%) were females, and 18.1% and 15.9% of the trainees participated in APTS and Standard Operating Procedure-manual (SOPm) trainings, respectively. 28% of the trainees were drawn from Amhara region, followed by Oromia region (21%) and over half (55.5%) were pharmacists.

Sub-Objective 2.1
Strengthening the effectiveness of DTCs

Progress toward sub-objective 2.1
In collaboration with PFSA, SIAPS supported hospital DTCs to develop, print and launch facility-specific drug lists. In the reporting quarter, a drug list development workshop was facilitated at Dessie hospital, a drug list was printed and handed over to Gondar University Hospital, and six drug lists are in press. SIAPS has been working to strengthen the establishment and institutionalization of DTCs throughout the country. A total of 13 DTCs have been established, 26% of the target set for the year.

Technical assistance was provided to DTCs in 22 hospitals to conduct ABC/VEN analysis to evaluate their resource utilization, identify gaps and design intervention through developing systems for proper selection, quantification, procurement, distribution and use of drugs. A SOP for compounding was also drafted to help hospitals strengthen pharmacy services.

Main challenges for sub-objective 2.1
At the facility-level:

- High staff turnover at health facilities which leads to shortage of pharmacy professionals at health facilities.

- Many of DTC activities depend on active/committed DTC members/leaders.
- Health facilities always seek technical/financial support from donors.

On the partners' (PFSA, FMHACA and RHBs) side:

- Existence of overlapping of activities leading to delay in performing planned activities (DTC training).
- Lack of focus on some planned activities at (e.g. DTC best practices sharing event).
- Lack of institutionalization of DTCs and the need for continuous follow-up DTC activities.

Steps to address challenges for sub-objective 2.1

- Provision of onsite trainings/mentoring and sensitization session has been proposed to overcome the challenges at the health facility level.
- A series of discussions with the partners is required to adhere to the planned activities and proposed time frame.

Deliverables for sub-objective 2.1

- Six draft facility-specific drug lists.
- Pharmaceuticals list development workshop report.

Sub-Objective 2.2

Scale up the establishment of Drug Information Services (DIS) to provide unbiased information on medicines to providers and patients

Progress toward sub-objective 2.2

Access to relevant, up-to-date, user specific and unbiased drug information is essential for appropriate drug use. Prescribers, dispensers and users all need objective information on medicines. Setting of a drug information service (DIS) is a vital part of efforts to promote appropriate medicines use. The primary role of a DIS is to give clear and definitive information on medicines and promote their appropriate and cost-effective use.

A Memorandum of Understanding (MOU) has been signed between JHU-TSEHAI and MSH/SIAPS for joint collaborative work in the area of DIS, where both parties have mutual interest towards the establishment and provision of DIS in four hospitals (Amanuel Hospital in Addis Ababa Region; Gambella Hospital in Gambella Region; Hawassa Referral Hospital in SNNP Region; and, Assossa Hospital in Benishangul Gumuz Region). According to the MOU, MSH/SIAPS provides technical assistance and capacity building (training), while JHU- TSEHI provides material and financial assistance to establish and operate the drug information services. Thus, assessment for material requirements and technical support for the facilities was jointly conducted and JHU-TSEHAI and SIAPS, and SIAPS were able to conduct trainings, while JHU-TSEHAI carried out procurement and distribution of the required materials. As a result of this collaborative work, one DIS was officially launched at Assossa hospital in the reporting quarter.

SIAPS is working to conduct trainings away from hotels, providing on-site trainings at health facilities whenever possible. To facilitate the anticipated on-site training, it was planned to conduct TOT trainings on DIS for SIAPS and PFSA staff. In this quarter, one DIS training event was organized for SIAPS regional technical advisors (RTAs) and PFSA staff. A total of 22

professionals of both organizations were successfully trained.

Similarly, on-site trainings were provided to service providers (CEOs, DTC Chair, prescribers and dispensers) to establish drug information services at the hospital level. In the reporting quarter, drug information services were initiated in a total of 10 health facilities, 50% of the target set for the year.

Deliverables for sub-objective 2.2

- DIS Book Handover Report
- DIS Initiation and Launch Report

Sub-Objective 2.4

Strengthen pharmaceutical human resource at different levels to ensure proper management and use of pharmaceuticals and related commodities

Progress toward sub-objective 2.4

In the reporting quarter, a 4-day training curriculum for harmonized DTC/RDU training for the newly established hospitals was finalized and modalities for the provision of onsite training for those facilities that had received DTC trainings were agreed upon. The onsite training involves: gap assessment using a standard checklist; orientation based on the gap assessment and planning; and support implementation of the plans. This approach is expected to improve the training delivery and subsequent change desired in regard to the management and use of pharmaceuticals. Two pre-service ART/AMDM trainings were successfully conducted at Jimma and Addis Ababa universities. This undertaking will help in the institutionalization of ART trainings at schools of pharmacy by building their capacity in the organization and conduction of such training events. The trainers selected for the purpose were senior physicians and TOT trained pharmacists with masters' degrees. SIAPS has trained the pharmacy lecturers for the same purpose. The topics presented include: basic ART topics (as per the standard in-service ART training curriculum); AMDM; overview on DTC, EHRIG, APTS, and the dispensing manual. In addition, trainees were briefed on new government initiatives and directions in the health sector.

A total of 88 students were successfully trained and certified, 44% of the target set for the year. Upon deployment to health facilities, these trained pharmacists will join the work force to deliver appropriate services in ART and Anti-malarial drugs management. One round of in-service training on clinical pharmacy/pharmaceutical care to EHRIG-implementing sites was carried out in collaboration with school of pharmacy of Jimma University. The main purpose of this activity was to train pharmacists on clinical pharmacy in an effort to initiate clinical pharmacy services in 21 selected hospitals (35% of the annual target). The training started in mid-May and finished in the first week of June (one week class-based and three weeks practical application). During the class-based training, the trainees were introduced to common laboratory tests and their interpretation for pharmacists; the most prevalent disease states, their pathophysiology and their management; and pharmacists' role in patient care. During these class based training, trainees were given cases and presented these cases daily. During their clinical attachment, trainees attend morning sessions of multi-disciplinary team (MDT), pharmacists' only morning sessions, major teaching round (MDT), and bed side teachings and/or business rounds. Immediately after the training, a one-day workshop was organized at Jimma University to discuss possible ways to

ensure a smooth implementation and startup of clinical pharmacy services at the targeted health facilities. Participants of this particular workshop were trainees/pharmacists, CEOs of the selected hospitals, and representatives of RHBs. After the workshop, the participants pledged to do all in their capacity to realize the clinical pharmacy services in their respective health facilities.

In this quarter, one round of training was organized to 39 pharmacists (39%) on Pharmaceutical Ethics and Ethical Standard of Practice for Pharmacists in Ethiopia. In addition, APTS training curriculum for pharmacy professionals, CEOs, MDs, cashiers and accountants training has been finalized, in an effort to standardize and guide the delivery of topics on the trainings. A 3-day curriculum/course outline has been developed and three round of training held at Mekelle, Finote-Selam and Debremarkos towns for 132 participants. A total of 723 professionals attended different training events in this quarter. Of these, 186 (25.7%) were female, and 18.1% and 15.9% of the trainees participated in APTS and Standard Operating Procedure-manual (SOPm) trainings, respectively. 28% of trainees were drawn from Amhara region, followed by Oromia region (21%) and over half (55.5%) were pharmacists.

Main challenges for sub-objective 2.4

- Delay in implementation of some activities due to overlapping activities and responsibilities with SIAPS partners.
- Invited trainees for Pharmaceutical Ethics and Ethical Standard of Practice for Pharmacists training were unable to attend the training as planned.

Steps to address challenges for sub-objective 2.4

Next quarter, priority will be given for those planned activities not performed.

Deliverables for sub-objective 2.4

- RDU/DTC training curriculum
- Training reports

Sub-Objective 2.5

Strengthen national capacity for safe, accountable management and timely disposal of pharmaceutical waste.

Progress toward sub-objective 2.5

SIAPS supported FMHACA to develop medicines waste management and disposal directives and a national framework to implement these directives. One popularization workshop (16.7% of the annual plan) was conducted, to familiarize stakeholders drawn from key administrative functions of the Amhara Regional State. The objectives were to: familiarize stakeholders on how to protect the public health and the environment by ensuring safe disposal of medicines waste, introduce cost effective and safe disposal methods based on international best practices and country context to stakeholders;, familiarize the roles and responsibilities of stakeholders working at different levels, introduce the importance of complying with the national disposal directives, promote the involvement of the private sector in medicines waste management and disposal, and strengthen monitoring and evaluation system of medicines waste management practices. The workshop was attended by 60 participants selected from the regional health bureau, zonal health department, district health office, FMHACA branch, PFSA branch, region's environment protection bureau,

referral hospitals, and city administrations. A short-term intervention plan was drafted in consultation with FMHACA to facilitate the development of country-wide plan of action for medicines waste disposal.

Main challenges for sub-objective 2.5
FMHACA has only one focal person for this task, who has another multiple responsibilities as member of the management.

Steps to address challenges for sub-objective 2.5
Advice was given to FMHACA to have additional focal persons and, as a result, they are recruiting additional staff.

Deliverables for sub-objective 2.5
Workshop proceeding.

Objective 3
Utilization of information for decision-making increased

Objective 3: Quarterly progress
SOP trainings were provided in collaboration with university partners in various venues. EDT training was also provided for participants from selected health facilities and some PFSA hubs. In the reporting quarter, 22 health facilities were technically supported regarding their pharmaceutical management information system. The support included conversion of ADT to EDT (18 health facilities) and proper use and maintenance of EDT (8 facilities). So far, ADT was converted to EDT in 55 health facilities (88.7% of the target set for the year).

Formal training sessions on EDT were also organized for a total of 63 pharmacists/dispensers, seven PFSA staff and two SCMS logistics data processors (LDPs). Onsite trainings were provided on how to manage patient and pharmaceutical information using EDT, on real-time dispensing and an orientation on basic functions of the tool was provided to pharmacists/dispensers, data clerks, CEOs and other newly assigned pharmacy personnel. As a result, a total of 54 health facilities started using the real-time dispensing tool. Also, 55 professionals were trained on standard operating procedure (SOPs). PMIS formats were distributed to 477 health facilities to strengthen the data recording and reporting activities. Computer and software (ADT and EDT) maintenance support was provided to 13 health facilities.

Patient uptake data and cumulative regimen breakdown were collected, compiled and reporting bi-monthly from 604 health facilities. The information generated was shared with SIAPS Management, USAID, CDC, SCMS, Regional Logistic Associates (RLAs), RHB, I-TECH Ethiopia, the Clinton Health Access Initiative (CHAI), regional HAPCO, and Johns Hopkins-Ethiopia.

Sub-Objective 3.1
Strengthen Pharmaceutical Management Information System at the dispensing level to improve quality of patient care

Progress toward sub-objective 3.1
SOP trainings were provided in collaboration with university partners in various venues so as to meet the said objectives. EDT training was also provided for participants from selected health facilities and some PFSA hubs. In the reporting quarter 22 health facilities were technically supported on pharmaceutical management information system. The support includes conversion of ADT with EDT (18 health facilities) and proper use and maintenance of EDT (8 facilities). So far, ADT was converted into EDT in 55 health facilities (88.7% of the target set for the year). Formal training sessions on EDT were also organized for a total of 63 pharmacists/dispensers, seven PFSA staff and two SCMS logistics data processors (LDPs). Similarly, onsite trainings were provided on how to manage patient and pharmaceutical information using EDT, on real-time dispensing and an orientation on basic functionalities of the tool provided to pharmacists/dispensers, data clerks, CEOs and other newly assigned pharmacy personnel. As a result, a total of 54 health facilities started using the real-time dispensing tool. Also, 55 professionals trained on standard operating procedure (SOPs). PMIS formats were distributed to 477 health facilities to strengthening the pharmaceutical recording and reporting activities. Computer and software (ADT and EDT) maintenance support also provided to 13 health facilities.

Main challenges for sub-objective 3.1
- Poor recording of patient information on both manual and electronic recording system.
- No adequate documentation system in some facilities; Patient information sheet not documented in file cabinet and not confidential.

Steps to address challenges for sub-objective 3.1
- Providing proper orientation to pharmacist/dispensers and health facility administration.
- Held discussions with health facilities, pharmacy heads, and prescribers/clinicians on the issue of inappropriate information recoding on prescription paper.

Deliverables for sub-objective 3.1
Training proceedings.

Sub-Objective 3.2
Produce information related to medicines use patient uptake, lost to follow-up and regimen breakdown reports

Progress toward sub-objective 3.2
ART patient uptake data and cumulative regimen breakdown were compiled bi-monthly from 604 health facilities, and reports were produced. The information generated was shared with SIAPS Management, USAID, CDC, SCMS, Regional Logistic Associates (RLAs), RHB, I-TECH Ethiopia, the Clinton Health Access Initiative (CHAI), regional HAPCO, and Johns Hopkins-Ethiopia.

Main challenges for sub-objective 3.2
Frequent computer and database failure at some HFs.

Steps to address challenges for sub-objective 3.2
- Provide computer maintenance support during field visits and use backup drives properly.

- Distribute external backup drives to all sites with electronic data management tool.

Deliverables for sub-objective 3.2
Patient uptake reports.

Objective 4
Financing strategies and mechanisms to improve access to medicines strengthened

Objective 4: Quarterly progress
Pharmaceutical transactions and services at health facilities in Ethiopia are not supported with adequate tools and systems that ensure transparency and accountability. The existing system does not generate adequate, reliable and consistent information that are relevant for effective auditing of pharmaceutical transactions and services. It also does not allow tracing the quantity and price of medicines that are dispensed, lost or damaged, and from where, by whom and to whom it is transferred. A total of 15 hospitals initiated APTS and 21 facilities implementing EHRIG. 440 copies of EHRIG pharmacy chapter booklet were distributed to 37 hospitals in SNNPR (16 hospitals), Tigray (15 hospitals), Dire Dawa, Harari and Eastern Oromia regions (6 hospitals).

Sub-Objective 4.1
Support regional health bureaus and health facilities to implement EHRIG –pharmacy chapter

Progress toward sub-objective 4.1
SIAPS works with the health management team of facilities to conduct analyses to inform policy makers regarding cost containment, greater efficiency, and options for mobilizing financing. The focus of this effort is on maximizing pharmaceutical resources through innovative cost containment strategies. Towards this end, SIAPS-E supports implementation of EHRIG/APTS. In this quarter, APTS training curriculum for pharmacy professionals, CEOs, MDs, cashiers and accountants training has been finalized in an effort to standardize and guide the delivery of topics during the trainings. A 3 day curriculum/course outline has been developed and three rounds of trainings held at Mekelle, Finote-Selam and Debremarkos towns for 132 participants.

Deliverables for sub-objective 4.1
- Training Manual
- Training PowerPoint presentations for 13 chapters
- Training report

Objective 5
Pharmaceutical services to achieve desired health outcomes improved

Objective 5: Quarterly progress
SIAPS works to improve pharmaceutical services by assuring product availability and ensuring that patients receive medications optimized to their clinical needs, in doses that meet their individual requirements, for an adequate time, and at the lowest cost to them and their community. SIAPS implements strategies to improve services that will result in optimal treatment outcomes. This is affected by building systems to train health professionals and providers, provide medicine information and counseling, conduct drug utilization reviews, formulate policies and regulations

for improved pharmaceutical care, and disseminate information and educational materials to promote public health.

Electronic copies of standard prescription forms were provided to all who need it and printed copies of prescription forms were also provided to 24 hospitals. This is estimated to be enough for approximately 6 to 12 months. SIAPS is supporting revision of the national STG, for which bid documents are currently being collected.

The National Antimicrobial Resistance Prevention and Containment Advisory Committee meeting was organized and discussed the national strategic framework for prevention and containment of antimicrobial resistance and progresses of AMR containment: advocacy and interventions activities. An antimicrobial resistance containment strategy familiarization and intervention plan workshop was organized to bring all stakeholders together to familiarize and develop a strategy, and also enrich the intervention plan and facilitate the implementation of AMR prevention and containment interventions. A total of 45 participants from the Ministry of Agriculture (MOA) and Animal Health Research Institute, Regional Health and Agricultural Bureaus, universities, FMHACA, hospitals and health centers, health professional associations, media and developmental partners, and a variety of professional categories.

During the quarter, 21 journalists were trained on the prevention and containment of antimicrobial resistance and rational medicines use. Objectives of the training were to provide concepts on prevention and containment of AMR and rational medicines use (RMU), practice RMU and AMR information abstraction and dissemination to the public, discuss the challenges faced in educating the public about RMU/AMR, and develop a plan of action to increase public awareness and to agree on follow up meetings.

Sub-Objective 5.1
Promote rational prescribing of medicines through educational, managerial and regulatory interventions

Progress toward sub-objective 5.1
Electronic copies of standard prescription forms provided and printed copies of prescription forms were distributed to 24 hospitals. This is estimated to be enough for 6 to 12 months. SIAPS is supporting revision of the national STG, for which bid documents are currently being collected.

Sub-Objective 5.3
Improve medicines use by clients

Progress toward sub-objective 5.3
Journalists were trained to disseminate essential and key messages on RMU and AMR using print and electronic media. In the reporting quarter, the majority of trained journalists posted or broadcast RMU and AMR news and public education messages. Similarly, articles/ IEC materials on RMU/AMR were provided for dissemination through the Drug Information Network Bulletin.

Sub-Objective 5.4
Provide technical and material assistance to the National AMR Advisory Committee, RHBs, and

universities to implement the National AMR Containment Framework

Progress toward sub-objective 5.4
The National Antimicrobial Resistance Prevention and Containment Advisory Committee meeting was organized and the national strategic framework for prevention and containment of antimicrobials resistance and progresses of AMR containment: advocacy and interventions activities were discussed. SIAPS supported FMHACA to conduct the "Antimicrobials Resistance Containment Strategy Familiarization and Intervention Plan workshop which was organized to bring all stakeholders together and increase awareness and enrich the intervention plan on AMR prevention and containment interventions. Specific objectives of the workshop were to:

- Sensitize all stakeholders on the rising magnitude and seriousness of AMR as a problem.
- Update and follow up on AMR interventions.
- Discuss systematization involvement of stakeholders and sustainability in the prevention and containment of AMR.
- Develop an intervention plan and follow up mechanism based on the AMR containment strategy.

A total of 45 participants from the Ministry of Agriculture (MOA) and Animal Health Research Institute; Regional Health and Agricultural Bureaus, Universities, FMHACA, hospitals and health centers, Health Professional Associations, media and developmental partners, and other professionals attended the workshop.

In the reporting quarter, Journalists were trained on the prevention and containment of antimicrobial resistance (AMR) and rational medicines use. Objectives of the training were to provide concepts on prevention and containment of AMR and Rational Medicines Use (RMU); practice RMU and AMR information abstraction and dissemination to the public; discuss the challenges faced in educating the public about RMU/AMR using their respective media outlets; and develop plan of action to increase awareness of the public on AMR and to agree on follow up meetings. The topics presented were carefully selected based on their significance and were delivered to the participants by trainers. In this training, 20 journalists working on the health programs of different federal and regional government print and electronic media such, as radio and television programs and print media participated (50% of the target set for the year). The participants prepared their own plan of action, based on their role on the prevention and containment of antimicrobial resistance and promotion of rational medicines use. The action plans were prepared by selecting priority activities to be covered and not limited to these activities. The plan of action was prepared: one copy was submitted to the organizers for follow-up and one copy was left with participants. During the planning, trainees were provided with topics on RMU and AMR (one year agenda) to be covered in the different media outlets.

Deliverables for sub-objective 5.4
Training proceedings.

Sub-Objective 5.5
Provide technical assistance to strengthen ADR monitoring and Pharmacovigilance (PhV) systems

Progress toward sub-objective 5.5
Ensuring the availability of reporting forms and allergy cards at health facilities is the prerequisite

to get adverse drug event (ADE) reports from health providers. Reporting forms and allergy cards were printed and distributed to two hospitals.

Awareness on pharmacovigilance aspects was the focus of face-to-face discussions in 4 private hospitals and at AAU school of pharmacy. This brings the total number of health facilities that organized face-to-face discussion to 10 (15.2% of the annual plan). A total of 52 service providers and 13 fourth-year pharmacy students participated in the discussion. Similarly, follow up on pharmacovigilance activities were made at nine facilities, to identify challenges and make corrective actions. SIAPS helped FMHACA to compile a Pharmacovigilance newsletter, which is ready for printing. For a complete and functional pharmacovigilance center, the presence of pharmacovigilance database is important to store and manage ADE reports collected from health providers. For this purpose, MSH/SIAPS supported FMHACA to develop a pharmacovigilance database.

In collaboration with various partners, a national pharmacovigilance strategic framework was developed to effectively carry-out drug safety monitoring activities. A familiarization workshop on the national pharmacovigilance framework was carried-out and a total of 51 participants drawn from the Federal Ministry of Health, Regional Health Bureaus, FMHACA, professional associations, MSH/SIAPS, WHO, JHU, local pharmaceutical manufacturers, pharmaceutical importers, academic institutions, government and private hospitals, health centers, and the media participated.

A complete pharmacovigilance system needs to contain passive surveillance and active surveillance. SIAPS has been supporting FMHACA to carry-out active surveillance in the form of cohort event monitoring (CEM) on antiretroviral drugs. A stakeholder meeting on the CEM program for antiretroviral drugs was completed in the presence of 45 participants drawn from hospitals, health centers, FMHACA branch offices, regulatory section of regional health bureaus, academia, HIV patients adherence supporters, professional associations, Federal Ministry of Health (HIV focal person), Federal HIV/AIDS Prevention and Control Office, MSH/SIAPS, World Health Organization and an importer. A task force was established for stakeholders and partners participate in the CEM activity, and members were selected from those present during the workshop.

Main challenges for sub-objective 5.5
Difficulty setting appointment dates for the face-to-face discussion, especially prominent at private facilities.

Steps to address challenges for sub-objective 5.5
Repeatedly postponed and waited until a convenient time was agreed upon.

Deliverables for sub-objective 5.5
Workshop proceeding on stakeholders meeting on the cohort event monitoring (CEM) on antiretroviral drugs.

Objective 6
Support FMHACA and RHBs to improve the quality of service given by Rural Drug Vendors

(RDV)

Objective 6: Quarterly progress

The majority of Ethiopians live in the rural area, where they are vulnerable to many health hazards including diarrhea, pneumonia, malaria, and skin problems. Rural Drug Vendors (RDVs) have a long history of serving the rural community of Ethiopia by providing access to essential medicines. SIAPS initiated need-based training support for RDVs in order to enhance their skills on Good Dispensing Practice and RDU, and thus improve the quality of pharmaceutical service they provide to the rural population.

This year, RDV training curriculum was updated under the title: Training Course on Drug Supply Management and Rational Use of Drugs for RDV Practitioners with the objective of improving access to and use of pharmaceuticals. The training for RDV practitioners addresses gaps in dispensing and counseling, storage of medicines, DSM, and regulatory affairs.

RHBs and FMHACA have demonstrated unreserved support to SIAPS in the training of RDVs and have promised to own and make the intervention sustainable. RHBs and FMHACA have adopted a system for following up the performance of RDVs through a monthly self-assessment activity report filled out by RDVs who have received training. In the reporting quarter, two rounds of RDV trainings were organized and 96 RDVs trained. This brings the total number of trained RDVs to 113 and participants from regulatory bodies to 30 (14% were females). This is 47.7% of the annual.

Follow-up on the trained RDVs was made by SIAPS regional technical advisors through supportive supervision visits and monthly self-assessment reports. During the visit, most of the trained RDVs were found to have cleaner dispensaries and stores; well organized pharmaceuticals both at dispensaries and stores; thermometers and fire extinguishers in place; dispensing and counseling guides available; decreased dispensing of medicines by non-professionals (“aids”); and a re-interpretation of inspections from the Woreda or Zonal health departments as “supportive” rather than “fault finding”.

Printing and distribution of RDV formularies, drug lists, over-the-counter (OTC) medicines list, and dispensing manuals were also completed.

Guinea

Portfolio Background

More than 90% of the clinical cases of malaria occur in Africa each year with much of the burden in children under five years of age. It is preferable that strategies to address malaria be implemented in coordination with programs following integrated approaches to childhood illness and reproductive health whilst ensuring that quality medicines are available and used appropriately. Guinea is a West African country where malaria is endemic throughout the country.

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 obtained through the Global Fund Round 6 grant and, more recently, through 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. ASAQ has 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. Contributing to the stock outs was the political instability experienced in Guinea, which led to delays in implementing planned Global Fund Round 6 activities. Delays in implementation in turn contributed to delays in disbursement of funds for Phase 2 of the Round 6 grant, which led to the stock outs. Additional contributing factors to the stock outs were, an inefficient information system which prevented appropriate decision making as well as logistical 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 is implemented by Management Sciences for Health (MSH). SIAPS has received field funds from PMI to provide technical assistance to improve pharmaceutical supply chain management in Guinea alongside other partners. In additional to facilitating optimal conditions for key pharmaceutical system actors (such as Guinea's Central Medical Stores --the Pharmacie Centrale de Guinée or PCG) to perform better, PMI also expects SIAPS to support implementation of Guinea's national malaria policy and treatment guidelines with the ultimate goal of help reducing recurrent stock outs of malaria commodities.

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 an amount of $1,000,000 to SIAPS for fiscal year (FY) 2011.

Quarter Overview

SIAPS worked with the NRA to set up a national essential medicine list revision committee. This committee will provide technical support in the process of the revision. Another aspect of the

committee is to define a timeline of different steps to consider from one revision to the next one. The document is ready to be signed by the General Secretary of Ministry of Health.

SIAPS participated in a coordination meeting of financial and technical partners (Groupe thematique secteur pharmaceutique) at the European Union Office, in order to follow-up on the round table recommendations. During this meeting, the European Union representative shared that their institution will help the Guinean Ministry of Health this year, and there are also funds available for the PCG. To assist the NRA, SIAPS contracted two international consultants to assess the NRA in the institutional and regulatory areas: terms of reference and dates are already fixed and the assessment will be carried out next quarter. This activity will contribute to reinforce the leadership and to make more clear how must be articulated and implemented the NRA's leadership throughout the pharmaceutical sector. SIAPS identified laptops and printers needed at the central (NMCP, NRA, CMS) and district level. SIAPS discussed with ETI (an internet connection provider in Conakry) options for internet connections.

Key challenges of quarter

This quarter, there were many planned activities at the MoH and date conflicts forced rescheduling of some activities to the next quarter. Also, SIAPS team has just one technical person and no office manager. The technical person is solicited for administrative, technical and financial aspects for SIAPS office.

Key activities for next quarter

The assessment of the NRA of Guinea will be carried out from July 2-13, 2012. This assessment will focus on institutional aspects and the regulation performance within the pharmaceutical sector. Some key partners will be met and the rough findings will be submitted to the Ministry of Health. In August, we plan for a group of consultants to develop an action plan to implement recommendations. Management tools and training manuals will be reviewed and harmonized to facilitate the common understanding and process for all stakeholders and partners.

Office Management

The process of work planning was launched and information was gathered for the strategic plan for SIAPS. The MOP team was in Guinea during the month of June 2012 and they met with several stakeholders from MoH (NMCP) and other Principal Recipients for the Global Fund. They confirmed their concern about the PCG (the central medical store).

Objective 1

Pharmaceutical sector governance strengthened

Objective 1: Quarterly progress

Consensus was reached between financial and technical partners to address the pharmaceutical sector. The meeting held at the EU office focused on key areas to methods for providing support to the PCG (central medical store). SIAPS was designated to gather all studies on PCG and DNPL and will share them with other partners. SIAPS met also with UNFPA, WHO and UNICEF to discuss the round table recommendations.

Sub-Objective 1.3

Improved governance in the pharmaceutical management

Progress toward sub-objective 1.3
Following the round table on the pharmaceutical system, a group of financial and technical partners called “sous groupe thematique secteur pharmaceutique"" met at the European Union Office to determine the next steps to address the key challenges of the pharmaceutical sector. These focused mainly on the CMS (PCG). The round table's recommendation follow-up committee proposed by the moderator of the round table did not hold a meeting as planned.

Haiti

Portfolio Background

USAID/Haiti has been supporting the Ministry of public Health and Population (MSPP) and other partners for many years to improve availability and access to quality pharmaceutical products for the Haitian population. It is through this support that USAID/Haiti has requested technical assistance from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) project to support the Direction de la Pharmacie du Médicament et de la Médecine Traditionnelle (DPM/MT) in identifying technical assistance needs for the Haiti Pharmaceutical Sector SIAPS team comprising of Sameh Saleeb, SIAPS Technical Deputy Director and Seydou Doumbia, SIAPS Principal technical Advisor conducted a preliminary visit from February 12 to 17, 2012 to ascertain USAID priority technical assistance areas through discussions with the Ministry of Health, USAID, and other key stakeholders. During the visit, the Ministry of Health communicated its utmost priority to be related to the elaboration of a revised National Medicine Policy (NMP).

Quarter Overview

The SIAPS team conducted two trips in Haiti during the reporting period from May 14-17 and from May 27-June 8, 2012. A situation analysis was carried out to identify gaps related to the pharmaceutical sector and discussions were held with DPM, WHO and USAID in support of the DPM's request to develop a new National Medicine Policy. SIAPS worked with the DPM team to write the revised version of the NMP document and the first draft of the NMP document was shared with the Chief DMP/MT.

Key activities for next quarter

- Incorporate comments from stakeholders into the first draft of NMP document.
- Finalize and print the revised NMP document.
- National and departmental dissemination of the revised NMP after adoption by Parliament.

Objective 1

Improve access to quality pharmaceutical products

Objective 1: Quarterly progress

SIAPS conducted a situation analysis to identify gaps related to pharmaceutical sector. Staff provided support to DPM/MT to engage stakeholders in National Medicine Policy revision. SIAPS discussed with USAID/Haiti issues related to the SIAPS STTA, including the Policy Advisor position to be embedded at the DPM/MT, the local SIAPS consultant to support the process for finalization, submission and potential operationalization of the national medicine policy process and the SIAPS budget. SIAPS conducted key stakeholders engagement workshop related to the revision of NMP and developed the new draft National Medicine Policy document.

Jordan

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. A study conducted by the Jordan Food and Drug Administration (JFDA) evaluated the use of prophylactic antibiotics in three hospital across the following sectors: MOH, a University Hospital, and a Private hospital. The results were published in 2009, and showed both overuse and misuse of prophylactic antibiotics.

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

This quarter, the portfolio made good progress in institutional system strengthening through continuous quality improvement (CQI) principles. Working with SIAPS, the hospital teams are continually monitoring and evaluating the implementation of the Cesarean Section prophylactic antibiotic protocol through the specified indicators. In addition, the teams are incorporating CQI principles into their daily routines, and are meeting more frequently under the Drug and Therapeutics Committees (DTC) to evaluate and discuss progress. With the hospital management,

the DTCs are evaluating the indicators directly, discussing areas of weaknesses and gaps, and mandating plans to improve outcomes. The indicator results, while slightly below SIAPS Jordan work plan goals, are consistently improving.

Key challenges of quarter

Communication with the MOH Hospital Administration (HA) and its Directorates. The MOH Directorates function independently of one another. Establishing an organized working relationship between the HA Directorates and the respective hospital departments.

Key activities for next quarter

At Hospitals:

- Continue with technical assistance at P. Hussein Hospital in their data entry, review, and interpretation.
- Assist in the technical and logistic work needed for the P. Hussein presentation to the MOH Directorates.
- Continue the development of the EMT to yield disaggregated information regarding patient follow-up as discussed with team. This will enable the team to better understand and describe infection rates.
- Schedule hospital technical visits to be performed alongside technical staff from the MOH Directorates.

At the Ministry of Health:

- A meeting has been scheduled with the Head of Medical Specialty for OBGY alongside the technical staff of the MOH Medical Specialty Directorate in order to provide a program briefing. During this meeting, the team will discuss the unification of the CS Protocols produced in the three hospitals for use throughout the MOH.
- Subsequently, SIAPS will provide technical assistant needed in planning and carrying out the unification of the protocol.
- Technical support will be provided, in the form of training, to relevant MOH Directorate technical staff.
- With the Quality Directorate lead through the NQSG initiative, SIAPS will assist with the technical aspects of NQSG number 2 (prophylactic use of antibiotics) in order to secure sustainability for the CS Program, in addition to expansion of the program's principles to cover other areas as mandated by the accreditation goal.

Objective 1

Strengthen national and institutional capacity for effective, safe, and cost-efficient use of antimicrobials to help contain antimicrobial resistance and improve patient outcomes

Objective 1: Quarterly progress

This quarter's work focused on strengthening the continuous quality improvement (CQI) system in the hospitals participating in the pilot initiative to improve antibiotic prophylaxis in CS. Hospital teams at Prince Faisal Hospital, prince Hussein Hospital, and Dr. Jameel Al Totanji Hospital continued to use CS Log and monitor the data/indicator results. In addition, Dr. Jameel Al Totanji and Prince Faisal Hospitals are working with DTCs to improve communication and patient satisfaction.

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

Progress toward sub-objective 1.1
Prince Faisal Hospital:

- The acceptance in the OBGY Ward of the protocol has also improved, and the nurses describe more positive interactions with the physicians. This improvement is illustrated by the overall increase in adherence as indicated through the measured indicators.
- Since the workshop in March, the department of pharmacy has utilized strategies from "Identifying Drug Use Problems" and "Drug Use Evaluation" (presented and exercised during the workshop) in order to quantify and control the number and amount of antibiotic prescribing through its outpatient pharmacy.
- Since successful activation of the Drug and Therapeutics Committee (DTC) during last quarter, the committee has met three times. The committee discussed protocol implementation and monitoring at the time, and compared it with the expectations resulting from the March workshop. Together, the committee discussed their weaknesses, and each department understood what is required of them in order to improve overall performance leading to improved outcomes in April.
- Although the DTC has met, communication gaps still exist among the team, and the resulting indicator data was not being shared directly, or often enough, with the entire team. SIAPS continues working with the hospital team, both on individual basis and on group basis in order to solidify the role of the DTC in implementation, monitoring, and CQI by increasing reporting of data to all relevant members and engaging the hospital administration.
- The hospital team continues to implement the protocol, to monitor through the use of the CS Log, and to measure indicators through Excel Monitoring Tool (EMT). There is dramatic improvement in the CS Log capture rate, increasing steadily from 21% in January to 94% in May. A review of the collected indicator data was performed with the assistance of SIAPS. Both the accuracy of information captured by the CS Log and the entry of data were checked to ensure quality of data. No errors or inconsistencies were discovered.
- The hospital presented an update of the program to the MOH Directorates during a meeting on June 5, 2012. SIAPS worked with the MOH and the hospital in organizing the meeting, and in the technical preparations for it. Discussions focused on the indicator results, and the mechanisms of work at the hospital. The hospital team explained their work, gaps and/or weaknesses existing in the work flow, and the steps taken to correct them.

Prince Hussein Hospital:

- Implementation and monitoring of the protocol continues with the use of the CS Log and the Excel Monitoring Tool (EMT), and data for January through March has been updated into the EMT for analysis. Analysis and evaluation of the new data was performed with SIAPS, and a few discrepancies in data reporting and entering appeared during this CQI process. The team decided to review all the CS Logs for those months, and to re-enter the data into the EMT once the review is completed. During review of the CS Logs, the nursing team also unveiled prescribing habits of some physicians, and was able to report them to the head of department for discussion and action.
- The hospital team completed the MOH Accreditation Process, and is now awaiting the final decision/announcement from the accrediting body. In addition, the team is involved in the

Hakeem Program, providing electronic health solutions in the MOH.

Dr. Jameel Al Totanji Hospital:

- The hospital team continues to implement the protocol, to monitor through the use of the CS Log and to measure indicators through Excel Monitoring Tool (EMT) with SIAPS technical assistance.
- The Infection Control Committee (ICC) team has provided their own evaluation and analysis of their numbers, and working with the SIAPS have outlined modifications to the Excel Monitoring Tool (EMT) in order to yield deeper analysis of patient follow-up rates. The ICC holds monthly meetings, and has discussed CS Protocol progress in each of these meetings. The ICC has also delivered results to the Drug and Therapeutics Committee (DTC), which in turn has held two meetings since the workshop in March. SIAPS continues working with the teams in broadening the responsibility for monitoring and evaluation from individual-basis and initiative to a more organized and scheduled process. This has been outlined by encouraging the ICC to submit the collected indicator data in an official manner to the administration and the DTC. In turn, the DTC is now responsible for carrying out meetings with all relevant stakeholders in order to discuss the results and to address any existing gaps. The DTC, needs to engage more of the relevant stakeholders during meetings, and must establish a stronger presence in the monitoring and evaluation of the protocol.
- After a good start, the CS Log Capture Rate has somewhat declined. The team has discussed the issue, its contributing factors, and possible solutions with both the head OBGY nurse and the head of nursing in the hospital. Given the results for Indicator 3 (prescribing other prophylactic antibiotics), the committee quickly communicated the matter with the OBGY physicians and the administration, which led to immediate action by the Head of OBGY. The numbers for April show significant improvement for that indicator.
- After several delays in setting-up a presentation for the MOH Departments, the meeting finally took place on July 1st, and all the relevant MOH Directorates were in attendance. The entire hospital team, including the new hospital director, attended the meeting. The measured indicators were presented and discussed.

Main challenges for sub-objective 1.1

The main challenge in this area is the establishment of a continuous and sustainable process. Working with the hospital administration and the MOH Directorates, SIAPS continues to synchronize technical activities between the MOH administration and the hospitals through policies and procedures.

Steps to address challenges for sub-objective 1.1

Unification of the CS protocol: With the Medical Specialties Directorate, SIAPS will review progress with the MOH specialist head of OBGY in order to gain further advocacy toward unifying the protocol. The position is currently held by the previous deputy head of OBGY at the MOH, who had participated in the first workshop and was supportive of the program. The goal is to incorporate the unified, agreed-upon CS protocol into the Quality Directorates NQSG 2.

Intensive training of the MOH Directorates staff regarding the protocol development, implementation, and the monitoring tools: Technical staff from the MOH Directorates will be presented with material produced during the CS pilot program, and will be trained in the process of protocol development, implementation, and in applying principles of Continuous Quality Improvement (CQI) for monitoring. Training in the use of the monitoring tools produced for the

hospitals will be held for the MOH Directorates. SIAPS will provide some technical assistance through the experience with the CS pilot program. Joint technical visits to the hospitals: With the training outlined above, the MOH Directorates' staff will be able to engage directly through the work with the hospitals. Routine duties currently carried out with SIAPS will take place jointly, enabling the MOH staff to gain experience.

Lesotho

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% . The GOL's current HIV/AIDS National Strategic Plan (NSP) recognizes the need to provide treatment, care and support services to cater to 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, and infrastructural resources and effective commodity procurement and distribution systems are put in place. Inadequate information management systems to support decision making in supply chain management 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. T

The United States Government (USG) has provided 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 of 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 in this endeavor.

Quarter Overview

The third quarter performance has seen the implementation of the Dispensing and Inventory Module of RxSolution. The implementation came as the next step following the training of users, which was completed mid-June. The LMIS training workshop was held for the laboratory personnel at the health centers. RxSoultion data management was completed at four hospitals (Berea, Seboche, Paray and Motebang). Supportive supervisions and mentoring were made with the directorate of disease control. The supervision tool that is used captures very critical information that will inform objective 4 of the work plan (increase and enhance the capacity of the pharmaceutical supply management and services). Some of this year's activities have been realigned to fit in the next financial year.

Key challenges of quarter

Following the support that has extended over the LMIS, it was identified that the reporting rates from the facilities are very low. This means the quality of data generated from sites is compromised and analysis that is done does not reflect the ideal situation. Pharmaceutical staff are not invited specifically for program specific trainings (such as PMTCT, ART, IMAII, FP and RH), yet they provide support in these programs. This challenge is not only a reflection of quarter three but has been an ongoing issue that needs to be addressed. Another area that needs strengthening is the human resource availability at the health centers, in order to relieve clinical and data management staff from being over-burdened.

Key activities for next quarter

- STTA for LMIS, including training of more facility staff and supportive supervision and mentoring on LMIS.
- Data generated by LMIS will continue to be analyzed and the information shared with the MOH and key partners and stakeholders to improve availability of key ART laboratory commodities.
- PMIS data generated by RxSolution will continue to be analyzed and the information shared with key stakeholders to sustain the availability of ARVs and other ART-related pharmaceutical commodities.
- Supportive supervision and mentoring visits, including collection of baseline data for performance of the PMIS, will continue. The data is being shared with key stakeholders within the MOH in order to improve performance of ART pharmaceutical service delivery in the country.
- Training on supply chain management for all cadres involved in SCM will continue, with 2 training workshops panned for August and September. These are aimed at building the capacity of staff at facilities in SCM.
- Roll-out of RxSolution will continue. This includes training of staff at the new facilities and support of staff at the facilities already using the system for its optimal use. Mobile internet cards will be procured for more sites in order to strengthen reporting and feedback.

- STTA for STGs and EML will help support finalization of these key documents for pharmaceutical management in the country. A national stakeholder consultative workshop will be held during the next quarter to validate and give consensus for the reviewed documents, following which, they will be edited, printed, launched and distributed.

Technical Activity Coordination

Regular touch base meetings were held with the portfolio manager, regular progress update meetings were held with the USAID activity manager, and regular update and planning meetings were also held with the MOH's DCD.

SIAPS participated in the Laboratory SC TWG and the SCM TWG meetings, the PEPFAR Implementing Partners Forum and the Health Development Partners Forum meetings. SIAPS also presented progress update and future plans at a MOH's forum, which included other PEPFAR implementing partners.

Regular staff meetings were held to monitor and manage activity progress. The OST, Program Support Associate and Admin-Coordinator also provided support on finance and operations.

Office Management

Payments were made to the suppliers and purchase requests were prepared and vendors were paid accordingly. Staff arranged travel logistics in support of technical activities. Logistical support and arrangements for MSH staff visiting Lesotho was completed. Monthly reconciliations of gas receipts were done and inventory was updated. Logistics for trainings and workshops were done. Staff arranged logistics for and participated in the SIAPS Strategic Planning Meeting.

Objective 1

Strengthen pharmaceutical sector governance

Objective 1: Quarterly progress

In order to strengthen pharmaceutical sector governance, the SIAPS Lesotho project would need to provide technical capacity for the registration of medicines in the country. Progress on registering medicines in the country has not been made because the bill has not been presented to parliament.

Sub-Objective 1.1

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

Progress toward sub-objective 1.1

SIAPS continued to support the implementation of the quality assurance system using the minilab at NDSO. The standards procurement has been initiated and they are expected to be available in the next quarter. SIAPS has further continued to support the finalization of the STGs and EML activities. The STGs were piloted and comments from stakeholders were incorporated into the draft documents. The documents will be finalized and be available in the next quarter.

Main challenges for sub-objective 1.1

There have been competing priorities at NDSO and the Ministry of Health. This has resulted in delays in implementation of the minilab and STG activities. There has been a delay in release of

funds at NDSO to procure the minilab standards.

Steps to address challenges for sub-objective 1.1
SIAPS will procure standards on behalf of NDSO to enable testing to commence. In addition to the consultant leading the STG and EML review process, SIAPS Lesotho will engage short-term technical assistant from SIAPS Swaziland to expedite the editing and stakeholder consultative process for the STGs.

Deliverables for sub-objective 1.1
The STG piloting trip report.

Objective 2
Increase and enhance the capacity for medical products supply management and services

Objective 2: Quarterly progress
SSM visits have been conducted and minutes were taken. Further suggestions have been made and progress is currently being monitored. The level of commitment of staff is expected yield good results on improving staff morale at hospitals. The staff and the central MOH team have made commitments towards improving inventory and information management practices and information sharing. SCM TWG meetings have been conducted, resulting in improved coordination of SC activities, and partner assistance. This improved coordination is noticed by the level of commitment exhibited by relevant stakeholders while the MOH leads the process. Noticeably, through meetings, challenges experienced have been dealt with and roles being assigned for specific action items. Information from PMIS and LMIS is now regularly shared among key stakeholders. Staff has been trained on SCM and use of RxSolution for pharmaceutical inventory and patient data management.

Sub-Objective 2.1
Strengthen medical products management capacity of individuals, institutions, organizations, and networks

Progress toward sub-objective 2.1
SCM TWG meetings have been held this quarter. The SCM and RxSolution trainings have resulted in more staff being skilled in appropriate management of inventory and information. The SSM visits have improved staff morale and this is expected to improve reporting rates and reduce stock outs.

Main challenges for sub-objective 2.1
Competing priorities at the MOH central level hinder optimal SSM program implementation. Sub-optimal attendance of SCM TWG meetings reduces impact of this forum in improving SC system performance.

Steps to address challenges for sub-objective 2.1
When planned visits are not conducted due to competing priorities, ad hoc visits are conducted. Use of support through the telephone has also been increased when facility visits cannot be done. SCM TWG meeting minutes circulated in a timely fashion and reminders to members done a day

before meetings. It is yet to be determined if this will improve attendance.

Deliverables for sub-objective 2.1
- SCM TWG meeting minutes.
- SSM visit trip reports.
- SCM training trip report.
- RxSolution support trip reports.

Sub-Objective 2.2
Adopt and implement innovative and proven approaches for human resource capacity building

Progress toward sub-objective 2.2
The above sub objective has not yet been implemented as it has been re-aligned to begin next FY. There is also a need to conduct a survey that will inform the need for human resource capacity building at health training institutions. This capacity needs assessment will be conducted during the next quarter.

Objective 3
Increase utilization of information for decision-making

Objective 3: Quarterly progress
A number of supportive supervision and mentoring (SSM) visits were conducted in support of PMIS implementation. In total, 7 hospitals were visited and 9 SSM visits were conducted. The purpose of the PMIS visits is to strengthen implementation of PMIS, making available timely information to enable appropriate decision-making for pharmaceutical management within the ART program. The ART unit in the DCD is also supporting implementation of the PMIS for the general essential medicines by supporting pharmacy staff at hospitals to manage all commodities at the facilities. SIAPS also provided support for implementation of the laboratory LMIS. For both these systems (PMIS and LMIS), monthly data was regularly analyzed and reports transmitted and shared with the MOH central level. Central level MOH is also being supported to manage these data and information management processes, and the target is to ensure that by the end of the project, the MOH central level is capacitated to manage both pharmaceutical and laboratory logistics data to inform procurement and inventory management decisions.

SIAPS also supported forecasting of rapid test kits for a period of 9 months. This forecast is expected to be re-visited after 6 months, and strengthened with the evidence from the LMIS reports, in order to prepare a more robust forecast of a 12 month period.

SIAPS also supported the DCD in conducting a training workshop on supply chain management where all facility staff handling both pharmaceutical and laboratory commodities were targeted. The trainees included laboratory technologists, pharmacy technicians and pharmacists, nurses, and senior counselors (responsible for HIV testing, counseling, and stocks of test kits). This training was a success, with participants expressing support for this type of training.

Sub-Objective 3.1
Strengthen use of pharmaceutical management information systems (PMIS) to support both

inventory and patient management

Progress toward sub-objective 3.1
There has been some progress on this sub-objective, with 2 hospitals submitting their reports. More support to the hospitals through intensified SSM visits is still needed to improve performance of this indicator.

Main challenges for sub-objective 3.1
HR shortages at hospitals hinder reporting rates and also affect data quality. Some staff has also not been trained on the DSM and RxSolution, and has learned these on the job. This compromises quality of data.

Internet connectivity is also a challenge, with some hospital pharmacy departments lacking any internet access. This, coupled with erratic transportation from the districts, affects reporting rates. Some staff at hospitals still does not see the importance of data management and regular reporting, and do not take it as an important part of their daily activities. This hampers reporting rates and data quality.

Steps to address challenges for sub-objective 3.1
SIAPS has procured data cards for some facilities to enable reporting via email. More data cards will be procured as RxSolution is rolled-out. The use of RxSolution also simplifies reporting in that it obviates manual data analysis and transcription of data from the paper data collecting forms onto the paper-based reports. It also minimizes error rates.

SSM visits are being intensified, and the DCD ART unit has developed a rolling SSM visit schedule. This is aimed at providing on-going support to the facilities in inventory management, data collection and information management.

Deliverables for sub-objective 3.1
Maluti Hospital and Nts'ekhe Hospital PMIS reports.

Sub-Objective 3.2
Improve availability and use of strategic information in order to strengthen laboratory systems and improve service delivery

Progress toward sub-objective 3.2
Facilities are reporting on the LMIS and these data are being analyzed to keep the laboratory directorate routinely informed of the stock status. More facilities are reporting and SIAPS is working with the laboratory logistics coordinator to improve her skills in managing the LMIS and using the information generated by the system.

Main challenges for sub-objective 3.2
Reporting rates are still low. A total of 7 out of 17 facilities have submitted reports, and some of these are not submitting their data regularly. The quality of the data reported is also still problematic. The commitment of the logistics coordinator to the system still needs improvement. Appropriate oversight and quick, appropriate action by the management of the laboratory

directorate to prevent crisis before they happen also needs to be improved. Some facilities do not have staff trained on LMIS, which has impacted on reporting.

Steps to address challenges for sub-objective 3.2
Intensified support to the facilities through regular phone calls seems to be improving reporting rates. An intensified SSM plan for LMIS implementation has also been planned for next quarter. More staff will be trained on LMIS to ensure that all hospitals have trained personnel to manage logistics data. STTA from Tanzania MSH will visit Lesotho to support these activities during the next quarter. SIAPS has procured data cards for facilities to improve reporting rates. The logistics coordinator is provided regular mentoring in data analysis and management and in disseminating the information generated by LMIS to key stakeholders (e.g. SCM WG and the laboratory TWG).

Deliverables for sub-objective 3.2
- SSM visits trip reports.
- LMIS data analysis reports.

Objective 4
Strengthen financing strategies and mechanisms to improve access to medicines

Objective 4: Quarterly progress
During the quarter, in collaboration with the Ministry of Health's Pharmacy Department, SIAPS conducted supportive supervision and mentoring exercises at Maluti hospital in Berea district. The stock cards were updated and properly completed.

Liberia

Portfolio Background

Liberia launched Presidents Malaria Initiative (PMI)-supported activities in 2007, through different mechanisms including the Strengthening Pharmaceutical System (SPS) Program, predecessor to the Systems for Improved Access to Pharmaceuticals and Services (SIAPS). In 2008, PMI supported an assessment of the pharmaceutical management supply system in which major problems were identified including lack of skills and capacities to manage (ordering, quantification, storage, inventory management and use) including antimalarials. To address these challenges, SPS has been providing support to strengthen the pharmaceutical management system focusing on capacity and skills building for staff of the Ministry of Health and Social Welfare (MOHSW). SPS collaborated with the MOHSW to conduct a quantification workshop for MOHSW /NMCP personnel responsible for malaria commodities quantification. SPS also conducted pharmaceutical management training of trainers (TOT) to build pharmaceutical management capacities of county pharmacists. These trainers have trained over 400 service delivery point health workers in their counties. SPS collaborated with training institutions; in this domain, SPS supported the development of a new curriculum for the University of Liberia, School of Pharmacy. SPS technically assisted MOHSW to review the outdated policy documents -the National Therapeutic Guidelines (NTG), National Formulary (NF), and the Essential Medicine List (EML) through consultation and feedback by various in-country stakeholders groups.

The Liberia National Malaria Control Program (NMCP) is trying to improve access to appropriate case management to 80% of the population. To support the NMCP, SPS in 2010, conducted an assessment of private sector capacities in the pilot site Montserrado County. The assessment consisted of mapping pharmacies and medicine stores, determining availability of antimalarials, assessing the drug supply, determining accessibility, case management practices, and supply and drug management issues. Assessment results were discussed in a stakeholders meeting and implementation of activities began. These activities have resulted in a solid foundation upon which SIAPS can further strengthen pharmaceutical management systems at the central and county levels. SIAPS will build on SPS's achievements to support Liberia in areas of strengthening pharmaceutical supply management system for malaria commodities at the county level, improving access to ACTs through the private sector, monitoring and supervision system for malaria commodities and rational use.

Quarter Overview

To monitor the use and availability of malaria commodities for decision making purposes, SIAPS implemented the EUV in two counties (Maryland and Grand Kru). A total of 24 health facilities were visited and reports were compiled and submitted.

To increase capacity for pharmaceutical supply management and services in targeted counties, 115 officers in-charge of health facilities (68 from Lofa and 47 from Bong counties) were trained on pharmaceutical management principles. In addition, all 95 functional health facilities (56 in Lofa County and 39 in Bong County) received the newly developed SOPs for the LMIS and were oriented on use of the tools.

To strengthen pharmaceutical sector governance, SIAPS disseminated and STG and EML in Lofa

and Bong Counties, covering 95 health facilities. Orientation and dissemination meetings were attended by all OICs and District Health Officers from Lofa and Bong. Also, 93 health facilities in Montserrado County benefited from orientation and dissemination meetings exercise conducted by SIAPS.

To increase capacity for pharmaceutical supply management and Services in Nimba County, SIAPS has developed the scope of work for Nimba Drug Depot Renovation to serve as a working guide for the project.

To increases access to ACT for management of malaria as first-line treatment protocol in Liberia, SIAPS is finalizing plans to conduct a feasibility study on the introduction of RDTs in private sector pharmacies and medicine stores. The feasibility study protocol has been developed and data collectors have been identified.

Key challenges of quarter

Change in the NMCP policy for private sector ACT approach (to now include RDTs).

Key activities for next quarter

- Implement EUV tool (data collection sites to be identified by NMCP).
- Collaborate with county pharmacists to conduct supportive supervision visits in Nimba, Bong and Lofa.
- Nimba County depot renovation: award of contract and commencement of the work.
- Train dispensers from medicine stores and pharmacies for ACT distribution.
- Conduct regular monitoring and supervision visits, in close collaboration with NMCP and the Pharmacy Board.
- Disseminate the NTG and EML.
- Collaborate with the LMHRA to strengthen the product registration system.
- Conduct feasibility study for introducing RTD in private sector pharmaceutical medicines shops and pharmacies.

Technical Activity Coordination

- Finalized plan to conduct feasibility study for introducing RDTs in private sector pharmaceutical medicines shops and pharmacies.
- Participation in Private Sector ACT Technical Working Group weekly meeting.
- Participation in meeting with PMI/USAID Liberia Mission.
- Participation in Weekly Supply Chain Technical Working Group.
- Participation in Private sector ACT Technical Working Group weekly meeting.

Objective 1

Strengthen pharmaceutical sector governance

Objective 1: Quarterly progress

SIAPS ensured continued to disseminate policy documents in Lofa, Bong and Montserrado counties.

Objective 2
Increase capacity for Pharmaceutical Supply Management and Services in 3 counties (Lofa, Nimba and Bong)

Objective 2: Quarterly progress
The total of 115 health workers (87 OICs and 28 clinical and district supervisors) from 95 functional health facilities (56 in Lofa and 39 in Bong) were trained on pharmaceutical management principles. All facilities received complete set of the revised approved SOPs tools for the LMIS system.

Objective 3
Monitor the use and availability of malaria commodities for decision making

Objective 3: Quarterly progress
To monitor the use and availability of malaria commodities for decision making purposes, SIAPS implemented the EUV in two counties (Maryland and Grand Kru) and a total of 24 health facilities. The final report was compiled and shared with NMCP and partners.

Objective 4
Improve pharmaceutical services

Objective 4: Quarterly progress
Upon request from the NMCP to introduce RDT and ACTs in the private pharmacies and medicines stores, SIAPS is developing a concept paper and is finalizing plans to conduct a feasibility study.

Mali

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.

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

During Q3, SIAPS was unable to actively contribute to any of the four SIAPS/Mali project objectives, as the suspension announced by USAID of aid to the government of Mali remained in effect and SIAPS was therefore unable to conduct any technical activities. As requested, SIAPS did submit an activity report to USAID detailing all activities conducted during Q1 and Q2, which was subsequently updated to respond to various questions and clarifications posed by the USAID Mission.

At USAID's request, SIAPS staff met with a team of USAID and CDC staff in Washington, DC who were undertaking Malaria Operational Planning for the FY13 Malaria Operational Plan of the US President's Malaria Initiative. Although the lifting of the suspension was announced at the end of Q3, SIAPS still awaits the official letter from USAID that will lift the suspension before it will resume technical activities.

Once SIAPS is allowed to resume technical activities in Mali, much remains to be done to operationalize certain aspects of pharmaceutical governance in Mali. During the suspension, USAID held several meetings with its implementing partners (including SIAPS) where SIAPS was given indications as to how its draft current-year work plan would need to change in response to the new political and security situation in Mali. With respect to the governance-related objective (Objective 1) in the draft work plan, SIAPS will be expected to focus on supporting the national key stakeholders involved in the pharmaceutical sector to activate or create space and dialogue to reinforce the coordination and improve transparence in decision-making. During Q3, SIAPS did produce PPMRc (May 2012) and PPRMm (April 2012) reports which provide the stock status of tracer commodities at the Central Medical Stores, as well as key contextual information. However, the suspension, made it impossible to validate data with national counterparts. During Q3, the SIAPS Mali team was asked by USAID to estimate contraceptive needs for Mali for a 6 month period: the SIAPS Mali team complied with this request.

Progress on the Objective 3, which focuses on improving the availability and use of pharmaceutical management information for decision has stalled. Improvement to the national logistics management information system (LMIS) in Mali has not yet started. The review and redesign of the existing LMIS would contribute to improving availability of information on the medicines by improving the transmission of this data within the health system and facilitating the use of this data for decision-making. During monthly discussions organized by USAID with its implementing partners, discussions occurred on how implementing partners might proceed once the suspension of aid to Mali was lifted. In the course of these meetings, USAID/Mali expressed that priority for strengthening the LMIS should be placed at the community health center (CsCom) level. At the end of Q3, SIAPS was awaiting its letter allowing resumption of activities, as well as USAID's final decision regarding the activities that could be implemented.

Key challenges of quarter

The main challenge for this quarter was the inability of SIAPS/Mali team to conduct technical activities in light of the suspension. Additional challenges included reviewing the work plan and adapting it to the new context in Mali, following the coup d'etat. Of particular concern was how SIAPS would manage to strengthen the pharmaceutical system without collaborating with the government, if SIAPS was indeed not permitted to work with the Malian authorities, as was initially anticipated.

Key activities for next quarter

The suspension of SIAPS activities into Mali was lifted at the end of Q3, but SIAPS still awaits the official letter from the USAID contract officer for SIAPS to resume activities. Depending on what the letter will allow SIAPS to do (e.g. to work or not to work with the Malian government), SIAPS plans to implement the following activities during Q4:

- Obtain final approval of the SIAPS Y1 revised work plan from the USAID Health Team following integration of a second round of feedback from the DPM.
- Conduct planning meetings with the DPM, PNLP, PPM and the USAID implementing partners to review and resume activities.
- Preparation and submission of the PPMRm and PPMRc reports (collection and organization of data, preparation and submission of reports in country, validation of reports with the MoH

prior to report submission to USAID Washington).
- Update ACT and RDT needs estimation report.
- Finalize the 6-month contraceptives needs estimation requested by USAID.
- Conduct the 2nd End User Verification survey.
- Conduct the assessment of Mali's LMIS (LSAT or any other tool).

Technical Activity Coordination

This third quarter started with the 'coup d'état' in Mali. During this period, the team participated in the 'cluster santé' meeting organized by WHO. These meetings were planned every Thursday and all partners (national and international) attended them. During these meetings, SIAPS contributed to write a contingent plan in which the interventions (donations) were coordinated. Two health team meetings were organized by the USAID Mission (04/24 and 05/30). During these meetings, SIAPS had the opportunity to present three scenarios for activities based on the current situation in Mali. The main challenge was to conceptualize activities for an updated work plan, so that if SIAPS is not allowed to work with the government in the future we are, SIAPS would focus on implementation of activities aimed at improving availability of drugs at the community level of the health system. SIAPS also developed a country strategic plan for Mali for the 4 next years on which annual work plans will be based. During Q3, SIAPS HQ and country-based team met with USAID and CDC staff charged with preparing the FY13 Malaria Operational Plan and summarized the main achievements of SIAPS to date, remaining gaps and weaknesses to be addressed to strengthen the pharmaceutical system, and proposed activities that SIAPS wished to implement to address these weaknesses and gaps in order to make malaria commodities available at all levels of the health system. During Q3, the USAID/Mali conducted a data quality audit which included interviewing SIAPS. SIAPS/Mali staff revised the current year work plan indicator list in light of this discussion.

Office Management

Apart from SIAPS/Mali implementing its security plan in the aftermath of the coup d'etat, there were no major developments on office management during Q3.

Objective 1

Pharmaceutical sector governance strengthened

Objective 1: Quarterly progress

No progress was made on this objective because the SIAPS Year 1 work plan was not approved. None of the activities contributing to this objective were among the selected activities approved by USAID approved for implementation while SIAPS awaited approval of the full work plan.

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

No progress was made on this Sub-Objective during Q3.

Main challenges for sub-objective 1.1

The SIAPS Y1 work plan was not approved and the coup d'etat forced the activities selectively approved to stop.

Steps to address challenges for sub-objective 1.1
Once SIAPS receives its official letter from USAID allowing it to resume collaboration with Ministry of Health counterparts, SIAPS will obtain work plan approval which in turn will allow implementation of all activities contributing to this objective.

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
Progress towards attainment of indicator targets under this Sub-Objective is behind schedule. This is because activities were not provisionally approved for implementation pending final approval of the SIAPS work plan.

Main challenges for sub-objective 1.2
The main challenge for implementing activities that contribute to this Sub-Objective is that the SIAPS year 1 work plan is still not approved and that the suspension of USAID to the Government of Mali during Q3 prevented SIAPS from conducting any activities requiring collaboration with the Government of Mali.

Steps to address challenges for sub-objective 1.2
Once the suspension on aid to Mali is lifted, SIAPS plans to implement an accelerated plan using short-term technical assistance to implement various activities simultaneously. Additionally, advocacy will be necessary to convince the DPM of the need to have a national coordination mechanism for the coordination of pharmaceuticals.

Deliverables for sub-objective 1.2
PPMRm and PPMRc reports submitted to USAID Washington.

Objective 2
Capacity for pharmaceutical supply management and services increased and enhanced

Sub-Objective 2.1
Technical and management capacity of key actors in Mali's supply chain strengthened

Progress toward sub-objective 2.1
There was no progress during Q3.

Main challenges for sub-objective 2.1
It was not possible to implement the key activity contributing to this objective because the work plan was not approved and because of the US government's suspension of aid to Mali.

Steps to address challenges for sub-objective 2.1

The evaluation of knowledge and practices of district pharmaceutical managers and health center pharmacy managers with respect to inventory management will be planned and implemented once the SIAPS Year 1 work plan is approved by USAID Mali.

Objective 3

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

Objective 3: Quarterly progress

SIAPS submitted the Procurement Planning and Monitoring Reports for Malaria and Contraceptives (PPMRm and PPMR). However, this data could not be validated by the Ministry of Health's malaria and RH programs due to the prohibition on communication with the Malian government.

Sub-Objective 3.1

Pharmaceutical management systems (PMIS) support both products and patients

Progress toward sub-objective 3.1

Apart from the creation of an operational plan for implementing this activity once the SIAPS Year 1 work plan is approved, this activity has not yet started.

Main challenges for sub-objective 3.1

Obtaining approval of the SIAPS year 1 work plan.

Steps to address challenges for sub-objective 3.1

The SIAPS Mali team developed an implementation plan for this activity. This plan would need to be discussed at length with stakeholders and validated by the Ministry of Health before being implemented. The proposed plan includes bringing in one or two persons from SIAPS HQ to provide short-term technical assistance (STTA) to help the SIAPS Mali team implement this activity rapidly, alongside the other work plan activities that SIAPS will implement simultaneously.

Deliverables for sub-objective 3.1

An operational plan for the review and redesign was developed by the SIAPS Mali team.

Objective 4

Pharmaceutical services improved to achieve desired health outcomes

Objective 4: Quarterly progress

There was no progress in this objective.

Sub-Objective 4.1

Stock outs of tracer pharmaceuticals are reduced

Main challenges for sub-objective 4.1

The withdrawal of SIAPS staff working in the regions at the request of the USAID Health has

made follow-up on the situation at DRCs and CsComs more difficult. The coup d'etat that occurred in March and the subsequent suspension of US government aid to Mali resulted in SIAPS halting activities.

Steps to address challenges for sub-objective 4.1
Discussions are ongoing between SIAPS and the USAID Health Team on whether SIAPS should resume having staff stationed in some of Mali's regions outside of Bamako. Once SIAPS is allowed to resume programmatic activities and communication with Government of Mali counterparts, it will move to rapidly get its work plan approved and to subsequently resume the activities contributing to this objective.

Deliverables for sub-objective 4.1
End Use Verification Survey report from the survey conducted in December 2011.

Mozambique

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

In this quarter, technical support was provided by the resident adviser for the registration process. The SOP's for receiving and evaluation of the application for the registration dossier were discussed and revised with the registration head of the department. These SOPS and the evaluation list were translated to English and presented in dual language format for easy access for both the applicants and the PD staff. Suggestions to improve the managerial activities of the department and on-the-job support were provided. Technical contributions to the PD biweekly meeting were provided by the resident adviser. Technical assistant was provided to the PD team in developing the department work plan for year 2012.

Key challenges of quarter

- Only one consultant available in the country and hiring of a national consultant has not started.
- MSH office is not registered; as a result the resident adviser must leave and re-enter the country every month.
- STTA planned for Y12 has not been initiated.
- Lack of response and cooperation from Pharmacy Department staff.
- Lack of proper management and support from the director of the pharmacy department.

Key activities for next quarter

Provide technical support for the development and institutionalization of processes, procedures and criteria for the registration of pharmaceutical products. Conduct a stakeholder meeting to build consensus on the framework for the national pharmacovigilance system and agree on roles and responsibilities. Assist the Pharmacy Department with the development of a monitoring and evaluation (M&E) plan. Conduct a baseline assessment of the regulatory system using the Regulatory System Assessment Tool (RSAT).

Provide technical support to the Pharmacy Department to develop a 5-year strategic plan and

corresponding annual work plan for the regulatory system. Assist the Pharmacy Department with a pharmacovigilance training for provincial-level staff. Conduct an options analysis to identify an appropriate information system in support of the regulatory system for pharmaceuticals (and initiate implementation).

Technical Activity Coordination

Close coordination between the portfolio manager, country director, David Lee, and resident pharmacy department advisory are occurring on a regular basis. This allows staff to address relevant issues and strategize on the best way to complete the planned activities, taking into consideration the available resources.

Office Management

MSH office space was co-rented; staff is sharing the space with HAI project in Mozambique. Because there is no regular staff, the resident adviser working hours are totally allocated for the pharmacy department TA. Once MSH is registered in Mozambique, office staff will be hired and a country or representative will be nominated.

Namibia

Portfolio Background

Namibia is one of the countries that have seriously been impacted by the HIV/AIDS epidemic. The Government of the Republic Namibia with support from PEPEPFAR and other agencies started the treatment program in 3 sites in 2003 and rapidly scaled it up to all the key health facilities in the country. The rapid scale up and the increasing numbers of the patients have brought a strain on pharmaceutical systems and threaten sustainable provision of quality ART services. The SIAPS program with support from USAID, 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: (1) Enhancing access to pharmaceutical products and services through improved medicine policies, regulation, quality assurance and governance. (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. (3) Strengthen pharmaceutical services to enhance achievement of planned TB and HIV program goals and objectives for both adults and pediatrics. This will include strengthened financing strategies and mechanisms for improving access to medicines. (4) Strengthened strategic information systems to ensure availability of reliable information for effective decision making in the pharmaceutical sector.

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 key strategies for transitioning the activities to MoHSS and other in-country partners.

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 provided technical assistance towards revision of the draft post marketing surveillance framework that was developed in the previous two quarters. The draft Pharmadex user requirements document was compiled, which will guide the development of the functional specifications document (FSD) upon which the enhanced web- based Pharmadex application will be developed during the fourth quarter. SIAPS provided TA for the electronic capture of data on revenues generated by NMRC product registration and facility inspection activities. The data is being collected for the options analysis for the autonomy of the NMRC. 77 medicines were registered and 47 samples were tested. The 2012 Pharmaceutical Services Support Supervision

report was finalized, printed and disseminated to all regions.

Through SIAPS' support, 25 pharmacy assistants graduated from the NHTC program. SIAPS provided TA to UNAM Department of Pharmacy in the drafting of specifications for the equipment that is required for the pharmaceutics research lab and the quality control laboratory. SIAPS initiated development of course module on pharmaceutical supplies management and supported 8 staff positions to the MoHSS.

SIAPS disseminated key findings and recommendations of the report "Comparison of Public and Private Sector Wholesale Cost of Antiretroviral Medicines in Namibia" to private sector pharmacists. A meeting is recommended for further discussions between the MoHSS, MSH and the Pharmaceutical Society of Namibia to develop a model of a public-private partnership that would work for Namibia.

Staff finalized the EDT Reporting Module and updated the ART Monthly Report template, and uploaded the updated module/template remotely to all EDT sites. SIAPS worked with the Pharmacy Coordinator at the Directorate: Special Programs (DSP) to compile a report on EDT-related equipment (desk-top computers, monitors, UPSs and EDT mobile) required for ART main and decentralization sites. SIAPS conducted a 1.5-day training for 8 NMPC and CMS staff to improve their data manipulation skills in Excel®. This will enable them to better aggregate and analyze data from facilities and regions, for evidence-based decision making. SIAPS provided TA in the design and typesetting of the 5th edition of the Namibia Essential Medicine List (Nemlist) and the camera-ready proof was approved by MoHSS for printing. Staff finalized the draft version of the report and the annual Therapeutics Committees activity report for FY2010/11. Staff supported MoHSS to prepare for the annual HIVDR EWI data abstraction by extracting patient statistics from the national ART dispensing database (NDB) to help determine the appropriate sample sizes per facility and continued working to compile the ART adherence survey report.

SIAPS commenced the revision of pharmaceutical SOPs to ensure that they remain relevant and current and also provided TA in the analysis and compilation of a report on the patterns of pediatric antiretroviral regimens used in Namibia, based on the EDT ART dispensing data for 2011. SIAPS presented the Annual Analysis of Adult and Paediatric ART Regimens used in Namibia in 2011, compiled with technical assistance from MSH, using data mined from the national database of EDT. A total of 63 adverse drug reaction reports were received by the TIPC in Quarter 3 and 9 requests for therapeutics information. National Guidelines for Medicine Safety Surveillance were launched. SIAPS completed the piloting of the e-TB manager came and began preparations to evaluate the pilot using and existing tool.

SIAPS completed compilation of integrated PMIS manual which includes NMPC, CMS, RMS and PC&I indicators, and forwarded them to the Division: Pharmaceutical Services for final review. Staff participated in data quality support visits organized by USAID/Namibia at selected sites in two regions of Namibia, analyzed EDT and ePMS summary patient data for March 2012, participated in DSP/PhSs quarterly data verification meeting, and compiled the March 2012 Data Verification Report.

Key challenges of quarter

Adherence Survey Report: Approval by USAID/Washington of the contract with North West University to finalize data analysis for the ART adherence survey took a long time before it was granted. This has caused this activity to run behind schedule, although efforts are being made to ensure that it is successfully completed in the fourth quarter.

PMIS review: The Integrated PMIS Indicators Manual was reviewed by the Deputy Director: Pharmaceutical Services on 6th June 2012 and guidance was provided to improve the document. However, limited progress was made in addressing issues raised, mostly with regard to the Pharmaceutical Control & Inspection indicators. This has slowed down the whole PMIS review process.

Key activities for next quarter

Anticipated Launch of the NMP/NPMP (dependent on MoHSS approval). e-TB Manager pilot phase assessment. Start of active surveillance activities at 2 sentinel sites in Windhoek (Windhoek Central and Katutura state Hospitals).

EDT Training: August 2012. Adherence Survey Data Analysis with North West University: July - September 2012. Annual HIV-DR EWI data abstraction and analysis: July - August 2012

Objective 1

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

Objective 1: Quarterly progress

SIAPS provided technical assistance in the revision of the draft post-marketing surveillance framework that was developed in the previous two quarters. The draft Pharmadex User Requirements Document (URD) has been compiled, which will guide the development of the Functional Specifications Document (FSD) upon which the enhanced web- based Parmadex application will be developed during the fourth quarter. SIAPS provided TA for the electronic capture of data on revenues generated by NMRC product registration and facility inspection activities. This data is being collected for the options analysis for the autonomy of the NMRC. 77/565 (14% of backlog) medicines were registered and 47/77 (61%) samples were tested. Of the 77 samples, 35 (45%) were tested within 2 weeks. The 2012 Pharmaceutical Services Support Supervision report was finalized, printed and disseminated to all 13 regions of Namibia.

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

Post marketing surveillance framework: SIAPS provided technical assistance towards revision of the draft post marketing surveillance framework that was developed in the previous two quarters. Pharmadex processes and user requirements document: The draft Pharmadex User Requirements Document (URD) has been compiled, which will guide the development of the Functional Specifications Document (FSD) upon which the enhanced web- based Pharmadex application will be developed during the fourth quarter.

Options analysis for NMRC Autonomy: Provided TA for the electronic capture of data on revenues generated by NMRC product registration and facility inspection activities. This data is being collected for the options analysis for the autonomy of the NMRC. Medicines registration and quality testing: 77/565 (14% of backlog) medicines were registered; 47/77 (61%) samples were tested. Of the 77, 35 (45%) were tested within 2 weeks.

Main challenges for sub-objective 1.1
The position of the SIAPS-seconded registration pharmacist, which fell vacant upon the resignation of the incumbent in Quarter 1, has not yet been filled, due to the current USG moratorium on back-filling of donor supported positions. This Ministry cannot process a replacement because the position in not yet established in the public service staffing structure.

Steps to address challenges for sub-objective 1.1
Through USAID, SIAPS will continue advocating for the establishment of a post additional to the establishment so that a registration pharmacist could be hired by the Ministry for the position.

Deliverables for sub-objective 1.1
- Draft Post Marketing Surveillance Framework.
- Pharmadex User Requirements Document (URD).
- Functional Specifications Document (FSD).
- Updated Pharmadex tool.

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
The 2012 Pharmaceutical Services Support Supervision report was finalized, printed and disseminated to all regions. The report shows that 48% of the 204 issues have been resolved.

Main challenges for sub-objective 1.2
There have been resignations and transfers of donor-funded pharmaceutical staff in the country (they are the majority), due to uncertainty of funding. This has been especially true to those funded by the Global Fund and the CDC. These changes and transitions have contributed to the reduced follow-up on the resolution of issues that were identified in the previous support supervision visits.

Steps to address challenges for sub-objective 1.2
MSH is a member of the MoHSS “HRH Technical Working Group” (HRH TWG) that was established in November 2010 to advise the Ministry's management on matters related to the transition of donor-funded staff to the MoHSS budget. SIAPS will utilize MSH's membership in this forum to advocate for the transition of donor-funded pharmaceutical staff to the Ministry's budget in Quarter 4.

Deliverables for sub-objective 1.2
Pharmaceutical Services Support Supervision report.

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

Quarter Progress: Objective 2
25 pharmacy assistants graduated from the NHTC program. SIAPS provided TA to UNAM Department of Pharmacy in the drafting of specifications for the equipment that are required for the pharmaceutics research lab and the quality control laboratory. Staff initiated development of course module on pharmaceutical supplies management. SIAPS supported 8 staff positions at the Ministry of Health and Social Services, all of whom applied to be considered for transitioning to the MoHSS budget. The 2 SIAPS-supported UNAM lecturers were absorbed into UNAM's payroll.

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

Progress toward sub-objective 2.1
SIAPS supported a total of 8 human resource positions at the Ministry of Health and Social Services (NHTC = 2, TIPC = 2, NMPC = 2, and health facilities = 2). IMSH contributed to the HRH TWG consultations and site visits in Ohangwena and Oshana, to prepare ground for the absorption of pharmacy staff, beginning May 2012. All 8 SIAPS-seconded staff applied to be considered for transitioning into the MoHSS budget. The two SIAPS-supported UNAM lecturers were successfully transitioned to UNAM budget.

Main challenges for sub-objective 2.1
The slow pace of transitioning of seconded staff into the MoHSS budget.

Steps to address challenges for sub-objective 2.1
MSH is a member of the MoHSS “HRH Technical Working Group” (HRH TWG) that was established in November 2010, with representatives from MoHSS, Global Fund, USAID, CDC, UNAIDS, WHO, and Intrahealth. The tasks of the TWG are to: Look at the details of MoHSS HR situation with regard to donor-supported posts; gather and examine needed donor and MoHSS regional human resource information to inform the absorption process; conduct regional site visits to examine HR issues pertinent to the transition; and to produce a report outlining suggested strategies along with financial and HR information to facilitate the transition. Following the absorption of medical officers to the MoHSS, the HRH TWG decided to initiate the transitioning of donor-funded pharmacy staff to the MoHSS in May 2012. In the next quarter, MSH will continue engaging with the HRH TWG to speed-up the process of absorption of pharmacy staff in quarter 4.

Deliverables for sub-objective 2.1
HRH-TWG Report.

Sub-Objective 2.2

Strengthen the institutional capacity of NHTC for sustainable training of pharmacist's assistants.

Progress toward sub-objective 2.2
25 pharmacy assistants graduated from the NHTC program, through SIAPS' support.

Main challenges for sub-objective 2.2
The employment contract of one of the SIAPS-seconded tutor for the NHTC pharmacy assistant's program was terminated due to absenteeism. The staff lodged a complaint of unfair dismissal with the Labor SIAPS subsequently contested this decision with the Magistrate's court and a decision is being waited. This slightly affected the teaching of some of the curriculum modules, which may have contributed to the slightly less than targeted number.

Steps to address challenges for sub-objective 2.2
Follow-up with the MSH lawyer so that the case is concluded within next quarter.

Deliverables for sub-objective 2.2
Report on SIAPS support to NHTC.

Sub-Objective 2.3
Strengthen the institutional capacity of UNAM to train pharmacists.

Progress toward sub-objective 2.3
Through SIAPS support, a total of 49 students (35 first year and 14 second year students) are currently enrolled on the UNAM Bachelor of Pharmacy program. SIAPS initiated the process of developing supply chain management teaching materials (lecturer guides, student workbook and slides) for pre-service training for the pharmacy course. This commenced with the development of the lecturer guide on supply chain management for pre-service training for the pharmacy course. SIAPS provided technical assistance to UNAM Department of Pharmacy in the drafting of specifications for the equipment that are required for the pharmaceutics research lab and the quality control laboratory. TA was also provided in the drafting of a concept paper for the development of a pharmaceutical manufacturing plant for the University. These two facilities will be used for the practical teaching of the pharmacy students in pharmaceutical product quality control and manufacturing, respectively.

Main challenges for sub-objective 2.3
Finding sites for the pharmacy students to do the practical sections of the course.

Steps to address challenges for sub-objective 2.3
Continue engaging the private community pharmacists and wholesalers to persuade them to consider taking up students for practical assignments.

Deliverables for sub-objective 2.3
- Draft Supply chain management teaching materials for UNAM pharmacy course.
- Draft concept paper for the development of a pharmaceutical manufacturing plant for the university.
- Draft Strategic Roadmap (Plan) for the development of the Pharmacy Department into a School

of Pharmacy.

Objective 3
Strengthen pharmaceutical services to enhance achievement of planned TB and HIV Program goals and objectives for both adults and pediatrics

Quarter Progress: Objective 3
SIAPS provided TA in the analysis and compilation of a report on the patterns of adult and pediatric antiretroviral regimens used in Namibia, based on the EDT ART dispensing data for 2011. Recommendations of this analysis will assist SIAPS to support sites in scaling up pediatric ART coverage and retention (technical assistance, training, equipment, EDT support). SIAPS also continued working with the consultant leading this activity to compile the survey report.

Sub-objective 3.1
Support and strengthen financing strategies and mechanisms that will enhance public private partnership in improving access to medicines

Progress toward for sub-objective 3.1
SIAPS disseminated key findings and recommendations of the report "Comparison of Public and Private Sector Wholesale Cost of Antiretroviral Medicines in Namibia" to private sector pharmacists. A meeting is recommended for further discussions between the MoHSS, MSH and the Pharmaceutical Society of Namibia to come up with a model of a public-private partnership that would work for Namibia.

Main challenges for sub-objective 3.1
It took too long for the Senior Technical Advisor assigned to this activity to disseminate these findings and enter into consultations with the private sector.

Steps to address challenges for sub-objective 3.1
This task has been reallocated to another Senior Technical Advisor, after the previously assigned STA resigned.

Deliverables for sub-objective 3.1
Technical report of options analysis for potential models of a public-private partnership for provision of ART in private sector pharmacies in Namibia

Sub-objective 3.2
Finalize Adherence PHE and implement initiatives to improve adherence to ART by patients as well as monitoring and measurement of adherence

Progress toward for sub-objective 3.2
SIAPS finalized the EDT Reporting Module and updated the ART Monthly Report template to strengthen reporting on adherence and HIVDR Early warning Indicators. Staff also uploaded the updated module/template remotely to all EDT sites. SIAPS worked with the Pharmacy Coordinator at Directorate: Special Programs (DSP) to compile a report on EDT-related equipment (desk-top computers, monitors, UPSs and EDT mobile) required for ART main and

decentralization sites.

Staff conducted a 1.5-day training for eight NMPC and CMS staff to improve their data manipulation skills in Excel®. This will enable them to better aggregate and analyze data from facilities and regions, for evidence-based decision making. This was implemented at all 46 sites with upgraded EDT facilities that have been equipped to monitor adherence and Early Warning Indicators (EWI) for HIV Drug Resistance. SIAPS staff also continued working with the consultant to compile the survey report and finalized the annual therapeutics committee's activity report for FY2010/11.

Main challenges for sub-objective 3.2
Approval by USAID of the contract with North West University (NWU) to finalize data analysis for the ART adherence survey took a long time before it was granted. This has caused this activity to run behind schedule, although efforts are being made to ensure that it is successfully completed in the fourth quarter.

Steps to address challenges for sub-objective 3.2
The challenge has been resolved.

Deliverables for sub-objective 3.2
- Adherence Survey Report
- The annual Therapeutics Committees activity report for FY2010/11.

Sub-objective 3.3
Improve treatment outcomes through effective use of evidence generated from pharmacovigilance and treatment literacy activities, implementing risk management strategies to reduce adverse events to ART

Progress toward sub-objective 3.3
A total of 63 adverse drug reaction reports were received by the TIPC in Quarter 3 and 9 requests for therapeutics information. National Guidelines for Medicine Safety Surveillance were launched. 1000 copies of the Namibia Medicines Watch were published and disseminated. SIAPS provided technical assistance for the analysis and drafting of a technical report on the signal of skin and liver reactions associated with nevirapine use. The report will be finalized in the next quarter. Additionally, SIAPS provided technical assistance in compiling a draft technical report on the patterns of adverse medicine reactions in the TIPC database since the 2008. The report shows a rise in nevirapine- related adverse reactions including dermatologic and hepatic reactions. This report will be finalized in the next quarter.

SIAPS developed draft tools for the implementation of active surveillance of the safety of antiretroviral medicines at the Windhoek Central hospital and Katutura Intermediate Hospital ART sites. The active surveillance program will be initiated in quarter 4. SIAPS also provided technical assistance to the NTLP in the design of data collection tool, analysis and interpretation of data on quantifying the prevalence of serum electrolyte and renal disturbances in patients treated for drug-resistant TB at the Katutura Intermediate Hospital in Windhoek.

Main challenges for sub-objective 3.3
Delays in the absorption of the 2 SIAPS-supported staff by the MoHSS.

Steps to address challenges for sub-objective 3.3
SIAPS, through the HRH-TWG will continue advocating for the absorption of staff by the MoHSS.

Deliverables for sub-objective 3.3
TIPC technical reports:
- Report on the signal of skin and liver reactions associated with nevirapine use.
- Report on the patterns of adverse medicine reactions in the TIPC database since the 2008.

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

Quarter progress: Objective 4
In this quarter, SIAPS supported 49/60 (82%) sites with the EDT system to track and monitor pharmaceutical utilization including ART stock management reports Six national and sub-national functional database systems were supported, which enabled stakeholders to access relevant data for policy formulation, program management and improvement (EDT, NDB, Pharmadex, PMIS, RX Solution and the eTB Manager).

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
SIAPS completed compilation of integrated PMIS manual which includes NMPC, CMS, RMS and PC&I indicators. This was forwarded to the Division: Pharmaceutical Services for final review.

Main challenges for sub-objective 4.1
SIAPS integrated the PMIS Indicators Manual reviewed by DD in June 2012 and guidance was provided to improve the document. However, limited progress was made in addressing issues raised, mostly with regard to the PC&I indicators. This has slowed down the PMIS review process.

Steps to address challenges for sub-objective 4.1
This challenge will be brought to the attention of the chairperson of the joint MoHSS/SIAPS project steering committee for resolution.

Deliverables for sub-objective 4.1
Integrated PMIS Indicators Manual.

Sub-objective 4.2
Support program monitoring and data quality

Progress toward sub-objective 4.2
SIAPS Participated in data quality support visits organized by USAID/Namibia to Oshikuku District Hospital, Onandjokwe Intermediate Hospital and Odibo Health Center. Staff analyzed EDT and ePMS summary patient data for March 2012, participated in the Directorate of Special Programs (DSP), the Division of Pharmaceutical Services quarterly data verification meeting, and compiled the March 2012 Data Verification Report.

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.

Steps to address challenges for sub-objective 4.2
Feedback will be provided to those facilities that have the greatest data quality challenges and technical support will be provided to the facility management to find ways of resolving the data quality challenges.

Deliverables for sub-objective 4.2
Data Verification Report.

Rwanda

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

As continuous support in strengthening pharmaceutical sector governance, during the third quarter, SIAPS continued to support the Ministry of health to improve patient access by working closely with the Ministry of Health/Pharmacy Task Force (MOH/PTF) in planning for the establishment of the Rwanda Food and Medicine Authority (RFMA); in order to determine the best option for the country regulatory system and structure, an assessment was conducted. SIAPS continued to assist MOH/PTF in finalization of laws and regulations. This quarter, the orders for the implementation of the narcotics law were developed submitted to the cabinet for approval. The pharmacy law is still at the parliament waiting for approval. In regards to the development of MPPD strategic plan, new development has evolved; the roadmap for the strategic plan was reviewed. The MPPD strategic plan will be developed in the next quarter with all the key stakeholders involved in the process. In relation to strengthening supply chain management of community case management, during the reporting period, SIAPS continued to assist the Community Health Desk (CHD) to monitor and analyze the use of medicines at the community

level. SIAPS also provided to the new pharmacy staff in CHD in charge of pharmaceutical management, on job training on the analysis of the LMIS indicators and continuous support (coaching) ensuring capacity transfer.

In line with supporting CHD to capacitate District Pharmacies in pharmaceutical management, two days orientation meeting took place from the April 14-15, 2012 between district pharmacist, CHD, PTF and MPDD. Follow on to the rapid assessment of pharmaceutical management of medicines and supplies for preventing and managing emergency obstetrics and new born conditions that was conducted during last quarter, SIAPS provided assistance in hiring a data analyst. The assessment report is under development.

To improve pharmaceutical services to achieve desired health outcomes, during this quarter, SIAPS continued to support King Faysal Hospital (KFH) to improve pharmaceutical management. 16 pharmacy staff (3 pharmacists and 13 dispensers) was trained specially in the following key area of priority, medicines selection and hospital formulary management, quality assurance of medicines, quantification of health commodities and pharmaceutical information management system, as recommended by the baseline assessment done.

During the same period, SIAPS strategy document to strengthening hospital DTC was developed and a half-day workshop was organized to validate it before being submitted to MoH officials for approval.

During the reporting period, a 5 day training of trainers of 30 health professionals (9 physicians and 21 pharmacists) was conducted from the of June 11-15, 2012. The purpose of the training was to form a pool of trainers at national level in DTCs to roll out different capacity building activities such as trainings and supportive supervisions.

SIAPS assisted as well in setting of indicators to be measured during PBF quarterly evaluations. The indicators were reviewed and submitted to the technical working group for final incorporation in the current PBF evaluation tool.

SIAPS assisted as well PTF to organize a workshop in May 2012 to validate SOPs for management of Adverse Event reports, medicines with poor quality reports and the risk communication strategy for medicine safety. The SOPs and risk communication strategy for medicine safety were validated.

In preparation to the training of the National Medicine Safety Committee (NMSC) members, SIAPS assisted PTF develop and submit NMSC terms of reference and proposed names of NMSC members to the Minister of Health for her consideration. Agenda and topics to cover in the orientation meeting of NMSC members were developed and shared with HQ and MOH/PTF for inputs and comments. The training curricula have also been developed. With support from HQ pharmaceutical system cluster, the training sessions are under development.

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 in different workshops

with specialists such ophthalmologists, pediatricians, gynecologists, and ENT specialists to provide their inputs to the current drafts in their respective areas of specialties. Others are yet to provide their inputs. The final document is due in August 2012.

SIAPS assisted also in the development of strategic document on the approach to be used during Clinical Protocol and treatment guidelines updates (from the revision to the implementation of the revised STGs). The first draft is available and will be shared with both the IHSSP team and clinical services within MoH

Key challenges of quarter

- Availability of the health care provider specialist for the technical review of the CPS and TGs.
- Waiting for the development of the overall RBC strategic plan before the development of the MPPD strategic plan.

Key activities for next quarter

During the next quarter, SIAPS Rwanda will mainly focus on closing out the project and completing remaining activities (contract is ending in September 30, 2012). This will include: (1) Training of NMSC members in causality assessment. (2) Finalization of CPs/TGs. (3) Development of the option analysis for the establishment of RFMA. (4) Finalization of RPSSP strategic plan 2013-2018. (5) Finalization of pending products. (6) Development of MPPD strategic plan.

Objective 1

Improved Patient Access

Objective 1: Quarterly progress

As continuous support in strengthening pharmaceutical sector governance, SIAPS continued to support MOH/PTF to plan for the establishment of the Rwanda Food and Medicine Authority (RFMA). An assessment to determine the country's regulatory structure, system, functions performed and stakeholders involved was conducted. The assessment will inform MoH with the best options for a regulatory structural framework; one that is feasible, adaptable, and sustainable to the country context. Different institutions and stakeholders were actively involved in the assessment, including: MoH/PTF, SIAPS, MoH/Clinical Services WHO local country office, JSI, National University of Rwanda's School of Pharmacy, Medicines Production Division (formerly Labophar), Ladamet (quality control lab under National University of Rwanda), the pharmacists association, wholesalers and details pharmacies, Rwanda Biomedical Centre, and BUFMAR (faith based medical stores).

SIAPS worked with the MPPD to review the developed scope of work to conduct the MPPD strategic/functional analysis. SIAPS was requested to work with other partners developing the RBC strategic plan, to be sure the MPPD strategic/functional analysis complies with the RBC assessment. This will be done next quarter.

SIAPS supported the MOH/PTF to evaluate the MoH/PTF 2009-2012 strategic plan and the development of the plan for 2013-2018. This is of great importance in strengthening pharmaceutical regulatory systems for improved access.

Sub-Objective 1.1
Pharmaceutical regulatory systems improved

Progress toward sub-objective 1.1
During this quarter, the orders for the implementation of the narcotics law were developed and await the approval from the cabinet.

Deliverables for sub-objective 1.1
Final draft of the Narcotic Law.

Sub-Objective 1.2
Transparent and accountable pharmaceutical management systems are created

Progress toward sub-objective 1.2
During the reporting period, SIAPS has supported the MPPD/RBC to review the draft of the scope of work and coordinated with the consultant for the development of the MPPD strategic plan.

Sub-Objective 1.3
Strategic and evidence-based national pharmaceutical sector development plans are utilized

Progress toward sub-objective 1.3
As continuous support in strengthening pharmaceutical sector governance, SIAPS supported the MOH/PTF to evaluate the MoH/PTF 2009-2012 strategic plan and the development of the plan for 2013-2018 The Rwanda Pharmaceutical Sector Strategic Plan (RPSSP) 2013–2018, based on the National Pharmaceutical Policy (NPP), serves as the overall implementation plan for improving pharmaceutical system strengthening in the public and private sectors. This strategic plan is also aligned with the Health Sector Strategic Plan (HSSP) III, which states that health service delivery depends on a reliable supply of medicines, vaccines and contraceptives supported by accurate and timely information on consumption and stock management. In June, a workshop on the validation of the RPSSP 2013-2018, with key stakeholders was organized. Presently, the development of RPSSP 2013-2018 is ongoing.

Objective 2
Increased availability of CCM commodities at the community level

Objective 2: Quarterly progress
During the reporting period, SIAPS continued to assist the Community Health Desk (CHD) to monitor and analyze the use of medicines at the community level. On-the-job training on the analysis of the LMIS indicators and continuous support (coaching) were provided by SIAPS to the new staff in charge. In line with supporting CHD to capacitate district pharmacies in pharmaceutical management, a two-day orientation meeting was held April 14-15, 2012. The orientation focused on: an introduction to monitoring and evaluation, validation of indicators for the PSM system detection, reporting substandard medicines, and substandard medicine report management. Also during the orientation, an open discussion was carried out between the DPs, CHD, PTF and MPDD, during which they shared experiences, challenges and lesson learned.

SIAPS assisted CHD to develop the draft of the guidelines to monitor and evaluate medicines procurement/consumption at the central level. This is part of transfer of capacity to CHD. The guidelines are under finalization. Following the maternal and child health (MCH) survey "Rapid assessment of pharmaceutical management of medicines and supplies for preventing and managing emergency obstetrics and new born conditions", a data analyst was hired to synthesize the findings. The report is being developed. A validation workshop will be organized in October 2012.

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

Progress toward sub-objective 2.1
SIAPS continued to assist CHD to monitor and analyze the rational use of medicines at the community level using SISCOM data. LMIS indicators related to stock level and LMIS indicators related to rational use of medicines were set to strengthen the system.

Objective 3
Patient safety and therapeutic effectiveness increased

Objective 3: Quarterly progress
SIAPS continued to support King Faysal Hospital (KFH) to improve pharmaceutical management. SIAPS provided training to 16 pharmacy staff members (3 pharmacists and 13 dispensers) in areas as medicines selection, hospital formulary management, quality assurance of medicines, quantification of health commodities, and pharmaceutical information management system. SIAPS finalized the MOH strategy document to strengthening hospital DTC and a half-day workshop was organized to validate it before being submitted to MoH officials for approval. A training of trainers in DTCs was conducted in June and 30 health professionals (9 physicians and 21 pharmacists) were trained as trainers. The purpose of the training was to form a pool of trainers at the national level, to roll-out capacity building activities.

SIAPS assisted PTF to organize a workshop in May 2012 to validate SOPs for management of adverse event reports, medicines with poor quality reports and the risk communication strategy for medicine safety. The SOPs and risk communication strategy for medicine safety were validated and submitted to MOH/PTF.

During this quarter, SIAPS assisted PTF to continue preparing for the training for National Medicine Safety Committee (NMSC) members. SIAPS assisted PTF to develop and submit NMSC terms of reference and proposed names of NMSC members to the Minister of Health for approval. SIAPS continued to assist PTF to ensure that hospitals are consistently reporting all adverse drug reactions (ADR) and medicine with poor quality (MPQ) reports. During this quarter, more reports were received, as a result of continuous follow up. 34 AE reports and more than 15 PQM reports were submitted. All have been entered into the developed database and preliminary analyses are being conducted by NPMIC staff.

During the same reporting period, SIAPS worked closely with the MSH Integrated Health System

Strengthening Project (IHSSP) and MOH Clinical Services to conduct an internal review of the clinical protocols/treatment guidelines (CPs/TGs). The draft was shared in different workshops with specialists (ophthalmologists, pediatricians, gynecologists, and ENT specialists) to provide their inputs to the current drafts in their respective areas. The final document is due in August 2012.

SIAPS assisted also in the development of a strategic document on the approach to be used during clinical protocol and treatment guidelines updates (from the revision to the implementation of the revised STGs). The first draft is available and will be shared with both the IHSSP team and clinical services.

Sub-Objective 3.1
Pharmacovigilance and ADR reporting system strengthened

Progress toward sub-objective 3.1
SIAPS continued to support King Faysal Hospital (KFH) to improve pharmaceutical management. SIAPS provided training to 16 pharmacy staff members (3 pharmacists and 13 dispensers) in areas as medicines selection, hospital formulary management, quality assurance of medicines, quantification of health commodities, and pharmaceutical information management system. SIAPS finalized the MOH strategy document to strengthening hospital DTC and a half-day workshop was organized to validate it before being submitted to MoH officials for approval. A 5-day training of trainers of 30 health professionals (9 physicians and 21 pharmacists) to form a pool of trainers at national level in DTCs to roll-out different capacity building activities was conducted in June.

A set of indicators to be measured during PBF quarterly evaluations has been reviewed and submitted to the technical working group for final incorporation in the current PBF evaluation tool.

Sub-Objective 3.2
Medication use improved

Progress toward sub-objective 3.2
SIAPS assisted PTF to organize a workshop to validate SOPs for management of adverse event reports, medicines with poor quality reports and the risk communication strategy for medicine safety.

In preparation to the training of the National Medicine Safety Committee (NMSC) members, SIAPS assisted PTF develop and submit NMSC terms of reference and proposed names of NMSC members to Minister for consideration. The approval of the NMSC members is scheduled in the coming inner Senior Management Meeting of the MoH. In addition, the agenda and topics to cover in the orientation meeting of NMSC members once nominated and for the training have been developed and shared with HQ and PTF for inputs. The training curricula have also been developed and training sessions are under development with the support from the HQ pharmaceutical system cluster.

In addition, SIAPS assisted PTF to ensure that hospitals are consistently reporting all adverse drug

reactions (ADR) and medicine with poor quality (MPQ) reports. The number of reports received at NPMIC level increased to more than 34 AE reports and more than 15 PQM reports. All have been entered into the developed database and preliminary analyses are being conducted by NPMIC staff.

During this quarter, SIAPS assisted PTF to continue preparing for the training for National Medicine Safety Committee (NMSC) members. SIAPS assisted PTF to develop and submit NMSC terms of reference and proposed names of NMSC members to the Minister of Health for approval. SIAPS continued to assist PTF to ensure that hospitals are consistently reporting all adverse drug reactions (ADR) and medicine with poor quality (MPQ) reports. During this quarter, more reports were received, as a result of continuous follow up. 34 AE reports and more than 15 PQM reports were submitted. All have been entered into the developed database and preliminary analyses are being conducted by NPMIC staff.

During the same reporting period, SIAPS worked closely with the MSH Integrated Health System Strengthening Project (IHSSP) and MOH Clinical Services to conduct an internal review of the clinical protocols/treatment guidelines (CPs/TGs). The draft was shared in different workshops with specialists (ophthalmologists, pediatricians, gynecologists, and ENT specialists) to provide their inputs to the current drafts in their respective areas. The final document is due in August 2012.

SIAPS assisted also in the development of a strategic document on the approach to be used during clinical protocol and treatment guidelines updates (from the revision to the implementation of the revised STGs). The first draft is available and will be shared with both the IHSSP team and clinical services.

Main challenges for sub-objective 3.2

The delayed nomination of NMSC by the MoH, the delayed process of involving all the concerned specialties in reviewing STGs

South Sudan

Portfolio Background

Under FY11, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS), the follow on project to SPS will aim to consolidate the achievements made under previous years. Using a systems strengthening approach consistent with the Global Health Initiative, SIAPS will aim to assure availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes.

The SIAPS South Sudan project activities will aim to strengthen pharmaceutical sector governance; enhance capacity for pharmaceutical supply management and services; introduce rational use and quality assurance interventions; improve malaria planning and coordination; and, strengthen malaria monitoring and evaluation systems.

Activities proposed under FY2011 are consistent with the USAID Result Areas for the SIAPS program and will contribute to the achievement of the USAID Sudan Field Office multi-sectoral strategy for infectious diseases and Intermediate Result 10.1 related development of core institutional structures for an effective, transparent, and accountable Government of South Sudan.

Quarter Overview

During the quarter, SIAPS made considerable progress towards the portfolio's objective 1 of strengthening pharmaceutical governance in South Sudan. Key achievements included: passage and publication of the South Sudan Food & Drug Control Authority Bill; further review and update of the draft autonomous CMS concept paper and associated Cabinet Memo to be submitted to Council of Ministers; facilitation of stakeholders meeting to review draft job descriptions for primary health care level staff in Eastern Equatoria State; inspection of an unlicensed private operator, DynaPharm, dealing in nutritional supplements in Yambio, WES; meeting with partners (like Catholic Diocese of Tambura and Yambio health programs) to discuss areas of collaboration; supporting DP&E to provide updates to the NGO Health Forum on regulatory issues regarding importation of pharmaceuticals/medical supplies and procurement processes and guidelines for donors/NGOs post-MDTF; and participation in the inaugural PPH TWG meeting that developed a blueprints for a draft TOR for the group.

Under Objective 2, increasing and enhancing capacity for pharmaceutical supply management and services, the project facilitated participation of two MOH officers from the Quality Assurance & Control Department in the 2012 Africa Pharmacovigilance Meeting in Nairobi, Kenya; created awareness on pharmacovigilance through presentation at the May 2012 malaria surveillance training workshop; co-funded, with i+Solutions, one staff member from the Directorate of Pharmaceuticals & Equipment to participate in training for Procurement & Supply Management of Essential Laboratory Commodities in the Netherlands; provided TA to World Vision International (WVI) in facilitating a pharmaceutical management training workshop for WVI-managed health facilities in Tambura, Ezo and Yambio counties; conducted a refresher training on PMIS for front-line health workers of Torit County health facilities through funding from NPA/MTDF; provided on-job training to one MOH staff (Mr. James Mayen) on Minilab® operations at the Juba Minilab® site at the CMS; supported D&PE to adapt training materials and develop training plan for rational drug use courses for the teaching hospitals; and commenced TA to DP&E for

development of a pharmacy graduate internship curriculum/guidelines.

Further progress was made towards the portfolio's objective 3, addressing the information for decision-making challenge. During the quarter, SIAPS conducted a series of supportive supervisions in CES, WES, and EES to strengthen pharmaceutical management systems and introduce PMIS tools. The project organized and facilitated two pharmaceutical management CRMS TOTs for Western Equatoria in Yambio in April and a joint Central Equatoria/Eastern Equatoria TOT in May 2012. SIAPS also participated in SHTP-II partners' meeting, and used the opportunity to introduce the new CRMS data collection and analysis tools to the program managers and M&E officers of sub-contracting partners (SCP). One CRMS coordination/peer review meeting was conducted in Eastern Equatoria.

Under objective 4, SIAPS provided TA for various quantification procurement, importation, clearance/receipt, storage and distribution processes for essential medicines and medical supplies, including those procured with USG-funding. Additional support was provided to finalizing the post-partum hemorrhage (PPH) prevention implementation plan. Advocacy was done to mobilize supplementary funds from partners like UNICEF to support renovation of the CES medical store. SIAPS also participated in MOH meetings with the GFATM pharmaceutical expert on the recent mission to South Sudan to explore integration of Global Fund supplies with the national system. In area of quality assurance, SIAPS conducted a joint supportive supervision visit to Kaya Minilab® site with USAID and MOH. MOH was also supported to organize a partners' consultative workshop on strengthening quality assurance systems in South Sudan.

Finally, SIAPS has also made considerable progress under objective 5, of achieving a better coordinated and documented scale up of malaria interventions. SIAPS worked with partners to plan and organize successful activities for World Malaria Day 2012 and publish the 2012 malaria newsletter. NMCP was supported to update the national malaria treatment guidelines and finalize/submit the Therapeutic Efficacy Testing (TET) protocol and request the study medicines from WHO. TET training was conducted for all the 3 sentinel study sites, while two workshops were executed on malaria sentinel surveillance. The projects also participated in key NMCP meetings, including TWGs, CCM and those involving the GFATM and EARN missions to South Sudan. NMCP was also supported to carry-out a gap analysis for malaria commodities in preparation for an RBM meeting held in Dakar, Senegal.

Key challenges of quarter

Despite the above successes, many challenges continue to hamper project implementation. Salient challenges in this respect include:

- Continued delays in disbursement of funds for malaria activities from the consolidated GFATM malaria grant. This is more critical especially given some SIAPS activities (e.g. trainings, M&E, etc.) relied on resources from the GFATM grant; this meant that major activities could not be initiated.
- Related to delayed disbursement, activities co-funded with the Global Fund could not be completed. For example, WHO provided initial funding for antimalarial efficacy studies; SIAPS worked with NMCP and WHO to train health workers from the sentinel sites, but enrollment of study subjects could not be initiated because of delayed release of Global Funds.
- Contracting vendors for renovation of the CES medical stores was delayed because the process

had to be repeated to accommodate available funding. Further, SIAPS was requested by the mission to mobilize funding from partners to complete the renovation. UNICEF has agreed to contribute 45K to the renovation. However, the slow pace of finalizing the renovation of the CES medical store may be having a negative impact on participation in SIAPS project specific activities (e.g. supportive supervision).

- Project leads play dual role as managers and technical advisors, and the project management aspects continuing to take considerable time.
- Urgent competing ad hoc requests for TA from donors and partners, which often take significant staff LOE.
- The DP&E has yet to regularize the pharmaceutical management TWG meetings.
- Internal changes in MOH that delayed start-up and/or smooth completion of some planned activities. Further, involvement of MOH counterparts in competing activities during the course of the quarter further hampered initiation of some activities.
- There continues to be funding constraints under the FY11 work plan, requiring further prioritization of planned activities. Some of the planned activities will not be carried out.

Key activities for next quarter

In the next quarter the project will focus on the following key activities:

- Carrying out more consultation and editing on the draft pharmaceutical sector master plan.
- Providing TA to MOH/DP&E on the plans for transforming CMS into an autonomous agency.
- Supporting distribution planning at central level for essential medicines/ medical supplies, donated products (e.g. antimalarials) and coordinating their distribution at the county level.
- Providing TA for pharmaceutical management aspects of the PPH start-up program.
- Conducting supportive supervision and on-job training to build pharmaceutical management capacity in the field.
- Creating state and central database for the CRMS to collate and manage the data collected from selected health facilities.
- Ensuring adequate knowledge and skills are transferred to the new MOH inspection officer earmarked for deployment to the Nimule Minilab® site to be set up soon by MOH.
- Continue supporting MOH/NMCP to conduct the Malaria Program Review (MPR).
- Support NMCP to initiate Therapeutic Efficacy Tests at 3 sentinel sites.
- Conduct one training workshop for malaria surveillance.
- Participate in malaria coordination meetings.
- Support the planning of 2012 Malaria Indicator Survey.
- Completion of outstanding trip reports and technical reports.
- Finalize SIAPS South Sudan strategic plan.
- Develop SIAPS South Sudan FY12 work plan.

Objective 1

Pharmaceutical sector governance strengthened

Objective 1: Quarterly progress

The deliverables (documents) planned were achieved last quarter. In addition, the South Sudan Drug & Food Control Authority Bill was passed into law by the Legislative Assembly during this quarter. The rest of the work in this area went towards support for review/ updating drafts of documents developed in Q2.

Sub-Objective 1.1
Improved medicine policies, legislations, regulations, norms & standards

Progress toward sub-objective 1.1
The South Sudan Drug & Food Control Authority Bill was passed into law and the Act published in the gazette. The MOH was supported to review/update the concept paper on establishment an autonomous agency. A Cabinet Memo to support submission of concept paper to the Council of Ministers was developed, as were the job descriptions for health facilities in EES.

Main challenges for sub-objective 1.1
Urgent, competing ad hoc requests for TA from donors and partners, which often take significant staff LOE. Internal changes in MOH delayed start-up and/or smooth completion of some planned activities.

Steps to address challenges for sub-objective 1.1
Reprogramming of some activities, based on MOH priorities.

Deliverables for sub-objective 1.1
- South Sudan Drug & Food Control Act, 2012 [Act No. 37]
- Reviewed concept paper for establishment of autonomous CMS
- Draft Cabinet Memo for submission of the concept paper for establishment of autonomous CMS to Council of Ministers
- Job descriptions for health facilities in EES.

Sub-Objective 1.2
Strategic & evidence-based national pharmaceutical sector plans developed

Progress toward sub-objective 1.2
Very little progress made towards the sub-objective during the quarter, simply because performance indicator 1.2a is next quarter and 1.2b is not scheduled for this current year.

Main challenges for sub-objective 1.2
- Involvement of MOH counterparts in competing activities during the course of the quarter, which limited scheduling some meetings, activities, and STTA.
- Urgent competing ad hoc requests for TA from donors and partners, which often take significant staff LOE.

Steps to address challenges for sub-objective 1.2
Reprogramming of some activities around MOH priorities

Objective 2
Capacity for pharmaceutical supply management and services increased and enhanced.

Objective 2: Quarterly progress
There was significant progress towards achievement of the objective this quarter. The number of

health facilities with at least one trained health worker capable of performing key pharmaceutical management tasks increased by 56, bringing the total to 91.

Sub-Objective 2.1
Enhanced individual, institutional and organizational capacity for pharmaceutical management

Progress toward sub-objective 2.1
The training materials for Rational Drug Use Training for Hospitals have been developed.

Main challenges for sub-objective 2.1
Other competing priorities.

Steps to address challenges for sub-objective 2.1
Prioritize activities.

Deliverables for sub-objective 2.1
Rational Drug Use training materials for hospitals.

Sub-Objective 2.2
Innovative & proven approaches for human resource capacity building adopted

Progress toward sub-objective 2.2
All the targets under this sub-objective have been achieved. Under the performance indicator 2.2a, three task shifting strategies and tools were developed: CRMS tools, pharmaceutical management tools, and job descriptions for Torit county health facilities (hospitals, PHCCs and PHCUs). Under performance indicator 2.2b, 199 health personnel have been trained on pharmaceutical management, exceeding the annual target of 100 by 99.

Main challenges for sub-objective 2.2
Most urgent priorities attended to first.

Steps to address challenges for sub-objective 2.2
Leveraging resources from partners.

Deliverables for sub-objective 2.2
- CRMS tools.
- Pharmaceutical management tools.
- Job descriptions for hospitals, primary healthcare centers and units.
- Training/workshop reports.

Objective 3
Information for decision-making challenge in the pharmaceutical sector addressed.

Objective 3: Quarterly progress
This quarter, significant progress was made in distribution of PMIS tools for use at the facilities and availability of CRMS data collection and analysis tools. 21 additional facilities in WES met

constraints hindering monthly submission of reports. Seven health facilities reporting monthly in EES are not captured in the quarterly progress report.

Sub-Objective 3.1
Pharmaceutical management information system (PMIS) in place to support products & patients.

Progress toward sub-objective 3.1
Significant progress made, with 32% of facilities having basic PMIS tools and 19% monitoring stock-with up to date stock-cards. Distribution of PMIS tools and stock cards is still ongoing.

Main challenges for sub-objective 3.1
CES counterparts were not able to join the program associates in some of the supportive supervision visits to disseminate the tools. Effective dissemination of tools requires concurrent on-job training. This is demanding and requires a lot of staff time per facility.

Steps to address challenges for sub-objective 3.1
- Reprogramming of some activities around MOH priorities.
- Empowering partners (pharmaceutical supervisors with NGOs, SMOH and CHD), to support dissemination.

Deliverables for sub-objective 3.1
- Trip report.
- Allocation/distribution report for PMIS tools and stock cards by state.

Sub-Objective 3.2
Information on pharmaceutical systems strengthening available and used

Progress toward sub-objective 3.2
The CRMS data collection and analysis tools were introduced through the CRMS TOTs. Supervisors from SIAPS, SMOH, CHD and NGO counterparts have started data collection and submission for the CRMS. A total of 47 facilities have reported (12 in CES, 6 in EES and 29 in WES) out of a target of 60 facilities for the year. One CRMS coordination/peer review meeting was conducted in Eastern Equatoria, based on results of analysis from the submitted CRMS data.

Main challenges for sub-objective 3.2
Comprehensive application of the CRMS tool requires a lot of staff time per facility. CRMS data is yet to be collected systematically.

Steps to address challenges for sub-objective 3.2
Empowering partners (e.g. pharmaceutical supervisors of NGOs, SMOH, and CHD) to implement the CRMS by including them in the CRMS TOTs.

Deliverables for sub-objective 3.2
- CRMS report for facilities that submitted data.
- Workshop report for CRMS review meeting.

Objective 4
Pharmaceutical services improved to achieve desired health outcomes

Objective 4: Quarterly progress
No progress made during the quarter, mainly due to competing priorities and time constraints. Activities have been re-scheduled.

Sub-Objective 4.1
Improved availability of pharmaceuticals and medical supplies

Progress toward sub-objective 4.1
While many facilities have started using PMIS tools, it is difficult to assess how many had no stock-outs as reporting is still erratic. There were delays in distribution of tracer medicines during the quarter.

Main challenges for sub-objective 4.1
Delays in distribution of the regular MOH essential drug kits due to delays in finalizing contracts for transporters. Health facilities are not yet routinely reporting consumption data to the state and central level. PMIS tools and the CRMS concepts have just been introduced.

Steps to address challenges for sub-objective 4.1
Provide TA for the distribution. Improve coordination between SMOH and CHD, to ensure consumption reports/requisitions reach MOH.

Deliverables for sub-objective 4.1
- Report on disposal of expired drugs from CES/MOH warehouse.
- Receiving report for USAID-donated ACTs and RDTs.
- First Response® test results from independent laboratory.
- CMS distribution plan for essential drug kits.
- Trip report for PPH prevention start-up assessments in Mundri East/West and Mvolo.
- Concept paper for SIAPS TA towards implementation of the PPH prevention start-up program.
- Malaria (PPMRm) and reproductive health (PPMRc) reports.
- AS+AQ emergency distribution plan for all counties (USAID/WHO donated stock of approximately 900,000 treatments).
- Minimum list of pharmaceuticals and medical supplies required to provide basic health services in South Sudan.
- General supply list for pharmaceuticals medical supplies and equipment for South Sudan.
- Trip report on joint SIAPS, USAID and MOH supervisory visit to Kaya Minilab®
- Technical presentations and meeting report on quality assurance stakeholders meeting.

Sub-Objective 4.2
Patient safety and therapeutic effectiveness assured

Progress toward sub-objective 4.2
There is one fully-functional DTC (Juba Teaching Hospital). Two additional/new DTCs were established in EES and WES, but are not yet fully-functional. ADR reporting not yet started.

However, MOH was supported to participate in the African Pharmacovigilance Meeting and ADR concepts were introduced during a training on Malaria Sentinel Surveillance System that involved 40 participants representing 4 different states and 13 health facilities.

Deliverables for sub-objective 4.2
- African Pharmacovigilance
- Meeting report.
- Pharmacovigilance presentation.

Objective 5
Scale up of malaria interventions better coordinated and documented

Sub-objective 5.1
Malaria planning and coordination mechanisms strengthened

Progress toward sub-objective 5.1
10 state malaria coordinators have been oriented on malaria policies. Planning meetings and trainings have been delayed due to funding constraints. Eighty-two health workers were trained in malaria case management, as part of other trainings (TET and Malaria Sentinel Surveillance).

Main challenges for sub-objective 5.1
Funding constraints did not allow for some activities (holding workshops to train and develop county malaria action plans). Delayed funding disbursements by the Global Fund for activities such as training of health workers in malaria case management. Time constraints: many partners are quite busy and attendance of malaria coordination meetings has not been adequate. SIAPS facilitated NMCP to develop partner planning and reporting tools, but the feedback from partners has not been positive.

Steps to address challenges for sub-objective 5.1
Further prioritization of activities in the FY11 work plan. Integration of SIAPS planned activities into other partner funded activities, as much as possible.

Deliverables for sub-objective 5.1
- Updated malaria treatment guidelines.
- Minutes of WMD meetings. Malaria Newsletter for 2012.
- Minutes of malaria TWG meetings.
- Malaria gap analysis document.
- NMCP presentation at GFATM/PSI coordination meeting.

Sub-objective 5.2
Malaria Monitoring & Evaluation systems strengthened

Progress toward sub-objective 5.2
SIAPS assisted the MOH to finalize and submit the TET protocol. Approval of the protocol was secured from both MOH ethics committee and WHO and shared with the Global Fund. SIAPS also assisted NMCP to request study medicines from the WHO.

SIAPS worked with the NMCP and WHO to organize a Therapeutic Efficacy Tests training that involved 14 health personnel from all 3 sentinel study sites. SIAPS was involved throughout the planning and implementation of the training, including adaptation of generic training materials and making presentations.

Main challenges for sub-objective 5.2
Delayed disbursement of funding from the Global Fund to continue activities started with WHO funding.

Steps to address challenges for sub-objective 5.2
SIAPS worked with NMCP/MOH to raise concerns over delayed disbursement of Global Fund monies. Funding will be released and available in next quarter.

Deliverables for sub-objective 5.2
- Final TET protocol.
- Approval letter for TET protocol.
- TET training report.

Sub-Objective 5.3
Malaria sentinel surveillance systems expanded

Progress toward sub-objective 5.3
SIAPS worked with NMCP and WHO to organize two trainings on malaria sentinel surveillance. In total, 68 health workers from 21 selected sentinel sites representing 7 states have been trained. Participants were introduced to the concepts of M&E, supportive supervision, surveillance, and the proposed indicators. SIAPS supported NMCP to develop training materials and facilitate key sessions of the training.

Main challenges for sub-objective 5.3
Coordinating the logistics associated with organizing sub-regional workshops such as travel of participants. State MOH did not fully adhere to the participant selection criteria that were provided – this was especially so for the first training. For many participants, this was the first M&E training making it difficult to capture some of the concepts discussed.

Steps to address challenges for sub-objective 5.3
Supportive supervision and follow-up of trainees to ensure smooth translation of acquired knowledge to practice. SIAPS will work with NMCP to ensure that state MOH better adhere to participant selection criteria.

Deliverables for sub-objective 5.3
- Presentations made at the trainings.
- Training reports.

South Africa

Portfolio Background

Since 2003, Management Sciences for Health (MSH) has been providing technical assistance to the SAG in the area of pharmaceutical management and systems strengthening, with PEPFAR/USAID support, through two centrally funded programs; the Rational Pharmaceutical Management Plus (RPM Plus) (2003-2007) and Strengthening Pharmaceutical Systems. The SPS program which started in 2007, as follow-on to RPM Plus, will be ending in June 2012. The Systems for Improved Access to Pharmaceutical and Services (SIAPS) program which has been newly awarded to MSH started in FY11 with PEPFAR/USAID support. The overlap between SPS and SIAPS over the next 8 months will create an opportunity to complete and phase out some of the activities that were started under SPS and start new ones to support the Intermediate Results (IRs) of SIAPS

PEPFAR has made a commitment to align its activities with the priorities of the SAG. Over the last few years the SPS team based in South Africa has built up an excellent working relationship with the SAG and local government counterparts at all levels (National, Provincial, District and Health Facilities). This has been achieved through extensive consultation with our counterparts and has been "sealed" by the signing of Memoranda of Understanding (MOUs) and the development and implementation of a set of technical interventions that focus on system strengthening and building local capacity. SPS has been involved in supporting the pharmacy component of all relevant NDoH initiatives at all levels.

The holistic approach used by SPS in terms of supporting pharmaceutical services to improve service delivery has allowed us to support areas that are not unique to pharmacy, including leadership development and infection control, to address the emerging priorities of government. SIAPS, which has a broader mandate than SPS, as it includes pharmaceuticals and services, will provide an opportunity to the SA based team to not only continue supporting these areas but also to expand its technical assistance program to new areas such as pharmaceutical financing.

Quarter Overview

During the quarter the team continued working primarily on SPS activities. The recruitment process for SIAPS was completed in preparation for implementation in the following quarter. Progress was made towards the first objective, relating to building capacity in the application of pharmacoeconomic (PE) principles in selection of essential medicines. SIAPS hosted a training of trainers' workshop on PE for academics from pharmacy schools, representatives from the National EDL Secretariat, and the Pharmacoeconomic Evaluations Unit of the National Department of Health. Recommendations have been developed for ongoing work to ensure that products at provincial and national levels are selected based on the evaluation of clinical outcomes, costs, and cost-effectiveness.

Key activities for next quarter

After the pharmacoeconomics workshop, the following recommendations were developed by SIAPS, the University of Washington and the PE Task Team as a way forward: (1) Develop a concept paper to further materialize proposed next steps with each group. (2) Implement the recommendations from the concept note (develop operational documents for the pricing

committee in implementing pharmacoeconomics guideline; and develop pharmacoeconomics training materials for pre-service and in-service programs). (3) Build into SIAPS SA support in strengthening PTCs (incorporating PE principles into the development of strategy for functional PTCs). (4) Develop generic pharmacoeconomics training modules based on workshops provided in South Africa and Namibia for other SIAPS countries to adopt and implement.

Technical Activity Coordination

The new organogram for SIAPS has been finalized. Staff members underwent an interview process in preparation for the transition to SIAPS. Appointments were completed by end June. SIAPS implementation on the new organogram will commence in the following quarter. Work began to develop the SIAPS strategy document, following the planning meeting held in the previous quarter. Work continued in liaising with HQ, via several teleconferences, to report progress on the transition of activities from SPS to SIAPS.

Objective 1

Pharmaceutical Sector Governance Strengthened

Sub-Objective 1.1

Policies and legislative frameworks relating to pharmaceutical services and products enhanced

Sub-Objective 1.2

Selection of medicines improved through development/revision and implementation of the National Essential Medicines List (EML) and formularies (provincial/institutional)

Progress toward sub-objective 1.2

A training for trainers' workshop on pharmacoeconomics (PE) was conducted from April 10-12, 2012 in Johannesburg. A total of 20 academic staff from pharmacy schools and personnel from the National EDL Secretariat, and the Pharmacoeconomic Evaluations Unit of the National Department of Health participated in the workshop.

The objectives of the workshop were to understand basic concepts, terminology, and methods of PE; gain an understanding of evidence-based approach to economic evaluation; develop an understanding of basic calculations of costs, health outcomes, and cost-effectiveness; gain an understanding of how to interpret/understand the results of PE studies; develop practical skills in the use of basic cost-effectiveness tools and measures; understand the budget impact of the introduction of new health technology on the essential medicines budget; and to promote discussion among the three types of practitioners attending the meeting.

The workshop included presentations, break-away group exercises following each lecture, and discussions of case studies. Participants were split into groups (academia, National EDL Secretariat, and pricing committee) to continue work after the workshop.

South Sudan

Portfolio Background

Over the last four years, the Republic of South Sudan and partners have worked closely to implement and strengthen the routine immunization services delivery system. Major achievements include: expansion and rehabilitation of the cold chain system; strengthened human and institutional capacity; ensuring no stock out of all six traditional vaccines; improved injection safety; broadened partnerships and alliances for immunization services; improved surveillance system that has attained certification-level polio eradication indicators; integration of immunization services with other child survival initiatives; adaptation of WHO approved tools and strategies; establishing international reporting practices to the global immunization partnerships; improved DPT-3 coverage in infants from 20% to 71% between 2007 and 2010 respectively; interruption of Wild Polio Virus; and, reduction of measles morbidity and mortality by over 90%. Under FY 2010, SPS supported EPI to: develop an integrated and comprehensive business plan; develop county immunization micro-plans; hold and document Inter-Agency Coordination Committee meetings; launch the EPI policy and Monitoring/Supervision Guidelines; adapt the WHO immunization in practice manual; develop the 2011 vaccination week guidelines, Measles follow up campaign field guidelines and National coverage survey guidelines; train 38 EPI program trainers and 129 operational level (OPL) vaccinators; conduct monitoring and supervision field visits; analyze and provide feedback to all states; conduct EPI data validation visits; print 500,000 child Health Cards; and produce an EPI newsletter.

However, several challenges remain including: sustaining the momentum of coverage gains; reducing the DTP-1 to DTP-3 dropout rate to at most 10%; attaining equitable distribution of immunization services i.e. 80% DTP coverage in 80% of states and counties; adoption of new vaccine antigens; expanding the cold chain infrastructure; enhancing capacity of the human resources; strengthening information systems; building the required political commitment; improving coordination mechanisms; and, ensuring adequate financing.

Under FY 11, SIAPS will build on SPS achievements to support the EPI program in assuring the availability of quality and effective vaccine products and their delivery services to achieve VPD control in RSS.

Quarter Overview

SIAPS made considerable progress strengthening vaccines and EPI services governance. The MOH was supported to complete the operational plan for EPI, in the context of Health Sector Development Plan. SIAPS facilitated the Annual EPI program managers review meeting with a view to harmonize operational objectives, progress and expectations for the remaining half of the year. Staff also completed and submitted the annual progress reporting to the international partnership for immunization and, provided technical assistance to capacity building on development and dissemination of briefing notes to the MOH leadership.

Under Objective 2, SIAPS enhanced the capacity to manage vaccines and EPI services by providing technical support to development of a response strategy for a confirmed vaccine derived polio virus in Western Equatoria State. SIAPS facilitated the training of 26 immunization coverage survey supervisors and 4 coordinators for the states of Upper Nile, Unity, Jonglei and Western

Bahr El Ghazaal. Staff also led the process of developing the proposal for Pentavalent (DTP-HepB+Hib) introduction in the South Sudan program for immunization. Significant progress was also made in increasing utilization of EPI M&E data for decision-making. SIAPS supported EPI to provide a quarterly immunization performance monitoring feedback; completed data collection for 4 state-specific coverage verification surveys in addition to completion of the National coverage verification surveys; supported two states of Upper Nile and Central Equatoria to develop immunization performance monitoring charts for 2012; and supported the development of six months operational plans for all states based on use of DTP-1 coverage (reached or missed children) and Dropout rates (measuring utilization).

Under objective 4, SIAPS assisted EPI to investigate and document measles outbreaks in Pibor County of Jonglei state and Yida camp of Unity State; supported development of measles outbreaks response guidelines given the sustained outbreaks in Quarter 3; and, all state EPI teams to design appropriate measles outbreak response during the quarter.

Key challenges of quarter

The human resources crisis at the immunization program persisted through quarter 3 of 2012. Completing the multi-year plan for immunization was delayed due to lack of support for costing the strategic road map. Under-estimation of the population of South Sudan, based on the 2008 housing and population census reports, continues to skew the coverage estimates from the administrative reporting system.

Key activities for next quarter

- Conduct costing of the multi-year plan for immunization systems strengthening.
- Complete and submit the GAVI application for introduction of new and underused vaccines.
- Disseminate the EPI policy and implementation guidelines to at least 2 counties.
- Conduct training of 20 Immunization Practice Trainers in Central Equatoria State.
- Conduct supportive supervision visits to at least 1 state and 2 counties.
- Support advocacy mission to one poorly performing state.
- Provide a quarterly feedback bulletin to all states on EPI performance in South Sudan.
- Support monthly data quality assurance visits to 1 selected state.

Technical Activity Coordination

The SIAPS-EPI program continued to do budget monitoring, progress monitoring, reporting and participation in technical meetings. It continued to work with MOH and other technical partners to coordinate and implement EPI activities during the quarter.

Office Management

As part of the MSH/SIAPS EPI activity plan, SIAPS contributed to cost sharing arrangements with SHTP II, including office utilities (internet, stationary) and other overhead charges.

Objective 1

Vaccines and EPI services governance strengthened

Sub-Objective 1.2

National comprehensive multi-year and annual plans of action are strategic and evidence-based

Main challenges for sub-objective 1.2
Lack of costing skills in the country.

Steps to address challenges for sub-objective 1.2
SIAPS mobilized WHO to procure a health economist to support costing of the multi-year plan for immunization systems development in South Sudan.

Deliverables for sub-objective 1.2
- cMYP for immunization systems development in South Sudan.
- Annual Plan of Action for Immunization Services in South Sudan.

Objective 2
Capacity for vaccines and EPI services management enhanced

Sub-Objective 2.1
Strengthen EPI Program management capacity of individuals, institutions, organizations, and networks

Progress toward sub-objective 2.1
Very little progress made towards this Sub-Objective due to limited financial and logistical resources.

Main challenges for sub-objective 2.1
Limited financial resources for SIAPS/EPI supported activities. Lack of operations funds to facilitate the immunization practice training sessions.

Steps to address challenges for sub-objective 2.1
- Postponed the planned training of trainers in immunization practice to the 4th Quarter.
- Mobilizing partner support to immunization practice training of trainers.
- Reschedule the training of vaccinators in immunization practice to the 4th Quarter of the financial year.
- Mobilizing other agencies in the immunization partnership of South Sudan to continue supporting immunization practice training especially in poorly performing states/counties.

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

Progress toward sub-objective 2.2
Very little progress made, due to lack of operational financing to support supervision and mentoring of EPI managers, competing priorities and human resource crisis in the immunization program.

Main challenges for sub-objective 2.2
Competing priority activities related to cMYP finalization, sustained measles outbreak response, and planning for new vaccines introduction delayed activities. The human resources shortage in

the immunization program that limits implementation of multiple-tasks concurrently or in a limited schedule of time also delayed progress on activities.

Steps to address challenges for sub-objective 2.2

- Reschedule the on-job training of immunization managers/supervisors in supportive supervision to the 4th Quarter of the financial year.
- Mobilizing other agencies in the immunization partnership of South Sudan to support on-job mentoring and training of immunization managers and supervisors especially in poorly performing states/counties.

Objective 3

Utilization of EPI M&E data for decision-making increased

Objective 3: Quarterly progress

Progress has been made towards all the indicators in objective 3 as follows. Progress of DTP-3 coverage was made to 20% (against a set target of 19%). 37% of the counties attained the annualized DTP-3 target of 80%. This indicator sets out to institutionalize the REC approach to immunization programming in addition to identification of priority counties for focused support. The large number of counties reaching high rates for the quarter is a result of immunization defaulters tracing campaigns implemented in the vaccination week (30 April to 5 May 2012). The immunization defaulters tracing campaign implemented during the 2012 vaccination week reached more DTP-1 than they did for the DTP-2 and DTP-3. Therefore, the dropout rate for this quarter was worse than the previous; the rate will continue to improve (decline), as more dropout tracing campaigns are planned and implemented in Quarter 4.

Sub-Objective 3.1

EPI Program information systems supports both immunization outputs and vaccines utilization

Progress toward sub-objective 3.1

Quarterly immunization monitoring feedback to all states and selected counties was done. This feedback bulletin aims at institutionalizing the use of EPI program data to inform performance improvements throughout the year. Significant progress was made towards with an achievement of 100% towards the set target. The Annual VPD Newsletter was rescheduled to the 4th Quarter of the financial year in order to provide an annual view of the program performance on an annual basis.

Main challenges for sub-objective 3.1

Competing priority activities related to sustained measles outbreaks and new vaccines application to GAVI/Vaccine fund.

Steps to address challenges for sub-objective 3.1

Rescheduling the Annual Newsletter production from the 3rd to 4th quarter.

Deliverables for sub-objective 3.1

Quarterly EPI program performance monitoring charts/feedback bulletin for all states.

Sub-Objective 3.2
Innovative and proven tools for EPI M&E broadly available and used

Progress toward sub-objective 3.2
Collection of the National Immunization Coverage Verification Surveys data was separated from the state-specific surveys as earlier planned. SIAPS supported the field data collection for a cumulative 28 out of the planned 30 clusters. The 2 missing clusters are due to poor data collection from ineligible children in Jonglei state and the state Ministries of Health have been instructed to repeat the data collection. Meanwhile, data entry of the National immunization coverage verification surveys have been entered, analyzed, and a report drafted. Finalization of the immunization coverage verification survey report for South Sudan has been scheduled to the 4th Quarter. The human resources crisis in the program, with the sustained measles outbreak response, and limited financial resources to facilitate Data Quality Assurance visits are delayed this activity.

Main challenges for sub-objective 3.2
- Delays in release of operational financing for the state-specific surveys that were linked to the National Verification Surveys.
- Delays with partners.
- Collection of immunization coverage verification survey data from ineligible children in 2 of the 30 clusters.
- Lack of an institutional strategy and tools for improving the quality of immunization data.
- Limited human resources.
- Evolving HMIS system based on the DHIS in a context of limited skills in data management.

Steps to address challenges for sub-objective 3.2
- Separating the data collection process of the national coverage verification surveys from the state-specific cluster surveys that are intricately related to delayed release of funding from UNICEF to the states through the central MoH.
- Parallel and independent data entry and analysis of the national coverage verification survey data has been completed.
- Draft report of the National Coverage Verification Surveys has been made and shared with all immunization partners for initial review and comments.
- Rescheduling the SIAPs supported DQAs to the 4th Quarter.

Deliverables for sub-objective 3.2
- Draft national immunization coverage verification survey for South Sudan.
- Completed state-specific surveys for Northern Bahr El Ghazaal, Lakes, Warrap and Jonglei.

Objective 4
Support EPI services delivery to achieve desired health outcomes

Sub-Objective 4.1
Availability of EPI vaccines (including new and underused vaccines) and services improved

Progress toward sub-objective 4.1
Due to careful review of the national vaccine store and lack of financing for the procurement of the

said vaccines, SIAPs worked on completing the cMYP, Global Annual progress reports and proposals to the GAVI/vaccine fund. Also, 37% of the counties attained the annualized DTP-3 target of 80%.

Main challenges for sub-objective 4.1

- All vaccines used in South Sudan are procured and warehoused by UNICEF.
- Dependency on the GAVI/Vaccine fund for new and underused vaccines introduction (makes the process lengthy).
- Sustained measles outbreaks continued to attract attention and prioritization by the national government.
- Renewed tensions between South Sudan and the neighboring Sudan.

Steps to address challenges for sub-objective 4.1

- Integrating new and underused vaccine requirements and costing institutional planning and management tools like the Social Development Plan, the Health Sector Development Plan and the cMYP for immunization systems development.
- Facilitate the drafting of the proposal/plan for new and underused vaccines to the GAVI/vaccine fund.
- Supporting routine immunization operations planning by county in 9 states at the EPI program review meeting held in June.

Deliverables for sub-objective 4.1

- ICC approved proposal/plan for new and underused vaccines introduction into the South Sudan program for immunization.
- Revised operations plan for routine immunization services delivery by county of all 10 states in South Sudan.

Sub-Objective 4.2

EPI services delivery standards defined, adopted and adherence monitored

Progress toward sub-objective 4.2

More technical coordination meetings were held in the process to finalize the annual progress report and preparations for the June EPI managers meeting. One ICC meeting was held this quarter and an additional ICC meeting has been planned for the 4th Quarter, to approve the proposal/plan to introduce new vaccines to GAVI/vaccine fund.

Main challenges for sub-objective 4.2

- Sustained lack of administrative support to document the proceedings of the technical working groups.
- Lack of command and control over implementation of recommendations and actions made during the technical working group meetings.
- Low cadre representation of ICC members.
- Limited follow-up in implementation of recommendations and actions made during the previous ICC meeting.
- Limited financing for the program operations.

Steps to address challenges for sub-objective 4.2

- Periodic documentation of the proceedings of the technical working group meetings.
- Advocacy and engagement of the Minister for Health to chair the ICC meetings and thus raised the profile of the ICC meetings.
- Documentation of ICC proceedings with a minute of record of action points with designated responsibility centers for all ICC meetings held in the quarter.
- Advocacy and engagement of the primary health care implementing NGOs to plan and conduct supportive supervision.
- Standardized and nationally adapted monitoring and supervision guidelines for immunization practice in South Sudan.

Deliverables for sub-objective 4.2

- Documentation of the proceedings of the EPI technical partners meeting.
- Minutes of the 13th ICC.

Swaziland

Portfolio Background

The Kingdom of Swaziland has a predominantly rural population (77%) of just over 1 million people. Women of child-bearing age (15 – 49 years) make up 26.2% of the population while all females account for 53% of the population. According to the Demographic Health Survey (2007), about 60% of the population is aged below 30 years of which 39.6% are children under the age of 15 years. The largest share of the Swazi burden of disease remains communicable diseases, with HIV/AIDS and TB rates the highest in the world. HIV has a high impact on the health of the population with 26% prevalence among the adult population (15-49 years), with higher prevalence rates among females (31%) compared to males (20%). (Demographic Health Survey, 2007).
As of June 2011, 86,356 clients had enrolled (at one time) for ART, while 67,871 were on treatment (6,448 children) a total coverage of 76.6%. It is estimated that 88,620 people are in need of ART treatment in Swaziland (National ART assessment report, 2010). There are 75 ART initiation sites and 35 combined (refill and initiation) sites. For TB, the case notification rate is at 847 cases/100,000 population. The case detection rate (78%) and the treatment success rate (68%, 2009) are both below the WHO targets, but are gradually approaching the targets set.

Medicines stock-outs are a common occurrence, in part due to the current national fiscal climate. The country relies on foreign suppliers for its essential medicines and laboratory products. The Central Medical Stores is the main point of receipt for all essential medicines to be used in the public sector. The country was maintaining a minimum national stock of 6 months for all priority health products but in the past year, this was reduced to 4 months due to financial constraints. The health sector is faced with a severe shortage of human resources across all cadres at all levels of the health system. In terms of human capacity development for health, there are 3 local training institutions for health professionals, mainly nurses and nursing assistants. There are no training facilities for pharmacists or pharmacy technicians (National Health Sector Strategic Plan, 2008 – 2013).

It was from this background that SPS and now SIAPS technical assistance to the government of Swaziland was established. SIAPS will build on the success of its predecessor programs such as the Strengthening Pharmaceutical Systems (SPS, since 2007) and Rational Pharmaceutical Management Plus (RPM-Plus, since 2006). The mandate of the SIAPS program in Swaziland is to promote and utilize a system strengthening approach consistent with GHI principles that will result in improved and sustainable health impact. In the previous year, MSH support was mainly on improving program implementation for the scale-up of treatment and care services. The SIAPS program will ensure the health system strengthening approach is implemented to support program implementation. Under this program, country ownership, capacity building and evidence based interventions will be central in all the intervention. The SIAPS program will work through the main building blocks: service delivery, health workforce, information, health products, and governance.

With FY11 funding, SIAPS will work to support the implementation of the five year goal for care and treatment of the PEPFAR/Government of the Kingdom of Swaziland Partnership Framework: decentralize and improve the quality of HIV care and treatment services to increase access and improve outcomes for PLWHA. SIAPS will also support the following technical areas of the

Swaziland Country Operational Plan: ARV Drugs, Adult Care & Support, Pediatric Care & Support, Adult Treatment, Pediatric Treatment, Laboratory Infrastructure, TB/HIV, Strategic Information and Human and Institutional Capacity Development.

Quarter Overview

In this quarter, SIAPS has moved forward in supporting the establishment of a legislative environment for pharmaceutical systems strengthening in the country. The Medicines and Related Substances Control Bill was approved by the cabinet and with support from the Ministry of Agriculture (responsible for veterinary medicines). The Bill is ready to be presented to the Parliament of Swaziland. The approval of this Bill therefore paves a way for the Ministry of Health to start thinking about the establishment of a Medicines Regulatory Authority (MRA). The Senior Pharmacist in the Ministry of Health and the Medicines Policy Advisor were supported to go on a study tour to the Medicines Control Authority of Zimbabwe (MCAZ). This study tour also served as an opportunity to explore possible collaborations between the Government of Swaziland Ministry of Health and the MCAZ. The MRA rapid assessment was conducted in partnership with WHO-Afro and a report has been prepared to guide the next steps for the country to establish an MRA. The Medicines and Related Substances Control Bill (2012) is expected to be presented to Parliament along with the Pharmacy Bill (2012) later this year.

ARV medicines forecasting and quantification remains a key area of SIAPS/Swaziland's work in assuring regular, uninterrupted availability of these lifesaving medicines to all eligible clients. Foresting meetings have been held and the supply plan revised to ensure that the appropriate quantity of ARVs is procured into the country. There was no stock-out of ARVs reported in this quarter.

SIAPS is supporting the procurement reforms in the MoH through the development of procurement guidelines and capacity building of the Procurement Unit officers. The country is faced with serious fiscal challenges and these threaten the availability of medicines. SIAPS is working with the MOH to improve the availability of logistics information to inform supply chain decisions. It is our belief that the availability of timely information (consumption, quantification, etc.) will ensure that sufficient funds are allocated to support procurement of essential commodities.

Swaziland has a growing number of TB cases who are treated in the communities. The number of MDR-TB cases is growing and the sector is forced to manage some of the clients at community level. TB re-treatment cases continue to be high amongst registered clients currently at 13%. In a rapid assessment conducted jointly with SIAPS, the National TB Control Programme has recorded an average of 75% adherence score for the selected clients. A group of 63 adherence officers and treatment supporters have been training across the country on adherence monitoring using a multi-method tool. These officers will implement this tool and report back in the next quarter. It is expected that an improvement in adherence monitoring will be observed and also the adherence score will be closer to 85% (from baseline of 75%).

Key challenges of quarter

Though SIAPS is doing everything possible in supporting supply chain systems for TB/HIV/malaria and reproductive health, the fiscal challenge remains the main obstacle in the

country. There have been cases of prolonged stock-outs of laboratory reagents, because of funding constraints. The recently implemented VAT law adds to the challenges; suppliers from outside the country are not willing to pay VAT for the goods that were contracted with prices agreed upon before the VAT was introduced.

Key activities for next quarter

- Finalize the draft Procurement Guidelines and get them approved by the Ministry of Finance (National Tender Board) continue the redesign of the RxPMIS.
- Refresher training on the Logistic Management Information System for HIV
- Develop a plan to integrate supply chain systems in the country
- Launch the STG/EML document
- Costing of the Swaziland Strategic Plan 2012 - 2016
- Conduct a baseline survey of the pharmaceutical sector with the MOH Monitoring and Evaluation Unit.

Technical Activity Coordination

SIAPS worked with the Global Fund Principal Recipient and the Ministry of Health to address some critical conditions precedent to disbursement of funds. The Pharmaceutical and Health Products Management Country profile document was updated and submitted to the Global Fund. Interviews were conducted for the positions advertised in Q2 (M&E Advisor and Technical Advisor Supply Chain). These two positions are planned to be filled in Q4. Regular touch-base meetings were held with the OST team in Washington and the Portfolio Manager. A two-day meeting was held with the technical team to develop the SIAPS/Swaziland Strategic Plan 2012 - 2016. The draft strategic plan is currently being reviewed by our HQ team. A Semi-annual report and Quarterly Performance Report were submitted to PEPFAR/Swaziland, and a quarterly touch-base meeting was held with the PEPFAR Activity Manager to review implementation of activities.

Office Management

We have moved offices in May to occupy a large office space of 303sqm. This space is occupied by SIAPS program and the PFSCM/SCMS project. During this quarter, a multi-purpose photocopier/printer was purchased for the office to replace the older photocopier. To support the operations team and the rest of the technical team, a driver and finance clerk were contracted. MSH internal audit was conducted for the period January 2011 - March 2012. A draft report of this audit is expected in Aug 2012.

Objective 1

Strengthen governance in the pharmaceutical sector

Objective 1: Quarterly progress

The Medicines and Related Substances Control Bill was successfully approved by cabinet for submission to Parliament in the next quarter. This is significant progress: we anticipate having the two legislative documents presented to Parliament before December 2012. Procurement guidelines were drafted and submitted to the Ministry of Finance for review and finalization. The National Procurement Plan for all health products was developed and submitted to the Ministry of Finance. The submission of a procurement plan was a condition set by the government before

funds can be released. The Ministry of Health's Senior Pharmacist and Medicines Policy Advisor were supported to go for a bench-marking/study tour of the Zimbabwe Medicine Control Council. This is a step in the establishment of a Medicines Regulatory Authority in Swaziland. The STG/EML implementation plan was developed and submitted to the Ministry of Health for approval.

Sub-Objective 1.1
Improve medicines policies, legislation, regulations, norms and standards

Progress toward sub-objective 1.1
The Medicines and Related Substances Control Bill and Pharmacy Bill are now approved by Cabinet. The two legislative documents will be submitted to Parliament for debate towards enactment. The STG/EML for the most common conditions in Swaziland has been printed and a dissemination meeting will be conducted in Q4. This dissemination meeting will be followed by a training/workshop for all health workers on the use of the documents.

Main challenges for sub-objective 1.1
Delays in getting a date for the dissemination of the STG/EML. This date is dependent on the availability of the Minister of Health, who wants to officiate the event.

Steps to address challenges for sub-objective 1.1
Two tentative dates have been proposed to the Minister; the event will most likely be held in the first week of August.

Deliverables for sub-objective 1.1
- Review of the Medicines Bill/Pharmacy Bill.
- Trip Report to Zimbabwe.

Sub-Objective 1.2
Support the development of strategic and evidence-based pharmaceutical sector development plans

Progress toward sub-objective 1.2
The Swaziland Pharmaceutical Strategic Plan was completed and we are waiting for the completion of the costing exercise.

Main challenges for sub-objective 1.2
The length of the consultant contracting process is long.

Steps to address challenges for sub-objective 1.2
Submission of STTA plans in advance: in the future, this will be done as soon as the work plan is approved and will be updated quarterly.

Deliverables for sub-objective 1.2
Draft/Final Strategic Plan 2012 - 2016 (without the costing).

Sub-Objective 1.3
Improve coordination of stakeholders in pharmaceutical systems

Progress toward sub-objective 1.3
The Supply Chain TWG is being recognized as an important structure in supply chain strengthening in the country. A Google group page has been developed to improve communication between all stakeholders on supply chain issues in the country (e.g. stock status, minutes of meetings, and other important communication).

Main challenges for sub-objective 1.3
Lack of commitment from other participants.

Steps to address challenges for sub-objective 1.3
The number of meetings scheduled has been reduced to quarterly and number of participants was reduced.

Deliverables for sub-objective 1.3
Meeting minutes.

Sub-Objective 1.4
Support the health commodity procurement system (pharmaceuticals, supplies and laboratory commodities) within the MOH Procurement Unit

Progress toward sub-objective 1.4
The Procurement Guidelines were developed and shared with the Ministry of Health and the Ministry of Finance for review. These guidelines were also reviewed internally by SIAPS technical experts (Mavere Tukai and Joseph Adu) to ensure technical quality. The Procurement Plan 2012/13 was completed and shared with the Ministry of Health/Finance.

As part of developing the procurement guidelines, SIAPS advised the MOH on key gaps in skills and expertise in the Procurement Unit. A procurement Manager (acting) has been identified within the Procurement Unit and SIAPS is supporting her to ensure that she fulfills her role. A capacity development report was shared with the WB/EU project that is willing to support the CIPS training of the Procurement Officers (2 Principal Procurement Officers, level 5 CIPS qualification).

Main challenges for sub-objective 1.4
There is no clear strategy in the MOH and Ministry of Finance to establish the Procurement Unit or the overall decentralization of procurement function from the Ministry of Finance to the different ministries. This makes it difficult to clearly define the roles and responsibilities of the stakeholders (MOH, MOF, and National Tender Board)

Steps to address challenges for sub-objective 1.4
SIAPS is continuously working with MOF to clearly define the role of Procurement Unit in relation to the Ministry of Finance's National Tender Board. The Procurement Guidelines will detail most of this.

Deliverables for sub-objective 1.4

- Draft Procurement Guidelines
- Trip report
- Capacity Building Plan

Objective 2

Increase capacity for pharmaceutical supply management and services

Sub-Objective 2.1

Increase pharmaceutical management capacity for individuals, institutions and organizations.

Progress toward sub-objective 2.1

SIAPS is working with regional pharmacists, Strategic Information Department, and the Central Medical Store in mentorship and supportive supervision of health workers in pharmaceutical management of HIV/AIDS and TB. SIAPS works with other PEPFAR partners in mentoring health workers on site in all area of medicines available.

In this quarter and after identifying a gap in adherence monitoring of TB clients, SIAPS embarked on an activity to train community health workers on adherence to TB Medicines. The majority of TB clients including those on MDR are dependent on the support by adherence and treatment supporters to complete their treatment.

Main challenges for sub-objective 2.1

The contracts of the regional pharmacists have come to an end and these posts were funded through Global Fund resources. Of the 4 regional pharmacists, there is one position that has been vacant since Dec 2011 and the MOH has not filled this position.

Steps to address challenges for sub-objective 2.1

Continue to provide guidance to the MOH on absorption of these pharmacists and also re-define their scope to fit into the newly developed regional clinical mentoring teams.

Deliverables for sub-objective 2.1

Training report.

Objective 3

Address information for decision making challenges in the pharmaceutical sector

Sub-Objective 3.1

Support the pharmaceutical Management information system for both products and patients

Progress toward sub-objective 3.1

Support was provided to facilities on hardware and software troubleshooting. A total of 18 ART initiating facilities were visited. An exercise to standardize the report for patient management and also medicines management began. It is expected that these will assist in addressing data quality issues in the facilities.

SIAPS worked with the Strategic Information Department to create Rx-Solution SQL queries, cross-examined and adapted into the Rx-Solution installation package. These queries supported four reports (Cohort, ART Monthly Monitoring, TB Monthly Monitoring, and Data Quality reports).

Main challenges for sub-objective 3.1
Data quality remains a concern due to shortage of data clerks at most pharmacies. In the 38 treatment sites, there is only a handful that has dedicated clerks responsible for data entry in the RxSolution. This means the data reported at the end of the month on LMIS or even RxSolution is incomplete.

Steps to address challenges for sub-objective 3.1
SIAPS is considering contracting short-term clerks to clear the backlog at some of the larger health facilities during Q4. This is being discussed with the M&E office and the Central Medical Stores. The focus of these clerks will mainly be on clearing the backlog of patient prescriptions and stock consumption data at facilities.

Deliverables for sub-objective 3.1
MOH quarterly report on ART patients.

Sub-Objective 3.2
Support proven, innovative tools for the pharmaceutical management information systems

Progress toward sub-objective 3.2
The process of standardizing RxSolution reports to support both patient M&E and quantification needs is underway. SIAPS is working with CHAI and other local partners to develop these standard reports in the country. The LMIS and cohort reports have been completed and further reports will be finalized in the next quarter. Support is provided to the CMS and Laboratory warehouse to address some hardware problems which compromise the functionality of the RxSolution system. Stock status reports are generated monthly for laboratory, TB, HIV and tracer essential medicines list. This report is discussed with MOH and disseminated to all stakeholder through the office of the Senior Pharmacist/Chief Laboratory Technologist. The Commodity Tracking Tool is close to completion. Training material (user training) has been developed as part of the CTS implementation program.

Main challenges for sub-objective 3.2
Some minor delays in contracting the CTS developing firm have further delayed the implementation of the commodity tracking system. The shortage of IT officers, especially dedicated to CMS and Laboratory Warehouse.

Steps to address challenges for sub-objective 3.2
Discussions are underway with the MOH to contract an IT firm to be responsible for hardware trouble shooting.

Objective 4
Improved Pharmaceutical Services to achieve desired health outcomes

Sub-Objective 4.1
Improved availability of pharmaceuticals

Progress toward sub-objective 4.1
The availability of products is reliant on good quantification and forecasting in the country. The use of tools like the LMIS has made it easy to access reliable data on medicines consumption in the health sector.

SIAPS supported the MOH/SNAP/CMS by facilitating one supply planning meeting for 5 days and another forecasting and supply planning TWG meeting. From the exercise, a one year supply plan was developed and submitted to the MOH procurement unit and Ministry of Finance (MOF). A National Quantification Guideline was developed and shared with all stakeholders. This has been found to be necessary in standardizing the quantification of health products.

Warehousing continues to be improved at all levels of the health sector. Working with NERCHA, the CMS and laboratory warehouses were supplied and fitted with new quality shelves. This activity was funded by Global Fund. Stock cards were printed and supplied to clinical laboratories in the country. This will assist laboratory personnel to record their entire inventory and monitor stock availability.

Main challenges for sub-objective 4.1
Data quality; incomplete and late submission of reports.

Steps to address challenges for sub-objective 4.1
Mentorship of facilities for completing LMIS forms and standardization of the electronic templates/report scripts.

Sub-Objective 4.2
Assure patient safety and therapy effectiveness

Progress toward sub-objective 4.2
AS pharmacist from the MOH was supported to attend and participate in the Africa Pharmacovigilance meeting in Kenya. This meeting was a forum for various stakeholders to share ideas on implementing pharmacovigilance activities in respective countries. It is from this conference that Swaziland prioritized the implementation of system approach to pharmacovigilance. Advocacy to have PTCs functional in all hospitals is ongoing. The PTCs are also tasked with monitoring medicines safety and use at their respective facilities.

Main challenges for sub-objective 4.2
Low reporting rate of adverse drug reactions caused delays.

Steps to address challenges for sub-objective 4.2
ADR forms have been printed and SIAPS will work with nurse mentors from ICAP/URC to support the reporting at facilities.

Deliverables for sub-objective 4.2
Medicines Safety Watch newsletter.

Sub-Objective 4.3
Provide technical Assistance in the decentralization of HIV, TB services to improve access to quality pharmaceutical services

Progress toward sub-objective 4.3
SIAPS works closely with the National TB Program and AIDS Program in pharmaceutical management of TB and HIV. Support is provided to the regional pharmacists to mentor the facility health workers especially pharmacy staff on good dispensing and stock management practice. Supportive visits are conducted to facilities to mentor providers.

Main challenges for sub-objective 4.3
The HIV/family planning integration SOP was drafted and shared with MOH for approval. The process is currently on hold and MOH has not approved the SOP.

Steps to address challenges for sub-objective 4.3
Continue to work with EGPAF and other partners to advocate for the finalization of the Family Planning/HIV integration SOP.

Vietnam

Portfolio Background

In the recent changing environments for pharmacy practice, including the pharmaceutical management demands placed by a huge increases in the supply of essential medicines for priority public health programs such as HIV/AIDS, TB and malaria, pharmacy students are expected to acquire sound pharmaceuticals supply management (PSM) knowledge and skills by the time they graduate and join the workforce. But, more often than not, pre-service pharmacy curricula in many places do not provide adequate exposure to the theoretical and practical aspects of this important pharmacy-related task. In this context, the Hanoi University of Pharmacy (HUP) is reforming the curriculum to ensure appropriate coverage of PSM elements in their pharmacy training course. With USAID support, SIAPS is assisting HUP in this task. This curricular reform activity will help generate "local" human resources skilled in PSM, strengthen local training capacity, and support sustainability. A systematic and step-wise process will be adopted to ensure that the resulting curricula for both undergraduate and postgraduate levels are tailored to suit the specific needs of Vietnam. SPS will work with HUP and other relevant stakeholders to:

- Map the existing gaps and the required competencies.
- Develop a draft of the curriculum, including the contents and instructional plans.
- Finalize the draft of the curriculum through a wide review and consultative process.

Quarter Overview

Progress continued during this quarter toward supporting the work plan objective (in-country human resource capacity for pharmaceutical services strengthened leading to improved patient outcomes [contributes to IR2.1 and 5.1]). Based on the curriculum review, competency assessment and curriculum outline, work started toward drafting the details of the curriculum, including content summaries.

Objective 1

In-country human resource capacity for pharmaceutical services strengthened leading to improved patient outcomes

Objective 1: Quarterly progress

The technical report entitled "Pre-service Curriculum Reform on Pharmaceutical Supply Management at the Hanoi University of Pharmacy: Technical Assistance for Curriculum Review and Competency Assessment" was developed finalized and disseminated during this quarter. A senior expert with experience in pharmaceutical management, including PSM, was hired by SIAPS during this quarter to assist with the development of the detailed curriculum along with objectives, topic areas, instructional methods, contact times and content summaries. The first section of the curriculum— Introduction/Contextualization of PSM/Governance— was developed and shared internally for review. Work is moving forward with the development of other sections of the curriculum.

Common Agenda

Portfolio Background

The Common Agenda portfolio is made up of a proportion of all the separate health elements, and with this funding and guidance from USAID, SIAPS is expected to identify overarching pharmaceutical management issues that have emerged as key technical areas for SIAPS, but are not limited to any particular health element. The Common Agenda portfolio also supports activities that recur each year and are essential to the programmatic expansion of SIAPS.

Objective 4

Improved Pharmaceutical Services

Objective 4: Quarterly progress

During Q3, staff participated and represented SIAPS and Management of Sciences for Health (MSH) in two ADMS Partners' meetings. The AIDS Medicine and Diagnostic Services (AMDS) network partners and stakeholders established to support the pharmaceutical supply chain management (PSM) systems to ensure uninterrupted supply of ARVs and other medicines, diagnostics and other HIV-related commodities met in Geneva, Switzerland for the annual meeting on June 17–18, 2012. Follow on to the AMDS partners meeting, the technical working group(TWG) of the stakeholders and partners who were charged with making recommendations on laboratory testing standardization and harmonization held in Maputo, 22-24 January 2008 met on July 19– 20, 2012. The need for guidance to assist procurement and supply chain management of laboratory equipment and related consumables was highlighted in the Maputo Declaration on Strengthening Laboratory Systems. The meeting in Geneva was a follow up of the meeting jointly organized by AIDS Medicines and Diagnostics service (HIV/AMDS) and the Diagnostic Laboratory Technology of the Essential Health Technologies (EHT/DLT) Department in October 2008. This meeting was convened to integrate comments on the widely reviewed draft document on procurement specifications for quantification of laboratory commodities before it is finalized and published.

Sub-Objective 4.1

Develop a review document for options for improving supply chain operations.

Progress toward sub-objective 4.1

This quarter, SIAPS developed a draft options analysis concept paper for approval by USAID; the document has been reviewed internally and is awaiting approval. In the past quarter, SIAPS communicated and engaged with three technical partners: Management Institute (LMI), William and Davidson Institute (WDI) and RTT Group. During this period, we initiated a contractual relationship with WDI (still pending the approval of USAID), worked with LMI on the options analysis, and provided technical assistance to specific supply chain areas (e.g. warehouse and logistics management in Swaziland). In addition, a meeting with RTT and several communications with RTT were done. SIAPS participated in the Supply Chain Advisory Meeting in South Africa (May 2012) and the ADMS meeting in Geneva in June 2012. These meeting will contribute to increased networking and insight into other supply chain stakeholders around the globe.

Main challenges for sub-objective 4.1

USAID contract approval processes have slowed the process of engaging WDI in the options analysis. Differing views on supply chain options analysis from key players.

Deliverables for sub-objective 4.1

- SOW for WDI's participation in the options analysis.
- Draft options analysis concept paper.

Objective 5

Contribute to dissemination of evidenced-based approaches and best practices

Sub-Objective 5.1

Collaborate with WHO/EDM for the development and maintenance of a SIAPS knowledge management portal for the documentation and dissemination of results and lessons learned.

Progress toward sub-objective 5.1

SIAPS Director Francis Aboagye-Nyame met with Richard Laing and the EDM team to discuss the knowledge management work and possible collaborations with the WHO.

Sub-Objective 5.3

Engage partners

Progress toward sub-objective 5.3

SIAPS brought together its core partners and specialized resource organizations including Accreditation Council for Pharmacy Education (ACPE), Harvard University, Logistics Management Institute (LMI), University of Washington, African Medical and Research Foundation (AMREF), Ecumenical Pharmaceutical Network (EPN), Results for Development (R4D), RTT Group, Village Reach, and William and Davidson Institute (WDI). During Q3, SIAPS had continuous discussions and interactions with its partners on the possible areas of collaboration. SIAPS had in-person or remote meetings with LMI, Harvard School of Public Health, ACPE, R4D, and RTT Group to further explore the partners' capability and potential contribution to the program. The brown bag presentations were organized to discuss the landscape assessment of health technology assessment by University of Washington and provide an overview of ACPE and its International Services Program in June 2012. SIAPS facilitated the engagement of partners in implementing activities for country programs in close collaboration with portfolio managers and contract officers, for example:

- Established and implemented task orders for University of Washington: (a) To assess pharmacovigilance systems and performance in Bangladesh in June 2012 (b) To facilitate pharmacoeconomics workshop in South Africa in April 2012 (c) To establish active surveillance for antiretrovirals in Namibia (for July 2012).
- Established task order for LMI to support the Swaziland Ministry of Health to strengthen warehousing, storage, and logistics management of Central Medical Store and National Laboratory Warehouse (planned in August 2012).

Main challenges for sub-objective 5.3

Due to changes in USAID contract approval process, SIAPS had challenges in moving forward with establishing the contract mechanism with resource organizations through IQC. SIAPS is in

the process of developing a concept note for each resource organization to outline strategies and potential activities for the areas of collaboration.

Steps to address challenges for sub-objective 5.3

SIAPS will explore ways of establishing the most suitable contract mechanism depending on the nature of activities and level of engagement for each resource organization.