SIAPS Quarterly Report

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About SIAPS

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

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

CONTENTS

ACRONYMS AND ABBREVIATIONS

AAH	Action Against Hunger
ACT	artemisinin-based combination therapy
AIDS	acquired immunodeficiency syndrome
AMI	Amazon Malaria Initiative
AMR	antimicrobial resistance
APTS	Auditable Pharmaceutical Transactions and Services (Ethiopia)
ART	antiretroviral therapy
ARV	antiretroviral
CAMEBU	Central Essential Medication Purchasing Agency (Burundi)
CDC	US Centers for Disease Control and Prevention
CECOMA	Central Medical Stores (Angola)
CENAME	National Essential Drugs Procurement Center (Cameroon)
CHAI	Clinton Health Access Initiative
CMS	central medicine store
CNLS	AIDS Control Program (Cameroon)
CRMS	Continuous Results Monitoring System
DGFP	Directorate General of Family Planning (Bangladesh)
DIGEMID	General Directorate of Drugs and Medical Supplies (Peru)
DNME	National Directorate of Medicines and Equipment (Angola)
DPML	Department of Pharmacy, Medicines, and Laboratory (Burundi)
DRA	drug regulation authority
DRC	Democratic Republic of the Congo
DRS	Direction Régionale de la santé
DTC	Drug and Therapeutics Committee
EDT	Electronic Dispensing Tool
EHRIG	Ethiopian Hospital Reform Implementation Guideline
EMF	Emergency Medicines Fund
EUV	end-use verification (survey)
FDA	US Food and Drug Administration
FMHACA	Food, Medicines and Health Care Administration and Control Authority (Ethiopia)
FP	family planning
FY	fiscal year
GDF	Global Drug Facility
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HCW	healthcare worker
HIV	human immunodeficiency virus
HPD	Hospital Pharmacy Department
IMCI	Integrated Management of Childhood Illness
JSI	John Snow, Inc.
LMIS	Logistics Management Information System
M&E	monitoring and evaluation
MCH	maternal and child health
MDG	Millennium Development Goal

MDR	multidrug resistant
MNCH	maternal, neonatal, and child health
MOH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare
MOHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
NDoH	National Department of Health
NHTC	National Health Training Centre (Namibia)
NMCP	national malaria control program
NMRC	Namibia Medicines Regulatory Council
NTP	national TB program
PAHO	Pan American Health Organization
PEP	post-exposure phophylaxis
PEPFAR	US President's Emergency Plan for AIDS Relief
PFSA	Pharmaceutical Fund and Supply Agency (Ethiopia)
PMI	President's Malaria Initiative
PMIS	pharmaceutical management information system
PMTCT	prevention of mother-to-child transmission
PNILP	national malaria control program (Burundi)
PNLP	national malaria control program (Guinea)
PNLS	national AIDS control program (DRC and Togo)
PNME	Program for Essential Medicines (Angola)
PPMRc	procurement planning and monitoring report for contraceptives
PPMRm	procurement planning and monitoring report for malaria
PSI	Population Services Inc.
PSM	procurement and supply management
PTCs	Pharmaceutical and Therapeutics Committees
PV	pharmacovigilance
RDT	rapid diagnostic test
SCMS	Supply Chain Management System (project)
SIAPS	Systems for Improved Access to Pharmaceutical Services
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems [Program]
STG	standard treatment guideline
SUGEMI	national pharmaceutical management system (Dominican Republic)
TB	tuberculosis
TIPC	Therapeutics Information and Pharmacovigilance Center (Namibia)
TOR	terms of reference
TOT	training of trainers
UCDC	Ukrainian Center for Disease Control
UNAM	University of Namibia
UNCoLSC	UN Commission on Life-Saving Commodities
UNICEF	United Nations Children's Fund
USAID	US Agency for International Development
WAHO	West Africa Health Organization
WHO	World Health Organization

XDR-TB	extensively drug-resistant tuberculosis

INTRODUCTION

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, awarded by USAID in September 2011, strengthens the management of essential medicines and health supplies so that more people can access the health care they need. Now in its fifth year, SIAPS works with local counterparts and partners in 19 countries, and 2 regional programs in, Latin America and West Africa. SIAPS takes a comprehensive approach to improving pharmaceutical systems: enhancing countries' capacity to procure and distribute high-quality medicines and health technologies, while working with local partners to develop strong systems for pharmaceutical financing, human resources, governance, information, service delivery, and pharmacovigilance. By promoting local ownership of wide-ranging initiatives, stronger, more sustainable health systems overall are fostered.

The program's five result areas are as follows:

- Intermediate Result 1: Pharmaceutical sector governance strengthened
- Intermediate Result 2: Capacity for pharmaceutical supply management and services increased and enhanced
- Intermediate Result 3: Information for decision-making challenge in the pharmaceutical sector addressed
- Intermediate Result 4: Financing strategies and mechanisms strengthened to improve access to medicines
- Intermediate Result 5: Pharmaceutical services improved to achieve desired health outcomes

This report presents highlights of SIAPS's activities organized both by intermediate result area, representing multiple countries where we work, as well as by our global, regional, and country portfolios for the January through March 2016 period.

SELECT PROGRESS TOWARD RESULT AREAS

IR 1. Pharmaceutical Sector Governance Strengthened

The SIAPS approach to improving governance focuses on assisting countries in establishing policies and legislation that are supported by rule of law; organizational structures that can exercise appropriate decision making, authority, and oversight; transparent, ethical, and accountable systems and processes that are based on best practice norms and guidelines; and human resource management systems that promote effective performance and ethical practices. One of SIAPS' primary strategies for improving governance in the pharmaceutical sector is to strengthen regulatory systems that ensure the safety, quality, and efficacy of medicines by regulating pharmaceutical products, establishments, professionals, and practices. SIAPS provides support to national medicines regulatory authorities to build their technical capacity; adopt standards that are harmonized with relevant international and regional regulatory standards; reform processes to make them more efficient and transparent; and upgrade information management systems for improved transparency, oversight, and accountability to enable timely access to medicines and other health supplies.

Policy, Legislation, and Contractual Agreements

In **Ukraine**, the MOH approved two regulations developed with assistance from SIAPS that provide for the establishment of a National Essential Medicines List (NEML) Committee and regulate the NEML's development and adoption process. The approval of these two regulations marks an important milestone in SIAPS technical assistance to the Government of Ukraine in establishing a NEML that will be used nationwide as the sole list for public procurement and potentially for reimbursement. SIAPS also helped to draft a ministerial order and procedures, which provide for the convening and functioning of the committee that will select members of the NEML expert committee, an important step in fostering good governance in the selection process that is expected to begin in the next quarter.

SIAPS is collaborating with international and local partners to assist the national medicines regulatory authority (DNPL) in **Guinea** in revising the national pharmaceutical legislation. In this reporting period, SIAPS helped the DNPL convene meetings of the national committee mandated to draft the pharmacy bill and with other stakeholders to review recommendations of USAID Promoting Quality of Medicines Project and incorporate accepted revisions into the draft legislation.

In **South Africa**, SIAPS worked with the National Department of Health's (NDOH) Directorate: Affordable Medicines to develop a policy for issuing authorizations to nurses to examine a patient, make a diagnosis, and prescribe medicines. The policy has been approved by the National Health Council and a circular distributed to clarify that prescriptions written by nurses can be dispensed by pharmacy personnel. This brings the number of national pharmaceutical policies that have been developed in South Africa with assistance from SIAPS to four. SIAPS also helped the directorate draft policies for 1) procuring medicines not registered in South Africa (e.g., for compassionate use); 2) fast-tracking applications for

registration of medicines not included in the NEML that are deemed essential to address an unmet health need; and 3) allocating medicines into therapeutic classes.

SIAPS provided support to **South Sudan's** National Malaria Control Program (NMCP) to develop the first draft of the national malaria policy. The policy, once finalized, will provide strategic direction for the NMCP and enable its staff to better coordinate and accelerate scale-up of program interventions.

A contract between the **Dominican Republic** National Health Service and PROMESE/CAL, the government logistics agency, was approved this quarter. The contract, developed with assistance from SIAPS, requires the agency to report monthly on differences between medicine products and quantities requisitioned by health facilities and those dispatched, thereby strengthening monitoring and oversight of PROMESE/CAL.

Standards, Guidelines, and Procedures

In this reporting period, SIAPS assisted several countries in developing, revising, and implementing a variety of lists, guidelines, and standard operating procedures (SOPs) that provide the foundation for good governance and better practices in pharmaceutical systems.

- In **Mali**, SIAPS helped the Directorate of Pharmacy and Medicines (PPM) convene a consensus workshop to develop a product catalog, an activity identified as a priority under PPM's new five-year strategic plan. The catalog, once finalized, will be available in hard copy and electronically and will provide PPM's clients with comprehensive information to facilitate procurement of commodities.
- SIAPS supported the update of the medicines and medical supplies catalogs in the **Dominican Republic,** which will provide the foundation for the national quantification exercise scheduled for June 2016.
- In January 2016, the MOH in **South Sudan** approved the malaria case management guidelines and training materials developed by the NMCP with assistance from SIAPS.
- SIAPS helped the National TB Program in the **Philippines** revise the guidelines for laboratory supply management, identified as a key action in the program's 2013-2016 laboratory network strategic plan.
- Also in the **Philippines**, job aids that outline procedures for managing expired, damaged, and near-expiring antituberculosis medicines and supplies were drafted with assistance from SIAPS. The job aids, which will supplement the existing department of health policy on health care waste management, are intended to help mitigate product wastage at all health-system levels, and ensure that expired and damaged products are taken out of circulation.
- As part of efforts to bolster **Angola's** central medical stores (CECOMA) institutional capacity, SIAPS is providing technical assistance to develop internal regulations for acquisition of medicines and medical devices in line with best procurement practices and Angola's public procurement regulations and procedures. The regulations and bidding documents were submitted to CECOMA's senior management for approval in this reporting period.

Transparency and Accountability

SIAPS is using anticorruption funding to help civil society organizations (CSOs) use price referencing and monitoring mechanisms to increase transparency in medicines pricing in **Ukraine**. A web-based price monitoring tool, developed with support from SIAPS, has now been transferred to the end-user, the All Ukrainian Network of People Living with HIV (the Network), and is fully functional. SIAPS has trained the Network staff, including tool administrators, reporters, and analysts, and the tool will be used to generate key price monitoring indicators in the next quarter.

Seven out of nine regions in **Ethiopia** have enacted regulations to support implementation of the Auditable Pharmaceuticals Transactions and Services (APTS) initiative, which SIAPS has helped introduce, to achieve greater transparency and accountability in the management of pharmaceuticals and related finances and services. In this reporting period, SIAPS helped the regional health bureaus in two regions—Oromia and Addis Adaba—organize workshops to increase awareness of recently enacted APTS regulations. The workshops were attended by 183 participants in Oromia and 262 in Addis Adaba, focused on sensitizing participants on the contents of the APTS regulation and expectations of regional government and creating consensus to facilitate APTS implementation at health facilities in the regions.

In **South Africa**, SIAPS has been assisting the NDOH to improve the management of contracts for pharmaceuticals and medical-related products. In this quarter, SIAPS worked with the Directorate: Affordable Medicines to determine criteria that will be used to objectively evaluate bidders and bids and is now developing software, adapting SOPs, and mentoring contracting unit staff to support implementation of the new criteria.

As part of efforts to clarify roles and responsibilities and enhance accountability of personnel, SIAPS helped **Guinea's** central medical stores develop a new organogram and job descriptions for staff working in its distribution unit.

Coordination, Partnership, and Advocacy

SIAPS assisted the MOH in convening a two-day national medicines coordination workshop in the **Democratic Republic of Congo (DRC)** that brought together DRC's technical and financial partners to determine their anticipated contributions toward the country's annual medicines plan for 2016. The product of the workshop was a nationwide mapping of planned medicines distribution that will enable better management of medicines allocation across the country.

In the **Philippines**, SIAPS is assisting the Quezon City Health Department to scale up the Barangay Health Management Council (BHMC) initiative in all six city districts. In this reporting period, SIAPS conducted a workshop for 22 staff from the 6 district health offices tasked with leading and managing the scale-up of the BHMC initiative. The initiative brings together community-based groups, officials, and health providers to improve TB program management and service delivery in urban-poor settlements (barangays). Workshop participants received information about the BHMC initiative and, with assistance from SIAPS, developed district-level scale-up plans.

In **Guinea**, the national malaria program's procurement and supply management thematic group (a coordination mechanism that SIAPS helped establish and continues to support) developed indicators for monitoring stocks of malaria products. A recommendation from this group led to the formation of a national supply chain thematic group, which will coordinate efforts of all supply chain technical assistance partners working in Guinea. The group, which is chaired by UNICEF with SIAPS as vice-chair, held its first meeting this quarter to discuss the implications of proposed changes to the institutional status of Guinea's central medical stores.

Partner coordination remains a critical component of **South Sudan's** effort to address gaps in the essential medicines stock management. SIAPS serves as the secretariat of the Pharmaceutical Technical Working Group (PTWG), which was established to provide technical support to the MOH and partners in information sharing and improving pharmaceutical services. In this role, SIAPS coordinated and facilitated four PTWG and emergency medicines fund meetings during this reporting period.

Strategic Planning

SIAPS has been providing technical assistance to **the Philippines** National TB Reference Laboratory to strengthen its capacity to lead, manage, and govern the laboratory network. In this quarter, SIAPS helped assess the performance of the laboratory network to identify strengths and areas for improvement. The assessment findings will be used to update the 2013-2016 laboratory network strategic plan.

The monitoring and evaluation framework developed with assistance from SIAPS to support implementation of **Swaziland's** pharmaceutical strategic plan was presented to the MOH for approval in this quarter. The next steps are to develop indicators and institutionalize monitoring and reporting at each level of the health care system.

SIAPS continued to work with **South Africa's** NDOH and USAID's Supply Chain Management System (SCMS) to develop a national strategy for improved access to and availability of health products. In this quarter, SIAPS helped develop and present a framework for national information systems and information management at a partners meeting.

Regulatory Systems Strengthening

SIAPS continued its long-term technical assistance to the **Namibia** Medicines Regulatory Council (NMRC) to strengthen medicines registration by providing support to the dossier review sessions conducted this quarter. Analysis of the medicine registration data generated by the electronic medicine registration tool Pharmadex showed that the average number of days taken to evaluate and approve a medicine registration application has reduced from 34 days in 2013 to 25.7 days in 2015. This improvement can be attributed to an increase in human resources at NMRC, the bimonthly dossier evaluation team's review sessions (now fully funded by NMRC), and continued SIAPS technical assistance in medicines regulation. In addition, 78.4% of the items listed in the official Namibia EML (Nemlist) used by the Government of Namibia for procuring medicines in the public sector now has at least one registered product, up from 61.0% at baseline.

SIAPS also continued its support to strengthen the medicine registration process in **DRC** by helping the DPM hold its quarterly registration session, during which 251 dossiers were analyzed out of the 263 dossiers received. Of those analyzed, 69 (27.4%) products were registered, 176 (70.1%) did not have sufficient information to complete registration, and 6 (2.4%) were rejected. This brings the total number of medicines that have been registered in DRC to 4,419, up from 400 in 2011. Evidence that the register of authorized medicines is being appropriately maintained and enforced is the de-registration of 1,392 products due to expiry of their marketing authorizations without renewal, bringing the total number of currently registered products in the country to 3,027.

Implementation of Pharmadex in **Bangladesh** is approaching its final phase of deployment in the Directorate General of Drug Administration (DGDA). A user acceptance testing was conducted at a workshop this quarter, the objective of which was to demonstrate Pharmadex's functions and provide an opportunity for hands-on practice for participants. As a next step, SIAPS and DGDA will jointly develop an action plan for the key activities that still need to be completed for full deployment of Pharmadex as the official online registration system for DGDA. To advance the DGDA's adoption of harmonized international technical documents for medicine registration, a four-day training was held to build the knowledge and capacity of DGDA officers (district- and Dhaka-based) and pharmaceutical industry applicants on the Common Technical Document (CTD) format. In an effort to sustain the implementation of the CTD and create a capacity development program, SIAPS and the DGDA designated 15 representatives from the DGDA and pharmaceutical companies as the master trainers for CTD and conducted the first orientation meeting for the team. In recognition that the success of both Pharmadex and CTD in Bangladesh depends on support and uptake by the national pharmaceutical industry, the DGDA and SIAPS brought together the company heads of the top 40 pharmaceutical companies for a dialogue on the new registration system and procedures. SIAPS' presentations on the new system helped build the confidence of the participants, who now better understand the benefits for them and have expressed their commitment to using it.

Support to the Food, Medicines, and Health Care Administration and Control Authority (FMHACA) of **Ethiopia** for the implementation of an electronic medicine registration system continued this quarter with the final drafting and review of three SOPs. In addition, 42 industry applicants were trained on the purchase order and pre-import permit tracks of the new system. In **Mozambique**, SIAPS helped establish Pharmadex in 2015 by providing adequate infrastructure, adapting the tool to local regulations and procedures, and training staff; however, use of the system has been lower than expected. In response, SIAPS and the Pharmacy Department held a workshop to ascertain the current situation of Pharmadex, identify barriers and root causes of low usage, and define interventions to remove the barriers. At the end of the workshop, participants drafted and adopted a Pharmadex mission statement, reached consensus on the problems and root causes to be addressed, and identified next steps to resolve the issues.

In countries where medicine registration systems have not existed previously and thus are in the early stages of development, SIAPS has been supporting the MOHs to develop plans and strategies for introducing medicine registration and taking preliminary steps to account for the medicines in circulation in their countries. This quarter, SIAPS discussed a plan to strengthen the registration system in **Angola** with the director of the National Directorate of Medicine

and Equipment (DNME) and helped arrange a one-week study visit for DNME staff with the Mozambican national medicine regulatory authority to share experiences and lessons learned. Preparations were also made for a SIAPS short-term technical assistance visit to support DNME in the development and implementation of a data collection tool to identify all medicines imported in the last three years as a starting point for establishing the national medicine registration process. In **Swaziland**, SIAPS continued to provide technical assistance to the medicines regulatory authority to update the medicines listing database and the registration status for all medicines used in the public sector in an effort to assist the MOH in regulating medicines imported into Swaziland.

SIAPS continued its support for the development and implementation of pre-service curricula for regulatory sciences/regulatory affairs in both Namibia and Ethiopia this quarter. SIAPS supported the University of **Namibia** (UNAM) School of Pharmacy in obtaining stakeholder input on draft materials for the pre-service training in medicines regulation, which SIAPS developed for inclusion in the UNAM bachelor of pharmacy curriculum. The pre-service training in medicines regulation will ensure that pharmacists graduating from UNAM are equipped with the essential knowledge and skills to assure the quality, safety, and efficacy of medicines, including antiretroviral and related medicines. In **Ethiopia**, SIAPS conducted a situation analysis to prepare the relevant institutions for the implementation of the new post-graduate regulatory sciences program, for which the curriculum was recently finalized. SIAPS worked with the School of Pharmacy of Addis Ababa University, FMHACA, and all stakeholders to identify capacity gaps and capacity-building needs among the intended instructors to ensure their readiness to deliver the course and to agree on the activities, deliverables, and timelines for preparing them.

IR 2. Capacity for Pharmaceutical Supply Management and Services Increased and Enhanced

Lack of qualified pharmaceutical professionals, institutions for pharmaceutical training, and updated curricula are challenges faced by resource-constrained countries. SIAPS collaborates with stakeholders to assess their capacity to manage pharmaceuticals at all levels, identifies areas for improvement, and develops interventions to strengthen the system and build capacity. To date, SIAPS has trained over 41,000 professionals from 22 countries in several areas of pharmaceutical management (31 % female and 62% male).

Pre-service training

During the last quarter, SIAPS **Dominican Republic** finalized the educational modules for the certified course (diploma) on rational use of medicines. During this quarter, 30 students started the course. Additionally, SIAPS continued supporting on-site trainings for the implementation of the Integrated Management System for Pharmaceuticals and Medical Supplies (SUGEMI) procedures in eight major hospitals. For the next quarter, SIAPS will scale the implementation of SUGEMI to the rest of the hospital network through a training of trainers (TOTs) course and cascade trainings, scheduled to start May 2016.

SIAPS provided technical assistance to the University of Namibia's (UNAM) School of Pharmacy (SoP) to develop course materials for a pre-service training in medicines regulation. The pre-service training is part of the curriculum for the UNAM bachelor of pharmacy and will ensure that pharmacists graduating from UNAM are equipped with the fundamental knowledge and skills to improve the quality, safety, and efficacy of medicines. SIAPS support to the UNAM-SoP focused on obtaining stakeholders' input on draft materials for the pre-service training. The 17 stakeholders participating in the drafting of the material included the Pharmaceutical Society of Namibia, the National Medicines Regulatory Center, the Health Professions Council of Namibia, pharmaceutical manufacturers, importers, and distributors of medicines in Namibia. Moreover, during this quarter, Namibia reported the development of a second pre-service health curriculum for the National Health Training Center pharmacy assistants' course, reaching the country's life-of-project target of two pre-service training curricula.

SIAPS **South Africa** provided continued support to the University of the Western Cape (UWC) School of Public Health in reviewing progress of the medicine supply management (MSM) online module, reviewing lessons learned from the rational medicine use online course, preparing for the 2016 Winter School, and planning the marketing strategy for online modules. SIAPS aims to support UWC in finalizing all 14 sessions of the MSM course by reviewing and providing comments on the 12 modules that will be developed by the university. Sessions of the MSM are expected to be finalized by PY5Q3.

To monitor and promote rational medicines use, SIAPS **Swaziland**, in collaboration with the Nelson Mandela Metropolitan University's Medicine Utilization Research in Africa initiative, supported Swaziland Christian University to host a workshop on medicines use research. This workshop was aimed at developing the skills of pharmacy and therapeutic committee representatives, National Essential Medicines Committee members, pharmacists in the public and private sectors, and pharmacy students on methods to conduct medicines research to contribute to the country's health research agenda; 30 health care workers participated in the training.

In-service training

Through the end of March 2016, SIAPS worked on the development of in-service training programs to improve capacity for pharmaceutical supply chain management and services. To date, 10 countries have developed or revised 35 in-service health professional training curricula with SIAPS assistance (Bangladesh [6], Cameroon [5], Dominican Republic [1], Ethiopia [3], Guinea [8], Namibia [5], South Africa [3], South Sudan [2], Swaziland [1], and Tajikistan [1]).

SIAPS **Angola** continued its mentoring program in eight of the nine health facilities (except at Hospital Pediatrico de Luanda) that were selected to receive direct support from PEPFAR. The aim of the mentoring program is to address identified issues in the pharmaceutical management of HIV and AIDS commodities. The team continued to implement stock cards in the health facilities' warehouse and the weekly ARV consumptions forms in the dispensing area. This has resulted in more transparent and reliable stock data used for improving health facilities' monthly

logistics reports and requisitions to get new stock from the Provincial Health Division of Luanda (DPS) or the National HIV and AIDS Control Institute (INLS).

Furthermore, a five-day training on HIV and AIDS and the pharmaceutical management of HIV commodities was conducted with 37 participants from the INLS, CECOMA, DPS Luanda, and SIAPS Angola. By the end of the training, participants had expanded their knowledge on the biological cycle of HIV, its pathogenesis, and antiretroviral treatment. Participants were also able to describe the pharmaceutical management cycle of HIV and AIDS products, master the use of product management tools, and learn about the importance of pharmacovigilance in HIV patient management, good dispensing practices, and the necessary skills to improve pharmaceutical management practices in their specific work environments.

SIAPS **Burundi** collaborated with SCMS to assist the DPML in finalizing training materials for the LMIS manual and tools approved in February 2015. The work led to the development of two guides, one for trainers and the other for participants. SIAPS and SCMS assisted the DPML in training 19 trainers at the central level, 26 trainers at the district level, and 114 health providers at the health facility level. LMIS training will cover approximately 425 persons including trainers for both SCMS and SIAPS from four health provinces. More than 35% of target participants have been trained.

In **Ethiopia**, eight training events were organized for: the APTS (3), the SOP for Pharmacy ART Information Management Manual (4), and EDT (1). These events were attended by 300 professionals (81 females and 219 males). Additionally, as part of building regional capacity to support implementation of APTS, two TOTs were organized in the Amhara and Oromia regions; 113 pharmacy and 53 finance professionals participated in the trainings.

SIAPS **Mali** supported the DRS (Direction Régionale de la santé) of Kayes to conduct training of supervisors and LMIS SOP users. During previous years, SIAPS supported DPM (Direction de la Pharmacie et du Médicament) and DRS to train 24 trainers on the newly developed LMIS SOPs and to subsequently roll out the process. During this quarter, SIAPS supported the district of Kita to finalize the last training of CSCom (Centre de Santé Communautaire) depot managers on storage; use of tools including stocks cards and logistic reporting tools; requisition forms; and how to calculate commodity needs as indicated in the new LMIS SOPs. SIAPS also supported Kayes Regional Directorate of Health to provide trainings for supervisors on supportive supervision. As result of these trainings, 23 supervisors (3 females and 20 males) were trained on supportive supervision and 29 users (6 females and 23 males) were trained on LMIS SOPs.

SIAPS **South Africa** has made headway in transitioning the Pharmaceutical Leadership Development Program (PLDP) activities. In particular, PLDP support to the Sefako Makgatho Health Sciences University has been handed over to the course conveners; the challenge model and some of the tools from LDP were integrated into the management of pharmaceutical services module of the masters' program; 14 students from the public and the private sectors were enrolled in the program. Students identified a challenge in their workplace, addressed the problem using the LDP approach, and presented their performance improvement plans and results during a final presentation designed to assess how students have used the LDP approach. Many indicated positive change in their workplace and practical skills developed. SIAPS

exceeded the targets of persons trained in pharmaceutical management (1,206 persons trained of the targeted 1,104) and new health care workers graduating from a program that includes pre-service training (499 graduates of the targeted 340).

Moreover, SIAPS South Africa continued to work with the Pharmaceutical Services Directorate in the Free State (FS) to implement the Pharmaceutical Leadership & Governance Initiative (PLGI) which is addressing challenges in MSM identified by the auditor general; 33 participants are in the final stages of completing the PLGI. SIAPS provided coaching by visiting teams, facilitated a coaching workshop to determine how teams are progressing toward achieving their measurable results, and provided guidance as needed.

To improve the storage of medicines in the country, SIAPS **South Sudan** provided on-the-job training to four health workers (one female and three males) on proper recording of data on stock cards. SIAPS conducted store rearrangement and stock-taking in four health facilities in Western Equatoria State (WES): Bazunguwa Primary Health Care Center and Yabwa, Saura, and Baguga Primary Health Care Units. Only albendazole and vitamin A were in stock. In the on-the-job training, SIAPS addressed issues in data recording and worked with the facilities to rearrange the stores.

Supportive supervision and mentoring

SIAPS **DRC** supported the supervision of 37 health workers (12 females and 25 males) in Kasaï Oriental health zones; 15 sites, 12 health facilities, and 3 Health Zone Central Office warehouses were visited. The supervision focused on malaria case management and antimalarial medicines management.

In **Ethiopia**, onsite technical support and mentoring was provided to 19 health facilities in Amhara; Benshangul gumuz; Southern Nations, Nationalities and Peoples (SNNP); and Oromia regional states to improve the identification and management of treatment errors, adherence counseling, and pharmaceutical care to ART and hospitalized patients. The results from nine hospitals in Amhara and Benshangul gumuz regions showed that these hospitals were able to serve 1,530 patients, where patient medication profile forms were documented for about 78% of them. Additionally, 387 drug therapy problems were identified and interventions were made for 81% (313) of the problems; out of the total interventions made, 89% (277) were fully accepted.

SIAPS **Mali** supported 50 districts to conduct coaching and mentoring to assist health information and district warehouse managers to enter LMIS reports into OSPSANTE. As a result, the percentage of trainees who successfully implemented their post-training action plans increased from 46% to 52% and the percentage of facilities that submitted a LMIS report for the previous month increased from 87% to 96%.

SIAPS Mali also supported the DRS in conducting joint supportive supervisions and coaching visits in five regional depots, four regional hospitals, 42 district depots, and 1,069 health-facility sales points in Kayes, Koulikoro, Sikasso, Segou, and Mopti. Approximately 93% of depot managers are now using consumption data to inform product ordering, and 1,091 facilities are now using a country-appropriate logistic tool for commodities management.

SIAPS **Mozambique** conducted two supervision visits to Lichinga Provincial Hospital DTC and Pemba Hospital DTC. The purpose of the visits was to strengthen the capacity of the Hospital Pharmacy Department (HPD) and to improve the functions of hospital DTCs at the central and provincial levels. During the visits, SIAPS assisted HPD to support the two hospital DTCs in improving studies on medicine use and apply study results at the facility level. During the visits, hospital pharmacists were trained in aggregate consumption, prescription indicator, and medicine error studies. SIAPS also provided training to hospital pharmacists on how to collect, analyze, and report results. At Lichinga, the team attended a DTC meeting where the results of the studies on medicine use were shared. SIAPS facilitated the discussion among DTC members, who prioritized one problem, conducted a root cause analysis, and designed interventions and follow-up activities.

SIAPS **Namibia**, in collaboration with SCMS, supported the MOHSS to assess and improve the performance of health facilities through supportive supervision visits for mentoring pharmacy staff on inventory management of ARVs and pharmaceutical service delivery. The scored checklists that SIAPS supported to update in FY16 were used to assess storage of medicines and clinical supplies, human resources, status of implementation of previous visit recommendations, inventory quantification, control and management, pharmaceutical management information system, functionality of therapeutics committees, ART services, therapeutic information and pharmacovigilance activities, and quality of dispensing practices. Relevant sections of the checklists have been used by the regional and district pharmacists to supervise their frontline health facilities during regular site visits thereby maintaining year-round mentoring and continuous improvement at the facility level.

To improve the capacity of health workers in case and logistics management of pharmaceuticals, SIAPS **South Sudan** conducted supportive supervision and mentoring in all six counties (Juba, Kajokeji, Lainya, Morobo, Terekeka and Yei) of the Central Equatoria State (CES). SIAPS also provided mentoring and malaria case management training to 37 health care workers (6 females and 31 males) in 13 health facilities from all 10 counties in WES.

Institutional Capacity Building

SIAPS **Bangladesh** trained 498 (65 females and 433 males) Directorate of General Drug Administration (DGHS) logistics officials from 10 districts on the standard inventory tools (stock register, issue voucher, indent and issue voucher, bin card, etc.). The key objective of the training was to provide information on general logistics issues and the newly developed inventory tools for timely reporting.

SIAPS **DRC** and the National Program for Medicines Procurement held a joint training for the management teams of 11 health zones in the province of Kolwezi. The training aimed to build the technical capacities of senior staff from the Provincial Health Division, Regional Medicine Depot, and Health Zone Management Team to manage medicines; 40 stakeholders (8 females and 32 males) participated in the training. Afterward, a post-training action plan was developed by participants and was validated by the Provincial Health Division.

The SIAPS **South Sudan** team conducted a final review of the malaria case management and training (MCM&T) guideline. The reviewed guideline will be used to improve the capacity of health workers to provide quality pharmaceutical products and services. The guideline was submitted to the director general for Preventive Health Services and the Office of the Undersecretary for Health for approval, which was granted on January 28, 2016. SIAPS will print and distribute 150 copies of the approved MCM&T guideline for training in-service health workers in CES and WES.

Ukraine is planning to conduct a national supply chain assessment (NSCA) to systematically review all existing gaps in the supply chain and prioritize them according to impact they might have if/when addressed. One of the four steps for the NSCA is to train data collectors to ensure that they are familiar with the capability maturity model questionnaire and can effectively collect data. During this quarter, SIAPS Ukraine conducted a five-day training for data collectors, which included piloting the data collection tool in six facilities in Odesa city and nearby districts.

SIAPS facilitated a capacity-building workshop on quantification coupled with long-term forecasting of ARVs in **Togo**. A total of 19 members of the National Quantification Committee (4 females and 15 males) came from various health programs including HIV and AIDS (PNLS), malaria (PNLP), TB (PNLT), Central Medical Stores (CAMEG), Pharmacy Ad Medicines Department (DPLET), and HIV and antiretroviral treatment sites (CHU Tokoin, CHR Tsevie, CSL). The quantification training included forecasting and supply planning, quantification methods, data collection and validation, among others. Participants were also trained on the use of Quantimed and Pipeline to perform forecasting and supply planning of health products.

Tools for capacity building

A selected team of 13 staff from INLS, CECOMA, USAID **Angola,** and SIAPS participated in a 9-day intensive training on quantification, data collection and validation, and the application of electronic tools for the quantification of health products, with specific attention given to HIV, AIDS, and malaria commodities. Participants were able to apply electronic forecasting tools (Quantimed and USAID | DELIVER PipeLine) to supply planning and stock-level monitoring. SIAPS **Bangladesh** has been working on strengthening TB patients' management and control through e-TB Manager (e-TBM) and the TB Logistics Management Information System. In January and February 2016, three batches of training were conducted on e-TBM for 86 persons from Rajshahi and Sylhet City Corporation TB staff. SIAPS visited 11 upazila health complexes in 4 districts and 2 chest disease hospitals at two drug-resistant TB sites to monitor the performance of the electronic recording and reporting system and the feasibility of the sites to run the online system.

In preparation for the EUV, SIAPS **Burundi** trained 23 staff from key institutions in EUV methodology and tools in a four-day seminar to ensure quality data collection and entry. The EUV survey is used to determine the availability of key malaria products at the health-facility level and draft corrective measures/recommendations to improve availability and uninterrupted supply of malaria commodities. The training participants served as data collectors and data entry clerks for the survey. The training seminar included a session on gender analysis to increase

participants' sensitivity on gender issues in regard to demand, access to, and use of malaria pharmaceuticals and services.

To ensure proactive supportive supervision by district health management teams to health facilities, **SIAPS/Sierra Leone** developed and introduced A Continuous Results Monitoring System (CRMS) which uses a checklist to monitor stock availability, stock-out, expiry, use of information system tools, status of storage conditions, and availability and capacity building of staff managing pharmaceuticals. The checklist, which tracks tracer and key medicines, including ARV, TB, malaria, and reproductive products, is used to monitor performance and results on a bimonthly basis. The reports from these continuous exercises are discussed by key stakeholders in a review meeting to provide feedback and address identified challenges in real-time. In Sierra Leone, a preliminary plan of action to use the CRMS checklist as a process of supportive supervision was developed in collaboration with the Directorate of Drugs and Medical Supplies and the Bombali district medical officer. Pharmacists in the Bombali district are expected to begin using the tool in April 2016.

IR 3. Utilization of information for decision making increased

SIAPS's approach to management information systems is to harmonize and integrate the collection and presentation of accurate, quality pharmaceutical and other commodities data in a timely and consistent manner. This data is intended to assist decision makers and health workers at all levels of a country's health system make evidence-based decisions, to manage health and laboratory commodities and pharmaceutical services, and to measure, monitor, and evaluate progress. SIAPS's approach includes careful assessment of interventions related to information systems to determine the feasibility and long-term effect of their implementation; striving to find the best solution to address health-related data collection, processing, reporting, and decision-making challenges; and supporting country ownership and sustainability. SIAPS' pharmaceutical management information tools, such as RxSolution, Pharmadex, e-TB Manager, QuanTB, OSP-SANTE, OSPSIDA, electronic dispensing tool (EDT), the PV Data Collection and Analysis Tool (DCAT), and the recently launched Pharmacovigilance Monitoring System (PViMS), support both product and patient information. The demand for these tools in SIAPS and non-SIAPS countries keeps growing, and SIAPS is working with various partners to expand the use of these tools.

Data Utilization

In **Angola,** the End User Verification (EUV) report conducted in November and December 2015 was submitted to PMI, providing a snapshot of the availability and use of antimalarial products at the health facility level. The EUV data analysis identified challenges such as poor management of malaria health commodities and a need for scaling up supportive supervision visits to reinforce the mandatory use of the pharmaceutical management tools. One quarterly Procurement Plan and Monitoring Report was submitted January 2016 after collecting stock information data from national and provincial level. This stock analysis allowed the National Malaria Control Program to review its distribution plan for rapid diagnostic tests and to balance availability of these commodities across the provinces.

In February 2016, SIAPS/**Mali** representatives for Kayes, Koulikoro, Sikasso, Segou, Mopti, and Bamako regions supported the organization of quarterly coordination meetings to discuss commodities procurement and distribution issues, as well as LMIS data recorded into OSPSANTE. During those meetings attendees discussed, analyzed, and validated logistic data.

SIAPS continued to provide routine technical support focused on the pharmaceutical management tools currently used in **Namibia**, including **EDT**, **RxSolution**, **e-TB Manager**, and the national database servers, to ensure optimal availability of data and improve pharmaceutical service delivery.

Based on outputs obtained from QuanTB, the National TB Program (NTP) in **The Philippines** was able to undertake critical actions during this quarter to mitigate stock-outs of capreomycin, levofloxacin, and isoniazid in the programmatic management of drug-resistant tuberculosis facilities. Actions included: (1) coordinating with Philippine Business for Social Progress (PBSP) for expediting delivery of levofloxacin and placing emergency orders of capreomycin, and (2) redistribution of isoniazid to stocked-out facilities. It was found that the stock-outs were caused by implementing the nine-month MDR-TB treatment regimen study, which increased consumption of these pharmaceuticals.

In **South Sudan**, SIAPS supported the Ministry of Health by providing stock status information on ART-related commodities and tracer medicines. SIAPS helped collect, review, analyze, and validate consumption data and indicators of 10 counties in Central Equatoria, Western Equatoria, and Unity States. Stock-outs of tracer medicines were found in 40% of the warehouses and 57% percent of health facilities. Due to increased insecurity, 15 county warehouses did not send in their consumption reports.

Data Quality

In **Cameroon**, the presence of four regional technical advisors and the support of central level staff have helped continuously enhance storage conditions and practices, as evidenced by the improvement of inventory accuracy at health facility level. The new Prevention of Mother to Child Transmission sites added in PY5 have each received four supervision visits (two per quarter).

Mali has also shown improvement in data quality as it relates to inventory accuracy. Since PY4 Q2 and with the support of SIAPS, the country has maintained a steady ascendant trend in stock record accuracy, and in PY5 Q2, 84% of records corresponded with physical counts, surpassing the target (81%) for the first time since its baseline date, June 2013.

Figure 1 shows improvements in data quality for both Cameroon and Mali.

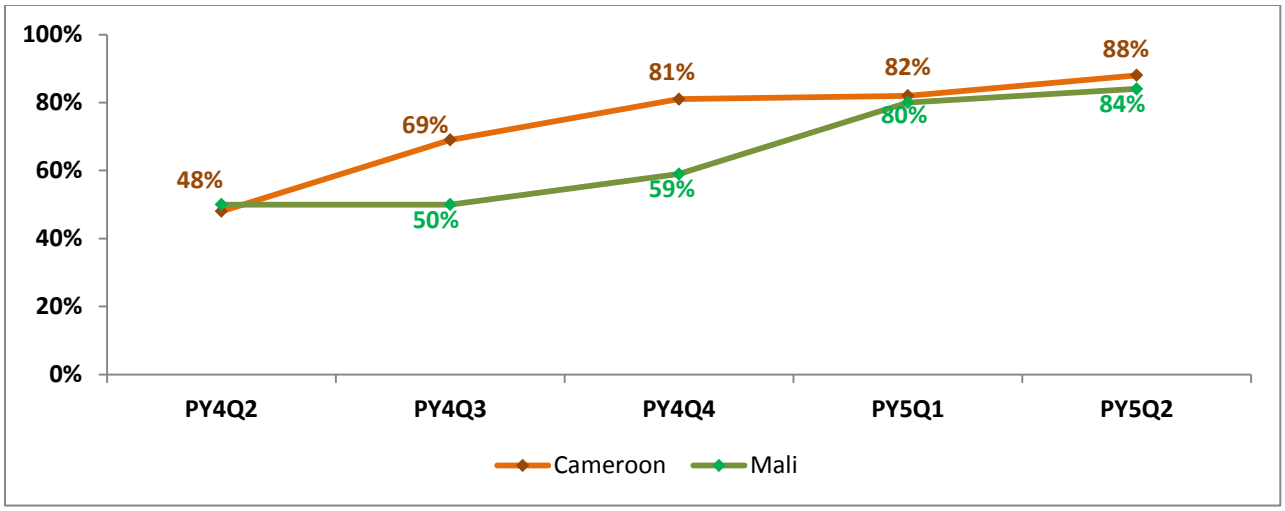

Figure 1: Data quality in Cameroon and Mali

Bangladesh's Supply Chain Management Portal data shows that 83% (N = 488) of total sites are maintaining a high data quality standard, as understood by measuring the timeliness, completeness, and accuracy of reports.

Information System Design and Collaboration

As part of its work to strengthen the Logistics Management Information System in **DRC**, SIAPS piloted the pharmaceutical management component of DHIS 2.0 in South Kivu and Mwene Ditu. Following the results of the pilot phase SIAPS continue working with the developers to optimize the module as inconsistencies were identified on the pharmaceutical management component during the field test. SIAPS will continue to optimize the DHIS 2.0 module during the next quarter.

In **Bangladesh,** SIAPS conducted a system study and finalized the customization/configuration of an off-the-shelf health information system (HIS) that would potentially improve the real-time patient-reported data for augmenting clinical decision making. It is expected that the HIS will be deployed for user acceptance testing at the end of April. SIAPS has also supported the configuration of the DGFP warehouse improvement management system (WIMS) to fit into TB central warehouse and deployed the system for beta testing. The users have come up with feedback, input, and recommendations for further improvements. Implementation of the final version of the desktop-based WIMS has been planned for April 2016.

To help **Mali's** Pharmacie Populaire du Mali (PPM) to have comprehensive information on commodities to procure, it was agreed that a product catalog will be developed. During this quarter, SIAPS provided technical support to PPM to start the process of developing a product catalog which will be available on hard and electronic copies for PPM's clients. SIAPS also provided options on product code nomenclatures to be selected, and included as part of the catalog. Prior to selection of the code nomenclature, a revision of the current PPM product lists was conducted during a workshop held on March 16 and 17, 2016, in consultation with relevant

stakeholders. The preliminary results from this workshop show that PPM achieved a 28% reduction of products from the list by eliminating duplicate products, unused presentations, etc.

As a core member of the HIS Technical Working Group (TWG) in **Namibia**, SIAPS supported the development and deployment of the updated data analysis tool on e-TB manager; SIAPS also presented ongoing work on the Pharmaceutical Information System Dashboard and electronic stock card, which are expected to be launched in April 2016. SIAPS continued providing training to staff at Okuryangava and Khomasdal clinics on the short message service-based adherence reminder service. The service allows automated short messages to be sent to ART patients reminding them about their pharmacy appointments.

In **South Africa**, SIAPS continued to provide technical assistance in the development and implementation of the Master Procurement Catalogue, the Essential Medicine List Tool (EMLT), the Tender Management Module, and customization of RxSolution reports. The EMLT will promote transparency and provide a repository for master data. SIAPS also supported the development of an interface between RxSolution and the Health Patient Record System, a national registry for patient data which will assist in tracking patient movement within the health care system.

IR 4: Financing Strategies and Mechanisms Strengthened to Improve Access to Medicines

The SIAPS approach to strengthening financing strategies and mechanisms for improved access to medicines encourages efficient use of existing financial resources, advocating for additional monetary resources, and reducing financial barriers that prohibit access to medicines. During this quarter, SIAPS supported countries by forecasting quantities of medicines needed in emergency requests, identifying budgetary gaps, and working as an advocate for health care financing reform. Additionally, SIAPS continued providing support to interventions that encourage transparent financial transactions at health facilities and, ultimately, highlight alternatives for resource allocation after expenditure analysis. SIAPS contributed to key discussions and workshops on health care financing and medicines benefits management within the context of universal health coverage.

Mobilizing Additional Financial Resources

Continuing its partnership with **Angola**'s quantification technical working group (TWG) on HIV/AIDS commodities, SIAPS contributed to on-going efforts in the forecasting and supply planning for HIV/AIDS commodities to be procured for the period from January 2016 to December 2018. The Instituto Nacional de Luta Contra a Sida (National Institute to fight AIDS, INLS) used the results of the quantification exercise to determine the quantity of commodities needed during the two-year period in emergency orders from the World Bank and the Global Fund. The Global Fund will also use the quantification report to inform procurements in an upcoming grant, which will begin being implemented in July 2016 through the UNDP (the Principal Recipient).

In **Namibia**, SIAPS advocated for funding from the Global Fund in its reprogramming initiative to be set aside for the review of the Namibia Standard Treatment Guidelines. Additionally, SIAPS emphasized the need for funds to be allocated to the Therapeutics Information and Pharmacovigilance Centre (TIPC) and the meetings of the District Hospital Therapeutics Committee.

In collaboration with USAID **Swaziland**'s Commodity Procurement Team, SIAPS forecasted the quantities needed of buffer stock of HIV Rapid Test Kits and pediatric ARVs. The gap analysis conducted by SIAPS was used to submit an emergency request to USAID to procure HIV Rapid Test Kits for the Swaziland Health Laboratory Services (SHLS). The procurement, valued at approximately US $1.8 million, will provide a stock supply of 10 months for HIV Rapid Test Kits.

SIAPS **Ukraine** continued providing technical assistance to the MOH on health care financing reform and medicines procurement reform. The concept note on health care financing reform was submitted this quarter and is being circulated for public discussion. In April, a concept note on the reform of medicines procurement in the Ukraine will be finalized and submitted for comment to the MOH.

Analyzing and Tracking Costs

In the **Dominican Republic**, SIAPS analyzed the MOH's financial gap related to the procurement of medicines and supplies and presented the results to key stakeholders in PY4 Q4. Although the activity demonstrated the need for greater budgetary allocations to be made in the national budget for the procurement of pharmaceutical products and supplies, the Ministry of Finance did not allocate the financial resources as initially requested in the MOH's 2016 procurement plan. This quarter, SIAPS focused on revising the procurement plan and analyzing how budgetary restrictions will affect the procurement of ARVs going forward. The recommendations from the analysis were presented to the MOH as a policy brief.

This quarter, Auditable Pharmacy Transaction Services (APTS), SIAPS Program's intervention for improved financial accountability of medicines expenditure and availability in **Ethiopia**, was introduced at Sawala Hospital in the Southern Nations, Nationalities, and People's Region (SNNP). Sixteen staff members at Sawala Hospital participated in on-site training and mentoring on the operationalization of APTS. Training was also provided beyond Sawala Hospital to a mix of pharmacists and accounts at ALERT Hospital and St. Peter Hospital. These professionals reviewed the process for recording pharmaceutical transactions and services through APTS and generating daily and monthly reports to be used in hospital decision-making. Additionally, SIAPS assisted St. Paul, Yekatit 12 and Menilik 11 Hospitals and three health centers in preparing financially to renovate their pharmacy departments for APTS implementation. Four hospitals in the Amhara and SNNP regions conducted ABC/VEN analyses with SIAPS Program's support, enabling current medicines consumption levels to influence financial planning for future procurements. Illustrating the utility of the APTS intervention, a key success was reported this quarter at Enat Hospital, where expenditure on x-rays was substantially reduced after a digital x-ray machine was purchased by the region eliminating the need for costly

x-ray supplies. Moreover, Enat and Felege Hiwot Hospitals initiated a stock transfer to nearby health facilities to avoid product expiry after reviewing APTS' Stock Status Analysis report.

In **Ghana**, SIAPS supported the National Health Insurance Authority (NHIA) in initiating a two-year retrospective medicines utilization review using data from the NHIA e-claims system. The results of the study will inform reforms in strategic purchasing of medicines under the countries national health insurance scheme. USAID, WHO and the NHIA organized the *Financial Protection and Improved to Access to Health Care: Peer-to-Peer Learning w*orkshop to identify and discuss solutions to common health systems challenges. SIAPS presented and led a panel discussion on importance of pharmaceutical in financial protection programs. The SIAPS presentation and the panel discussions highlighted key considerations for designing pharmaceutical benefits in health systems working towards improving access to health care though financial protection programs.

IR5a: Availability of pharmaceuticals improved

SIAPS has continued to ensure the availability of medicines and improved supply chain systems by using a holistic pharmaceutical system strengthening approach. The interventions related to supply management include human resource capacity building, streamlining logistics systems, timely redistribution and ordering plans, improving warehouse processes, and standardizing logistics management tools.

The SIAPS Program in **Angola** supported the national quantification technical working group in a forecasting and supply planning exercise covering a two-year period from January 2016 to December 2018. The results from this exercise so far have been used to conduct emergency orders with World Bank and Global Fund support, which mitigated stock-outs. SIAPS worked with the government and various implementing partners to mitigate stock-outs by redistributing supplies from health facilities that would have faced expirations due to overstock to facilities that were at risk of stock-out. SIAPS also supported the distribution of 54,000 male condoms and 12,000 female condoms. The team also worked closely with the provincial warehouse in Luanda to prepare their quarterly requisitions, ensuring that the estimates were accurate and based on reliable data from health facilities in their catchment area. The National Malaria Control Program (NMCP) has worked directly and actively with 18 malaria provincial supervisors, with SIAPS support, to provide supervision and logistics data analysis. SIAPS facilitated the data collection tool development and process, and eight data collection teams visited 90 health facilities in two PMI- supported provinces. This past quarter, SIAPS has also been the lead supporter and facilitator for DNME to set up bimonthly meetings of the Logistics, Operations, and Procurement Sub-Committee. At this forum, stakeholders discuss and identify bottlenecks that affect the supply chain for health commodities and services. Given these activities, Angola, and specifically within the malaria program, has seen a significant decrease in stock-outs at the warehouse level, from 79% last quarter to only 39% stock-out rate this quarter.

In **Ethiopia**, 97% of Drug Therapeutic Committees (DTCs) participated in quantification of annual medicines needs for their health facilities. This ensures collaboration across the health system allowing use of the most up-to-date and accurate information to conduct these

quantification exercises. Furthermore, implementation of the Auditable Pharmaceutical Transactions and Services (APTS) Program has taken place in 72.2% of surveyed health facilities. APTS has been crucial for tracking stock status and allowing for the smooth operation of supply chain functions. Data revealed that only 15.9% of health facilities were stocked out of artemisinin-based combination therapies (ACTs) in the last three months, surpassing the end-of-project target of 17%. Only 13.6% of warehouses were stocked out of antimalarials for more than three days in the last three months—also better than the end-of-project target of 16%.

SIAPS **Mali** supported the family planning and malaria technical working group (TWG) with a two-day workshop on updating their national supply plans. As a result, 17 supply plans were finalized, which is one less than the end-of-project target. The TWG reviewed and validated stock status reports on the pipeline of health commodities, which were the basis of decisions made on avoiding stock-outs and overstock, as well as granting the opportunity to address supply chain bottlenecks at the regional level. SIAPS also conducted a situational analysis of Mali's central medical store (Pharmacie Populaire du Mali, PPM), developing a five-year strategic plan and a product catalog. These interventions will assure procurement of medicines and other commodities on the basis of accurate information. Furthermore, SIAPS is working directly at the Regional Health Directorate-level to conduct supportive supervision and coaching visits in five regional depots, four regional hospitals, 42 district depots, and 1,060 health facilities this quarter. The focus of these visits was new stock management standard operating procedures and training on the new Logistics Management Information System. SIAPS also worked with the NMCP and PPM to finalize three malaria commodities distribution plans. Given these milestones, activities, and interventions, Mali has seen a drastic increase in the percentage of health facilities using a standardized checklist to monitor storage conditions, from 52% to 96% this quarter, meeting the end-of-project target of 79%.

SIAPS **Swaziland** is supporting the country's HIV efforts to meet the goal of 90% of all people living with HIV knowing their HIV status, 90% of all people with diagnosed HIV infection receiving sustained ART, and 90% of all people receiving ART having viral suppression by 2017. These objectives will not be achievable without the consistent availability of essential HIV products. SIAPS worked with the MOH to maintain the required stock levels of ARV medicines this quarter. However, the pediatric lopinavir and ritonavir formulation was stocked out at the Central Medical Store for two weeks due to the financial crisis Swaziland has been facing (fluctuations in foreign currency). Given that Swaziland's suppliers are all in Asian and European markets, the currency volatility has presented challenges in regard to suppliers honoring the prices in the contracts signed in June 2015. However, SIAPS has worked with MOH to revise the forecast and made price adjustments for this financial year. SIAPS also worked on a gap analysis of HIV rapid test kits, leading to an emergency order for procuring $1.8 million worth of commodities to avoid a stock-out at laboratories and fulfilling the next 10 months of stock requirements. The MOH has also requested SIAPS support with the rollout of the new web-based commodity tracking system at four health facilities. These facilities have showed that using the system has contributed to improvements in reporting rates and data quality on ARVs and laboratory commodities. The Swaziland team has also conducted training on inventory management tools for 18 participants in two facilities, as well as supportive supervision visits for 24 health care workers. Overall, SIAPS's work in Swaziland has

contributed to the maintenance of 0% stock-out of commodities at warehouse and facility levels this quarter, despite the challenges faced.

IR5b. Pharmaceutical Services Improved to Achieve Desired Outcomes

SIAPS improves pharmaceutical services by using a holistic approach that ensures that patients receive medicines 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. During this quarter, SIAPS provided support to countries through various technical areas and strategies including pharmacovigilance (PV), rational medicine use (RMU), pharmaceutical care, essential medicines lists (EMLs), formularies, standard treatment guidelines (STGs), drug information and patient education, antimicrobial resistance (AMR), drug and therapeutics committees (DTCs), medicine use reviews, and treatment adherence.

Pharmacovigilance

SIAPS **Democratic Republic of the Congo** (DRC) has supported the National TB Control Program (NTP) since May 2014 in implementing an active surveillance PV program for all patients on second-line TB medicines in 14 health facilities in Kinshasa and has trained health workers on adverse drug events (ADEs) reporting in five USAID-supported provinces. During this quarter, SIAPS DRC also provided technical and financial assistance to the NTP to collect ADE data from cases undergoing treatment for multidrug-resistant tuberculosis (MDR-TB) and TB/HIV co-infection from those health facilities in Kinshasa and the USAID-supported provinces.

In **Ethiopia**, various PV tools and documents were distributed to health facilities; these included 280 ADE reporting forms, 295 allergy cards, and 210 newsletters. To create awareness on PV among health providers, face-to-face discussions were carried out at nine health facilities (seven in Addis Ababa and two in Oromia region). A total of 215 health providers participated in the discussions. During the quarter, 20 ADEs were reported to the national PV center from five hospitals in Amhara. As a result of analyzing the ADE reports received by the PV center, regulatory measures were taken on chloroquine and paracetamol syrup, iodine tincture, and hydrogen peroxide-containing products. The manufacturers were instructed to stop production, investigate the causes, and address quality issues.

In the **Philippines**, the National Center for Pulmonary Research (NCPR) submitted their October- December 2015 quarterly report to NTP in January 2016 for the nine-month MDR-TB treatment regimen study, which captured 293 adverse events, including six serious ones. Of the 293 adverse events, the more frequent ones were gastrointestinal effects (44%), ototoxicity/ vestibular toxicity (16%), musculoskeletal effects (10%), and neurotoxicity (7%). In addition, NTP and SIAPS are continuously advocating to the Programmatic Management of Drug-Resistant Tuberculosis (PMDT) treatment facilities that they comply with the existing SOPs for active surveillance PV to ensure completeness, accuracy, and timeliness of adverse events reports. SIAPS will also assist the Philippines FDA PV Unit on the review of adverse and serious adverse event reports, causality analysis, and decision making. As of February 2016, eight

treatment facilities have enrolled patients in the nine-month MDR-TB treatment regimen study. NTP and NCPR facilitated a meeting to discuss the issues and concerns related to the study implementation. The main challenges encountered were lack of completeness in reporting and recording adverse and serious adverse events; errors and inconsistencies in the current study database, and inadequate capacity of treatment facility staff to implement the study.

During the quarter, SIAPS **South Africa** continued working with the National Pharmacovigilance Centre (NPC) to improve mother and child health. SIAPS provided technical assistance to the NPC to develop the first issue of the NPC *Sub-Dermal Contraceptive Implant (SDCI) Bulletin* which provides health care professionals with a summary of relevant local data and trends on the use of and adverse reactions to SDCI in South Africa. Future bulletins will be issued quarterly. SIAPS also assisted in improving efficiencies and data quality for the national sentinel surveillance system for major external birth defects among live and still births delivered in high-volume maternity units. In addition, SIAPS supported the NPC with the review and analysis of adverse drug reaction (ADR) reports related to TB medicines. The ADR database has 5,063 reports; 511 of them are TB cases. The majority of cases were drug-sensitive (DS) TB (480) and 31 were for MDR/XDR-TB. Co-morbidities were only documented in 80 of the DS-TB cases, with 45 patients having hypertension, 28 diabetes, and 7 Kaposi's sarcoma.

SIAPS Swaziland continues to support MOH in ensuring patient safety and therapeutic effectiveness. During this quarter, 150 ADEs were analyzed for a cumulative total of 450 cases. SIAPS also supported development of the February 2016 issue of the *Medicines Safety Watch* newsletter. Job aids on improving spontaneous ADE reporting were designed and printed for distribution. The next steps are to monitor the impact of these job aids on facility practices relating to patient safety monitoring and ADE reporting. SIAPS also supported the printing of additional passive surveillance reporting forms and is in the process of transitioning this printing to the MOH. SIAPS also supported the National TB Control Programme in the implementation of bedaquiline for the management of XDR-TB patients. The support included development of bedaquiline and delamanid clinical guidelines and testing the redesigned web-based PV information management system in preparation for piloting.

Rational Medicine Use

In the **Dominican Republic**, 30 students enrolled in the certified course (diploma) on RMU on January 30, 2016. SIAPS facilitated the first module in February 2016. The course will be completed in June 2016.

During this reporting quarter in **Ethiopia**, 246 medication errors were identified and prevented at antiretroviral therapy (ART) pharmacies in health facilities in Amhara, Southern Nations Nationalities and Peoples Region (SNNPR), Dire Dawa, and Harari regions.

SIAPS **South Sudan** provided technical assistance in the final review of the malaria case management and training guidelines, which were approved by MOH on January 28, 2016. SIAPS printed and distributed 150 copies of the approved guidelines for trainings in Central and Western Equatoria.

Pharmaceutical Care

In **Ethiopia**, SIAPS provided onsite technical support and mentoring in 19 health facilities in Amhara, Benshangul gumuz, SNNPR, and Oromia regional states to improve the identification and management of treatment errors, adherence counseling, and pharmaceutical care for ART and hospitalized patients. The results from nine hospitals in Amhara and Benshangul gumuz regions showed that these hospitals were able to serve 1,530 patients; of these, 1,185 (77.5%) patients' medication profile forms were documented. A total of 156 ward rounds and 113 morning meetings with multi-disciplinary teams and six pharmacy-only morning meetings were conducted; 387 drug therapy problems were identified, and interventions were proposed for 313 (80.9%) of the problems, of which 277 (88.5%) were fully accepted by the prescribers.

In addition, SIAPS provided technical support to Dessie and Debre Berhan Referral Hospitals to expand their clinical pharmacy services to maternity wards. As a result, the hospitals assigned dedicated, full-time clinical pharmacists to gynecology/obstetrics wards. In addition, many hospitals in East Amhara region are providing clinical pharmacy services in pediatric wards. During this quarter, the Debremarkos Referral Hospital in Amhara region started clinical pharmacy services in the maternity ward. Within a month after launching the services, 347 mothers obtained pharmaceutical care. Through this service, 68 drug-therapy problems were identified; pharmacists proposed interventions, of which 48 were fully accepted by the prescribers.

During the quarter, SIAPS Ethiopia assessed 33 health facilities on major indicators to monitor progress toward achieving life-of-project (LOP) targets. Most (97%) of these health facilities started providing clinical pharmacy services, and 28 (84.8%) are reported to have clinical pharmacy-trained personnel. Of the 28 facilities with clinical pharmacy-trained personnel, 27 (96.4%) had developed action plans after training, of which 88% claimed that they are implementing post-training action plans, which is higher than the LOP target of 79%. In addition, 97% of the surveyed facilities keep complete information on ART patients; 78.8% of the facilities received feedback on the reports or data they supplied (LOP target 96%). All the surveyed facilities monitor adherence of ART clients to their treatment, and 75.8% of the facilities identified and managed treatment errors.

EMLs, Formularies, and STGs

In the last quarter, SIAPS **DRC** received the first consignment of printed STGs with support from headquarters in Arlington, VA. During this quarter, the dissemination and training plan was developed for implementation in hospitals with DTCs in five USAID-supported provinces. These STGs will help health workers and facilities improve case management.

SIAPS **Namibia** provided technical assistance to the MOHSS for the review of motivations for 97 requests for medicines inclusion in the NemList. A total of 69 medicines were recommended for inclusion in the sixth edition of the NemList during the EML committee meeting held on March 16-17, 2016; 11 formulations for ARVs were recommended for addition to the NemList.

SIAPS **Philippines** continued to provide technical support to NTP in the introduction of new pediatric formulations (the dispersible tablets of the fixed-dose combination [FDC] of rifampicin 75 mg + isoniazid 50 mg + pyrazinamide 150 mg; FDC of rifampicin 75 mg + isoniazid 50 mg; and ethambutol 100 mg). The new pediatric formulations are now included in the Philippine National Formulary and the national essential medicines list, with the collaborative efforts of NTP, Pharmaceutical Division, SIAPS, World Health Organization, and the Global Drug Facility.

SIAPS **South Africa** has been helping the Essential Drug Program (EDP) Unit develop academic detailing slides for the *Adult Hospital Level STGs and EML*, which highlight changes and summarize evidence for decision making. During the quarter, such slides were completed for four of the ten chapters received. SIAPS also provided technical assistance to complete clinical editing of 23 chapters and provided inputs to drafting the introduction and foreword for the *Adult Hospital Level STGs and EML*. SIAPS also provided assistance in completing phase 1 activities of an analysis of all past tertiary EML documents. In January 2016, SIAPS South Africa helped evaluate the novel oral anticoagulants used in the treatment and prophylaxis of venous thrombotic embolism and post-hip and knee surgery. Health economics models and budget impact analyses for these were compiled using detailed costing templates. Reports were prepared and presented to the Adult Level EML Committee for discussion at the January meeting. SIAPS also helped the EDP Unit with the development of an abstract on strengthening implementation of STGs to improve RMU for presentation at the Health System Trust (HST) conference which will be held in Johannesburg in May 2016. The abstract has been accepted for a poster presentation.

Drug Information and Patient Education

SIAPS **Burundi** assisted the newly created communication unit within the National Malaria Control Program (PNILP) in validating a malaria prevention behavior change communication guide. The guide explains appropriate communication methods and key messages on malaria prevention. SIAPS helped PNILP train 30 central-level trainers, 20% of whom were women. SIAPS also supported the PNILP central trainers to train another 340 trainers (26% of whom were women) on malaria prevention communication guidelines, including methods and messages. The trainers will assist in training CHWs on raising awareness, sensitization techniques, and malaria prevention communications. CHWs will in turn sensitize populations in their catchment areas to change attitudes and adopt positive behaviors to prevent malaria.

SIAPS **Ethiopia** continued to provide support to health facilities to strengthen medicine use education. In this quarter, 12 health facilities in Tigray, Addis Ababa, and Oromia regions conducted 146 sessions on medicine use education for 10,287 people, of whom 56% were female. In assessing LOP targets in 33 health facilities, it was found that drug information services were available in all of the surveyed hospitals and all the DISs have basic resources including reference materials and computers. Regarding patients' knowledge of medicine use, the majority (91.4%) claimed that they know the frequency of taking their dispensed medicines (91.4%) and the doses (75.5%). Knowledge about duration and how to store medicines at home was found to be moderate at 75.4% and 67.8%, respectively. The majority (83.3%) of patients

that were interviewed expressed their satisfaction with the information they received from dispensers.

Antimicrobial Resistance and Infection Prevention and Control

When LOP targets were assessed, SIAPS **Ethiopia** found that only 57.6% of the facilities had implemented AMR advocacy or containment-related activities; 58% of the sampled prescriptions contained antibiotics, whereas the LOP target is 30%.

SIAPS **South Africa** supported nine provinces in developing AMR provincial implementation plans in a workshop attended by 18 provincial AMR champions. They developed action plans and will share them with provincial heads of departments and heads of pharmaceutical services. National Department of Health (NDOH) will monitor the provinces' implementation progress. SIAPS also worked with the Gauteng Provincial Pharmaceutical and Therapeutics Committee (GPPTC) to analyze the data collected from nine hospitals, six community health centers, and 15 primary health care clinics during World Antibiotic Awareness Week. A total of 962 outpatient and 569 inpatient prescriptions were captured. The preliminary findings were presented and discussed during the GPPTC meeting held in March. The results provide a baseline for antibiotic prescribing practices in the province. The GPPTC will implement interventions to enhance rational use of antibiotics.

Drug and Therapeutics Committees

During the previous quarter, SIAPS **DRC** supported the Health Provincial Division (DPS) to begin conducting medicine use studies in several provinces to draw comparisons between hospitals with a DTC and those without. The study was conducted in four USAID-supported provinces (Sud Kivu, Kasai Oriental, Kasai Occidental, and Province Orientale) at ten hospitals (five with DTCs and five without). During this quarter, the study was completed and the technical report is under development. The study revealed the following findings:

- Health care providers (prescribers) had better prescribing behaviors/habits in hospitals with DTCs than in hospitals without DTCs:
  - On average, only two medicines were prescribed per patient encounter in hospitals with DTCs, whereas up to four medicines were prescribed in hospitals without DTCs; this confirms the extent to which polypharmacy practice characterizes prescribing behaviors in hospitals without a DTC.
  - The percentages of medicines prescribed using generic names were 70% and 58% in hospitals with and without DTCs, respectively.
  - The percentage of outpatient prescriptions with at least one antibiotic was higher (59%) in hospitals without DTCs than in those with DTCs (47%).
  - The percentage of prescriptions with at least one injectable was also higher (35%) in hospitals without DTCs than in those with DTCs (12%).
- Patients had better knowledge of their medication in hospitals with DTCs than in those without DTCs. In hospitals with DTCs, 58% of patients who underwent an exit interview knew all the aspects of their medication (name, dose, frequency, treatment duration, and route of administration) whereas only 23% did in hospitals without DTCs.

- Adherence to treatment guidelines was better in hospitals with DTCs compared to hospitals without DTCs: 60% of malaria cases were treated as per the recommended malaria treatment guidelines in hospital with DTCs, whereas only 40% were in hospitals without DTCs.

In **Ethiopia**, the LOP target assessment revealed that practicing pharmacy personnel in the surveyed health facilities claimed that they attended at least one in-service training related to pharmaceutical services. DTCs were available at all the surveyed health facilities. DTCs at all hospitals have a plan of action; 82% of the DTCs conduct meetings on a regular basis, and 97% of DTCs have approved terms of references; 97% of the surveyed health facilities have produced and printed facility-specific drug lists.

SIAPS **Mozambique** continued to strengthen the capacity of the Hospital Pharmacy Department (HPD) to improve the functions of hospital DTCs at the central and provincial levels. During this reporting quarter, SIAPS and HPD conducted supervisory visits to Lichinga Hospital DTC and Pemba Hospital DTC. During the visit, SIAPS provided training to the hospital pharmacists on conducting medicine use studies relating to medication errors, prescription indicators, and aggregate consumption. The trainees were able to perform data collection and analysis and report the results. The Lichinga Hospital DTC members were able to perform root cause analysis, through which they found that clinicians did not adhere to the new procedures to review patients' medication. The DTC planned to train the clinicians on the new procedures and monitor their compliance. The Pemba Hospital DTC members were not available for post-study discussions and proposed to do that later. SIAPS will provide remote support to Pemba Hospital DTC for post-study interventions.

SIAPS **South Africa** conducted 41 ABC analyses during this quarter in 38 health facilities in Gauteng province (GP) and one at the GP provincial level, one at the KZN provincial level, and one national consolidated analysis. Although the target was only three, the number of analyses accomplished was much higher because of high demand from GP and implementation of an ABC project to support facilities within the province.

Medicine (Drug) Use Review/Medicine Use Evaluation

In **Ethiopia**, the LOP target assessment revealed that 72.7% (24/33) of health facilities carried out drug use studies; 78.8% (13/24) conducted ABC/VEN analyses and had some interventions on prescribing, dispensing, and use.

Responding to the request of the EDP Unit, SIAPS **South Africa** developed a concept note for the development of criteria for a medicine utilization evaluation (MUE) using a mobile application. SIAPS also provided support for the development of a prevalence model and budget impact analysis model to assess the potential impact of using fosfomycin in different indications for urinary tract infections (UTIs), including penicillin allergy in pregnant women, first-trimester UTIs, and UTIs in pregnant and non-pregnant women. SIAPS also provided technical assistance to the Western Cape Department of Health in the analysis of an aspirin MUE and supported the development of a presentation of the results for the South African Association of Hospital and Institutional Pharmacists conference. In addition, SIAPS received

permission from the North West Department of Health Research Committee to conduct a study on using electronic pharmacy dispensing data to examine outpatient antibiotic consumption and monitor antibiotic prescribing practices at district and provincial hospitals in the public sector in the province. Database extraction and cleaning have commenced. All processes will be documented for inclusion in the final research report.

In an effort to monitor and promote RMU, SIAPS **Swaziland** collaborated with Swaziland Christian University to host a workshop on the methods used to conduct medicines use research, with support from the Nelson Mandela Metropolitan University's Medicine Utilization Research in Africa initiative. This workshop was aimed at pharmacy and therapeutic committee representatives, National Essential Medicines Committee members, pharmacists in the public and private sectors, and pharmacy students. The workshop is expected to contribute to Swaziland's health research agenda. A total of 30 health care workers participated in the training.

During this reporting quarter, SIAPS **Ukraine** finalized the technical reports on drug utilization review for HIV and TB sectors and prepared the presentation of the reports for a stakeholders meeting in early April. This meeting will be attended by core national-level bodies (MOH, State Expert Center, UCDC), as well as international entities (WHO, USAID) and participants in drug utilization reviews from regions (AIDS centers and TB dispensaries).

Treatment Adherence

In **Namibia**, SIAPS used supportive supervision visits to support the MOHSS in mentoring staff on effective ART service provision and closing the gap of patients lost to follow-up as captured in the EDT. The visits were conducted in February 2016 in six PEPFAR priority regions (Oshana, Kavango East and West, Zambezi, Oshikoto, and Ohangwena regions). All 50 sites providing ART services to approximately 140,000 patients were visited. During the visits, SIAPS compared the data from the EDT and electronic patient management system platforms to identify data gaps. In facilities with more than 5% data variations, SIAPS facilitated stakeholder meetings to identify solutions for tracing patients and updating both records. SIAPS also provided detailed guidance on transitioning patients on second-line lopinavir/ritonavir-based regimens to atazanavir/ritonavir-based regimens. Additionally, SIAPS provided training to two ART sites (Okuryangava and Khomasdal) implementing short-message system (SMS) reminders aimed at enhancing ART patients' adherence to treatment and minimizing loss to follow-up. The training included implementation of SMS reminder activities and the importance of recruiting patients, as well as counselling them before recruitment; ten staff members, including doctors, pharmacists, nurses, and community counsellors, were trained.

Portfolios and SIAPS IRs in the Year 5, Quarter 2 Report

COUNTRY/PORTFOLIO	IR1	IR2	IR3	IR4	IR5
Africa					
Angola	•	•	•	•	
Burundi	•	•	•		
Cameroon	•		•	•	
Democratic Republic of Congo	•	•	•	•	•
Ethiopia	•	•	•	•	
Guinea	•	•	•	•	
Mali	•	•	•		•
Mozambique	•	•			
Namibia	•	•	•	•	
Niger	•				
South Africa	•	•	•		•
South Sudan	•	•	•	•	
Swaziland	•	•	•	•	
West Africa Regional	•		•		
Asia and Middle East					
Bangladesh	•	•	•		
Philippines	•	•	•		
Europe and Eurasia					
Ukraine	•	•	•		
Uzbekistan			•		
Latin America and the Caribbean					
Amazon Malaria Initiative	•	•	•		
Dominican Republic	•	•	•	•	
Haiti	•				•
Core Portfolios					
Cross Bureau	•	•	•	•	•
Malaria Core	•	•			
MCH Core	•	•	•		
NTD Core	•	•	•		
TB Core	•	•	•		•
Total Portfolios	25	19	22	10	6

CROSS BUREAU

Objective 1: Pharmaceutical sector governance strengthened

SIAPS is participating in a working group to assist the WHO Good Governance for Medicines (GGM) Program to update and expand the scope of their assessment instrument for measuring transparency in the public pharmaceutical sector. At the end of this quarter, WHO invited selected experts, including SIAPS program staff members, to review the second draft of the revised tool, which has now been expanded to assess accountability in addition to transparency. SIAPS will submit detailed comments on all eight modules of the tool in the next quarter by April 11, 2016, as per the request of WHO.

Last quarter, SIAPS launched the eLearning course Good Governance in the Management of Medicines, developed by SIAPS with assistance from the Knowledge for Health (K4H) Project and launched on USAID's Global Health eLearning Center. Since the course was launched on December 2, 2015, 123 learners have completed it in 31 countries: Cambodia, Canada, China, Cote d'Ivoire, Ethiopia (3), Haiti (2) Kenya (5), Lesotho, Liberia, Mexico, Myanmar, Nepal, Nigeria (8), Pakistan (3), Philippines, Rwanda, Saudi Arabia (3), Singapore (6), Somalia, South Sudan (2), South Africa (2), Sudan (57), Switzerland, Tanzania (2), Tunisia, Ukraine, United States (8), Vanuatu, Wales, Zambia (2), and Zimbabwe (3). Information available denoted participation of 4 USAID staff, 1 USG, 19 international nongovernmental organization staff, 66 national government, 10 non-US university, and 7 others. The participants included 1 academic, 5 clinical, 9 programmatic, 4 students, 10 non-US university, and 24 others. In terms of gender, 31 (46%) females and 77 males completed the course. In addition, SIAPS is using Cross Bureau funding to develop two additional animations to replace the text versions currently included in the eLearning course. The contractor has developed draft animations based on the storyboards and style guides and is incorporating the audios developed in conjunction with SIAPS. The animations will be completed and incorporated into the course early next quarter.

Also in this reporting period, SIAPS began developing the first of the technical briefs that provide guidance and describe strategies for improving governance in pharmaceutical systems and provide case study examples to be used by countries. This first brief will focus on developing or updating terms of reference for any committee making decisions or providing oversight in the pharmaceutical sector.

Constraints to progress

SIAPS support to WHO GGM Program activities has been pending receipt of the draft assessment tool for review.

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

During this quarter, SIAPS finalized the terms of reference for completing the pooled procurement guidance document. The guide will build on the recent pooled procurement experience for the Ecumenical Pharmaceutical Network (EPN) Cameroon network of organizations. The outline for the guide was developed, and the draft was initiated. The document will provide faith-based organizations (FBOs) elsewhere with guidance on creating a pooled procurement system in their own settings, on the basis of the EPN Cameroon experience.

In support of African Medicines Regulatory Harmonization Initiative, SIAPS participated in a meeting that was held early March in Nairobi with the two regional centers of regulatory excellence (RCOREs) in pharmacovigilance (PV): the World Health Organization (WHO) Collaborating Centre for Advocacy and Training in Pharmacovigilance (CC) in Accra, Ghana, and the Pharmacy and Poisons Board (PPB) of Kenya. The attendees discussed the recommendations and next steps outlined at the PV RCORE meeting in Accra in May 2015 and explored options for moving forward with the recommendations. The linkages between the two PV RCOREs and the most efficient governance structure were all discussed in broad terms. A few significant activities that could be undertaken by the PV RCOREs were also discussed, including mapping the PV infrastructure in Africa and the creation of a database of Africa PV experts.

There was consensus that both PV RCOREs need clear governance structures as soon as possible, as this will permit them to function optimally and oversee implementation of the recommendations of the Accra meeting. The meeting participants therefore requested technical and financial support from SIAPS to hold another face-to-face meeting in May 2016 with the following objectives:

1) Define and agree on the governance structure of the PV RCOREs
2) Identify a few specific activities that can be undertaken immediately with clear deliverables

Partner contributions

This quarter, EPN followed up with suppliers to investigate pending orders and receipt recent orders. On March 13, 2016, EPN hosted a postmortem meeting/stakeholder evaluation in Limbe for the pooled procurement activity. At the meeting, achievements were compared to the objectives, lessons learned were discussed, and recommendations for the future were made.

Constraints to progress

The major problem that the EPN pooled procurement experienced was a delay in the fulfillment of the largest consignment scheduled to be delivered by a major supplier. The order was finally delivered on March 18, 2016. With this, the pooled procurement exercise has been completed.

Objective 3: Information for decision-making challenges addressed in the pharmaceutical sector

SIAPS revised the manuscript that reviews the literature on pharmaceutical system strengthening (PSS) and proposes definitions and components critical for tracking progress in system strengthening. These revisions were based on input from external reviewers, including experts from SIAPS' partners Harvard Pilgrim Health Care Institute and Boston University School of Public Health (BUSPH). The manuscript will be edited and submitted to a peer reviewed journal in the next quarter.

In this quarter, SIAPS worked with partner BUSPH to conduct a literature search to identify criteria for selecting indicators to measure PSS. Six criteria that have the most commonality and consensus in the literature were deemed the most relevant. These criteria were used to score indicators identified from assessment tools related to pharmaceutical systems to identify candidate indicators for measuring PSS. SIAPS is working with BUSPH experts to review the candidate indicators and select those for inclusion in a PSS measurement tool for piloting.

Partner contributions

BUSPH conducted a literature review of criteria for selecting PSS indicators and applied them to a database of pharmaceutical system-related indicators to identify candidates for inclusion in a tool for measuring PSS.

Objective 4: Strengthened financing strategies and approaches

In this quarter, feedback on the structure, flow, and completeness of the universal health coverage (UHC) policy paper was received from SIAPS technical leads. A technical writer and two final reviewers have been identified, and they will assist in finalizing the production of the paper in the coming quarter.

Finally, on the basis of new updates from USAID, SIAPS has notified the Global Health e-learning Center of its interest in developing an e-learning course on key design considerations for pharmaceuticals in UHC programs. The planned course will target USAID staff, donors, national policy makers, and program managers and will highlight key considerations in the design of medicine benefit packages and the role of different pharmaceutical functions within UHC programs. The course will describe policies, strategies, regulatory requirements, and approaches for developing an equitable and accountable financial protection program that enables sustainable access to essential pharmaceuticals.

Last quarter, SIAPS began reviewing the pharmaceutical expenditure tracking activity. The plan for this quarter was to share our findings with the Health Financing and Governance (HFG) Project, however, the meeting has been delayed. In the next quarter, SIAPS and HFG plan to jointly discuss the best options and required tools to pursue tracking pharmaceutical expenditures.

Partner contributions

HFG is a key partner in the activity for establishing an institutionalized mechanism for tracking pharmaceutical expenditures.

Constraints to progress

The workload of existing staff and delays in recruiting consultants to assist with production of the UHC paper caused delays this quarter. Additionally, there was a delay in scheduling the meeting with HFG as there were many conflicting demands on the time of SIAPS and HFG staff.

Objective 5: Quality of pharmaceutical products and services improved

The final draft of the options analysis guidance document, *Analyzing Options for Strengthening Pharmaceutical Systems,* was completed and technically reviewed. The draft is now going through the SIAPS editorial process and will be formatted for distribution in the next one or two quarters.

Following publication of the new AMR part 2 course on USAID's Global Health eLearning platform last quarter, SIAPS began working to update part 1 of the course this quarter. Sessions were updated with new information, statistics, and developments and new content and photos were added to complement and align with the information presented in part 2. SIAPS is coordinating with K4H during the revision process and in the creation of relevant infographics to enhance presentation of course material. The next step is to send the revised course to USAID for review and then finalize, publish, and disseminate it in collaboration with K4H.

In its continued efforts to strengthen regional-level capacity, SIAPS worked with EPN headquarters in Nairobi to finalize three results-oriented proposals from EPN member organizations on topics related to antimicrobial stewardship and AMR. The three proposals were submitted by Gertrude Children's Hospital in Kenya, Christian Health Association of Malawi, and the Zimbabwe Association of Church Related Hospitals; all three proposals have now been approved by USAID.

Based on the detailed outline developed during the previous quarter, SIAPS also developed the draft of an article entitled Building Country- and Regional-Level Advocacy and Coalitions to Combat Antimicrobial Resistance: Multi-Country Examples and Lessons Learned. The next step is to review, revise, and finalize the article before submitting to a peer-reviewed journal.

SIAPS has accepted EPN's invitation to participate in the Biannual EPN Forum 2016 being held May 19-21 in Tubingen, Germany. SIAPS has agreed to make a presentation on antimicrobial stewardship during the event, along with facilitation of a session on that topic. SIAPS is also working with EPN to update its existing call-to-action document on AMR and has already supported EPN in developing a revised draft. EPN's plan is to finalize the updated call-to-action document during the upcoming forum in Germany.

During the quarter, SIAPS started revising the guide on building local coalitions for containing drug resistance. A literature search was done to identify relevant resources, and an initial set of ideas for revision were generated.

As in previous quarters, the SIAPS headquarters team continued to provide guidance and oversight to field offices in implementing AMR-related activities. Lastly, in an effort to improve accessibility of information and results, the pharmaceutical services pages on the SIAPS website were updated, particularly focusing on creating a repository of key resources on AMR.

SIAPS is in the final stages of making revisions to the regulatory system assessment tool (RSAT) on the basis of an internal technical review as well as discussions with WHO last quarter. SIAPS remains on track to develop a more concise version of RSAT that complements existing tools, but is distinct in its orientation toward less developed, low-functioning regulatory systems; RSAT is also distinct in that it can be rapidly implemented with limited financial and human resources for baseline assessment and on-going monitoring. SIAPS will share the draft with technical partners at the beginning of the next quarter for comment and consult with the program team to explore different platforms to make the tool, including data collection and analysis, as user-friendly and practical as possible.

Partner contributions

EPN headquarters in Nairobi actively collaborated with SIAPS in supporting the member organizations to submit and revise proposals relating to AMR, infection control, and antimicrobial stewardship, thus strengthening its own and its member organizations' technical capacity.

Objective 6: Contribute to the generation of new knowledge and dissemination of evidence-based approaches and best practices

As stated in the PY5 Q1 report, SIAPS will continue to provide financial support to Human Info, an IT contractor, to continue maintenance and development of the WHO EMP Portal. In January, Human Info began working on a mobile version of the website, enabling access to the entire collection on mobile devices. They have also begun integrating improvements requested by users in the user survey conducted in August 2015. These include adding functionality to the user interface to enable import and export of batches of publications in CSV and XML and improving search functionality with pop-up suggestions of existing and new tags.

As of March 31, 2016, the collection of documents increased modestly from 5,207 to 5,293. Google Analytics provided by Human Info also showed that in January and February 2016, 79.9% of visitors to the EMP Portal were new, whereas 20.1% were returning visitors. Overall, 1.6 million users visited the site between October 2015 and February 2016, resulting in 3 million page views.

In this quarter, SIAPS finalized a draft scope of work (SOW) for a gap analysis of the WHO EMP Portal. The gap analysis aims to complement the results of the user survey conducted in

August 2015 in gathering feedback on usability and user experience. The objectives of the gap analysis are to (1) identify which pharmaceutical management technical themes are missing in the portal and determine which should be considered priority themes, based on the aforementioned user survey and (2) provide recommendations for alternative processes for screening and capturing national pharmaceutical sector resources. The draft SOW has been submitted to WHO for final review.

For the review of the Health Systems Assessment Approach (HSAA) Manual, during this quarter, SIAPS was busy working on revisions to module 6 in line with guidance agreed to at the December 2015 partners meeting. The conceptual framework for the revision remains the Pharmaceutical Management (PM) Framework, including medicines management considerations that connect PM to UHC goals. Another important proposed revision is to incorporate select, newly developed pharmaceutical system strengthening metrics, which allow assessment of management system structure, processes, and outcomes. SIAPS is also collaborating with PQM on the revision process, which is expected to be concluded by mid-April 2016.

Also this quarter, SIAPS staff conducted outreach to the BUSPH Pharmaceuticals Program in March. Students in this program are uniquely qualified for engaging in global pharmaceutical management upon graduation. At BUSPH's request, SIAPS staff made a presentation on campus on approaches to pharmaceutical systems strengthening, with an emphasis on SIAPS' approach and success thus far. Students and staff had positive reviews of the presentation and expressed interest in future collaboration.

Lastly, during this quarter, SIAPS participated in a three-day workshop in Dhaka entitled WHO Regulatory System Strengthening and Roadmap for Prequalification Workshop. The workshop was organized by the WHO HQ Regulatory Systems Strengthening team with the Directorate General of Drug Administration (DGDA), Bangladesh's national regulatory authority for health products. As part of the efforts to build the technical capacity of the DGDA through collaborative efforts, WHO proposed this meeting and invited all partners including USAID, SIAPS, USP/PQM, World Bank, Gates Foundation, Korea International Cooperation Agency, and Ministry of Food and Drug Safety (MFDS) of South Korea. The main outcome from this workshop for SIAPS was a commitment from the USAID Mission to develop a five-year strategic plan to strengthen the Bangladesh regulatory system through SIAPS.

Partner contributions

- WHO continues to contribute to improving and managing the EMP Portal.
- For the HSAA activity, HFG and PQM have supported progress and success.

Appended EAC Update

In line with SIAPS's agreed-upon work plan for the East African Community (EAC) PV system strengthening initiative, which is part of the EAC's medicines regulation harmonization program, SIAPS participated in a video conference to review and plan the way forward on the EAC harmonized PV assessment tool. In addition, SIAPS and their partner, the University of

Washington (UW), conducted a thorough technical review of the PV assessment tool and provided feedback.

Next quarter, SIAPS will assist the PV expert working group (EWG) and EAC to finalize the PV assessment tool, develop training materials, and undertake a training of trainers workshop for members of the EWG to equip them with the necessary skills to train their in-country teams and conduct the baseline PV assessments in all of the EAC partner states. The training will include sessions on data management and analysis.

Partner contributions

UW jointly conducted a technical review of the PV assessment tool with SIAPS this quarter.

GLOBAL PROGRAMS

Malaria

Goal: Improve access to and appropriate use of quality-assured malaria commodities to reduce the malaria burden

Under the first objective, SIAPS began documenting its contribution towards reducing malaria morbidity and mortality through systems-strengthening approaches in five countries.
Under the second objective, SIAPS facilitated PMI procurement decisions by reporting on stock status of malaria commodities (PPMRm) from Angola, Burundi, Ethiopia, Guinea, Kenya, Mali, South Sudan, and Uganda.

Objective 1. Strengthen pharmaceutical sector governance

To document SIAPS's contribution toward reducing malaria morbidity and mortality through systems-strengthening approaches and other interventions, key stakeholders including the Ministries of Health, health workers, community leaders, and nongovernmental organizations were interviewed. Information was collected in DRC, Ethiopia, Guinea, Kenya, and South Sudan. Whenever possible, interviews were videotaped for future reference and corresponding qualitative and quantitative data, reports, and other materials were collected to support evidence of SIAPS's achievements.

Objective 2. Increase utilization of pharmaceutical information for decision making

To facilitate procurement decisions at PMI, SIAPS aggregated data and reported on stock status of malaria commodities from Angola, Burundi, Ethiopia, Guinea, Kenya, Mali, South Sudan, and Uganda. During the quarter, End Use Verification surveys were conducted in Ethiopia and Burundi.

Objective 3. Strengthen pharmaceutical financing strategies and mechanisms to improve access to medicines and services

No activity during this quarter.

Neglected Tropical Diseases

Goal: Assure the availability of quality medicines and supplies and effective pharmaceutical services to increase efficiency of NTD control and elimination programs

Overall Quarter Progress

The SIAPS NTD portfolio hosted a supply chain management (SCM) workshop in Accra, Ghana, in late February, which was attended by participants from Ghana, Sierra Leone, and Nigeria. SIAPS completed the post-workshop report and submitted it to USAID.

The assessment of the Senegal NTD SCM is complete and translated and with RTI for final review before submission to the MOH.

Objective 1: Strengthen NTD global coordination and oversight mechanisms

This is an ongoing objective to build relationships. By attending working group meetings and scientific conferences, SIAPS will build relationships with MOHs and implementing organizations and increase awareness of the importance of proper supply chain management in the control and elimination of NTDs.

Objective 2: Support NTD capacity building initiatives

The SIAPS NTD portfolio hosted the SCM workshop in Ghana in February 2016, attended by 37 people from Ghana, Sierra Leone, and Nigeria. SIAPS completed the post-workshop report and submitted it to USAID and the participants with feedback from the workshop. SIAPS will follow up with the participants in mid-2016 to determine progress. SIAPS NTD is coordinating with RTI to host the next workshop in Nigeria in April 2016. Initial contacts have been made and the names of participants, dates for the workshop, and specific topics have been worked out.

The assessment of the Senegal NTD SCM is complete and translated. It is currently with RTI for final revisions for submission to the MOH

Partner contributions

SIAPS met with members of RTI and USAID to discuss the Nigeria workshop logistics and to decide the possible list of attendees who would get the most out of the workshop.

Objective 3: Support NTD medicine safety programs

During this quarter SIAPS NTD completed a first draft of the guidelines and SOPs and is revising within the SIAPS Program with review by other supply chain experts.

MNCH

Goal: Assure the availability of quality medicines and supplies and effective pharmaceutical services to reduce maternal, newborn and child mortality

Overall Quarterly Progress

SIAPS/MNCH continued to contribute significantly at the global and country levels to ensure the availability of quality medicines and supplies and effective pharmaceutical services to reduce maternal, newborn, and child mortality. A highlight of this quarter was SIAPS' participation in a meeting for countries scaling up iCCM under the Global Fund held February 16-18, 2016, in Nairobi, Kenya. The SIAPS principal technical advisor (PTA) for MNCH not only contributed to the preparation of the procurement supply management (PSM) session, but also presented and co-facilitated the session. Also, with significant input from SIAPS, the lessons learned document on zinc and ORS which was developed by the zinc/ORS subgroup of the Pneumonia and Diarrhea Working Group was disseminated. SIAPS also participated in the annual USAID Mini-University and presented on two topics: Building Systems for Access and Appropriate Use of iCCM Medicines and Increasing Access to Lifesaving Commodities for Women and Children: Getting the Numbers Right!

At the country level, SIAPS continued to support efforts to increase access to life-saving commodities and services for newborns and children. In Afghanistan, SIAPS coordinated with the Chlorhexidine Working Group (CWG), Ministry of Public Health (MOPH) Afghanistan, and SPS Afghanistan on the procurement of the first stock of chlorhexidine, which is scheduled to arrive in Afghanistan in April 2016. In DRC, two major deliverables were finalized: the report of the newborn antibiotic landscape analysis and the study to validate the amoxicillin dispersible tablets job aids and product presentations.

Objective 1. Global Awareness of the Importance of Pharmaceutical Management for MNCH Medicines and Supplies Increased

SIAPS/MNCH continued to be actively engaged in global partnerships, initiatives, and working groups to ensure that appropriate pharmaceutical management for medicines and supplies is included in the global MNCH agenda. This quarter, the SIAPS PTA for MNCH participated in the UN Commission's Technical Resource Teams conveners' meeting in New York, and facilitated a meeting of the Maternal Health Supplies Caucus (MHSC).

SIAPS also participated in the Operational Research Subgroup and Supply Chain Management Subgroup meetings of the CCM Taskforce held on February 1 and February 10, 2016, respectively.

Also this quarter, in mid-February, the SIAPS PTA for MNCH participated in a meeting in Nairobi, Kenya, for countries interested in scaling up iCCM under their Global Fund grants. SIAPS contributed to the organization of and co-facilitated the PSM session. During the meeting, countries identified weaknesses in PSM that needed strengthening and started discussions among their country teams and between countries on how to do that. At the end of the meeting, country

teams submitted technical assistance requests to the organizers. Also, SIAPS represented the Supply Chain Management Subgroup and participated in a one-day meeting of the Monitoring and Evaluation (M&E) Subgroup to discuss revision of the iCCM indicators, contributing particularly to the discussion on supply chain indicators. The final report of the Nairobi meeting included inputs from SIAPS.

This quarter, SIAPS also chaired the meeting of the SCM Subgroup of the CCM Taskforce on March 11, 2016. During the meeting, the next steps from the Nairobi meeting were discussed, as well as the next planned webinar, the annual plan, and a peer-reviewed journal supplement on commodities. Next quarter, the group will review the technical assistance requests made by countries during the Nairobi meeting and finalize the SCM mapping of the CCM Taskforce.

In March, SIAPS participated in the annual USAID Mini-University and presented on two topics: Building Systems for Access and Appropriate Use of iCCM Medicines and Increasing Access to Lifesaving Commodities for Women and Children: Getting the Numbers Right!

Last quarter, SIAPS received useful feedback from WHO and members of the health systems and policy working group from Countdown on the preliminary draft of the review of current pharmaceutical management policies and systems that affect access to essential MNCH medicines and supplies. After incorporating the feedback, the draft of the next version of the Countdown paper on commodities was finalized and circulated to the co-authors for review. Next quarter, SIAPS will attend the final technical meeting of Countdown to 2015 in New York and present the paper on commodities.

Objective 2. Guidance and Tools for Improving Pharmaceutical Management for MNCH Developed and Disseminated

Last quarter, SIAPS finalized and began dissemination of the intervention guide for increasing access to and appropriate use of medicines for the management of child illnesses. SIAPS continued to disseminate the guide as widely as possible through the CORE Group and the Diarrhea and Pneumonia Working Group of the UN Commission. Although UNICEF has not responded to the proposal to use extracts of the guide in the DIVA (diagnose-intervene-verify-adjust) approach, SIAPS will continue to follow up with UNICEF HQ next quarter. SIAPS will also conduct targeted follow-up in at least three SIAPS countries and with participants from the New Information Circuit session that happened during the CORE Group's spring meeting.

The guideline for national program managers to introduce new and under-used medicines and supplies for MNCH has been finalized and sent to editorial. A scale-up guideline on the use of chlorhexidine is also being developed by the CWG. The steps in the introduction guideline will also be shared with the CWG to ensure that the scale-up plan for the guideline is in line with the chlorhexidine introduction steps. The guideline will be available to countries next quarter.

Endorsement letters for the subnational procurement assessment from the MOH in Kenya were finalized and sent to county officials. In consultation with the MOH and the Division for Reproductive Health (DRH), three counties have been selected for data collection. The HCSM team in Kenya is now working to hire a local consultant to assist with the data collection. The

tracer list for MNCH medicines was also discussed and finalized. It includes the three maternal health medicines (oxytocin, misoprostol, and magnesium sulfate), two newborn health commodities (gentamicin and dexamethasone), and two child-health commodities (amoxicillin and zinc sulfate). Initially, it was planned that the SIAPS technical advisor for MNCH would travel to Kenya to collect the data; however, because of concerns from the USAID Mission, it has now been agreed that the local consultant will collect data from all the counties. As a result the data collection tools were enhanced with more instructions and questions, particularly for collecting qualitative data, and interview guides as well as a data collection manual are being developed. Next month, the data collection tools and guides will be finalized, a local consultant will be hired and trained, and data collection will happen April 25–May 6, 2016.

Constraints to progress

Getting approval and endorsement from the Kenya DRH has been delayed because of competing priorities at DRH and has delayed conducting the subnational procurement assessment in Kenya.

Objective 3: Evidence Base for Effective Strategies to Improve Access to MNCH Pharmaceuticals and Services Increased

In support of the UN Commission on Life-Saving Commodities (UNCoLSC), SIAPS continued to participate in the following working groups' meetings: the Maternal Health Technical Resource Team (MHTRT), the Supply Chain Technical Resource Team, the CWG, the Injectable Antibiotics Working Group, and the Diarrhea and Pneumonia Working Group, which includes the amoxicillin and zinc subgroups. SIAPS provided country support for UNCoLSC activities in Afghanistan, Angola, Bangladesh, DRC, and Mali.

In addition to participating in the monthly calls of the MHTRT, SIAPS prepared the first draft of a document that details what factors need to be considered if oxytocin is going to be integrated into the EPI cold chain (the document has been circulated internally). Feedback was provided and the next iteration will be available in early April. SIAPS also attended the UN Commission's Technical Resource Team conveners' meeting in New York. In preparation for the meeting, SIAPS helped update the slide decks for both the MHTRT and the Supply Chain Technical Resource Team (SCTRT). During the meeting, SIAPS further participated in the MHTRT and SCTRT post-conveners' meeting conference calls. Next quarter, SIAPS will assist in preparation of the MHTRT legacy document and develop the final draft of the oxytocin integration document.

In January, the SIAPS PTA participated in the International Conference on Family Planning in Indonesia. During the conference, SIAPS presented on the forecasting supplement developed by the SCTRT and distributed flash drives containing resources developed by the Maternal Health, Supply Chain and FP TRTs. Flash drives were placed at the UNFPA, International Consortium on Emergency Contraception , and MSH booths at the conference and were distributed during the presentation. Additionally, SIAPS also attended a meeting of the SCTRT and developed their semi-annual report. Next quarter, SIAPS will draft an outline for a SCTRT legacy document.

The RMNCH forecasting supplement was also presented in March at this year's USAID Mini-University. SIAPS worked with JSI to develop the presentations and materials for the Mini-U session, as well as a webinar on the supplement to be held in early April. SIAPS plans to conduct English and French versions of the webinar on the forecasting supplement next quarter.

SIAPS/MNCH senior technical advisors (STAs) continued to participate in the biweekly calls of the CWG and support follow-on activities in Afghanistan, Angola, and DRC. In Afghanistan, SIAPS will provide technical assistance for managing supply chain for chlorhexidine at the health-post level, including chlorhexidine in the logistics information systems and developing M&E indicators. SIAPS coordinated with the CWG, MOPH Afghanistan, and SPS Afghanistan on the procurement of the first stock of chlorhexidine, which is scheduled to arrive in Afghanistan in April 2016.

The SIAPS STA also had discussions with Angola CPD and deputy director of CECOMA MOPH Angola to discuss the feasibility of introducing chlorhexidine in Angola. Because of recent changes in the oil price, MOPH and CECOMA will not be able to procure chlorhexidine, even if SIAPS supports activities for its introduction. It was decided to put a hold on activities at this time, until SIAPS Angola receives a confirmation from MOPH. This information was communicated to the CWG.

The SIAPS STA provided support to the DRC team in the preparation of a chlorhexidine use evaluation which will provide the MOH with data to measure progress during the scale-up phase. Chlorhexidine use evaluation materials from Nepal were shared with the DRC team to be used as resource materials in developing the DRC evaluation. A protocol for the chlorhexidine use survey was finalized and is scheduled to be implemented next quarter.

The lessons learned document developed by the zinc/ORS subgroup of the Pneumonia and Diarrhea Working Group, and with significant contributions from SIAPS, was disseminated this quarter. Additionally, the report of the study to validate the amoxicillin DT job aids and product presentations in DRC was finalized and submitted to UNICEF as was the report on Pneumonia Day activities in DRC, funded under the UNICEF lead partner contract. Next quarter, SIAPS will work to disseminate the results of the amoxicillin study in DRC and share results with PATH. It was agreed that PATH will translate the report into English.

Finally, this quarter, the report on the newborn antibiotic landscape analysis conducted in DRC through the Kinshasa School of Public Health with co-funding from Save the Children was finalized and sent to Save the Children. Next quarter, SIAPS will continue contributing to the development of the new global recommendations for managing newborn sepsis and will follow up on the DRC landscape analysis recommendations presented in the report.

TB Core

Goal: Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve global TB goals

Overall Quarter Progress

A number of activities were completed during quarter 2 of project year (PY) 5. Private sector work in Pakistan was concluded and a final report is being completed. An e-TB Manager desktop version was developed and tested in Bangladesh, the introduction and module 1 of the QuanTB eCourse was developed, and five country summaries for the e-TB Manager end of project report were written.

SIAPS also presented our work on the introduction of new TB medicines at the 15th Global Health Mini-University, a one-day learning forum for professionals and students in the field of global health that was hosted on March 4, 2016, by USAID, the George Washington University Milken Institute School of Public Health, and the Global Health Professional and Organizational Development Program. The event featured more than 60 sessions covering a broad range of topics. SIAPS presented on an overview of health systems strengthening approaches to introducing new medicines and regimens for treating drug-resistant TB infections.

During quarter 2, SIAPS submitted two workshop proposals, six symposium, and 10 abstracts proposals to the upcoming 47th UNION conference and participated in the 2016 Joint National TB Program (NTP) Review of the Philippines, as well as served as a technical leader in an mHealth workshop focused on how to scale up the use of mobile technologies for the prevention and management of tuberculosis.

Objective 1. Pharmaceutical governance for TB strengthened at global level and country level

Activity 1.1.1

SIAPS continued to provide support to the Global Drug Facility (GDF) by updating over a hundred standard operating procedure documents related to the transition in operations since moving from WHO to the United Nations Office for project services. SIAPS is working closely with the GDF staff to update and finalize this process.

In the previous quarter, SIAPS staff traveled to Cairo, Egypt, to participate in the workshop "mHealth for TB-Tobacco: Advancing efforts towards prevention and management of tuberculosis and tobacco consumption" workshop from February 22 through February 26, 2016. The workshop focused on how to scale up the use of mobile technologies for the prevention and management of tuberculosis and tobacco consumption using a human-centered design approach. The more than 80 participants included delegates from country Ministries of Health and Telecommunications, academics working on mHealth, academics working on TB and tobacco, technology and design experts, World Health Organization (WHO) staff, International Telecommunications Union (ITU) staff, Be He@lthy, Be Mobile secretariat staff, global experts

on mobile tobacco cessation and mobile TB support, and bilateral and multilateral agencies supporting the Be He@lthy, Be Mobile initiative. The workshop was hosted by the Be He@lthy, Be Mobile; a joint initiative between the WHO and the ITU launched in 2012 to provide national health services to citizens all over the world using mobile phone-based technology. SIAPS provided technical support and shared experiences with other organizations and experts during the workshop.

Activity 1.2.1

During quarter 2, SIAPS submitted several proposals to the 47th UNION World Conference on Lung Health in Liverpool, United Kingdom, which will take place in October 2016.

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

Activity 2.2.1

During quarter 2, considerable progress was made in the development of the online training course for QuanTB. The SIAPS consultant developing the QuanTB eCourse was hired in mid-February and a project kick-off meeting was held on February 26, 2016, with SIAPS team, LeaderNet, and the consultant. Basecamp (a project management tool) was set up which allows all project schedules, to-dos, messages, weekly updates, relevant documents, and files to be stored and easily accessible for team revision and progress tracking.

Additionally, updated course content was provided to the consultant along with photos, websites, and relevant logos. The first deliverable for this project, the overall eCourse design concept, was created and agreed upon by the team. LeaderNet teams have been testing and providing feedbacks related to interaction, screen skins, and content to the course developer. Drafts for introduction module and part 1 modules have been developed and tested.

During the next quarter, plans are underway to finalize customization of the technical training content for eLearning, including adding knowledge checks to improve learners' experience with the course and developing a glossary for common terms. Scripts for the course narrative are also being developed and SIAPS plans to make videos with narration to be inserted in the course during quarter 3. In the next quarter, SIAPS plans to begin testing the finished modules.

Objective 3. Improved utilization of information for TB control decision making

Activity 3.1.1:

e-TB Manager has been continuously improved with additional features and general fixes for increased use worldwide. Updated versions have been regularly released and shared with selected countries using the system with e-TB Manager currently operating at a total of 1,983 sites in 11 countries. Globally, 3,389 active users are managing 515,754 TB cases, DR-TB cases, and presumptive TB individuals. During quarter 2, SIAPS attended Nigeria Challenge TB work planning meetings, and assessed the feasibility of scaling up e-TB Manager to cover all types of

TB in the country and to define the requirements and activities for expanding the work plan. All partners agreed to include e-TB Manager scale-up activities in Challenge TB work plans for year 2 and 3. Management Sciences for Health will be responsible for system customization according to requirements agreed upon; and the Nigeria NTP will be responsible for capacity building. MSH along with the NTP will be responsible for monitoring and evaluation of the implementation countrywide. Infrastructure regarding computers and internet connection will be provided by the Global Fund.

During this quarter, SIAPS convened a technical meeting attended by IT and TB specialist teams for strategic planning of the new e-TB Manager version 3.0. The new prototype will offer enhanced functionalities and the ability to run in any kind of device. The 3.0 version will be released as beta version by quarter 4 for user testing in eligible countries. e-TB Manager Desktop (a case management local application that is synchronizable with the web) customized to fit the needs of Bangladesh was successfully implemented at five sites during quarter 2.

By the end of the quarter, there were more than 240 downloads of QuanTB version 3.0 from the SIAPS website, in total more than 1,300 downloads of all versions of the tool to-date. During quarter 2, development of QuanTB version 4.0 began in order to provide users with enhancements and new functionality for supply planning. It is expected to be released during quarter 3.

Activity 3.2.1

Of the 13 countries' implementation experience reviewed, analyzed, and documented for the e-TB Manager end of project report, only one was targeted for an in-depth evaluation in January 2016. A total of six hospitals in the North and South regions of Vietnam, were visited—the visits included 10 key informant interviews. The qualitative information gathered identified good examples of lessons learned, achievements, and challenges. An 18-item anonymous survey regarding e-TB Manager user satisfaction was completed, with an estimated 88% response rate among active users.

Additionally, during quarter 2, 11 key informant interviews were conducted in Brazil. The next step is to synthesize this information into a country report. Anonymous surveys are ongoing in other countries with interim user responses as follows:

- Bangladesh— 86 responses
- Brazil— 130 responses
- Namibia— 30 responses
- Nigeria—101 responses

Synthesized country summaries have been completed for Armenia, Azerbaijan, Namibia, Turkmenistan, and Uzbekistan. Country summaries for additional countries will be completed in the next quarter.

Constraints to Progress

Activity 3.1.1

Constraints to progress this quarter included deficiency of in-country support to sustain e-TB Manager implementation and monitoring (e.g., high staff turnover; deficiency of local management information systems, and paucity of IT and TB specialists). Lack of or no reliable data regarding number of TB cases and TB medicine stock status at country level to feed into QuanTB for regular update and analysis for decision making was also a constraint experienced during quarter 2. Some countries were unable to follow recommendations to improve TB procurement and supply management based on QuanTB results and early warning system, due to factors unrelated to the quantification and forecasting processes.

Activity 3.2.1

We could not conduct the survey in Azerbaijan, despite repeated follow-up with NTP/Azerbaijan. In the last quarter, there was agreement to conduct the survey and a translated version was prepared. Support from WHO/EURO is being sought to ensure that the survey is accomplished in Azerbaijan. There were difficulties in engaging Challenge TB project (KNCV) to conduct the anonymous e-TB Manager user survey and planned key informant interviews. Changes in NTP Indonesia leadership and Challenge TB project leadership were major constraints in Indonesia. Further attempts will be made as Indonesia is among the best implementing countries for e-TB Manager.

Objective 5. Improved pharmaceutical services and access to TB products to achieve TB goals

Activity 5.1.1:

SIAPS participated in the 2016 Joint NTP Review of the Philippines, serving as international leaders for the drug and supply management component of the review. The final report and list of recommendations will be released by the program review coordination committee by quarter 3.

During quarter 2, SIAPS participated in a GDF/Green Light Committee monitoring mission to Ethiopia on behalf of Stop TB partnership. SIAPS provided technical support in conducting a quantification meeting in Ethiopia. During the meeting, 17 staff members from the central medical stores, Ethiopia NTP, Federal Ministry of Health, Regional Health Bureau and partners were given a brief demonstration on how the tool works and then coached on how to use the tool to analyze their stock status. Through this process, SIAPS was able to identify overstocks of second line TB and pediatric medicines in Ethiopia, as well as potential expiries. SIAPS technical support helped prevent wastage in Ethiopia by delaying delivery of additional second line TB medicines; the equivalent of USD $1,421,864.84, which was originally expected to arrive in April 2016; and another consignment worth USD $514,108.31 initially planned to arrive in February 2017. In addition, SIAPS advised Ethiopia to defer shipment of overstocked SLDs worth USD $117,888.80 from April 2016 to the end of 2016, while closely monitoring

stock status and patient enrolment trend to avoid wastage. Based on these recommendations, Ethiopia immediately responded by immediately sending a request to GDF to postpone delivery.

Upon STOP TB partnership's request, SIAPS participated in a Global Fund planning workshop in Malawi to strengthen TB program activities. During this meeting, SIAPS provided technical leadership in Tb pharmaceutical management and support the national TB program with quantification. SIAPS continues to provide remote support and plans to conduct a formal training on QuanTB by quarter 3.

Tanzania
SIAPS continued to support Tanzania in monitoring TB stock status as part of technical assistance in implementing an early warning system to prevent wastage or stock out of TB medicines. During the quarter, a TB stock analysis was conducted based on the QuanTB files shared; country specific medicine availability reports were produced and shared with the NTP for review. Based on the stock analysis report, SIAPS advised the Tanzania NTP how to address the identified stock related challenges. Additionally, SIAPS participated in the Global Fund Situation Room for Tanzania on January 17th-19th, 2016. As part of the mission, SIAPS reviewed the country's stock situation and provided recommendations to the country's stakeholders. SIAPS also assisted Tanzania's NTP to plan for a TB medicine quantification review meeting scheduled to take place from April 5-8, 2016. SIAPS helped to organize the workshop and develop workshop materials. SIAPs also provided technical support to NTP Tanzania to finalize standard operating procedures (SOPs) for TB medicines quantification. The first draft was submitted to NTP for comments and inputs. SIAPS continued to maintain close communication with the Global Drug Facility (GDF) on the need to expedite delivery of TB medicines for Tanzania, while also holding delivery of overstocked medicines.

Uganda
During quarter 2, SIAPS continued to provide support to Uganda in monitoring TB stock status as part of technical assistance in the implementation of early warning system to prevent wastage or stock out of TB medicines. SIAPS conducted a TB stock analysis based on the QuanTB files shared and country specific medicine availability reports were produced and shared with Uganda NTP for review. Based on information generated in the stock analysis, SIAPS advised the Uganda NTP on how to address the identified stock related challenges. SIAPS also maintained close communication with GDF on the need to expedite delivery of TB medicines for Uganda, while also holding delivery of overstocked medicines. During quarter 2, SIAPS provided technical support in conducting a quantification meeting in Uganda. In Uganda, seven participants were trained on TB medicines quantification using QuanTB.

Activity 5.1.2

Significant progress was made in the economic impact of stock-outs activity during quarter 2. SIAPS collected data through short interviews with stakeholders in Nairobi, Kenya, and through interviews with service providers, NTP managers, and staff in the Philippines. SIAPS also conducted interviews on the impact of technical support to NTPs in improving access to TB medicines. Interviews were conducted with the NTP, USAID country staff and members of the Philippines Joint Program Review team. The analysis of the data is well underway and should be

completed by the end of May 2016. During separate meetings with WHO and government representatives from the WHO Regional Office for the Western Pacific, a lot of interest was expressed in seeing the results of this work.

Activity 5.2.1

This activity was closed out in the previous quarter. A final report was drafted and submitted to the SIAPS editorial team for review prior to publication and dissemination.

Constraints to Progress

Activity 5.1.2

The analysis relies on the availability of certain TB cost data that could not be found in published literature; proxy data will be used instead.

TB Core Add-On

Objective 5: Improved pharmaceutical services and access to TB products to achieve TB goals

Activity 5.1.2:

Provide technical support to NTPs in strengthening drug management practices and establishing early warning systems to avoid stock-outs

Kenya
During the previous quarter, SIAPS supported Kenya to generate and disseminate EWS reports to stakeholders to ensure that action points are followed through with. A major achievement during quarter 2 was to ensure that Kenya did not experience any stock-out for TB medicines. The EWS reports have also been critical in guiding the ongoing process of phasing out of old pediatric formulations and introducing the new ones.

In addition, SIAPS supported the National TB Program (NTP) to review the procurement, supply, and management (PSM) plan in January 2016. The review was intended to examine enrollment targets for MDR-TB patients, as well as quantities of medicines to be procured. The review also incorporated bedaquiline (BDQ) companion medicines to be procured. During the quarter, SIAPS also provided technical assistance to develop a roadmap for implementing a logistics management information system (LMIS) reporting via the DHIS 2 platform during a meeting held January1–5, 2016.

DRC
During this quarter, SIAPS in collaboration with the Union provided technical support to the NTP during the quantification exercise for anti-TB medicine needs for 2017. A major achievement of this quarter was maintaining no stock-outs of either first or second-line anti-TB medicines in February and March.

Philippines
SIAPS staff continued to provide technical support to the NTP and partners during quarter 2 and during the Drugs and Supplies Management technical working group meeting. Based on a review of QuanTB data, the NTP was able to analyze the stock status of medicines and facilitate emergency procurement, particularly for capreomycin and kanamycin, in order to prevent stockout. A major achievement of this quarter is that the Philippines was able to maintain a 0% stock-out of first- and second-line medicines since SIAPS technical support began in April 2014.

Nigeria
During quarter 2, SIAPS continued its technical assistance for PSM activities for Global Fund and USAID TB projects. SIAPS also continued to provide technical guidance to the NTP for introducing new pediatric TB medicine formulations. SIAPS staff also collated, analyzed retrospective data on isoniazid, and prepared reports to share with NTP and partners. As a consequence, a gap analysis showed that there was inadequate isoniazid 300 mg quantity planned

through Global Fund new funding model (NFM). This resulted in the country seeking approval from the Global Fund to procure more isoniazid 300 mg to meet the country's needs.

Zimbabwe
SIAPS continued to support Zimbabwe in monitoring TB stock status as part of technical assistance in implementing an early warning system to prevent wastage or stock-out of TB medicines. During the quarter, a TB stock analysis was conducted based on the QuanTB files shared and country specific medicine availability reports were produced and shared with the NTP and stakeholders for review. Based on information generated in the stock analysis report, SIAPS advised the Zimbabwe NTP how to address the identified stock related challenges.

Zambia
SIAPS has continued to support the NTP to ensure that EWS reports are generated regularly and used to help make decisions regarding TB medicine stocks. The NTP still encounters other PSM challenges, as evidenced by frequent delays in procurement/delivery schedules that often result in emergency situations. SIAPS will continue to support the program to overcome these challenges. Quarterly EWS reports were generated in March 2016 for first-line and second-line TB medicines and action points were shared with the NTP. A review of previous quarter recommendations was done. Procurement of first-line and second-line medicines were initiated, which was recommended as a key action point in quarter one.

SIAPS made a trip to Zambia March 15–18, 2016, to provide technical assistance for PSM for TB medicines. During the trip, SIAPS identified key areas that needed strengthening and provided recommendations and a plan of action to NTP. Some of the recommendations were sensitizing staff on revised pediatric guidelines, reviewing the pediatric cases target that is used for quantification, quarterly rationalization of MDR-TB expected cases against the actual enrolled cases, roll out plan for the new pediatric formulations, improving supportive supervision, and strengthening human resource capacity in the NTP.

South Sudan
During the quarter, SIAPS supported the NTP to generate an EWS report in February 2016. Action points were shared and SIAPS worked with the GDF to fast track the delivery of pending pediatric medicines to prevent stock-outs. The supplies were delivered by GDF in March 2016, averting a stock-out. In the coming quarter, SIAPS plans to visit to finalize plans for introduction of patient kits, as well as develop job aids/SOPs for the sensitization of workers.

Constraints to progress

Kenya
The main constraint to progress during quarter 2 has been competing priorities among the key ministry of health staff who are expected to drive the activities. Therefore, work on activities was slow and planned activities were cancelled.

Nigeria
Constraints to progress during quarter 2 in Nigeria included funding challenges to introduce new pediatrics formulations and inadequate number of personnel, delay in approval and delivery of

medicines shipment, and inadequate central level pharmaceutical management training to address skill and knowledge gaps.

Zambia
Constraints in Zambia included inaccurate target number of patients enrolled on treatment, resulting in procurement of excess pediatric medicines. Additionally, inadequate staffing levels (only one staff person at NTP) in charge managing both upstream and downstream sections of the SCM pipeline led to bottlenecks in completing work.

South Sudan
Constraints in South Sudan included a delay by the supplier to deliver an accelerated order for pediatric medicines that resulted in an emergency situation. Human resources are also a major challenge in South Sudan. The country has inadequate numbers of qualified staff, so could benefit from capacity building initiatives by SIAPS.

Partner contributions

Kenya
In Kenya, SIAPS partnered with the Center for Health Solutions-Kenya (CHS) who provided logistical and financial support, while SIAPS provided technical assistance. Other partners included WHO, CDC, AMREF Kenya, and Health Commodities and Services Management (HCSM).

South Sudan
SIAPS worked closely with UNDP and Challenge TB. During quarter 2, UNDP has been in the area of procurement as the principal recipient for the Global Fund. SIAPS has developed a good working relationship with the Challenge TB program, leveraging both technical assistance and resources.

TB Bedaquiline Implementation Program

Goal: Provide technical support to the bedaquiline implementation program for TB new medicines pharmacovigilance

Overall Quarter Progress

SIAPS provided continuing technical support to Georgia, Philippines, Swaziland, Kenya, and Uganda to introduce bedaquiline (BDQ) under the donation program. Plans are underway for SIAPS to collaborate with the royal Netherlands Tuberculosis Association (KNVC) for the introduction of BDQ in Bangladesh in the upcoming quarters. SIAPS created a new website newtbdruginfo.org for countries to introduce new medicines and novel regimens for TB treatment; the site was updated with revised materials, new documents, and enhanced navigation of resources. Additionally, SIAPS attended a stakeholders meeting at the KNCV offices in the Hague for the introduction of BDQ in USAID-funded TB countries. The meeting was held to optimize collaboration and share materials and tools among all groups.

Activities by country:

Georgia:
As of March 2016, 91 cases were enrolled in the BDQ treatment with the use of USAID-donated medicine. SIAPS continues to help coordinate working group meetings with all stakeholders involved in TB control in the country to implement active tuberculosis drug-safety monitoring and management (aDSM). SIAPS will be conducting cascade trainings countrywide in quarter three; this will consist of two parts: adverse event (AE) management and recording and reporting on AEs.

In addition, SIAPS provided conducted remote familiarization training for staff in the pharmacovigilance committee members supporting NTP on the SIAPS-developed eHealth tool to monitor medicines safety and effectiveness called Pharmacovigilance Monitoring System (PViMS). SIAPS is currently working with this group to get hardware specifications ready in preparation for in-country deployment of the system planned for May 2016.

Philippines:
Implementation previously scheduled for the middle of December 2015 has been delayed until May 2016.

Swaziland:
Following the arrival of donated BDQ in Swaziland in the previous quarter, staff members worked to ensure timely delivery of the medicines to the central medical stores (CMS). In an effort to streamline distribution of BDQ, the pharmacists at the treatment sites, including the National TB Hospital, had to follow internal country protocol in ordering the medicine from the CMS. This helped ensure that the medicines were successfully delivered to the treatment sites to reach eligible patients.

During quarter two, a comprehensive clinical guideline document for BDQ and delamanid use was developed by SIAPS and approved for use at the facility level by the NTP. The document outlines key issues such as: eligibility criteria, patient inclusion, informed consent, therapeutic regimen design etc., for reference by health care workers who are managing patients on the medicines. Guidance on reporting serious adverse events, defined by the National Pharmacovigilance Unit, was also developed with SIAPS support during the previous quarter.

Kenya:
Following a stakeholder meeting in December 2015, the established BDQ implementation taskforce held their first meeting on January 14, 2016, to discuss next steps. During the meeting, seven health care facilities were designated as clinical centers of excellence and the treatment sites for patients receiving BDQ. As an outcome of the meeting, key implementation steps and infrastructural gaps to be met were agreed upon. During this quarter, Kenya received the order of BDQ from the donation program, and made plans to re-order more based on projected need. SIAPS is supporting with the quantification and ordering process.

Furthermore, SIAPS supported the National TB, Leprosy and Lung Disease (NTLD) Program to create a package to justify the introduction of BDQ in country. The package contained safety and efficacy data, as well as WHO recommendations for use of BDQ under programmatic conditions, a brief description of country requirements to introduce BDQ, assessment of gaps and areas which need to be addressed, and other support documents. This package was endorsed by the NTLD and was submitted to the Registrar of the Pharmacy and Poison Board (PPB) and the Ministry of Health. On March 7-11, 2016, two consecutive clinical training workshops were conducted with SIAPS support for approximately 47 MDR-TB health care workers (doctors, clinical officers, nurses, and pharmacists) from different counties in Kenya who manage MDR-TB patients.

Uganda:
A successful introductory workshop for stakeholders (NTP, TRACK TB, clinicians) was held on January 14, 2016, with SIAPS support and as a result the NTP intends to move forward with the adoption of BDQ as soon as possible. Following the creation of a BDQ implementation taskforce, SIAPS met with taskforce leadership to establish next steps and assign roles on January 15, 2016. While there is currently no other implementing partner introducing BDQ in-country, one patient is receiving it under compassionate use. Clinicians at the patient's treatment site expressed interest in having clinical support as soon as possible. There are currently two other patients who are awaiting treatment. Plans are underway to host a clinical training workshop in April 2016. The target audience is 50-60 health care workers from all over the country.

Plans for the next quarter include finalizing the contract for the recently hired consultant, and continuing to improve the newtbdruginfo.org website. Plans for quarter 3 for the implementation of BDQ include conducting a training in the Philippines and official launch on May 29, 2016, working with KNCV to introduce BDQ and reach patients who do not have access through the EndTB project, and supporting other countries as requested to implement BDQ.

Partner contributions

Swaziland:
National TB Control Program, WHO, and MSF were instrumental in the review of the SIAPS-developed clinical guideline document. The document has since been approved for use in healthcare facilities, including treatment sites for patients on BDQ.

Kenya:
National TB, Leprosy and Lung Disease Program provided oversight and worked with SIAPS to define and meet the needs of the country with regards to BDQ use and overall Program Management of Drug Resistant TB.

Uganda:
TRACK TB has been instrumental in planning the clinical training workshop and in working to address some of the shipping and distribution costs associated with BDQ and the companion medicines. TRACK TB has also assisted within addressing the costs associated with clinical monitoring equipment, such as ECG machines that are critical to ensure the appropriate care of patients put on BDQ.

Constraints to progress

Philippines:
Progress in the Philippines continues to experience delays obtaining national IRB approval. SIAPS is working with the NTP to introduce BDQ under programmatic conditions, instead of under a study protocol requiring IRB approval to expedite the implementation process.

Swaziland:
There has been a significant delay in briefing key personnel within the Ministry of Health due to scheduling issues; this has affected the official BDQ launch program. The NTP is currently working on addressing this.

Kenya:
There has been a challenge in accessing funds to acquire the necessary companion medicines to use with the donated BDQ. These funds have been assigned and we are currently awaiting disbursement.

Uganda:
Challenges in the adoption of BDQ in Uganda fall under two broad categories—(1) funding for associated costs and (2) gaps in clinical capacity and infrastructure. While BDQ is free through the donation program, additional costs such as shipping, distribution, port clearance, and waivers still need to be addressed. Also companion medicines have additional cost implications, which must be addressed. There is also a challenge in accessing funds to acquire the companion medicines to use with BDQ and determining where they can be procured from. SIAPS facilitated a discussion between the NTP and the Global Drug Facility to address this issue.

REGIONAL PROGRAMS

LAC AMI

Goal: By the end of 2016, AMI countries will have institutionalized national and regional mechanisms to ensure a continuous supply of antimalarials as the key malaria control strategy, particularly in low-incidence locations and areas at risk for the emergence of ACT-resistant pathogens.

Overall Quarter Progress

Nine countries reported stock levels for antimalarials this quarter. The availability of antimalarials in central warehouses decreased to 74% from 85% the previous quarter, due to stock-outs at the central level in three countries. A few countries are still facing problems with the local procurement of antimalarials. As in the previous quarter, there is a risk of artemisinin mono-therapy in Peru, due to the stock-out of mefloquine.

Objective 1: Pharmaceutical sector governance strengthened

SIAPS finalized a performance assessment of Colombia Integrated Management Strategy for Malaria Control (EGI, by the Spanish acronym). The results were presented and discussed with the Colombia Director of Malaria National Control Program in March 2016. For the next quarter, and based on the agreements reached during this meeting, SIAPS will support a workshop to present and discuss the results of the study and the development of "gap closure" plans for low performance activities.

In December 2014, SIAPS supported the monitoring of the performance of the malaria control strategies in nine Brazilian states. The participants prepared the gap closure plans to be implemented during the following 12 months. During this quarter, SIAPS collected information to assess the current situation using an "adequacy approach." For the next quarter (May 2016), SIAPS will facilitate another workshop to present the results of the assessment and preparation of "gap closure" plans for 2016/2017.

Constraints to progress

The implementation of activities in Colombia has been delayed due to other dengue and Zika epidemiological emergencies national counterparts had to face.

Objective 2: Pharmaceutical management information available and used for decision making at different levels of the health system

The regional meeting to discuss current problems in the availability of antimalarials (originally scheduled for May 2016) was canceled, due to the proximity with the AMI regional meeting. However, during the AMI regional meeting (May 3-6, 2016) PAHO and SIAPS will present

the challenges LAC countries are still confronting to assure a continuous supply of antimalarials.

Through its local consultants, SIAPS supported the compilation of information and analysis for the Quarterly Bulletin on Availability and Consumption of Antimalarials, disseminated by PAHO on February 2016. Nine countries shared information. The availability of antimalarials in central warehouses decreased (74%) compared with the previous quarter (85%). Certain countries still face problems with the estimation of needs and procurement of antimalarials. These problems will be analyzed and discussed during the next AMI regional meeting (May 3–6).

In Guatemala, SIAPS supported the estimation of needs for the donations on antimalarials through PAHO's Strategic Fund.

Partner contributions

The presentation and discussion of current problems with access to antimalarials during the AMI Regional Meeting will be moderated by PAHO and SIAPS.

Objective 3: Pharmaceutical services improved to achieve desired health outcomes

During this quarter, SIAPS met with the Peruvian Medicine Directorate (DIGEMID) to present illustrative experiences in malaria pharmaceutical management, implemented and documented in Loreto and Madre de Dios. SIAPS proposed short-term technical assistance for the scale up of these activities to the rest of the country. SIAPS and DIGEMID agreed on an implementation work plan and cost sharing. The implementation of the work plan started in March 2016.

During this quarter SIAPS provided technical assistance for the design of a "graphic prescription" that will facilitate the introduction of mefloquine + artesunate fixeddose combination in Loreto. No other technical assistance has been requested for this intervention.

SIAPS continued working with local counterparts in Pará and Roraima (Brazil) to systemize interventions to improve access to malaria diagnosis and treatment in gold mining areas. SIAPS finalized a technical report on the "Systematization of Malaria Control Interventions in Pará Mining Areas." The report includes a proposal for the monitoring of results. For the next quarter, SIAPS will complete a rapid assessment on the situation of access to malaria treatment in Roraima underserved communities, as the basis for the design of interventions.

In Guatemala, SIAPS supported a pilot intervention in Escuintla, which will lead to the integration of malaria medicines to a unified supply chain system. The "Malaria Logistic Management Manual" was validated in Alta Verapaz and Escuintla.

Partner contributions

PAHO facilitated the contact with Ecuador health authorities.

Constraints to progress

The systematization of interventions to improve access to malaria diagnosis and treatment in Brazil has been delayed due to difficulties accessing mining communities during the rainy season, and conflicting agendas of the local malaria program.

West Africa Regional

Goal: Facilitate the availability of quality pharmaceutical products especially those related to HIV and AIDS to achieve high level desirable health outcomes in target West Africa countries.

Overall Quarter Progress

In collaboration with the Global Fund, SIAPS facilitated the deployment of the HIV and AIDS commodity management tool in West Africa known as OSPSIDA at the regional level in Burkina Faso. This regional deployment has been identified as the best way to sustain the tool's use in Burkina Faso by fixing data entry issues which hampered using OSPSIDA to improve availability of HIV and AIDS commodities.

In Togo, SIAPS built the capacity of the national quantification committee on methods of quantification, making assumptions, data collection, and the use of Quantimed® and Pipeline® software to perform forecast and supply planning of HIV and AIDS products. SIAPS also supported the National AIDS Control Program (PNLS) of Togo to perform a long-term forecast (October 2015 to December 2018) of ARVs and opportunistic infection medicines needed for care and treatment of patients living with HIV and AIDS. SIAPS also helped the program to collect consumption data from OSPSIDA that helped to update supply plan using Pipeline.

Objective 1: Increase the use of pharmaceutical management information for decision making at national and regional levels

Since September 2014, OSPSIDA has been used in Burkina Faso at the central level. However, its effective use has been hampered by the lack of data entry by the HIV and AIDS National Control Program. The issue has been the shortage of human resources within HIV and AIDS control program to perform data entry despite availability of validated commodity and patient data collected by paper-based logistics and management information system (LMIS) forms.

SIAPS, in collaboration with the Global Fund and the HIV and AIDS Control Program, organized a workshop at Koudougou where regional pharmacists and pharmacy technicians from each of the 13 regional health directorates were trained on data entry and use of OSPSIDA reports for decision making on HIV and AIDS commodity management. As of December 31, 2015, the OSPSIDA dashboard showed that the risk of stock-out was about 3% but more than half (51.5%) of ARVs were overstocked with serious risk of expiry. The months of stock of those overstocked ARVs ranged from 34 to 857 months. Despite this fact, orders have been placed for 53% of overstocked ARVs with huge projected pipeline going from 43 to 1,600 months of stock.

Seeing all these issues of expiries, SIAPS helped the HIV and AIDS National Control Program to develop a list of recommendations to implement as quickly as possible to avoid wastage of ARVs. During the workshop in Burkina Faso, participants studied Benin's and Togo's experiences on use of OSPSIDA. OSPSIDA has been deployed in Benin since September 2014 at central level with support from USAID through SIAPS. To speed up data entry and be able to use the tool for making decision, the HIV and AIDS program with

support from Global Fund deployed the tool at regional level. The Global Fund also supported the hiring of data clerks to enter historical data of 2014. Success has been noted with deployment in Benin, such as early detection on February 2015 of stock-out of abacavir pediatric formulations, re-distribution of zidovudine and lamivudine (adult formulations), improvement of data quality, availability of site consumption data, and ability to cross check data with two sources (OSPSIDA and monitoring and evaluation). Despite success noted since deployment at central and regional levels in Benin, there are still a few challenges to address such as inputting data into OSPSIDA promptly to allow the right decisions to be made on time.

Objective 2: Improve coordination among regional and national stakeholders involved in ensuring ARVs and HIV and AIDS commodity availability

No activities this quarter.

Objective 3: Enhance capacity for pharmaceutical supply management

SIAPS facilitated a capacity building workshop on quantification and long-term forecasting of ARVs and OI medicines in Togo. Nineteen members of national quantification committee (4 females, 15 males) from various health programs (HIV and AIDS [PNLS], malaria [PNLP], and TB [PNLT]), Central Medical Stores (CAMEG), Pharmacy and Medicines Department (DPLET) and HIV and antiretrovirals treatment sites (Centre Hospitalier Universitaire Okoin, Centre Hospitalier Regional Tsevie, Centre de Sante de Lome have been trained on quantification processes such as forecasting and supply planning, quantification methods, data collection and validation, and making assumptions. Participants also learned about symptoms of good and bad quantification (stock-outs and overstock) which result in erroneous quantification.

Participants from national quantification committee of Togo have been trained on the use of Quantimed and Pipeline to perform forecasting and supply planning of health products.

SIAPS also supported the national quantification committee to review data and prepare assumptions for four years' forecasting of ARVs and OI medicines. The number of patients on ART will go from the starting point of 41,807 (October 1, 2015) to 62,381 (December 31, 2018) as projected.

For adults on ART, the first choice was TDF/3TC/EFV as recommended by World Health Organization. Unfortunately, Togo still had a huge number of patients who receive AZT/3TC/NVP. As of September 2015, the percentage of second-line patients on AZT/3TC/NVP was 66.5% comparing to 29.6% on TDF/3TC/EFV. For the long-term forecast, the national quantification committee under leadership of the HIV and AIDS coordinator program decided to switch majority (95%) of patients on AZT/3TC/NVP to TDF/3TC/EFV and only keep 5% on AZT/3TC/NVP. For second-line regimen, ATV/r will be used for 80% of patients and LPV/r for 20% in combination with other drugs. For third-line regimen, darunavir + raltegravir + ritonavir will preferably be used in combination with other drugs.
The forecasted amount (ex-work) of ARV and co-trimoxazole from October 2015 to December 2018 was USD $30,309,630.

COUNTRY PROGRAMS

Angola

Goal: Improved availability of quality products for effective pharmaceutical service delivery and better health outcomes

Overall Quarter Progress

During the reported period, SIAPS continued to support the national quantification technical working group for HIV and AIDS commodities in forecasting and supply planning for the period January 2016–December 2018. Results from this quantification exercise were used to inform the National HIV and AIDS Control Institute (*Instituto Nacional de Luta Contra o Sida*, INLS) on needed quantities to be procured by emergency orders with funds from the World Bank and Global Fund and to mobilize other financial resources to cover the quantified period. The same report will be used by Global Fund procurement in its new two-year grant to be officially initiated in July 2016 through UNDP, the principal recipient of the grant.

The program supported the organization of one of two planned bi-monthly Logistics, Operations, and Procurement Sub-Committee (*Sub-Comissão para a Logística, Aprovisionamento e Operações*, SCLAO) meetings.

Direct support was provided to the pharmacy teams in eight selected PEPFAR-supported health facilities through a mentorship program and through close collaboration with the INLS and the Luanda Provincial office for Health's (*Gabinete provincial de saúde de Luanda*, GPSL) HIV and AIDS team.

The data analyst embedded within the National Malaria Control Program (NMCP) continued to actively collaborate with all 18 malaria provincial supervisors in the compilation and analysis of all provincial malaria case management and logistics reports. In addition, SIAPS facilitated all logistics for the malaria health facility survey that was conducted in two selected PMI-supported provinces (Uige and Huambo) under the coordination of CDC Atlanta and the NMCP. In total, 90 health facilities were visited by eight data collection teams. By using SIAPS-developed electronic data collection tools, data collectors were able to complete the field work on time, and the data was made available to facilitate analysis, interpretation, and dissemination.

SIAPS continued to support Central Procurement Agency for Medicines and Medical Supplies (*Central de Compras de Medicamentos e meios medicos de Angola*, CECOMA) in finalizing its internal regulations manual for acquiring medicines and medical devices, in line with the public tendering statute 20/10 (*Regulações internas dos concursos públicos*). This manual of internal regulations was submitted to CECOMA senior management for approval, together with the necessary bidding documents, all the appendices, the annual procurement plan, and the draft of the CECOMA capacity-building training material for procurement.

SIAPS collaborated with DPS Luanda and INLS to conduct a five-day training in pharmaceutical management of HIV- and AIDS-related commodities, the first training of its kind in Angola. The

program also worked with NMCP to continue monitoring stock status of antimalarial commodities and submitted both the Angola quarterly procurement plan and monitoring report (PPMRm) to the global database managed by USAID | DELIVER and the end-use verification (EUV) report covering six provinces. In the reproductive health program, SIAPS collaborated with other local stakeholders in family planning (FP) (UNFPA, CECOMA, and the National Reproductive Health Program [NRHP]) to conduct the physical inventory of all FP commodities and to follow up with both Luanda and Huambo provinces to improve timeliness and quality in FP commodity reporting.

Objective 1: Pharmaceutical supply chain system governance strengthened

During the quarter, the program continued to support coordination among pharmaceutical supply chain stakeholders. In February 2016, SIAPS supported the National Directorate of Medicines and Equipment (*Direcção Nacional de Medicamentos e Equipamentos*, DNME) to organize a bi-monthly meeting of the SCLAO to discuss and identify specific bottlenecks that affect public health supply chain services. Issues of generalized stock-outs of key health commodities came up again, in light of the continuous financial crisis that Angola is facing due to low oil prices. A plan to strengthen registration systems was discussed with the DNME director, and contacts were made with the Mozambican national medicine regulatory authority to facilitate a one-week study visit for DNME staff to share experiences and learn from their Mozambique counterparts. Preparations were made for an internal consultancy scheduled for April to support the DNME in developing and implementing a data collection tool to identify all medicines imported in the last three years; this information will serve as a starting point of the national medicine registration process.

At the INLS level, SIAPS continued to support the national quantification working group to finalize the three year forecasting and supply planning of all HIV and AIDS health commodities, including antiretroviral medicines (ARVs), rapid tests kits, and reagents for CD4 and viral load counts. The results of this exercise are also used to mobilize necessary funds, including the new Global Fund grant that should start by July 2016 and will be implemented directly by UNDP as the principal recipient. INLS has also approached the World Bank and some supportive countries to mobilize enough products to mitigate the current stock-outs of some key commodities and to manage the transition period until INLS can procure its own HIV and AIDS commodities.

As a direct result of this collaborative quantification mechanism for HIV and AIDS commodities, the Global Fund has recommended establishment of the same quantification technical working group for malaria commodities as one of the key conditions before a new grant is signed with the MOH.

SIAPS continued to work with INLS and DPS Luanda to improve the availability of HIV commodities at the health-facility level. A quantification exercise was conducted at the DPS Luanda-level to identify all the needs of the health facilities in its catchment area as a solution to past requisitions that were based only on warehouse distributions, which were always significantly less than what was actually needed.

Finally, a consultant was hired to provide technical assistance to INLS and to work with DPS

Luanda and selected health facilities to develop a pharmaceutical management manual with simple, succinct SOPs in a user-friendly modular format to provide clear guidance on the management of HIV and AIDS pharmaceutical products at the health facility level. Other pharmaceutical management manuals and SOPs that SIAPS has developed in other countries will be used as a basis for the revision.

Partner contributions

- DNME: Leadership role in organizing the SCLAO and other meetings to advocate for strengthening medicine regulatory systems
- INLS: Coordination of the national quantification technical working group
- UNDP/Global Fund: Review and revision of process and output of the HIV and AIDS quantification exercise
- GPSL: Coordination in forecasting the province's ARV needs

Constraints to progress

- Due to the current financial crisis, MOH has other burning priorities that are delaying the finalization of the national pharmaceutical supply chain strategy.
- Most of the visited health facilities were experiencing stock-outs of key products because the provincial warehouse was not adequately responding to their real needs. In addition, the team had difficulties getting to some health facilities because of the poor road conditions during the rainy season.
- Establishing transparency and good working relationship between health care providers at certain health facilities remains a concern.

Objective 2: Local capacity for pharmaceutical management enhanced

During the reported period, a five-day training on HIV and AIDS and the pharmaceutical management of HIV commodities was conducted with 37 participants from INLS, CECOMA, DPS Luanda, and SIAPS. By the end of the training, participants had updated their knowledge on the biological cycle of HIV, the pathogenesis of AIDS, ARV treatment, and monitoring patients living with HIV. They were also able to describe the pharmaceutical management cycle of HIV and AIDS products, had mastered the use of product management tools, and learned about the importance of pharmacovigilance in HIV patient management, good dispensing practices, and improving pharmaceutical management practices in their specific work environments. Facilitators were drawn from INLS, DNME, CECOMA, and SIAPS.

In addition, a selected team of 13 staff from INLS, CECOMA, USAID Angola, and SIAPS participated in a nine-day intense training in quantification data collection and validation, assumptions, processes, and methods and in applying some electronic tools for quantification of health products with specific attention given to HIV, AIDS, and malaria commodities. Participants were able to apply electronic forecasting tool Quantimed® and USAID | Deliver's PipeLine® tool for supply planning and stock level monitoring.

SIAPS continued its mentoring program in eight selected health facilities (except Hospital

Pediatrico de Luanda) that had been selected to receive direct support from PEPFAR to address identified issues in pharmaceutical management of HIV and AIDS commodities. The team continued to implement stock cards in the health facility warehouse and the weekly ARV consumption forms in the dispensing area. This has resulted in more transparent and reliable stock data that is used to make monthly logistics reports and requisitions more accurate.

The program continued to second a short-term consultant to CECOMA to develop the necessary documents and tools that are needed to build the procurement capacity of the warehouse, both on an institutional and individual level, in line with best procurement practices and current Angolan public procurement regulations and procedures. The consultant finalized and submitted the internal regulations for acquisition of medicines and medical devices, the bidding documents with all the appendices, annual procurement plans, and the training manual to implement these guiding documents.

Finally, SIAPS worked with CECOMA to draft a memorandum of understanding (MoU) that will be signed between USAID/PMI and CECOMA to channel, manage, and distribute some PMI-funded commodities through the warehouse, as a result of significant efforts to build CECOMA's capacity over the past few years and for country ownership and sustainability. Once this MoU is finalized and signed by both parties, efficiency in malaria health commodity logistics management will be improved by avoiding parallel distribution systems that were not empowering CECOMA to monitor PMI commodities at the provincial level.

Partner contributions

- INLS, DNME, CECOMA, and DPS Luanda in the preparation and conduct of HIV, AIDS, and pharmaceutical management training
- INLS, NMCP in the preparation of quantification training
- CECOMA in the current consultancy to develop guiding documents in medicine procurement
- Individual health facilities' management in selected PEPFAR-focus health facilities for their coordination in the mentorship of their pharmacy staff by SIAPS

Constraints to progress

- Insufficient human resources at CECOMA and health facilities (both in numbers and skills)
- Lack of warehousing space and poor storage conditions for pharmaceutical products
- Delays in approval have hindered the timeline for SIAPS to provide support to one health facility (Hospital Pediatrico de Luanda)
- Challenges in adequately coordinating and engaging with responsible staff in another health facility (Sanatorio)
- More health facility staff is needed, as are improved storage conditions for HIV and AIDS commodities
- Internal supervision is needed to reinforce the use of pharmaceutical management tools

Objective 3: Information for pharmaceutical management decision making improved

SIAPS staff that is embedded at the NMCP continued to support compiling all provincial reports in collaboration with the SIAPS M&E officer and with all 18 malaria control provincial supervisors. This support is ensuring regular updates of the NMCP database for malaria case management and logistics data that is compiled at the national level. At the same time, all 18 provinces have been receiving feedback on their reports to improve completeness and quality.

The EUV report conducted in November and December 2015 was submitted to PMI, providing a snapshot analysis of the availability and use of antimalarial products at the health facility level. In total, six provinces were visited to collect malaria case management and logistics data from six provincial warehouses, nine municipal warehouses, five provincial hospitals, 10 municipal hospitals, and 24 health centers. Findings suggested: a weak HR force, poor management of malaria health commodities, lack of supportive supervision visits to reinforce the mandatory use of pharmaceutical management tools, and stock-outs of sulfadoxin and pyrimethamin that is used in malaria intermittent preventive treatment in pregnancy.

The program also submitted one quarterly PPMRm in January 2016 after collecting stock information data from the national and provincial levels. This stock analysis allowed NMCP to review its distribution plan for rapid diagnostic tests for a balanced availability of these commodities across the provinces.

The program assisted the NRHP in revising the monthly reporting rates, with a focus on Luanda and Huambo provinces. In addition, SIAPS collaborated with UNFPA and CECOMA to conduct three monthly stock takes and to compile all the distribution data for the past six months to compare it with the national distribution plans and the remaining stock. One area of improvement is the proper and consistent use of stock cards at CECOMA; in the past, most of the physical counts did not correspond to the quantities recorded in the Excel files used to manage CECOMA commodities. Finally, one country coordinated procurement plan for HIV commodities was submitted to USAID Angola to inform next year's country operational planning and the current issues that affect HIV and AIDS commodity security.

Partner contributions

- NMCP and provincial malaria teams: Coordination role in data collection of malaria case management and monthly stock status
- UNFPA, CECOMA, and NRHP: Conducted physical inventory for FP commodities
- NRHP: Analyzed provincial monthly FP commodity reports, looking for patterns of use

Constraints to progress

- Delays in sending monthly reports from the provinces due to unreliable, intermittent Internet connectivity and non-use of collected data in monitoring and/or improving the provinces' daily activities
- Lack of recognition of the importance of validating data at the health facility level so as to

minimize reporting inconsistencies and improve data quality
- Shortages, resulting in non-use of proper patient registers and stock cards at the health facility level to capture all EUV indicators
- Remote collection of stock status data by telephone or emails which limits the possibility of validating these data for PPMRm through field visits
- Insufficient human resources at NMCP, NRHP, and CECOMA due to the current national financial crisis

SIAPS will continue to advocate for adequate staffing at the national public health programs levels and to collaborate and capacitate the available staff to sustain the gains of our interventions. The mandatory use of pharmaceutical management tools at all levels will also be reinforced starting from the internal supervision inside the HFs. SIAPS is also organizing targeted field visits to support provincial teams that are having challenges in producing quality and timely reports.

Objective 4: Pharmaceutical service to achieve desired health outcomes improved

During the reported period, the program worked with implementing partners to facilitate the exchange of products between selected health facilities to mitigate stock-outs in facilities with high needs and prevent expirations and wastages due to overstock of supplies with a short remaining shelf-life in others. Some health facilities (Cajueiros, Kilamba Kiaxi, Dispensario, Sanatorio, and CS Viana) received 4,500 HIV rapid test kits (Determine) from Hospital Esperanca and Hospital Divina Providencia; CS Viana provided some 900 treatment-months of lamivudine 150 mg tablets and 100 treatment-months of zidovudine 60 mg/lamivudine 30 mg (dispersible tablets) that were at risk of expiring to the Hospital Esperanca, which was in need. SIAPS also supported the active distribution of 54,000 male condoms and 12,000 female condoms to selected hospitals in need. The program also worked directly with the provincial warehouse of Luanda to prepare their quarterly requisitions to incorporate accurate estimates from all health facilities in their catchment area to mitigate recurrent stock-outs at health facilities when there are enough products at the central level. Ensuring the proper and consistent use of the pharmacy book (also known as book 2/livro 2) was emphasized, so that all pharmacy visits are registered for each patient encounter.

For malaria, the program facilitated all the logistics for data collection of the malaria health facility survey conducted in two provinces (Uige and Huambo). SIAPS developed electronic tools that were used during data collection to cut the time and costs of data entry and shorten the period for data analysis. The use of new technologies in this survey has allowed the program to enhance local experience, capacity, and expertise in using electronic forms in surveys, and this has been recognized by the team of CDC principal investigators. The developed tools will be implemented in other routine data collection exercises, such as EUVs and supervision visits. In coordination with NMCP and CDC Atlanta, 90 health facilities were included in the study, and the study team has started data analysis. Findings will inform NMCP and PMI to evaluate and redesign their interventions to ensure improved malaria case management and address current gaps.

Partner contributions

- INLS, DPS Luanda, and selected health facilities in the active distribution of selected HIV and AIDS commodities to avoid waste due to imminent expiration if not distributed by the central level
- NMCP in stock monitoring of antimalarial commodities
- CDC Atlanta, NMCP, DPS Uige, and DPS Huambo in conducting the malaria health facility survey

Constraints to progress

- Continuous gap between quantities of supplies needed by health facilities and what is actually issued and distributed by the central and provincial levels because of poor management at the health facility level, insufficient stock at the national level, and lack of reliable data on consumption (poor logistics reporting and poor requisitions)
- Inadequate human resources in the health facilities to work with SIAPS mentors, where staff absences have hindered the progress of successful mentorship
- Use of a "push" system (rather than using a customer-driven "pull" system, based on the actual needs from health facilities and provinces) for malaria commodities is resulting in under- or overstocking at the user facilities

Bangladesh

Goal: Improved availability of quality pharmaceuticals and effective pharmaceutical services to contribute achieving desired health outcomes

Overall Quarter Progress

On February 24, USAID's Director of the Office of Population, Health, Nutrition, and Education (OPHNE), Melissa Jones, visited Fultola upazila family planning store, health store, and DOTS center to ascertain the implementation status of different SIAPS interventions. On the following day, the director inaugurated the central oxygen supply systems at Khulna Shishu Hospital (KSH), which were commissioned by SIAPS for the hospital. The director also visited inpatient departments, including newborn, child, and diarrheal units, and met with patients' mothers, physicians, nurses, and other hospital support staff. The director was excited to see the availability of bedside oxygen, which saves many lives including newborns. The director strongly assured the mothers' accompanying their babies that KSH is the right place for appropriate treatment and management of their children. The director noted that "SIAPS has delivered exactly what USAID was aiming for, to save lives of children and newborns." The director was happy to see that the SIAPS intervention is functioning well and saving lives.

As part of institutionalizing the SIAPS-supported electronic logistics management information system (eLMIS) for maternal, neonatal, and child health (MNCH), the Directorate General of Health Services (DGHS) issued two government orders to front-line Government of Bangladesh (GOB) officials in five districts to use the eLMIS using DHIS2 platform. DGHS wants to ensure the availability of priority MNCH medicines to save lives.

The Directorate General of Family Planning (DGFP) reached a milestone in regard to timely and accurate submission of logistics reporting by using the Upazila Inventory Management System (UIMS). Almost 100% of upazilas reported this time with 83% (n = 488) submitting a report that was timely, complete, and accurate.

As part of capacity building, during this quarter, a significant number of GOB officials have been trained in basic logistics management, tuberculosis (TB), eLMIS, etc.

SIAPS, in discussion with key donors, including the World Bank (WB), has identified two categories of equipment (medical, office and IT equipment) that would be part of the asset management system. The system will be ready to demonstrate to the donors next quarter.

For the first time ever in Bangladesh, the heads of the top pharmaceutical companies were brought together for a dialogue on the online registration system, Pharmadex. The meeting was called up by the director general of the Directorate General of Drug Administration (DGDA) with SIAPS' technical assistance. The SIAPS presentation on Pharmadex and the Common Technical Document (CTD) built the confidence of the participants, and finally they committed to introduce the Pharmadex system in the country.

SIAPS shared activities and a booth with Challenge TB at the 12th International Congress on

AIDS in Asia and the Pacific organized in Dhaka. The booth was visited by the Honorable Minister Mr. Mohammd Nasim, MP, who discussed SIAPS activities in the country with the program head. The minister praised SIAPS innovative interventions.

Objective 1: Supply chain management systems of the MOHFW and component procuring entities strengthened

The Procurement and Logistics Management Cell (PLMC) of the Ministry of Health and Family Welfare (MOHFW) endorsed the sustainability plan of Supply Chain Management Portal (SCMP) and its related tools, technologies, and methodologies that were submitted last quarter. PLMC trained 12 IT personnel in March on the management and maintenance of the SCMP. In this quarter, the SIAPS Technical Advisor provided nine written opinions on different procurement issues raised at the MOHFW to expedite the procurement process.

The pricing guide for medical equipment has been submitted to the MOHFW to issue government notification to the users. A technical session on the table of organization and equipment (TOE) of 500-bed hospitals was held on January 31, chaired by MOHFW's joint secretary for development. The draft version of the TOE was shared with the technical group, and the participants were pleased to see the final draft of the TOE for a 500-bed hospital.

Key decisions and recommendations made at the meeting were as follows:

- The government has been transitioning an upazila health complex from 31 beds to 50 beds to be completed within the next five years, so updating the TOE may be required within this period.
- The human resource part of the TOE will be taken care of by the MOHFW.
- Instruments, office equipment, vehicles, etc., may be added to the next version of the TOE.
- The list of equipment may vary based on the inflow of patients. MOHFW will consider such factors when making decisions related to addition or deletion of items.
- SIAPS will upload the TOE and related documents, including an instruction manual, in SCMP, following MOHFW approval.

In addition, a process report on the development of the TOE for 50- and 250-bed hospitals has been finalized. SIAPS has incorporated the relevant section of 500 beds in the process report and submitted it to HQ for technical review and finalizing.

SIAPS organized a workshop on January 9 for 31 procurement officials from the Central Medical Store Depot (CMSD), which is part of DGHS, on customizing new bidding documents for the WB; in addition, necessary material and equipment were provided to ensure good warehousing practices in two store rooms at CMSD.

The central oxygen supply system at KSH was inaugurated on February 25 by USAID's director of OPHNE. The uninterrupted oxygen supply system has been used on 2,800 children, including six newborns, since it was commissioned on November 4, 2015. SIAPS is also supporting KSH to introduce a web-based health management information system and LMIS to use data for

improved health service delivery. The USAID team also visited Fultola upazila family planning store, health store, and DOTS center to ascertain the implementation status of different SIAPS interventions. The team was happy to see the program and its functionality. Later in the evening, the USAID and SIAPS teams attended a working-dinner meeting hosted by KSH, where members of the KSH Board, academics from medical institutions, and high officials of Khulna were present. One of the important issues discussed was a possible assessment of the current status of specialized newborn service facilities at Khulna Medical College Hospital (KMCH) and other hospitals of Khulna. USAID tentatively plans to conduct the assessment in April 2016 and will provide support to ensure availability of quality specialized newborn care units in Khulna.

The final report on the situational analysis of district-level management of RMNCH commodities was shared with DGHS officials, the National Technical Working Group for Newborn Health (NTWG-NB), and MaMoni Health Systems Strengthening. The findings will be shared at the MNCH Technical Working Group (TWG) meeting on April 4, 2016.

A firm has been selected to prepare a procurement manual and customized bidding documents for procurement at the sub-national level and a training module for the trainers. The firm is expected to complete the assignment within one month of the awarding of the contract.

The service delivery point (SDP) dashboard module is an enhancement in the SCMP to track contraceptive stock status among the service providers at the delivery points. In this quarter, SIAPS oriented 771 participants (74% female) from 10 selected upazilas. The key objectives of the orientation were to make them aware about the SDP dashboard module and the importance of correct and timely reporting for avoiding stock-outs. The participants also learned about their roles and responsibilities and about increased supervision and monitoring at the field level.

SIAPS trained 498 DGHS logistics officials (13% female) in another 10 districts on the standard inventory tools (stock register, issue voucher, indent and issue voucher, bin card, etc.). The DGHS high officials attended inaugural and closing sessions. The key objective of the training was to orient on generic logistics issues and the newly developed inventory tools for timely reporting. The participants learned about using bin cards and a temperature monitoring system and management of unusable items occupying the stores.

SIAPS has provided technical assistance to the National Tuberculosis Program (NTP) in forecasting the drug needs (for 250 patients) of a shorter (nine months) regimen to be implemented by Challenge TB. The order has been submitted and the GDF is in the process of completing the procurement. It is expected that the drugs will be arriving by the beginning of the third quarter. A special meeting has been held to avoid expiry of forecasted pediatric TB drugs in 2017. Under the Global Fund new funding model, procurement of TB drugs has also been drafted by using QuanTB and is currently under review.

SIAPS has taken a significant role in improving storage conditions and renovation of the Shyamoly drug store for NTP. SIAPS has completed its part by providing all the technical materials and equipment as per commitment in March 2016. Now, SIAPS extended its technical assistance in mobilizing resources from the Global Fund and GOB funds in places where general prohibition of USAID funding applies. NTP has done renovation work, electrification (including

fans and lights), floor tiling and structural work, and other civil engineering work undertaken by the Public Works Department.

SIAPS has been working on strengthening TB patients' management and control through e-TB Manager (e-TBM) and strengthening logistics through the TB Logistics Management Information System (TB-LMIS). In January and February, three batches of training were conducted on e-TBM for 86 TB staff in Rajshahi and Sylhet City Corporation. SIAPS provided necessary logistics for these sites to get optimum TB data through electronic recording and reporting to cover the entire division and to address quick decision-making by regularly analyzing TB data. In this connection, BRAC have selected their staff to receive training on e-TBM for urban sites. SIAPS is going to organize a quarterly TB partners' coordination meeting and also is planning to observe World TB Day at the end of March. SIAPS visited 11 upazila health centers in four districts and two chest disease hospitals at two drug-resistant TB (DR-TB) sites to monitor the performance of the electronic recording and reporting system, as well as the feasibility of the sites to run the online system.

SIAPS, along with Challenge TB project, participated in the 12th International Congress on AIDS in Asia and the Pacific (ICAAP), March 12-14 in Bangladesh.

Partner contributions

- Director, CMSD allocated two rooms for SIAPS as a work station.
- SMC worked with SIAPS in the successful inauguration of the oxygen system at KSH.
- DGHS provided their own conference room for training purposes for at least three districts. Also, DGHS high officials from national, divisional, and district levels attended the training to inspire the store officials and staff to use the standard inventory tools.

Constraints to progress

- Desk officers, in-charges, and assistants do not all have the same level of understanding of procurement activities, causing some inconsistency in the execution of these activities.
- Turnover of procurement desk officers, the director, and other senior-level staff at CMSD is challenge to moving the huge numbers of procurement packages through CMSD/DGHS.

Objective 2: Systems for evidence-based decision making established

SIAPS conducted a system study and finalized the customization/configuration of an off-the shelf health information system (HIS) tool to fit into the KSH context. It is expected that the web-enabled HIS tool would be deployed for user acceptance testing at the end of April. This tool has the potential to improve real-time, patient-reported data for augmenting clinical decision making.

SIAPS consulted with all relevant parties, including GOB entities, to develop an asset management system. It was decided at a recent meeting at MOHFW that the system will initially capture two types of equipment (medical, office and IT equipment), and the draft version of the system would be presented to MOHFW and other stakeholders at the end of April 2016 for

gathering input and reaching consensus on the next steps. An asset management system is an integral part of the next sector-wide program, which is why donors are emphasizing it and they are relying on SIAPS to handle it.

SIAPS has configured the DGFP/Warehouse Improvement Management System (WIMS) tool to fit into TB central warehouse (CWH) context and deployed it for beta testing. The users have provided feedback, input, and recommendations for further incorporation into the system. It is planned to implement the final version of the desktop-based WIMS at the TB CWH in April 2016.

SIAPS has been working with Routine Health Information System (RHIS) team to design the logistics module in the RHIS platform. The logistics module, which is almost complete, includes building interoperability between the SCMP and RHIS platforms to exchange real-time logistics data. The logistics data for MNCH commodities are visible now in SCMP/DGHS eLMIS module; it has also been observed that the data quality (timeliness, accuracy, and completeness of submitted reports) has emerged as a critical issue, and the team is exploring ways to resolve it.

The SCMP data shows that approximately 83% (n = 488) of total sites maintained high data-quality standards (timeliness, completeness, and accuracy) in December 2015. It has also been observed that direct uploading of logistics data through UIMS to the web-based DGFP/eLMIS has also improved significantly (100% upazilas directly uploaded in January 2016 comparing to 97% in November 2014). After nationwide roll-out of SDP dashboard in June 2015, the stock-out rate for contraceptives at the SDP level is maintained at less than 2% (as of January 2016).

A capacity building assessment of SIAPS Bangladesh has been ongoing; the draft final report is being shared in-country and will be finalized by next quarter.

A pre-post analysis of these 20 districts' site performance since August 2015 showed the following:

- As of December 2015, 45,103 cases were entered into e-TBM against 50,836 cases registered on TB cards (Source: NTP MIS report, 2015 and e-TBM).
- The difference between paper-based and electronically generated reports decreased to 8.3% in the fourth quarter compared to 21.7% in the first quarter of 2015.
- The performance rate regarding data quality aspects (timeliness, completeness, accuracy) has improved by 26.8 percentage points between the first and fourth quarters of 2015.

The deputy director for MIS at DGHS issued a letter to the four districts concerned about entering data on priority MNCH medicines into the eLMIS using DHIS2 platform. In this connection, DGHS MIS has instructed Gazipur district's storekeepers and statisticians to enter the back log of data into the eLMIS and edit wherever necessary. SIAPS will work on the dashboard to share with the TWG for tracking MNCH priority medicines and the NTWG-NB at the next meeting on April 4, 2016.

SIAPS presented an abstract on "Saving Lives of Women and Children: Pharmaceutical Systems Strengthening to Improve Access to Contraceptives" in Bangladesh at the International FP

Conference in January 2016.

Partner contributions

WHO, NTP, BRAC, DGHS, DGFP, WB, UNFPA, Global Fund, JSI, Save the Children, Damien Foundation, etc. are working together in the TB, FP, and MNCH programs. The civil surgeons from four training districts provided instructions on entering data on priority MNCH medicines into the DHIS2 platform.

Constraints to progress

The NTP yet not taken full leadership for procurement supply management working group (PSMWG) meetings and e-TBM functioning.

Objective 3: Pharmaceutical regulatory systems strengthened

Implementation of the Bangladesh-specific Pharmadex is approaching its final phase of deployment in DGDA. To further build the capacity of DGDA and pharmaceutical companies, a user acceptance testing was provided in a two-day workshop held on February 8 and 9, 2016. The objective of the workshop was to demonstrate Pharmadex's intricacies and provide an opportunity for hands-on practice for the participants. On the first day, two representatives from 10 pharmaceutical companies were present; on the second day, 25 DGDA officials from all tiers of the directorate focused primarily on understanding the review process of medicine dossier that has been integrated into Pharmadex. The director general of DGDA was also present during the workshop, where he showed his commitment to SIAPS for operating Pharmadex in DGDA. In a separate meeting with the DGDA team on February 10, 2016, the director general demonstrated his ownership and made a decision to host Pharmadex on the DGHS server, thereby moving it from its current location on the MSH server, until the DGDA is able to develop its own data center. As a next step, SIAPS and DGDA will jointly develop an action matrix for the key activities that need to be done by April 30, 2016, for the deployment of Pharmadex as the official online registration system for DGDA.

The implementation of Pharmadex in DGDA serves as a platform for adoption of the harmonized international technical documents for registering medicines in Bangladesh. SIAPS has facilitated several trainings for DGDA officials to build their capacity on the CTD. A four-day training was facilitated on February 17–20, 2016. On day 1 of the training, 50 DGDA, district-based officers participated in an overview of the CTD, including acquainting them on the benefits and impact of adopting CTD-based dossiers. During the next three days, 65 participants (40 representatives from pharmaceutical companies and 25 Dhaka-based DGDA officials) focused on a comprehensive training program on the CTD from the regulatory and applicants' perspectives. The training program was well received by the trainees based on the pre- and post-assessment reports. To sustain the activity and design a capacity development plan for Bangladesh, 15 representatives from the DGDA and pharmaceutical companies were identified and designated as the master trainers for the CTD, and the first orientation meeting was facilitated for the team on February 22, 2016, on how to become future trainers on the CTD.

On February 23, 2016, at the initiative of the director general, the executives of the top 40 pharmaceutical companies were invited for a dialog session in the DGDA office. SIAPS made a presentation and provided the background on Pharmadex, the CTD, and the benefits to users and DGDA. The director general reiterated his commitment and emphasized to start this new initiative and process. There were positive responses from the majority of the executives and they supported implementation of Pharmadex and adoption of CTD-based dossiers for registering medicines. The managing director of Square Pharmaceuticals, the largest in Bangladesh with approximately 60% of the market share, commented that "online registration is a unique opportunity and is about time that CTD-based dossiers proceed in Bangladesh." The group identified some key points and suggestions on how DGDA can proceed, with the continued technical assistance of SIAPS. As a follow-up, the director general will issue an official letter and a time frame to the manufacturers on when the new registration process will commence. In addition, SIAPS will develop concrete steps and timelines for this activity.

Partner contributions

DGDA selected the participants and organized the entire training. The director generals' initiated coordination with the Bangladesh Association of Pharmaceuticals Industries to move forward with this activity.

Constraints to progress

- The DGDA did not allow sufficient time for the CTD training, which was evident as some of the trainees complained about insufficient time
- Continuous challenge with the senior managers of DGDA on computer usage, including knowledge and skills

Benin Ebola Portfolio

Goal: To ensure the availability, accessibility, and rational use of effective, safe, and high-quality Ebola-related medicines and equipment at affordable prices by strengthening the national pharmaceutical management system

Overall Quarter Progress

SIAPS provided technical assistance to national stakeholders in Benin to identify key issues affecting supply chain management for Ebola and other hemorrhagic fevers during an outbreak of Lassa fever in Benin. SIAPS and national stakeholders have identified a list of activities to be implemented in the short and medium term to improve the Ebola supply chain.

SIAPS provided technical assistance to the Pharmacy and Medicine Department (DPMED) of the Ministry of Health and SIAPS to prepare upcoming quantification of Ebola commodities.

Objective 1. Enhance capacity of Benin MOH for effective pharmaceutical system management

The SIAPS Regional Project Director travelled to Benin to meet with stakeholders engaged in the Ebola response. The Regional Project Director discussed SIAPS technical assistance to strengthen supply chain management for commodities related to Ebola and other hemorrhagic fevers, as recommended by USAID. This trip had been urgently requested by USAID/Benin since Benin was facing an outbreak of Lassa fever, a hemorrhagic fever similar to Ebola. Representatives from SIAPS met with three subcommittees where supply chain activities are embedded: the subcommittee of epidemiological surveillance and management of laboratory diagnosis; the subcommittee on medical care, physiology, and infection control; and the subcommittee on resources mobilization, logistics, and financial management. The three subcommittees are set within the Ebola response committee put in place by the government of Benin.

SIAPS discussed with subcommittees about supply chain issues and identified critical interventions required to strengthen supply chain management of Ebola and other hemorrhagic fever related health products. As a result, stakeholders agreed on list of interventions proposed by SIAPS to support Ebola supply chain management, such as the establishment of list of Ebola and other hemorrhagic fever products, capacity building in the quantification of products for Ebola and other hemorrhagic fevers, and support to storage, distribution and logistics management information system of those products.

These meetings with Ebola subcommittees also helped to identify potential members of the national quantification committee for Ebola commodities, including national stakeholders, and representatives from the Ministry of Health and its partners. SIAPS and the Pharmacy and Medicine Department of the Ministry of Health also agreed on pairing exercises for quantification capacity building and the quantification of Ebola commodities.

Burundi

Goal: Contribute to a 75 % reduction in malaria-related morbidity and mortality in Burundi by 2017.

Overall Quarter Progress

Civil unrest in Burundi has created challenges for ensuring access to donor funding. While the unrest subsided over the course of the quarter, the country's economy does not currently allow access to foreign currencies, including US dollars. The government no longer has access to direct financial support from several donors, including the European Union. This may affect security of malaria commodities that are not directly procured by donors or implementing partners, as well as international trips of health managers.

SIAPS continued to support the Ministry of Health (MOH) through the National Malaria Control Program (PNILP), the Department of Pharmacy, Medicines and Laboratories (DPML), the Central Medical Store (Centrale d'Achat des Medicaments Essentiels au Burundi, CAMEBU), and health districts to fight malaria. The quarter was marked by a sizable rise in malaria cases in 18 health districts, located mainly in the north of the country. SIAPS assisted the PNILP in responding to this emergency by supporting mobile clinics in highly affected communities to allow easier access to services by all patients—women, men and children—to limit deaths due to malaria.

To strengthen governance and leadership, SIAPS supported the PNILP and DMPL in the development of annual reports for 2015 and annual work plans for 2016. Key achievements in pharmaceutical governance included the nomination of the quantification committee and the endorsement of the terms of reference, which were developed through collaboration of SIAPS and SCMS. The committee will support quantification, capacity building, logistics, and information management. The committee has already assisted the PNILP in reviewing quantification and supply plans, and identifying gaps in commodities security to respond effectively to the escalation of malaria cases.

SIAPS assisted the PNILP, CAMEBU and DPML in conducting data collection and analyses activities. The PNILP implemented the End Use Verification (EUV) survey with SIAPS technical and financial assistance. EUV reports will be available in the beginning of April 2016. SIAPS assisted the DPML in conducting a baseline study before the implementation of newly approved harmonized LMIS tools. Analysis and report writing is in progress. SIAPS helped the PNILP and CAMEBU analyze stock status levels of malaria commodities at the central medical store/CAMEBU and produce the procurement planning and monitoring reports for malaria commodities (PPMRm).

SIAPS collaborated with SCMS to assist the DPML in conducting a training for trainers, district managers, and health facility managers on new LMIS tools. To date, 35% of the targeted FY16 trainees have been trained in the LMIS tools.

To strengthen malaria services, SIAPS continued to assist the PNILP and Programme National

de Santé de la Reproduction/National Reproductive Health Program (PNSR) in implementing the Intermittent Preventive Treatment in Pregnancy (IPTp) strategy and the Integrated Community Case Management of Child Diseases (iCCM) policy. During the quarter, SIAPS assisted in training 442 health care providers from six health provinces on the implementation of IPTp policy. SIAPS plans to assist in 13 health provinces during FY16. Furthermore, SIAPS assisted the PNILP and Directorate for the Supply and Demand of Health Services (DODS) to implement iCCM in three health districts, focusing on malaria. Thus far, 121 Community Health Workers (CHWs) have been trained in two health districts. SIAPS plans to assist in five health districts during FY16.

SIAPS assisted the PNILP in implementing malaria prevention behavior change communication (BCC) through CHWs. During the quarter, SIAPS assisted in training 340 trainers, who will train CHWs on BCC for malaria prevention. The CHWs will in turn promote strategic malaria prevention measures in their communities.

Objective 1: Leadership and governance for key institutions (PNILP, DPML, CAMEBU, and districts) improved

SIAPS assisted the PNILP in developing the annual activity report for 2015 and work plan for 2016 through two workshops conducted with SIAPS assistance. The work plan will guide malaria activities for 2016, and serves as a basis for quarterly and annual evaluations. SIAPS supported the keys institutions (PNILP and DPML) by providing IT equipment, including six laptops, nine power back-up stabilizers and two printers to DPML, as well as 12 laptops and four power stabilizers to PNILP. This equipment will contribute to improved operational capacities of these key institutions in fighting malaria.

Partner contributions

None

Constraints to progress

None

Objective 2: An uninterrupted supply chain mechanism for malaria commodities is in place

To increase capacity for commodities quantification, SIAPS is assisting the MOH and partners to create a National Commodity Security Committee, which will help ensure optimal supply of commodities to meet the country's goals for priority public health programs, including the malaria program. This quarter, the MOH nominated the members of the committee and endorsed the terms of reference, developed with technical support from SIAPS, in collaboration with SCMS. Its work will focus on supply availability issues related to quantification and procurement, personnel training, logistics management information systems (LMIS), and inventory control. With the support of SIAPS through a three-day workshop, the newly nominated committee assisted the PNILP in reviewing quantification, analyzing and updating

supply plans, and analyzing gaps in malaria commodities following the rise in malaria cases noticed in January 2016. The committee found a gap of 40% in ACT and rapid diagnostic tests (RDT) needs due to the rise of malaria.

Regarding procurement and distribution, SIAPS assisted the PNILP to facilitate the delivery of 1,250,000 RDTs and 1,401,737 blisters of ACT in-country, purchased by the President's Malaria Initiative (PMI). SIAPS assisted the PNILP and CAMEBU in distributing malaria commodities from the central store to the 46 health districts by assisting districts to estimate monthly needs based on monthly distribution reports, and communicating CAMEBU's distribution calendar.

SIAPS assisted CAMEBU, PNILP and DPML in collecting and analyzing data for decision making, and helped the PNILP to implement an EUV survey. Data collection is complete, and report writing is ongoing and will be available in the third week of April. SIAPS also collaborated with SCMS to assist the DPML in conducting a baseline study prior to the implementation of the newly approved LMIS manuals and tools, and report writing is ongoing. SIAPS assisted CAMEBU and PNILP to assess monthly stock levels for malaria commodities at CAMEBU, and results of this analysis have been shared with stakeholders, including Global Fund (GF), UNICEF, PMI and the Permanent Executive Secretariat-National AIDS Control Commission (Secretariat Exécutif Permanent-Commission Nationale de Lutte contre le Sida, SEP- CNLS). Main recommendations included speeding up the GF delivery of 360,000 ACT treatments for children 6-13 years, which has been stocked out at CAMEBU since mid-January 2016. This formulation was delivered in late February 2016. Another key recommendation was to review the malaria commodity quantification produced by the Quantification Committee, and help the malaria program identify gaps, particularly for ACTs and RDTs due to the rise of malaria in the country. SIAPS used the results of monthly stock status analyses from the previous quarter for malaria commodities at CAMEBU to develop the PPMRm for January 2016.

To build human resources capacity, SIAPS collaborated with SCMS to assist the DPML in finalizing training materials for the LMIS manual and tools approved in February 2015. The work led to the development of two guides: one for trainers and the other for participants. SIAPS and SCMS assisted the DPML in training 19 trainers at the central level, 26 at the district level, and 114 health providers at health facility level. LMIS training will cover approximately 425 persons including trainers for both SCMS and SIAPS from four health provinces. More than 35% target participants have been trained. In preparation for the EUV survey, SIAPS trained 23 staff from key institutions in EUV methodology and tools in a four-day seminar to ensure quality data collection and entry. These participants served as data collectors and data entry clerks for the survey. The training seminar included a session on gender analysis to increase participants' sensitivity on gender issues in relation to the demand, access and use of malaria commodities and services.

Partner contributions

None

Constraints to progress

The rise of malaria cases in the country led to the implementation of emergency actions, including mobile clinics, to treat patients in communities. The EUV previously planned in January was postponed to February as most data collectors were involved in implementing the emergency response to limit the rise of malaria cases and deaths. The surge in malaria cases posed a pressure on the supply chain, resulting in stock out of ACT for children aged 6 to 13 years. SIAPS assisted the PNILP in informing health providers on alternative use of AS-AQ 100/270 mg with adapted dosage for both adolescents and adults while waiting for the next GF shipment by UNICEF.

Objective 3: Pharmaceutical services are improved to ensure best practices in malaria case management

SIAPS supports the PNILP and PNSR in scaling up IPTp with sulfadoxine-pyrimethamine (SP). This quarter, SIAPS supported the PNILP and PNSR to train 40 trainers from three health provinces (Bururi, Mwaro and Makamba) on IPTp policy. Of those trained, 18% were women. With SIAPS support, these trainers assisted the PNILP and PNSR to train 442 healthcare providers to implement the IPTp policy. To date, six health provinces comprised of 12 health districts have been trained out of 13 provinces planned for FY16.

SIAPS assisted the PNILP and PNSR in conducting sensitization seminars to inform local administration on the implementation of IPTp. In all, 326 local administration agents located in the trained six health provinces have been sensitized. The sensitization aimed at seeking ownership of the policy by local leaders, who will contribute to relaying information to communities and generating demand for health center-based IPTp services among women and families in their areas.

SIAPS assisted the PNILP and DODS to validate the iCCM training module and train 17 trainers of the central level, comprising seven women; on training techniques and iCCM policy focusing on community case management of malaria. Central trainers helped in training 45 trainers at the province and district levels. Among trained province and district persons, 24% are women. During the quarter under review, trained province and district level trainers assisted in training 56 trainers at health center level, 20% being women. To date, 121 CHW of two health districts (Bubanza and Mpanda) have been trained on iCCM focusing on malaria community case management. Trained CHW have been provided with necessary equipment and materials to start treating malaria since March 2016.

SIAPS assisted the newly created communication unit within the PNILP to validate a malaria communication guide and train 30 central-level trainers, 20% being women. The guide explains appropriate communication methods and key messages on malaria prevention to be transmitted to the population. During the quarter, SIAPS supported the PNILP to train 340 trainers on malaria prevention communication guidelines, methods and messages. Overall 26% of participants were women. Trainers will assist in training CHWs on awareness raising, sensitization techniques and malaria prevention communication. CHWs will in turn sensitize populations in their catchment areas on malaria, to change attitudes and adopt positive behaviors to prevent malaria.

SIAPS assisted the MOH in responding to the rise of malaria cases by supporting mobile clinics organized to treat malaria cases in communities across 18 affected health districts. Teams of health care providers reached patients in their communities, which allow easier access to malaria services by all patients.

Partner contributions

CARITAS contributed facilitation expertise and logistics aspects of iCCM trainings

Constraints to progress

None

Cameroon

Goal: Assure availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

Overall Quarter Progress

The MOH and the Global Fund have signed the HIV grant that will cover 2016 and 2017. As a consequence, SIAPS was called to assist the HIV program to ensure that limited access to HIV commodities will not impede the Acceleration Plan to reach 257,000 patients on treatment by the end of 2017. Specifically, SIAPS assisted in designing a new distribution strategy to optimize the storage space available at the regional and central levels and conceptualizing the first approach to distribute antiretroviral medicines (ARVs) through some retail pharmacies in the private sector.

Also, during this quarter, PEPFAR launched the new policy to guide the planning of the next country operational plan, COP 16. Some elements of the policy, such as dispensing multiple-months of ARV supplies to clinically stable patients, requires rethinking dispensing and reporting systems, and therefore SIAPS assisted USAID in planning for new interventions to strengthen supply systems and pharmacy services to support the PEPFAR strategy.

SIAPS was also called to play a leading role in proposing actions to strengthen the pharmaceutical system for the Global Financing Facility (GFF) investment case to be submitted to the World Bank. Several discussions were engaged with representatives of the World Bank, members of the Medicines Cluster, and the government to identify key strategic areas of work.

Finally, the Electronic Logistics Management Information System (eLMIS) is a multiple-partnership project to improve the LMIS at central and regional levels, through the harmonization of software and development of a dashboard for data analysis. SIAPS has been involved in this project, led mainly by UNFPA and the Clinton Health Access Initiative (CHAI) since 2012. During this quarter, SIAPS assisted with the coordination of this project to mitigate the risks created by the absence of the focal point at UNFPA, who has not yet been replaced. SIAPS reported on the progress of the committee to the technical and financial national and international partners, and also provided guidance to the Directorate of Pharmacy to align with different donors' requirements.

At the peripheral level, stock-outs at the facility level continued to decrease from 28% in Q1 to 23% in Q2. Stock-outs during this quarter were mostly attributed to issues managing the transition from the second-line HIV product lopinavir/ritonavir, which is no longer being procured, to atazanavir/ritonavir which is currently the preferred option. The capacity of health facilities to maintain stock levels within the minimum and maximum levels remained challenging, but improved from 29% in Q1 to 37% in Q2. Different factors affect this indicator in health facilities and regions, the most frequent being low storage capacity of health facilities, bottlenecks in the requisition approval process, and the tendency to overstock because of the fear of future possible shortages. Maintenance of updated records and on-time reporting showed good progress, with indicators approaching life-of-project targets. For example, in one year, the

percentage of stock records that corresponded to physical counts has improved from 48% to 88%.

The first shipments of PEPFAR-funded PMTCT commodities arrived at the four PEPFAR-supported regional medical stores at the end of December 2015, adding to the existing Global Fund and Government contributions. Distribution to PMTCT sites was organized and partially implemented during this quarter. Some difficulties encountered were the mismatch between the list of health facilities that should provide PMTCT B+ services and the list of health facilities that have actually started implementing Option B+. This is possibly related to the delay of programmatic activities waiting for Global Fund grant signature. But also, there is discrepancy between the list of health facilities that should implement PMTCT Option B+ and the list of facilities that are clients of the regional medical stores; for the Littoral regions, this difference is very significant (150 health facilities that are clients of the regional medical stores versus 500 PMTCT sites needing commodities). This situation creates a significant additional burden for the regional medical stores that need to expand distribution beyond their normal mandate.

Implementation of the new strategy to update the OSPSIDA web-based dashboard by using civil society organizations and associations of people living with HIV and AIDS to assist with data entry also showed good results. In this quarter, 98% of the last six months of health-facility reports are complete in the system. Also, the timeliness in completing health facility reports significantly improved from 9% in Q1 to 58% in Q2. However, timely completion of reports for the regional warehouses was still dragging, at 17% in Q2. This low result was partly attributed to the need to catch up from previous delays.

Objective 1: Pharmaceutical sector governance strengthened

For PY 5, SIAPS Cameroon aimed to improve pharmaceutical governance and transparency through three levels of intervention: first, by seeking strategic collaboration among national and international partners through the SIAPS-led Medicine Cluster and SIAPS support to other committees such as the PMTCT Task Force, the LMIS Committee, and the Regional Funds for Health Promotion (RFHP) Partners Committee; second, by improving the efficiency of the Quantification and Stock Monitoring Committee by standardizing reports as per donor and partner requirements (though this committee continues to face leadership and governance issues); third, by enhancing collaboration with the civil society organization Positive Generation (PG) to improve data quality of its *Treatment Access Watch* magazine and enhance the joint analysis of indicators.

The revitalization of the HIV Quantification and Stock Monitoring Committee is not progressing as effectively as wished, but thanks to the efforts of the permanent secretary of the HIV program, the committee finally met this quarter. SIAPS facilitated discussions on improving the efficacy of the committee, and members agreed on the need for sessions to jointly adopt a revised data analysis methodology with predefined performance indicators. The potential use of OSPSIDA reports was to be presented during the March session of the committee, but was postponed due to a series of PEPFAR and Global Fund visits.

As part of the activities carried out by the Medicines Cluster, SIAPS worked closely with Expertise France to propose an intervention to be integrated into the GFF investment case to improve governance across the four most important pharmacy institutions in Cameroon, which are the Directorate of Pharmaceutical Inspection, Directorate of Pharmacy, Quality Control National Laboratory (LANACOME), and Central Medical Stores (CENAME). The proposed approach intends to seek complementarity between the Performance-Based Financing (PBF) Project and the new GFF, both financed by the World Bank, by using an adapted PBF model in which the four institutions would collaborate and be accountable to some common indicators with the objective of improving quality and access to mother and child life-saving medicines.

SIAPS also provided significant support to the eLMIS Committee which coordinates the financial contribution of different partners for the implementation of a national and regional eLMIS. Until December 2015, UNFPA and CHAI had coordinated the committee and supported the Directorate of Pharmacy in this activity. However, the focal persons left, and financial and technical coordination remained challenging. SIAPS therefore took a leading role in informing and alerting the different partners of immediate actions to be taken, including establishing adequate mechanisms to ensure that funding gaps currently secured through the Global Fund grant are disbursed in a timely manner. Partners agreed that the coordination of this committee will continue under UNFPA, with a new assigned person who arrived in March 2016 who will ensure execution and coordination of the activities budgeted under the Global Fund grant.

SIAPS and PG conducted a joint analysis of the overall stock-out situation of HIV and TB commodities and compliance with price policies in PEPFAR-supported versus non-supported regions. Interestingly, stocks-outs of most health commodities were consistently higher in non-PEPFAR regions than in PEPFAR regions. In relation to compliance with price policies, overall over-fees were significantly higher in PEPFAR regions than in non-PEPFAR regions. During this exercise, the SIAPS M&E adviser noted some weaknesses and challenges with the methodology used by PG for compilation and analysis of data. Therefore, SIAPS supported PG in redesigning the data collection and also started recruitment of a consultant to help design an automated dashboard that will permit quick visual analysis.

Constraints to progress

Despite the permanent secretary's acknowledgement of the need to have a functional HIV Quantification and Stock Monitoring Committee, leadership and accountability of the assigned focal point staff remain the major barrier.

Objective 3: Use of information for decision making

In PY5, SIAPS Cameroon is implementing activities to improve the capacity of health facilities and regional institutions to improve management of HIV commodities with the use of available records and reported information. This is conducted through supervision and on-site training for dispensers and stock keepers at the health facilities and also through regional meetings for ART and PMTCT clinic coordinators and regional managers. Data and information are captured through routine reports and during supervision visits. In addition, this objective also includes

activities to improve timeliness and accuracy of the information reported in OSPSIDA for the four PEPFAR-supported regions.

The presence of regional technical advisers deployed to the four regional medical stores continues to be a successful strategy to improve management capacity at the regional and health-facility levels. At health facilities, 88% of the stock records verified during the supervision visits corresponded with the physical counts, which was a significant improvement from the last quarter (82%) and the last 12 months (42%). In the South West, all 15 health facilities supervised are updating stock cards daily, and in 10 facilities, the ART site coordinators conducted regular internal supervision of the pharmaceutical services. Overall, health facilities maintain high results on reporting, with 70% reporting on time (63% in Q1) and 89% of sites keeping complete patient information (87% in Q1).

The use of logistics records and improvements in reporting seemed to have a positive effect on reducing stock-outs, with 23% of health facilities experiencing stock-outs in Q2 compared to 28% in Q1. Stock-outs this quarter were mainly attributed to the shortage of lopinavir/ritoravir adult formulations at the central level, which the National HIV Program intentionally replaced with atazanavir/ritonavir and which was available for distribution. However, the lack of communication between the central and peripheral levels did not allow prescribers to change patients to atazanavir/ritonavir in an organized manner, thus maintaining the demand on the old regimen and creating a stock-out. In addition, shortages of lopinavir/ritonavir pediatric formulations were also reported, due to the late deliveries of both pellets from PEPFAR and syrup formulations from the Global Fund, attributed to manufacturers' lack of production capacity.

However, maintaining stock levels within the minimum and maximum agreed values remained problematic at the regional (44% in Q2, 37% in Q1) and facility (29% in Q1 and 33% in Q2) levels. One limiting factor is the inefficient distribution system from the central medical stores to the regions. The Central Region reported a two-month lead time for an order placed in December. In addition, quantities approved by the National HIV Program for distribution to the regions often differ from requisitions. This especially affects rapid test kits, where apparently the problem is the discrepancy between the numbers of reported patients tested and quantities of tests distributed. At the health facilities, quantities distributed were also constrained by the limited stock at the regional level and the need for preapproval by the Regional HIV Program Delegation. Under these circumstances, health facilities tend to request quantities beyond the recommended maximum level, because of the fear of future shortages.

SIAPS engaged in several discussions with the National HIV Program to explore the possibility of revising roles and responsibilities of the Regional HIV Program Delegation and regional medical store and, to the extent possible, make the stores fully accountable for storage and distribution of HIV commodities, as for any other health commodities. Health facilities would therefore order directly from the regional stores, and regional stores would report monthly on quantities distributed to the Regional HIV Program Delegation.

In the implementation of OSPSIDA, using civil society organizations for data entry in the Center and Littoral regions was very satisfactory. The experience of PG in the Center was used to make

a similar arrangement with SunAIDS in the Littoral, which is an association of people living with HIV and AIDS. Both satisfactorily completed data entry every month. In the NW and SW regions, the Regional HIV Program is able to enter the data successfully, because of the lower number of sites and therefore fewer patients. For OSPSIDA, SIAPS wants to keep up with data entry such that, at any given moment, at least 85% of the past six months of reports can be consulted online, which represents a sufficient sample of data for decision making. For this quarter, the availability of the past six months of facility data was 98%. The level of timely completion of stock data at the warehouse level (regional and central) is still challenging. Therefore, PG and SunAIDS agreed to complete these reports in their respective regions.

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

Under this objective, SIAPS Cameroon PY5 reports on contributions that are made to strengthen the capacity of the National HIV Program deal with pharmaceutical challenges that hamper access to Global Fund or other donors' funds.

As previously indicated, the New Funding Model Grant for HIV and TB for the implementation period of 2016 and 2017 was finally signed during this quarter after a long process. The first concept note was submitted in October 2014, and after rejection, a second concept note was finally submitted in May 2015. Grant signing was expected in December 2015, but took place in March 2016. During this time, the HIV program was run with limited funding, and therefore the program needs to accelerate programmatic activities to attain the targets set for 2016 and 2017. This new grant has some elements intended to strengthen the pharmaceutical system under the health systems strengthening element, which were integrated with the contribution of SIAPS. These elements include some equipment and rental of storage space for CENAME, rental of storage space for the Central Region, funding for recruiting regional supply advisors in non-PEPFAR regions, and the budget needed to cover the gap for implementing eLMIS. All these interventions were selected under the principles of complementarity and synergy with other donors including PEPFAR, and also with the intent to address bottlenecks in the HIV program that could hamper implementation of the grant.

Constraints to progress

- The use of the CENAME fund for equipment and rental is conditional on the organizational audit that the Government of Cameroun was to conduct in 2015. However, there is little indication that this audit will take place soon.
- Some of the elements of technical assistance, such as rental of spaces or payment for services in implementing eLMIS, could be hampered by the public procurement procedures that must be followed. Discussions with UNFPA are on-going to find alternative solutions.
- Recruiting regional supply advisors will not be enough to improve the supply system if these new staff is not adequately coached, and there is not a system to improve consistency across regions. SIAPS has brought this challenge to the attention of the Global Fund and other international partners to find adequate solutions.

Objective 5: Pharmaceutical services improved to achieve desired health outcomes

For PY 5, this objective includes activities to ensure efficient distribution of PEPFAR-funded commodities to the regional medical stores and to ART and PMTCT sites. In addition, SIAPS assists the German Development Agency (GIZ) and national partners in an on-going initiative to standardize the procedures manual of the regional medical stores. Although the consultants leading this process were funded by GIZ, SIAPS provides technical oversight to ensure quality of the chapters related to procurement, warehousing, and distribution of health products.

During this quarter, SIAPS implemented the distribution strategy for ARVs to PMTCT sites, in the four PEPFAR-supported regions, as approved in the work plan and aligned with Government and PEPFAR strategies. The Ministerial Decision of November 13, 2014, describes the progressive implementation of Option B+ in health facilities to reach full coverage at the end of 2016. Then, the PEPFAR strategy in Cameroon defines the different packages of technical assistance according to the definition of scaling-up, sustained, and transition-out sites.

SIAPS provides technical assistance to 45 scale-up sites and 87 sustained sites in the four regions for a total of 132 sites. However, SIAPS needs to ensure distribution to at least an additional 617 PMTCT Option B+ sustained sites. The 132 sites receiving SIAPS support have been capacitated to quantify their own needs and use the normal requisition system for ARVs. SIAPS, during the supervision visits and through phone calls, monitors the stock levels of these health facilities and implements corrective actions for identified problems.

However, for low-volume sites, (less than 10 HIV-positive pregnant women per year) SIAPS' coordinated efforts with regional and district authorities to pre-position PMTCT commodities in each of the health facilities. This strategy intends to reduce the likelihood that these women diagnosed in clinics with low HIV prevalence will not be able to access treatment because of the unavailability of products in the pharmacy. Stock monitoring of ARVs at these health facilities would be conducted only once or twice per year. In the SW and NW regions, many health facilities received the PMTCT commodities integrated in the quarterly distribution plans of essential medicines. However, during the exercise, SIAPS found that hundreds of low-volume PMTCT sites especially in the Center and Littoral regions, were not clients of the regional medical stores, thus requiring a different approach. The focal points of PMTCT sites were therefore called to pick-up their products at the health district offices of more than 40 districts, on an agreed date. The main principles of Option B+ implementation were re-discussed, and health facilities signed reception of their products. By the time this report was submitted, approximately 65% of the low-volume health facilities had collected their products.

In relation to the RFHP procedures manual, several delays caused by administrative procedures at the national level were compromising SIAPS's capacity to guide review of the chapters on procurement, storage, and distribution of pharmaceuticals. As such, SIAPS has moved forward with these chapters, which will be handed over to the GIZ consultants to be integrated with the rest of the procedures manual. The exercise is well advanced and will likely be concluded by the end of April 2016.

In addition to these activities, SIAPS was called by the HIV program to assist in defining a new distribution plan for PEPFAR and non-PEPFAR regions that would consider direct distribution to the regional medical stores, similar to the delivery strategy implemented by SCMS and SIAPS in the four PEPFAR regions. SIAPS conducted an analysis of the storage capacity at CENAME and at the ten regions in view of the expected volume of patients by the end of 2017. SIAPS proposed direct distribution to seven of the ten regional stores, plus CENAME. The detailed plan will be discussed with the Minister of Health and the different warehouses.

Also, in light of the new PEPFAR recommendations for dispensing multiple-month supplies of ARVs to clinically stable patients, SIAPS is being consulted on the possibility of quickly moving in that direction. If implemented through a staggered approach, this strategy can significantly contribute to decreasing the number of patients refilling their medications every day, thus improving the quality of service at the dispensing point. However, if the transition is done too quickly, the work load at the dispensing point could be unevenly distributed creating congestion of patients at certain months or weeks, which will be difficult to realign afterward. Another challenge is that, when using the current registers, health facilities would have difficulty reporting patients on treatment since they would not be refilling their prescriptions at the pharmacy every month. SIAPS is therefore engaging in discussions with the HIV program to develop some quick guidelines for health facilities willing to implement multiple-month supplies of ARVs.

Finally, SIAPS has also been called upon to start discussions about the possibility of dispensing ARVs through the private sector and through the community, as additional interventions that would decrease the workload at HIV clinics and that could also improve patients' adherence. SIAPS elaborated in a concept note on the strategy for distribution of health commodities in the private sector for the HIV program. In addition, SIAPS has taken the lead in mapping out the different activities that NGOs and community-based associations are already implementing for ARV dispensing.

Constraints to progress

- The next deliveries of PMTCT and pediatric treatments funded by PEPFAR through SCMS were supposed to arrive in the country at the end of March, although there seems to be some delays.
- Also, the expected new pediatric formulation of lopinavir/ritonavir pellets seemed to have some delays at the manufacturer, and the delivery expected for February did not arrive during this quarter, which has created additional stock tensions.
- Both the HIV program and PEPFAR are pushing to implement the new distribution and service delivery strategies which had not yet been defined during the elaboration of this PY5. Given the urgency of attaining targets and catching up with program delays, the work plan needs to be adapted to these additional activities which in principle should be part of the next implementation year. The current human and financial resources are being stretched to accommodate new demands.

Democratic Republic of the Congo

Goal: Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

Overall Quarter Progress

During this quarter, SIAPS continued to provide technical and financial support to the MOH to improve pharmaceutical governance, ensure individual and institutional capacity-building, strengthen the information system for informed decision-making, enforce control measures and find new financing mechanisms to improve access to pharmaceuticals, and improve pharmaceutical care provision at the point of care. Apart from the routine activities implemented this quarter, SIAPS had a special focus on PEPFAR activities in the Haut-Katanga province.

As mandated by USAID/DRC, SIAPS assisted the CAMELU, the Haut-Katanga Regional Distribution Warehouse (CDR) to manage and distribute ARVs at ART sites under USAID/PEPFAR in saturation health zones in the Haut-Katanga province and also in maintenance health zones in Lwalaba province.

The rational medicines use study conducted in December 2015 was finalized during this quarter. Two more hospitals from Tshopo/Province Oriental were added to the study for a total of 10 referral hospitals (five with Drug and Therapeutic Committees [DTCs] and five without). The technical study report is being compiled; the key findings are included below.

SIAPS conducted the first end user verification (EUV) survey for 2016.

SIAPS conducted a baseline study and situation analysis in Haut Katanga province on the availability and management of ARV drugs.

Objective 1: Pharmaceutical sector governance strengthened

In January 2016, SIAPS supported the Drug Regulatory Authority (DRA) to hold the quarterly registration session in which 263 dossiers were received and 251 were analyzed. Of those analyzed, 69 (27.4%) were registered and authorized, 176 (70.1%) did not have sufficient information to complete registration, 12 (4.6%) were deferred to next session because of time constraints, and 6 (2.4%) were rejected. This brings the total number of registered medicines in DRC to 4,419, up from approximately 400 in 2011 at the beginning of SIAPS.

The register of authorized medicines currently comprises 3,027 products, as 1,392 were deregistered because of the expiration of their marketing authorizations.

From February 26-27, 2016, in Kinshasa, SIAPS supported the MOH to hold a two-day workshop of technical and financial partners (TFPs) of the National Medicine Committee. The workshop aimed to evaluate each TFP's respective contributions to the DRC annual medicines plan for 2016. The workshop produced a nationwide medicine distribution map that will allow adequate allocation of commodities across the country.

Following DRC's recent restructuring of the health provinces, SIAPS continued to support the MOH in establishing Provincial Medicine Committees (CPMs) in newly established provincial health divisions (DPSs). The CPMs plays a critical role in coordinating medicine provision, distribution, and use among all the MOH partners. During this quarter, SIAPS supported the establishment of CPMs in three new provinces (Mweneditu, Kamina, and Kalemie).

Partner contributions

- WHO, UNICEF, UNFPA

Constraints to progress

- Newly created provinces lack resources, thereby making it difficult to establish their CPMs.

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

During January 18-21, 2016, SIAPS and the National Program for Medicines Procurement (PNAM) held a joint training for the management teams of 11 health zones in the province of Kolwezi. The training aimed to build the technical capacities of senior staff from the Provincial Health Division, Regional Distribution Warehouse (CDR), and health zone management team (Equipe Cadre de la Zone de Santé, ECZ) to manage medicines; 40 stakeholders participated in the training including 32 men and 8 women.

After the training, a post-training action plan was developed by participants and was validated by the Provincial Health Division. The same training is scheduled for March 21-25 in Lubumbashi in the province Haut Katanga.

During this quarter, SIAPS also supported the MOH to incorporate the 13 life-saving medicines for women and children into the 2016-2020 National Health Development Plan (PNDS). A total of 20 experts from various international organizations, USAID implementing partners, and the MOH participated in the workshop. During this session, the following changes were made to the PNDS related to the 13 medicines:

- Guarantee universal access to products that are vital to maternal, newborn, and child health while ensuring their quality and rational use.
- Improve the quality of services and care provided to the population, particularly for mothers and children
- Guarantee the availability of medicines in health facilities as per UNCoLSC recommendations

SIAPS provided technical and financial support to the National Tuberculosis Program (NTP) warehouse at the central level. SIAPS helped conduct a physical inventory, properly classify medicines, and identify current stock available and stock at risk of expiry to improve management and storage conditions of TB medicines.

Using the stock data obtained from the physical inventory, SIAPS, working in partnership with the NTP and CARTITAS (Global Fund principal recipient), conducted a quantification of first- and second-line TB medicines for 2016.

From February 27 to March 5, 2016, SIAPS also supported the supervision of health workers in Kasaï Oriental health zones; 15 sites, consisting of 12 health facilities and 3 Health Zone Central Office (Bureau Central de la Zone Santé, BCZS) warehouses were visited and 37 health workers (12 women and 25 men) were supervised. The supervision focused on malaria case management and antimalarial medicines management.

Partner contributions

- PNAM WHO, UNICEF, Clinton Foundation, PSI, and IHPPlus: Incorporation of the 13 life-saving medicines for women and children into the PNDS
- CARITAS (Global Fund principal recipient) and UNION: Quantification of first- and second-line TB medicines for 2016

Constraints to progress

- Logistical constraints

Objective 3: Utilization of information for decision making increased

As part of its work to strengthen the Logistics Management Information System (LMIS), SIAPS piloted the pharmaceutical management component of DHIS 2.0 in South Kivu and Mwene Ditu. Following the results of the pilot phase, SIAPS will continue working with the developers to optimize the module.

With SIAPS financial and technical support, the National Reproductive Health Program (Program National de la Santé de la Reproduction, PNSR) held a meeting to validate PPMRc data on contraceptives use and distribution; 27 participants attended the meeting including 17 women. The meeting participants recommended the validation of data at each level of coordination before submission to the national level.

In March, SIAPS began collecting data for the first EUV survey of 2016. As with previous EUVs, SIAPS is again working closely with PNLP. However, in contrast to past surveys which included PMI-supported facilities only, the current EUV also includes Global Fund-supported facilities. The findings of the EUV will be available next quarter.

In the previous quarter, SIAPS conducted a baseline study and situational analysis on the availability and management of ARVs at PEPFAR-supported ART sites in the Katanga province. The results of the baseline study were finalized during the current quarter. Of note, the study revealed that 54% of facilities (ART sites) had a shortage of at least one tracer ARV in the three months previous to the survey and only 14% of orders were completely and accurately filled. The study also revealed that 15 ART regimens are used and adherence to the national ART guidelines is low.

Partner contributions

- CHAI, IMA, UNDP, UNFPA, PSI, ABEF-ND

Constraints to progress

- Using the pharmaceutical management component of DHIS 2.0 in its current state to make decisions will be difficult because of inconsistencies identified during the field test. SIAPS will continue to optimize the module.
- Logistic issues and poor archiving at health facilities made it difficult to conduct the baseline study for ARV medicines.

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

No activities were conducted this quarter under this objective. However, SIAPS will continue encouraging good financial practices and make it a key component of regular supportive supervision visits to health zones.

Objective 5: Pharmaceutical services to achieve desired health outcomes improved

The PEPFAR activities conducted during this reporting period focused on three main areas:

1) Implementation of recommendations from the baseline study on PEPFAR supply chain indicators and the level of ARV stock
2) Support to the HIV disease program (PNLS), especially to ARV procurement and the management technical group (GAS)
3) Distribution of ARVs and related supplies

WHO has recommended the use of antiseptics for umbilical cord care since 1998. New recommendations published in 2013 stressed the use of chlorhexidine digluconate 7.1%. This medicine was introduced in the DRC in July 2014 as part of essential newborn care. In 2015, the MOH developed treatment guidelines on the 13 life-saving medicines for mothers and children, including chlorhexidine digluconate 7.1%.

During this quarter, SIAPS continued to provide technical and financial assistance to the NTP to collect adverse drug reaction data for the treatments given to patients with multidrug-resistant tuberculosis and TB/HIV co-infection in Kinshasa and five USAID-supported provinces.

SIAPS provided financial and technical assistance to the MOH to complete the first consignment of printed standard therapeutic guideline (STGs). The dissemination and training plan was developed for hospitals with DTCs in five USAID-supported provinces. These STGs will help health workers and facilities improve case management.

SIAPS also proceeded with the quarterly supply of malaria commodities to 44 PMI-supported health zones. Technical and logistic support was provided to the Kamina and Kisangani CDRs to improve storage conditions. Among other improvements, SIAPS helped relocate CAMEKIS (Kisangani's largest depot) into a better building under improved storage conditions, and provided Kamina's CDR with refrigerators, hygrothermometers, and palettes.

During the previous quarter, SIAPS supported the DPS to begin conducting medicine use studies in five provinces to draw comparisons between hospitals with DTCs and those without. The study was conducted in four USAID-supported provinces (Sud Kivu, Kasai Oriental, Kasai Occidental, and Province Orientale) at 10 hospitals (five with DTCs and five without DTCs). During this quarter, the study was completed and the technical report is under development. The study revealed the following findings:

- Health care providers (prescribers) had better prescribing behaviors/habits in hospitals with DTC versus hospitals without DTCs:
  - On average, only two medicines were prescribed per patient encounter in hospitals with DTCs, whereas up to four medicines were prescribed in hospitals without DTCs; this confirms the extent to which polypharmacy practice characterizes prescribing behaviors in hospitals without DTCs
  - Percentage of medicines prescribed using a generic name is 70% and 58% in hospitals with and without DTCs, respectively
  - Percentage of outpatient prescriptions with at least one antibiotic was higher (59%) in hospitals without DTC versus hospitals with DTCs (47%)
  - Percentage of prescriptions with at least one injectable was also higher (35%) in hospitals without DTCs versus hospitals with DTCs (12%)

- Patients had better knowledge of their medication in hospitals with DTCs versus those in hospitals without DTCs. In hospitals with DTCs, 58% of patients who underwent the exit interview knew all the aspects of their medication (name, dose, frequency, treatment duration, and route of administration) whereas only 23% did in hospitals without DTCs.
- Adherence to treatment guidelines was better in hospitals with DTCs compared to hospitals without DTCs; 60% of malaria cases were treated as per the recommended malaria treatment guidelines in hospitals with DTCs, whereas only 40% were treated in hospitals without DTCs.

Partner contributions

CNPV

Constraints to progress

- Difficulty accessing sites because of logistical and infrastructures constraints
- Resistance to change by certain partners

Dominican Republic

Goal: Increase the availability of critical medicines and diagnostic materials, including the ones used for HIV, AIDS, and tuberculosis through the implementation of the different elements of the SUGEMI system and building the capacity of national counterparts to effectively and efficiently operate the integrated system.

The SUGEMI pharmaceutical management system continued to operate as expected in this quarter, with the majority of health facilities reporting their data and receiving feedback (1388/1400, 99%). ARV availability in health facilities remains high (92%). The estimation of needs for 2016 considers the progressive adoption of the 90/90/90 goals.

Objective 1. Pharmaceutical sector governance strengthened

SIAPS supported the adjustment of 2016 procurement plans for the MoH's medicines for hospitals and primary health facilities, ARVs, and high-cost medicines, taking into consideration the assigned budget. The priority criteria have been included in the National List of Essential Medicines and national protocols as a reference. SIAPS supported the revision and validation of the therapeutic guidelines and medicines formulary for primary health facilities, with the final edition of both documents to be printed and distributed during Q2 of FY16. In December, SIAPS organized a meeting to discuss with national counterparts and decision makers the preliminary results of a study on medicines consumption profiles in Dominican Republic. The feedback provided by the participants will be useful for the Certified Course on Rational Use of Medicines, set to be implemented in February 2016 in partnership with the Universidad Central del Este.

During the previous quarter, SIAPS finalized technical reports of the estimation of needs for 2016 national pooled procurement, and individual reports for the estimation of need for 2016 procurement of disease control programs: Maternal and Child Health; High Cost Medicines Program, HIV/AIDS and TB. During this quarter, a consolidated report was uploaded to the SIAPS webpage: http://siapsprogram.org/publication/procurement-planning-for-medicines-and-supplies-in-the-public-health-system-of-the-dominican-republic/

Partner contributions

There were no partner contributions this quarter.

Constraints to progress

There were no constraints to progress this quarter.

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

During this quarter SIAPS finalized the educational modules for a certified course (diploma) on rational use of medicines. In December SIAPS conducted a workshop to train the facilitators of the certificate course. The implementation of the course is scheduled for February 2016. During

this quarter, SIAPS supported the training of nine regional health services personnel in the analysis of SUGEMI pharmaceutical management reports, and continued supporting on-site trainings for the implementation of SUGEMI procedures in eight major hospitals. For the next quarter, SIAPS will scale the implementation of SUGEMI to the rest of the hospital network through a training of trainers course and cascade trainings.

Partner contributions

The certified course on rational use of medicines will be implemented in partnership with the Universidad Central del Este.

Constraints to progress

There were no constraints to progress this quarter.

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

The July-September 2015 SUGEMI quarterly bulletin was disseminated to a wide audience in October 2015, and it is also available in the MoH website. SIAPS has supported the revision and update of the SUGEMI information and monitoring system. During this quarter, SIAPS trained nine regional health services personnel in the interpretation and use of pharmaceutical management indicators for decision making. SIAPS developed terms of reference to adjust the SUGEMI pharmaceutical information system and transfer the administration to national counterparts. During the previous quarter, SIAPS developed a proposal for a monthly report that PROMESE, the national logistics agency, must provide to its clients with data on procurement, requisition, dispatch and inventories. During this quarter, SIAPS presented and discussed the proposal with PROMESE authorities and technicians, and agreed on an implementation plan.

Partner contributions

There were no partner contributions this quarter.

Constraints to progress

There were no constraints to progress this quarter.

Objective 4. Improved allocation of resources for procurement and pharmaceutical management-related operations

During this quarter SIAPS consultants met with MoH counterparts and USAID officials to discuss the implications of the financial gap between the planned budget for the procurement of ARVs, and the resources that were finally assigned by the Ministry of Finance. SIAPS' support to improve HIV/AIDS financial strategies were presented at the International Society for Pharmacoeconomics and Outcomes Research Congress in Milan, Italy in November 2015. The two poster presentation were: "Closing the Financial Gap of Antiretroviral and HIV supplies for

Sustainability of HIV National Response in the Dominican Republic" and "Success story: Strategies- Based on Evidence- to Rationalize the National High Cost Drugs List in the Dominican Republic."

Partner contributions

There were no partner contributions this quarter.

Constraints to progress

There were no constraints to progress this quarter.

Objective 5. Pharmaceutical services improved to achieve desired health outcomes

During this quarter SIAPS continued supporting the integration of eight major hospitals to SUGEMI. A training of trainers to scale up and accelerate the implementation is scheduled for next quarter. SIAPS presented and discussed with MoH authorities the operational plan for the transfer of family planning commodities to SUGEMI. The transference of the inventory from provincial to regional warehouses is scheduled for the first quarter of 2016.

Partner contributions

Baseline study was technically and financially supported by UNFPA.

Constraints to progress

There were no constraints to progress this quarter.

Ethiopia

Goal: Strengthen pharmaceutical system to ensure access to quality pharmacy services that will lead to improved health outcomes

Overall Quarter Progress

In Q2 of FY16, the third follow-up assessment was conducted to generate basic information on major indicators for SIAPS Ethiopia interventions to monitor progress toward life-of-project (LOP) targets.

Practicing pharmacy personnel in the surveyed facilities claimed that they attended at least one in-service training related to pharmaceutical service (100% of the surveyed facilities have certified pharmacy personnel). Drug and Therapeutic Committees (DTCs) were available at all the surveyed facilities. DTCs at all hospitals have a plan of action: approximately 82% conduct meetings on a regular basis and 97% of DTCs have approved terms of reference. It was also found that 97% (32/33) produced and printed facility-specific drug lists and all of them participated in quantification of annual medicine needs for their facilities; 72.7% (24/33) carried out drug use studies and 78.8% (13/24) conducted ABC/VEN analyses and had some interventions on prescribing, dispensing, and use. However, only a little over half (57.6%) implemented AMR advocacy or containment-related activities. Drug information services (DISs) were available in all of the surveyed hospitals and all the DISs have basic resources including reference materials and computers.

All of the surveyed facilities except one started providing clinical pharmacy services and (84.8%) reported having clinical pharmacy-trained personnel. Of the 28 facilities with clinical pharmacy-trained personnel 27 (96.4%) developed an action plan after training, of which approximately 88% claimed that they are implementing their plans, which is higher than the LOP target of 79%.

All the surveyed facilities except one keep complete information on ART patients, 78.8% of the facilities received feedback on the reports or data they supplied (LOP target 96%). All the surveyed facilities monitored adherence of ART clients to their treatment and 75.8% of the facilities identified and managed treatment errors.

Implementation of Auditable Pharmaceutical Transactions and Services (APTS) started in 72.2% (24/33) of the surveyed facilities. Moreover, the survey revealed that the number of the Ethiopian Hospital Reform Implementation Guideline (EHRIG)-Pharmacy Chapter standards implemented (out of 12 standards) ranges from 7 to 12. Well over two-thirds of the surveyed facilities implemented at least 11 standards out of 12. On average, about 11 standards were found to be implemented per facility at the time of the survey.

Results of the survey further showed that 58% of the sampled prescriptions contained antibiotics, while the LOP target is 30%. The overwhelming majority of patients claimed that they know how frequently they are supposed to take the dispensed medicines (91.4%) and its dose (75.5%). Knowledge about duration and how to store medicines at home was found to be moderate, i.e.,

75.4% and 67.8%, respectively; 83.3% of patients that were interviewed expressed their satisfaction with the information they received from dispensers.

With regard to antimalarial drug management, data on stock-outs revealed that 15.9% of the health facilities experienced stock-out of ACTs (4 × 6) in the last three months prior to the survey (LOP target 17%), and 13.6% of warehouses experienced stock-out of the same product for three days or more in the last three months (LOP target 16%). Approximately 73% of the health facilities use a standard checklist to monitor storage conditions (LOP target 94%), and 97% of the health facilities have a copy of the standard treatment guideline (LOP target 100%).

Technical Assistance

The senior technical advisor visited Ethiopia to conduct a situation analysis with the School of Pharmacy at Addis Ababa University; the Food, Medicines, and Health Care Administration and Control Authority (FMHACA); and all relevant stakeholders to identify gaps and needs for support and agree on deliverables and timelines to establish a post-graduate regulatory science program in Ethiopia.

Objective 1: Pharmaceutical sector governance strengthened

During the quarter, Oromia Regional Health Bureau (RHB), in collaboration with SIAPS, organized a one-day APTS regulation implementation workshop at Adama. The objective of the workshop was to sensitize participants on the APTS regulation and expectations of regional government and to create consensus to facilitate implementation of the initiative at health facilities. The workshop was attended by 183 participants from different bureaus of the Oromia region (Health Bureau, Civil Service and Good Governance Bureau, Audit Bureau, Finance and Economic Development Bureau, Justice Bureau), regional hubs of the Pharmaceutical Fund and Supply Agency (PFSA), the Federal Ministry of Health (FMOH), and hospitals identified for the first phase of APTS implementation.

In collaboration with the Amhara RHB, SIAPS conducted a workshop to review APTS reporting practices, focusing on timeliness, completeness, and accuracy. The workshop was attended by 47 participants from 19 hospitals. PFSA hub representative, Amhara RHB core- process owners, and SIAPS experts attended. The forum created a perfect opportunity for hospitals to discuss challenges, gaps, and opportunities in APTS reporting practices.

Similarly, a sensitization workshop was conducted in the Amhara region to address issues related to APTS scale-up to health centers; 34 participants including zonal health department (ZHD) heads, ZHD logistic officers, PFSA hub managers, ZHD engineers, and RHB experts participated. The workshop was meant to create awareness on the benefits of APTS implementation at hospitals in the region and beyond and to discuss ways to expand it to health centers. The success and challenges of APTS implementation were reviewed and consensus was established on the strategies to scale up APTS to at least 20 health centers this year.

In this quarter, another workshop was conducted in Addis Ababa on the regulation of the pharmaceutical service delivery system for health facilities in the Addis Ababa City

Administration. The main purpose of the workshop was to disseminate and create awareness on the APTS regulation (No. 74/2016 which was enacted by the Addis Ababa City Administration Council of Cabinets) and create consensus with relevant stakeholders to facilitate scale-up and smooth implementation of APTS at health facilities. A total of 262 professionals attended the workshop in two rounds, of which 23.3% were females. At the event, an overview and best practices of APTS implementation, redesigning existing pharmacy premises to meet APTS implementation requirements, details of the regulation, roles and responsibilities of stakeholders, and strategies and requirements for APTS implementation were presented and discussed in detail.

The APTS indemnity finalization workshop was attended by 13 participants drawn from the Dire Dawa city administration health bureau, finance and economic development bureau, audit bureau, justice bureau, and PFSA Dire Dawa branch.

SIAPS' support to build capacity of the Health Regulatory Information Center (HRIC) at FMHACA continued this quarter. Training was provided to FMHACA staff on how to receive, process, and answer inquiries over the telephone. The training was delivered by experts from Johns Hopkins University's Center for Communication Programs (JHU-CCP).

Partner contributions

- Dire Dawa RHB organized a workshop and made the final draft of the APTS indemnity guideline.
- Addis Ababa RHB pharmacy assigned responsibilities to each pharmacist (according to hospital and service category) to enable timely submission of reports; the RHB pharmacy also provided feedback on data quality issues, report aggregation, and information dissemination. Currently assigned staff started collecting and aggregating reports generated by health facilities.
- Addis Ababa RHB committed to popularizing APTS regulation and enforcing its implementation to facilitate scale-up of the system to all health facilities.
- The enactment of the APTS legislation was the untiring effort of the Oromia RHB. Major stakeholders from Oromia region participated in the workshop organized by the RHB to popularize APTS.
- JHU-CCP contributed to the effective delivery of HRIC training by assigning experts to cover most of the sessions.

Constraints to progress

Because of time constraints and continued engagement of RHB and PFSA with other priorities, the health extension workers handbook customization could not be completed.

Objective 2: Pharmacy services at facility level improved

In Q2 of FY16, three training events were organized on APTS, four on the SOP for pharmacy ART information management manual, and one on EDT. These events were attended by 300 professionals, of which 81 (25%) were female. As part building regional capacity to support

implementation of APTS, two training of trainers (TOT) events were organized in Amhara and Oromia regions, in which 113 pharmacy and 53 finance professionals participated.

Premises improvement is one of the key aspects of APTS interventions, and SIAPS has supported health facilities in redesigning their pharmacy setup to prepare for renovation. As a result, pharmacy dispensing-area design has been developed and provided to seven health facilities in the Oromia region.

During this reporting quarter, onsite technical support and mentoring was provided to 19 health facilities in Amhara; Benshangul gumuz; Southern Nations, Nationalities and Peoples (SNNP); and Oromia regional states to improve the identification and management of treatment errors, adherence counseling, and pharmaceutical care for ART patients and hospitalized patients. The results from nine hospitals in Amhara and Benshangul gumuz regions showed that these hospitals served 1,530 patients, for which a patient medication profile form was documented for 1,185 (77.5%) of them. Within the reporting period, 387drug therapy problems were identified and interventions were made for 313 (80.9%) of the problems. From the interventions made, 277 (88.5 %) were fully accepted. Moreover, to strengthen patient-centered pharmacy service in this reporting period, 156 ward rounds and 113 morning meetings with multidisciplinary team and 6 pharmacy-only morning meetings were conducted.

A total of 20 ADRs were reported to the national pharmacovigilance center from five hospitals in the Amhara region. Of the hospitals providing clinical pharmacy services, Debremarkos Referral Hospital started providing such services in the maternity ward. Within a month, 347 mothers obtained pharmaceutical care; from this service, 68 drug therapy problems were identified and interventions were proposed by pharmacists, of which 48 were fully accepted by prescribers.

To create awareness on pharmacovigilance among health providers, face-to-face discussions were carried out at nine health facilities (seven in Addis Ababa and two in Oromia regions); 215 health providers participated in the discussions. During the quarter, various pharmacovigilance tools and documents were distributed to health facilities, including 280 ADE reporting forms, 295 allergy cards, and 210 newsletters.

As a result of analyzing ADE reports received by the pharmacovigilance center, regulatory measures were taken on chloroquine, paracetamol syrup, iodine tincture, and hydrogen peroxide. The manufacturers were informed to stop production, investigate the causes, and address quality control issues.

The support SIAPS provides to health facilities to strengthen medicine use education has continued. In this second quarter of FY16, 12 health facilities in Tigray, Addis Ababa, and Oromia regions have conducted 146 sessions on medicine use education attended by 10,287 people, of which 56% were female.

In Q2, 246 medication errors were identified and prevented at ART pharmacies in health facilities in Amhara, SNNP, Dire Dawa and Harari regions.

Dessie and Debre Berhan Referral Hospitals were given the necessary support to expand their clinical pharmacy services to maternity wards. Accordingly, the hospitals assigned a dedicated full-time clinical pharmacist to the GYN/OB ward. Many hospitals in East Amhara region are providing clinical pharmacy services in the pediatric ward.

Partner contributions

- Health facilities are covering the expenses for renovating dispensing pharmacies and SIAPS is covering procurement costs for the supplies for the model APTS hospitals
- Almost all DTCs are interested in participating in AMR containment activities and want to revise their plans of action according to the national strategy
- The National AMR Advisory Committee members have committed to meet regularly
- FMHACA has committed to take action on product defects reported from health facilities through the ADE reporting mechanism

Constraints to progress

- Although health facilities are working hard to improve their service, there are still challenges in properly documenting and communicating results. Tools are being developed and supplied as part of the support to health facilities to be able to document and communicate results to decision makers.
- Poor-quality data received from health facilities
- Lack of internet access at hospitals to run DISs and share pharmacy service reports with RHBs and partners

Objective 3: Capacity to use information for decision making strengthened

Support to FMHACA to automate the medicine registration system has continued. The drafting of three SOPs was finalized this quarter and reviewed by experts. The SOPs cover agency agreement management, medicines regulatory information system (MRIS) users' management, and data entry and data quality management. The experts provided feedback, and the final versions are currently under review for endorsement by the change management team. The other activity planned in this quarter was training industry applicants on purchase order/pre-import permit tracks; 42 industry applicants were trained on these two tracks.

SIAPS and its predecessor programs have been instrumental in the initiation and expansion of the PMIS in Ethiopia. Moreover, during the past four years, SIAPS has worked with PFSA and RHBs to improve site-level implementation of PMIS and generation of national reports. As the SIAPS Program is coming to a close, there is an urgent need to work closely with PFSA, FMOH, and other stakeholders to effectively transition the core activities to ensure that these best practices are properly transitioned and continue to support decisions on key functions of the ART program including national quantification and program monitoring. Accordingly, a consultative meeting was held in Addis Ababa to discuss and agree on how to implement the smooth transition of PMIS activities to PFSA. Other concerned stakeholders, such as FMOH, RHBs, USAID, SCMS, and other NGOs were invited and contributed to the success of the meeting. The meeting was concluded by establishing a taskforce to develop options and provide

recommendations for decision makers.

Continued support was provided to health facilities to maintain patient medication records and submit reports every two months. In Q2, two patient uptake and regimen breakdown reports were produced and shared. Patient uptake data were collected from 681 health facilities and regimen breakdown data from 380 health facilities. According to the recent patient uptake report, 360,399 patients were on ART, of which 315,233 patients (87.5%) were covered in the regimen breakdown report.

As part of ensuring continuous patient information recording at the health facilities and generation of various reports for decision making, computers were given to six health facilities in Oromia region and one in SNNPR. Computer hardware and software maintenance support was provided to 42 ART electronic sites nationally. On-site training was provided to 22 pharmacists and IT professionals. Two health centers in Addis Ababa started using the EDT for real-time dispensing.

During the quarter, EDT training was organized for 34 participants from 9 sub cities, the Addis Ababa Health Bureau, and PFSA. The training created a favorable environment to discuss the basics of the tool, how it can be used for dispensing, and further utilizing it to prevent medication errors.

The third round countrywide EUV survey data was collected from seven regions for a total of 27 sites comprising nine hospitals, eight health centers, four health posts, and six ZHD stores.

Data showing available stock and stocks with less than six months expiry was collected from 83 health facilities in Oromia, Amhara, Tigray, and SNNP regions. Based on the months of stock established for each health facility, a report was prepared by analyzing overstock and stock of products near expiry; the reports were disseminated to each RHB, PFSA hubs, and USAID-PMI for follow-up and actions.

Partner contributions

- Health facilities' interest, awareness, and commitment in implementing EDT for real-time dispensing has increased; some health facilities allocate computers to implement EDT at the dispensary

Constraints to progress

- Discrepancies in the quality of data and reports coming from some health facilities
- Frequent power interruptions affecting data capturing and updating
- Frequent staff turnover of trained staff at some health facilities
- Frequent hardware and software failures
- Delay in implementation of MRIS

Objective 4: Revenue from sales of medicines increased

APTS was implemented at Sawla Hospital in SNNPR. As of the end of this quarter, APTS is being implemented in 49 health facilities throughout the country. Out of these 49 health facilities, 35 (71.4%) track their sales of medicines by using APTS and report regularly to their respective regions and FMOH. APTS-implementing health facilities regularly submit performance reports to the FMOH and RHBs through an email account dedicated to this purpose. FMOH and RHBs give feedback through email, phone calls, supportive supervision, and review meetings.

Onsite training and mentoring on implementation of APTS was provided to 16 participants from Sawla Hospital. As a result, APTS was successfully implemented.

In the reporting period, technical assistance was provided to eight pharmacy professionals and two accountants from Zewditu Memorial Hospital; two pharmacy professionals and two accountants at ALERT Hospital; and five staff from St. Peter Hospital on how to record pharmaceutical transactions and services and generate daily summaries and monthly reports in a way that can be used for decision making. SIAPS also provided technical assistance to St. Paul, Yekatit 12, and Menilik II Hospitals and 3 health centers that allocated budget for renovation of pharmacy units in preparation for APTS implementation.

Four health facilities (Dessie Referral Hospital, Enat General Hospital, Borumeda Hospital in Amhara region and Adare Hospital in SNNPR) conducted ABC/VEN analyses this quarter. These hospitals were able to identify the amount of budget consumed by each medicine, and this information will be used to prioritize their budget for subsequent procurements. After conducting ABC/VEN analysis in the first quarter, Felege Hiwot Referral Hospital conducted stock status analysis. The purpose of this stock status analysis was to identify understocked and overstocked medicines so that medicines in short supply are procured in time and near-expiry medicines are either consumed or transferred to a facility that can use them. This practice saves lots of resources by avoiding unnecessary wastage and contributes to improved availability by enabling hospitals to identify a potential stock-out well ahead of time.

One of the major results of APTS has been efficient utilization of budget allocated to medicines. Some of the hospitals implementing APTS have achieved the following results:

1) Enat Hospital found that X-ray supplies were one of the items that consume 80% of the budget. The hospital DTC examined the situation and found that injuries, which require X-rays as part of diagnosis, are one of the key problems treated in the hospital's catchment. They requested help from the RHB for support. The region responded by providing a digital X-ray machine; the consumption of X-ray supplies went down to almost zero. The hospital wrote a recognition letter to the RHB expressing their appreciation for their prompt response to their requests, a decision guided on the basis of ABC analysis.

2) Following a stock status analysis, Felege Hiwot and Enat Hospitals transferred stock to neighboring health facilities to avoid unnecessary wastages due to expiry of overstocked items. By doing so, the hospitals saved medicines with a monetary value of more than ETB 185,000 and ETB 15,984, respectively.

Partner contributions

- SNNPR RHB and Sawla Hospital facilitated APTS training at the hospital
- RHB heads and hospital chief executive officers' commitment facilitated scale-up of APTS implementation

Constraints to progress

- Resistance to record and report APTS activities as per requirements
- Knowledge gap among pharmacy accountants in compiling daily summaries and generating monthly reports
- Lack of computers at health facilities to record and report financial and service reports
- Absence of incentive packages related to APTS and the shortage of pharmacy professionals in some district hospitals compromises pharmacy service provision (counseling, appropriate evaluation, and documentation)

Guinea

Goal: Improve availability of quality pharmaceutical commodities and efficient pharmaceutical services to achieve desired health outcomes

Overall Quarter Progress

During this quarter, SIAPS Guinea made significant strides in several of its key objectives, including strengthening pharmaceutical sector governance (Objective 1). SIAPS assisted the Direction Nationale de la Pharmacie et Laboratoires (DNPL) with organizing meetings with the national committee mandated to develop the Pharmacy Act, to review and finalize the draft law in line with recommendations from the United States Pharmacopeia's Promoting the Quality of Medicines (USP/PQM) Program's recently concluded technical assistance. SIAPS also provided support to the DNPL to complete the development of equivalence tables for medicines in use in Guinea.

To improve the pharmaceutical management capacity of institutions and individuals (Objective 2), SIAPS continued to coordinate meetings and workshops with the Programme National de Lutte contre le Paludisme (PNLP) and Catholic Relief Service (CRS) for stock status analyses of malaria products. Moreover, the PNLP Procurement and Supply Management (PSM) Thematic Group developed indicators for stock monitoring of malaria products. A recommendation from this workshop led to the formation of a sub-group called Supply Chain Technical Assistance made up of representatives from SIAPS, CRS, WHO, Projet d'Appui à la Santé/Union Européenne (PASA/UE), and UNICEF that will serve as a platform for better coordination of all supply chain technical partners.

To improve the availability of pharmaceutical management information for decision making (Objective 3), SIAPS worked with the DNPL focal person to put together a joint implementation plan capturing all activities from the SIAPS work plan aimed at strengthening both the DNPL and the Logistics Management Unit (LMU). SIAPS also technically assisted the Pharmacie Centrale de Guinee (PCG) to finalize the coding and classification of all pharmaceutical products stored at PCG, in preparation of the anticipated installation and use of SAGE Saari 100 software. Stock counting of malaria products was also completed in the Boke region. Additionally, the supervisions conducted jointly with PNLP took place in the Conakry region.

In terms of improvement of pharmaceutical services to achieve desired health outcomes (Objective 5), SIAPS coordinated the reception of 500,000 pairs of gloves and completed the stock count of all PMI-funded malaria products stored at PCG. SIAPS also participated in a series of meetings of the logistics committee for the long-lasting insecticidal net (LLIN) mass distribution campaign organized by PNILP with other partners such as CRS and STOP Palu.

Overall, the SIAPS technical staff supported and participated in different technical coordination meetings with other technical partners to harmonize the technical support provided to PCG, DNPL, and PNLP. SIAPS also worked with USAID | DELIVER to complete the handover of the management oversight of USAID-funded contraceptives for Guinea.

Objective 1: Pharmaceutical sector governance strengthened

Improved DNPL's governance

A meeting was held with the DNPL and the USP/PQM delegation from January 5–8, discussing the Pharmacy Act under development. Follow-on meetings were held between DNPL and other country-level stakeholders to analyze and integrate recommendations from USP/PQM into the existing draft. SIAPS also worked with DNPL to complete the equivalence tables for the essential medicines in use in Guinea.

Improved governance of PCG

At a request of PCG management, SIAPS assisted in reviewing the organogram and procedures for the distribution unit of PCG to reallocate roles and responsibilities. A new organogram and job descriptions were proposed.

SIAPS technically supported the new coding, classification, and naming of all pharmaceutical products stored at PCG. This preliminary work will facilitate the upload of the product master file within the SAGE Saari 100 software, an electronic warehouse management system that SIAPS helped PCG acquire.

SIAPS also participated in various discussions and meetings with the PCG Board of Directors, management team, and partners on the effor to change the institutional status of PCG. In fact, PCG is an EPIC (Etablissement Public Industriel a Caractere Commercial) and recently the International Monetary Fund (IMF) recommended that the Government of Guinea (GOG) eliminate this status, thereby encouraging the country to switch to SA (Societe Anonyme) status (100% public or semi public-private, etc.). After a consultation meeting between all technical and funding partners (TFP) of the MOH and a joint meeting between PCG and TFP, there is an emerging consensus that PCG should be transformed into a not-for-profit organization (Association Sans But Lucratif) with a board of directors comprising the GOG, the TFP, and PCG clients.

SIAPS participated in the annual joint work plan meeting between PNILP and its partners. All partners presented their work plans and all activities were integrated into the PNLP annual work plan template. This will help improve coordination and ensure that there are no overlaps in terms of activities and timeline.

Two RBM partners' meetings were held under the auspices of PNLP. The discussion included preparations for World Malaria Day (April 25) and the long lasting insecticidal nets (LLINs) mass distribution campaign planned for early May. PNLP informed the meeting that Guinea had been named the best country in the fight against malaria at the latest congress of African Leaders Malaria Alliance in Addis Ababa. All partners were also reminded at the meeting to plan activities over the next the months having in mind that the top priority will be the preparation and implementation of the LLINs mass distribution campaign.

Partner contributions

DNPL, PCG, PNLP, PASA/UE, USP/PQM

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

During this quarter, SIAPS continued to provide technical support for effective management of pharmaceuticals, especially malaria products. Regular PSM Thematic Group monthly meetings were held to provide the group with a comprehensive stock status and the supply plans of malaria products. Also, working sessions were held that helped define key indicators for stock monitoring.

SIAPS participated in a logistics committee meeting for the mass distribution campaign of LLINs. At the meeting, all practical considerations were reviewed including repositioning points for LLINs, which will all be regional PCG depots plus a few selected health facilities. Additionally, a meeting was organized for all stock managers of the regional depots. It was suggested that the army should be recruited to handle the logistics of the LLIN mass distribution campaign.

The semi-annual supervision carried out by PNLP with support from SIAPS took place in health facilities in the Conakry region. This activity revealed low levels of utilization of artesunate-amodiaquine (ASAQ) in both public and not-for-profit health facilities. Findings showed an overstock of ASAQ and stock-out (or threat of stock-out) of RDTs and SP. With the predominance of private pharmacies in Conakry, it was found that prescribers tend to prescribe ACTs to patients other than those subsidized by the MOH; patients end up buying these with out-of-pocket money.

Regarding the monitoring of consumption and management of malaria products, a meeting of the PSM thematic group was held on March 18. Working sessions between PNLP, SIAPS, and CRS helped develop a technical one-page recap of best practices for managing medicines in health facilities.

SIAPS supported the organization of the PCG staff's annual meeting; trainings were also conducted for all pharmacists of PCG regional depots to prepare them for the decentralization of the distribution of malaria products.

Partner contributions

- PNLP spearheaded campaign activities
- CRS supported the LLIN mass distribution campaign in Global Fund-supported regions while STOP Palu supported this activity in PMI-supported regions
- PCG

Objective 3: Pharmaceutical management information available and used for decision making

Having received the go ahead from USAID for the purchase and installation of the SAGE software at PCG, SIAPS coordinated the first meeting between PCG and the vendor to agree on the timeline for the system requirements review, software installation, user training, and go-live.

A meeting was also held with the supply chain focal point at MOH during which a joint work plan was developed for the DNPL and LMU activities that SIAPS will support. Note that DNPL and the Bureau Stratégie et Dévéloppement/Health Management Information System (BSD/HMIS) have engaged in a number of activities:

- Recruitment of a consultant to develop a roadmap for implementation of LMIS activities
- Meeting with all HMIS stakeholders (DNPL, Direction de la Santé de la Ville de Conakry [DSVCO], PASA/UE, BSD, UNFPA, PCG, PNLP, etc.)
- Participation in a workshop to finalize and validate the HMIS strategic plan
- Meeting with BSD to identify SIAPS contributions to the LMIS in collaboration with the supply chain focal person at MOH

SIAPS participated in meetings organized by MOH's HMIS unit in which Research Triangle Institute (RTI) International presented an update on the development and implementation of the work to consolidate patient registers in health facilities as well as the codification of all health facilities in Guinea. The implementation timeline for DHIS2 was also presented. Recall that SIAPS is supporting DNPL in developing supply chain indicators that will be integrated into the list of indicators to be tracked by DHIS2. A series of preparation meetings with BSD, DNPL, and HMIS took place to prepare the workshop for the definition of supply chain indicators; the workshop, supported by SIAPS, took place on March 23 and 24, 2016.

Constraints to progress

The quarterly regional meetings initially planned did not take place as PNLP and partners were focusing on organizing the LLIN mass distribution campaign.

Partner contributions

BSD/HMIS and DNPL led the LMIS work, RTI International, DSVCO, PASA/UE, BSD, UNFPA, PCG, and PNLP.

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

No update for this quarter

Objective 5: Pharmaceutical services improved to achieve desired health outcomes

Following the decision by USAID to assign the distribution of infection prevention and control (IPC) materials to SIAPS, the project held several meetings with the Logistics Sub-Committee of the Ebola Coordination Committee (ECC). The discussions from the meetings showed that there was little information at the central level on the stock status of these items. It was recommended to the Logistics Sub-Committee that a nationwide inventory exercise be organized in all health facilities to assess commodities' stock status and their levels of consumption during the past period. The terms of reference for this activity have already been approved by the ECC. The first regional teams began working in the regions of Boke and N'Zerekore. A team from the central level that is mandated to supervise and validate their work will join them in the last week of March. This activity will continue and conclude in April in the other parts of the country and will help provide reliable data on the inventory and consumption levels of the protective materials against epidemics in health facilities.

During this quarter, two review meetings took place with the Office of US Foreign Disaster Assistance (OFDA) team to discuss the storage, distribution, and use of protective materials against epidemics. A meeting took place to discuss PCG's readiness to take over the central storage of these protective materials because the World Food Program warehouse would be closing in June 2016. A visit to the World Food Program's storage facilities took place to assess the volumes of commodities currently in stock.

An inventory of malaria products was completed in all facilities in the Conakry region. Findings from the inventory helped identify stock imbalances (overstocks, stock-out threats, expiry risks); as follow-on action, a redistribution plan was developed which will be implemented in the next two weeks.

The analysis of the inventory levels revealed the following: in the 56 health facilities visited, the majority were overstocked. On the other hand, a number of facilities had stock-outs of malaria RDTs and SP. It was found that there are other multiple and parallel distribution channels through which organizations, such as UNICEF and UNFPA, distribute products directly to health facilities. It has been recommended that all donations should flow through the existing distribution channel starting from the PCG down to facilities; this will avoid overstocking health facilities and hence minimize expiries. Although the private sector benefits from subsidized ASAQ formulations, it was found that ASAQ is not optimally used in the private sector.

SIAPS completed receipt and stock count of PMI products delivered during this quarter:

- 500,000 pairs of gloves
- 1,002,690 treatments of artemether-lumefantrine
- 1,865,000 malaria RDTs

Several meetings between PNLP, CRS, STOP Palu, and SIAPS for the preparation of the LLIN mass distribution campaign took place. STOP Palu will conduct the distribution in PMI-supported regions and CRS will support this activity in Global Fund-supported regions, with the

participation of its sub-contractor, Plan International. LLINs will first be positioned at the regional level and then transferred to the health facility level before being delivered to the identified distribution points. Trainings for all stock managers that will be involved in this activity will take place with technical support from a CRS international consultant.

For cost-effectiveness reasons, the PNLP decided to combine the celebrations of World Malaria Day and the launching of the LLIN mass distribution campaign on May 12, 2016. The celebrations will take place in the Kindia region.

Partner contributions

PAM, PCG

Technical coordination

At the national level, a supply chain thematic group was created to coordinate the efforts of all supply chain technical assistance organizations in Guinea. SIAPS has a vice-presidency role while UNICEF chairs the group. The first meeting of this group involved CRS, UE/PASA, WHO, and SIAPS where the project on the new institutional status of PCG was discussed.

Staff from HQ visited in February 2016. The aim was to evaluate how SIAPS Guinea has contributed to the achievements of PMI targets and identify potential success stories and lessons learned that could be shared at the global level. Deliverables from this visit will be ready in April.

Two other staff from HQ were in-country to support the finalization of both the PMI and the Ebola Supplemental Fund work plans. Their work helped integrate new activities that were assigned to SIAPS by USAID/PMI Guinea, in particular the management oversight and distribution of contraceptives and Ebola IPC materials. The two work plans were finalized on February 9 and 12 and were immediately shared with the PMI country team. Comments from the Mission were received and a revised version accounting for the Mission's feedback was completed. The work plans are currently pending approval by the PMI country team.

SIAPS participated in a meeting organized by the National Directorate of Public Hygiene in collaboration with UNDP on biomedical waste management, which is now more than ever a major concern with the Ebola outbreak. In addition, the stock of expired drugs that piled up in health facilities poses a major concern, as these have not been destroyed for years.

Haiti

Goal: To ensure availability of quality health products and effective pharmaceutical services to the Haitian population

Objective 1: Pharmaceutical Sector Governance Strengthened

The National Medicines Policy (NMP), developed through a stakeholder participatory process, aims to ensure the availability, accessibility, and optimal use of quality essential medicines for the entire Haitian population. SIAPS's support for the new NMP, which included development, launch, and roll-out, was completed in October 2015.

Objective 2: Strengthening National Supply Chain System

The supply chain integration cost and operational analyses have also been completed and the results were presented to, and adopted by, the technical committee assigned to supervise the planning process for the setup of the proposed integrated health commodities procurement and distribution system (SNADI). However, the technical committee and USAID have requested that SIAPS presents the analyses results to SNADI Steering Committee for a decision to be made about the configuration of SNADI.

Therefore, in this quarter, SIAPS presented the results of the supply chain analyses to members of the SNADI Steering Committee (SC) at a meeting chaired by Haiti's Minister of Health. Four out of seven partner organizations represented on the SNADI Steering Committee, attended this meeting, along with representatives of Ministry of Health and Population (MSPP).

The analyses focused on warehousing and transportation costs, and the setup and operational requirements of three possible network configurations. Three planned configuration options were analyzed, each including a central warehouse (CENADI). One configuration (Option 1) includes CENADI and three regional warehouses (CRADI), and the other configuration (Option 2) includes CENADI, 3 CRADIs, and 13 departmental warehouses (CDAI). The third configuration (Option 3) includes use of private logistics service providers (3PL) for the management of warehousing and transportation services.

Among other things, the private logistics service provider (3PL) transportation costs in Option 3 were significantly highest, but explanations about the difficulty of gradually decreasing the contracted 3PL transport unit costs in a scenario of increasing volumes allowed everyone to understand the scope of these results. Limitations of the analyses included weaknesses in data quantity and quality. SC members raised questions about products included in the analysis and cost data used. It was explained that transport cost analysis considered active distribution of all medicines for priority public health programs and other essential medicines distributed by Program on Essential Medicine and Supplies (PROMESS) and other partners, and products considered for distribution to health institutions in the entire country.

SC members commended SIAPS for carrying out these analyses. The committee deliberated on the analyses results and contextual information provided by the Department of Pharmacy, and

then discussed a transitional arrangement that was proposed by the technical committee. The proposition by the technical committee, as adopted by the steering committee, is to use PROMESS and SCMS warehouses as central warehouses, representing CENADI under SNADI, and employing two modes of active distribution, one involving use of contracted 3PLs transporting priority public health products from central warehouses directly to health care institutions. The second option would use contracted 3PLs; however, essential medicines requiring cost recovery will be transported first to department warehouses (CDAIs) and then on to health care institutions. The SC approved this proposal as an interim measure pending construction of the central and regional warehouses. In the meantime, the Minister requested analysis of an additional SNADI network configuration, which would involve active distribution by 3PL from a central level warehouse to departmental warehouses and then to health facilities (option 4). SIAPS has completed this additional analysis, which will be included in a comprehensive technical report on the analyses to be completed by end of May 2016.

Mali

Goal: Ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

Overall Quarter Progress

During the second quarter of PY5, SIAPS supported the MoH in implementing several activities with the aim of strengthening pharmaceutical governance, building capacity of individuals and institutions in pharmaceutical management, making logistics data available for decision-making, and improving pharmaceutical services. Support was given to the MOH to organize quarterly coordination meetings and to review supply plans for malaria and family (FP) commodities. The FP and malaria technical working group (TWG) updated the national supply plans during a two-day workshop (February 10 and 11, 2016) using PipeLine software. As a result, the number of supply plans updated with SIAPS support increased from 15 to 17, out of the 18 targeted by the program.

The National Coordination Committee (CNC) meeting, chaired by the MoH pharmaceutical advisor and held on March 10, 2016, validated the updated supply plans presented by the FP and malaria TWG, and analyzed and reviewed the stock status and the pipeline for health priority programs. Decisions were made to avoid stock-out and overstock based on stock status information.

At the regional levels, quarterly coordination meetings were held in the regions of Kayes Koulikoro, Sikasso, Segou Mopti and Bamako to address supply chain bottlenecks. As a result of this technical assistance, a total of 24 civil society organizations (CSOs) at the international, national and local levels continue to monitor pharmaceuticals management operations through functioning committees, which provide oversight and promote accountability in the pharmaceutical sector. In PY4, SIAPS Mali supported the Pharmacie Populaire du Mali (PPM) in conducting a situational analysis for the development of the 5-year strategic plan. The lack of a product catalog and relatively weak documentation on laboratory and diagnostic commodities were identified as challenges. For PPM to have comprehensive information on commodities to both procure and provide accurate information to customers, SIAPS Mali started providing technical support to develop a product catalog. To build individual and institutional capacity, SIAPS supported the Regional Directorate of Health (DRS) of Kayes to conduct training of supervisors and logistics management information system (LMIS) standard operating procedure (SOP) users.

The total number of people trained on pharmaceutical management increased from 1,593 to 1,645. Support was also given to 50 districts to conduct coaching and mentoring to assist health information and district warehouse managers to enter LMIS reports into the OSPANTE dashboard. As a result, the percentage of trainees who successfully implemented their post-training action plan increased from 46% to 52%, and the percentage of facilities that submitted a LMIS report for the previous month increased from 87% to 96 %. To improve availability of pharmaceutical management information for decision making, SIAPS explored the possibility to

include nutrition and HIV commodities into OSPSANTE by holding several meetings with country key stakeholders. During this reporting period, SIAPS also submitted to USAID/Washington a PPMRm report in January and a PPMRc report in February to inform the national stakeholders and donors on the availability and pipeline of malaria and FP commodities at central level. These reports identified bottlenecks in the supply chain and made recommendations relating to commodities security. With the aim to improve pharmaceutical services, SIAPS supported the DRS to conduct joint supportive supervisions and coaching visits in five regional depots, four regional hospitals, 42 district depots, and 1,069 health facilities sales points, in Kayes, Koulikoro, Sikasso, Segou and Mopti. 93% of depot managers are now using consumption data to inform products ordering, and 1,091 facilities are now using country appropriate logistic tool for commodities management.

Objective 1: Pharmaceutical sector governance strengthened

Regarding governance, SIAPS assisted the MoH in organizing a quarterly meeting of the CNC and two meetings of the malaria and FP TWGs. The CNC meeting was hosted by the Directorate of Pharmacy and Medicines (DPM) and chaired by the MoH pharmaceutical advisor on March 10, 2016. Participants from MoH, USAID implementing partners, UN agencies, and CSO attended these meetings. The objective was to present and validate the results of the updated supply plans of contraceptives and malaria commodities and to monitor the management of products for malaria, maternal and child health, HIV/AIDS, TB, and family planning. Through presentations and discussion, several recommendations were made to avoid stock-outs, and to improve commodities availability at the central level.

One of SIAPS Mali's sound achievements during the past two years is the development and validation of quantification exercises for HIV/AIDS, malaria, and FP commodities, after MOH staff were trained on quantification principles and subsequent use of Quantimed, Reality Check, and PipeLine software. The developed supply plans needed to be regularly updated to ensure that commodity deliveries were adjusted in response to variations in consumption patterns. During this quarter, SIAPS provided technical support to the malaria and FP TWG lead by the DPM and national programs to update supply plans based on logistic data (consumptions, stock on hand) generated by OSPSANTE by using PipeLine software. The donor's orders were also updated into the PipeLine software, and several recommendations regarding commodities procurement were made by the participants of a two-day workshop, held on February 10 and 11, 2016.

The results of the workshop showed that there is an overstock for FP commodities as certain donors ordered FP commodities outside of the agreed-upon and validated national supply plan. It was also noted that malaria needs are not completely covered. Based on these findings, participants recommended that donors delay some FP commodities shipments, and that the government order a gap analysis of malaria commodities.

In February, SIAPS regional representatives of Kayes Koulikoro, Sikasso, Segou Mopti, and Bamako supported the organization of quarterly coordination meetings to discuss commodities

procurement and distribution issues, as well as LMIS data recorded in OSPSANTE. Chaired by the regional directorate of health, the meetings were attended by stock managers from district and regional levels, as well as USAID implementing partners and CSO. During those meetings, attendees discussed, analyzed, and validated logistics data, and used the OSPSANTE dashboard to support evidence-based decision making for improving the availability of key products at the lowest level of the health system. Discussions were also focused on data availability and data quality regarding timeliness and completion.

In PY4, SIAPS Mali supported the PPM in conducting a situational analysis for the development of a 5-year PPM strategic plan. The lack of a product catalog and relatively weak documentation on laboratory and diagnostic commodities were identified. To ensure PPM has comprehensive information on commodities to procure, it was agreed that a product catalog would be developed during the first year of the PPM strategic plan. During this quarter, SIAPS provided technical support to the PPM to start the process of developing a product catalog, which will be available on hard and electronic copies for PPM's clients. A revision of the current inventory list for PPM products was conducted during a consensus workshop held on March 16 and 17, 2016 in consultations with relevant departments and references. Out of 12 lists, guide and SOPs planned as project target, a total of 13 lists, guides or SOPs were developed. Additionally, SIAPS facilitated the finalization of three malaria commodities distribution plans drafted by the NMCP. Out of 20 planned, 23 distribution plans were developed.

Partner contributions

The following partners participated to national and or regional coordination meetings on supply chain, and they contributed to identifying bottlenecks and solution: MoH DPM Comité National de Coordination; CNC Donors: USAID; Global fund/PSI; UNFPA. PPM staff contributed to restructuring the catalog list.

Constraints to progress

Some donors ordered FP commodities outside of the agreed-upon and validated national supply plan.

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

After the existing LMIS for health commodities was assessed and redesigned in the previous years of the program, new SOPs were developed to focus on stock management and LMIS. SIAPS Mali provided assistance to the MOH to develop training materials for different levels of the health system. During the third and fourth project year, SIAPS Mali supported the DPM and the DRS in training 24 trainers on the new developed LMIS SOPs, and in subsequently rolling out the process. During PY4, trainings on the new LMIS (dissemination of specific SOPs and tools related to LMIS) expanded beyond the regional level, and involved stock managers at district and the community health centers (CSCOM).

During this quarter, SIAPS supported the Kita District in finalizing the last training of CSCom depot managers on storage, use of tools including stocks cards and logistic reporting tools, requisition form and how to calculate commodities needs as indicated in the new LMIS SOPs.

SIAPS also supported Kayes Regional Directorate of Health in providing trainings of supervisors using the supportive supervision guide. As a result of these trainings, 23 supervisors (20 males and 3 females) were trained on supportive supervision and 29 users (23 males and 6 female) on LMIS SOPs. Additional support was given to the Regional Directorate of Health of Bamako in conducting coaching of 62 health depot managers and health care providers. These coaching sessions showed that 52 of 62 health depot managers successfully completed their post-training action plans.

During the FY14-funded period, SIAPS provided technical assistance to the MOH to develop and roll out a web-based portal dashboard for malaria, MNCH, and FP commodities. SIAPS supported the MOH to accomplish the user acceptance testing, and orient warehouse managers and Health Management Information System managers in 50 districts. Each of them received their credential to enter monthly data into OSPSANTE.

As was planned into the year five work plan, during this quarter, SIAPS continued to provide technical and financial support to MOH at the regional and district levels to support the warehouse and HIMS managers in capturing monthly LMIS reports in the dashboard. To this end, internet access was provided to warehouse managers in 50 districts, as well as to five regional pharmacists and six regional information system managers.

Partner contributions

- DPM,
- Direction Régionale de la Santé of Kayes, Koulikoro Sikasso Segou, Mopti and Bamako.
- 50 Health Districts of Kayes, KoulikoroSikasso Segou, Mopti and Bamako regions (including six districts of Bamako)

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

During FY14, SIAPS provided technical assistance to the MoH (DPM, DRS, PNLP, and DSR) to develop and roll out a web-based portal dashboard for malaria, MCH, and FP commodities. The dashboard was designed to capture, track, aggregate, and make information available and accessible about malaria, MCH, FP and tracer drug products, and to improve information availability and accessibility for better and faster decision making at the national level. The web portal assists MoH and relevant stakeholders in improving forecasting, supply planning and procurement to support the continuous availability of malaria, MCH, and FP-related commodities. It also offers a platform to easily share information on funding flows and stock-out risks.

During the user acceptance testing of OSPSANTE, all stakeholders requested that HIV/AIDS and Nutrition commodities be included in OSPSANTE. During this quarter, SIAPS Mali worked with the developer, the DPM, and the relevant stakeholders to discuss how to add HIV and AIDS commodities into OSPSANTE. Two consensus workshops were conducted under DPM leadership on March 8 and 10 to collect information and agree on forms and reports to be used in the country to report on HIV and nutrition commodities. The decisions made in these workshops included:

- The master list of nutrition and HIV commodities
- The reporting forms
- The frequency of reporting
- The flow of information

To finalize data collection and address remaining requests, a working group for nutrition and HIV was established. The next steps will be the development of nutrition and HIV commodities portal, the user acceptance test before starting data entry into OSPSANTE dashboard.

The handover of the OSPSANTE tool was also discussed with the MOH during a meeting with DPM and the MOH IT Department ANTIM. It was agreed during this meeting that ANTIM will provide DPM with the all the resources needed to maintain OSPSANTE after the handover to DPM. During the reporting period, SIAPS and Measure Evaluation held several meetings called by USAID/Mali to explore interoperability option between OSPSANTE and DHIS2 platform.

During this quarter, SIAPS also submitted to USAID Washington a PPMRm report in January 2016 and a PPMRc report in February 2016 after collecting stock information data from the national and facilities levels by using OSPSANTE. The major findings and recommendations resulting from these two reports were:

- Stock levels for malaria commodities are generally very low throughout the country;
- To avoid stock-out Global Fund/PSI must expedite in emergency the expected quantity of AL 6X1, 6X2, and 6X4 before the end of March 2016;
- Contraceptives received by the DPM should be transferred to the PPM to be distributed to health facilities

Partner contributions

- DPM, PPM, SG/HCNLS, CSLS, USAID, UGP/UNDP DPM, DNS, UNICEF, PPM, USAID and USAID/Service de Santé à Grand Impact (SSGI)/Save the Children participated in the consensus meeting
- PPM, PSI, DPM, DSR, USAID, KJK and UNFPA provided data and participated to data analysis and validation for the PPMRm and PPMRc reports

- DRS, PPM Regional warehouses and 50 health districts of Kayes, Koulikoro, Sikasso, Segou, Mopti regions and Bamako participated to data collection and entry in OSPSANTE

Constraints to progress

Poor ownership of actors at all levels to analyze data and make relevant decisions.

Deliverables

- Technical report of OSPSANTE extension
- PPMRc report
- PPMRm report

Objective 4: Pharmaceutical services improved to achieve desired health outcomes

To improve pharmaceutical services to achieve desired health outcomes, SIAPS Mali worked with DRS to conduct joint supportive supervision and coaching visits to the regional depots, regional hospitals, district depots, HFs, health center pharmacies/sales points, in Kayes, Koulikoro, Sikasso, Segou and Mopti. A total of five regional warehouses, four regional hospitals, 42 district warehouses, and 1,069 health facilities received supervision.

The methodology used to conduct this supervision included:

- A two-day orientation workshop of supervisors on the supportive supervision guide.
- Supervision planning by district senior staff according to the supervision guide.
- Identification of itineraries.
- Identification of bottleneck with local staff and development of an action plan.

The supportive supervisions contributed significantly to progress made in medicines management at the facility level. As a result, accurate stock records increased from 80% to 84% (1761/2093) The majority of depot managers (93%) are now using consumption data to inform ordering. A total of 1,091 facilities that submitted logistics management information system report during the last month are using country-appropriate tools. They have also contributed to improving LMIS roll-outs, to the implementation of the essential medicines procurement and distribution scheme (SDADME), and to strengthening the capacity of field-based health workers to use the newly developed reporting tools for medicines stock status, consumption, and treated patients. During supervision and coaching visits, supply chain bottlenecks and problems were identified and discussed with all stakeholders, and corrective actions were taken accordingly.

Partner contributions

DRS, PPM Regional warehouses, and 50 health districts in the Kayes, Koulikoro, Sikasso, Segou, Mopti and Bamako regions

Constraints to progress

None

Mali Ebola Portfolio

Goal: Assure the availability of quality pharmaceutical products (infection prevention and control commodities) and effective pharmaceutical services to achieve desired health outcomes

Background

In October 2014, a case of Ebola virus disease was detected in Mali, leading to concern about the possibility of an outbreak of Ebola in Mali. A child brought to Mali from Guinea died in the northwestern city of Kayes. Mali traced over 100 people who had contact with the child; tracing was completed in mid-November with no further cases discovered. In November 2014, a second unrelated outbreak occurred in Mali's capital city, Bamako. Several people at a clinic were thought to have been infected by a man traveling from Guinea. On January 18, 2015, Mali was declared Ebola-free after 42 days with no new cases. There had been a cumulative total of eight cases with six deaths.

As of late 2014, the Ebola virus epidemic in Mali's southern neighbors Liberia, Sierra Leone, and Guinea has led to thousands of deaths. Mali, a country of about 16.5 million people, was ranked as one of the top four countries at risk for an outbreak prior to its first reported case.

The financial resources that have become available to Mali through its participation in the Global Health Security Agenda (GHSA) provide Mali with the opportunity to accelerate its progress toward strengthening health security by implementing the International Health Regulations (IHR). These resources provided by the US Government focus on prioritizing coordinated action and specific, measurable steps focused on preventing epidemics, detecting biological threats early, and rapidly responding to disease outbreaks, whether naturally occurring, intentionally produced, or accidentally caused.

The US Government support may also include infection prevention and control (IPC) activities, safe burial teams, case management and infection control training, the distribution of infection control commodities, and support to the Government of Mali's newly established Ebola Emergency Operations Center (EOC).

The US Agency for International Development's (USAID) mission in Mali requested that the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program provide

technical assistance to Mali to make an inventory and needs assessment for IPC commodities and provide recommendations to the EOC/Center des Opérations d'Urgences. The EOC was established by November 14, 2014, as part of the response to health emergencies in Mali and since the beginning of the Ebola epidemic in Mali, leads activities to fight against the virus. In this context, the EOC is the central coordinating mechanism of information and resources for the strategic and operational management of events and public health emergencies, especially those that may constitute a public health emergency of international scope.

The Mission also asked SIAPS to provide technical assistance and training on forecasting, storage, and distribution of Ebola commodities to USAID partners and health centers in USAID-supported districts.

Overall Quarter Progress

Progress was made during the second quarter of PY5 to finalize and validate the work plan as well as the budget for Ebola funds. The following activities were validated to be conducted during this current fiscal year:

- Support the MOH through the EOC to conduct a needs assessment for IPC commodities
- Provide technical assistance and training on forecasting, storage, and distribution of Ebola commodities to USAID partners and health centers in USAID-supported districts
- Add IPC commodities, if feasible, to the existing dashboard OSPSANTE to facilitate aggregation of logistic data for decision making

Support was also given to the MoH to implement the first activity with the aim to build capacity of individuals and institutions in pharmaceuticals management. A rapid assessment of the current situation in the health facilities in terms of equipment, human resources, as well as the inventory of the existing IPC commodities, were conducted in Kayes, Koulikoro, Sikasso, and Bamako district.

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

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

Activity 2.1.1: Support the MOH through the EOC (COU) to conduct a needs assessment for IPC commodities (source of funds: Ebola)

In response to the Ebola virus disease outbreak in October 2014, the top country officials have implemented the EOC to respond to Ebola outbreaks and work toward preventing future epidemics. Following joint efforts with all partners, Mali was declared Ebola free on January 18, 2015. However, on March 18, 2016, WHO announced the recurrence of cases of disease in Ebola virus in Guinea. Facing the risk of reintroduction of the virus in Mali, actions were urgently taken to ensure better protection of the population. During this quarter, SIAPS supported the MoH to conduct an assessment, as well as the inventory of equipment and IPC commodities in

the health facilities of the regions located in the border areas with Guinea: Kayes, Koulikoro, Sikasso, and Bamako district. A technical visit was conducted by the EOC to the border facilities and it showed that there is a need to improve equipment and IPC commodities in the field. The next step will be the analysis of the assessment and the forecasting of the needs.

Partner Contributions

All USAID implementing partners participated in the activity.

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

No activities to report.

Mozambique

Goal: To ensure access to safe, efficacious and quality pharmaceutical products and services that help achieve desired health outcomes.

Overall Quarter Progress

In this quarter SIAPS provided support to the Pharmacy Department (PD) to improve medicines policies, legislation, regulations, norms, and standards, with the aim of handing over the mechanism for monitoring and periodic revision of the national essential medicines list to the Ministry of Health (MOH). SIAPS submitted the terms of reference (TOR) for the Committee of Selection and Use of Essential Medicines for MOH approval, submitted the proposal to train the Committee secretariat at PD on the use and monitoring of the NEML for MOH approval, and finalized the training materials to train the committee in the use and monitoring of the NEML.

At the end of quarter SIAPS supported the PD M&E staff to conclude the PD M&E report, presenting information on 13 pilot indicators; five new indicators were added to the PDP Performance Monitoring Plan (PMP) and Performance Indicators Reference Sheets (PIRS). These two documents were submitted to the head of the Pharmaceutical Department.

SIAPS also supported the implementation of the hospital pharmacy M&E system. In this activity, support was provided to the Hospital Pharmacy Department (HPD) to develop the Hospital Pharmacy M&E performance monitoring plan. In this stage the technical group, composed of one SIAPS staff member and two HPD staff members, worked on the selection of the most suitable indicators to monitor sector performance.

SIAPS also supported the HPD in developing a data quality assessment tool, which will allow HPD to analyze the quality of the medicine use data sent from the health facilities to HPD. To provide technical support for the implementation and handover of the electronic medicines registration system (Pharmadex), SIAPS responded to low usage of Pharmadex by holding a workshop by in collaboration with the PD, in January 2016, with the objectives of: (1) Assessing the current situation of PharmaDex (interventions and outcomes); (2) Identifying barriers and root causes; (3) Define interventions to remove the barriers to the use of PharmaDex.

To strengthen the capacity of the HPD to improve the functions of hospital drug therapeutic committees (DTCs) at the central and provincial levels for the second quarter, two supportive supervision visits were performed at the Lichinga Hospital DTC and the Pemba Hospital DTCs. The purpose of supportive supervision visits was to help the HPD support the Pemba and Lichinga Provincial Hospital DTCs in improving medicine use studies, and to use results to improve medicine use at the health facility level.

Objective 1: Governance in the pharmaceutical sector strengthened

In this quarter SIAPS provided support to the Pharmacy Department (PD) to improve medicines policies, legislation, regulations, norms, and standards, with the aim of handing over the mechanism for monitoring and periodic revision of the national essential medicines list to the

MOH. At the end of the quarter SIAPS submitted the TOR for the Committee of Selection and Use of Essential Medicines for MOH approval. Therefore, the next steps for this activity are: the national essential medicines list 2015 Publication in the Republic Bulletin; and a review of the monitoring plan for the LNME.

SIAPS also supported the PD in the implementation of the M&E Plan, SIAPS at the end of the quarter was possible to obtain the following outputs: Pharmaceutical Department M&E report presenting information on 13 pilot indicators, five new indicators added to Pharmaceutical Department, Performance Monitory Plan (PMP) and Performance Indicators Reference Sheets (PIRS), these two documents were submitted to the head of the Pharmaceutical Department.

To develop the report, a SIAPS technical adviser supported the two M&E staff in developing the report structure, determining which relevant information should be included, as well as how this information should be displayed. Each section started with the overall vision of the pharmaceutical department, its objectives and a brief summary of the revitalization process of the indicators. Lessons learned and recommendations for improvement of the Pharmaceutical Department Monitory and Evaluation functions were included in each chapter.

Main takeaways from the data collection included:

- Although the adverse drug reactions report rate has increased, the responsiveness of the National Pharmacovigilance Unit decreased, taking on average 116 days to respond to a notification
- A reduction of the time for registration was verified in 2013; however, in 2014 there was an increase of 34 to 69 days to complete registration. The number of days to obtain the market authorization for abbreviated registration, remained stable at approximately 345 days.
- The average time for medicines registration continued to increase in 2015
- In regard to the 397 products included in the EML, we can see that only 62% were registered by 2015.

The next steps for this activity are:

- Present the results of the first data collection in the board meeting
- Support PD M&E staff to prepare the second MOH Quarterly Report
- Support PD to hold a results-based management workshop

To provide technical support for the implementation and handover of Pharmadex, SIAPS in 2015 provided adequate infrastructure to support the electronic tool, adapted the tool to local registration regulations, trained registration staff, and launched PharmaDex in Mozambique. Since then, the use of PharmaDex became lower than expected.

Thus, SIAPS, in collaboration with the PD, held a workshop on January 20, 21, and 26 of 2016, with the objectives of:

- Assessing the current situation of Pharmadex (interventions and outcomes);
- Identifying barriers and root causes behind low Pharmadex use;

- Defining interventions to remove the barriers to the use of Pharmadex.

Partner contributions

- PD registration sector staff are collaborating in the implementation of PharmaDex
- 2 PD staff were very active members of the TWG, and contributed to the update of the PIRS and PMPs
- The PD committee secretariat has collaborated with SIAPS to accelerate the NEML list

Constraints to progress

- Reduced availability of PD M&E technicians due to other activities than M&E,
- Some units, such as PV and registration, have poor data management capabilities
- Most of the targets have not yet been defined by the PD units
- The National Essential Medicines List is still not publicly available (but is a top priority for the next quarter)

Objective 3: Pharmaceutical Services improved to achieve health outcomes

To strengthen the capacity of the HPD to improve the functions of hospital drug therapeutic committees (DTCs) at the central and provincial levels for the second quarter, two supportive supervision visits were performed at Lichinga Hospital DTC and Pemba Hospital DTCs. The purpose of supportive supervision visits was to help the HPD support the Pemba and Lichinga Provincial Hospital DTCs in improving medicine use studies, and to use results to improve medicine use at the health facility level.

The activities in support of the Departamento de Farmacia Hospitalar/Hospital Pharmacy Department (DFH) for this visit included a pre-supervisory visit review of the procedures and tools for medicine use studies and for to evaluate and rectify medicine use problems, as well as provide DFH with basic guides and protocols to conduct medicine error studies.

During the supervisory visit, hospital pharmacists were trained by SIAPS staff in aggregate consumption studies, prescription indicator studies, and medicines errors studies, learning how to collect and analyze report results. The trainees were able to produce reports and analyze results based on prescription indicator, ABC, VEN and therapeutic group analysis based on consumption data retrieved from the hospital requisition of medicines from the provincial warehouse.

In Lichinga Province, the team was able to attend a DTC meeting where the results of the studies were shared. SIAPS staff facilitated the DTC members' discussion, and DTC members were able to prioritize one problem, conduct the root cause analysis, and design interventions and follow-up activities. The DTC prioritized the inconsistency of data from clinical records and pharmacotherapeutic records, and concluded that the root causes were resistance by doctors to adhere to the new procedures to review the medication. As a result, the DTC planned to train clinicians on the new norm for completing medical charts and monitor clinicians on the compliance of the new procedures for completing medical charts.

The next steps for Pemba Hospital are to: remotely support DTC pharmacists in conducting medicine use studies (consumption, prescription and medicines errors); support the DFH in facilitating DTC meetings to determine the root cause of the problem; and design, implement and evaluate interventions for improving medicine use problems. The next steps for Lichinga Hospital are: ensuring prescriptions are written by the clinicians both in the clinical process as well as in the pharmacotherapeutic form; developing a norm to formalize the decision; ensure counseling and dissemination of the norm; and monitor the adherence to the norm.

In addition to these activities, SIAPS supported the HPD in improving internal productivity by improving basic office work conditions. The HPD has a very small and cramped office space, which initially was quite disorganized, causing staff to spend an increased amount of time hunting files down and constantly reorganizing. The department was also not able to use the IT equipment procured through MSH in October 2015, without connectivity interruptions; as cables, wires and extension cords were currently running all over the floor and someone always stepped over a wire and switched off the entire connectivity, increasing the risk of IT equipment being damaged. In January 2016 office furniture specific to small office areas, was set up at the Ministry of Health Building, helping staff to remain organized and better focused on their work.

Partner contributions

- The DFH was responsible for preparing all official and administrative arrangements for the two visits
- The DFH played an important role in providing technical assistance to the DTCs

Constraints to progress

- In Pemba Hospital it was not possible to conduct a DTC session; instead the DFH and SIAPS staff met with the President of the Pemba Provincial Hospital to discuss the results of the studies and plan the way forward.
- The DFH expanded their role and responsibilities, and therefore expected SIAPS support to be expanded to these activities. SIAPS country team had meetings with the DFH to agree that support will remain confined to DTC activities as planned in PY5 work plan.
- Availability of time to finalize the technical report and SOPs has been a challenge as the project has a limited number of technical advisers. The CPD has been acting as the main technical adviser to fast-track this activity, and the project has hired one technical adviser.
- The department was also not able to use the IT equipment procured through MSH in October 2015, without connectivity interruptions; as cables, wires and extension cords were currently running all over the floor and someone always stepped over a wire and switched off the entire connectivity, increasing the risk of IT equipment being damaged..

Namibia

Goal: To improve the quality and safety of pharmaceutical products and services for sustained HIV epidemic control in Namibia

Overall Quarter Progress

SIAPS continued to work with the Namibia Medicines Regulatory Council (NMRC) to support the reconfiguration and deployment of the web-based Pharmadex tool. The tool will improve efficiency of the NMRC, facilitate review of applications for medicines registration, and improve dissemination of information on essential medicines. This will contribute to ensuring the availability of safe and high-quality medicines for treating HIV and related co-infections; for maternal, newborn and child health; and for other public health diseases. Through SIAPS technical assistance (TA), the post-market surveillance of medicines quality in the country has been transitioned to the NMRC.

SIAPS provided TA to the University of Namibia's (UNAM) School of Pharmacy (SoP) to develop course materials for a pre-service training in medicines regulation, as outlined in the curriculum of the UNAM Bachelor of Pharmacy degree. In February 2016, SIAPS facilitated a consultative stakeholders' review of the draft learning outcomes and course content of the medicines regulation module. Seventeen key stakeholders participated in the meeting to review training materials. SIAPS also supported the Ministry of Health and Social Services (MoHSS) National Health Training Centre (NHTC) to conclude the production of a 15-minute video on support to strengthen the Pharmacist's Assistant (PA) training program. The video highlights SIAPS's support to human resources for health capacity enhancement, particularly the PAs' role in providing ART services.

With SIAPS support, more than 50 ART sites that are serving over 140,000 patients were visited to mentor staff on effective ART service provision and closing the gap of patients lost to follow-up, as identified through the Electronic Dispensing Tool (EDT) to maintain high quality ART service delivery.

Site-level support and data quality audits have been the cornerstone of targeted TA to health facilities in Q2. SIAPS visited the seven PEPFAR priority regions and towns during annual pharmaceutical support supervisory visits (SSVs) and on-the-job support to implementation of the short message reminder for ART adherence. During the visits, SIAPS provided detailed guidance on transitioning ART patients on second-line lopinavir/ritonavir-based regimens to atazanavir/ritonavir-based regimens. Data on active patients and newly enrolled patients for the preceding month was compared between the EDT and the electronic patient management system (EPMS) used by clinicians for any data gaps. In facilities with more than 5% variation in data entries, SIAPS facilitated stakeholder meetings with the MoHSS staff and partners to identify solutions on tracing patients who were not accounted for in the system and updating both records.

SIAPS is a core member of the newly formed MoHSS Health Information System (HIS) Technical Working Group (TWG). Work on ensuring interoperability of the EDT and EPMS

are at an advanced stage. SIAPS, in collaboration with IntraHealth Namibia, is part of the task team within the HIS/TWG mandated to ensure that the protocols and standards for the tools (EDT and EPMS) to allow them to work together are developed. In this quarter, SIAPS with IntraHealth developed an application to extract data from both tools to an SQL database and enable data manipulation, comparisons, and file sharing, including data quality checks.

SIAPS provided TA in the Global Fund reprogramming to ensure new funding is allocated for key pharmaceutical services areas, such as the review of the Namibia Standard Treatment Guidelines, support to the Therapeutics Information and Pharmacovigilance Centre, and for District Hospital Therapeutics Committee meetings.

Objective 1: Quality and safety of ARVs and medicines for opportunistic infections assured

Post-market surveillance activities have been transitioned to the NMRC through SIAPS TA. Continuous post-market surveillance will ensure quality and safety of ARVs and related commodities that are integral in HIV and AIDS treatment including those for treatment of opportunistic infections.

In this quarter, SIAPS provided support to the NMRC dossier evaluation team during the review session from February 1 to February 5. NMRC has taken on the activity previously supported by SIAPS and is funding it. The review sessions are organized every two months to sustain the SIAPS interventions to improve efficiency and ensure access to safe, effective, and quality medicines by the population of Namibia.

Analysis of the medicines registration data from the Pharmadex medicines registration tool show that the average number of days taken to evaluate and approve a medicine registration application reduced from 34 days in 2013 to 25.7 days in 2015. The interventions for this performance included increased number of human resources at NMRC, bimonthly group review sessions fully funded by NMRC and continued SIAPS TA in medicines regulation. A total of 197 products (25.4%) received in 2015 were registered in 2015. A positive note is that 78 (4%) of the items listed in the official National Medicine List (Nemlist) used by the government for procuring medicines in the public sector are registered in the Pharmadex desktop tool.

SIAPS provided TA to the MoHSS for the review of 97 recommendations of medicines for inclusion in the Nemlist. A total of 69 medicines were recommended for inclusion in the Nemlist 6th edition during the Essential Medicines List Committee (EMLC) meeting held March 16-17, 2016. Eleven of the recommended formulations for addition to the Nemlist were ARVs.

SIAPS continued to work with the NMRC to support the reconfiguration and deployment of the web-based Pharmadex tool. There is commitment from the MoHSS and feedback has been documented on how to improve the current version. A web-based Pharmadex tool will greatly assist NMRC and applicants to improve efficiency and transparency in medicines registration.

Partner contributions

NMRC provided feedback and support towards implementation of the web-based Pharmadex tool for medicines registration and also collaborated on dossier reviews in February 2016.

Constraints to progress

The implementation of the web-based Pharmadex has not progressed as anticipated. The country team is still waiting for instructions and setup links from the programmer to deploy the tool at NMRC and start user testing.

Objective 2: HR capacity in pharmaceutical management and service delivery strengthened for improved HIV and AIDS treatment outcomes

SIAPS supported the UNAM-SoP to obtain stakeholders' input on draft materials for pre-service training in medicines regulation, as outlined in the curriculum of the UNAM B.Pharm degree. The reviewed training materials were drafted in FY 2015 with SIAPS TA. The 17 stakeholders who participated included the Pharmaceutical Society of Namibia, the NMRC, the Health Professions Council of Namibia, pharmaceutical manufactures, and medicines importers and distributors in Namibia. The pre-service training in medicines regulation will ensure that graduating UNAM pharmacists are equipped with the essential knowledge and skills to assure the quality, safety and efficacy of medicines, including ARVs and related medicines.

In support of the National Health Training Center (NHTC) documentation of successes and support from USAID, SIAPS edited the video recordings to develop a 15-minute video. The video highlights SIAPS support for enhancing human resources for health capacity, particularly the PAs in the provision of ART services.

SIAPS, in collaboration with Supply Chain Management System project, supported the MoHSS to assess and improve the performance of health facilities through SSVs for mentoring pharmacy staff on ARV inventory management and pharmaceutical service delivery. Scored checklists that SIAPS supported to update in FY16 were used to assess storage of medicines and clinical supplies; human resources; status of implementation of previous SSV recommendations; inventory quantification, control, and management; pharmaceutical management information system; functionality of therapeutics committees; ART services; therapeutic information and pharmacovigilance activities; and quality of dispensing practices. Relevant sections of the SSV checklists have been used by the regional and district pharmacists to supervise their frontline health facilities during regular site visits; this maintains the year round mentoring and continuous improvement at the facility level. Health workers reported that the SSVs have helped them to maintain high quality pharmaceutical standards in ART service delivery and allowed them to share experiences from other regions as regional pharmacists are involved in SSVs in other regions.

Site level support and data quality audits have been the cornerstone of targeted TA to facilities in Q2. SIAPS supported the MoHSS to mentor staff on effective ART service provision and closing the gap of patients lost to follow up as captured on the EDT. The TA aimed to maintain high quality ART service delivery in the PEPFAR priority regions and towns. SIAPS provided the support during SSVs conducted in February 2016. Six PEPFAR priority regions

were visited: Oshana, Kavango East and West, Zambezi, Oshikoto, and Ohangwena. All 50 sites providing ART services to about 140,000 patients were visited including the two multi-regional medical depots distributing ARVs and other essential medicines to these sites. SIAPS provided detailed guidance on the transitioning of patients on second-line lopinavir/ritonavir-based regimens to atazanavir/ritonavir-based regimens. Data on active patients and newly enrolled patients for the preceding month was compared between the EDT and EPMS used by clinicians for any data gaps. In facilities with more than 5% data variations, SIAPS facilitated stakeholder meetings to identify solutions on tracing patients and updating both records.

Partner contributions

- UNAM-SoP, Health Professions Council of Namibia (HPCNa), Pharmaceutical Society of Namibia (PSN), NMRC, Pharmacy Council of Namibia on the review of the pharmaceutical regulatory affairs course materials for pre-service training of B. Pharmacy students
- A member of the Pharmacy Council of Namibia acknowledged the relevance and utility of the regulatory affairs training materials in building the capacity of local pharmaceutical personnel in medicines regulation. She wrote, "This module will give the students valuable exposure to sectors of pharmacy that not many pharmacists have any experience of. It will be valuable to the industry to have interns/young pharmacists who know how inspections are done. It will also hopefully create an interest with students to pursue their careers in industry and regulatory affairs."

Objective 3: Availability and use of pharmaceutical service data is enhanced for improved quality of ART services

SIAPS continued to provide routine technical support to MoHSS' 50 main EDT sites, Rx Solution at Intermediate Hospital Oshakati, e-TB Manager and national database (NDB) servers to ensure optimal availability of data from these tools to improve pharmaceutical service delivery, especially for people living with HIV and AIDS. SIAPS conducted a user satisfaction survey on the use of the e-TB manager on how to improve the tool, and will compile the feedback into a consolidated report to inform improvements on the tool. SIAPS also supported the development and deployment of the updated data analysis tool on the e-TB manager that can be used to filter data by dates, and save customized reports for later retrieval with an option to show them on the home page (or dashboard).

During the SSVs conducted in February 2016, SIAPS provided on-the-job TA to over 20 PHC facilities using the mobile EDT (mEDT) for ARV dispensing and ART data capture. The TA included data upload from the main EDT to the mEDT, dispensing using the mEDT and download of patients' data from the mEDT to the main EDT. Maintenance and troubleshooting instructions were also explained to the staff members.

SIAPS is a core member of the newly formed MoHSS Health Information System (HIS) Technical Working Group (TWG). Work on ensuring interoperability of the EDT and EPMS are at an advanced stage. SIAPS in collaboration with IntraHealth Namibia are part of the task team with the HIS/TWG mandated to ensure that the protocols and standards are developed for the tools to be interoperable. In the quarter under review, SIAPS and IntraHealth developed an

application to extract data from both tools to a local SQL server database and enable manipulation of EPMS and EDT data to identify files that can be shared. Within the same TWG, SIAPS presented ongoing work on finalizing the MoHSS pharmaceutical information system dashboard. The tool, in particular the electronic stock card, has been pre-tested with regional pharmacists from Hardap and Karas regions who provided insightful feedback for further enhancement and ensuring that the tool is user friendly. The dashboard and electronic stock card is expected to be launched in April 2016.

SIAPS supported MoHSS Div: PhSs to compile the consolidated ART pharmaceutical management information system (PMIS) feedback report for the period Oct to Dec 2015 which includes information on ART patients' adherence and retention in care. According to the report, the total number of active patients on ART was 145,246 at the end of December 2015. Several Early Warning Indicators (EWIs) for HIV Drug resistance (DR) were also reported. Retention in care for ART patients in cohorts started a year ago remained high at 94.9%. SIAPS continued providing technical assistance to MoHSS to retrain staff at Okuryangava and Khomasdal clinics on the short messaging system (SMS)-based adherence reminder service, updated the SMS database structure to improve interoperability with other systems. The SMS service allows automated short messages to be sent to ART patients reminding them about their pharmacy appointments, encouraging adherence to ART.

Partner contributions

- MoHSS Division of Pharmaceutical Services sub-division National Medicines Policy Coordination (NMPC) on support to public health facilities using the EDT and mEDT
- MoHSS-Directorate of Special Programs on support to primary health care (PHC) facilities using the mobile EDT for ARV dispensing and ART data capture

Objective 4: Quality, efficiency and accessibility of pharmaceutical services strengthened to attain 90% treatment coverage and 90% viral suppression

A routine PMIS feedback report is compiled and disseminated by MoHSS on a quarterly basis. SIAPS provided TA in the analysis and data presentation on ART medicines and service delivery for the period July to September 2015. The feedback report was compiled on 13 pharmaceutical service delivery indicators and was disseminated to all 14 regions on January 7, 2016.

SIAPS provided TA in the Global Fund reprogramming to ensure new funding is allocated for key Pharmaceutical Services areas such as the review of the Namibia Standard Treatment Guidelines, support to the Therapeutics Information and Pharmacovigilance Centre, funding for facility Therapeutics Committee meetings and supply chain related activities at the Central Medical Stores.

The latest Nemlist (6th edition) is currently being printed by the MoHSS. SIAPS provided TA for reviewing 97 recommendations for medicines to be included in the Nemlist. Eleven new ARV formulations were recommended for inclusion in the Nemlist in line with the recommendations of the MoHSS HIV treatment guidelines to support the new test and treat

approach for HIV positive patients. In March, SIAPS supported the review of literature, compilation and submission of these recommendations to the Policy Management Development and Research Committee (PMDRC) to seek approval for updates to Nemlist.

SIAPS Namibia continued to work with MoHSS and the Harvard Pilgrim Health Care Institute to seek ethical approval for the assessment focused on pediatric ART data analysis, using information from electronic logistics and patient data management tools. MoHSS guided SIAPS on ensuring that the objectives of the analysis are in line with their priorities; the proposal was resubmitted in February.

SIAPS supported MoHSS to compile the October-December 2015, ART PMIS feedback report. This report provides feedback on ART pharmaceutical services and obtains most of its data from the electronic dispensing tool. The report is always done a quarter later to allow complete data to be transmitted to national level for analysis.

SIAPS provided TA to two ART sites implementing short message system (SMS) reminders aimed at enhancing ART patients' adherence to treatment and minimize lost to follow up. The Okuryangava and Khomasdal clinic staffs were trained on the purpose of the SMS reminder activity and the importance of recruiting patients as well as counselling them before recruitment. The ten staff members trained included doctors, pharmacists, nurses, and community counsellors.

Partner contributions

- MoHSS HIV case management unit and Directorate of Special Programs on ART adherence and retention initiatives including providing direction for SMS reminder implementation and roll out
- Harvard University on systematic process for review of EDT data elements and queries to assist in the strengthening of ART EWI data use for decision making

Niger

Goal: To strengthen pharmaceutical management of health products to treat malaria

Highlights of activities this quarter include the preparation of SMC 2016 campaign and Global Fund New Funding Mechanism (NFM) grant negotiation. Also, December stock inventory at the central medical store indicated needs of analysis and discussion to address potential issues.

As results of these and other activities, the Global Fund to fight AIDS, Tuberculosis and Malaria (Global Fund) Procurement and Supply Management plan found agreement among NMCP, CRS and Global Fund. Also Global Fund will support supply chain strengthening activities through the health system strengthening fund and they will allocate sufficient funding within the NFM amount to fill major commodities gap for the years 2016, 2017 and 2018. Additionally, the SMC campaign commitment from partner for 2016 show an estimate coverage needs for 58% of the estimated target

Objective 1. To strengthen the systems for malaria commodities management

Seasonal malaria chemoprevention
In 2015, the NMCP is implementing seasonal malaria chemoprevention (SMC) in 11 districts in Niger with funding from the Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS-SMC) project. The project implementation is led by Malaria Consortium in partnership with Catholic Relief Services (CRS). To improve SMC implementation in 2016, the second planning meeting was held in January to review 2016 targets, coverage area, and funding gaps. The targets, funding levels, and new gaps are summarized in Table 1 below. Approximately 23 districts will be covered (with 17 totally covered) out of the 36 eligible districts.

For SMC 2016 campaign, the ACCESS-SMC/UNITAID and the World Bank represent around 73% of the total target covered for this year. Around 17 districts will be totally covered and five partially covered out of the 36 eligible districts.

During this quarter, the SIAPS technical advisor and NMCP staff followed up on the procurement/ ordering status of SMC commodities by each partner to ensure timely delivery of the products. A supply table has been developed to help the NMCP to better follow up orders with partner.

Partner contributions

The SMC activities in 2016 will be financially supported by many partners such UNITAID through the ACCESS-SMC project, World Bank, Doctors without borders (MSF), UNICEF, and Islamic Relief Service

Constraints to progress

Current funding is insufficient to cover all 2016 SMC targets

Global Fund New Funding Model Grant Negotiation
During January and February, the NMCP and the CRS (principal recipient) held several meetings to negotiate the new malaria grant under the Global Fund New Funding Model with the Global Fund team. A SIAPS technical advisor led the PSM part of the negotiations, with support of the NMCP manager and the CRS team. The negotiations were successful and all the parties reached an agreement.

Based on the technical documentation presented and some savings and internal cost cutting by the country, the Global Fund agreed to reallocate some funds to cover more commodities needs within the grant threshold. Also taking account of the current status of malaria commodities at the central level, the delivery time of the products and the anticipated late beginning of this new grant (signature expected for early May 2016), the Global Fund agreed to place an emergency order in December 2015 and also an order for year one (2016 orders).

Constraints to progress

Change in Global Fund Portfolio with new clarification, which delayed final approval of the grant.

Strengthening Commodities Supply Chain in Niger
Under the supervision of the Country Coordination Mechanism (CCM), commodities supply chain partners met multiple times to identify major activities and develop a work plan that can be funded by Global Fund through the TB-Health System Strengthening grant. An amount of one million Euros is planned for supply chain activities. Based on recommendations from previous assessments, the following activities were proposed:

- Develop and implement a logistics management system and tools
- Set up a national commodities committee
- Support the extension of stock management and dispensing software after its development and pilot phase funded by France Expertise Internationale (5% of funds) and the HIV and AIDS Global Fund grant
- Strengthen the central medical store (Office National des produits Pharmaceutiques et chimiques [ONPPC]) capacity by rehabilitating one regional warehouse, and procuring warehouse, storage material, and truck for distribution

The SIAPS technical advisor was involved in all discussions on strengthening the commodities supply chain. In addition to these activities, specific actions to improve malaria commodities supply chain have been identified and funding will come from the Global Fund upcoming grant. Activities identified to strengthen NMCP capacity include:

- Support to malaria supply chain committee
- Recruitment of a procurement and supply manager at NMCP
- Design a logistics management information system for malaria product
- Support training courses on NMCP supply chain unit regarding stock management and procurement

- Training of stock managers at district and health levels

Partner contributions

Large part of the plan will be funded by the Global Fund. Additional partner should be found.

Constraints to progress

Duration of the NFM grant reduced from three years to less than two years (May 2016 to December 2017) instead of December 2018.

Development of NMCP National Strategic Plan 2016–2020

During this quarter, the NMCP started the review and evaluation of their 2011–2015 national malaria strategic plan and also the development of the 2016–2020 strategic plan. To complete this activity, the NMCP has the financial and technical support of the World Health Organization. SIAPS's contribution was to provide support on evaluating and developing the supply chain activities in the document.

Partner contributions

WHO supported the development of this activity; the Global Fund and UNICEF may also support the next step.

Coordination with Partners

During this quarter, SIAPS has supported the NMCP in conducting meetings with partners involved in malaria management including supply chain. SIAPS also contributed in the revision of malaria data collection tools and the review of the reporting system and information flow. Coordination meetings took place with all partner involved in commodities supply chain to discuss activities and work plans to strengthen commodities management in Niger and to implement integrated community case management and SMC (Table 1).

Table 1. Coordination Meetings held January to March 2016

Partners	Dates	Purpose
CRS, NMCP, CCM, Direction de la Statistique, Save the Children, Direction de la Pharmacie et Médecine Traditionnelle, ONPPC	January and February 2016	Development of work plan to improve and strengthen supply chain activities through Global Fund RSS grant.
Direction des Etudes et de la Programmation Ministry of Health, CCM, Global Fund, UNICEF, USAID, NMCP, CRS	January 27, 2016	Coordination meeting on iCCM and SMC activities involving Global Fund and UNICEF
CRS, All Regional Health Directorate (represented by regional Malaria coordinator, Data Manager), NMCP, Plan Niger	March 2016	Revision of malaria data collection tools
CRS, MSF Spain, MSF France, MSF Belgium	December 3, 2015	Planning of SMC intervention in 2016

Constraints to Progress

- If not addressed, lack of supply chain stock analysis, lack of capacity of supply chain staff at NMCP, lack of proper stock management, and delays on Global Fund and government procurements could result in repeated stock-outs of malaria commodities this year.
- Government procurement of LLINs, rapid diagnostic test kits, and malaria commodities could not be delivered in time due to political environment with Presidential and parliamentary vote. This challenge has been discussed and the LLIN campaign in a region has been rescheduled for next year and ACT orders scheduled to be delivered during the last quarter of 2016.
- The NMCP lacks essential staff members to properly manage medicines including malaria commodities. Also, the NMCP lacks the organizational capacity to effectively manage the program and achieve desired results. To better achieve its objectives, the NMCP management team needs more leadership and management training. The newly developed NMCP activities and capacity strengthening plan will address some weakness during the next two years.
- Partners' commitment and SMC funding is still insufficient to cover all 2016 SMC targets.

Philippines

Goal: To strengthen key institutions in reducing TB burden through increased access to quality and effective pharmaceutical and laboratory services

Overall Quarter Progress

SIAPS is working with the National TB Control Program (NTP) to improve access to effective and sustainable-quality TB pharmaceuticals and services by strengthening health systems in laboratory management, community health leadership, management and governance, pharmaceutical management, information systems, and pharmacovigilance.

As part of its laboratory organizational strengthening work, SIAPS continues its support to improve laboratory human resource development. Consultative meetings with the National TB Reference Laboratory (NTRL) and regional partners were conducted to develop the strategies and standards for decentralizing laboratory trainings.

SIAPS is also supporting the Quezon City Health Department (QCHD) to scale-up the Barangay Health Management Council's (BHMC) initiative in Quezon City. SIAPS conducted a workshop attended by 22 participants from the QCHD, district health offices, and representatives from the Barangay Operations Center of the Department of Interior and local government, where district-level scale-up plans were developed. In this scale-up initiative, the QCHD, with technical assistance from SIAPS, is closely working with the Barangay Operations Center, which is mandated to strengthen barangay initiatives to deliver quality services to their constituents. SIAPS is also providing inputs for the development of implementing rules and regulations for the city's BHMC ordinance passed in 2015.

SIAPS is continuing its technical support to NTP for the introduction of new pediatric formulations. These formulations are now included in the Philippine National Formulary, the country's national essential medicines list, because of the collaborative efforts of NTP, the Pharmaceutical Division (PD), SIAPS, WHO, and the Global Drug Facility (GDF). In this quarter, NTP, with the assistance of SIAPS, quantified the needs and submitted a USD $2 million procurement order to cover the estimated 55,712 patients from April 2016 to December 2017.

In lieu of the revised registration exemption for all goods procured through international organizations and specialized agencies, NTP is processing the Accelerated Certificate of Product Registration (aCPR) for donated TB medicines and exploring options to routinely register products by contracting a local marketing authorization holder. SIAPS, in collaboration with USAID-funded Promoting Quality of Medicines Project, is continuing its technical assistance to NTP to ensure that medicine dossiers of all 16 second-line drugs (SLDs) are available and accurate for registration. While medicine dossiers are being secured and reviewed, NTP is coordinating with the DOH Bureau of International Health Cooperation and Food and Drug Administration (FDA) on aCPR requirements and exploring potential options to be the market authorization holder for the SLDs.

SIAPS assisted NTP in the conduct of the 2016 Philippines NTP Joint Program Review, providing team leadership in the areas of laboratory and pharmaceutical management.

Objective 1: Capacity for pharmaceutical and laboratory leadership, governance, and management improved

SIAPS is working with the NTRL to strengthen its capacity to lead, manage, and govern the laboratory network. In 2016, SIAPS began its technical work with NTRL and regional offices to assess the performance of the NTP laboratory network, identifying barriers and key areas for improvement. The assessment results will also be used by NTP and NTRL to update the NTP 2013-2016 Laboratory Network Strategic Plan. The laboratory network performance assessment is expected to be completed by June 2016.

In this quarter, SIAPS organized consultative meetings with NTRL, regional offices, city health offices, and the private sector to develop guidelines and define processes for the decentralization of laboratory trainings, including basic courses on TB microscopy, external quality assessment, and Gene Xpert. The outputs from these meetings include draft revised policies and standards for trainers, trainees, and training facilities. The working group is currently enhancing the course design and content for the Basic Microscopy Course training of trainers.

SIAPS is providing technical support to QCHD to strengthen grassroots-level health leadership, management, and governance. With the passage of a Quezon City Ordinance in 2015 that called for the establishment of BHMC in the city, SIAPS is assisting QCHD district health offices to lead and manage BHMC scale-up in all six city districts. During this reporting period, SIAPS conducted a workshop to inform the district-level teams on the BHMC intervention and assisted the teams in developing their district-level BHMC scale-up.

SIAPS continued to support the NTP in strengthening its governance capacity on overall TB supply chain management through the development of guidelines, references, and tools. As a key action in the NTP 2013-2016 Laboratory Network Strategic Plan, NTRL requested that SIAPS provide technical assistance in the review and enhancement of guidelines for laboratory supply management. SIAPS drafted and presented the guidelines to NTRL, NTP, and other TB partners for review and is working to finalize the guidelines. SIAPS also started to collaborate with the newly hired NTRL staff responsible for laboratory supply management.

One of the identified priorities of the Drugs and Supplies Management (DSM) Sub-Technical Working Group in PY4 was the development of references targeted to health staff at all levels on the proper management of expired, damaged, and near-expiring anti-TB medicines and supplies. NTP, with assistance from SIAPS, developed the draft of job aids and presented these in a consultation meeting with stakeholders including, FDA, Philippines Business for Social Progress (PBSP), regional offices, hospitals, health facilities, and civil service organization (i.e., Healthcare without Harm). The job aids provide standard procedures for minimizing wastage and act as supplemental material to the existing DOH policy on health care waste management. As next steps, SIAPS and NTP will work to finalize, disseminate, and institutionalize waste management job aids with DOH.

SIAPS is strengthening the coordination and engagement of the regional, intermediate, and peripheral stakeholders on TB pharmaceutical management in region IV-A through its support to the regional DSM Working Group. To institutionalize the regional pharmaceutical working group, a draft terms of reference was presented at this quarter's meeting and is currently being finalized by the regional office, with assistance from SIAPS and the USAID-Innovations for Multisectoral Partnerships to Achieve Control of Tuberculosis (IMPACT) Project.

Partner contributions

Region 4A office provided the venue for the regional DSM Working Group meeting, while USAID-IMPACT provided support in coordinating participants.

Constraints to progress

SIAPS activities with DOH partners were delayed because they conflicted with the intensified immunization activities; meetings with the LGU/Barangay partners were postponed because of electoral campaign preparations.

Objective 2: Capacity for transparent and evidence-based decision making improved

SIAPS is supporting NTP in consolidating, reviewing, and validating TB medicine information from Programmatic Management of Drug-Resistant Tuberculosis (PMDT) facilities. Based on the QuanTB outputs, NTP took action to mitigate the stock-outs of capreomycin, levofloxacin, and isoniazid at PMDT facilities. NTP closely coordinated with PBSP for an emergency procurement of capreomycin and an expedited delivery of levofloxacin. NTP also redistributed isoniazid to facilities with low stocks. Isoniazid stock-outs were caused by increased consumption due to the implementation of the nine-month MDR-TB treatment regimen study. Additionally, SIAPS is continuously building the capacity of NTP in the use of QuanTB to properly quantify needs for the introduction of new TB regimens.

Initial consultations with FDA identified the need to strengthen their regulatory capacity including registration and monitoring of pharmaceutical products. At the request of the FDA, SIAPS will be providing technical assistance on a pharmaceutical registration system, particularly in the analysis of the current drug registration processes; identification of key systems requirements, IT infrastructure, and data and reporting needs; and developing a project plan for the roll-out of a drug registration information system. Activities on the assessment of the existing drug registration processes and identification of gaps are scheduled for next quarter.

Constraints to progress

Difficulty scheduling meetings with NTP and other central TB stakeholders because of competing activities and priorities (i.e., Joint Program Review).

Objective 3: Capacity of NTP to deliver pharmaceutical and laboratory services improved

SIAPS continues to strengthen the capacity of NTP, FDA of the Philippines, the National Center for Pulmonary Research (NCPR) and other TB partners on pharmacovigilance, particularly on governance, active surveillance, and cohort monitoring.

As of February 2016, eight treatment facilities have enrolled patients in the nine-month MDR-TB treatment regimen study. NTP and NCPR facilitated a meeting this quarter to discuss the issues and concerns related to study implementation. The main challenges encountered were the lack of completeness in reporting and recording adverse and serious adverse events, errors and inconsistencies in the current study database, and inadequate capacity of treatment facility staff to implement the study.

In January 2016, NCPR submitted to NTP their October-December 2015 quarterly report for the nine-month MDR-TB treatment regimen study capturing 293 adverse and 6 serious adverse events. Of the 293 adverse events, the majority were gastrointestinal (44%), ototoxic/vestibular toxic (16%), musculoskeletal (10%), and neurotoxic (7%). NTP and SIAPS are continuously advocating that PMDT treatment facilities comply with existing standard operating procedures on active PV surveillance to ensure completeness, accuracy, and timeliness of adverse and serious adverse events reports. In addition, SIAPS will assist the FDA PV Unit in reviewing adverse and serious adverse event reports, causality analysis, and decision making.

SIAPS will be joining the monitoring and mentoring visits of the NTP, the FDA, and the NCPR in April 2016 to build the capacity of treatment facility staff in study implementation.

SIAPS received a formal request from the FDA to conduct a comprehensive assessment to ascertain the IT requirements for the adoption and implementation of the Pharmacovigilance Information Management System (PViMS). Assessment activities will commence next quarter.

SIAPS is also working with NTP and NCPR to prepare for the introduction of bedaquiline for DR-TB treatment. To date, four treatment facilities have already received ethical approval, and six more facilities are waiting for their clearance. SIAPS's technical support to NTP in this area included collaboration with the GDF, UNOPS, and the PBSP in securing the customs clearance of the donated bedaquiline medicines and preparing for the upcoming bedaquiline clinical orientation for the study sites in May 2016.

SIAPS provided local technical leadership in NTP's 2016 Joint Program Review for the laboratory and pharmaceutical management components. SIAPS assisted NTP in developing the overall strategy and tools for data collection, led the field data collection processes in Davao and Occidental Mindoro regions, and worked with international consultants to draft the area and thematic reports.

Key findings for the laboratory network:

- Access to laboratory services is still limited, despite the introduction of new diagnostic

technologies
- Capacity to manage the laboratory network is still weak, especially at the regional and provincial levels
- Support systems for the laboratory network (e.g., maintenance, supply management, staff training and supervision, monitoring, and financing) are not yet fully organized

Key findings for pharmaceutical management:

- Stock-outs of category II and pediatric TB medicines
- Lack of a TB pharmaceutical information system (e.g., quarterly medicine inventory reporting mechanism)
- No standard forecasting and quality assurance system for procuring TB medicines at the regional, provincial, and peripheral levels
- Regional, provincial, and service delivery staff have limited capacity in pharmaceutical management

Constraints to progress

In PY5Q1, the FDA began to invite local experts to participate as members of the national advisory committee; however, the FDA is still waiting for these experts to participate. SIAPS is continuously coordinating with the FDA on the status of the committee to ensure that the structure exists before implementation of other pharmacovigilance-related technical assistance.

Sierra Leone Ebola Portfolio

Goal: Strengthen pharmaceutical management systems to ensure availability of quality pharmaceutical products and rational use to achieve desired health outcomes

Overall Quarter Progress

SIAPS has identified the Directorate of Drugs and Medical Supplies (DDMS), which is Ministry of Health and Sanitations'(MOHS) directorate responsible for oversight and support in the pharmaceutical sector, as the primary beneficiary of capacity building and entry point to district health management teams (DHMTs) and health facilities. As part of SIAPS technical assistance, the restructuring of DDMS is progressing well. Support in improving the report, request, & issue voucher (RR&IV) and the design of the treatment register is complemented with the introduction of a Continuous Results Monitoring System (CRMS) as a strategy in supportive supervision; implementation is planned for over 1,300 health facilities in all districts.

Objective 1. DDMS' ability to effectively support health facilities is strengthened

SIAPS provided technical assistance in the review of the DDMS organogram. The new organogram was discussed with the senior staff of DDMS and a final draft adopted. To define the roles and responsibilities of the units (governance, capacity building, products and technologies, coordination, pharmaceutical information system, and M&E/QA) of the organogram, SIAPS helped to draft terms of reference (TORs). To support DDMS's role in coordination, SIAPS initiated a tripartite discussion between the three pharmacy entities of the MOHS, DDMS, National Pharmaceutical Procurement Unit (NPPU) and the Pharmacy Board so that consensus could be reached for regular meetings for to share information and harmonize their roles in ensuring access to quality and safe medicines and promote rational use.

Partner contributions

DDMS made a collaborative gesture by availing its staff to work closely with SIAPS and NPPU to provide office space so that contact was continuous and discussions were held as needed.

Constraints to progress

The absence of a revised operational organogram, TORs, and staff assigned to the units causes a level of uncertainty on the part of the staff. Although the NPPU was established by act of an government three years ago, it is still not fully operational and lacks staffing, infrastructure, and resources for its mandated operations.

Objective 2. Strengthen supply chain management from district to peripheral health unit level

The role SIAPS has played in supply chain management was limited to participation in weekly partners meeting with NPPU, DDMS, UNICEF, DFID, Crown Agents/International Procurement Agency, and CHAI. To become familiar with the pharmaceutical management system at district

and health facilities, SIAPS made several visits to selected districts, which informed the fine tuning of planned activities and prioritizing interventions. SIAPS succeeded in advocating and promoting the management of expired and unusable products that have been congesting storage facilities at all levels. As a result, trucks that distribute quarterly supplies to districts also bring back expired products from each of the districts to the NPPU for disposal under the oversight of the Sierra Leone Pharmacy Board.

To ensure proactive supportive supervision by DHMTs at health facilities, SIAPS introduced the CRMS, which uses a checklist that tracks stock availability, stock-out, expiry, availability and use of information system tools, status of storage conditions and availability, and capacity building of staff managing pharmaceuticals. The checklist tracks tracer and key medicines, including health program products, such as ARVs, TB, and malaria and reproductive products, and is used to monitor performance and results on a bimonthly basis. The report from these continuous exercises is discussed by key stakeholders in a review meeting to provide feedback and address identified challenges in real-time.

A preliminary plan to use the CRMS checklist as a part of supportive supervision was developed in collaboration with DDMS, the Bombali district medical officer, and the district pharmacist. The exercise will begin in April so that it can be rolled out to all other districts in May and June.

Analysis of expired products collected recently from five districts and the analysis/validation of RR&IVs collected from six districts is in process and will be completed in April. The information from this analysis and validation will be used to contribute to future quantification and planning a "pull system" of ordering and distribution.

Partner contributions

DDMS and the DMO of Bombali district played key roles in the discussion on CRMS and review of the checklist as well as initiating the first CRMS exercise. The staff of DDMS, pharmacists of the health programs (HIV, TB, malaria, RH), and DHMT members (district pharmacy and M&E staffs) are being availed by their respective offices to be part of the CRMS checklist/supportive supervision.

Constraints to progress

Different meetings are organized for the same cadre of professionals and getting the professionals to prioritize this exercise may be challenging.

Objective 3. Utilization of information for supply chain decisions is increased

SIAPS provided technical assistance in the review of the RR&IV, which is now ready for validation and printing. This will make the RR&IV more user-friendly and applicable for different levels of services.

The key contribution that SIAPS made in this quarter is designing a user-friendly, facility-level treatment or dispensing register to capture consumption and key morbidity data for each patient

and dispensed product on a daily basis. The existing consultation register, which tries to capture the same information, is not practical, and it is impossible to pull reliable and usable data from it to make procurement and distribution decisions. The designed tool has been reviewed by DDMS, NPPU, and CHAI and is now ready for validation and printing with the RR&IV.

Another key tool developed by SIAPS in this quarter is a supportive supervision checklist, which is the backbone for the planned CRMS to be implemented in all facilities and districts. The checklist captures observations and quantifiable data of several system and service indicators and continuously tracks trends in performance and results at district and health facilities in holistic pharmaceutical management, including rational use of medicines.

Partner contributions

The DDMS, NPPU, and CHIA are actively involved in the review and finalizing of draft tools. It is anticipated that health programs funded by the Global Fund and other donors will contribute resources in making the nationwide CRMS a success.

South Africa

Goal: Strengthen the capacity of pharmaceutical systems at all levels to support the South African Government's priority health programs and initiatives to improve health outcomes

Overall Quarter Progress

During PY5Q2, SIAPS made progress with some activities being transitioned to partners and working toward achieving key targets. A key achievement was support provided in developing the policy for issuing authorizations to professional nurses to perform functions provided for in Section 56(6) of the Nursing Act 33 of 2005 and in developing a tool to determine current practices for issuing authorizations in provinces and municipalities. To date, SIAPS has helped develop four national pharmaceutical policies.

SIAPS has made headway in transitioning Pharmaceutical Leadership Development Program (PLDP) activities. In particular, PLDP support to the Sefako Makgatho Health Sciences University has been handed over to the course conveners; 14 students from the public and the private sectors were enrolled in the program. Students presented their performance improvement plans and results, many indicating positive change in their workplace and practical skills developed. One student reported that, "I have managed to make an actual link between theory and practice and I have learnt that this 'connection' is the golden thread in all activities in my workplace. By applying the lessons learned from the program, I have learnt to look at everything in my workplace through analytical glasses and to 'unpack' matters..." SIAPS exceeded the target of 1,104 with 1,206 persons trained in pharmaceutical management and exceeded the target of 340 new health care workers with 499 graduates from a program that includes pre-service training.

SIAPS has installed RxSolution at 416 sites of a targeted 494 health facilities that have implemented electronic or mobile technology systems to document and report on specific components of the pharmaceutical system. RxSolution was installed in 15 new sites, including seven in Eastern Cape (EC), five in KwaZulu-Natal (KZN), two in Limpopo (LP), and one in North West (NW) province. SIAPS also developed an RxSolution implementation dashboard to assist in tracking the system roll-out, including versions and modules in use. This approach is particularly important to ensure that SIAPS support toward the National Department of Health's (NDOH) annual performance plan targets are monitored.

SIAPS received permission from the NW DOH's Research Committee to conduct a study on using electronic pharmacy dispensing data to examine outpatient antibiotic consumption and monitor antibiotic prescribing practices in hospitals in the South African public sector. Database extraction and cleaning have commenced. All processes will be documented for inclusion in the final research report.

Objective 1: Pharmaceutical sector governance strengthened

SIAPS is working with the NDOH to strengthen pharmaceutical system governance through the development of key policies, guidelines, norms, and contractual documents. In 2015, SIAPS

began working with the NDOH to develop a national strategy for improved access to and availability of health products. During this quarter, SIAPS worked with the NDOH and SCMS on components of the strategy, including a framework for national information systems and information management to support master data, transactional data, and analytics. The framework was presented at a partners meeting held in March. Work continued on the final strategy document.

Progress was made toward the development of a web-based tool to support the national pharmaceutical services management dashboard. A project initiation document was drafted for submission to the NDOH IT unit.

The Bid Evaluation Committee's (BEC) terms of reference (TORs) were revised and finalized using the standardized template for TORs designed by SIAPS. The BEC is responsible for evaluating bids for tenders for pharmaceutical and medical-related items. Consultation with the Directorate: Affordable Medicines (DAM) on the TORs commenced. SIAPS shared a revised version of the TORs for the National Essential Medicines List Committee (NEMLC) with the EDP for review. Work commenced on the revision of the TORs for the National Health Insurance task team responsible for the Central Chronic Medicine Dispensing and Distribution (CCMDD) Program.

A challenge facing the NDOH is the uncertainty related to the authority of nurses to examine a patient, make a diagnosis, and prescribe medicines. SIAPS worked with the DAM and the units within the NDOH that deal with primary health care (PHC) and human resource development to develop a circular to provinces to clarify whether pharmacy personnel can dispense prescriptions written by nurses. A policy for issuing authorizations to professional nurses to perform functions listed in Section 56(6) of the Nursing Act 33 of 2005 was prepared. In addition, a tool to determine current practices in provinces and municipalities regarding the issuing of authorizations to nurses was also prepared. The documents were shared at a meeting of the National Health Council (NHC) using a presentation prepared with technical assistance provided by SIAPS. Following further consultation with provinces, revised documents were presented to the NHC.

SIAPS worked with DAM to draft a policy for the procurement of medicines that are not registered in South Africa, a policy to provide a standardized approach to making recommendations to the Medicines Council for the fast-tracking of applications for registration of nonessential medicines, and a policy dealing with the allocation of medicines into therapeutic classes. Final consultation with DAM is underway on these three policies. Assistance was provided to SCMS from a legislative perspective in the development of software to facilitate the issuing of licenses by the NDOH.

Assistance continued to be provided with implementation of the M&E framework for the CCMDD Program. Stakeholder engagement meetings were held with CCMDD service providers to better understand data processing and inform further technical support in improving data quality and flow for monitoring. A geo-map dashboard of pickup points and an interim cell phone and desktop application to support current reporting were developed. SIAPS is facilitating a series of planning meetings with key players to clarify roles and responsibilities and improve management of the program. Assistance was also provided in the holding of a symposium in the Umzinyathi district of KZN where successes of the CCMDD Program in the district were

highlighted. SIAPS was a co-author on two abstracts on work done on the CCMDD, submitted for the 21st International AIDS Conference.

SIAPS assisted the Central Procurement Unit (CPU) in drafting the October–December 2015 quarterly report for submission to the Global Fund-NDOH Principal Recipient and provided recommendations on how reporting could be improved in the future.

SIAPS provided ongoing support in the management of pharmaceutical and medical-related contracts. Technical evaluation of bids for compliance with the condition of contract is being included in the tender management module. Criteria for evaluation of bidders and bids were developed in collaboration with DAM. SIAPS is currently developing the software to achieve this, and mentoring contracting unit staff on the application of the criteria. Standard operating procedures (SOPs) are being adapted to accommodate changes. SIAPS provided technical assistance at various stages of the award of two main and two supplementary contracts which were awarded within the target of eight weeks as per project plan.

Partner contributions

- SCMS: Contract demand forecasting and demand analysis, tender management, drafting of strategy, development of licensing software
- CHAI: Development of supplier reporting tool for performance analysis and pipeline analysis

Constraints to progress

- Unclear roles and responsibilities for reporting within the CPU (action: SIAPS developed SOP to promote monthly report generation to feed into quarterly report)
- Conflicting priorities of members of team drafting strategy (SIAPS, SCMS, and the NDOH) (action: set aside dedicated time)

Objective 2: Capacity of personnel to provide pharmaceutical services enhanced

SIAPS continued to work with the Pharmaceutical Services Directorate in the Free State (FS) to implement the Pharmaceutical Leadership & Governance Initiative (PLGI), which helps address challenges related to medicine supply management identified by the auditor general. A total of 33 participants are in the final stages of completing the PLGI. SIAPS provided coaching by visiting teams; they also facilitated a coaching workshop to determine how teams are progressing toward achieving their measurable results and provided guidance as needed. Teams are implementing projects that focus on improving contract management at the medical depot, reducing expired stock, reducing over-expenditure, and improving medicine availability.

Abstracts were submitted by seven groups who completed the PLDP or Leadership Development Program (LDP) to the conference organized by the Health Systems Trust (HST), which will be held in May. Five abstracts were accepted for podium presentations and two for poster presentations.

In terms of a memorandum of understanding (MOU) between the Department of Pharmacy, Sefako Makgatho Health Sciences University (SMU), and SIAPS, the challenge model and some

of the tools from the LDP were integrated into the management of pharmaceutical services module of the masters' program (public health pharmacy and management); 14 students from both the public and the private sectors were enrolled in the program. Students identified a challenge in their workplace and addressed it by using the LDP approach. A final presentation was held in January 2016 at SMU and attended by senior management of the university and representatives from the public sector. The purpose of the final presentation was to assess how students have used the LDP approach to address challenges and provide students an opportunity to present their results. A team of five assessors, including a SIAPS representative, evaluated the presentations. Students also developed abstracts and presented their posters as part of the module requirements. This activity is being transitioned to the university.

It was decided during PY5Q2 that because of funding constraints, the Medicine Access Initiative planned for implementation in KZN in conjunction with the province would be cancelled. The province will be informed.

SIAPS provided continued support to the University of the Western Cape (UWC) School of Public Health in reviewing progress of the medicine supply management (MSM) online module, reviewing lessons learned from the rational medicine use (RMU) online course, preparing for the 2016 Winter School, and planning the marketing strategy for online modules. SIAPS aims to support UWC in finalizing all 14 sessions of the MSM course by PY5Q3. The support will be in the form of reviewing and giving comments on the 12 modules that will be developed by the university. Lessons learned on the format and structure of the RMU course will be applied in preparing the online MSM course.

The NDOH has embarked on a process to collaborate with universities on research to benefit the health sector in South Africa. SCMS is the lead partner supporting this initiative. SIAPS provided technical support in the development of the relevant materials.

Partner contributions

- UWC and SCMS: Collaboration in the development of the online MSM course
- SCMS: University visits by the NDOH

Objective 3: Use of information for decision making in pharmaceutical services improved

SIAPS continued to provide technical assistance in the development and implementation of the Master Procurement Catalogue, the Essential Medicine List Tool (EMLT), and the tender management module and customization of RxSolution reports.

Work commenced on the EMLT by the service provider appointed by SIAPS. This tool will serve as the foundation for business intelligence, promote openness and transparency in EDP processes, and provide a repository for master data, including products on the EML, as well as national contracts.

SIAPS also provided technical assistance in developing the interface between RxSolution and the

Health Patient Record System (HPRS), a national registry for patient data which will assist in tracking patient movement within the health care system. The business process for the interface and options for the implementation were finalized.

SIAPS has installed RxSolution at 416 sites. During the quarter, 15 new sites were installed: EC (7), KZN (5), LP (2), and NW (1); 13 facilities are using the stock management module, with three facilities also using the dispensing module. Of the installed sites, only two district offices are using the budget module of RxSolution. The Umzinyathi district in KZN has rolled out RxSolution at 55 PHC clinics with 40 pharmacist's assistants being placed at these clinics. Assistants have been trained on the stock and dispensing modules and seven officials within the district were trained as super users; 11 sites were supported post-implementation (two in KZN, nine in LP). The roll-out of RxSolution to the Department of Correctional Service (DCS) was halted at the request of USAID.

SIAPS has released a new version of RxSolution that supports ordering via the PMPU. The process of upgrading facilities to this new version is in process, with a focus on PMPU priority facilities in the EC and FS. All of the identified 13 hospitals in EC and seven of the identified 18 hospitals in the FS have been upgraded to the latest version of RxSolution.

During the quarter, SIAPS developed an RxSolution implementation dashboard to assist in tracking the system roll-out, including versions and modules in use.

During the quarter, 262 staff members (14 in EC, 73 in GP, 80 in KZN, 56 in LP, 39 in NW) were trained on the stock management and dispensing modules, as well the use of RxSolution reports.

SIAPS is providing support to the NDOH in the development of a dashboard for the early detection of stock-outs at 52 health facilities (10 central, 17 tertiary, and 25 regional hospitals) across all provinces. The dashboard will import relevant data from the hospital level and will be accessible to stakeholders. To date, RxSolution has been implemented in five of 10 central hospitals, 16 of 17 tertiary hospitals, and all 25 regional hospitals. The other six facilities are using other systems. The dashboard has been developed and information from six central hospitals (Chris Hani Baragwanath, Charlotte Maxeke, Dr. George Mukhari, Steve Biko Academic, King Edward, and Universitas Hospitals) is accessible on the dashboard. A script has been developed and loaded to extract data while awaiting approval for automatic updates. Some challenges are being experienced in obtaining data from hospitals that do not use RxSolution.

SIAPS provided further technical support to FS, GP, NW, and LP to improve their use of data in decision making. A new RxSolution report for the early detection of stock-outs, which enables facilities to identify medicines at risk of running out, thus allowing facilities to take timely corrective action, was introduced at eight facilities in FS and eight facilities in the Waterberg district in LP (19 people trained). In GP, NW, and LP, SIAPS facilitated the review, standardization, generation, and use of RxSolution generated reports for decision making.

SIAPS received permission by the NW DOH Research Committee to conduct a study on using electronic pharmacy dispensing data to examine outpatient antibiotic consumption and

monitoring of antibiotic prescribing practices at hospitals in the South African public sector. Database extraction and cleaning commenced. All processes will be documented for inclusion in the final research report.

SIAPS conducted five workshops on the ABC/VEN matrix tool to introduce it for routine monitoring and analysis of pharmaceutical expenditure to support informed decision-making. The workshop was attended by 87 participants from 38 hospitals and regional and district pharmacies within GP. Participants are currently implementing different strategies to address the challenges identified.

Partner contributions

- The following partners provided support in conducting assessments, installation, and training on RxSolution:
  - MatCH: eThekwini Metro in KZN
  - FPD: Tshwane Metro in Gauteng
  - BroadReach: Ekurhuleni district in Gauteng
  - ANOVA: Mopani district in LP
- Harvard Pilgrim Health Care Institute supporting research in NW

Constraints to progress

- Lack of and outdated infrastructure, which affect the pace of the roll-out (action: need to obtain provincial buy-in)
- Non-involvement of hospital IT personnel on RxSolution support (action: engage hospital management and provincial IT to discuss ways of getting IT support)
- Unable to link JAC reports (WC hospitals) on dashboard (action: obtain provincial support to access the data)
- Delays in obtaining ethical approval and provincial permission, creating tight timelines for the completion of the research project (action: focus on data collection, extraction, and analysis)

Objective 5: Pharmaceutical services improved to achieve desired health outcomes

SIAPS provided support to Dr. George Mukhari Academic Hospital (DGMAH) on the hospital pharmacy model focusing on effective use of RxSolution. An operational planning workshop was held with SIAPS, SCMS, and SMU to review the current status and map a way forward with respect to making DGMAH a model pharmacy. SIAPS provided additional training to DGMAH staff to align key processes. During the quarter, it became apparent that the facility is not utilizing RxSolution fully for the management of stock. A team representing SIAPS and SCMS is assisting the facility to optimize use of the system. The target is to implement the dispensing system at satellite pharmacies (ARV, ophthalmic, and psychiatric) by June 2016.

SIAPS is helping the EDP unit with the development of academic detailing slides for the *Adult Hospital-Level STGs and EML* which highlight changes and summarize evidence for decision

making. Academic detailing slides have been completed for four of the ten chapters received. Assistance was provided with the clinical editing of the 23 chapters of the *Adult Hospital-Level STGs and EML* which has been completed. Assistance is also being provided with an analysis of all tertiary EML documents. Phase 1 of this work has been completed.

In January, the novel oral anticoagulants used in the treatment and prophylaxis of venous thrombotic embolism and post-hip and knee surgeries were evaluated. Health economics models and budget impact analyses for these were compiled using detailed costing templates. Reports were prepared and presented to the Adult-Level EML Committee for discussion at the January meeting.

SIAPS analyzed 47 applications for selection of PHC Expert Review Committee members, developed an SOP for analysis for applications, provided input for improvement on the interactive pdf application forms, and wrote a full summary of the analysis for use in the selection discussions. SIAPS gave input on drafting the introduction and foreword to the adult STGs and EML, supporting the analysis of the applications for Ministerial Advisory Committee (MAC) members on Antimicrobial Resistance (AMR), and developing a concept note regarding a request by the EDP unit to develop criteria for a medicine utilization evaluation using a mobile application. SIAPS helped the EDP with the development of an abstract about strengthening implementation of STGs to improve RMU for presentation at the HST conference in Johannesburg in May 2016. The abstract has been accepted for a poster presentation.

SIAPS supported the development of draft AMR provincial implementation plans; 18 AMR champions from 9 provinces participated in the workshop. The provincial AMR champions developed action plans that they would share with provincial heads of department and heads of pharmaceutical services. The NDOH will monitor the progress of the provinces.

Further technical assistance provided by SIAPS included the development of a prevalence model and budget impact analysis model to assess the potential impact of the use of fosfomycin in different indications for urinary tract infections (UTIs) including penicillin allergy in pregnant women, first-trimester UTIs, and UTIs in pregnant and non-pregnant women. Motivations for the inclusion of tigecycline and tobramycin in the treatment of antibiotic-resistant infections in the ICU setting were developed in 2015. Guidelines have been developed by the Gauteng Pharmaceutical and Therapeutics Committee (GPPTC) for the down-referral and transferring of patients to step-down levels of care. These were circulated for review and editing.

SIAPS also worked with the GPPTC to analyze the data collected from nine hospitals, six community health centers, and 15 PHC clinics during World Antibiotic Awareness Week. A total of 962 outpatient and 569 inpatient prescriptions were captured. The preliminary findings were presented and discussed during the GPPTC meeting held in March. The results provide a baseline for antibiotic prescribing practices in the province. The GPPTC will implement interventions to improve the rational use of antibiotics.

SIAPS also provided technical assistance to the WC DOH in the analysis of the aspirin medicine use evaluation and also supported the development of the presentation of the results at the South African Association of Hospital and Institutional Pharmacists (SAAHIP) Conference.

SIAPS conducted an ABC analysis for the KZN PTC to assist in their decision-making processes. SIAPS conducted 41 ABC analyses during this reporting quarter: 38 health facilities in Gauteng province (GP), 1 GP provincial, 1 KZN provincial, 1 National, in addition to 1 GP provincial conducted in 2015, reaching the total of 42 cumulatively. The target was 3 and it is far exceeded due to high demand from GP and implementation of a ABC project to support facilities within the province.

During the quarter, SIAPS continued working with the National Pharmacovigilance Centre (NPC) to improve mother and child health. SIAPS provided technical assistance to the NPC to develop the first issue of the NPC *Sub-Dermal Contraceptive Implant (SDCI) Bulletin* which provides health care professionals with a summary of relevant local data and trends on the use of and adverse reactions to SDCI in South Africa. Future bulletins will be issued quarterly. SIAPS also assisted to improve efficiencies and data quality for the national sentinel surveillance system for major external birth defects among live and still births delivered in high-volume maternity units.

SIAPS supported the NPC with the review and analysis of adverse drug reaction (ADR) reports related to TB medicines. The ADR database has 5,063 reports, 511 of them for TB cases. The majority of ADRs were for drug-sensitive TB (480) and 31 were for MDR/XDR-TB. Co-morbidities were only documented in 80 of the drug-sensitive TB cases for 45 patients with hypertension, 28 with diabetes, and 7 with Kaposi's sarcoma.

Partner contributions

- SCMS, SMU: Support use of RxSolution at DGMAH

South Sudan

Goal: Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes

Overall Quarter Progress

During this quarter, SIAPS conducted activities aimed at improving pharmaceutical services in the two states of Central Equatoria (CES) and Western Equatoria (WES) and continued to store and distribute the artemisinin-based combined therapy (ACTs) and long lasting insecticide-treated nets (LLINs) and county medical stores shelves that were procured by USAID, coordination of meetings between the Ministry of Health (MoH) and partners (e.g., Health Pool Fund [HPF]) regarding the newly formed Logistics Management Unit (LMU) and other joint activities (e.g., supportive supervision) aimed at improving stock status reporting. SIAPS conducted store rearrangement and stock taking efforts in four health facilities in WES and provided on-the-job training to four health workers (three males, one female) on proper record-keeping.

SIAPS provided mentorship and technical assistance to the antiretroviral therapy (ART) center's staff on use of the installed electronic dispensing tool (EDT) to ensure its functionality in providing information for informed decision making. The storekeeper at the Juba Teaching Hospital (JTH) ART center was given on-the-job training and mentoring on proper updating of the stock cards to improve the accuracy of ARTs consumption reports.

SIAPS conducted supportive supervision and mentoring in all six CES counties. SIAPS also delivered malaria case management training to 37 health care workers ten counties in WES.

SIAPS provided information to MoH on stock status for ART-related commodities and tracer medicines and provided updates on key pharmaceutical use indicators for four out of the six counties in CES, four out of the ten counties in WES, and two out of the nine counties in Unity. 40% of warehouses and 57% of health facilities had stock-outs of tracer medicines.

SIAPS quantified, valued, and disposed of expired medicines (both tracer and non-tracer) collected from eight health centers within Juba City. The total value was USD $21,216.

As the secretariat of the Pharmaceutical Technical Working Group (PTWG), SIAPS coordinated and facilitated four PTWG and emergency medicines fund meetings during the quarter.

SIAPS provided support to the LMU to install and customize the South Sudan Pharmaceutical Dashboard—an online platform for managing stock levels of essential medicines in the pharmaceutical sector including ART-related commodities—to provide more accurate information for quantification of medicines and informed decision making. Consumption data for 35 medicines used at the JTH ART center was computed for the period of June-December 2015.

SIAPS provided technical assistance to revise, finalize, and submit the national malaria control program (NMCP) biannual report for July–December 2015, as well as help develop the National Malaria Policy (first draft).

SIAPS did final review of the malaria case management and training guideline and submitted it to MoH for approval, which was obtained on January 28, 2016. SIAPS printed and distributed 150 copies of the approved malaria case management and training guideline for use in malaria case management trainings in CES and WES.

In preparation for commemoration of the 2016 World Malaria Day (WMD), SIAPS held planning meetings with NMCP and partners, drafted a concept note for WMD, and initiated the development of a malaria newsletter.

Objective 1: Pharmaceutical services improved to achieve desired health outcomes

During this quarter, SIAPS conducted a number of activities aimed at improving pharmaceutical services in CES and WES. The activities included a de-junking of the Juba county medical store in Central Equatoria State (CES), and continued storage of the 535,650 ACTs, 400,000 LLINs, and 250 shelves for the county medical stores procured by USAID. Following USAID approval of the distribution plan for ACTs, LLINs, and shelves, SIAPS began distributing the shelves to the Juba County medical store and Al Sabbah Children's hospital and the ACTs to CES counties Lainya, Morobo, Terekeka, and Yei. SIAPS has initiated a procurement and vendor selection process for transporting the remaining ACTs, LLINs, and shelves to counties in both WES and CES.

SIAPS also assisted the Juba County Health Department to distribute the emergency medicines fund's 86,400 doses of ACTs to Munuki primary health care center (PHCC), Kator PHCC, Gurei PHCC, and Nyokuron PHCC. This activity was important to improve the availability of essential commodities at the facilities.

Partner coordination remains a critical part of South Sudan's effort to improve on and address gaps in the essential medicine stock management. During the quarter, SIAPS coordinated a meeting between the MoH and the HPF on developing a strategic road map for the newly formed LMU. The meeting also discussed and scheduled joint supportive supervision visits to counties by the LMU, SIAPS, and the HPF to improve the stock status reporting rates by the counties and the health facilities.

As part of improving of storage of medicines in the country, SIAPS plans to commence the non-structural improvements to the Yambio warehouse in WES during this quarter. The Bill of Quantities for building the Yambio warehouse was already completed in the last quarter.

SIAPS conducted store rearrangement and stock taking in four health facilities in WES. These were Bazunguwa PHCC, Yabwa PHCU, Saura PHCU, and Baguga PHCU. During the exercise, it was identified that one of the facilities (Yabwa PHCU) had stock-outs of essential medicines (amoxicillin, ciprofloxacin, paracetamol, sulfamethoxazole-trimethoprim, artesunate-

amodiaquine (adult, child, and toddler)—only albendazole and vitamin A were in stock. SIAPS therefore provided on-the-job training to four health workers (three males, one female) on proper recording of data in the stock cards. SIAPS worked with the facilities to rearrange the store as part of on the job training.

Constraints to progress

- New national security regulation limiting travel time between facility from 8:00 a.m. to 4:00 p.m. caused implementation delays
- Some counties experienced deteriorating security conditions especially Mundri West, Mundri East, Maridi, Ezo, and Nagero in WES which will hinder distribution of the USAID procured commodities (LLINs, ACTS, and shelves)

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

During the quarter, SIAPS provided on the job training and mentorship to the storekeepers at the JTH ART center. The training focused on proper updating of the stock cards and reporting to improve the accuracy of the reporting of the ARTs consumption.

SIAPS conducted supportive supervision and mentoring in all the six counties (Juba, Kajokeji, Lainya, Morobo, Terekeka, and Yei) in CES. This activity was implemented to improve the capacity of health workers in logistics management of pharmaceutical as well as malaria case management.

SIAPS also conducted training on malaria case management to 37 health care workers (31 male, 6 female) from 13 health facilities in all the ten counties in WES. SIAPS provided oversight and mentoring during the training.

Constraints to progress

SIAPS had planned to deliver a pharmaceutical management training workshop in February 2016 for storekeepers and dispensers from health facilities in Yambio County in WES. This training workshop however was, postponed to the next quarter due to increased insecurity in the area.

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

During this quarter, SIAPS provided support to the MoH by providing information on the stock status for ART-related commodities and tracer medicines by collecting, validating, reviewing, and analyzing county consumption data and providing updates on key pharmaceutical use indicators for the following four CES counties in (Lainya, Morobo, Kajo Keji and Terekeka counties); four WES counties in (Ibba, Mvolo Nzara, and Tambura counties); and two Unity State counties in (Abiennhom and Pariang counties). Forty percent of the warehouses and 57% of health facilities had stock-outs of tracer medicines.

SIAPS quantified and valued the expired medicines (both tracer and non-tracer) collected from health centers within Juba City. These included Gabat, Gurei, Lologo, Nyakuron, Munuki and Kator PHCCs as well as Gudele-2 and Hai Jebel Primary Health Community Units (PHCUs). These medicines were disposed of in January 2016. The total value was USD $21,216.

As the secretariat of the PTWG, which provides technical support to MoH and partners, SIAPS coordinated and facilitated four PTWG and emergency medicines fund meetings during the quarter.

SIAPS provided technical assistance to the LMU to help install and customize the South Sudan Pharmaceutical Dashboard, an online platform for managing stock levels of essential medicines in the pharmaceutical sector, including ART related commodities. The dashboard provides more accurate information for quantification of medicines and informed decision making. During this quarter, consumption data for 35 medicines used at the JTH ART center was computed for the period of June to December 2015. SIAPS also held several stakeholders meetings to get buy of the dashboard.

SIAPS continues to provide mentorship and technical assistance to the ART center's staff on use of the installed electronic dispensing tool to ensure its functionality in provision of information for informed decision making. Continuous mentorship and technical ensures errors in the quantification of antiretrovirals and other medicines are eliminated and the quality of data entered into the system is improved.

Constraints to progress

Fifteen county warehouses in the three states of Central Equatoria (2), Western Equatoria (6) and Unity States (7) did not send in their consumption reports. The collection of stock status reports from counties in WES, particularly in Yambio, Ezo, Greater Mundri, Maridi, and Nagero counties, was hampered due to increased insecurity. SIAPS will resume this activity once the security situation stabilizes.

Objective 4: Scale-up of malaria interventions accelerated, better coordinated, and documented

During this quarter, SIAPS provided technical assistance to the NMCP to revise and finalize the biannual report for July–December 2015 for submission to the Director General for Pharmaceuticals and Medical Supplies.

SIAPS provided support to the NMCP to develop the first draft of the national malaria policy, a document that will provide strategic direction for the NMCP to better coordinate scale up and accelerate its interventions. In addition, the SIAPS team did a final review of the malaria case management and training guideline. The reviewed guideline which will be used to improve the capacity of health workers to provide quality pharmaceutical products and effective pharmaceutical services was submitted to the Director General for Preventive Health Services and the office of the Undersecretary for Health for approval. The final approval was obtained on January 28, 2016. SIAPS will print and distribute 150 copies of the approved guideline for

training of in-service health workers in the two states of Central and Western Equatoria.

To prepare for commemorating the 2016 World Malaria Day (WMD), SIAPS held a number of planning meetings with the NMCP and the World Health Organization. As part of the preparatory work, SIAPS drafted a concept note for the WMD and initiated the development of a newsletter to highlights NMCP malaria interventions since last year's WMD.

In consultation with the NMCP Program Manager, pharmacists, and logistic officers, SIAPS developed a distribution plan with options and scenarios for 284,166 LLINs to six HPF supported states— Eastern Equatoria (EES), Lakes, Northern Bahr el Ghazal (NBG), Unity, Warrap, and Western Bahr el Ghazal (WBG) states.

To ensure availability of commodities, SIAPS and the MoH conducted a quantification of antimalarial-related commodities for 2016 and 2017.

Constraints to progress

- There was a delay in the submission of the NMCP reports for compilation. SIAPS agreed with the NMCP to resolve this issue so that the next report is not late.
- SIAPS received approval to distribute USAID procured commodities to counties in only CES and WES based on the work plan. The request from USAID to distribute to six additional HPF supported states can be done if additional funds are provided. USAID is currently considering options for additional funding.

Swaziland

Goal: The goal of the SIAPS program in Swaziland is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes for HIV/TB care and treatment

Overall Quarter Progress

SIAPS works to support the Ministry of Health (MOH) to assure the availability and rational use of HIV/tuberculosis (TB) medicines by the prescribers and clients. The activities in this program year are focused on contributing to the country's efforts to achieve the 90-90-90 goal in the fight against HIV. This goal cannot be achieved if quality assured antiretroviral medicines and diagnostics commodities are not available and used rationally by both the consumer and the prescriber. TB has not been left behind especially since about 85% of people living with HIV are also co-infected with TB. SIAPS supports efforts to assure uninterrupted availability of TB medicines and the introduction of new medicines, such as bedaquiline, in the treatment of drug resistant TB.

Significant achievements have been made in this quarter in product availability. The MOH has successfully maintained required minimum-maximum levels for tracer antiretroviral (ARV) medicines. However, pediatric lopinavir/ritonavir (LPV/r 80/20 mg/ml) was stocked out at the Central Medical Store (CMS) for two weeks. The stock status for HIV rapid test kits (Determine® kits and Chase Buffer) has been 1.7 months of stock (MoS)—below the recommended minimum stock of 3 months. The challenge that the country has faced in this quarter is the currency fluctuations which have been unfavorable for the Swaziland market. All medicines and health products in Swaziland are imported from foreign markets, such as Asia and Europe. The currency volatility has made it difficult for suppliers to honor the contract prices signed in 2015. The price increase to cushion against the currency decline has made it more costly for the government to procure the drugs. SIAPS has worked closely with the MOH to provide advice on recommended price adjustment and also revising the forecast given the remaining budget for the financial year ending March 31, 2016.

SIAPS has supported the MOH to roll out the web-based commodity tracking system (CTS) to four health facilities. The use of the CTS has contributed in improving reporting rates and data quality for ARVs and laboratory commodities logistics management. The logistics data from the CTS has been used to determine the procurement requirement for this quarter to be submitted to the Ministry of Finance.

Rational medicines use is an important activity toward safeguarding the therapeutic effectiveness of medicines, including antiretrovirals and anti-TB medicines. SIAPS has supported a local university to establish a medicine use research activity under the leadership of the MOH in collaboration with the Nelson Mandela Metropolitan University in South Africa.

SIAPS has prioritized transitioning of certain activities to local counterparts during this program year, as guided by the Global Health Initiative principles of sustainability and country ownership. During this reporting period, SIAPS has been working with MOH to transition the

activities on legislation and pre-service training of pharmacy students to the MOH and Southern Africa Nazarene University (SANU), respectively.

Objective 1: Strengthen Governance in the Pharmaceutical Sector

SIAPS continues to support the MOH to ensure sustainability of the gains realized in strengthening governance and also improve transparency and accountability in the pharmaceutical sector. SIAPS helped established three additional committees, cumulatively 25 committees have been established through the life of the project, to provide oversight to pharmaceutical decision making, namely:

- Pharmaceutical importation and exportation committee: to assist in assuring the quality and regulatory status of all medicines used in the country, including ARVs and anti-TB medicines, are of the highest quality.
- National patient safety monitoring advisory committee: to monitor medicines safety and treatment effectiveness and inform decisions to reduce risks associated with ARVs and anti-TB medicines. This committee will support the National Pharmacovigilance Unit and help validate its decisions.
- Pharmaceutical recruitment committee: contribute to assuring the quality of pharmaceutical services provided to people living with HIV. The committee will guide MOH and the Medical and Dental Council on registration of foreign and locally trained pharmacy personnel.

The committees mentioned above are meant to coordinate and oversee the interim functions relating to governance in the pharmaceutical sector. Once the bills currently in parliament are enacted into law, these committees will then formally be incorporated under the medicines regulatory authority and the pharmacy council, once established.

Two other ad-hoc committees were established to support in pharmaceutical personnel recruitment and demand planning for HIV rapid test kits.

SIAPS provided technical guidance to various committees that make decisions affecting pharmaceutical and supply chain management in the health sector. SIAPS supported the MOH in conducting a public sector pharmacists' meeting to share updates and best practices with the aim of improving pharmaceutical service standards and fostering collaboration. SIAPS continued to provide technical guidance in monitoring supplier performance, warehousing and distribution, stock status, tender processes, and supply planning to the Swaziland Health Laboratory Services (SHLS) supply chain team. SIAPS further supported the National Quantification Committee and the National Condom Technical Working Group (TWG) in the development of their annual work plan. SIAPS supported the National Essential Medicines Committee (NEMC) by initiating processes towards the review of the STG/EML to promote rational use of medicines, including ARVs, anti-TB medicines and companion therapy for these medicines. SIAPS also provided guidance on supply management and rational use of medicines in TWGs on the following topics: non-communicable diseases, pediatric HIV, TB, and HIV.

SIAPS continued to provide technical assistance to the medicines regulatory authority (MRA)

pharmacist through updating the medicines listing database and updating the registration status for all medicines used in the public sector to assist the MOH to control the quality of medicines imported into Swaziland. All activities relating to medicines legislation are currently being transitioned to the MRA pharmacist in the Office of the Chief Pharmacist. SIAPS also facilitated the development of narcotics importation and consumption monitoring tools and standard operating procedures (SOPs) to ensure an uninterrupted supply of opioid analgesics for palliative care and maternal health.

SIAPS continues to support the MOH in interventions that ensure that national pharmaceutical sector development plans are strategic and evidence-based. SIAPS is providing technical guidance to the Office of the Chief Pharmacist on drafting the national antimicrobial resistance (AMR) strategy. The terms of reference and appointment of the committee members to lead the activity has been completed. The first meeting of the committee is scheduled for the third quarter. The monitoring and evaluation framework of the Swaziland Pharmaceutical Sector Strategic Plan was also presented to the MOH senior staff for approval and to the public sector pharmacists for ownership and endorsement. The next steps are to develop a compendium of indicators for the different levels of health care and institutionalize the monitoring and reporting of key indicators to influence improved governance in the pharmaceutical sector.

Constraints to progress

Legislation has not yet been scheduled for debate and approval.

Objective 2: Increase capacity for pharmaceutical supply management and services

SIAPS has been working to develop the skills of MOH frontline health workers and recently PEPFAR partners' clinical mentors on good pharmacy practice and supply chain management in the four country regions. Training on anti-TB medicines supply management was offered, funded through and in collaboration with ICAP/Columbia University and USAID/AIDS-free, and reached 60 health care workers (HCWs). Participants were trained on inventory management principles, stock card update, reporting and ordering using the LMIS, and storeroom management for health commodities. SIAPS has trained 18 HCWs from two health facilities on establishing a functional pharmaceutical and technical committee (PTC). SIAPS has also supported the University Research Co, LLC (URC) to facilitate an inventory management training as a component of the point of care testing and quality improvement training for mini-laboratories. SIAPS also presented on supply chain management during a training held by URC for HCWs on the management of clients on TB and HIV therapy.

In an effort to monitor and promote rational medicines use, SIAPS collaborated with Swaziland Christian University to host a workshop on medicines use research, with support from the Nelson Mandela Metropolitan University's Medicine Utilization Research in Africa (MURIA) initiative. This workshop was aimed at developing skills of PTC representatives, National Essential Medicines Committee members, pharmacists in the public and private sectors, and pharmacy students on methods to conduct medicines research to contribute to the country's health research agenda. A total of 30 health care workers participated in the training.

SIAPS provided mentorship and support to 24 HCW at 18 health facilities. The mentorship focused on good stock management practices, correct reporting using the LMIS including inventory management through RxSolution, implementing pharmacovigilance, and good dispensing practices to patients taking ARVs and anti-TB medicines. Pharmacovigilance support provided by SIAPS and the pharmacovigilance focal person (CMS quality control pharmacist) included:

- Monthly supportive visits and data collecting visits to all seven sentinel sites
- Feedback meetings to share system updates, conduct refresher on-site trainings, and develop pharmacovigilance reporting strengthening strategies were conducted at five health facilities
- Presentations and trainings for new facilities to commence active surveillance of ARVs and anti-TB medicines were conducted at two health facilities

SIAPS has also continued to support health facilities to apply an approach for participatory and continuous performance improvement in implementing their interventions. This quarter, SIAPS supported six health facilities in implementing quality improvement projects focused on improving patients' adherence to ARV treatment.

Constraints to progress

Facilities still lack the minimum requirements for good commodities storage. With new facilities now providing HIV treatment services, space and other equipment required for good storage of medicines is inadequate. We are expecting the MOH to address some of these gaps in the next fiscal year (April 1, 2016 to March 31, 2017).

Objective 3: Address Information Utilization for Pharmaceutical Management Decision Making

The priority in this reporting period has been to ensure that all SIAPS-supported electronic tools are functioning efficiently and will be sustainably owned by the government. Following the successful establishment of the web-based commodity tracking system (CTS) at the central level, SIAPS has directed efforts to rolling out the system to four health facilities as part of the second phase of implementation. In the next quarter, SIAPS shall focus on scaling-up rollout activities to cover all main laboratory facilities with network connectivity countrywide. SIAPS also engaged a vendor to support and troubleshoot CTS system-related bugs for six months. The purpose of the exercise is to strengthen and ensure sustained implementation of the CTS through reduced turnaround time for issue resolution, strict version control of the tool, and capacity building for MOH information technology support staff. SIAPS continued to provide support to the data management unit (DMU) by conducting orientation on the basic data extraction skills for the data analysis tool. The tool was also available at the CMS server so DMU staff could easily generate custom reports to inform supply chain decisions.

SIAPS supported the MOH in generation and collection of datasets for patients on second-line ARV regimen. These were collected from the SIAPS developed Patient Management Information System (RxPMIS) targeting six main treatment sites in two regions. The targeted

indicators were based on a tracker developed by Swaziland National AIDS Programme (SNAP) as part of strengthening follow-up of patients on second-line ARV regimen.

Aligning efforts to the MOH eHealth strategy, SIAPS engaged the Institute for Health Measurement (IHM) to explore options of possibly building data-exchange capabilities between RxSolution and CMIS. Output from the collaborative meetings resulted in both parties agreeing to undertake a business analysis exercise, which will provide comprehensive analysis of interfacing RxSolution and the web-based solution (CMIS). SIAPS has reached out to the RxSolution developers at SIAPS/South Africa to assist in the business analysis. It is envisaged that the exercise shall serve as a feedback mechanism for MOH to understand the technical requirements necessary to address gaps between the two systems and also to produce a document to serve as reference in the proposed syncing of RxSolution with CMIS.

In an effort to ensure strategic information on pharmaceutical systems is used for decision making in the pharmaceutical sector, SIAPS partnered with United Nations Population Fund (UNFPA) to facilitate the first round of logistic data feedback to 19 health facilities in two regions of the country, which was also feedback for the current fiscal year. Furthermore, during the quarter, 91% (n = 43) of HIV treatment facilities completed and submitted an ART LMIS report for the most recent reporting period. This reflected a decline in performance from 93% reported in the previous quarter. An improvement was seen in timely reporting by ART facilities (i.e., 56% this quarter compared with 52% last quarter). The laboratory reporting rate was maintained at 100% in the current quarter.

Partner contributions

Harvard Pilgrim Health Care Institute continued to assist in building skills of local team in research. A protocol has been submitted to the Swaziland health research ethics committee for the operational study on ARV switching patterns by using data from RxSolution.

Constraints to progress

Since the MOH is in the process of procuring a warehouse management system through the Global Fund HIV/TB grant, SIAPS has been excluded in the process. This affects planning around the prioritization of activities that support MOH. SIAPS will continue to engage with the officials leading this process to ensure efficiency in the planning and use of resources.

Objective 4: Improve Pharmaceutical Services to Achieve Desired Health Outcomes

Contributing to the achievement of HIV targets, SIAPS continued to support MOH to ensure that the ARV stock situation is stable and within the recommended minimum-maximum levels throughout the national pipeline (facility and central warehouses). However, pediatric LPV/r (LPV/r 80/20 mg/ml) was stocked out at the CMS earlier in March. MOH has been working with the contracted supplier to expedite the shipment of the stock ordered in quarter 1; 51% (133) of facilities were found to have maintained the required minimum-maximum levels of ARV tracer products during the quarter. This was an improvement from the 47% recorded in the previous quarter.

The stock situation for HIV RTKs (Determine and Chase Buffer) was below the recommended minimum, at 1.7 MoS. This situation is likely to impact negatively the achievement of targets for this quarter in the HIV testing and counseling program. SIAPS conducted a gap analysis for HIV rapid test kits and submitted an emergency request to USAID to support the SHLS by procuring at least USD 1.8 million worth of rapid test kits. Forecast analysis shows that this funding will be adequate to fill the in-country pipeline of rapid test kits to ten months of stock and it is hoped that the government will then be in a position to continue to address the challenges in the procurement of HIV test kits.

SIAPS has participated and contributed to the country's plan to introduce the HIV test-and-start initiative. This project seeks to treat all HIV-positive patients. SIAPS has assisted in estimating the additional quantities of stock required for the cohort to be enrolled from January 2017.

SIAPS also supported the MOH in conducting supply planning for TB medicines. During the supply planning exercise, SIAPS was able to compare actual and forecasted consumption and adjusted the need accordingly. Order quantities were adjusted according to data obtained from the LMIS on the actual consumption patterns of the various anti-TB medicines. At least a total of SZL 8 million was planned for and submitted to procurement unit to generate purchase orders.

SIAPS continues to support MOH in ensuring patient safety and therapeutic effectiveness. SIAPS provided technical assistance in conducting the causality assessment of adverse events. This quarter, 150 adverse drug events (ADEs) were analyzed, bringing the cumulative total to 450 analyzed cases. SIAPS also supported the development of the February 2016 edition of the Medicines Safety Watch newsletter. Job aids on improving spontaneous ADE reporting directed at health care workers and patients were designed and printed for distribution. The next steps are to monitor the impact of these job aids on facility practices relating to patient safety monitoring and ADE reporting. SIAPS also supported the printing of additional passive surveillance reporting forms and is in the process of transitioning this printing to the MOH.

SIAPS supported the National TB Control Programme in the implementation of bedaquiline for the management of XDR-TB patients. The support included development of bedaquiline and delamanid clinical guidelines and testing the redesigned web-based pharmacovigilance information management system in preparation for piloting.

Partner contributions

William Davidson Institute: assisted and completed the supply chain analysis study conducted in FY15/PY4

Constraints to progress

The process for establishing a bedaquiline clinical access program was lengthy, which led to minor delays in starting to use the medicine after its arrival in the country in December 2015.

Ukraine

Goal: Assure availability of affordable quality pharmaceutical products and effective pharmaceutical services to achieve the desired outcomes for HIV and patients.

Overall Quarter Progress

In the second quarter of the PY5, SIAPS Ukraine continued to demonstrate noticeable advancements toward the following three objectives. Activities outstanding from PY4 are being successfully managed as well.

For Objective 1, preparatory work for the National Supply Chain Assessment (NSCA) was completed, and the data collection has begun.

For Objective 2, the technical reports on Drug Utilization Review (DUR) for both HIV and TB sectors were finalized and staff members are making preparations for them to be presented at a stakeholders meeting early in April.

For Objective 3, the Regulations on National Essential Medicines List (EML) and Regulations on EML Expert Committee were approved by a Ministry of Health (MOH) order. In collaboration with the MOH, the process has started the selection of the EML Expert Committee members.

Additionally, the web-based price monitoring tool is now fully functioning, and the SIAPS indicators will be measured in April.

The verification of the data protection system developed for the Pharmacovigilance Automated Information System (PAIS) has been completed and the security certificate was issued by the Ukraine Security Service.

SIAPS Ukraine continues to provide TA to the Ukraine government by contributing to the working groups involved in developing National Drug Policy (NDP), medicines procurement reform, and health care financing reform.

Objective 1: Support improvements in national supply chain management.

The preparation stage of the NSCA has been completed. The methodology was adapted to include the Capability Maturity Model questionnaire and Key Performance Indicators data points and data collection forms.

The MOH order to facilitate the NSCA was signed. Pursuant to the order, regional focal points were assigned to local health authorities. SIAPS met with them to explain methodology, roles, and expectations.

Thirty data collectors out of 89 applicants were selected based on defined criteria, and they attended a five-day training in March. The training included piloting the data collection tool in

six facilities in Odesa city and nearby districts. The data collection tool was programmed on tablet computers. Data collectors used the tablets to guide the interview and submit collected responses. The data collection process started on March 21 and is expected to end on April 1.

Partner contributions

The head of MOH pharmaceutical department coordinated the communication between MOH, SIAPS, and Local Health Administrations, providing relevant political support to NSCA. The Odesa oblast health statistics office helped data collectors secure access to the facilities during the piloting of the data collection tool.

Constraints to progress

The time needed for the methodology adaptation and preparation of the training and data collection process was underestimated. This resulted in a high pressure experienced by SIAPS Ukraine staff involved in the NSCA.

Objective 2: Improve pharmaceutical services for HIV and TB Programs.

The DUR reports in both HIV and TB sectors were finalized and sent to SIAPS headquarters for review. After the reports were reviewed, SIAPS incorporated the HQ recommendations and prepared the final versions of reports. These reports will be first presented to main stakeholders, which are the Ukrainian Center for Disease Control (UCDC), AIDS centers, and TB dispensary. Their feedback will be incorporated and then final reports will be presented on April 6 at a inclusive stakeholders meeting that will include core national level bodies (MOH, State Expert Center/SEC, UCDC), as well as international entities (WHO, USAID) and participants of DUR staff from regions (AIDS centers and TB dispensary). The preparation for the training for Drug Therapeutic Committees has started and it is anticipated that the training will be delivered in Q3, Y5.

Partner contributions

Major contributors for implementing DUR in HIV area are AIDS facilities, UCDC, and SEC.

Objective 3: Improve pharmaceutical management and governance.

The Cabinet of Ministers of Ukraine (CMU) Decree #333 on the Essential Medicines List (EML) was amended by CMU decree drafted by SIAPS Ukraine (January 2016). Regulations on the National List of Essential Medicines and Regulations on the Expert Committee on Selection and Use of Essential Medicines were approved by MOH Order #84 (February 2016). The draft methodology is developed and approved by MOH for public discussion, which was expected to begin this quarter (see Constraints).

The process has started on the selection of the EML Expert Committee members. SIAPS Ukraine provides TA to the MOH to prepare procedures for creation of a Competition Committee, which will be responsible for conducting the competition-based selection of candidates for EML Expert Committee. The draft MOH order regulating the foundation and functioning of the Competition

Committee was developed and submitted to MOH for approval. The competition is expected to start in April.

The competition for selection of vendor to perform the training on Health Technology Assessment (HTA) for EML Expert Committee members, which was expected to be completed in December is still in progress (see Constraints).

Pharmacovigilance (PV) Guidelines
There was no meeting of the working group on developing the National PV guidelines in this quarter (see Constraints).

Partner Contributions

The MOH and State Expert Center collaborated on creation of the Competition Committee and finalization of the methodology for selection of medicines for the National EML. WHO helped in organizing the competition for a HTA training provider.

Constraints to Progress

EML
The public discussion of the finalized methodology for selection of medicines to National Essential Medicines List was not held because CMU recently approved a new procedure for approval of legislative acts. Among other conditions, this procedure requires that an analysis of legal consequences has to be conducted. Such analysis should be based on economics considerations, and MOH does not have capacity to perform it because of staff and capabilities limitations. A strategy to deal with this constraint is being developed with the MOH.

Concerning training for the EML Expert Committee, only one organization responded to RFQ for training on HTA out of 12 organizations contacted and invited to participate in the competition. The only offer exceeded SIAPS Ukraine's budget limits, so the competition was prolonged. As of the end of March, there are two bidders. The current plan is that early in April the vendor will be selected.

PV Guidelines
The State Expert Center has been under the investigation of Ukraine Security Service (USS) since January. Their work in many areas is blocked. Thus, no advancement was made in developing PV guidelines modules.

Other PY5 Q2 Activities

Workgroups
SIAPS Ukraine continues providing TA to the MOH on developing the Concept of the Reform of the procurement of medicines. The concept is expected to be finalized and submitted to the MOH for public discussion in April.

SIAPS Ukraine participated in development of the Concept of Healthcare Financing Reform. The concept was finalized in February and was submitted to MOH for public discussion, which is in progress now.

SIAPS Ukraine has drafted several components of the NDP; its development was initiated by MOH within specially established working group. These components (NDP chapters) are Medicines Selection and M&E. These chapters were agreed upon with MOH and WHO. The NDP group continues its work.

Other Activities
SIAPS Ukraine continued providing feedback to the "Concept on deregulation of pharmaceutical sector in Ukraine," developed by Arzinger law firm and Patients of Ukraine Civil Society Organization.

Partner contributions

Work groups members, EU consultant (procurement reform group)

Outstanding Activities from PY4

Price observatory
The end user (Network of People Living with HIV [PLWH]) of the web-based price monitoring tool has procured and installed a new server in March. This server was needed to handle the software and data for the tool. Trainings for administrators, reporters, and analysts of the tool were conducted from December 2015 to February 2016. Google analytics was installed on the tool to allow for measurements of SIAPS indicators.

PAIS
The independent IT company assigned by the USS to verify the data protection system in PAIS has completed its analysis and results were positive. Based on this conclusion, USS issued a data security certificate for PAIS in the last week of February. The PAIS transition plan has been reviewed by SEC, but not signed yet due to the difficulties experienced by consignee (see Constraints). However, most of the transition plan activities has been already completed, and the signing the transition plan is becoming a formality.

Constraints to progress

Price observatory
Procuring a server to handle the tool has taken longer than planned because of organizational and financial peculiarities of the Network of PLWH.

PAIS
The SEC has been under the investigation of the State Security Service since January. Their work in many areas is blocked. The transition plan was not signed.

Uzbekistan

Goal: The primary goal of the project is to strengthen the TB control system to address the threat of increased MDR-TB.

Overall Quarter Progress

SIAPS supports the country in the implementation of the early warning and forecasting/quantification system with the use of the QuanTB. Recently, based on the request from Ministry of Health (MOH) officials, USAID Uzbekistan Country Office recommended SIAPS to continue assistance for countrywide rollout of the early warning and quantification system using the QuanTB tool. In this regard, an amendment to the existing work plan was approved by the USAID Mission in Uzbekistan as well as by the AOR. The work plan describes providing assistance to update the national pharmaceutical management guidelines in both Russian and Uzbek languages to include guidance on the utilization and application of the early warning system, refinement and the translation of the QuanTB user's manual in Uzbek language, and support of quarterly monitoring visits and on-the-job training for the Uzbekistan's regions.

Objective 3: Strengthen Supply System of anti-TB medicines

Since January 2015, an information management system using QuanTB for quantification and early warning is being piloted in three regions (Samarkand, Khorezm, and Fergana oblasts) and Tashkent City, which is managed and coordinated by the central level. In September 2015, SIAPS trained representatives of remaining regional TB facilities and partner organization, Project HOPE, which implements USAID funded TB program at four regions of country and aims to implement early warning system on how to use QuanTB.

An abstract entitled "Uzbekistan's new approach to tackle MDR-TB burden through an institutionalized early warning and quantification system" was submitted for poster presentation to the 47th Union World Conference on Lung Health taking place in Liverpool, UK, October 26-29, 2016.

In December 2015, SIAPS was requested by USAID mission in Uzbekistan to support the NTP to expand the rollout of the early warning and quantification system with QuanTB in 2016.

In February 2016, a SIAPS consultant visited the country and worked with the TB pharmaceutical management working group, which is established by the Ministry of Health, to define the scope and format of the changes in the national TB pharmaceutical management guidelines to ensure that they are integrated into the early warning system. The National TB Program already started working with the Ministry of Health and, as a result, the MOH now requires regional TB facilities to submit QuanTB summary tables and quantification dashboard to the central level along with the QuanTB files on quarterly basis. During the SIAPS consultant's visit, the National TB Program organized a meeting of the managers of all regional TB facilities and coordinators who are responsible for TB medicines supply for entire region. The meeting regional coordinators were instructed on the essential elements for early warning and quantification system for TB medicines and using QuanTB reports. They also developed

skills in using the reports for making prompt and accurate decisions for uninterrupted supply of TB medicines.

The NTP gave SIAPS all respective and available legal documents for TB pharmaceutical management to develop an updated TB pharmaceutical manual that incorporates early warning system utilization. This will be presented to the Ministry of Health for endorsement and incorporation into the ministry's 2014 Universal Order, which is the document that regulates prevention, diagnosis, and treatment of TB and DR-TB patients in Uzbekistan but does not yet include TB pharmaceutical management aspects.

SIAPS facilitated elaboration of the supervision and on-the-job training plan for the supported regions, which is already submitted to SIAPS for identifying a vendor that will be responsible for organization national counterpart's travel to regions.

Partner Contributions

The National TB Program, acknowledging the importance of the rollout of early warning system countrywide and SIAPS valuable role in this regard, requested the USAID country mission to engage with SIAPS for further support.

All above mentioned activities are being done in close coordination with the Project HOPE. It is agreed that SIAPS will provide its expertise to the tuberculosis pharmaceutical management working group to help implement and use of early warning system countrywide; Project Hope will then implement recommended activities in their pilot regions accordingly. According to the approved work plan for the next year, Project HOPE will cover needs of supervision and on the job training visits countrywide for early warning system rollout beyond the end of the SIAPS (thus far Project HOPE is only responsible for four pilot regions).

Constraints to Progress

There may be high turnover of the trained staff that can affect the function of the early warning and quantification system—this has already been experienced by the one of the oblasts.