

**SIAPS Quarterly Report**  
Project Year 4, Quarter 2

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January-March 2015



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**SIAPS** 

The SIAPS logo consists of the word "SIAPS" in a bold, green, sans-serif font, followed by a stylized blue graphic of a person with arms raised in a 'V' shape.

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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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## 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  |
| 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  |
| 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 prophylaxis                                       |
| 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 fourth year, SIAPS works with local counterparts and partners in 23 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' 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 2015 period.

## SELECT PROGRESS TOWARD RESULT AREAS

### IR 1. Pharmaceutical Sector Governance Strengthened

The SIAPS approach to improving governance focuses on assisting countries to establish policies and legislation supported by rule of law; organizational structures that can facilitate appropriate decision making, authority, and oversight; transparent, ethical, 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 our primary strategies for improving governance in the pharmaceutical sector is to strengthen regulatory systems, which ensure the safety, quality, and effectiveness of medicines by regulating pharmaceutical products, establishments, professionals, and practices. SIAPS provides support to national medicine regulatory authorities to build their technical capacity; 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**, SIAPS continued to assist provincial-level (oblast) procurement authorities to establish framework contracts for the public procurement of health products with anticorruption funding. Framework contracts can help achieve better pricing as well as reduce opportunities for kickbacks, which can occur with separate tenders for multiple, small, and frequent medicines purchases. Significant achievements were made during this reporting period at the national level and in two oblasts. A legislative amendment was approved, which expands the range of products that can be procured under framework contracts. In Poltava oblast, following SIAPS trainings on framework contracting and meetings with stakeholders in the previous quarter, the oblast issued a local decree naming the procurer-in chief, which is a prerequisite to introducing framework contracts. In Dnepropetrovsk oblast, SIAPS delivered three trainings on framework contracts, which reached a total of 85 participants from health facilities, the regional pharmaceutical warehouse, and oblast authorities. In addition, SIAPS helped the contracting team hold two information-sharing events for public and private sector stakeholders; a total of 33 pharmaceutical manufacturers attended the two meetings to learn more about framework contracts. At the end of the trainings, the head of the Dnepropetrovsk Health Administration announced to local media that the oblast would advertise public tenders through the framework mechanism in the coming year.

SIAPS is also using anticorruption funding to assist the government of **Ukraine** to update and establish a national essential medicines list (NEML) that will be utilized nationwide as the sole list for public procurement and reimbursement. When multiple, non-harmonized lists of medicines are available, as is the case currently in Ukraine, and procedures for their use in public procurement are not well described, procurements become vulnerable to duplications, inefficiencies, and even potential conflicts of interest or corruption. In this reporting period, SIAPS worked with the government to identify the appropriate legislative instrument for



formally adopting the NEML and regulating the medicines selection process and the quickest approach for getting the decree approved. A decree of the Cabinet of Ministers submitted through parliamentary committees' hearings was determined to be the best approach, and a first draft of the decree has now been formulated with input from SIAPS.

In the **Democratic Republic of Congo (DRC)**, SIAPS assisted the national medicines regulatory authority convene a workshop to review the legislation that outlines the criteria pharmacy service providers must meet to operate in the country and, based on that review, helped revise the requirements for attaining and maintaining authorization to practice.

SIAPS continued to assist the chief pharmacist's office in **Swaziland** to advocate for enactment of the Medicines and Related Substances Control Bill and the Pharmacy Bill, which will replace the existing legislation, which dates back to 1929. In this quarter, SIAPS supported a meeting with private sector pharmacists to engage them in advocacy activities and helped develop and distribute a briefing note to inform pharmacists about the bills and encourage uniformity in their advocacy messages.

### ***Standards, Guidelines, and Procedures***

In this reporting period, SIAPS assisted several countries to develop, revise, and implement a diverse set of guidelines, lists, and standard operating procedures (SOPs) that provide the foundation for good governance in pharmaceutical systems and support better service delivery.

A notable achievement of the SIAPS **MNCH Core Portfolio** was the finalization of the intervention guide for the management of childhood diseases, which assists district managers in developing interventions to improve availability and use of medicines for childhood illness. In **Burundi**, the Ministry of Health (MOH) adopted two guides that were developed with assistance from SIAPS to support malaria prevention, treatment, and care strategies: the integrated community case management (iCCM) implementation guide and the policy guide for intermittent preventive treatment for malaria in pregnancy. In **Swaziland**, SIAPS helped the chief pharmacist's office develop medicine donation guidelines to facilitate the importation of donated products, such as bedaquiline and delamanid for the treatment of multi-drug resistant tuberculosis (MDR-TB).

Also during this quarter, technical assistance provided by SIAPS in the **Dominican Republic** culminated in the finalization and validation of the revised NEML. SIAPS helped review the bylaws of the committee responsible for approving the NEML and revise the therapeutics guidelines for primary health care committees to align them with the revised NEML. Once the revised NEML is approved and published, a ministerial decree will be issued making use of the list compulsory for medicines procurement. In addition, an update of the national catalogues of medicines, medical supplies, laboratory reagents, and materials was completed with SIAPS assistance.

Additional good governance tools developed by SIAPS include the following:

- In **Mozambique**, SIAPS worked with the Pharmacy Department and the World Health Organization (WHO) to convene a workshop with health professionals to review the final draft of the NEML.
- **Bangladesh** now has standardized tables of medical equipment for primary- and second-tier hospitals as a product of SIAPS-facilitated workshops with officials from the Ministry of Health and Family Welfare (MOHFW) and clinicians.
- SIAPS collaborated with partners in the **Philippines** to develop SOPs for cohort event monitoring in two studies: a nine-month MDR-TB treatment regimen and a bedaquiline study.

### ***Transparency and Accountability***

SIAPS continued to provide ongoing assistance to the **Ethiopian** Government to further institutionalize the Auditable Pharmaceuticals Transactions and Services (APTS) initiative, which has been introduced to achieve greater transparency and accountability in the management of pharmaceuticals and related finances. In this reporting period, SIAPS helped the Harari region conduct a consultative workshop to review and finalize APTS regulations that enforce the implementation of transparent and accountable medicine transactions at health facilities. As a next step, the head of the Harari regional health board will present the directive to the regional cabinet for approval. This brings to four the number of regions that have enacted or submitted APTS regulations to their respective councils for approval. APTS is now being implemented in 37 health facilities in the country.

In this reporting period, **South Africa's** National Department of Health (NDOH) published the master procurement catalogue, developed with assistance from SIAPS, on the NDOH website. The catalogue contains an inventory of all items on pharmaceutical contracts. All nine provinces in the country are now using the catalogue to monitor and report on availability of medicines that appear on the NMEL that are used in their respective provinces.

In **Cameroon**, SIAPS met with a local NGO that produces a weekly newsletter containing reports on the availability of HIV-related diagnostics and medicines at 74 health facilities as well as notable incidents, such as when health workers demand inappropriate or elevated fees and charges. The discussions focused on opportunities for collaboration, including leveraging advocacy, monitoring, and reporting efforts to improve patients' access to critical products, particularly antiretroviral (ARV) medicines.

### ***Coordination, Partnership, and Advocacy***

SIAPS continued to provide assistance to help institute and strengthen coordination mechanisms in a number of countries to enhance government stewardship and stakeholder engagement and to achieve results set out in pharmaceutical or disease-specific strategic plans. Highlights of SIAPS assistance in this reporting period include supporting the first meeting of the Medicines Cluster in **Cameroon**, a taskforce of the committee of financial and technical partners working on health in the country. The SIAPS-led cluster brings together representatives from WHO, the US Centers

for Disease Control and Prevention (CDC), USAID, and the French and German development agencies to agree on common strategies to improve the availability and quality of pharmaceutical products in the country.

In **Mali**, SIAPS helped the Direction de la Pharmacie et du Medicament (DPM) convene meetings of its HIV, malaria, and family planning technical working groups to validate the HIV commodity quantification results and to update the malaria and family planning commodity supply plans. The attendees included representatives from nine local and national civil society organizations. In the **Philippines**, SIAPS continued to support three Barangay Health Management Councils (BHMCs) that bring together community-based groups, officials, and health providers to improve TB control program management and results in Quezon City's barangays (urban poor slums). In addition, SIAPS helped the Quezon City Council develop guidelines to support expansion of the BHMCs to other barangays to increase community ownership of TB programs citywide, improve diagnosis and treatment, and reduce TB medicine stock-outs.

SIAPS assisted **Burundi's** Department of Pharmacy, Medicines, and Laboratory (DPML) to finalize the terms of reference for the newly constituted commodity security coordination committee and its three technical committees for HIV/TB, malaria, and MNCH health commodities. SIAPS also helped the National Malaria Control Program (PNILP) develop a briefing note and meet with the MOH and Central Essential Medication Purchasing Agency (CAMEBU) to advocate for the purchase of quinine tablets and consumables for the administration of artesunate injection in accordance with the malaria standard treatment guidelines (STGs).

### ***Strategic Planning***

In **Burundi**, SIAPS assisted the PNILP to organize a workshop to update the national malaria strategic plan for 2013-2017 to comply with requirements of the Global Fund to Fight AIDS, Tuberculosis and Malaria. SIAPS also helped the DPML conduct workshops to develop the DPML strategic plan for 2015-2017 and the 2015 work plan.

As part of ongoing assistance to the Supply Chain Technical Working Group in **Lesotho**, SIAPS worked with members to develop performance indicators for the MOH's Procurement and Supply Chain Strategic Plan for Medicines and Health Products (2013-14 to 2016-17).

In **South Africa**, SIAPS helped the pharmaceutical services directorates of two provincial Departments of Health with their strategic planning processes in this reporting period. The provincial strategic objectives and indicators for the directorate in Limpopo are now aligned with the National Medium-Term Strategic Framework 2014-2019 and the National Development Plan 2030, and the directorate in the Northern Cape has a draft action plan with proposed indicators.

### ***Regulatory Systems Strengthening***

In **Namibia**, SIAPS continued to provide technical assistance and mentorship to the Namibia Medicines Regulatory Council (NMRC) dossier evaluation team to facilitate the registration of

essential medicines. Ten trained technical assessors from the Ministry of Health and Social Services (MoHSS) and the private sector evaluated 42 medicine registration applications received by the NMRC in 2013 in a five-day dossier evaluation session. SIAPS also helped the NMRC to analyze medicine registration data for the 2014 calendar year and review key performance measures. The analysis showed that processing time had increased from 34 days in 2013 to 48 days in 2014, as the NMRC worked to reduce the backlog of over 550 applications dating back to 2010. The backlog has now been reduced by 49% through training, mentoring, and prioritization of applications received in the earlier years (first in, first out). Also during the quarter, SIAPS collaborated with MoHSS and Intrahealth to upgrade the NMRC website, which will host the online version of the medicine registration software that SIAPS developed, which will be fully implemented later this year. NMRC staff and other stakeholders provided feedback on key features to be included in the website upgrade, user acceptance testing, and training of the NMRC webmaster. The new website and online registration tool will enable NMRC to disseminate timely information about medicine regulatory activities in Namibia for improved transparency and accountability. In addition, SIAPS continued to work with the University of Namibia, School of Pharmacy (UNAM-SoP) to strengthen the pharmaceutical management module by developing course materials on pharmaceutical regulatory affairs.

SIAPS continued supporting the automation of the medicine registration process in **Ethiopia** through the introduction of an online information system at the Food, Medicines, and Health Care Administration and Control Authority (FMHACA). Based on the optimized requirements submitted in the last two quarters, SIAPS Ethiopia and two experts from SIAPS headquarters carried out the software user acceptance test, during which feedback was collected from dossier reviewers, technical working group members, and FMHACA senior management. Four superusers were identified within the agency and trained to master the software so they can provide day-to-day software application support to their colleagues. In addition, SIAPS trained five industry applicants on initiating applications online and accessing information on the status of their application. A total of 28 experts from FMHACA, including experts from the port of entry, were trained on use of the tool.

In the **DRC**, SIAPS supported the quarterly session of the medicine registration committee, which reviewed 323 dossiers. Of those, 199 (62%) were approved and given market authorizations, 17 (5%) were rejected, 71 (23%) were put on hold because of incomplete data, and 36 (11%) were deferred for the next session. SIAPS also finalized the procurement of medicine registration software, which was installed at the regulatory authority's office. User training will be conducted next quarter for all the members of the registration committee. In addition, SIAPS helped the regulatory authority disseminate the second edition of the national directory of registered medicines in the country, particularly to pharmacist inspectors and custom services at the border posts, which are the main entry points for medicines and related supplies.

In **Bangladesh**, SIAPS worked with the Directorate General of Drug Administration (DGDA) to convene a workshop with 40 participants representing the national pharmaceutical industry, including pharmaceutical companies and the Bangladesh Association of Pharmaceutical Industries (BAPI), to share information about DGDA's on-going efforts and plans to adopt a more-stringent medicine registration process. The participants provided feedback on proposed plans to introduce the Common Technical Document (CTD) format for applications as well as

the online application system, specifically requesting that the new requirements and processes be phased in over a reasonable period of time to give companies an opportunity to prepare themselves and for DGDA to provide them with appropriate guidance. SIAPS continued to advocate for greater investment in DGDA's institutional and technical capacity to perform its regulatory functions more effectively by helping the DGDA build institutional linkages and partnerships with other national and international agencies. These efforts have contributed to the World Bank's recent decision to more than double its funding from BDT 20 million to 50 million for FY 2015-2016 and the formal engagement of the Korean International Cooperation Agency (KOICA) in DGDA's capacity building strategy.

SIAPS continued to work with partners in the **Philippines** to address the regulatory requirements for introducing second-line drugs and new treatment regimens for TB. In close coordination with the National TB Program (NTP), Global Drug Facility (GDF), and International Dispensary Association Foundation (IDA), SIAPS helped collect and submit the requisite information for registering all second-line drugs for TB with the Food and Drug Administration (FDA) of the Philippines. In addition, they addressed challenges to this process stemming from non-English language medicine dossiers from some manufacturers and registration applications for off-label use of some medicines based on recent recommendations from WHO. In addition to ensuring that second-line drugs for TB get registered, SIAPS and partners drafted a protocol for cohort event monitoring of a short-course treatment regimen for MDR-TB as well as an implementation guide for introducing the second-line drug, bedaquiline, both of which the NTP and FDA of the Philippines will finalize in the next quarter.

During the quarter, SIAPS contributed strategic and technical direction to multiple regional and international initiatives to harmonize medicines regulation, including the African Medicines Regulation Harmonization Program and the East African community and West African community medicines regulation harmonization efforts. Notably, SIAPS attended the Economic Community of West African States stakeholder consultation meeting for the launching of the West African Medicines Registration Harmonization Steering Committee and African Union Model Law on Regulation of Medical Products and Harmonization for West Africa on February 2-5, 2015, in Accra, Ghana.

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

Sustainable access to medicines and other health technologies critically relies on the availability of skilled workers to provide and manage pharmaceutical services. Lack of qualified pharmaceutical professionals, institutions for pharmaceutical training, and updated curricula are challenges faced by resource-constrained countries. To enhance countries' human resource capacity, SIAPS collaborates with stakeholders to assess their capacity to manage pharmaceuticals at all levels, and then identifies areas for improvement and develops interventions to strengthen the system and build capacity.

### ***Pre-service Training***

In partnership with the Universidad Central del Este, SIAPS **Dominican Republic** facilitated 8 training sessions for 25 people on the third certified course (diploma) on pharmaceutical supply management. This course builds capacity among national health care providers so they can effectively operate Dominican Republic's unified national pharmaceutical management system. Also, SIAPS finalized a rapid evaluation of the first and second courses. In addition, SIAPS prepared draft versions of the administrative proposal and educational modules for a certified course (diploma) on rational medicine use (RMU), also to be implemented by the Universidad Central del Este.

SIAPS **Namibia** participated in the launch of the pharmaceutical technician (PT) curriculum at the UNAM-SoP. A total of 30 working pharmacist's assistants (PAs), mainly drawn from the public sector, were enrolled in the program. The PT course will be offered by the institution on a two-year, part-time basis, which will enable the PAs to progress academically while enhancing their career path. The PT will enhance provision of ART pharmaceutical services and contribute to the quality of patient care once they graduate from UNAM.

Building on the initiative from 2013, SIAPS **South Africa** worked with the University of Western Cape (UWC), Schools of Public Health and Pharmacy, and Boston University to develop an online RMU elective module for the master of public health program. Additionally, SIAPS assisted Nelson Mandela Metropolitan University (NMMU) with updating training material for the Pharmaceutical and Therapeutics Committee and medicines supply management courses. As part of the focus on ensuring sustainability, SIAPS has transitioned training materials to NMMU where these courses will be offered as core modules for third-year BPharm students.

### ***In-service Training***

Through the end of March 2015, 26 in-service health professional training curricula from 7 countries had been developed or revised with SIAPS assistance. In **Bangladesh**, 23 health professionals were trained to track the proper use, maintenance, and management of the equipment used in health facilities. SIAPS facilitated a consultative workshop with Central Medical Store Depot, the National Electro Medical Equipment Maintenance Workshop (NEMEW), and district-level decision makers to pilot the equipment tracking module in Moulvibazar district. During the workshop, the participants developed a comprehensive action plan outlining the operational, logistics, and capacity-building issues for piloting.

SIAPS **Burundi** supported the Directorate of Pharmacies, Medicines, and Laboratories (DPML) to conduct training for 21 new health district and hospital pharmacy managers to strengthen their competencies in pharmaceutical management and Channel software. Additionally, SIAPS assisted the DPML and PNILP in conducting 2 trainings on entomology surveillance and pharmacovigilance (PV) for 24 persons from the 8 sentinel sites for PV and entomology surveillance. The two-day training targeted 16 health promotion technicians plus the 8 heads of health centers in the sentinel sites.

Currently, the APTS is being implemented in 37 health facilities throughout **Ethiopia**. To assist new APTS sites to properly grasp and understand the tools, concepts and processes, SIAPS provided 5 rounds of regular trainings to over 150 finance and pharmacy staff from 3 hospitals. Additionally, 87 participants from hospitals in the southern region and Ethiopian Sugar Corporation were trained as trainers.

As part of the efforts to stem the outbreak of Ebola in **Guinea**, SIAPS, in collaboration with World Food Programme (WFP), supported the Central Pharmacy of Guinea to train 60 pharmacists and storekeepers on the management of Ebola health commodities and supplies. The six-day training covered key management activities, such as quantification, reception, storage, and distribution, and finished with a site visit to a WFP warehouse storing Ebola-related health commodities and supplies.

SIAPS **Lesotho** delivered two Supply Chain Management Leadership Development Program (SCMLDP) training workshops at Botha-Bothe and Mokhotlong districts for 45 health care workers. The SCMLDP seamlessly combines leadership with supply chain management of both pharmaceutical and laboratory commodities to improve the health care workers' capacity in inventory and logistics management systems for these commodities. Furthermore, SIAPS Lesotho mentored 17 laboratory technologists in inventory management, compiling laboratory logistics management information system (LMIS) reports, and completing laboratory requisition forms. As a result of this technical assistance and support, 94 of the laboratories submitted LMIS reports.

SIAPS **South Africa** assisted the Western Cape Pharmacy Services with an RMU training of 46 pharmacists, doctors, and nurses who are responsible for medicine management. During the training, participants developed criteria for the evaluation of aspirin use within the province. This tool will be developed further to allow a province-wide medicine use evaluation. Additionally, following the success of the Leadership Development Program (LDP) in the Western Cape–Northern Tygerberg Sub-structure, 27 facility, clinical, and pharmacy managers from 11 facilities of the Khayelitsha Eastern Sub-structure participated in a workshop to reflect on how the pharmacy profession in South Africa is nurturing the leadership mindset.

As part of capacity building efforts, SIAPS **South Sudan** provided several in-service trainings to capacitate the warehouse managers for future computer-based management of commodities. SIAPS provided introductory training on computer use and its application for Central Equatoria State (CES) warehouse staff. In addition, SIAPS conducted on-the-job training on the use of pharmaceutical tools and store arrangement for 18 facility staff from four primary health care units (PHCUs) and three primary health care centers (PHCCs). Furthermore, SIAPS facilitated a three-day pharmaceutical management training, focused on best practices and standards for the handling and proper storage of pharmaceuticals, for 20 staff members in Nimule (CES). Finally, SIAPS conducted a three-day pharmaceutical management training, focused on inventory management through proper use of stock cards, dispensing registers, issue and receipt vouchers, and proper storage management, for 24 staff in Kajokeji (CES).

Other in-service trainings included the following:

- To plan and adapt curriculum and materials for the second medicine safety surveillance TOT, SIAPS **Namibia** held meetings with the Therapeutics Information and Pharmacovigilance Center (TIPC). The training drew 13 pharmacists and medical doctors from district hospitals and regional offices from the Southern, Central, Eastern, and Western regions of Namibia.
- In the **Philippines**, SIAPS collaborated with Department of Health (DOH) regional offices and the Innovations and Multi-sectoral Partnerships to Achieve Control of Tuberculosis (IMPACT) Project in the rollout and training of the *Practical Guide for the Management of the Pharmaceuticals and other Health-related Commodities* (PGMP).
- In support of the National Malaria Control Program (NMCP) in the **DRC**, SIAPS conducted training on malaria care for 287 health care workers from 9 of the 43 PMI health zones. The training covered the prevention, diagnosis, and treatment of malaria, and included a module on quantification of malaria commodities and PV.

### **Supportive Supervision and Mentoring**

SIAPS **Ethiopia** provided technical and financial support to the Tigray regional health bureau to conduct joint integrated supportive supervision at 14 hospitals in the region. The Ethiopian Hospital Reform Implementation Guideline (EHRIG) implementation status was assessed and results showed that 64% of the hospitals implemented more than 80% of the operational standards.

Using both cluster and health-facility visit approaches, SIAPS **Lesotho** conducted 135 supportive supervision and mentoring visits to health facilities in SIAPS-supported districts, providing mentoring to 331 health care workers in inventory management and PMIS. As result of the support to the district, 92% of the assessed health facilities used country-appropriate tools to report logistic and patient data; 95% keep complete patient information as per national standards; 9% have ARVs stocked according to plan; and only 10% experienced stock-out of ARVs for more than three days.

In **Mali**, SIAPS supported the MOH through the Department of Pharmacy and Medicines (DPM) and regional health authorities to conduct supportive supervisions and coaching sessions at the national and regional levels; 48 health districts in the regions of Kayes, Koulikoro, Sikasso, Segou, and Mopti and the district of Bamako were visited.

SIAPS **Namibia** conducted supportive supervision visits to all Namibia's 14 regions to support the implementation of the Electronic Dispensing Tool (EDT) Mobile in Rundu district. Seven PHC sites, including three clinics and four health centers were visited; 17 health care workers were trained on the use of the EDT Mobile. In the Zambezi region, support and training on EDT Mobile was also provided to four nurses in charge at the four PHC facilities visited.

To improve facilities with poor stock status reports and drug requisitions, SIAPS **South Sudan** conducted supportive supervision for 13 staff in 8 PHCUs and 3 PHCCs in Yei, Morobo, and Terekeka counties in CES; 56 health facilities were visited for supportive supervision across all



regions of **Swaziland** and 42 health care workers were mentored on warehouse management, inventory management, dispensing, and PV. In addition, SIAPS visited 12 mini laboratories and two main laboratories to observe improvements in stock management and provide mentorship and support the laboratory staff on commodity management.

### ***Institutional Capacity Building***

Following a request by the Central Procurement Agency for Medicines and Medical Supplies (CECOMA) and the recommendations of Imperial Health Sciences (IHS) facilitators, SIAPS **Angola** facilitated CECOMA senior staff, the deputy director, and warehouse manager to participate in a three-day practical training session at the IHS warehouse in Centurion, Pretoria, South Africa. IHS provided executive training in warehouse management, human resource management, quality assurance, distribution, safety, and warehouse management information systems. For institutional capacity building of the DGDA in **Bangladesh**, SIAPS collaborated with KOICA and WHO to provide a long-term training program on regulatory functions. Moreover, SIAPS assisted the DGDA to find an appropriate training center and design a training program to strengthen their overall regulatory functions.

To support the preparations for two operational research studies, SIAPS **Philippines** provided training on good PV practices to 23 participants from the NTP, FDA of the Philippines, National Center for Pulmonary Research of the Lung Center of the Philippines, National Center for Pharmaceutical Access and Management, WHO Philippines, IMPACT, and the Technical Assistance Support to Countries Project. The training topics included cohort event monitoring, PV systems strengthening, causality assessment, and PV data interpretation and reporting.

Through ongoing capacity building efforts, SIAPS **Ukraine** continued to systemically improve pharmaceutical procurement practices. In Dnepropetrovsk Oblast, trainings were well received by both local and central authorities. The head of the Health Administration not only expressed his support of framework contracting during trainings, but also announced to the press that this year, they would advertise public tenders through this mechanism.

Other activities to build institutional capacity included the following:

- To increase governance and accountability within the PNILP and build their capacity to serve as a Global Fund principal recipient, SIAPS **Burundi** assisted the PNILP to conduct a training on internal administrative, finance, and HR procedures for 36 PNILP personnel.
- SIAPS **Swaziland** conducted a two-day training session for 30 participants from 2 health facilities (Mbabane and Mankayane Government Hospitals) on the establishment of PTCs. The terms of reference have been drafted and these two health facilities are expected to have their first meeting for the establishment of a PTC during the next quarter.
- In **Tajikistan**, the draft TB pharmaceutical management manual and training materials for post-diploma education curriculum developed in the previous quarter were translated to Russian, presented to the NTP and chief TB specialist of the MOH, and are currently being reviewed by the national counterparts. After their comments, the documents will be

finalized and presented for approval as part of the existing in-service trainings for TB doctors and nurses.

### **Tools for Capacity Building**

As part of SIAPS technical assistance to the MoHSS in decentralizing ART services to PHC facilities through use of mobile technology for data capture, SIAPS **Namibia** trained 43 nurses and 5 pharmacists in Kavango and Zambezi regions on the use of the EDT. Nurses began using EDT Mobile at 41 outreach sites. In the Zambezi region, 2,979 patients, representing 37% of ART patients in the Zambezi region, are now being directly managed at PHC facilities through EDT Mobile devices. This has contributed to increased access to ART for hard-to-reach populations, while preserving the accuracy and completeness of ART data in Namibia.

To better manage HIV and AIDS commodities, **SIAPS Cameroon** conducted a two-week training on the HIV and AIDS Commodity Tracking Tool (OSP-SIDA) for all regions. Staff from the regional warehouses and from the regional National AIDS Control Committee (NACC) was trained on the dashboard through an exercise that aimed to input data from 2014 into the system. By the end of the exercise, the available data from January to November 2014 from all ART sites were introduced into the database and the dashboard was updated.

SIAPS **Ethiopia** has continued supporting the automation of the medicine registration system. Based on the optimized requirements submitted in the last two quarters, the software user acceptance test was carried out in this quarter in collaboration with two experts from SIAPS HQ. SIAPS identified and trained four superusers to master the software so they could provide day-to-day software support. Additionally, 5 industry applicants and 28 FMHACA experts from different directorates were trained on how to start an online application and follow-up on its status.

Other tool-related achievements include the following:

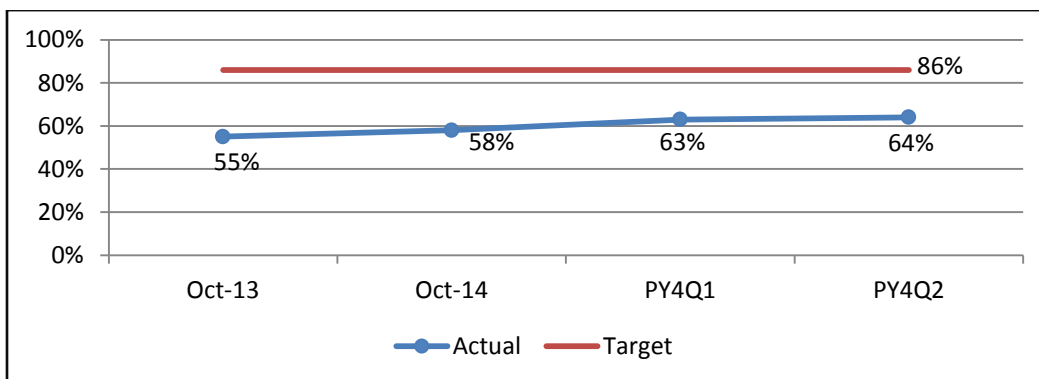
- In January, SIAPS **Uzbekistan** conducted a workshop on setting up an early warning and quantification system. The National TB Pharmaceutical Management working group was represented by 15 participants and 4 pilot regions. The participants were trained on use of QuanTB and the Excel tool for data collection. After the workshop, the pilot oblasts collected the data from the respective raions and analyzed it with QuanTB.
- In **Bangladesh**, SIAPS facilitated quantification and forecasting training for 16 NTP and WHO staff using QuanTB for first- and second-line drugs.
- SIAPS **Ukraine** continued piloting the Pharmacovigilance Automated Information System (PAIS) in AIDS centers. The data entry on adverse reactions started in March and by the end of the same month, 41 cases were entered in the system. After the trainings and field visits, the doctors are showing great interest and readiness to work with the system.

### IR 3. Utilization of Information for Decision-Making Increased

SIAPS activities focus on capture, aggregation, analysis, presentation, and dissemination of information to support evidence-based decision making. Through our tools, software solutions, and pharmaceutical management information system (PMIS) activities, SIAPS helps ensure that quality information is available to formulate pharmaceutical policy and plans and monitor supply chain systems and pharmaceutical services. To address these areas, SIAPS strategies include assessing and evaluating local information needs; leveraging technologies in designing tools; harmonizing tools to help integrate PMISs; and strengthening local organizations to customize, maintain, and take ownership of the tools as well as to analyze, manage, and use the resulting data. As a result, SIAPS country partners use innovative and proven tools to generate accurate and timely information on pharmaceutical systems to improve access to products and services. The SIAPS approach includes careful assessment of interventions related to information systems to determine the feasibility and long-term benefits of their implementation and strives to find the best solution to address health-related data collection, processing, reporting and decision-making challenges, supporting country ownership and sustainability.

SIAPS’ pharmaceutical management information tools, such as RxSolution, Pharmadex, e-TB Manager, QuanTB, and EDT, support both product and patient information. These tools are intended to build capacity in pharmaceutical management and provide increased access to services for the population on a whole, including hard-to-reach populations and other domains, such as penitentiary systems. Demand for these tools, in both SIAPS and non-SIAPS countries, continues to grow.

Data received in the second quarter of this fourth project year supports the evidence that the total percentage of SIAPS-supported health facilities receiving feedback on a previously submitted report or data continues to increase (figure 1). There is steady quarterly progress in countries using appropriate tools to regularly monitor the availability of essential medicines. The number of health facilities that have implemented electronic or mobile technology systems to document and report on specific components of the pharmaceutical system increased from 1,385 in Q1 to 1,394 at the end of Q2 (PY4 target: 1743). The number of health facilities that are using country-appropriate tools for reporting logistics and patient data increased from 1,347 (Q1) to 1,686 (Q2) in PY4 (target: 2,358).



**Figure 1. Total % of health facilities that received feedback on a previously submitted report or data, through March 2015 (aggregate of all portfolios)**

## **Data Utilization**

SIAPS tools, technical assistance, and the overall systems strengthening approach allow for effective use of data for analysis and decision making based on findings. In **Ethiopia**, information on prescribing patterns generated from the patient uptake and regimen breakdown reports allowed monitoring of the phase-out of d4T-based regimens for adults and children. In September 2012, at the start of the implementation of the d4T phase-out, there were 205,832 adult patients on ART. Of these, 30% were on the d4T-based regimen. By the end of September 2014, 98% of patients on d4T had been successfully shifted to milder regimens, mainly ZDV and TDF. By the end of January 2015, the phase-out of d4T among adults was completed. Similarly, in pediatric ART, prescribing of the d4T-based regimen has continued a sharp decline from 44% in July 2014 to 6% in January 2015.

In **Mali**, the percentage of health facilities that completed and submitted an LMIS report for the most recent reporting period increased from 34% last quarter to 53% at the end of this quarter. Stock records that corresponded to physical counts for a set of indicator medicines in regional and health facility warehouses increased from 43% to 50%. The percentage of health facilities that used consumption data to inform ordering increased from 50% to 77%, nearly reaching the yearly goal of 80%. As a result, a significant reduction of three-day stock-outs for these medicines was observed: from 66% to 31% in warehouses and from 84% to 48% in health facilities.

SIAPS continues to assist the Quezon City health staff in the **Philippines** to improve recording and monitoring of stock through the TB Supply Tracking tool. SIAPS and the Quezon City health office facilitated an inventory management meeting to address issues of stock-outs and overstocks of TB medicines. An outcome of this meeting was a redistribution of excess stock among nine facilities in the district. In **Tajikistan**, data collected and analyzed in QuanTB contributed to the early detection of potential problems with the second-line anti-TB medicine supply. In particular, the analysis of QuanTB data showed that the stock on hand and the stock on order, which was expected through direct procurement from the GDF, exceeded country needs, which would lead to a large stock expiry. As a result of the quantification exercise conducted with QuanTB, Tajikistan requested changes to the expected orders to avoid wasted medicines or stock-outs.

Globally, 3,142 active users manage 343,020 TB, DR-TB, and presumptive TB-infected individuals through e-TB Manager. The final version of 13 common indicators to be monitored through the use of e-TB Manager was shared with internal staff along with a set of accompanying data collection forms. Staff was trained to identify opportunities for in-depth analyses of the data to assess the impact of e-TB Manager in decision making and as a system strengthening tool.

## **Data Quality**

Quality-assured data is an important element for accurate analysis and appropriate decision making. SIAPS **Ethiopia** continues strengthening the patient-medication records information

system by using EDT at ART pharmacies to enable easy identification and prevention of medication errors by pharmacists. Six ART sites from the Amhara and Dire Dawa regions were able to identify and resolve 147 medication/prescribing errors, which could have endangered patient safety.

In **Lesotho**, SIAPS provided technical assistance to the Supply Chain Coordinating Unit to strengthen the implementation of the laboratory LMIS in all 18 hospital laboratories, as well as mentored 17 laboratory technologists in inventory management. As a result, 94% of laboratories submitted their LMIS reports and only 6% of hospital laboratories experienced stock-outs of HIV rapid test kits (RTKs) during the reporting period. SIAPS **Namibia** supports the implementation of nurse-initiated and managed ARV therapy by strengthening ARV stock, patient, and management data by using the EDT and its mobile version in PHC facilities. EDT Mobile allows users to enter real-time patient data in a clear and concise format, minimizing errors and gaps; 41 outreach sites in the Zambezi region currently use EDT Mobile and 2,979 patients (37% of ART patients) are directly managed through EDT Mobile devices. The mobile tool contributes to increased access to ART for hard-to-reach populations while preserving the accuracy and completeness of ART patient data.

### ***Information System Design and Collaboration***

SIAPS HQ and field teams work together with various national and international partners to continuously develop new solutions for effective implementation of information systems. In **Angola**, SIAPS received a request from CECOMA to advise them on acquiring a suitable warehouse management system (WMS). SIAPS has started to develop a guidance document, which will define goals, objectives, scope and scale, features, functions, and requirements of the required WMS. The document also outlines the steps of implementing the WMS, such as the selection process, vendor evaluation, use, support, and post-implementation review.

SIAPS is currently in the process of testing the latest version of RxSolution in **South Africa**. The new version is expected to be rolled out this year and includes new features such as biometrics for patient registration and identification. Provincial steering and technical committee meetings for the implementation of RxSolution were held in the Eastern Cape, KwaZulu Natal (KZN), and the Northern Cape provinces. There has been an unprecedented increase in the demand for the program following the MOH's announcement in 2014 that RxSolution would be rolled out countrywide, therefore the team is developing a revised implementation strategy. SIAPS continues to work in close collaboration with SCMS to support the implementation of the Provincial Pharmaceutical Management Unit (PPMU) and associated management information system (RxPPMU) in the two priority provinces of Gauteng and Limpopo.

In **South Sudan**, SIAPS assessed the ART center in the Juba Teaching Hospital to determine the feasibility of EDT implementation by using questionnaires to identify the gaps in the facility's supply system. When introduced, EDT would help improve the supply chain system for ART management in facilities by capturing patient uptake, consumption data, and stock status. Based on the assessment and discussion with the NTP in **Tajikistan**, and partner organizations such as Project Hope and KNCV, the plan for development and implementation of e-forms for TB medicines stock reporting and monitoring at the district level was outlined. LMIS quarterly

reports from districts and summary reports will be generated automatically based on the received Excel reporting forms. The new automated process is expected to support the standardization of the reporting process and its efficiency and timeliness. Working together with the Center of Disease Control (CDC) in **Ukraine**, SIAPS made progress in the implementation of e-TB Manager in the State Penitentiary System. The undertaken activities included approval of the 2015 e-TB Manager implementation plan, assigning staff to act as regional administrators of the system, and the development and dissemination of internal operation procedures on entering data into the system among regional administrators and users.

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

The SIAPS approach for strengthening financing strategies and mechanisms for medicines focuses primarily on making efficient use of existing financial resources, generating additional funding resources, and tackling the key financial barriers in accessing medicines. During this quarter, SIAPS supported the countries by providing innovative ways to raise funds at the facility level and developing grant documents and refining concept notes for submission to donor groups. Furthermore, SIAPS worked to ensure the efficient use of existing financial resources by helping countries improve their reporting mechanisms, as well as promoting transparency in financial transactions and providing technical assistance with pharmacoeconomic analyses.

##### ***Mobilizing Additional Financial Resources***

During this quarter, SIAPS continued to provide support to countries in raising additional funds. In **Cameroon**, SIAPS played a dual support role in accessing funds from the Global Fund. The first role involved providing technical assistance to the CNLS (a Global Fund Principal Recipient for HIV) and CENAME-selected regional medical stores and health facilities to ensure compliance with Global Fund requirements concerning forecasting and management of HIV and AIDS commodities. Furthermore, SIAPS also represents the technical and financial partners within its role as a member of the country coordinating mechanism. The second key role that SIAPS played this quarter was to support the CNLS in conducting an HIV and AIDS commodities quantification exercise in an attempt to gain an extension of the current grant. The Global Fund has since approved the grant extension to address ARV needs until June 2016. In the interim, SIAPS has also been involved in the development of a concept note for the new funding model, which is scheduled to be submitted by mid-May.

Insufficient government budgetary allocations and heavy dependence on donors have led to medicine stock-outs and unavailability of funds in the **DRC**. As a result, SIAPS in collaboration with the MOH, recommended that donated medicines should be dispensed to patients at a user fee cost of 30% of ex-work value. This nominal fee will be collected at the health-facility level and used to procure additional medicines. The goal is to provide capital for medicines in the event of a delay in supply. Recently, it was determined that health facilities have recovered USD 333,560 out of an expected USD 1.7m (20% recovery rate). This is in comparison to previous years when no funds had been recovered from the health facilities.

## **Analyzing and Tracking Costs**

In **Ethiopia**, SIAPS continues to support the optimal use of financial resources through the implementation and use of the APTS in hospital facilities across the country. The APTS has been instrumental in increasing transparency in pharmacy transactions and improving the way finances are received and documented. To date, APTS has been implemented in 37 health facilities in Ethiopia, with both finance and pharmacy staff being trained to use the system.

Following the Global Fund's approval of a concept note for **Swaziland**, the National Emergency Response Council on HIV and AIDS and Central Medical Stores (CMS) have started the grant development process. As a department within the MOH responsible for the procurement, storage, and distribution of health commodities, the CMS has been charged with integrating the supply chain of all health commodities. In **South Africa**, SIAPS has provided strategic technical support to the NDOH Global Fund Cluster in developing and submitting their quarterly report to the Global Fund, which includes updates on the pharmaceutical supply management plan. SIAPS provided technical assistance and expertise in the monitoring of procurement activities and expenditures on ARVs and TB medicines funded by the global fund. By assisting the NDOH in strengthening their reporting process, SIAPS has also helped them ensure compliance with Global Fund requirements and the maintenance of existing funding.

## **IR 5. Pharmaceutical Products and Services Improved to Achieve Desired Health 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 supported countries through various technical areas and strategies including supply planning and management, community case management, PV, RMU, EMLs, formularies, STGs, treatment adherence, drug information and patient education, antimicrobial resistance (AMR), Drug and Therapeutics Committees, medicine use reviews, and infection prevention and control.

### **Supply Management**

SIAPS **Angola** has been assisting the National Institute for the fight against HIV and AIDS (INLS) in monitoring the stock levels of HIV and AIDS commodities, including RTKs, opportunistic infection medicines, and condoms. By conducting of stock analysis, SIAPS has provided recommendations to INLS on how to improve stock management at their facilities. Based on these recommendations, INLS made an emergency order of selected ARVs to ensure the low stock on these medicines did not lead to a stock-out. Furthermore, facilities were advised to use already available products that were overstocked to prevent wastage. SIAPS, along with partners at UNFPA and Pathfinder, conducted a complete inventory of family planning products at the central medical store (CECOMA). Furthermore, SIAPS advised on the distribution of the Global Fund's RTKs for malaria, since the kits were overstocked and had been kept at the

national level for the past year. These interventions have led to national improvements in RTK availability at warehouses, where stock-out levels fell from 67% to 27% this quarter, outperforming the target of 50%. At the same time, stock-outs at the health-facility level also decreased from 71% to 19%.

SUGEMI, the integrated supply management system implemented in the **Dominican Republic**, has continued to prove to be a valuable and useful tool. Almost all health facilities (97%) reported and received feedback on their data. This data is then analyzed and disseminated in the quarterly bulletin, which is used by the stakeholders for decision making. The bulletin was also updated this quarter, further clarifying any information for decision making to stakeholders. These interventions are complemented by capacity-building activities in supply chain management. The Universidad Central de Este, with SIAPS facilitation, delivered their third training course (diploma program) in pharmaceutical supply management.

In **Lesotho**, SIAPS assisted the National Drug Service Organization (NDSO) to avoid any further stock-outs by updating the supply plan for HIV RTKs; NDSO plans to adhere to the modified plan to ensure availability of RTKs nationally. SIAPS also facilitated the SCMLDP for 45 health care workers in 2 districts. The participants developed action plans during the workshop and SIAPS will continue to work with the district health management teams to provide peer-to-peer mentorship so that participants can review progress against supply chain performance indicators. SIAPS staff also conducted supportive supervision visits to districts, leading to improvements in indicators logged in the PMIS and LMIS. No stock-outs were reported at any facility in the country for first-line fixed-dose combination ARVs for more than 28 days. Furthermore, the NDSO has also ordered more quantities of first-line ARVs, bringing the stock level up to the maximum (18 months). Only 10% of health facilities experienced stock-outs of pre-selected medicines for three days or more in the last three months, which is an improvement from the 15% rate last quarter.

SIAPS **Mali** has been working diligently with the Central Medical Store (PPM) to finalize their supply chain management strategic plan for 2015-2019. This quarter, the plan was validated and consensus was reached among stakeholders in a workshop, including improving supply chain operations, SOPs, staff training plans, and improvement of the PPM management information system. Because of the improved accuracy and timeliness of LMIS reporting at the regional, district, and health-facility levels, there was a significant reduction in stock-outs for three days or more on tracer medicines from 66% to 31% in warehouses and from 84% to 48% in health facilities. The improvements in availability can be attributed to maintaining and regularly updating supply plans for malaria and family planning products, using consumption and inventory replenishment data.

In the **DRC**, SIAPS supported the NMCP to train 287 health workers from 9 health zones on quantification of malaria commodities. The training was timely, in that it helped health professionals close the gap on performance indicators related to the management of malaria in their regions. The National Program for Reproductive Health (PNSR) also held a meeting, supported by SIAPS, on monitoring and improving the supply of contraceptives. The stakeholder discussions brought about the realization that Microgynon, 3 Combinaison, Depo-Provera, and Jadelle products had a short shelf-life left. Furthermore, the analysis revealed that IUDs, male



condoms, and Collier du Cycle products were overstocked at the warehouses. This meeting allowed the PNSR to make appropriate and immediate consignments to health facilities that were low or stocked out of these products. In addition, other products that were overstocked and at risk of expiry were delivered to health facilities, including 370,000 ORS kits (combined with zinc and oral zinc), 72,000 doses of artemisinin-containing regimens (ASAQ), over 20 million male condoms, and 30,500 female condoms. SIAPS helped develop a distribution plan for the health programs and will assist in monitoring products that have a short shelf-life to improve availability and avoid expiry and wastage. These interventions, along with the supportive supervision visits that SIAPS supported in 10 health zones across 3 provinces, helped decrease the national stock-out rate at health facilities to 38%, improving from last quarter's reported 45% stock-out rate.

### **Pharmacovigilance**

In **Bangladesh**, SIAPS continues to strengthen the PV system. Since January 2014, 270 adverse drug event (ADE) reports, including 30 reports during this quarter, were submitted from 30 hospitals and pharmaceutical companies to the DGDA. The Adverse Drug Reaction Monitoring (ADRM) Cell reviewed the submitted reports. Following last quarter's SIAPS-facilitated workshop for the focal points of selected hospitals and pharmaceutical companies, Bangabandhu Sheikh Mujib Medical University Hospital developed a database for reporting ADEs that is aligned with the standard ADE form. To evaluate and analyze the ADE reports and make recommendations of actions to be taken by the DGDA, SIAPS facilitated a technical session for the ADR advisory committee. The committee decided to establish a five-member sub-group within the advisory committee, which will be responsible for reviewing all ADE reports before further validation by the entire committee.

SIAPS assisted the Department of Pharmacy, Medicines, and Laboratory (DPML) in **Burundi** to establish a PV system in eight selected sentinel sites. SIAPS assisted with the validation of guidelines and training materials, as well as training of 24 health care providers from the sentinel sites. SIAPS also conducted a sensitization meeting to raise awareness for 48 health workers and managers on the importance of and their roles in implementing PV activities.

SIAPS **Ethiopia** continued to support efforts to raise awareness on PV among health care providers. During this quarter, 240 health care providers participated in face-to-face discussions at 9 health facilities in Addis Ababa and SNNPR. In addition, 245 ADE reporting forms, 350 allergy cards, 210 copies of the national PV framework, 590 newsletters, and 280 preventable adverse event bulletins were distributed to health facilities and regional health boards. During this quarter, 124 ADEs were entered into the national database and acknowledgment/feedback was provided to 110 health care providers who reported the ADEs. Investigation and analysis was carried out at eight hospitals on an ADE report of a fixed-dose ARV medicine. The report has been communicated to the Facility Inspection Directorate, a sample of the suspect medicine was collected, and corresponding action is awaited.

SIAPS worked with **Namibia's** TIPC and the University of Washington to write an abstract and a manuscript on the sentinel surveillance results carried out at the Katutura Intermediate and Windhoek Central Hospitals. The abstract was submitted for presentation at the International

Society for Pharmacoeconomics and Outcomes Research (ISPOR) conference in May 2015. SIAPS assisted the TIPC to plan and adapt curriculum and materials for the second Medicine Safety Surveillance TOT conducted in March 2015. The training drew 13 pharmacists and physicians from district hospitals and regional offices of the 4 regions of Namibia.

To support the preparation for two operational research studies in the Philippines—the nine-month MDR-TB treatment regimen and the bedaquiline trial—SIAPS provided training on good PV practices to 23 participants from NTP, FDA of the Philippines, National Center for Pulmonary Research of the Lung Center of the Philippines, National Center for Pharmaceutical Access and Management, WHO Philippines, IMPACT, and Technical Assistance Support to Countries Projects. SIAPS and partners have also developed PV SOPs for cohort event monitoring, which are currently being reviewed by the NTP and FDA of the Philippines. In **South Africa**, SIAPS continued to support the National Pharmacovigilance Center (NPC) to implement the decentralized PV system in Mpumalanga (MP) and North West (NW) provinces. During this quarter, SIAPS facilitated the roll-out of the NPC decentralized PV system in 24 clusters (comprising 266 feeder clinics) that are currently reporting adverse drug reactions (ADRs) in MP. A further 20 clusters were formed from 294 facilities in NW. During this quarter, 137 ADRs were reported from MP (29) and NW (108). SIAPS also assisted in phase 1 and 2 trainings in preparing for roll-out to Northern Cape. SIAPS is currently involved in the planning phase of a new concept related to developing a “PV district support team” made up of nurses, doctors, and pharmacists for monitoring and support of the clusters in each district. In addition, SIAPS provided ongoing technical assistance for the interpretation of data collected from sites where NPC activities have been rolled out. SIAPS also chaired a session at the Symposium on Clinical Research in Africa where PV systems throughout East, Central, and Southern Africa were discussed.

With the introduction of the new Integrated HIV Management Guidelines, SIAPS **Swaziland** prioritized active ADE monitoring interventions at all treatment sites. During this quarter, three health facilities were added beyond the five existing HIV/TB active surveillance sites reported in the previous quarter. After numerous sensitization exercises, the MOH Pharmacovigilance Unit has received 40 ADE reports from health facilities between November 2014 and March 2015, compared to the previous period when no reports were received. SIAPS continued to provide guidance on introduction of new medicines, such as antimalarials, and active surveillance of ADEs caused by these newly introduced medicines. SIAPS also supported the second stakeholder feedback forum to disseminate the findings from the causality assessment of 30 ADE reports.

In **Ukraine**, SIAPS continued to provide support in developing and implementing the PAIS, which doctors have shown great interest in and readiness to work with. The State Expert Center (SEC) provided comments for improvements in PAIS. The improved version was tested and piloted in AIDS centers and by the end of March, 41 cases were entered in the system. SIAPS also worked with SEC to develop PV guidelines. The first four modules of the National PV Guidelines were submitted to the MOH by the SEC, to be approved by order of the Ministry.

**SIAPS TB Core Portfolio** has been supporting the active monitoring of bedaquiline, a new medicine for drug-resistant TB. In discussion with WHO and other TB partners, SIAPS

participated in the revision of documents related to the standards and SOPs for active PV and cohort event monitoring for bedaquiline. Based on this, SIAPS received additional funding of USD 2 million to provide technical assistance in establishing active surveillance for bedaquiline to countries that are eligible to receive the donation. In January 2015, SIAPS participated and chaired the national PV technical committee meeting organized by the Tanzania Food and Drug Regulatory Authority. During this meeting, SIAPS provided technical support in the review of the PV training manual and trainers' guide following a recent revision of these documents.

### ***Rational Medicine Use***

SIAPS **Burundi** assisted the PNILP in conducting a workshop to update and validate the supervision guide for malaria activities. Updates included integrating all key malaria indicators, including indicators to measure performance of pharmaceutical services, compliance of prescriptions to STGs, and patient and medicines safety. Seven organizations/projects participated in this process, namely PNILP, UNICEF, PSI, IHPB, World Vision, SEP/CNLS/malaria, and SIAPS.

During this quarter, SIAPS **Ethiopia** provided technical and financial support to Tigray Regional Health Bureau to conduct joint integrated supportive supervision at 14 hospitals in the region. During the visit, it was found that 10 hospitals initiated clinical pharmacy and drug information services and documented interventions. EHRIG implementation status was also assessed and the result showed that 64% of the hospitals implemented more than 80% of the operational standards.

SIAPS also conducted a follow-up assessment on major program indicators at 24 EHRIG and 37 PMI sentinel sites after the baseline assessment conducted two years ago. The results showed that health facilities implementing APTS has increased from 29.2% (baseline) to 66.7%; health facilities that keep complete patient information for chronic illnesses has increased from 20.8% to 41.7%; SIAPS-assisted Drug and Therapeutics Committees that have implemented AMR advocacy or containment-related activities increased from 29.2% to 54.2%; and facilities implementing good practices for medicine dispensing has increased from 54.2% to 91.7%. Prescriptions with antibiotics have remained more or less the same (58.8% at baseline and 59.6% at present).

In **Namibia**, SIAPS participated in a meeting with clinical mentors who supervise the management of ART patients in Khomas, Rundu, Zambezi, Omusati, Kunene, and Oshana regions. This meeting is held quarterly to review treatment options for ART patients on salvage regimens. In this meeting, three cases showing resistance to second-line regimens were reviewed, and new regimens were prescribed for each.

SIAPS **LAC** participated in a meeting in Peru to analyze the conditions and factors leading to the recent increase in malaria incidence in Loreto, and agreed on alternative strategies to confront the epidemic. Based on these agreements, SIAPS will, starting next quarter, support plans for the introduction of artemisinin-based fixed-dose combinations and rapid diagnostic tests.

In **South Africa**, SIAPS assisted in the development of a master set of SOPs for pharmaceutical services for the NDOH. SIAPS has identified and categorized relevant SOPs according to the

specific functions performed in a hospital pharmacy. SIAPS also supported the NDOH to facilitate a stakeholder consultation meeting for private sector service providers of centralized dispensing services and the provinces on the review and revision of the South African Pharmacy Council's Board Notice 49 of 2015, which relates to Good Pharmacy Practice rules. In addition, SIAPS assisted Western Cape Pharmacy Services with training 46 health care professionals in RMU. Finally, SIAPS South Africa has worked with stakeholders to build a hospital pharmacy model at Dr. George Mukhari Academic Hospital that can serve as a center of excellence for pharmaceutical services. During this quarter, notable progress was made including conducting a stakeholder engagement workshop, establishing a steering committee and four project teams, conducting a needs assessment, and developing an implementation plan.

### ***Essential Medicines Lists, Formularies, and Standard Treatment Guidelines***

SIAPS assisted the National Directorate of Medicines and Equipment in **Angola** to finalize the NEML and to promote the newly developed NEML to all pharmaceutical companies and pharmacists.

In **Bangladesh**, SIAPS provided technical input and helped revise the sections on ADR monitoring and inclusion of all the anti-TB medicines and regimens in the updated Bangladesh National Drug Formulary. In supporting the implementation of STGs, SIAPS **Burundi** assisted the MOH in reviewing the plan and producing an advocacy note for introducing clindamycin for uncomplicated malaria and scale-up of artesunate injection for severe malaria as per the malaria STG. The MOH developed a decree accompanying the advocacy note for further advocacy to the Ministry of Finance and the Cabinet. In the **Dominican Republic**, SIAPS assisted the MOH to finalize the NEML. SIAPS also supported the revision of the therapeutic guidelines for primary health facilities to make it compatible with the NEML.

SIAPS **MNCH Core Portfolio** is supporting chlorhexidine introduction activities in Afghanistan, Angola, DRC, Pakistan, and South Sudan and shared the new product introduction guide for health program managers within the relevant MOHs. The MNCH Core Portfolio also provided technical assistance to SIAPS DRC and the MOH DRC to finalize the chlorhexidine treatment guideline for umbilical cord care and misoprostol for the prevention and treatment of post-partum hemorrhage. These new guidelines and the chlorhexidine introduction strategy document have now been adopted by the Secretariat General of the MOH in DRC for dissemination and implementation.

In **Namibia**, SIAPS continues to support the Health Professions Council of Namibia (HPCNa) in distributing the STGs to practitioners and recovering the cost for reprinting. In the previous quarter, through SIAPS assistance, the HPCNa received a seed stock of 1,300 copies of the STG. In February, nurses, pharmacists, medical doctors and allied health professionals procured the STG at a fee determined by HPCNa (400 Namibian dollars per copy). This was the first time that the STG was distributed under a cost-recovery mechanism.

SIAPS supported the MOH in **Swaziland** to convene the National Essential Medicines Committee meeting to discuss amendments to the list of medicines availed to clinics, with particular focus on MNCH medicines to facilitate achievement of the PMTCT goals and Ending

Preventable Child and Maternal Deaths Initiative. A list of MNCH priority medicines was approved for inclusion in the tracer commodities list and categorized as vital medicines. This meeting also received and deliberated on results of the STG post-implementation survey. SIAPS also worked with the non-communicable diseases technical working group on listing medicines for Diabetes Mellitus Algorithm Rapid Assessment Tool to be implemented in health facilities.

In **South Africa**, SIAPS completed the academic detailing for 21 sections of the PHC STG and EML (STG/EML) 2014. These are a set of slides that explain the changes to the STGs. In addition, SIAPS supported the NDOH in developing an implementation and roll-out strategy for the PHC guidelines. SIAPS is also working with Limpopo and Gauteng provinces to finalize their formularies.

In **Ukraine**, based on the situation analysis performed in the previous quarter, establishing a NEML was recommended for public procurement and reimbursement. During this quarter, support was received from three parliamentary committees and the first draft of the decree of the Cabinet of Ministers for approval of a NEML was developed. SIAPS has started to help develop the NEML with local experts.

### ***Treatment Adherence***

As part of ensuring adherence to ARVs and minimizing the chances of defaulting and subsequent development of resistance, SIAPS **Ethiopia** provided support to selected ART sites to have access to phones so that patients can be called when they are lost to follow-up or miss appointments. During this quarter, 12 health facilities in 4 regions called 237 patients out of 259 (92%) who missed their appointments or were lost to follow-up. Overall, 155 patients out of 237 (65%) were brought back to treatment, 12 were transferred to other health facilities, and 17 were reported deceased.

### ***Drug Information and Patient Education***

SIAPS **Ethiopia** has continued supporting health facilities to conduct medicine use education for patients in waiting areas. During this quarter, 10 health facilities in Amhara and Tigray regions organized 40 medicine use education sessions for 262 patients.

### ***Antimicrobial Resistance***

In **Ethiopia**, 34 media personnel and pharmacy professionals were trained on AMR in Tigray region.

SIAPS is a technical resource to the UNAM School of Medicine's project on infection control and hospital hygiene in **Namibia**. SIAPS participated in a stakeholders meeting to plan for a workshop on these topics and provided technical assistance in the development of presentations on RMU and AMR in Namibia. The presentation was made by MoHSS representatives from Namibians Against Antimicrobial Resistance (NAAR) and Windhoek Central Hospital and included the role that SIAPS has played in developing Namibia's AMR advocacy strategy.

In **South Africa**, the National Strategic Framework for Antimicrobial Resistance 2014-2024 and the AMR background document, developed with SIAPS assistance, were signed by the minister of health and the director general of the NDOH. This brings to 13 the number of key pharmaceutical sector governance documents developed with SIAPS assistance. SIAPS also assisted with the finalization of the Implementation Plan for Antimicrobial Stewardship in South Africa. In addition, SIAPS provided input for the development of a policy framework for the management of DR-TB, initiated by the MDR-TB Directorate of the NDOH.

Working with the Malaria Technical Working Group in **South Sudan**, SIAPS participated in the preparation of the implementation of the 2015 therapeutic efficacy testing study. The study will monitor efficacy of the currently used first-line antimalarials (including ASAQ) to enable early detection of resistance.

During this quarter, SIAPS technical staff at HQ addressed all the feedback and instructional design suggestions made by Knowledge 4 Health on the Global Health eLearning Course on AMR (Part 2). The course was then submitted to USAID for review and feedback. Additionally, SIAPS continued to provide guidance and oversight to SIAPS field offices in implementing AMR-related activities. SIAPS also presented a session on Fight Antimicrobial Resistance or Go Back to the Pre-Antimicrobial Era at the USAID Global Health Mini-University held on March 2, 2015. The presentation is available on the Mini-University website at <http://mini-university.org/resources/fight-antimicrobial-resistance-or-go-back-pre-antimicrobial-era>.

### **Drug and Therapeutics Committees**

In **Namibia**, SIAPS assisted the Khomasdal Health Center by presenting on the role of therapeutics committees (TCs) in combating AMR including HIV drug resistance and the TC's role in managing medicine use in health facilities; 25 medical doctors, pharmacy staff, nurses, and administrators attended the TC meeting, which raised awareness among health care workers of their role in monitoring HIV-DR early warning indicators and promoting rational use of ARVs and other medicines.

In **South Africa**, in preparation for the submission of the National Policy for the Establishment and the Functioning of Pharmaceutical and Therapeutics Committee in South Africa to the National Health Council (NHC), SIAPS worked with the NDOH on the writing of the foreword and introduction for the policy document, which were signed by the minister of health and director general of NDOH, respectively. The policy is expected to be submitted to the NHC in the next quarter. SIAPS also trained members of two district PTCs in KZN. The eThekweni District PTC was established as a result of the PLDP offered by SIAPS in KZN.

SIAPS **Swaziland** has been monitoring the progress of the quality improvement projects implemented by health facilities. During this quarter, three sites submitted results of their QI projects, which will assist them to make informed decisions on AMR advocacy. Additionally, five sites reported to have held at least one pharmaceutical and therapeutics committee meeting.

### ***Medicine Use Review***

During the quarter, SIAPS **TB Core Portfolio** supported the TB program in Kenya in planning for a drug use review (DUR) for MDR-TB. Draft guidelines, activity plans, and budgets were developed. Execution of this activity is expected in the upcoming quarter. In **Ukraine**, SIAPS continued supporting the DUR pilot project at the Kyiv Oblast TB dispensary. During this quarter, the DUR protocol was approved by the ethics committee, and the data collection was performed in TB facilities. Following this success, the DUR is now being initiated in AIDS facilities. SIAPS assisted the NTP of **Uzbekistan** to pilot a DUR in three TB facilities in Tashkent City. Data collected from 105 patient cards is currently being analyzed.

### ***Infection Prevention and Control***

SIAPS **South Africa** was invited by the KZN Department of Health to conduct a refresher course on the Infection Control Assessment Tool, during which a hand hygiene activity was conducted. At the request of the NDOH-Quality Assurance Directorate, SIAPS provided the Free State DOH with 1,250 copies of the hand hygiene posters to support infections prevention and control activities. In addition, SIAPS South Africa presented a poster entitled “Strengthening Infection Prevention and Control Systems in Resource-Limited Settings by using a Self-Assessment and Continuous Quality Improvement Approach” at the 15th International Congress of the International Federation of Infection Control held in March 2015 in New Delhi, India.

**Portfolios and SIAPS IRs in the Year 4, Quarter 2 Report**

| <b>COUNTRY/PORTFOLIO</b>               | <b>IR1</b> | <b>IR2</b> | <b>IR3</b> | <b>IR4</b> | <b>IR5</b> |
|--|------------|------------|------------|------------|------------|
| <b>Africa</b>                          |            |            |            |            |            |
| Angola                                 | •          | •          | •          |            | •          |
| Burundi                                | •          | •          | •          | •          | •          |
| Cameroon                               | •          | •          | •          | •          |            |
| Democratic Republic of Congo           | •          | •          | •          | •          | •          |
| Ethiopia                               | •          | •          | •          |            | •          |
| Guinea                                 | •          | •          | •          |            | •          |
| Lesotho                                |            | •          | •          | •          | •          |
| Mali                                   | •          | •          | •          |            | •          |
| Mozambique                             | •          |            |            |            | •          |
| Namibia                                | •          | •          | •          | •          | •          |
| South Africa                           | •          | •          | •          | •          | •          |
| South Sudan                            |            | •          | •          | •          | •          |
| Swaziland                              | •          | •          | •          | •          | •          |
| West Africa Regional                   | •          | •          | •          | •          |            |
| <b>Asia and Middle East</b>            |            |            |            |            |            |
| Bangladesh                             | •          | •          | •          |            | •          |
| Philippines                            | •          | •          | •          |            | •          |
| <b>Europe and Eurasia</b>              |            |            |            |            |            |
| Tajikistan                             |            | •          |            |            |            |
| Turkmenistan                           |            | •          |            |            |            |
| Ukraine                                | •          | •          | •          | •          | •          |
| Uzbekistan                             | •          |            |            |            |            |
| <b>Latin America and the Caribbean</b> |            |            |            |            |            |
| Dominican Republic                     | •          | •          | •          | •          | •          |
| Amazon Malaria Initiative              | •          | •          | •          | •          | •          |
| <b>Core Portfolios</b>                 |            |            |            |            |            |
| Cross-Bureau                           | •          | •          | •          | •          | •          |
| Malaria Core                           |            | •          | •          |            |            |
| MCH Core                               |            | •          | •          |            | •          |
| NTD Core                               | •          | •          |            |            | •          |
| TB Core                                | •          | •          | •          |            | •          |
| <b>Total Portfolios</b>                | <b>21</b>  | <b>25</b>  | <b>22</b>  | <b>13</b>  | <b>21</b>  |



## CROSS BUREAU

### ***Objective 1. Strengthen Pharmaceutical Sector Governance***

Work continued this quarter on developing the USAID e-Learning module on good governance in pharmaceutical systems. SIAPS reviewed the course following rearrangement of the content and formatting by the Knowledge for Health (K4H) project staff and developed the test questions based on the reorganized course content. After the questions are reviewed by K4H, they will be uploaded and the course will be shared with SIAPS AOR team; USAID Bureau of Democracy, Rights, and Governance; and WHO staff working on WHO Good Governance for Medicines (GGM) program for final review.

Also in the area of governance and collaboration with international organizations on key pharmaceutical governance, at the invitation of the WHO, SIAPS is participating in a working group to assist WHO's GGM Program to update their assessment instrument for measuring transparency in the public pharmaceutical sector. There was no activity this quarter while the WHO worked to revise the tool based on comments on the objectives and proposed scope provided by the working group in the previous quarter. SIAPS will attend a meeting of the working group in Geneva on May 7–8, 2015, to review the revised tool. SIAPS will also meet with WHO prior to the meeting to discuss other potential collaborative activities.

#### *Constraints to Progress*

Finalization of the course is pending inputs by K4H project which experienced staff shortages this quarter.

#### *Partner Contributions*

K4H project continue to make valuable contributions to this activity.

### ***Objective 2. Increase and enhance capacity for pharmaceutical management and services***

Upon invitation from the Economic Community of West African States (ECOWAS) and the West Africa Health Organization (WAHO), SIAPS Program Director and one of SIAPS's Senior Advisors for Policy and Governance attended the WAHO meeting that was held on February 2–5, 2015 in Accra, Ghana. The meeting was held to launch of the Steering Committee of the West Africa Medicines Registration Harmonisation Project (WA-MRH) and to provide regional consultation on the draft African Model Law. Prior to the meeting, SIAPS had also provided comments to the first version of this law. The model is intended to provide a comprehensive guide to member states reviewing or developing their respective national pharmaceutical laws.

As member of the Capacity Building Technical Working Group (TWG) of the African Medicines Regulatory Harmonisation (AMRH) Programme, SIAPS Program Director attended the consultation meeting in February for AMRH Regional Centers of Regulatory Excellence and that

was held in Cape Town, South Africa from February 18-21, 2015. Specific objectives of the meeting were to discuss the regulatory and capacity role of the regional centers, and to initiate their development and implementation.

Prior to this quarter, SIAPS provided input to the Pharmacovigilance (PV) TWG of the East Africa Medicines Regulatory Harmonization (EAC/MRH) programme, specifically in the development and the review of their proposal for strengthening pharmacovigilance in the region and which is expected to be implemented with funding support from several donors. Upon invitation, SIAPS attended the PV TWG meeting held in Kigali, Rwanda, March 5–6, 2015. The meeting was attended by representatives of the five National Medicines Regulatory Authorities (Burundi, Kenya, Rwanda, Tanzania, and Zanzibar). The meeting was an opportunity for SIAPS to help review the plan and assist the TWG in incorporating partners' support as well as the work plan objectives agreed upon during the Arusha meeting in February. Following the Kigali meeting, and at the request of EAC, SIAPS submitted a draft MOU for their comments, defining SIAPS roles and responsibilities and potential areas of collaboration.

***Objective 3. Increase the Utilization of Information for Decision Making in the Pharmaceutical Sector***

In this quarter, SIAPS finalized the end of Year 3 partner meeting report that agreed on a working definition and the components of a measurement framework for pharmaceutical systems strengthening. The report includes the discussion paper prepared for the meeting that synthesized the findings of the literature search on definitions, frameworks, and approaches that have been proposed or used to characterize a pharmaceutical system and pharmaceutical systems strengthening and tools and the domains/categories that have been used to assess a pharmaceutical system or to track pharmaceutical strengthening initiatives.

SIAPS continued work to develop a framework for measuring pharmaceutical systems strengthening based on the definitions and components identified at the partners' meeting.. Also in this quarter, SIAPS worked on developing the background discussion paper and meeting outcomes into a paper for peer-reviewed publication. The first draft is now undergoing an internal review.

During the quarter, a final draft of the standard treatment guidelines (STG) how-to manual was finalized and submitted to editorial for editing, layout, and design. Once completed, the document will be published.

***Objective 4. Strengthen Pharmaceutical Financing Strategies and Approaches***

Following the “Universal Health Coverage: Considerations in Designing Medicines Benefits Policies and Programs” conference held in October 2014, a technical overview paper is being drafted that will articulate the necessary elements for sound pharmaceutical management within a Universal Health Coverage (UHC) program. This will be based on an outline that was completed in early February. In addition to defining the role of the different pharmaceutical functions within UHC programs and addressing the policies, strategies, approaches, and regulatory requirements to develop equitable and transparent systems, the paper will

also contain a number of recent case studies. The latter will draw on an evaluation of the Ghanaian insurance program which is currently underway, together with prior assessments of the Namibian and South African Medicines Benefits Management (MBM) systems. These case studies will contribute to the approaches to developing and strengthening MBM policies.

### ***Objective 5. Improve Quality of Pharmaceutical Products and Services***

During the quarter, additional revisions were made to the advanced draft of the medication adherence guidance document. The next step is to circulate the draft for internal peer review.

Also, much progress was made on antimicrobial resistance (AMR) activities. All feedback and instructional design suggestions made by K4 Health on the Global Health eLearning course on AMR (part 2) were addressed. The course was then submitted to Jim Shelton and Tony Boni of USAID for review. Once all comments have been received, the next step is to address their feedback, and then submit the course for final review/approval and publication.

SIAPS continued to provide guidance and oversight during the quarter to field offices in implementing AMR-related activities. SIAPS also presented a session on “Fight Antimicrobial Resistance or Go Back to the Pre-Antimicrobial Era” at the USAID Global Health Mini-University held on March 2, 2015. The presentation is available on the Mini-University website and can be downloaded from <http://mini-university.org/resources/fight-antimicrobial-resistance-or-go-back-pre-antimicrobial-era>.

In line with more recent developments, SIAPS revised the focus and orientation of the Regulatory System Assessment Tool (RSAT) activity to reflect the expected level of coordination with WHO, which is also in the process of developing a regulatory assessment tool. The revised activity has now been reflected in a revised work plan that has been submitted to USAID.

Meanwhile, SIAPS has identified and initiated communication with key collaborators at WHO, namely those who are involved in developing the agency's regulatory assessment tool, and scheduled meetings to discuss how to harmonize the respective tools and coordinate our efforts. The outcome of these meetings will shape the direction of the collaboration of this activity.

### ***Objective 6. Contribute to the Generation of New Knowledge and Dissemination of Evidenced-Based Approaches and Best Practices***

To support knowledge sharing through the WHO EMP portal, SIAPS continued support to the IT contractor responsible for the software platform. SIAPS support included (1) the development of a single web page access point for a more streamlined and efficient user experience; (2) establishment of an investigate options to save search queries to help improve WHO's understanding of user requirements/expectations, (3) updates to the library web pages for improved mobile use and thereby bridge from web-only to the wider mobile market, and (4) update to the sub-collection web pages for improved access to customized information collections.

The documentation upload process continued leading the document collection growing from

4,660 to 4,735 documents. The latest submissions from SIAPS included two key publications: Akpabio E, Kagoya HR, Mafirizi D, et al. *Assessment of Compliance of Outpatient Prescribing with the Namibia Standard Treatment Guidelines in Public Sector Health Facilities*. March 2014; and Adinew A, Ejigu E, Geremew E, Tadeg H. *Auditable Pharmaceutical Transactions and Services (APTS): Findings of the Baseline Assessment at Federal, Addis Ababa, and Teaching Hospitals*. July 2014.

Having received new obligations this quarter, SIAPS-related activities for PY4 were also identified. These will include further support to the documentation upload including from past and current USAID programs as well as from other sources including international organizations and initiatives. The plan also calls for conducting an analysis of thematic areas already captured by the portal so to make informed recommendations as to what document collection will need to be further targeted.

### *Partner Contributions*

WHO continued to coordinate software feature development, document approval, and collections development by adding an estimated additional 75 documents this quarter to the portal and worked with the IT contractor on the web features listed above.

## GLOBAL PROGRAMS

### **Malaria Core**

**Goal: Improve the supply, quality, and use of malaria commodities to reduce malaria burden**

SIAPS contributed to improving metrics and monitoring of malaria commodities by conducting end use verification (EUV) surveys in three countries and submitting stock status of malaria commodities from Angola, Burundi, DRC, Ethiopia, Guinea, Kenya, Mali, South Sudan, and Uganda. SIAPS also participated in a EUV summit

#### ***Objective 1. Improve Coverage of Malaria Interventions***

Reviewed and submitted year 4 malaria core and country work plans per PMI recommendations. SIAPS continued to hold monthly coordination meetings with PMI/Washington to discuss implementation of PMI activities in supported countries.

#### ***Objective 2. Improve Metrics and Monitoring and Evaluation of Malaria Interventions***

A one day EUV summit was held to review progress and challenges in implementing EUVs and discuss future plans and improvements in methodology and inclusion of MCH commodities. Summit attendants included PMI Washington, DELIVER, and SIAPS. To facilitate procurement decisions at PMI, SIAPS aggregated data and reported on stock status of malaria commodities from Angola, Burundi, DRC, Ethiopia, Guinea, Kenya, Mali, South Sudan, and Uganda.

## **Neglected Tropical Diseases**

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

### ***Objective 1: Strengthen NTD global coordination and oversight mechanisms***

SIAPS participated in a telephone working group on soil-transmitted helminth control, led by the Centers for Disease Control and Prevention (CDC). During the sessions, SIAPS provided input on issues related to supply chain management of diagnostics for surveillance and monitoring and evaluation (M&E). This is an important aspect of the entire NTD control and elimination program that needs to be addressed as programs begin to scale down.

### ***Objective 2: Support NTD Capacity-Building Initiatives***

SIAPS met with the RTI and USAID NTD to review the three-day training workshop to be held in Ethiopia. RTI made suggestions on improving the workshop material, and Dr. Simon edited the materials accordingly. The materials are now with MSH editorial for finalization. Dr. Simon also developed a survey to be distributed to participants before the workshop, which will be used to assess the effectiveness of the workshop.

#### *Partner contributions*

SIAPS met with members of RTI and USAID to discuss materials to be included in the workshop and how to improve the packet.

### ***Objective 3: Support NTD medicine safety programs***

SIAPS previously met with USAID personnel. In this meeting USAID informed SIAPS to stop moving forward on this project until the work plan has been approved internally.

## **MNCH**

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

### ***Overall Quarterly Progress***

A major accomplishment of the MNCH Core portfolio this quarter was the finalization of the intervention guide for the management of childhood illnesses. Harvard Pilgrim Health Care, a core SIAPS partner, submitted the final versions of the intervention guide, the report on the validation of the guide and a dissemination plan to Zambia. SIAPS/MNCH is now working with UNICEF to see how the guide can be used to complement UNICEF's Diagnose-Intervene-Verify-Assess (DIVA) approach to district-level health systems strengthening. Also this quarter, in support of the Integrated Community Case Management (iCCM) Finance Task Team (FTT), the checklist for Procurement and Supply Management (PSM) planning was completed along with the guide to iCCM PSM planning for Global Fund grantees and the PSM package overview. These tools were distributed to specific countries going through the Global Fund New Funding Model process.

The MNCH Core portfolio also remained actively engaged in global partnerships and key initiatives aimed at ending preventable child and maternal deaths. For example, the portfolio staff members were actively involved in the various working groups of the UN Commission on Life-Saving Commodities (UNCoLSC), especially the chlorhexidine working group. SIAPS/MNCH is supporting chlorhexidine introduction activities in Afghanistan, Angola, DRC, Pakistan, and South Sudan and shared the new product introduction guide for health program managers to the relevant ministries of health. In DRC specifically, technical assistance was provided to the MOH DRC to finalize the treatment guidelines for chlorhexidine for umbilical cord care and misoprostol for the prevention and treatment of post-partum hemorrhage. These new guidelines and the chlorhexidine introduction strategy document have now been adopted by the Secretariat General of the MOH in DRC for dissemination and implementation.

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

SIAPS/MNCH remained 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. SIAPS/MNCH principal technical advisor worked with the Maternal Health Supplies Caucus (MHSC) and the Maternal Health Task Force (MHTF) to finalize the call for posts for a blog series on maternal health commodities, which was launched in March. She also contacted key members of the Maternal Health Technical Resource Team and MHSC to encourage them to post blogs based on their work. The series was launched on March 18. SIAPS/MNCH principal technical advisor posted on lessons learned over the past three years about increasing access to maternal health supplies since the last time the MHTF hosted a blog series on commodities in 2012.

A senior MNCH staff remained active in the Procurement and Supply Management (PSM) subgroup of the iCC Finance Task Team (FTT) biweekly calls, calls with the Global Fund PSM hub, and the wider FTT meetings. In March, SIAPS participated in the UNICEF, UNFPA, and Global Fund meeting on “Enhancing integrated PSM programming for increased RMNCH impact.” SIAPS not only provided invaluable technical input to the shaping and organization of this meeting for UNICEF and UNFPA global and regional advisors but also presented on PSM lessons learned from integrated programming, drawing on examples from iCCM as well as other SIAPS and MSH country PSM activities. SIAPS also contributed to the report on the meeting. Next quarter, SIAPS will contribute to a mapping of PSM resources in six priority countries by the iCCM FTT to determine a mechanism of ongoing PSM support to those countries.

The iCCM PSM checklist and PSM guidance document that were developed by the PSM subgroup with SIAPS leadership were reviewed by the Global Fund, finalized, and distributed to specific countries going through the Global Fund New Funding Model (NFM) process as well as during the March meeting. The SIAPS editorial team formatted and edited the English versions this quarter and next quarter will edit the French translation of the PSM package. SIAPS will also design a two-page flyer aimed at malaria program managers advocating the additional benefits to malaria control an iCCM platform can provide.

In addition, SIAPS/MNCH was requested by the Department of Maternal, Newborn, Child, and Adolescent Health at WHO to review a document summarizing the work of the UNCoLSC to date to be circulated among WHO country offices. SIAPS provided comments in a timely fashion that will be taken into account in the document’s final version. The request for SIAPS input is a reflection of the appreciation of the global technical leadership that SIAPS is recognized for.

On March 30-31, SIAPS/MNCH senior technical advisor participated in a meeting of the Health Systems and Policy Working Group of the Countdown initiative in Geneva. The costs of her trip were covered by the Countdown group. During the meeting, she presented the progress on the paper on MNCH pharmaceutical management policies and systems and received useful feedback from the group discussion to shape the paper. It was agreed that the paper would focus on a subset of Countdown countries and would present and analyze only data relevant to assuring availability of three tracer commodities. SIAPS felt that a report of the full set of data would still be valuable and so will continue to work on that. SIAPS will continue to analyze the data set and determine which countries and commodities to highlight in the paper and will aim to submit the first draft of the paper for review by the end of May.

SIAPS and WHO also continued to review data relevant to the paper that was included in two recent WHO surveys. SIAPS and WHO also discussed potential ways in which the data not included in the surveys but necessary for the paper could be collected. A draft literature review on the same topic was developed and will be integrated into the background section of the paper. Co-authors of the WHO review were contacted to assess their willingness to be involved and to see if they have existing data, or if they can support data collection especially on the proposed financing indicators, to be included in the paper. Additionally, SIAPS is also reviewing the information on including key MNCH commodities in national essential medicines



lists.

The Supply Chain Management (SCM) subgroup of the iCCM Taskforce, which SIAPS/MNCH now chairs, met twice this quarter and discussed its annual action plan. The role of the SCM subgroup will be widened to include the role of the PSM of the iCCM FTT as the group is essentially the same people. The SCM subgroup will present on the challenges of scaling up SCM interventions to national programs at the CORE group spring meeting.

USAID as a partner to the UN Commission on Life-Saving Commodities (UNCoLSC) is interested in using a tool developed by UNCoLSC to gather RMNCH information in five MNCH priority countries—Ghana, Kenya, Mozambique, Nepal, and Rwanda. The tool will be used to profile the current status of RMNCH programs, particularly in terms of factors that affect access to the 13 priority commodities. This quarter, SIAPS was asked to conduct the landscape synthesis of RMNCH and life-saving interventions and commodities in these five countries. SIAPS identified and contracted with consultants in each country and trained them in the data collection tools and modules; the data collection has already begun. Next quarter, SIAPS aims to finish the data collection, review the data and send to the RMNCH Strategy and Coordination team of the UNCoLSC.

### *Constraints to Progress*

An enormous amount of work was generated by SIAPS's participation in the iCCM FTT. In addition, SIAPS' global technical leadership of SIAPS was appreciated and seen as useful. The March meeting was the climax of the PSM group work, and activities will now focus more at country level. There have also been significant challenges in the communication with WHO staff and their contribution to the Countdown paper. The meeting in Geneva served as stimulus, however, and the process is now ongoing.

The RMNCH data collection was slow to start because of delays in obtaining approval from the ministries of health in all of the countries except Nepal.

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

This quarter, a major product of the portfolio was finalized. Harvard Pilgrim Health Care produced the validation report presenting the potential uses of the intervention guide for the management of childhood illnesses and a dissemination strategy for the guide. Harvard also finalized the intervention guide based on the comments and feedback from the validation exercise in the three districts in Zambia. SIAPS also completed reviewing the rights of references for distribution to ensure they can be disseminated as part of the guide. The guide will be edited and packaged electronically for dissemination next quarter. It will be presented in the New Information Circuit of round tables during the CORE group meeting in April 2015.

SIAPS/MNCH continued to follow up with UNICEF Zambia on the possible use of the guide in the DIVA approach as well and had discussions with the MSH Malawi team that is implementing the DIVA approach in Malawi on whether the guide could be a useful resource.

It was agreed that while the guide somewhat duplicates the DIVA approach, the examples and classification of interventions may be a useful additional resource. Next quarter, a first draft of the interventions section of the guide will be developed for review and discussion with UNICEF as a possible complement to their DIVA district strengthening approach.

In January, SIAPS/MNCH developed a set of questionnaires specific to MNCH that will be used for the pharmacy benefit management assessment. The team discussed the feasibility of conducting the assessment in Kenya, Bangladesh, or Ghana; it was decided that the tool will first be tested in Ghana to assess MNCH commodities management under the Ghana National Health Insurance Scheme. Based on the experience in Ghana, the tool will be refined. A pre-assessment questionnaire was developed and sent to the Ghana National Health Insurance Authority (NHIA). This included information on the list of essential medicines approved by NHIA, the standard treatment guidelines, and a list of health facilities that offer RMNCH services (by level and by cadre of service providers). The assessment will be conducted next quarter and includes interviews with stakeholders at the NHIA, MOH staff, service providers, and pharmacies.

The first draft of the program managers' guide on the introduction of new and under-used MNCH medicines and supplies is being reviewed internally by SIAPS/MNCH before it is shared externally for feedback. The guidance tool has also been field tested in DRC and Pakistan, and shared with the MOH in Afghanistan for their feedback and will be used for chlorhexidine introduction in May 2015 in Afghanistan which will be facilitated by SIAPS/MNCH.

Finally, SIAPS/MNCH participated in the End-Use Verification (EUV) Summit this quarter. During the summit, the results of the inclusion of MNCH commodities in the EUV in DRC and Mali were presented, and the advantages and disadvantages to using EUV to collect data on availability of key MNCH commodities were discussed. SIAPS/MNCH also held a follow-up meeting with USAID/MNCH staff to go through the data in more detail. In the meantime, SIAPS/Mali completed a second EUV including MNCH commodities and produced a report.

### *Constraints to Progress*

Delays in the implementation of the validation in Zambia held up the process of finalizing the intervention guide for childhood illnesses. Additionally, we had wanted to discuss the use of the guide in the DIVA approach in Zambia to get field perspective, but it was not possible to communicate with the field UNICEF staff.

### *Partner Contributions*

Harvard Pilgrim Health Care produced the final versions of both the intervention guide for the management of childhood illnesses and its validation report in three districts in Zambia, making recommendations for its use and dissemination based on the validation that the Harvard team helped to initiate. The Harvard team has a wealth of knowledge of literature in interventions to improve access to medicines and approached this project in a systematic way.

### **Objective 3. Evidence Base for Effective Strategies to Improve Access to MNCH Pharmaceuticals and Services Increased**

The SIAPS/Guinea team met with the IMCI coordinator and is planning a workshop to review the quantification conducted in 2013; this now requires revision given all the changes the country has gone through due to the Ebola outbreak. Additionally, a community LMIS system has been developed to generate data on consumption and stock-outs among community health workers on a regular basis to inform the quantification; this community LMIS guide needs to be validated by stakeholders. As the stakeholders are the same for both activities, the two will be combined in one workshop. SIAPS has started to prepare for evaluating LMIS to provide recommendations to the MOH on how to strengthen the existing system; this activity is in partnership with Village Reach. Now that the Ebola epidemic is receding, planning of that activity will progress faster. SIAPS plans to conduct the diagnostic assessment of the national LMIS with Village Reach in June.

With a focus on pharmaceutical services, SIAPS shared the new WHO pneumonia guidelines in French with the MOH Guinea MOH this quarter and, together with other partners, will support the MCH unit to update their standard treatment guidelines and implement the new recommendations. SIAPS/MNCH will continue to provide assistance and coordinate with the MOH for the updating of the pneumonia STGs as part of the overall updating of STGs process planned for this year. Note that this activity is primarily funded by Mission funding to SIAPS and so is reported in the SIAPS/Guinea quarterly report as well.

SIAPS/MNCH continued to follow-up with USAID on which countries SIAPS should support in iCCM. Discussions revolved around DRC, Uganda, and Madagascar. SIAPS facilitated a meeting with the SIAPS staff in DRC during a Maternal and Child Survival Program (MCSP) staff visit and met the MCSP team in Washington, DC, after their exploratory trip to discuss potential collaboration. There is a possibility of collaboration on supply chain management for iCCM in Kisangani, which is feasible due to the presence of a SIAPS regional advisor there. USAID/MNCH team is currently awaiting the approval of the USAID mission in Uganda and Madagascar.

Also this quarter, SIAPS proceeded to participate in the following working groups' meetings: the Maternal Health Technical Resource Team, the Supply Chain Technical Resource Team, the chlorhexidine working group, the injectable antibiotics working group, and the diarrhea and pneumonia working group, which includes the amoxicillin and zinc subgroups. SIAPS provided country support for the UNCoLSC activities in Afghanistan, Angola, Bangladesh, DRC, Ethiopia, Mali, Pakistan, and South Sudan.

SIAPS/MNCH continued to support the Maternal Health Technical Resource Team (MHTRT) and participated in the monthly calls. The French translation of the Mali case study on integration of oxytocin in the EPI cold chain was finalized and shared with the SIAPS/Mali team. The options analysis work has been delayed due to competing priorities with the MOH. The SIAPS/Mali team will meet again with the MOH early next quarter to determine when work on the options analysis can begin. SIAPS principal technical advisor for MNCH represented the Supply Chain Technical Resource Team (SCTRT) on a call of the Global Markets and Regulatory Technical Resource Team to discuss an upcoming workshop scheduled for May

2015 on procurement of quality medicines in Malawi. The Global Markets and Regulatory team requested that a representative from the SCTRT present the tools developed by the group. SIAPS also met with JSI to discuss plans for validation of the quantification guidance.

As usual, SIAPS/-MNCH senior technical advisors participated in the biweekly calls of the chlorhexidine working group (CWG) and also attended the in-person meeting in January 2014. SIAPS worked with in-country teams to facilitate introduction of chlorhexidine in Afghanistan, Angola, and South Sudan this quarter and shared the new product introduction guide with the MCH department of the MOH in Afghanistan. The chlorhexidine introduction guide was shared with the MOH in South Sudan and SIAPS/ MNCH will be providing technical assistance for a stakeholder's meeting next quarter. Additionally, SIAPS/MNCH supported a Portuguese translation of the chlorhexidine material in Portuguese to facilitate discussions with Angola's Reproductive Health department at the MOH. Finally, SIAPS was asked to provide an update on the quantification guidance during one of the chlorhexidine working group's biweekly calls.

Technical assistance was also provided to SIAPS/DRC and the MOH to finalize treatment guidelines for chlorhexidine for umbilical cord care and misoprostol for the prevention and treatment of post-partum hemorrhage. These new guidelines and the chlorhexidine introduction strategy document have been adopted by the Secretariat General of the MOH for dissemination and implementation. The guidelines were officially launched at a central level workshop, which was supported and facilitated by SIAPS/DRC. A summary on chlorhexidine introduction in DRC was sent to the chlorhexidine working group to be incorporated in an abstract the group will be submitting for the Global Maternal Newborn Health Conference in Mexico City in October 2015.

SIAPS/MNCH staff provided support to the injectable antibiotics working group activities in DRC. In February 2015, SIAPS/DRC staff participated in a meeting, facilitated by WHO, of all stakeholders in DRC to form a technical support unit for implementing a new regimen of antibiotics for newborn sepsis. SIAPS, with other in-country partners, will be part of the technical unit and support the implementation of the new regimen for newborn sepsis. The regimen is pending WHO recommendation but is likely to include oral amoxicillin instead of one injectable antibiotic. The group is planning to conduct a newborn sepsis landscape assessment in DRC as soon as possible to inform the implementation; the protocol is currently under development. Discussion is underway with Save the Children to fund the field costs of the survey as a cost-share for SIAPS.

### *Partner Contributions*

In Guinea, the activities have been delayed due to the Ebola crisis, not just because of problems mobilizing participants for activities, but also coordinating with MOH staff who were taken up in Ebola response activities. The rate of new cases is declining now and so activities to strengthen the health system can restart. There were also delays in disseminating the new guidelines at provincial and health zone levels in DRC. SIAPS/DRC is currently assisting the MOH to develop terms of reference for the dissemination workshops and coordinate with partners that received RMNCH trust funds to release funding for these activities.

## **TB Core**

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

### ***Overall Quarter Progress***

Quarter 2 saw significant progress in strengthening pharmaceutical governance for TB at the global level. The SIAPS Program, in collaboration with the Stop TB Partnership Global Drug Facility, held the conference “Building the Post-2015 Agenda: Novel Approaches to Improving Access to TB Medicines and Pharmaceutical Services” held March 2–6, 2015, in Bangkok, Thailand. Seventy-seven people from 15 countries in the Africa and Asia regions participated in the conference and jointly developed, committed to, and signed the Bangkok Commitment (comprised of six sections: preamble, early warning systems, data quality and collection, pharmacovigilance, public-private mix, and finance) to support the WHO End TB Strategy.

In the past quarter, SIAPS was asked by USAID to provide technical assistance to develop the bedaquiline donation policy and revise standards and SOPS related to pharmacovigilance for the introduction of this new TB medicine. This strategic opportunity resulted in SIAPS growing our portfolio by receiving additional funding of 2 million US dollars (USD) to provide technical assistance to establish active surveillance for bedaquiline to countries that are eligible to receive the donation.

To accelerate efforts to coordinate and design a package of technical assistance for countries to engage in monitoring and managing adverse drug reactions, SIAPS participated in meetings with WHO on pharmacovigilance systems for new TB medicines, helping to define roles of WHO, USAID/SIAPS, GDF, and other partners; and laying the foundation for a future yield of results in strengthening national PV systems.

Building on SIAPS’s past successes in increasing capacity for TB pharmaceutical supply management, there were 250 downloads of the new QuanTB tool (version 2.0.0) during quarter. During the Bangkok conference, six countries reviewed their own data collection and consolidation processes required for accurate TB medicine quantification and identified weaknesses in data quality. This activity resulted in the countries including the implementation of QuanTB in the countries’ action plans in an effort to improve the pharmaceutical management of first- and second-line TB medicines. Furthermore, continued regional TA to national tuberculosis programs (NTPs), including four GDF monitoring missions in the past quarter, resulted in procurement decisions that will avoid stock-outs and prevent wastage of TB medicines in Tanzania and Uganda.

Expanding the knowledge base on TB pharmaceutical services in the private sector, SIAPS produced a draft manuscript for USAID on lessons learned in engaging private pharmacies in public-private mix (PPM) strategy with evidence from both global and country sources, despite earlier delays and challenges in manuscript development. Plans to develop recommendations for countries that are facing the challenge of a strong private sector market, but are not adequately

engaged with private pharmacies and regulatory authorities are underway for the next quarter and will further build on SIAPS's work in the private sector.

**Objective 1: Pharmaceutical Governance for TB Strengthened at Global Level and Country Level**

**Provide technical leadership to global TB initiatives and donors**

SIAPS continued to provide technical leadership to donors and global initiatives; this quarter the main focus was on the activities related to the introduction of new TB medicines, specifically bedaquiline. The activities addressed the development of a policy and mechanism for the donation of bedaquiline (Janssen Pharmaceuticals and USAID agreement) via GDF, and the development of a policy and related documents and forms for Cohort Event Monitoring (CEM) (active pharmacovigilance). SIAPS worked with USAID TB team and the GDF on donation forms, and with WHO on CEM forms and processes. The donation was announced by USAID on the 2015 World TB Day in March and all pertinent documents were published on the GDF and WHO web sites.

Next steps: SIAPS received additional funding from USAID to provide technical assistance to USAID priority countries in establishing active pharmacovigilance processes required for the introduction of bedaquiline.

- This past quarter, SIAPS addressed questions and provided technical assistance to the Global TB Alliance regarding their plans for the launch of a new pediatric regimen.
- In Quarter 2, SIAPS intensified its work in pharmacovigilance through participating in coordination meetings via phone with WHO. The coordination meetings served to progress dialogue concerning the potential role of WHO, USAID/SIAPS, GDF and other partners in technical assistance for pharmacovigilance and laid the foundation for a future yield of results. Additionally, SIAPS provided technical feedback on the WHO drafted "FAQs on bedaquiline," which were accepted by WHO.

In March 2015, after extensive preparatory work and consultations with global TB partners, USAID in conjunction with Janssen Pharmaceuticals announced a donation of 30,000 treatments with bedaquiline, a first new TB medicine in the past 50 years to be delivered to drug-resistant TB patients via Global Drug Facility (GDF). SIAPS was asked by USAID to provide technical assistance in the development of the donation policy and revision of the GDF documents and forms related to the donation. Because bedaquiline, as an innovative medicine, it requires special active monitoring, SIAPS was also involved in the discussion with WHO and partners and revision of documents related to standards and SOPs for active pharmacovigilance and cohort event monitoring for bedaquiline. This activity resulted in SIAPS receiving additional funding of 2million USD for the provision of technical assistance in establishing active surveillance for bedaquiline to countries that are eligible to receive the donation.

In 2014, SIAPS conducted a workshop at the World and Regional UNION TB Conference on Innovations and Best Practices in Pharmaceutical Management for TB.

In preparation for the upcoming 2015 UNION World Conference on Lung Health and following discussions with partners, SIAPS developed joint proposals for two full-day workshops.

- With WHO, Royal Netherlands Tuberculosis Association (KNCV), Médecins sans Frontières (MSF), and Partners in Health (PIH), a joint proposal on active pharmacovigilance for new and existing medicines used in treatment of multidrug TB was proposed; if accepted, it is anticipated that it will position SIAPS as one of the key thought leaders in advocating a systems approach for pharmacovigilance rather than focus on a single drug.
- With the GDF, UNITAID, and Global Fund, a joint proposal was developed for a 2015 UNION workshop on “Access to TB medicines beyond 2015: The dynamics of demand and supply.”

At the Global TB conference, the SIAPS Program, in collaboration with the Stop TB Partnership Global Drug Facility, hosted representatives of 15 countries---they included national TB program managers/ deputy managers, procurement and supply management leads, and monitoring and evaluation leads for TB/data managers. In addition to attendees, partners and donor organizations including USAID, the Global Fund, Global TB Alliance, KNCV, WHO, BRAC, and FHI 360 participated in the conference. The main goal of the conference was knowledge exchange and co-generation of new knowledge to enable countries to validate their ideas and seek input and advice from others. All countries identified their main challenges in pharmaceutical management and developed an action plan prioritizing the problems for implementation. On the last day of the conference, participants, donors and partner organizations jointly developed, committed and signed the Bangkok Commitment.

### ***Objective 2. Capacity for TB Pharmaceutical Supply Management and Services Increased and Enhanced***

No capacity building activities were planned for this quarter. SIAPS discussed and coordinated several trainings on early warning systems with the GDF and partners, such as KNCV.

### ***Objective 3: Improved Use of Information for TB Control Decision Making***

#### ***Improve and Maintain e-TB Manager and QuanTB as a systems strengthening and Early Warning Tool for TB Control***

e-TB Manager has been continuously improved and new features have been added for expanded use worldwide. New versions have been regularly released, incorporating the most recent standards and guidelines published by WHO for TB and DR-TB management. e-TB Manager is currently operating at 2,549 sites in 10 countries, and globally, 3,142 users are managing 343,020 TB cases, DR-TB cases, and presumptive TB individuals. The final version of the 13 common indicators characterizing the use of e-TB managers was shared with SIAPS internal staff along with rationale for the indicators and data collection forms. Consensus on the indicators and data collection processes was sought among the SIAPS staff assigned to collect data from 12 countries. Data will also be collected from countries where SIAPS did not work, but where other USAID-funded TB projects exist such as the former TB Care 1 countries

(Indonesia, Vietnam, Cambodia). Staff members were trained on identifying opportunities for in-depth analysis to assess any impact of e-TB manager in decision making and as a system strengthening tool. Comments were solicited for the end-of-project report on e-TB manager to harvest lessons learned with recommendations.

The QuanTB tool (downloadable app for forecasting, quantification and early warning of TB medicines) version 2.0.0 has been used under SIAPS support as the national tool for quantification and monitoring of TB medicines in 14 countries. It has been tested by many partners, and is now integrated with the early stock-out warning system of Stop TB Partnership GDF as a part of global forecasting for TB medicines. QuanTB has been used during GDF monitoring missions to collect and analyze data for decisions around forecasting and procurement of TB medicines. By the end of the quarter, there were more than 250 downloads of the new version of the tool from the SIAPS website, in addition to more than 600 downloads of previous versions.

- During the Global TB Conference in Bangkok, Nigeria, Cambodia, South Sudan, Pakistan, Swaziland, and Myanmar reviewed their data collection and consolidation processes required for accurate quantification and monitoring of TB medicines. Each country identified their main data quality weaknesses and included the implementation of QuanTB in their countries' action plans in order to improve the pharmaceutical management and procurement processes of first- and second-line TB medicines in upcoming quarters.
- The desktop application e-TB Manager for case management that can be synchronized with the web version has been under controlled testing by the SIAPS team. The first generic version to be later adapted to suit specific country needs is expected for next quarter.
- An e-TB Manager stand-alone downloadable version not reliant on the internet to run has been under development. Testing for the generic version prototype is planned to start during upcoming quarters.
- Support combining SIAPS, TBCARE, and country funds for adapting, monitoring and implementing e-TB Manager in Azerbaijan, Brazil, Bangladesh, Cambodia, Indonesia, Namibia, Nigeria, Turkmenistan, Ukraine, and Vietnam has been continued.

### *Partner Contributions*

Partners provided software maintenance and improvement for e-TB Manager and QuanTB. Local partners have provided important feedback for MIS enhancement and development of new features and derivative tools. In countries where SIAPS presence is significant and a strong linkage with partners exists, local support for system implementation, monitoring, and reporting of key activities has been crucial to achieve successful outputs.

### *Constraints to Progress*

- The pace of data collection for e-TB manager indicators is variable. In some countries, staff needed further clarification. In other countries such as Ukraine, relevant permission and cooperation was necessary from authorities due to data privacy concerns.
- There is a lack of in-country champions to implement and monitor e-TB Manager activities (e.g., high turnover or deficiency of local MIS, IT and TB specialists).



- Lack of data quality about TB cases and inventory at country level to feed into QuanTB tool.
- Difficulty of countries to follow recommendations to improve TB pharmaceutical management based on QuanTB results due to factors unrelated to the quantification and forecasting processes.

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

*Provide Technical Assistance to Improve Access to Medicines for TB Control through SIAPS Regional and Country TA Mechanisms*

**Technical Assistance to Tanzania and Uganda**

SIAPS continued to be actively engaged by the NTP in Tanzania in various TB pharmaceutical management activities including provision of support in responding to PSM-related comments raised by the Global Fund Technical Review Panel and revision of TB medicines quantification data in line with the patients targets included in the performance framework agreed between NTP and the Global Fund. SIAPS also participated in the NFM grant making meeting which took place on March 23, 2015, in Tanzania and supported the NTP in clarifying pending PSM issues and finalizing TB medicines supply plan for the years 2015–2017.

In January 2015, SIAPS participated and chaired the national pharmacovigilance technical committee meeting organized by the Tanzania Food and Drug Regulatory Authority (TFDA). During this meeting, technical support was provided in the review of the pharmacovigilance training manual and trainers' guide following a recent revision of these documents. Additionally, in collaboration with other members of the National Pharmacovigilance Technical Committee, SIAPS provided technical advice to TFDA on appropriate regulatory actions that need to be taken based on various medicine quality issues submitted for discussion by the committee.

During this quarter, stocks situation was analyzed in collaboration with NTPs in Tanzania and Uganda; results were discussed with NTP teams and actions that need to be taken were jointly agreed. For example, Uganda and Tanzania requested the GDF to accelerate some pending shipments to avoid stock-outs or postpone other shipments to avoid wastage. The ability to identify potential stock-outs or overstocks is one of the achievements contributed by SIAPS support in the implementation of QuanTB as an EWS.

SIAPS supported NTP Tanzania and Uganda in preparing for the Global Supply Chain meeting. Three people, including TB Program Managers from both Tanzania and Uganda, attended the meeting. The countries shared experience on the implementation of PPM interventions related to engaging private drug outlets in TB case finding and factors that can contribute to inadequate availability of TB medicines despite having EWS in place. Participation in this meeting increased NTPs' enthusiasm on the need to improve TB pharmaceutical management activities beyond supply chain. For example, after returning from the meeting, Tanzania incorporated pharmacovigilance activities in the draft concept note submitted to the Global Fund while Uganda is considering implementation of PPM activities through engaging private drug outlets subject to finding availability.

### *GDF Monitoring Missions*

In February and March 2015, SIAPS, in collaboration with other consultants, conducted three GDF monitoring missions in Uganda, Kenya, and Nigeria. The main objectives of these missions were to review GDF's support with key officials, assess adherence to GDF terms and conditions of support, provide technical support for program management, case management, and drug management, and help the country national TB control programs to determine the country's TB medicine needs and prepare its medicine request for the coming year. Apart from these generic objectives, the three missions had additional terms of reference as requested by the Global Fund. These include provision of technical assistance in review of TB medicines needs estimated for New Funding Mechanism (NFM) grant period and in supply planning, assess status of procurement of different commodities and equipment planned under the current grant, assess stock status and advise the Global Fund and GDF, accordingly.

In response to a request from the GDF in February, SIAPS conducted a monitoring mission March 8 to 12, 2015, in Bangladesh on its TB medicine supply system and also supported the quantification of first and second-line medicines using the QuanTB tool at the national level. SIAPS introduced a simple manual wall chart along with an SOP for use as a visual EWS for stock-outs to be placed at all locations where TB medicines are stored. SIAPS will work with the GDF to create a manual for GDF consultants to ensure coordination of monitoring and technical support, and timely follow-up of recommendations from monitoring missions.

However, a Global Fund visit was scheduled during the same week which competed for meeting time with key NTP and pharmaceutical management contacts that was required to obtain information to successfully conduct the mission in a timely manner. SIAPS has discussed this issue with GDF representatives who will take care to ensure that the NTP does not have any competing priorities when scheduling upcoming missions.

Setting ambitious targets versus the actual capacity to detect and enroll patients on treatment, particularly MDR-TB patients, is a challenge especially now. Many countries are in the process of finalizing NFM grant applications in which Global Fund requires that patients' projections applied in the forecasting process should be in line with Global Fund targets and performance framework. The forecasting process supported by SIAPS and other partners will only be accurate if the TB programs are able to achieve the ambitious targets. To address this challenge, SIAPS has been advising countries to ensure well staggered deliveries; though this also has limitations due to cost implications. In addition, regular stock status monitoring and postponement of deliveries is also advised if enrollment of patients does not happen as planned.

In Uganda, procurement of kanamycin under government funding did not happen as planned despite disbursement of funds by the MOH to the National Medical Stores (NMS)—this led to stock-outs. The main reason given for this was that there was a limited availability of kanamycin from suppliers as most of them were already engaged by the GDF.

### **Public-Private Mix (PPM) Lessons Learned**

Following WHO PPM expert Dr. Mukund Uplekar's recommendation after a UNION panel presentation on engaging private pharmacies in PPM strategy, a report was drafted to review lessons learned, with synthesis of available evidence from both global and country sources. For the next quarter, SIAPS will develop recommendations aligned with WHO's END-TB strategy and tailored to the burden certain countries face with a strong private sector market but poor engagement of private pharmacies, wholesalers, and regulatory authorities. The annex consists of lessons learned from 15 countries, drawing upon 90 peer-reviewed publications, 60 UNION conference abstracts and from over 25 global documents is ready to support the narrative in the manuscript. Drafting of the manuscript was delayed due to competing priorities.

In Pakistan, the pharmacy referral process in the pilot districts is going well, despite several challenges faced in the referral process. SIAPS held a meeting with the NTP to find resolutions to the challenges faced and a quarterly meeting will be held with providers in the next quarter.

### **Drug Use Review**

The Drug Use Review (DUR) is moving forward in Ukraine. The DUR document will be updated to ensure it is consistent with the End TB Strategy's revised version of the "Companion Handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis" which is currently in draft form and expected to be released in May.

In Swaziland, the ethics committee approval to conduct the DUR in Swaziland is still pending. SIAPS Arlington staff is following up with SIAPS Swaziland staff.

The activity is still on hold in Bangladesh until the position to lead the DUR activity is filled. The search for suitable candidates continues.

### **Risk Management Activity**

SIAPS supported the participation of two Swaziland MOH staff members in the Bangkok global TB conference. Their main role was to learn about approaches for implementing risk minimization measures to reduce the effect of adverse drug events and promote patient safety for TB. The Swaziland team is currently developing a risk mitigation plan to support health care workers to do their work more efficiently and effectively to promote patient safety.

### **Promote active surveillance for monitoring the safety of TB/HIV co-medication**

During this quarter, SIAPS sent a team of consultants to provide technical support to Swaziland to implement the Cohort Event Monitoring (active surveillance) activity for TB medicines to ensure patient safety. During this trip, the SIAPS and MOH staff were trained on how to conduct causality assessment using real data collected from the facility and signal detection. A rapid assessment of the activity was also conducted to identify areas that need to be strengthened.

SIAPS is also in discussions with a developer to re-platform the tool used for data collection and analysis of cohort event monitoring activity into an internet-based tool with mobile and offline capacity for more efficient data exchange and analysis. Conversation is still ongoing to finalize the Request for Quotation and tool development will commence by next quarter.

## **TB Core Add On**

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

### ***Overall Quarterly Progress***

SIAPS continued to provide ongoing support to select NTPs in monitoring TB medicines stock status using QuanTB. In the past quarter, stock status reports were collected and analyzed from Mozambique, Philippines, Myanmar, Kenya, South Sudan Zambia, and Zimbabwe. Quarter 2 was also marked by the filling of key roles to provide enhanced technical support and improve the availability of TB medicines in DRC, Myanmar, and Nigeria.

### ***Objective 5: Improved Pharmaceutical Services and Access to TB Products to Achieve TB Goals***

SIAPS provided technical support to NTPs to strengthen drug management practices and establish early warning systems (EWS) to avoid stock-outs.

### ***Cambodia***

Three people from the NTP Cambodia team participated in the Bangkok Global Supply Chain meeting. The team was able to identify their current pharmaceutical system challenge and came up with an action plan to address their priority challenges. Participation in this meeting increased NTP's enthusiasm on the need to improve TB pharmaceutical management activities in Cambodia. The NTP has requested QuanTB training and implementation of EWS in country.

Therefore, SIAPS plans to join a GDF Monitoring Mission to Cambodia and use that opportunity to assess the TB pharmaceutical management data for weaknesses and strengths. SIAPS will also quantify the country's TB medicine needs using QuanTB. Cambodia NTP team is undertaking data collection for quantification based on the data requirements shared by SIAPS.

### ***Democratic Republic of the Congo (DRC)***

The STA position was filled and the new staff member started work on March 16, 2015. Most of March activities involved orientation of the STA on policies and procedures, operations, security and safety, procurement, travel, and communications; on SIAPS program's global, country, and TB core programs. The SIAPS staff met with the Director of the National TB Program to discuss the envisioned collaboration and technical support to improve availability of TB medicines in the DRC.

### ***Next Steps***

The TB team will discuss with NTP and agree on a roadmap for activities leading to implementation of the EWS to prevent stock-outs and wastage of TB medicines. The French

version of QuanTB continues to be revised and updated. A technical meeting will be scheduled to introduce QuanTB and start implementation of the EWS system in DRC.

### **Kenya**

SIAPS has continued to support the National Tuberculosis, Leprosy, and Lung Disease Unit (NTLD) in Kenya to implement an EWS to monitor the pipeline for anti-TB medicines. During the quarter, two EWS reports were generated—one at the end of January 2015 and at the end of March 2015. The action points were discussed with the TB program. Based on the EWS reports, Kenya was able to avert a stock-out of levofloxacin 250 mg and 500 mg through emergency procurement to mitigate effects of delayed shipment.

SIAPS participated in a review of Kenya's annual performance against set targets for TB program of the county governments in February 2015. Each of the 47 county pharmacists presented their TB medicines stock status. Reports revealed irregular distribution of TB medicines in the periphery. NTP has planned to conduct a countrywide redistribution exercise to even out TB medicines stock levels in the field. SIAPS provided support to plan the redistribution which is expected to take place in April 2015.

SIAPS supported NTLD Kenya to prepare presentations and discussions for the Global TB conference held in Bangkok. Kenya was represented by its NTP manager, senior program pharmacist, and PSM pharmacist. Country participants developed an action plan based on their priority area of challenge identified during the conference. Kenya identified pharmacovigilance as its priority. SIAPS will support the countries to implement the plans as needed.

### *Next Steps*

SIAPS will provide continuous technical support to Kenya to generate quarterly EWS reports.

### *Constraints to Progress*

The lack of efficient LMIS system in Kenya has resulted in using the push system for providing medicines to the facilities, resulting in irregular distribution of medicines in the periphery. Also, procurement and shipment have been delayed, resulting in emergency situations.

### **Mozambique**

SIAPS provided remote support to NTP's pharmacist to help update QuanTB data and results—consolidating the stock balance from the regional warehouses and updating enrolled cases from November and December 2014 and what planned orders were received.

### *Next Steps*

SIAPS staff will visit Mozambique to provide training to remaining NTP's pharmacist left out of the original three trained, and also assist with updating QuanTB for the next national TB quantification exercise.

### *Constraints to Progress*

Out of the three pharmacists trained in the previous quarter on QuanTB, the consultant from TB CARE I left after program ended, and the second pharmacist was transferred out of the program, leaving a single pharmacist.

### **Myanmar**

The technical advisor (TA) position was filled and the new staff member started work on February 23, 2015. Initial activities involved orientation of the TA on policies and procedures, operations, security and safety, procurement, travel, and communications; on SIAPS program's global, country, and TB core programs.

SIAPS discussed with the NTP terms for secondment, reporting, and SOW for the advisor. A draft work plan for particular SIAPS activities aligned with SCMS program in Myanmar from October 2014 through June 2016 in the country was agreed upon in response to the country's needs and USAID Mission vision and objectives. SIAPS also conducted a training workshop on "Improving Access to TB Medicines: Forecasting, Quantification, and Early Warning Systems" for 22 participants (11 male, 11 female) from NTP/MOH central and regional levels, WHO, SCMS, CHAI, and FHI360.

The QuanTB tool has been customized for the NTP needs. Data on TB cases and anti-TB medicines required for national baseline forecasting and quantification available prior to and during the workshop were reviewed, organized, analyzed, and validated by the workshop participants. After SIAPS training, the new technical advisor continued to collect missing or incomplete data for encoding in QuanTB with remote support from SIAPS HQ.

### *Next Steps*

SIAPS will work with USAID, NTP and SCMS to finalize and disseminate SIAPS Myanmar work plan by next quarter. SIAPS will work with NTP and partners to finalize data collection and encoding in QuanTB to generate figures as of December 2014 to be analyzed as baseline and update data as of March 2015 in QuanTB for comparison and decision making by next quarter. SIAPS staff will attend the annual Global Fund procurement meeting to support the NTP and its staff in using QuanTB together with other sources of information to enhance the quantification process for next year.

### *Partner Contributions*

The NTP and the SCMS program staff have played a crucial role both technically and logistically in making possible to start the implementation of the tool in the country. SIAPS counts on this collaboration to put in place recommended actions to improve data quality such as reviewing and adapting quarterly reporting forms currently in use to fit the QuanTB data format and improve data quality and quantification process.

### *Constraints to Progress*

It was not possible to finalize the data entry process in QuanTB and generate results about first- and second-line TB medicines forecasting needs for the country during the short-term technical assistance because of inaccurate, incomplete, or missing data. This task is planned to be completed by next quarter. Currently, there is no electronic system for TB or DR-TB case management in the country.

### ***Nigeria***

SIAPS hired a senior technical advisor (STA) for Nigeria who started work in February to provide technical assistance to NTP, track medicines in TB pipeline, and ensure uninterrupted supply and minimal wastage of TB medicines. The advisor participated in the Global TB Conference. During the conference, the Nigerian NTP team identified the key challenges in their pharmaceutical management system and came up with an action plan to address the challenges.

The STA also participated in a GDF monitoring mission in Nigeria to review GDF's support with key officials, assess adherence to GDF terms and conditions of support, provide technical support for program management, case management, and drug management to help the NTP to estimate the country's TB medicine needs and prepare its medicine request for the coming year.

The advisor supported the NTP logistics team in collecting base-line information and tracked report submission and completeness as a preliminary step to improve data recording and reporting. The STA has also been supporting supply chain and pharmaceutical services meetings, participated in and contributed to development of PSM activities and task for State Operational Plan from the Nigeria HIV/TB concept notes with focus on six states.

### *Next Steps*

The SIAPS STA will:

- Train the NTP and partners on QuanTB since NTP has agreed to adopt the tool.
- Build the Logistics team members' skills and competencies through one-on-one contact and group mentoring/coaching sessions to increase their capacity to make inferences and detect likely overstock, understock, and stock-outs.
- Collaborate with PRs and IPs to leverage on opportunities for skills transfer and strategy, guidelines, and tools development.
- Advocate for regular meetings and forum that will help address gaps in drug management practices and make national decision to prevent stock-outs and wastages in the pipeline.

### ***Philippines***

SIAPS facilitated a medicine request for drug-resistant TB cases for 2016 and used QuanTB output in determining the quantities and delivery schedule indicated in the procurement form. Program staff also helped work on a medicine request in preparation for the nine-month treatment regimen implementation and used QuanTB data to set up the procurement form. The

QuanTB report was discussed and analyzed with partners during the regular Drugs and Supplies Management sub-technical working group meeting. Also, as a result of QuanTB data review, acceptable expiry dates of pending deliveries were identified and communicated to the GDF, and overstocked medicines with potential expiration were identified and redistributed.

### *Next Steps*

SIAPS will continue to build capacity of staff and other partners involved in forecasting and procurement of TB medicines at the central level. There are plans to train new staff on QuanTB to learn how to generate and analyze reports to strengthen supply management at the central level. Mentoring sessions will be conducted with the new DSM officers.

### **South Sudan**

SIAPS has continued to support the NTP to implement an EWS to monitor the pipeline for anti-TB medicines. During the quarter, two EWS reports were generated; one at the end of January 2015 and at the end of March 2015, and the findings were discussed. Reports were used for immediate procurement of retreatment medicines, which were running low while seeking to donate excess medicines to prevent expiry.

SIAPS conducted a rapid assessment of PSM systems. Areas that need immediate strengthening included capacity building for quantification and inventory management, LMIS system, tools, and SOPs for drug management at the facilities. Recommendations and a plan for interventions were developed jointly with other partners, mainly UNDP and Challenge TB program, with SIAPS providing direct support in drafting the PSM plan.

SIAPS provided technical support to the NTP in New Funding Model (NFM) 2015–2017 for Global Fund grant-making process. SIAPS conducted quantification of the program needs for first-line medicines for the three-year period in line with approved concept note. Quantification of initial requirements of second-line medicines was also conducted. The country awaits Green Light Commission recommendations to start DR-TB treatment.

Together with GDF consultant, SIAPS conducted a monitoring mission in March 2015 to estimate drug needs for the next year to insure that the country has an uninterrupted supply of TB drugs.

### *Next Steps*

SIAPS will work to:

- Build capacity of national level staff for forecasting, quantification, and application of EWS and continue to support generating quarterly EWS reports .
- Design and support implementation of facility data collection tool and SOPs.
- Support NTP to implement a simple LMIS at the central level that enhances collation of quarterly TB medicines reports submitted from facilities.



## **Zambia**

SIAPS has continued to support the NTP to implement an EWS to monitor the pipeline for anti-TB medicines. During the quarter, two EWS reports were generated; one at the end of January 2015 and at the end of March 2015. Results were discussed with NTP teams and actions that need to be taken were jointly agreed upon.

SIAPS also assisted the NTP to prepare for the Global TB conference meeting. The team developed an action plan based on their priority area of challenge. Zambia identified private-public mix (PPM) as one of their priorities. SIAPS will support Zambia to implement the plans as needed.

### *Constraints to Progress*

There were delays in initiating procurement process due to various reasons despite stock-outs alerts generated by QuanTB. For example, Zambia was advised to start procurement process in July 2014, especially for pyrazinamide, but the process has been delayed due to insufficient funding.

## **Zimbabwe**

In Zimbabwe, the NTP person trained to use and update QuanTB data has left. Currently, there is no one on the NTP team that can use QuanTB. As Zimbabwe has requested training for new staff, SAIPS is in the process of finalizing dates for this training with the country team. Zimbabwe also participated in the Global TB Conference. During this time, the three-person delegate that included the NTP manager came up with challenges they are facing in their pharmaceutical system and developed an action plan to address them.

### *Next Steps*

SIAPS will:

- Conduct training on QuanTB in Zimbabwe by next quarter
- Continue to provide technical support to generate quarterly EWS reports

## REGIONAL PROGRAMS

### LAC AMI

**Goal: The key malaria control strategy is for AMI countries to institutionalize national and regional mechanisms to assure a continuous supply of antimalarials, particularly in low-incidence areas.**

Ten countries reported stock levels for antimalarials this quarter. That is the highest participation rate since second quarter of 2013. The bulletin seems to have been integrated into eight countries quarterly reporting, since these countries have reported continuously for the past five quarters. The availability of antimalarials decreased in the last quarter compared to the previous quarter. This is partly due to Guatemala reporting data for the first time since fourth quarter 2012: they had many stock-outs, which affected the overall availability

#### ***Objective 1. Pharmaceutical sector governance strengthened***

Nine estates in Brazil are implementing strategies to close the gaps for an adequate implementation of the malaria control strategies. A workshop to monitor the progress was carried out last quarter. During this quarter, SIAPS finalized the technical report and distribute it among counterparts and partners. SIAPS has proposed a similar intervention in Colombian departamentos with high malaria incidence, but the technical assistance plan has not been endorsed by national counterparts. For the next quarter, SIAPS will discuss alternative strategies with local counterparts in Colombia for implementing this activity. A follow on monitoring exercise in Brazil is scheduled for February 2016.

#### *Constraints to progress*

National counterparts in Colombia have been dealing with other technical and administrative priorities. For this reason, the implementation of an evaluation of malaria control strategies has been delayed.

#### ***Objective 2. Pharmaceutical Management Information Available and Used for Decision Making at Different Levels of the Health System***

The technical report on the situation of malaria pharmaceutical management and the impact of AMI supported interventions in seven AMI countries was finalized. During this quarter, SIAPS processed and analyzed the consolidated data. The results were presented at the AMI Annual Technical Meeting (Rio de Janeiro, March 24–26). For the next quarter, SIAPS will review and start the editing of the technical report and disseminate hard copies and electronic versions to all AMI partners and counterparts.

Through its local consultants, SIAPS supported the compilation of information and analysis for the Quarterly Bulletin on Availability and Consumption of Antimalarials, disseminated by Pan American Health Organization (PAHO) on February 2015. Ten countries shared information.

The availability of antimalarials in central warehouses has slightly decreased (from 86% last quarter to 79%), due to the stock-out of a few antimalarials presentations in some countries. For the next quarter, SIAPS consultants will continue supporting this activity.

In Colombia, major inaccuracies in the estimation of needs and distribution are a consequence of a poorly estimated percentage of non-registered malaria cases. Along with national counterparts, SIAPS developed the first draft of a research protocol to estimate the percentage of malaria cases that are not registered in high burden departamentos. For the next quarter, the protocol will be finalized. SIAPS will then discuss with national counterparts and other agencies alternatives for the financing of the study.

### *Constraints to progress*

National counterparts in Colombia have been dealing with other technical and administrative priorities. For this reason, the implementation finalization of the research protocol and data collection has been delayed.

### **Objective 3. Pharmaceutical Services Improved to Achieve Desired Health Outcomes**

SIAPS participated in a meeting organized in Iquitos, Loreto, Peru (March 2–5) to analyze the conditions and factors leading to the recent increase in malaria incidence in Loreto, and agree on alternative strategies to confront the epidemic. Based on these agreements, SIAPS will support plans for the introduction of artemisinin-based fixed dose combinations, and rapid diagnostic tests starting next quarter.

SIAPS consultants visited the Loreto medical store. With the technical assistance of SIAPS, this facility was certified in good storage practices (only the second one in Peru to obtain this certification). For the next and following quarters, SIAPS will continue providing limited technical assistance to keep the certification valid.

SIAPS continued working with local counterparts in Pará and Roraima (Brazil) in the systematization of interventions to improve access to malaria diagnosis and treatment in gold mining areas. For next quarter, SIAPS will finalize the technical report on the systematization of these interventions, and will start monitoring the implementation progress and preliminary results, based on a monitoring plan to be completed by April 2015.

SIAPS participated in the Technical Review Panel for Global Fund Malaria Concept Notes at the PAHO office in Washington, DC, March 17–19.

### *Constraints to progress*

The introduction of guidelines to support malaria pharmaceutical management in primary health facilities and monitor the availability of antimalarials used by primary health volunteers has been delayed due to conflicting agendas of national counterparts.

## **West Africa**

**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 and Central Africa countries.**

### ***Overall Quarter Progress***

SIAPS provided technical support to each of the five focus countries to enter data into the HIV and AIDS HIV and AIDS Commodity Tracking Tool regional dashboard in West and Central Africa (OSPSIDA.org). Despite challenges still faced in Niger and Burkina to keep the tool up to date, progress has been made in Togo, Benin, and Cameroon to make the tool more useful as early warning system (EWS).

To ensure the sustainability of the regional dashboard and its replication in other Economic Community of West African States (ECOWAS) countries, SIAPS initiated strategic discussion with West African Health Organization (WAHO) to transition and hand over the tool to them by end of September 2015. The regional Project Director and the senior regional technical advisor from SIAPS regional team based in Accra, Ghana, traveled to Bobodioulasso/Burkina Faso on February 2015 to meet with WAHO key staff to prepare transition and handover of OSPSIDA.org to WAHO. A Joint EWS Project Management Team (WAHO and SIAPS) has been set up and the roles and responsibilities of each team member have been defined. An action plan with steps to follow until the end of transition and roll-out in rest of ECOWAS countries has been drafted and budgeted for discussing with USAID/West Africa in the new proposal of SIAPS's last year (FY16).

SIAPS, in conjunction with the National AIDS Control Program (PNLS) of Togo visited four of the five ART sites where EDT software is currently being piloted to identify successes and issues faced by dispensers when using the tool. Then SIAPS met with PNLS and all the dispensers from the five ART piloting sites and EDT trainers to fix most of problems raised by the dispensers and trainers. A supervision check list has been developed and orientation has been provided by SIAPS to PNLS IT expert on proper use of this tool for upcoming supervisions and to be able to generate feedback to SIAPS on data quality.

A stock-out situation and risk of stock-out for many antiretrovirals (ARVs) in Togo threatens treatment of more than 95% of antiretroviral therapy patients as estimated by OSPSIDA. SIAPS worked closely with the country's HIV and AIDS program to reassess the stock status, review the current pipeline, and identify corrective actions needed to prevent stock-out of ARVs that are at high risk. SIAPS also discussed with Togo about using PEPFAR's Early Commodity Funding (ECF) to procure few ARVs that were needed urgently in country. Then SIAPS supported Togo's HIV Program (PNLS) and the Central Medical Stores (CAMEG) to complete all paperwork needed to apply for ARVs through from ECF and PEPFAR through USAID/West Africa.

SIAPS attended USAID Regional Health Office partners meeting held in Accra on February 18–20, 2015, where SIAPS presented its HIV and AIDS regional dashboard. The presentation was made during a session focused on commodity security co-hosted by SIAPS and DELIVER.

SIAPS attended the Joint UN Regional Team on AIDS (JURTA) annual retreat organized by UNAIDS Regional Support Team for West and Central Africa in Dakar, Senegal, on March 18–20, 2015. SIAPS has officially integrated JURTA Procurement and Supply Management and Treatment Technical Working Group (TWG) as team coordinator under the leadership of WHO, the chair of this TWG.

SIAPS attended ECOWAS’s stakeholders consultation meeting at the launching of the West African Medicines Registration Harmonization Steering Committee and African Union Model Law on Regulation of Medical Products and Harmonization for West Africa, on February 2-5, 2015, in Accra, Ghana.

SIAPS is currently preparing its upcoming regional stakeholders meeting to review the progress of deployment of the HIV and AIDS regional dashboard by discussing with participants about successes, challenges, and the way forward.

***Objective 1. Increase the Use of Pharmaceutical Management Information for Decision Making at National and Regional Levels***

SIAPS provided technical support to each of the five focus country to enter data into the HIV regional dashboard. Despite challenges still faced in Niger and Burkina to keep the tool up to date, progresses have been made in Togo, Benin, and Cameroon have made progress in making to make the tool more useful as an EWS.

As of March 31, 2014, Togo has entered and published data from January 2014 to February 2015 on 100% of patients and commodities. In Benin, the Global Fund supported the recruitment of data clerks to enter data into the dashboard tool as well provided funds to train central and regional/district data users to enter data and generate reports.

In Cameroon, SIAPS country program supported the National AIDS Control Program to enter health facilities and medical stores data from January to November 2014 and started entered health facility data from December 2014 to February 2015.

In conjunction with the National AIDS Control Program (PNLS) of Togo, SIAPS visited four of the five ART sites where a current pilot of EDT software is taking place to identify successes and issues faced by dispensers when using the tool. Then SIAPS held a meeting with all dispensers coming from the five ART piloting sites and electronic dispensing tool (EDT) trainers to fix most of issues raised concerning dispensers and trainers. We added new regimens that were not part of the previous setting of EDT and also reviewed list of products linked to each regimen and deleted and added products. The IT expert of the PNLS has also been trained on use of check list that has been developed to supervise EDT users. The supervision check list has been tested in two pilot sites (AMC and Hospital of Be).

SIAPS provided refresh training for the dispenser at the nongovernmental organization Espoir Vie Togo, Lome. Previous stock movements in EDT have been cleared and the dispenser has been asked to receive all products in his store. This has been done successfully. The dispenser then officially started using EDT as dispensing tool the same day.

### *Partner Contributions*

- The Global Fund made a second contribution to allow the Benin HIV Program to keep the tool up to date and make it as EWS.
- The HIV programs in Togo, Benin and Cameroon have also made significant contribution to keep the tracking tool up to date in these countries.
- The commitment of Togo's PNLs and the five ART sites where EDT is deployed contributed to effective use of EDT as dispensing tool for the HIV and AIDS program in Togo.

### *Constraints to Progress*

Niger's reporting rate is very low so it still faces challenges to update the tool. Patients and commodities data are not transmitted by ART sites to the central level to allow OSPSIDA country operators and managers to enter and validate data into the tool.

In Burkina Faso, patients and commodity data collected from ART sites are available at National AIDS Control Program, but the HIV program is suffering of lack of time to dedicate to data entry into the tool.

Regarding EDT piloting in Togo, despite problems with computer bugs, dispensers can still use EDT for their daily dispensing activity. The problem may come from computers where EDT software has been installed since they are too old. We did not face any issue using MSH computers to run database collected from the pilot sites.

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

SIAPS travelled to Bobodioulasso/Burkina Faso to meet with WAHO key staff to prepare transition and handover of OSPSIDA.org to WAHO.

SIAPS met with key people from the West Africa Essential and Vaccines Programme, HIV and AIDS Programme, Information and Communication Technology and Health Information Systems.

In close collaboration with above persons, a Joint EWS Project Management Team (WAHO and SIAPS) has been set. Then the joint team named a Chairman (WAHO), Team Coordinator (WAHO), and EWS administrator (WAHO) and also defined roles and responsibilities of each joint team member. An action plan with steps to follow until the end of transition and roll-out in rest of ECOWAS countries has been drafted and budgeted for discussing with USAID/West Africa for the new proposal of SIAPS last year (FY16).

SIAPS has set aside meeting with WAHO Professional Officer in Charge of Essentials Medicines and vaccines Program leading this process to identify priority activities that SIAPS can urgently focus on and which can guide discussion with USAID/West Africa while SIAPS is preparing its proposed budget for FY16.

***Objective 3: Enhance Access to Financial Resources for the Procurement of ARVs to Prevent Stock-Outs in Selected Countries***

Then SIAPS supported the HIV Program (PNLS) and The Central Medical Stores (CAMEG) of Togo to complete all paper works needed to apply for ECF and PEPFAR through USAID/West Africa has made a donation of requested ARVs to Togo.

***Partner Contributions***

SCMS has helped speed up the process of getting approval from USAID regarding the donation, procurement, and delivery required products to Togo HIV and AIDS Program.

The HIV Program (PNLS) and Central Medical Stores (CAMEG) of Togo contributed to success of using ECF as emergency mechanism to get products in country as quickly as possible to face the stock-out situation.

## 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 implement the planned activities toward achieving the project's objectives. SIAPS assisted the National Directorate for Medicines and Equipment (DNME), the national medicines regulatory authority, to validate and submit the national essential medicines list (NEML) after its review by the long-awaited national medicines technical commission appointed by the minister of health in January 2015. SIAPS continued to support DNME to promote the newly developed NEML by organizing two meetings, one with all the pharmaceutical companies and the other with all the pharmacists.

After a request from DNME and given the current oil price crisis, SIAPS was requested to provide its technical assistance to define strategies to respond to this crisis in the area of pharmaceutical policies and supply chain. One of the priorities was to assist DNME develop a national pharmaceutical pricing policy. An internal consultant to develop this policy was identified and preliminary desktop review started.

During this quarter, the US ambassador conducted a study tour in Huambo to see the impact of the USG's investments in this province. The ambassador visited the provincial warehouse at Huambo where she saw Good Storage Practices for medicines in action, how the entire circuit of medicines and other medical supplies are organized from the central level (mainly the national warehouse CECOMA) down to the health-facility level, and the role that the provincial warehouse plays in collecting and managing logistics information, estimating province needs, and filling the requisitions from municipalities and health facilities. During the visit, the provincial warehouse staff expressed their satisfaction with the recent improvements after SIAPS's interventions in areas such as the use of pharmaceutical management tools, the use of consumption data in requisitions (instead of data on passive distribution), and the programming of requisitions.

The ambassador was also able to see the tools used in HIV and AIDS and malaria commodities that MOH developed and disseminated with SIAPS assistance; the DPS technical staff also explained to the ambassador how information flows and is used to prepare monthly reports and requisitions.

The staff expressed their desire for more training at the health-facility level and to keep supervision support ongoing to supplement trainings.

The program facilitated the reception of PMI-funded malaria products and followed up their distribution to the provincial warehouses in collaboration with USAID | Deliver. End user



verification (EUV) and PPMRms were submitted and shared with the PMI team locally and globally. SIAPS also continued its technical assistance to support CECOMA to regularly measure selected key performance indicators (KPIs) and to organize technical meetings to address the identified bottlenecks in CECOMA operations.

Finally the program continued to conduct a physical inventory of family planning products under the coordination of the National Reproductive Health Program and in collaboration with UNFPA and Pathfinder.

### ***Objective 1: Pharmaceutical supply chain system governance strengthened***

In the reported period, SIAPS continued to support DNME to organize coordination meetings to promote the NEML. One meeting of the National Medicines Technical Commission was organized to review the NEML before it was submitted to a broader audience in a validation workshop. Under the coordination of DNME, two more meetings were organized to promote this NEML, namely a meeting with all the pharmaceutical importers, distributors, and community pharmacy representatives and another meeting with all pharmacists. In this quarter, the report of the mid-term review of the Pharmaceutical Strategic Plan was submitted to DNME for final inputs and incorporated by the consultant. The DNME work plan for 2015 was submitted to the higher level of the MOH for implementation.

In this quarter, SIAPS continued its advocacy to get buy in of principal stakeholders in the development of the national supply chain strategy. SIAPS will continue to follow up with DNME to assume full leadership and ownership throughout the entire process of this strategy. The DNME work plan was elaborated with the assistance of the SIAPS consultant and the translated document was submitted to MOH together with the budget.

Under coordination with DNME, a scope of work was developed to assist the MOH/DNME to build the capacity of the Medicine Registration Unit as a part of SIAPS technical assistance to improve the DNME's regulatory functions. An internal consultant was identified to work with DNME to strengthen their capacity to establish the medicine registration system with an emphasis on addressing the critical requirements, including an appropriate, functional, and operational structure; skilled staff to do the work; and appropriate policies, procedures, and tools. After a thorough desktop review, the consultant will provide on-the-job practical skills training on the roles and responsibilities related to medicines registration and other related functions to the Medicine Registration Unit, and will facilitate revision of the annual operational plan.

In response to the current financial crisis created by falling oil prices, SIAPS facilitated DNME and CECOMA to develop strategies for the MOH to improve efficiency in medicines procurement and the supply chain system. These strategies have been incorporated into the overall responsibilities of the MOH. Following this financial crisis and in reference to findings suggesting that Angola's pharmaceutical prices are among the highest in the southern African region, the MOH instructed DNME to develop a national pharmaceutical pricing policy to reduce this negative trend and increase access to pharmaceutical products. DNME requested SIAPS to provide technical assistance to develop this policy; the preliminary desktop review is underway

to develop a brief policy that will guide the development of the national pharmaceutical policy, the first of its kind in Angola.

#### *Partner contributions*

- MOH/DNME overall coordination
- CECOMA collaboration in the development of strategies to improve efficiency in procurement and supply chain management
- UNDP/Global Fund for logistics support in the promotion of the NEML

#### *Constraints to progress*

The main challenge was the changes in priorities of MOH due to falling oil prices; DNME therefore requested that this urgent matter be addressed with respect to the development of the national pharmaceutical pricing policy. This has slowed down the development of the national supply chain strategy. The ICC/R's logistics, procurement, and operations sub-committee meetings were also postponed to finalize and promote the NEML.

#### ***Objective 2: Local capacity for pharmaceutical management enhanced***

In this quarter, SIAPS Angola initiated the adaptation and translation of the training material in pharmaceutical management of HIV and AIDS commodities and the development of the national guidance in managing HIV and AIDS health commodities. The program will then organize capacity-building sessions to select health facilities in HIV and AIDS pharmaceutical management. SIAPS participated in different meetings organized by PEPFAR Angola to design the new integrated model that will increase PEPFAR interventions at the site level to ensure a continuum of care for people living with HIV. SIAPS was requested to develop interventions that will ensure commodity security of antiretroviral (ARV) medicines and other HIV-related products, promote Good Dispensing Practices in the pharmacies of HIV and AIDS clinics, and improve patient adherence to treatment.

The program has selected CECOMA's deputy director and warehouse manager to participate in a three-day practical training session at the Imperial Health Sciences (IHS) warehouse in Centurion, Pretoria, South Africa, that uses world-class distribution and management practices. The participants were guided through each department of the warehouse and received executive training in warehouse management, human resource management, quality assurance, distribution, safety, and warehouse management information systems. The CECOMA staff were highly appreciative of what they learned and are committed to implement what they have learned back home.

SIAPS also provided its technical assistance to develop CECOMA's 2015 annual work plan and budget, using a participatory approach involving all the heads of departments in CECOMA. The work plan was submitted to MOH for approval and SIAPS will continue to support implementation of this plan. SIAPS continued to provide technical assistance to CECOMA management to collect daily data that allow the monitoring of KPIs and to organize weekly KPI review meetings at CECOMA to address the identified bottlenecks. Using these KPIs, SIAPS

worked with the deputy director of CECOMA to prepare a presentation to summarize the last six months of findings to the senior management; the meeting recommended improvements in operations.

### *Partner contributions*

- CECOMA coordination in monitoring and improving KPIs
- CECOMA provided staff to participate in the South Africa study tour and warehouse management executive training; MOH provided the authorization needed

### *Constraints to progress*

Documents for HIV and AIDS training are not available in Portuguese. Documents will have to be translated either from French or English. The new directive from PEPFAR is to increase direct technical assistance to health facilities that require changes in the implementation of the SIAPS work plan, especially in the area of capacity building. SIAPS is suggesting to directly conduct capacity-building sessions with pharmacy staff instead of conducting indirect cascade training, starting with a national training of trainers.

### ***Objective 3: Information for pharmaceutical management decision making promoted***

One PPMRm quarterly report was elaborated and submitted to PMI Washington and to Global Fund Geneva (through the national technical coordination unit of the Global Fund).

One semi-annual EUV report was submitted. The EUV was carried out November–December 2014 and covered the provinces of Luanda, Uige, Malange, Benguela, and Huila. The team, composed of DNME, NMCP, provincial health directorates, and SIAPS visited 5 provincial warehouses, 10 municipal warehouses, and 27 health facilities. Major findings were shared with NMCP and the PMI team.

During the last EUV, most of the health facilities (except provincial warehouses) were not using any stock cards as a necessary pharmaceutical management tool to document stock transactions. The non-use of standard tools for pharmaceutical management in many health facilities is becoming generalized and very worrying. Some of the observed reasons are lack of enforcement of the use of stock cards at facility and municipal levels and lack of motivation of staff managing these medicines to register stock movements in the current push system, with a passive role in requisitions by facilities. In other instances, only one person is working in the facility warehouse, suggesting that there is no time for filling stock cards. Without proper documentation of stock movements, products are at a high risk of mismanagement and pilferage. SIAPS will continue to advocate to the DNME and to CECOMA for effective reinforcement of the compulsory use of pharmaceutical management tools, in coordination with municipal and health-facility leadership. Although all provincial warehouses received hygro-thermometers through the Global Fund quality assurance program, the storage conditions in most facilities are poor, exposing pharmaceutical products to deterioration, resulting in a lack of effectiveness and/or increased risk

of toxicity. SIAPS will continue to advocate for the monitoring and improvement of storage facilities to ensure that the quality of medicines throughout the supply chain is maintained.

In a response to a request from CECOMA to advise them in acquiring a suitable warehouse management system (WMS) that will build on what SIAPS has already implemented in CECOMA, SIAPS started to develop a guidance document for identifying, selecting, and implementing a WMS. Specifically, this guiding document defines goals, objectives, scope, and scale of the WMS, its features, functions, and requirements, and provides a roadmap outlining preparatory and implementation steps (such as requirements, selection process, vendor evaluation, implementation, support, and post-implementation review). The document is being discussed with CECOMA management for their inputs; MOH is also examining the document and will decide which WMS to implement in.

#### Partner contributions

- CECOMA coordination in developing its annual work plan.
- DNME and NMCP coordination role in EUV
- Provincial warehouse managers and malaria supervisors in PPMRm

#### Constraints to progress

- Review of the government budget that will affect implementation of work plans
- Difficulty in collecting data from NMCP and provinces due to withdrawal of Global Fund support to pay some (malaria) staff at the provincial level
- Non-use of pharmaceutical management tools at the health-facility level jeopardizes stock movement records
- A generalized weak logistics management information system across all health commodities that results in a weak supply chain and risk of stock-outs on one hand and wastages due to expired products on the other

#### ***Objective 4: Pharmaceutical service to achieve desired health outcomes improved***

Availability of HIV and AIDS commodities, such as medications for prevention and management of opportunistic infections, ARVs, and necessary diagnostic testing supplies, are essential to ensure the continuum of care. Regular forecasting and supply planning for these commodities are necessary to avoid stock-outs and/or wastages due to overstocking and expiration to ensure that people living with HIV are maintained on treatment.

SIAPS continued to provide its technical assistance support to regularly conduct national stock-level analysis of HIV and AIDS commodities. Findings were discussed with INLS (Instituto Nacional Luta contra a SIDA) logistics team to define recommendations for commodity security improvements. As a result of this analysis, an emergency order was placed to speed up the availability of selected products at risk of stock-out, and facilities were advised to use ARV products already in stock to avoid wastage. For pediatrics, healthcare workers were instructed to use fixed-dose combinations of ARVs in tablets instead of individual oral solutions per WHO

recommendations. For adults, large quantities of a once-daily fixed-dose combination of tenofovir/emtricitabine/efavirenz were available, so all new adult patients were put on this treatment to avoid the medicines expiring if not used.

The program collaborated with UNFPA and Pathfinder to conduct inventory of all family planning products at CECOMA, in coordination with the National Reproductive Health Program. SIAPS also continued to monitor the availability of antimalarial medicines in all 18 provincial warehouses and at CECOMA. Following this monitoring, SIAPS advised the distribution of last year's stock of Global Fund rapid tests kits that were still kept at an outsourced warehouse (Neofarma). Unfortunately, NMCP decided to use the morbidity model to determine quantities for each province, which has resulted in some provinces being overstocked with rapid test kits, exposing them to mismanagement or wastages.

During this quarter, meetings were carried out with INLS management to discuss the new interventions of SIAPS at the health-facility level in the overall contribution of PEPFAR for an AIDS-free generation. Currently, all PEPFAR implementing partners including SIAPS will focus their technical assistance directly to selected health facilities in Luanda and Cunene, reducing support at upper levels to maximize impact throughout the continuum of care.

SIAPS participated in the COP16 exercise with other implementing partners to define the new targets using data collected from INLS and health facilities and simulations where there was no data and to select the first 10 health facilities where this new integrated model will start. The defined targets were entered into the DATIM reporting system.

#### Partner contributions

- INLS coordination in stock monitoring of HIV and AIDS commodities
- National Reproductive Health Program coordination role in family planning inventory
- CECOMA, UNFPA, and Pathfinder collaboration role in family planning commodities inventory
- NMCP and provincial warehouse managers and supervisors in monitoring antimalarial products at provincial level

#### Constraints to progress

The main challenge in this quarter was lack of reliable data to define the targets in the new integrated model of PEPFAR to be implemented at selected health facilities.

## **Bangladesh**

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

### ***Overall Quarter Progress***

SIAPS strides one step forward to strengthen the Procurement and Logistics Management Cell (PLMC) as the overarching body in the Ministry of Health and Family Welfare (MOHFW). With SIAPS facilitation, the PLMC stopped a costly procurement of the long-acting contraceptive Implanon to avoid overstocking. The Directorate General of Family Planning (DGFP) had planned to order 400,000 pieces/sets of Implanon in FY 2015. However, on the basis of the SIAPS quantification exercise and the World Bank (WB), who also had the same information, the PLMC stopped the excessive procurement and revised the order to 80,000 pieces/sets, thereby avoiding a serious overstock situation.

As part of strengthening the procurement management system, SIAPS worked with key stakeholders to develop tables of equipment (TOEs) for primary and secondary tiers of hospitals. SIAPS facilitated technical sessions with relevant MOHFW officials and clinicians to develop the same TOE for tertiary-level hospitals with 500 or more beds. .

To ensure the efficient use and maintenance of medical equipment, SIAPS collaborated with MOHFW, WB, Central Medical Stores Depot (CMSD), the National Electro Medical Equipment Maintenance Workshop (NEMEW), and 23 district-level decision makers to enhance the equipment tracking module that is part of the Supply Chain Management Portal (SCMP). SIAPS started piloting the equipment tracking module in Moulvibazar district to demonstrate its functionality.

Several initiatives by SIAPS to strengthen the recording and reporting system at the Directorate DGFP gained momentum this quarter. DGFP inventory management tools have been upgraded with new features, especially the service delivery point (SDP) module in the Upazila Inventory Management System (UIMS). The capacity building of the champions (master trainers), including joint monitoring visits, resulted in direct uploading of logistics data through UIMS to the web-based DGFP/LMIS, which increased to 98% in February 2015. Further analysis showed significant reduction (1.63% in February 2014 to 0.53% in February 2015) in stock-out rates for contraceptives at the SDP level in 20 piloted sites.

As part of the sustainability plan, SIAPS built capacity for the National Tuberculosis Program (NTP), other TB partners, and WHO officials on quantification (forecasting and supply planning) of TB drugs by using QuanTB. SIAPS also facilitated the Procurement and Supply Management (PSM) Working Group meeting to improve the functionality of e-TB Manager. SIAPS facilitated trainings for the NTP and partner NGO officials to improve the e-TB Manager data management system.

SIAPS' continuous advocacy efforts to build institutional linkages and partnerships with national and international agencies have resulted in additional technical support for the MOHFW. WB

doubled its fund (BDT 20–50 million for FY 2015–2016) for the Directorate General of Drug Administration (DGDA) as part of regular pooled fund support through Reimbursable Project Aid, whereas the Korea International Cooperation Agency and WHO agreed to build capacity of DGDA officials on regulatory affairs. SIAPS also assisted DGDA to find an appropriate training center and design the training program to strengthen their overall regulatory functions. SIAPS continued providing assistance to implement Good Manufacturing Practice guidelines and a pharmacovigilance program to ensure quality standards for drug registration by DGDA and further maintain the quality of drugs and their rational use.

SIAPS made good progress in this quarter to contribute to the Ending Preventable Child and Maternal Deaths (EPCMD). After the cost sharing agreement with Khulna Shishu Hospital (KSH) in the last quarter, SIAPS obtained USAID Washington approval for installation of oxygen systems at KSH.

As part of support for MOHFW officials, SIAPS implemented a number of capacity-building initiatives in logistics reporting, TB patient case management, pharmaceutical regulatory functions, etc. In addition, SIAPS supported the Engineering Staff College, Bangladesh (ESCB), to provide basic training on procurement and logistics management for Government of Bangladesh officials.

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

The PLMC quarterly meeting in January expedited the process of creating permanent positions for the PLMC. In addition, the PLMC proposed that three employees be responsible for smooth functioning of the SCMP. The proposal is awaiting approval from the competent authority.

SIAPS and experts from the NEMEW under the MOHFW updated the specifications for core medical equipment for hospitals with up to 250 beds. After several consultative group discussions with potential bidders, SIAPS facilitated the specification finalization workshop on March 7-9 with nearly 23 participants from the MOHFW, Directorate General of Health Services (DGHS), Central Medical Stores Depot (CMSD), NEMEW, and clinicians from district and medical college hospitals.

Key decisions made in the workshop:

- SIAPS would include the updated specifications in the TOE for 10-, 20-, 50-, and 250-bed hospitals and will make the document available for all levels of health facilities, policy makers, and procuring entities wherever needed throughout MOHFW.
- This document will serve as a guide for planners, policy makers, and health managers for planning and acquisition of medical equipment in health facilities.

For procurement efficiency in CMSD/DGHS, SIAPS facilitated two workshops on standardizing bidding documents for different categories of items with procurement officials from CMSD and WB. The participants agreed on necessary customization of relevant sections and contents of a

bidding document for pharmaceuticals and goods, i.e., bid data sheet and particular conditions of contract.

SIAPS facilitated the Fourth Supply Chain Coordination Forum meeting for CMSD held in January 26, 2015. Some key decisions of the meeting were that:

- All line directors need to submit their procurement plans for the next year on time (by July).
- Because of the unavailability of funds, the Framework Agreement (FWA) for selected items would not be implemented. The WB and DFID requested that CMSD select another item for FWA during the current fiscal year.

### *Constraints to progress*

- Presence of participants, especially clinicians/experts/hospital managers in TOE development technical sessions and workshops was limited because they are busy with their work at the hospitals and private practices. Implementation of the TOEs will require strong policy guidelines for infrastructure development and HR deployment at the health facilities. SIAPS team plans to have technical sessions for a short period followed by a finalization workshop to actively engage key stakeholders.
- Due to political unrest, adequate field visits by field-based technical advisors could not be done and many events had to be rescheduled.

### *Partner contributions*

- The CMSD director allocated one more room at CMSD for SIAPS technical advisors to use as their work station.
- TB partners, e.g., WHO, BRAC, DF, HEED, LEPR, and district health authorities along with divisional TB experts played the key role in conducting training on e-TB Manager and the TB drug reporting system for NTP and NGO staff.

### ***Objective 2: Systems for evidence based decision making established***

Analysis of the DGFP's Supply Chain Information Portal (SCIP) data showed that 79.5% ( $n = 488$ ) of sites maintained high data-quality standards (timeliness, completeness, and accuracy) in the UIMS in February 2015 (which is lower compared to November 2014 [92%]) due to a country-wide road blockade and political unrest.

SIAPS facilitated quantification training for NTP and WHO staff using QuanTB for first- and second-line drugs. SIAPS also recommended that NTP take necessary actions to avert the potential stock-out alerts (red flagged) for a couple of second-line drugs (the Global Drug Facility also raised this issue).

SIAPS facilitated a consultative session on the readiness assessment of the SCMP; the SIAPS local consultant shared the SCMP sustainability (policy and advocacy) plan. The proposed timeline for handing over the SCMP was agreed.



SIAPS facilitated the PSM Working Group meeting at NTP to discuss TB drugs and supply chain issues, especially the physical inventory of TB drugs. SIAPS was a member of NTP's committee for physical inventory. With SIAPS assistance, a technical working group formed in the last quarter developed the recording and reporting formats for e-TB Manger sites at all DR-TB treatment facilities.

SIAPS finalized the SOW to support MOHFW for a comprehensive exercise to map out all existing and agreed IT initiatives and provide strategic guidance and specific recommendations to strengthen the National Health Information System.

After several consultative sessions internally and with the director of MIS at DGHS, SIAPS came to a consensus that DHIS-2 would be used as a platform for the DGHS eLMIS and that beta testing would be done at Gazipur district using the "proof of concept on eLMIS" for scaling up in 10 districts. A working group was formed, with specific TORs issued by the line director, MIS, DGHS for designing the eLMIS module in the DHIS-2 platform. A joint action plan was developed for the eLMIS.

Upon request from MOHFW, SIAPS facilitated a field visit for the Cambodian NTP leadership team and chief of party of the international NGO Future Group to observe the feasibility and functionality of electronic recording and reporting, i.e., use of e-TB Manager in Bangladesh, aiming to adopt it for the Cambodian TB program. The visiting team observed satisfactory onsite performance, data flow, validation, and monitoring and expressed their future plan to adopt e-TB Manager.

Based on the request of USAID, the SIAPS team worked with the Bangladesh Country Coordination Mechanism to develop its website. SIAPS also filled the Global Contraceptive Security indicator survey with recent information and submitted it to USAID for further action.

SIAPS submitted following abstracts, which were accepted for presentation at the 2015 international UHC conference:

- Data-Driven Supply Planning and Decision Making Leads to Cost-Savings and Greater Access to Contraceptives at Service Delivery Points
- Use of a Web-Enabled Logistics Information System that Visualizes Data from Reproductive Health Service Delivery Points in Bangladesh: Initial Experience and Opportunities for Improved Decision-Making

#### *Constraints to progress*

- Political blockade/unrest severely impacted the performance of UIMS and e-TB Manager
- The concept and modalities for an eLMIS had to be altered to use the DHIS-2 platform; the USAID local Mission was also involved and agreed with revised proposal

### *Partner contributions*

- All TB partners including NTP and WHO were actively engaged for providing technical inputs to strengthen the functionality of information management tools.
- The MIS-DGHS department worked with SIAPS to prepare the TORs for the working group designing the eLMIS module in the DHIS-2 platform and customizing the medicine reporting forms.

### **Objective 3: Pharmaceutical regulatory systems strengthened**

To create an environment for early engagement in DGDA's effort to adopt a stringent medicine registration process, SIAPS facilitated a workshop to sensitize 40 pharmaceutical industry stakeholders, representatives of USAID, and the Bangladesh Association of Pharmaceutical Industries. The participants confirmed implementation of the online registration form and requested that it be phased out, beginning with certain therapeutic classes of drug, and that a grace period should be instituted so that industries can be better prepared to use the online registration process. The next steps are to provide a hands-on testing of the updated Pharmadex, provide detailed training on CTDs, and establish master trainers within the pharmaceutical stakeholders.

So far, 270 ADR reports from 30 hospitals and pharmaceutical companies have been submitted to the DGDA and reviewed by the ADRM Cell. SIAPS facilitated a workshop for the focal points of selected hospitals and pharmaceutical companies, resulting in development of a database for reporting ADRs that is tailored to the standard ADE form. This form was adopted by one of the biggest hospitals in Bangladesh, Bangabandhu Sheikh Mujib Medical University. To evaluate and analyze the ADR reports and make recommendations for actions to be taken by DGDA, SIAPS facilitated a technical session of the ADR Advisory Committee on January 14, 2015; the committee decided to establish a five-member expert sub-group within the committee. The sub-group will be responsible for reviewing all ADR reports, which will be further validated by the entire committee.

One major system to control substandard and counterfeit medicines on the market is the quality control testing of products before registration and approval by DGDA and continuous sampling and testing of medicines on the market. SIAPS has been providing assistance to DGDA to strengthen its medicine regulatory functions and the product registration process through the adoption of international technical document standards. As a part of the process, the Drug Testing Laboratory (DTL) of Bangladesh is required to perform quality control testing of pharmaceutical products and issue official results before product marketing authorization is granted by the DGDA, which is not the current procedure. In addition, DTL is responsible for testing all post-marketing samples received from DGDA drug inspectors throughout the country. SIAPS identified that DTL needs assistance with these activities, therefore upon USAID request, TORs were shared with the USAID Bangladesh Mission to strengthen DTL's capacity. The result is that the USAID Mission requested that its program, Promoting the Quality of Medicines, extend their technical expertise to DTL.

As a working group member, SIAPS provided technical inputs and revised the section on ADR monitoring and included all anti-TB drugs and regimens in the updated Bangladesh National Drug Formulary.

*Constraints to progress*

- Political unrest interrupted timely implementation of planned activities, especially major events, such as workshops and trainings

*Partner contributions*

DGDA completed needs assessment and survey forms provided by the Korea International Cooperation Agency for training on regulatory functions.

## Burundi

**Goal: Contribute to a reduction in the malaria-related morbidity and mortality in Burundi**

### **Overall Quarter Progress**

SIAPS continued to achieve results in assisting key institutions involved in reducing malaria mortality and morbidity in the areas of leadership, governance, supply chain for malaria commodities, and services. In leadership and governance, the MOH adopted two key documents, namely the integrated community case management (iCCM) implementation guide and policy guide for intermittent preventive treatment for pregnant women (IPTp) developed with SIAPS assistance. SIAPS assisted the National Malaria Control Program (*Programme National Intégré de Lutte contre le Paludisme* [PNILP]) to update the malaria strategic plan and carry out a self-evaluation of internal capacity to comply with Global Fund requirements and to finalize the concept note submitted in January 2015. The submitted proposal is the third out of three planned for the life of the project. SIAPS also assisted the PNILP to develop an implementation plan for the Global Fund grants.

SIAPS assisted the PNILP to hold a stakeholder meeting to track progress against PNILP's 2014 work plan as well as to validate the 2015 work plan. In addition, SIAPS assisted the PNILP to develop a plan to build their capacity to mobilize partners and stakeholders, as well as to lead malaria control efforts under the PNILP's upcoming new role as Global Fund Principal Recipient.

To strengthen supply chain management, the MOH adopted the harmonized LMIS manual and tools validated with SIAPS assistance. This manual allows effective management of pharmaceuticals and access to information for decision making.

SIAPS assisted CAMEBU (*Centrale d'Achat de Medicaments Essentiels du Burundi* (Central Purchasing [and warehouse] for Essential Medicines of Burundi) and PNILP in conducting the annual inventory, monitoring stock levels, reviewing and updating supply plans for malaria commodities, and sharing findings and recommendations with key partners and donors including PMI and Global Fund. The results were used to advocate to PMI and Global Fund to accelerate planned deliveries of ACTs and rapid diagnostic tests to meet an anticipated shortage in the country and to fund an additional 488,792 blister packs.

SIAPS supported the DPML in conducting training for 21 new health district and hospital pharmacy managers in pharmaceutical management and Channel software. SIAPS assisted the DPML and PNILP in conducting a training of 24 persons on the pharmacovigilance (PV) system. So far, 2,630 persons have been successfully trained in pharmaceutical management out of a targeted 3,200.

SIAPS assisted the PNILP in analyzing malaria commodity reports and requisitions from districts. All district pharmacies submitted reports and placed orders; 82% of them received relevant formal feedback.

As for malaria services, SIAPS assisted in conducting workshops to update and validate the supervision guide and checklists for malaria activities and to review the plan for introduction of clindamycin for uncomplicated malaria in 10 districts and scale-up of injectable artesunate for severe malaria in 13 districts. A key accomplishment this quarter was lobbying the GOB to purchase medicine (quinine tablets) and consumables for injectable artesunate necessary for service providers to prescribe in accordance with STGs. The MOH has endorsed the request and forwarded to the Ministry of Finance and the Cabinet for consideration.

SIAPS assisted the DPML to establish a PV system in eight selected sentinel sites. In addition to assisting the validation of guidelines and training materials and training 24 healthcare providers, SIAPS assisted in conducting a meeting to engage 48 health workers and managers in the implementation of PV activities.

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

SIAPS collaborated with the USAID-funded Leadership, Management and Governance Project (LMG) in assisting the PNILP to finalize their Global Fund concept note. SIAPS assisted in organizing a workshop to update the national malaria strategic plan 2013-2017 to comply with Global Fund requirements. The proposal for Global Fund and its annexes (modular tool, analysis of gaps, programmatic gaps, financial gap, and list of annexes) were sent to the CCM on January 24, 2015. SIAPS will continue to assist PNILP to address comments from the Global Fund.

SIAPS assisted the PNILP to conduct the RBM partners' quarterly meeting in January 2015. The meeting covered evaluation of PNILP 2014 activity implementation, validation of the PNILP work plan for 2015, and analysis of malaria trends. The PNILP work plan for 2014 has been implemented at 65%. PNILP lacked funding for 14 activities that had been planned by the Global Fund, and the concept note and mosquito net distribution campaign took much of PNILP leadership's time as these activities were national priorities. For the 2015 work plan, the meeting validated updates made to comply with Global Fund requirements for the new funding mechanism. Concerning malaria prevalence, trends slowed down in the second semester of 2014, following the LLIN campaign conducted in June 2014.

SIAPS assisted the PNILP in training 36 PNILP personnel on internal administrative, finance, and HR procedures, 39% of participants being women. The training intended to increase governance and accountability within the PNILP and build their capacity to serve as a Global Fund principal recipient.

SIAPS assisted the PNILP to identify training needs and develop a training plan for their personnel. Three areas have been targeted: (1) general training for all PNILP personnel in, for example, English and computer courses, (2) technical training tailored to improve performance of the technical staff, and (3) managerial training for key leadership staff. PNILP will share the plan with RBM partners for validation.

SIAPS collaborated with LMG to assist the PNILP in conducting a self-assessment of internal capacity as requested by the Global Fund. The assessment was based on a Global Fund capacity

assessment tool that focuses on governance, management, and monitoring and evaluation.. PNILP took advantage of the Local Fund Agent visit to the Mission to seek feedback and improve the assessment report before transmission to the Global Fund.

SIAPS provided technical assistance to PNILP to develop the plan for implementing the Global Fund grant. This plan is crucial as it is one of the conditions that must be fulfilled for the Global Fund to make a decision on the submitted concept note. SIAPS led the development of chapter 1 of the plan, which consists of a presentation of the grant including aspects such as goals and objectives, key target groups, priority modules, key activities, and key indicators.

#### Partner contributions

- PNILP co-facilitated the training of personnel on internal administrative, finance, and HR procedures

#### **Objective 2: National supply chain strengthened**

During the quarter, SIAPS assisted in preparation and submission to PMI of the PPMRm as of the end of PY4Q1.

SIAPS assisted CAMEBU to conduct the annual warehouse inventory as of December 31, 2014. SIAPS assisted the PNILP and CAMEBU to develop and share the monthly stock status reports with key stakeholders including Global Fund, UNICEF, PMI, and MSF-Belgium. This report highlights the stock levels of tracer commodities including malaria commodities at the central level, stock imbalances, and recommendations to avert supply interruption. Recommendations consisted of speeding-up PMI deliveries of (1) 731,373 blister packs for adult treatment and (2) 130,776 treatments of artesunate 100 mg + amodiaquin 270 mg for children 6-13 years of age to avoid stock-outs in the country.

SIAPS supported the DPML to finalize the terms of reference of the Commodity Security Coordination Committee that include three quantification technical committees for HIV/TB, malaria, and mother-child health commodities. The terms of reference and the appointment letter have been submitted at MOH for approval. Additionally, SIAPS assisted the DPML to conduct workshops to develop the DPML strategic plan 2015-2017 and work plan for 2015.

SIAPS supported PNILP to review quantification of ACTs, quinine, and clindamycin for uncomplicated malaria, artesunate injectable for complicated malaria, sulfadoxine-pyrimethamine (SP) for IPTp and rapid diagnostic tests for *P. falciparum* diagnosis. This quantification update helped PNILP determine adequate budgets for malaria commodities for the concept note submitted to Global Fund. SIAPS also supported PNILP to quantify required consumables for artesunate and quinine for clindamycin administration.

SIAPS supported the PNILP to conduct the first-ever coordinated quarterly meeting with key counterparts (DPML, CAMEBU, PNILP, and the current Global Fund/Principal Recipient: SEP/CNLS-Malaria) to review and update the supply plan for malaria commodities. After validating key data such as stock on hand, consumption or issues, and delivery status, these data

were captured in the Pipeline database for January–March 2015; the team reviewed and made necessary adjustments to ensure that the stock levels of all products fluctuate between the established minimum and maximum levels for the in-country supply chain. The major recommendations were to speed-up a Global Fund delivery of 203,925 infants’ treatments to avoid stock-out and identify funding for an additional 488,792 blister packs that will be required to adequately meet upcoming needs.

SIAPS supported the DPML in conducting training for 21 new health district and hospital pharmacy managers to strengthen their competence in pharmaceutical management and Channel software. Pre- and post-tests indicate that participants benefited from the training. Before the training, the average score was 65% and after training, the average score was 85%, for an increase in 20 percentage points.

SIAPS continued to assist the PNILP in analyzing malaria commodity reports and requisitions from districts. Generally, 100% of district pharmacies submitted reports and placed orders and 82% received formal feedback focused on deadlines, accuracy, completeness, min-max stock levels, and/or ordering parameters.

CAMEBU introduced a new distribution system with the support of SCMS; now health districts place their orders and receive commodities following a pre-established calendar developed by CAMEBU. SIAPS assisted PNILP in communicating with districts about the new distribution system and calendar and encouraged districts to place orders on time in order to comply with the new system and avoid stock-outs. From January to March, the trend of placing orders on time improved from 53% to 100%.

During the quarter, SIAPS assisted the Medicines Thematic Group (MTG) under the leadership of DPML to conduct a meeting to validate the harmonized LMIS manual and tools. The MOH adopted the LMIS manual and tools in January 2015.

#### *Partner contributions*

- DMPL provided facilitation expertise for several sessions of the training for new pharmacy managers in pharmaceutical management and Channel software

#### **Objective 3: Malaria services improved**

SIAPS assistance contributed to two key benchmarks: the IPTp policy implementation guide and the iCCM implementation guidelines. SIAPS assisted in conducting a workshop to update and validate the supervision guide for malaria activities. Updates concerned integrating all key malaria indicators including those that measure performance of pharmaceutical services, prescriptions in compliance with STGs, and patient and medicines safety. Seven organizations/projects participated in this process, namely, PNILP, UNICEF, PSI, IHPB, World Vision, SEP/CNLS-Malaria and SIAPS.

SIAPS assisted the PNILP to review the plan to introduce clindamycin for the second-line treatment of uncomplicated malaria cases in 10 selected districts and scale-up of artesunate for

injection for severe malaria cases in 13 selected districts. The plan includes a distribution plan for both products, a training plan for hospital health providers on malaria STG and refresher training of healthcare providers on the use of artesunate for injection, instruction note on the use of clindamycin as well as a mapping of partners that are to be mobilized to support training/refresher training of health workers on malaria STGs.

SIAPS assisted the PNILP in advocating for CAMEBU to purchase quinine tablets and consumables to be used with clindamycin and injectable artesunate to treat uncomplicated malaria (second line) and severe malaria, respectively, per the malaria STGs. The advocacy note was developed and submitted to PNILP. Based on the note, the PNILP conducted an advocacy meeting with the Directorate of Resources under the MOH and CAMEBU to advance the question to the MOH and plan for the distribution of clindamycin and artesunate for injection. A revised note has been availed to the MOH who developed a decree to accompany the note for further advocacy before the Ministry of Finance and the Cabinet.

SIAPS assisted DPML and PNILP in strengthening the ADR reporting mechanism for antimalarial drugs to ensure patient safety. SIAPS assisted the DPML with conducting the MTG meeting to validate guidelines and training materials for PV and submitted them to MOH for adoption. SIAPS assisted in conducting a sensitization meeting on the PV system for 12 heads of health districts, 12 malaria focal points, 12 health promotion technicians (HPTs), and 12 heads of health centers in health districts that shelter 8 sites implementing entomology surveillance and PV. The objective of the sensitization meeting was to raise awareness on the importance of reporting ADRs and to explain objectives and functionality of the PV system and their role in its implementation.

SIAPS assisted the DPML and PNILP in conducting two trainings in entomology surveillance and PV for 24 persons from the 8 sentinel sites. The two-day training on PV targeted the 16 health promotion technicians plus 8 heads of health centers in sentinel sites. It aimed at building the capacity of healthcare providers in the rational use of medicines and good dispensing; in promoting adherence to treatments; and in collecting, analyzing, interpreting, and reporting PV-related information so that healthcare workers can take appropriate interventions to promote patient and medicine safety. Participants completed the training, with an average increase from pre-test to post-test of 41 percentage points. The training on entomology surveillance covered 9 days and targeted 16 HPTs (2 persons per site). The goal was to equip health workers at sentinel sites with knowledge and competence in systematic collection, analysis, and interpretation of entomological data for effective interventions in malaria vector control. The average increase from pre-test score to post-test was 15 percentage points.

### *Partner contributions*

- The USAID-funded Africa Indoor Residual Spraying (AIRS) project and PNILP provided facilitation expertise and the training module for entomology surveillance training
- PNILP and DPML provided facilitation expertise for PV training



## Cameroon

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

### ***Overall Quarter Progress***

During the second quarter of its PY4, SIAPS Cameroon conducted the most critical activities at the health system peripheral level. With support from two technical advisers already deployed to regional warehouses of the North West and South West, Comite National de Lutte contre le Sida CNLS and SIAPS conducted a joint supervision visit to 104 health facilities, out of which 70 were new facilities transitioning to PMTCT Option B+. Additionally, a two-week workshop on the implementation of a dashboard that tracks availability of HIV and AIDS commodities (known as OSP-SIDA) was made available to regional staff of all 10 regions in Cameroon to deploy countrywide.

At the national level, SIAPS was highly involved in activities related to the Global Fund and provided technical support to develop documents requested by the Global Fund to extend its current HIV grant to the country. The extended grant is needed to fill the financial gap until the New Funding Model grant obtains approval and related disbursements are effective. SIAPS actively participated in the review of the concept note for HIV/TB to ensure that its content aligned with PEPFAR pharmaceutical management-related activities and that financial resources were leveraged. The finalized concept note is expected to be ready for submission to the Global Fund in May 2015.

This quarter, SIAPS started a new initiative called the Medicines Cluster, which is a task force under the Committee of Financial and Technical Partners Working in Health. . This subcommittee is composed of, among others, WHO, CDC, USAID, and the French and German Government Agencies for Development; the committee aims to coordinate efforts, share information, and agree on common strategies when dealing with interventions to improve the availability, quality, and affordability of medicines and health commodities.

This quarter, data showed an improved availability of ARVs in the supervised sites. As such, the percentage of facilities that had ARV stock-outs dropped significantly from 94% to 41.3%. This indicator-based improvement is explained by an obvious availability of ARVs at the central level. However, data showed persistent stock-outs at the health-facility level that would probably be related to management issues at health facilities or at the regional warehouse. The overall quality of storage conditions at the health-facility level seemed to be stable, with 67% of the facilities meeting Good Storage Practices; at the same time, training the staff was proceeding well with 313 people trained out of the 328 targeted for the year. The progress for the OSP-SIDA implementation was noticeable as a result of the last training; 50% of regional warehouses and 33% of the regional National AIDS Control Committee (NACC) captured data into the OSP-SIDA database. However, the indicators related to recording and reporting significantly dropped as indicated by the percentage of stock records matching physical counts that decreased from 84% to 48%. The percentage of facilities that reported logistics information also decreased from 79% to 33.7%. This is explained by the number of additional sites that SIAPS is now

supervising, where registers and reporting tools were introduced only recently during the last supervision visit. However, the indicator may be showing the need to intensify supervision in more problematic sites and to better customize supportive supervision to health facilities' needs. This strategy change can be gradually implemented through the regional advisors' support.

***Objective 1: Pharmaceutical sector governance strengthened***

During this quarter, SIAPS supported CNLS to analyze and make decisions related to the use of different budget lines for procurement and delivery of ARVs during 2015 to ensure adequate coordination. In addition, SIAPS assisted CNLS in responding to ad-hoc requests from the MOH in relation to the stock status of ARVs.

SIAPS met with Positive Generation, an NGO that produces a weekly newsletter on the availability of HIV and AIDS commodities (ARVs, diagnostics) and incidents reported by volunteers (health professionals and patients) from 74 health facilities related to inappropriate ART costs and fees. SIAPS and Positive Generation discussed how to improve HIV and AIDS commodities availability and subsequent access to ART for patients.

***Constraints to progress***

The SIAPS Cameroon team unsuccessfully attempted discussions with the Quantification Committee members and, as a result, little progress was made during this quarter to standardize reporting tools on medicines stock status. There is a need to keep this committee more functional with more tasks delegated to available members.

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

This objective includes activities to maintain some support to the Central Medical Stores (CENAME) and regional medical stores (CAPRs), especially in terms of human resources capacity building.

During this quarter, SIAPS continued providing technical support to UNFPA and partners to upgrade the LMIS. Several meetings were held to validate the road map for the upgrade and to discuss partners' contributions. SIAPS contributed to drafting the TORs for creation of a LMIS unit at the Directorate of Pharmacy.

The SIAPS team started gathering materials to prepare training on pharmaceutical management that CENAME requested. Progress to define the training scope and a tentative date was slowed by lack of CENAME responsiveness and providing their internal SOPs for storekeepers and other key information at a late date.

***Constraints to progress***

The overall progress of the LMIS activity is dependent on individual partners' contributions. The Clinton Foundation is willing to recruit a consultant that will be placed at the Directorate of

Pharmacy for nine months to follow up on the upgrade of the enterprise resource planning systems at the national and regional warehouses, if funding for this project is approved. The availability of this consultant will be key in the process, as this is a complex project that requires full-time qualified staff to follow it up. In agreement with USAID, the financial contribution of SIAPS to this activity will be held up until it is certain that a consultant will be adequately positioned to manage this activity.

### *Partner contributions*

UNFPA funded a second workshop to follow up on the implementation of the harmonized codification system for essential medicines in the country which is a prerequisite to upgrade the LMIS. Unfortunately, due to a conflict of agendas with the Global Fund concept note writing, SIAPS could not participate.

### **Objective 3: Use of information for decision making increased**

During this quarter, for the first time, SIAPS and CNLS conducted a supervision activity that targeted 104 health facilities, including 98 from 4 PEPFAR-supported regions (Central, Littoral, North West, and South West), and an additional 6 in other USAID-supported regions (Adamawa and East). These sites represent 78% of the total number of HIV patients under treatment in the country at the moment. The main objectives of the supervision were to gather baseline information on logistics capacity and ensure implementation of recording and reporting tools to monitor HIV commodities and patients. Feedback meetings in each of the supervised regions will be organized in April 2015.

The supervision exercise took more than six full weeks because of the increased number of sites, but also because of the increasing need for data in the context of scaling-up PMTCT Option B+. Data on consumption of ARVs at PMTCT clinics and consumption of HIV RTK were integrated into supervision tools for further analysis and required supervisors to oversee the maternity and laboratory services in addition to the pharmacy and ART clinics. In addition, the PMTCT Option B+ sites included for the first time in this supervision needed more time than usual for them to integrate recording and reporting tools after they were explained and demonstrated to health workers.

In addition, during the month of January, SIAPS conducted a two-week training on OSP-SIDA for all regions. Staff from the regional warehouses and from the regional NACC was trained on the dashboard through an exercise that to input data from 2014 into the system. By the end of the exercise, the available data from January to November 2014 from all ART sites were introduced into the database so that the dashboard could be updated. Through interactive exercises, participants were confronted with data quality and data availability issues. It is expected that regional advisers will ensure routine updates of the system.

### *Constraints to progress*

USAID Cameroon granted SIAPS a non-objection to the request to abandon implementation of the Electronic Dispensing Tool. This activity was included in previous work plans, but given the

number of competing priorities and the complexity of the environment where SIAPS operates in Cameroon, the activity has not been started, despite several attempts with NACC. At this point, SIAPS could not justify investing a high level of effort in this activity, with low expectations on achieving results in the remaining time of the project.

### *Partner contributions*

The Clinton Foundation partnered with SIAPS to ensure availability of ARVs at the Central Region. In December 2014, the Clinton Foundation ensured the distribution of ARVs to kick off the implementation of PMTCT Option B+. This one-time activity was misinterpreted by health facilities that expected the Clinton Foundation to keep distributing HIV and AIDS medicines to prevent stock-outs in the future. During the joint supervision with NACC and the Clinton Foundation, SIAPS clarified this misunderstanding, and every one came to the conclusion that only one additional delivery of ARVs will be needed to cover needs for the next few months.

### **Objective 4: Financial barriers reduced**

During this quarter, SIAPS worked with CNLS to conduct an HIV and AIDS commodities quantification exercise so that an extension of the Global Fund grant could be made and future stock-outs avoided. As a result, the Global Fund approved the grant extension to cover ARV needs until June 2016, while waiting for the concept note for the new funding model to be submitted in mid-May.

In addition, SIAPS was involved in ensuring that the procurement and supply management component of the concept note narrative had been adequately analyzed and integrated in the revised documents to be submitted in May. One of the key challenges that the country is facing is ensuring sufficient storage capacity for ARVs to cope with the increased need of HIV commodities to reach national targets. Alternative supply systems for PEPFAR and eventually Global Fund commodities may need to be considered. SIAPS also added a request in the concept note for the Global Fund to fund capacity-building intervention and human resources in non-PEPFAR regions. This will ensure alignment in the supply management interventions in both PEPFAR and non-PEPFAR regions.

### *Constraints to progress*

USAID and CNLS initially agreed that SIAPS had to contribute to the review of the concept note draft to provide comments and to make information available to the committee that writes the final documents. However, because of CNLS' failure to mobilize resources in a timely manner to engage a consultant with the necessary skills and knowledge in procurement and supply management of HIV and AIDS commodities, SIAPS finally stepped in and put a lot of effort into this activity.

In addition to this, SIAPS' technical support faced resistance from some country partners to technically analyze options for distribution that may involve private sector or mixed-solutions to overcome the storage capacity problems of the Central Medical Stores.

### ***Objective 5: Availability of pharmaceuticals improved***

During this quarter, two technical advisers were deployed to the North West and South West regions. . The CPD and deputy CPD travelled to the regions to formally introduce the new staff to the directors of the regional warehouses and to the coordinators of the regional NACC. The memorandum of understanding with the regions was discussed before being legally reviewed by the regional warehouse directors.

In addition, SIAPS facilitated a process for procuring PEFAR-funded ARVs through SCMS. A conference call was organized between SCMS, USAID, CNLS, Directorate of Family Health, and SIAPS in order to agree on the process for reviewing, approving, and processing orders. The orders were reviewed by SIAPS and approved by CNLS before processing through USAID and SCMS.

Finally, SIAPS initiated discussions with USAID on an alternative distribution system to the regions for PEPFAR commodities to mitigate possible risks related to the dysfunctions of CENAME and its limited capacity to store and distribute commodities. While options for distribution of PEPFAR-funded ARVs are being discussed internally with USAID and PEPFAR, SIAPS is engaging with CENAME on a possible contract for storage and distribution fees to ensure storage space of the imminent deliveries.

#### ***Constraints to progress***

There are some uncertainties about the best distribution approach for PEPFAR-supported ARVs procured under country operational plan 14 (COP 14), as well as for additional commodities to be procured in COP 15. Given the risks of using the national systems, complementary systems that may bypass CENAME were envisioned. Distribution systems may need to be customized to high and low volumes of PMTCT sites. Therefore, SIAPS closely worked with USAID and CDC to clarify possible expectations for COP 15 and to adapt COP 14 to new needs.

## **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 DRC continued providing its support to the MOH and the Ministry of High Education. Most activities conducted this quarter were follow-on activities that have been initiated during previous quarters.

SIAPS appointed a consultant to assist the Faculty of Pharmaceutical Sciences (FOPS) of the University of Kinshasa develop a strategic plan for the period 2015–2019, per ACPE report recommendation. A five-day workshop was held on February 1–5, 2015, where all stakeholders including members of the Curriculum Committee participated and contributed to conduct a situation analysis of the FOPS. As a result, a first draft of the strategic plan was produced and shared with all stakeholders for further input, which will be presented to the plenary during the next quarter for final adoption of the strategic plan.

Regarding support to the Medicine Regulation Authority (MRA or DRA) this quarter, SIAPS finalized the steps concerning the procurement and installation of the medicine registration software. Training on the use of the software will be conducted next quarter for all members of the Registration Committee.

SIAPS assisted the PMI-Expansion Project to redistribute stock of malaria commodities (ACTs and rapid test kits) that were close to expiry, thereby avoiding wastage of more than 72,000 doses of artemether-containing regimen (ASAQ). In addition, SIAPS conducted trainings for 287 health care workers (HCWs) on malaria care (case management) and quantification of malaria commodities in 9 of the 43 new PMI health zones (HZs). During the third and fourth quarters, SIAPS will continue training HCWs for the remaining new PMI HZs.

Regarding medicine financing, SIAPS, jointly with the provincial health departments (DPS) managed to help HZs generate funds from medicines donated by global development partners to ensure sustainability of services, especially during the close-out of funded projects.

### ***Objective 1: Pharmaceutical sector governance strengthened***

On March 9–11, 2015, SIAPS provided technical and financial assistance to DRA to hold a workshop regarding the requirements that have to be fulfilled to obtain authorization to operate as pharmaceutical service providers and also the conditions to be met regarding the functioning of all pharmaceutical service providers. As mentioned last quarter, to reinforce transparency and professionalism during the medicine registration process, SIAPS finalized the process for the procurement and implementation of the medicine registration software for the DRA called *Système Intégré de Gestion Informatisée des Processus Réglementaires au sein d'une autorité de réglementation pharmaceutique* (SIGIP-ARP). The software has been installed at the DRA with the assistance of an expert from Burkina Faso's DRA. SIAPS also supported the Medicine

Registration Committee to hold its quarterly sessions. During this quarter's session, 323 dossiers were received, out of which 199 (62%) were approved and given market authorization; 17 dossiers (5%) were rejected, 71 dossiers (23%) were put on hold due to incomplete data, and 36 dossiers (11%) were not examined and were deferred to the next session.

During PY4, SIAPS provided financial and technical support to *the Programme National d'Approvisionnement en Médicaments Essentiels* (PNAM) to revise the technical datasheet (standard procedures) and medicines management tools to be disseminated at health facilities of USAID-supported provinces. SIAPS also assisted in the printing and dissemination of the updated National Essential Medicines List in the provinces.

In addition, SIAPS provided technically assistance to the National Tuberculosis Program (NTP) for the quantification of first-, second-, and third-line TB medicines to be provided by various partners, including the Global Fund and USAID. During these activities, the main challenge was to identify emergency orders required to avoid stock-out of these medicines. After this quantification, SIAPS accompanied the NTP to place emergency orders by Global Fund-supported facilities.

The provincial Pharmaceutical Services (B3) is responsible for ensuring that pharmaceutical services at the regional level run smoothly. Given the reliance of the country on global partner support, B3 has to further ensure that partners' efforts and support are well coordinated. Unfortunately, B3 has almost no control on how medicines funded by global partners are managed, resulting in mismanagement and wastage of stock due to expiry. To address this, SIAPS provided focused support to B3 to develop its roadmap for 2015 that provides an overview of all planned activities and interventions to mitigate and address challenges regarding medicines at the regional level. Therefore, roadmaps were developed and presented to B3.

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

During this quarter, SIAPS supported the national disease program against malaria (PNLP) in Katanga province to conduct training on malaria care for 287 HCWs (121 females and 166 males) from 9 HZs out of the 43 new HZs under the Presidential Malaria Initiative (PMI) support in DRC. The training covered prevention, diagnosis, and treatment of malaria. It also covered a module on quantification of malaria commodities and pharmacovigilance. Prior to this training, a training of trainers was organized for 55 persons who trained 232 HCWs. As stated by the regional health authority during the official launch, the trainings came at the right time, to address and close the gap in performance in the management of malaria cases in the region.

Regarding family planning activities, SIAPS supported the National Program for Reproductive Health to meet on February 17 to assess and monitor the supply of contraceptives to improve stock management of those commodities and mitigate stock-outs and wastage due to expiry. The analysis revealed that stocks of Microgynon, Depo-Provera, and Jadelle had a short-shelf life. Overstock of Sterilet TCU 389 A (IUD), male condoms, and Collier du Cycle were also identified. Corrective measures have been agreed upon to ensure that facilities do not experience stock-out and that no contraceptives are wasted due to expiry.

### *Constraints to Progress*

The 43 additional PMI HZs are spread over 6 DPS, which has increased the logistics burden.

### ***Objective 3: Utilization of information for decision making increased***

Using the alert system setup in the stock monitoring tool at the MSH depot in Kinshasa, SIAPS identified 370,000 kits of oral rehydration salt combined with zinc called Ora-Zinc in risk of expiry, more than 20 million male condoms, and 30,500 female condoms at risk of expiry as well. Urgent action was taken and a consignment of those commodities was sent immediately to HZs for use.

SIAPS assisted in the dissemination of the LMIS evaluation report and participated in the development of the LMIS roadmap in January and February 2015, respectively.

During this quarter, SIAPS assisted the USAID | DELIVER Project to produce the PPMRm for the period October–December 2014. Data analysis regarding the stock and distribution of antimalarial commodities was submitted in January 2015 after conducting data validation jointly with USAID | DELIVER, Integrated Health Project (IHP), and PMI-Expansion. As mentioned last quarter, ASAQ was still overstocked in the Lubumbashi warehouse, thereby exposing a huge quantity of medicines to expiry. To address this, SIAPS organized jointly with NMCP an urgent redistribution of commodities at risk of expiry to 10 HZs, and thus successfully avoided wasting more than 72,000 doses of ACT treatments.

SIAPS supported the NMCP to hold its quarterly workshop January 29–30, 2015. Through this workshop, the PNL and its main partners (PMI, SANRU Rural Health Program /Global Fund, and DFID) shared and analyzed data for malaria commodities. It became apparent during the workshop that PMI has a huge stock of mosquito nets while SANRU/Global Fund is experiencing a stock-out. Therefore, PMI agreed to distribute bed nets at SANRU/Global Fund-supported zones. This has been registered as a SIAPS effort to coordinate partners' interventions in DRC. Meeting participants also agreed to develop a memorandum of understanding that will allow regional depots (CRDs) to apply stock management rules to all medicine consignments in their depots, regardless of which partner supplies the consignment (e.g., FEFO rule).

### *Partner contributions*

IHP, USAID | DELIVER, PMI-Expansion, SANRU/Global Fund, DFID, USAID/local mission

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

In DRC, health financing remains weak because of insufficient budget allocation by the Government; health services depend heavily on global partners' support through implementing partners' projects. The big challenge is that at the close-out of those projects, health facilities experience stock-outs of pharmaceuticals and unavailability of funds to obtain medicines and



related supplies. To address this critical issue, SIAPS recommended that medicines donated by partners should be dispensed to patients at a user fee cost of only 30% of its ex-work value. The 30% should be recovered from the health-facility level and be recycled to reconstitute medicines capital for respective health facilities. The amount generated from respective health facilities should provide capital for to purchase medicines in case of delay in supply and partners' project close-out. During this quarter, SIAPS provided support to provinces to assess the level of funds that have been generated so far, and it was revealed that health facilities under IHP managed to recover USD 333,560 out of USD 1.7 million expected, representing a 20% recovery rate. This constitutes a big achievement, as some years back, no funds could be raised from health facilities. During the third and fourth quarters, SIAPS will provide its support to improving the recovery rate.

***Objective 5: Pharmaceutical services to achieve desired health outcomes improved***

During this quarter, SIAPS started the distribution of malaria commodities to 19 of the 43 new PMI-supported HZs. A total of 312,293 doses of ACTs and 325,718 RDTs were distributed to HZs. Prior to that, most of those HZs were experiencing stock-outs of malaria commodities.

In addition, SIAPS supported the PNLP and the Provincial Pharmaceutical Inspection (PIP) Unit to conduct a joint supervision to ensure good malaria case and stock management in 10 HZs in 3 provinces. SIAPS also supported supervisory visits to four regional central depot warehouses (Kamina, Kolwezi, Kalemie, and Kisangani). As a result, given the poor management of medicines in those warehouses, SIAPS recommended that the contract between MSH and the central depots in Kolwezi and Kamina be terminated immediately. Alternatively, SIAPS is working with the central depot CAMELU in Lubumbashi to set up a warehouse in Kolwezi and with Malemba Nkulu in the district of Kamina to take over the disqualified depots.

Over the past years, the Global Fund provided provincial pharmaceutical inspection with Minilabs to systematically conduct routine medicines quality control to ensure that medicines are up to standard. Unfortunately, it has been noted with concern that those Minilabs are no longer functional because of the erratic provision of reagents and lack of standards. To address this, SIAPS provided assistance to provincial pharmaceutical inspection to assess the functionality of Minilabs in all provinces. During the third and fourth quarters, SIAPS will ensure that Minilabs are functional and used efficiently in the provinces.

***Constraints to Progress***

Mismatch between data collection tools used at the health-facility level and those used at HZ level; therefore important data captured from the HZ level is not captured at the HZ level. As a result, much important information is lost, with a negative impact on decision making.

***Partner contributions***

Plan National de Développement Sanitaire (PAPNDS)

## **Dominican Republic**

**Goal: Increase the availability of critical medicines and diagnostic materials including the ones used for HIV/AIDS 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 on their data (1,358/1,400—97%). This was a slight increase over the previous quarter when 94% of facilities reported their medicine availability. The quarterly bulletin was updated this quarter to improve decision making ability by clarifying data in the report. Universidad Central del Este held the third course on pharmaceutical management. SIAPS conducted an evaluation of the first and second years of the course to evaluate its quality and update it where needed.

### ***Objective 1. Pharmaceutical Sector Governance Strengthened***

During this quarter, the MOH, with SIAPS technical assistance, finalized and validated the final version of the Essential Medicines List (NEML) and the by-laws of the Inter-Sectorial Committee that must approve it. For the next quarter, the NEML will be published with the backing of a Ministry Decree.

SIAPS supported the revision of the therapeutic guidelines for primary health facilities to make it compatible with the NEML. For the next quarter, SIAPS will facilitate a workshop for the validation of this guideline.

During this quarter SIAPS finalized the electronic tools and catalogs that will be used for the estimation of needs exercise. For the next quarter, SIAPS will support the estimation of needs for the 2016 national pooled procurement of medicines and supplies. Unlike previous years, this programming exercise will be decentralized to transfer competencies and tools to Regional Health Services.

### ***Constraints to progress***

The publication of the essential medicines list was scheduled for this quarter. However, the NEML has to be approved by a multi-sectorial committee which has not met in a year and whose function is not backed by any law or procedure. The organization of the committee and approval of its by-laws has delayed the publication of the NEML

### ***Objective 2. Capacity for Pharmaceutical Supply Management and Services Increased and Enhanced***

During this quarter, SIAPS facilitated training sessions of the third certified course (diploma) on pharmaceutical supply management. SIAPS also finalized a rapid evaluation of the first and second course. The evaluation was completed and will be distribute on the next quarter. SIAPS also prepared draft versions of the administrative proposal and educational modules for a

certified diploma course on rational medicines use to be implemented by the Universidad Central del Este. For the next quarter, these modules will be reviewed and validated. The implementation of the course is scheduled for the second semester of 2015.

During this quarter, SIAPS supported the training of NGO personnel responsible for ARV supply management. For the next quarter, SIAPS will facilitate a workshop to train decision makers on the analysis of pharmaceutical management indicators.

### *Constraints to Progress*

The implementation of SOPs for the transportation of laboratory samples is awaiting its official approval and publication by the MOH.

### *Partner Contributions*

The certified course has been implemented in partnership with the Universidad Central del Este.

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

The SUGEMI quarterly information bulletin was redesigned including new graphics that may facilitate the interpretation of information. The October-December bulletin, in this new format, was disseminated to a wide audience on February 2015, and it is also available in the MOH website.

SIAPS has supported the revision and update of the SUGEMI information and monitoring system, and collected information to develop a proposal for the integration of medical materials and laboratory reagents and supplies statistics into the SUGEMI information system. During this quarter, SIAPS consultants discussed with the MOH information technology manager the need to implement an electronic application in hospitals to provide standardized reports on the availability and consumption of medicines and supplies. The MOH agreed to develop a simple electronic application for this purpose. For the next quarter, SIAPS will facilitate a workshop to train decision makers on how to analyze pharmaceutical management indicators, and will finalize the proposal for the integration of medical materials and laboratory reagents and supplies statistics to the SUGEMI information system.

### ***Objective 4. Improved Allocation of Resources for Procurement and Pharmaceutical Management Operations***

No activities were scheduled for this quarter. For the next quarter, SIAPS will update the financial gap analysis for the procurement medicines and supplies.

### *Constraints to Progress*

The public logistics provider (PROMESE/CAL) has not provided the necessary information to finalize the analysis on the correspondence between requisition and

dispatches.

**Objective 5. Pharmaceutical Products and Services Improved to Achieve Desired Health Outcomes**

The implementation of SUGEMI in two major hospitals continues and will be finalized by the end of next quarter. For next quarter, the SOPs will be implemented in two additional hospitals.

SIAPS has collected information for the integration of medical supplies, laboratory reagents, and materials statistics to the SUGEMI information systems. For the next quarter, an implementation proposal will be drafted and discussed with national counterparts.

SIAPS provided technical assistance for the transfer of high cost medicines dispensing from the MOH central offices to hospital pharmacies. From these pharmacies, medicines will be managed following SUGEMI procedures.

SIAPS discussed and agreed with the Maternal and Child Program Director on the need and convenience to transfer the supply management of this program to SUGEMI. For the next quarter, SIAPS will support the implementation of a baseline assessment to document the impact of SUGEMI.

**Constraints to Progress**

The training of trainers for the implementation of SOPs for transportation of laboratory samples and delivery of results was delayed. The expenses for this training were going to be covered by the MOH/Global Fund Project, but the use of the resources has not been authorized.

## Ethiopia

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

### ***Overall Quarter Progress***

In this quarter, USAID/SIAPS conducted a second follow-up assessment on major indicators that SIAPS-Ethiopia identified to measure the results of its interventions. This assessment was conducted at 24 Ethiopian Hospital Reform Implementation Guidelines (EHRIG) and 37 PMI sentinel sites to measure the outcomes of program intervention and the changes observed after the baseline assessment, which was conducted two years ago. Assessment results show improvements in most of the SIAPS global and country specific indicators. To mention some of the improvements, the percentage of facilities implementing the Auditable Pharmacy Transactions and Services (APTS) has increased from a baseline of 29.2% to 66.7%, and the percentage of health facilities that keep complete patient information for chronic illness has increased from 20.8% to 41.7%, the percentage of SIAPS-assisted structure (Drug and Therapeutics Committees) that have implemented antimicrobial resistance (AMR) advocacy or containment-related activities increased from 29.2% to 54.2% and the percentage of facilities implementing good dispensing practices for medicine has increased from 54.2% to 91.7%.

The data collected from the 37 PMI sentinel sites also shows improvement in most indicators, such as the percentage of facilities with stock records that correspond with physical counts for AMDs in warehouses and health facilities has increased from 32% to 100%, the percentage of facilities that use CRMS tools to monitor availability of malaria products has risen from 91.7% to 95% and the percentage of health facilities using a standardized checklist to monitor storage conditions has increased from 16.7% to 72.5%.

There were, however, some indicators that decreased. For example, the percentage of health facilities that received feedback on reports and data decreased from 50% to 47.8%, and the percentage of prescriptions with antibiotics described rose slightly from 58.8% to 59.6%. Two other indicators decreased when compared to the first follow-up conducted last year. The percentage of warehouses with stock-outs of a pre-selected group of medicines for three days or more in the last three months rose from 35.1% to 54%, and the percentage of health facilities with stock-outs of a pre-selected group of medicines for three days or more in the last three months rose from 62.2% to 89%.

### ***Objective 1. Strengthen pharmaceutical system to ensure access to quality pharmacy services that will lead to improved health outcomes***

In preparation for implementation of APTS in Oromia region, Oromia Regional Health Bureau (ORHB) has been technically and financially supported to customize APTS tools (vouchers, sales tickets, and registers). A two-day workshop was organized for the purpose. The expectation is that once the regulation is enacted, APTS vouchers will be printed and APTS will be implemented at selected hospitals. According to the plan, 18 potential and 5 model hospitals will be receive the first round of APTS implementation.

In the quarter, a consultative workshop was organized to discuss Harari regional states APTS regulation. The workshop was attended by 38 participants drawn from Harari regional health bureau, finance and economic development bureau, audit bureau, justice bureau, health facilities, Harari mass media, and Pharmaceutical Fund and Supply Agency Dire Dawa branch. Most of the participants hold supervisory position in their institutions. The topics that were discussed included consistency of the professionals' intention with the rule of law, pharmaceutical ethics, finance principles, audit disciplines, and public health issues as well as faults and penalties when professionals violate the regulation. Moreover, indemnity issues were discussed with the current practice and experience of finance bureau. Finally the Harari RHB head took on the assignment to present the final regulation for approval by the regional cabinet.

### *Partner Contributions*

- ORHB has taken a leading role in the customization of the vouchers, selection of the potential hospitals for implementation of APTS.
- ORHB (Pharmacy Unit) is working to get the APTS regulation enacted.
- Harari-RHB organized the consultative workshop and provided input to the final draft of APTS regulation.

### *Constraints to Progress*

- The enactment of the APTS regulation was delayed due to the competing priorities at the regional level.

### **Objective 2: Pharmacy Services at Facility Level Improved**

In this quarter, two rounds of training of trainers (TOT) on APTS was conducted for seven hospitals in southern region and nine health facilities (four hospitals and five health centers) from Sugar Corporation—a total of 86 pharmacy and finance professionals. In addition, 153 professionals drawn from Amhara and Tigray regions were trained on APTS. Similarly, 34 media personnel and pharmacy professionals were trained on AMR in Tigray region. Standard operating procedures for providing clinical pharmacy services was produced during the quarter and sent for final printing.

In this quarter, SIAPS provided technical and financial support to Tigray RHB to conducted joint integrated supportive supervision at 14 hospitals in the region. During the visit, it was discovered that 10 hospitals initiated clinical pharmacy, drug information services, and documented interventions. Thirteen hospitals measured wastage rate, patient satisfaction, vital drugs availability, procurement, and stock-out rates on a monthly basis and compiled quarterly data. EHRIG implementation status was also assessed and the result showed 64% of the hospitals implemented more than 80% of the operational standards.

As part of improving pharmacy premises in preparation for initiation of APTS, six health facilities renovated their pharmacy infrastructure and improved the workflow. In the renovation, SIAPS gave technical assistance on the design of the premises and associated costing. All the

renovation costs are completely covered by the health facility themselves, which is a clear sign of ownership and sustainability.

The Federal Ministry of Health has been supported in the procurement of antimalarial drugs for malaria prevention and control activity. The quantities and delivery dates required for the artemether-lumefantrine tablets were communicated to UNICEF for procurement with PMI funds. In addition, the ministry was supported in the quantification of essential and specialty drugs for 22 federal and referral hospitals. Pharmacists and medical directors from 22 hospitals were oriented on quantification and data collection; also, malaria supplies quantification was presented and discussed.

Face to face discussions with 240 health providers on pharmacovigilance were held at nine health facilities (seven in Addis Ababa and two in Southern Nations, Nationalities and Peoples Region. Various pharmacovigilance tools and documents were distributed to health facilities and RHBs; this includes 245 adverse drug event reporting forms, 350 allergy cards, 210 national pharmacovigilance frameworks, 590 newsletters, and 280 preventable adverse event bulletins. In this quarter, 124 adverse drug events data were entered into the national database and acknowledgment/feedback was given to 110 healthcare providers who reported ADEs.

Investigation and analysis was carried out at eight hospitals on ADE report of a fixed dose ARV medicine. The report has been communicated to the FI directorate, sample was collected, and corresponding action is being awaited.

SIAPS has continued supporting health facilities to conduct medicine use education to patients at waiting areas. During this quarter, ten health facilities in Amhara and Tigray regions organized a total of 40 medicine use education sessions. A total of 262 patients attended out of which 109 (42%) were female.

As part of ensuring adherence to ARVs and minimize the chances of defaulting and subsequent development of resistance, SIAPS provided support to selected ART sites to have access to phones to be able to call to patients when they miss appointments or are lost to follow-. During this quarter, 12 health facilities in four regions telephoned about 237 patients out of 259 (92%) who missed their appointments or were lost for follow-up. Overall, 155 patients out of 237 (65%) were brought back to treatment, 12 transferred to other health facilities, and 17 were reportedly deceased.

### *Partner Contributions*

- Pharmaceutical Fund and Supply Agency was involved in the collection of clinical pharmacy updates from the 65 hospitals.
- SIAPS collaborated with its partners such as health facilities, EFMHACA, EPHI, mass media agencies and other media outlets.

### *Constraints to Progress*

- A late budget approval process for FY15 delayed implementation of some of the activities planned for the quarter.
- In Oromia region, most health facilities register prescriptions manually and there are complaints of increased work burden. They also requested USAID/SIAPS to support on preparing and printing standardized comprehensive prescription registration book. The concern was shared with AMDM/PMI coordination office and SIAPS is now supporting the ORHB to prepare standardized prescription registration books.
- Clinical pharmacy intervention, drug information services activities, and health education activities are not regularly reported.

### **Objective 3. Capacity to Use Information for Decision Making Strengthened**

In Q2, patient uptake data collected from 680 health facilities and regimen breakdown reports collected from 380 health facilities were compiled and shared with partners and stakeholders for decision making. A total of 334,995 patients were on ART, of which 291,570 patients were covered in the regimen breakdown report (87% of those covered in the patient uptake report).

The information generated on prescribing patterns has consistently been used to monitor the phase out of D4T-based regimens both in adults and children. At the start of the d4T phase out in September 2012, there were 205,832 adult patients on ART. Out of these active patients, 61,981 (30%) were on d4T-based regimen, while 73,553 (36%) and 67,090 (33%) of the patients were on ZDV and TDF based regimens, respectively. By the end of September 2014, 98% of patients on d4T were successfully shifted to more tolerated regimens, mainly ZDV and TDF. By the end of January 2015, the phase out of D4T in adults was completed. Similarly, in pediatric ART, the prescribing of D4T-based regimen has continued to show a sharp decline since July 2014 from 44% in July to 6% in January 2015.

SIAPS has continued strengthening the information system (patient-medication records using EDT) at ART pharmacies to enable easy identification and prevention of medication errors by pharmacists. Six ART sites from Amhara and Dire Dawa region were able to identify and resolve a total of 147 medication/prescribing errors, which could have otherwise endangered patient safety. During the quarter, one computer was given to Amanuel hospital to help them implement EDT and on-the-job training was provided for two pharmacy professionals. Computer hardware and software maintenance support was provided to 62 ART sites with EDT. External backup drive was also given to one health center to ensure continuous data backup and protecting loss of data on patient uptake and regimen breakdown.

SIAPS has continued supporting the automation of medicine registration system. Based on the optimized requirements submitted in the last two quarters, the software User Acceptance Test (UAT) was carried out in this quarter. UAT feedback was collected from Food, Medicine and Health Care Administration and Control Authority (FMHACA) experts, the automation TWG members, and the management. The UAT was carried on in collaboration with two experts from SIAPS HQ. We also identified four expert users and train them to master the software so that they can give day to day software application support to their colleagues. One of the important parts of



the automation project is for customers to be able to see information online related to medicine registration and apply their application online. To this end in the UAT and application training, SIAPS staff were able to train five industry applicants on how to start application online and access information on the status of their application. During the short-term technical assistance (STTA), 28 FMHACA experts coming from different directorates including the port of entry were trained.

Licensing and inspection of regulatory core function is the second module where SIAPS plans to automate, based on the needs of FMHACA. In this quarter, with another STTA from the HQ experts, Ethiopia SIAPS staff carried out a detailed assessment of the processes and processes inventories. To this end, the HQ staffs generated report and outline their recommendations and areas of next steps to Ethiopia team. However, in recent steering committee meeting, FMHACA directed SIAPS to focus resources and time to develop comprehensive registration tool that allows the registration of medical devices, narcotic and psychotropic substances, and food products registration. SIAPS team is currently reviewing the cost implication and the challenges of the task shift and will present their decision on this issue to FMHACA.

### *Partner Contributions*

- Health facilities CEOs and dispensary staffs wish to implement EDT for real time dispensing
- The USP/PQM regulatory affairs officer in Ethiopia is a member of the TWG for registration module and he has continued to contribute toward automating work through active participation in the TWG members meeting, UAT, and by taking assignments and meeting expected deliverables.

### *Constraints to Progress*

- Discrepancy of reports of data gathered by phone and actual data at some health facilities, frequent power interruptions, and inappropriate handling and use of computers.
- Shortage of pharmacists trained on ART due to high staff turnover at some health facilities; as a result, manual pharmaceutical information system and electronic dispensing tool is not filled properly.
- Medicine Registration and Licensing Directorate is a busy department and serves several clients each day. Also, the TWG members have limited time in which to provide all deliverables on a timely basis. Decisions by the management for issues that require the management approval takes unnecessarily long time.
- The pharmacy monthly antimalarial drug management activity report is not used enough for decision making.
- The supply of antimalarial drugs from ZHD/WHO is erratic and there is a poor trend in availability of all ACT package forms.

### ***Objective 4. Optimal Use of Financial Resources Ensured***

In quarter 2, APTS implementation has been started in in four hospitals—two federal hospitals—Ayder and Gondar University hospitals, and Amanuel Specialized Referral Hospital and Metema hospital). Renovations of dispensing outlets were completed in Amanuel Referral Hospital, St. Paul Referral Hospital, Addis Ketema health center, and Ayder Referral Hospital for APTS

implementation to streamline patient flow, improve convenience for patients, and create a one-stop shopping service.

The inauguration of APTS at Ayder Hospital was honored by first lady Mrs. Roman Tesfaye and the presence of his excellency Dr. Kesetebirhan Admassu, Ministry of Health. Hospital management and staff witnessed that this implementation of APTS was a huge undertaking that transformed the way pharmacy service is provided and medicines-related transactions are managed.

The event was attended by more than 250 officials and department heads. A similar event was also conducted during inauguration of APTS at University of Gondar. This inauguration was made in the presence of the university president, the city Mayor, and director of medical service directorate of the Federal Ministry of Health. Both inaugurations were covered by Ethiopian television.

Currently, APTS is being implemented in more 37 health facilities throughout the country. Since APTS is a new intervention, all finance and pharmacy staff require training prior to its implementation.

To assist new APTS sites to properly grasp and understand the tools, concepts and processes, five rounds of regular trainings were provided to the finance and pharmacy staff from the three hospitals during which a total of 153 individuals participated.

In this quarter, Woldia, Enat, Ayder, and Mehal-Meda hospitals performed an ABC/VEN reconciliation analysis.

To support ORHB to implement the guideline for redistribution of overstock and near expiry antimalarial drugs between public health facilities, discussions were held with the bureau on how to proceed with this activity. As part of implementation of APTS, ORHB has mentioned its concern about the need to have a comprehensive guideline for redistribution of all overstock and near expiry drugs (not only AMDs) between public health facilities and suggested revising the previously developed guideline for AMDs so that it can be used for other medicines.

### *Constraints to Progress*

- Poor quality of records and report on pharmaceutical transactions and services due to absence of permanent pharmacy accountants at general and primary hospitals.
- Minimal use of APTS reports for decision making purposes
- Health facilities implementing APTS have started auditing; as a result, the facilities are making pharmacy professionals responsible for covering deficits of any magnitude (prior to implementing indemnity). This is against the principles incorporated in the APTS proclamation.

### *Partner Contributions*

- Renovation of pharmacies to meet APTS requirements and hospital management personnel encouraging pharmacy professionals to be committed to implementing APTS.
- SNNP RHB facilitated the APTS TOT training at Arbaminch.
- Arbaminch General Hospital provided training hall (for APTS TOT training) free of charge.

## **Guinea**

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

### ***Overall Quarter Progress***

During this quarter, SIAPS Guinea continued its support in the areas of pharmaceutical sector governance, capacity-building for organizations and individuals on pharmaceutical management, and the collection and use of pharmaceutical information for decision making. While leveraging efforts and resources with other partners, SIAPS work targeted the National Medicines Regulatory Authority (DNPL), the National Malaria Control Program (PNLP), the Central Medical Store (PCG), and health workers at community level.

Additionally, some out of scope activities were conducted in January and February 2015 as part of expanded efforts to manage the Ebola outbreak in the country and to develop a recovery plan for the Guinea health system that has been negatively affected by Ebola disease. In collaboration with WHO, UNICEF, USAID, World Bank, and European Union (EU), SIAPS supported MOH to elaborate pharmaceutical components of this recovery plan.

To improve medicines policies, legislation, and regulations, SIAPS supported the DNPL to organize preparatory sessions of a workshop that was planned to take place on March 2015 to address pharmaceutical legislation and regulatory issues in Guinea and subsequently revise medicines regulatory documents.

As part of a continuous effort toward transparent and accountable pharmaceutical management in Guinea, SIAPS collaborated with WHO and EU-funded Pan African Sanctuary Alliance project to revise the PCG strategic plan. As a result, PCG adopted an integrated strategic plan that includes the EU-funded Regional Medical Store of Nzérékoré. Other activities were conducted to improve PCG quality assurance system.

To build capacity of organizations and individuals for pharmaceutical supply management, SIAPS supported a training of PCG staff to improve medicines storage conditions and the inventory management of health commodities, including those related to Ebola disease.

Finally, SIAPS worked with the PNLP to improve the pharmaceutical management information system. Major activities included support to Malaria Technical Working Group (TWG) to develop its annual operational plan and organize incoming distribution of PMI-funded health commodities, joint supervision visits on pharmaceutical management of malaria commodities (March 2015), and technical assistance to regional quarterly review meeting in Global Fund-supported districts under PNLP leadership (February 2015).

### ***Objective 1. Pharmaceutical Sector Governance Strengthened***

During this quarter, SIAPS supported the DNPL to organize preparatory sessions of a workshop that will take place on March 2015 to address pharmaceutical legislation and

regulatory issues in Guinea and to subsequently revise medicines regulatory documents. These sessions took place in February and March 2015, and the following were achieved:

- Existing legislation acts and regulatory documents were identified.
- International reference documents related to pharmacy and medicines regulation were collected.
- Insufficiencies in existing medicines regulation documents were identified
- A training module on international reference documents related to pharmacy and medicines regulation was developed
- The agenda for the incoming workshop on pharmaceutical legislation and regulation was developed.

As part of reform efforts to improve transparency and accountability of the PCG, SIAPS and representatives from six Regional Medical Stores participated to its annual meeting of the board of directors. In addition, SIAPS conducted a series of training that PCG technical and administrative staff attended to improve a documentation process for finances and commodities management and to enhance the quality assurance system in place.

Finally, SIAPS collaborated with WHO and EU-funded PASA project to revise the Central Medical Stores strategic plan that conducted to an integrated approach that includes the EU-funded Regional Medical Store of Nzérékoré.

### *Constraints to Progress*

Ebola-related activities remained the top priority for all departments of the Ministry of Health and the PCG. Therefore, all planned activities were put on hold.

### *Partner Contributions*

During the quarter, SIAPS worked with the wide range of local and international partners, including WHO, World Food Programme (WFP), and EU-funded PASA Project.

### ***Objective 2. Capacity for Pharmaceutical Supply Management and Services Increased and Enhanced***

During this quarter, SIAPS conducted a series of trainings for PCG technical staff to improve their capacity in health commodities management, quality assurance systems, and medicines storage conditions in PCG main and regional warehouses. As a result, job descriptions of three pharmacists in charge of quality assurance and their annual action plans were revised. Based on developed tools and ensuing supervision, corrective actions were suggested for the Regional Medical Store in Boke and some health facilities.

In collaboration with WFP, SIAPS supported PCG to train 60 professionals (pharmacists and storekeepers) on management of Ebola health commodities and supplies. From March 23, four groups of 15 professionals attended a six-day training that was completed after a site visit in

WFP warehouse where Ebola-related health commodities and supplies were stored. The training covered key management activities such as quantification, reception, storage, and distribution, and provided basic technical specification of hazmat protections.

### *Partner Contributions*

WFP, PCG, DELIVER, Stop Palu, CRS, and USAID

### *Constraints to Progress*

The PNLP working group on malaria commodities involves partners such as the PCG, DELIVER, Stop Palu, CRS, and USAID; it still needs support to enable better functionality.

### ***Objective 3. Pharmaceutical Management Information Available and Used for Decision Making***

During this quarter, SIAPS worked with the PNLP's TWG to improve the pharmaceutical management information system through joint supervision visits.

In February 2015, SIAPS provided technical assistance to PNLP to conduct regional quarterly review meetings in Global Fund-supported districts. Supervision visits took place in Mamou, Nzérékoré, and Kankan to harmonize collection tools for epidemiologic and pharmaceutical management data. Given insufficient capacity of pharmacists and statisticians to properly collect and organize data for routine reporting purpose, on-site trainings were provided on a collection of malaria commodities consumption data.

In collaboration with MSH/LMG project, SIAPS supported the PNLP to develop priority actions plans that included improving management for epidemiologic records and medicines consumption data. Therefore, workshops were organized under PNLP leadership from February 14 to 15, 2015, in Kindia Region and Conakry (Health Districts of Ratoma and Matoto).

Other activities included support to Malaria TWG to develop its annual operational plan and organize incoming distribution of PMI-funded health commodities. From March 9 to 15, 2015, the TWG conducted supervision on management of malaria commodities in Conakry with a focus on good practices of distribution, commodities stock status, and free delivery of PMI-funded commodities.

From March 15 to 31, 2015, SIAPS supported the PNLP to conduct a biannual supervision countrywide after a template of an integrated supervision was finalized with SIAPS technical assistance. The supervision findings showed an availability of huge quantities of commodities at health facility level, insufficient use of pharmaceutical management tools, and an inefficient order process due to the push system in place.

Finally, SIAPS worked with PNLP and USAID/PMI representatives to conduct a gap analysis and review the country needs of malaria commodities to be ordered in 2015

*Constraints to Progress*

Because of the Ebola outbreak, the implementation of some activities was delayed

*Partner Contributions*

SIAPS collaborated with PNL, CRS, and MOH representatives.

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

SIAPS participated in negotiations that led to funding of the PCG by the eHealth Africa project for a commodity distribution related to Ebola. As mentioned earlier, eHealth is funded by the CDC Foundation to support trainings related to sanitation and the protection of health workers against Ebola.

The cost recovery study described in the work plan for this fiscal year is anticipated to take place in early 2015.

## **Lesotho**

**Goal: To assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes.**

### ***Overall Quarter Progress***

During this quarter, SIAPS participated in the writing and quantification for ARVs, TB and ART-related laboratory commodities as part of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) concept note for 2016-18. This process is being led by consultants for the Ministry of Health (MoH). The concept note will be completed and sent to the GFATM by April 2015. SIAPS also provided technical assistance to the National Drug Service Organization (NDSO) to update the supply plan of HIV Rapid Test Kits (RTKs) in order to avoid stock-outs. The RTKs in the country were low because of poor supply plan and it is now NDSO will adhere to the new supply plan that will ensure the availability of the HIV RTKs in the country. There is now an increased need to test and treat people in Lesotho as the country has the second-highest rate of HIV infection in the world, at 23% and is ranked number two in the world after Swaziland.

Additionally, SIAPS delivered the Supply Chain Management Leadership Development Program (SCMLDP) to 45 health care workers of the Butha-Buthe and Mokhotlong districts. The SCMLDP was designed in the last FY and was only delivered to the Maseru and Mafeteng Health districts, helping them to achieve enormous improvements in their supply chain and logistics indicators. As a result, other districts are now funding this training for themselves and SIAPS is providing the needed TA to deliver the training.

There were marked improvements in the PMIS and LMIS supply chain indicators this quarter as a result of the SIAPS supportive supervision and mentoring to the districts. This is the exception of the stocking according to plan (SC\_STOCK) which was a result of low levels of TDF/3TC/EFV at the NDSO. There were, however, no stock-out of first-line antiretrovirals (ARVs) for more than 28 days at any facility in the country. NDSO has ordered quantities that will bring these FDC ARVs to above the maximum stock level (18 months) by the next quarter.

### ***Objective 1: Capacity for pharmaceutical supply management and services increased and enhanced***

In this quarter, SIAPS provided technical assistance to develop the Lesotho Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Concept Note for 2016-18. SIAPS also collaborated with the Clinton Health Access Initiative (CHAI) and Global Fund Coordinating Unit (GFCU) to provide technical assistance to the Ministry of Health (MoH) to conduct quantification for the delivery of ARV, TB and antiretroviral therapy (ART) laboratory commodities as part of the concept note.

SIAPS provided technical assistance to the National Drug Service Organization (NDSO) to revise the supply plan of the HIV Rapid Test Kits (RTKs) that were procured in December 2014 in order to have a once-off supply of these commodities as the quantities procured were

only enough for six months which is the NDSO's maximum stock level. SIAPS also advocated for the MoH and NDSO to initiate the procurement of HIV RTKs for the 2015/16 fiscal year in order to prevent the stock from dropping below the minimum stock level (four months of stock at the NDSO).

During this quarter, SIAPS organized two SCMLDP training workshops for health care workers in the Botha-Bothe and Mokhotlong districts. The training at Botha-Bothe was sponsored by the Botha-Bothe District Health Management Team, while the one in Mokhotlong was funded by African health NGO SolidarMed. A total of 45 health care workers (seven males and 38 females) attended this SCMLDP training. The SCMLDP seamlessly combines leadership and the supply chain management of both pharmaceutical and laboratory commodities in order to improve the health care workers' capacity for managing these commodities with inventory and logistics management systems. The participants form clusters made of two to four facilities that work together to complete the action plans developed during the workshops. SIAPS will continue to work with both the Mokhotlong and Botha-Bothe District Health Management Teams (DHMTs) to support peer-to-peer mentoring and to review the progress against the set Supply Chain Management (SCM) performance indicators.

SIAPS provided technical assistance to the MoH Supply Chain Coordinating Unit (SCCU) to develop a comprehensive assessment tool for the SCM activities for laboratory, dental and pharmaceutical commodities. SIAPS will support SCCU to implement this tool, and the information generated by it will be used to inform development of the SCCU operational plan.

Two SCM Technical Working Group (TWG) meetings were held in this quarter. In the first, the members of the newly formed SCCU were introduced to all the MoH stakeholders and a task team was formed to review the Terms of Reference (ToRs) of the SCM TWG. In the second meeting, the SCMTWG developed performance indicators for the MoH Procurement and Supply Chain Strategic Plan for Medicines and Health Products (2013/1 –2016/17).

### *Constraints to progress*

There was a delay in conducting quantification exercises due to a lack of coordination among stakeholders. SIAPS is working in close collaboration with the SCCU to establish the national quantification committee of the Supply Chain Management Technical Working Group, which will be responsible for coordinating the quantification processes.

### *Partner contributions*

SIAPS collaborated with the MoH, NDSO, CHAI and GFCU to conduct quantification of ARVs, TB and ART-related laboratory commodities, which was necessary for the GFATM Concept Note. SIAPS also collaborated with SOLIDAMED and MoH to conduct the SCMLDP workshop for health care workers in Botha-Bothe and Mokhotlong districts.



**Objective 2: Utilization of information for pharmaceutical and laboratory decision making increased across all levels of the Lesotho health system**

SIAPS initiated testing of data transfer from health facilities to the Maseru DHMT through mHealth technologies developed for the 20 health facilities in Maseru. SIAPS has encountered challenges with the synchronization technology, which has failed to deliver integral data. SIAPS is working to resolve the challenge and to develop a robust alternative technology that will guarantee integrity of data being transferred from health facilities to DHMT. The alternative solution will be used in the next quarter. The use of mHealth is expected to improve data completeness, accuracy, and the timely submission of data to the DHMT.

SIAPS provided support for the implementation of RxSolution at Machabeng and Tebellow Hospital. The United States Agency for International Development (USAID) mission has now instructed SIAPS to transition the support for RxSolution to the MoH. The transition plan will be completed in the next quarter to ensure sustainability of RxSolution in the country.

SIAPS oriented the newly established SCCU staff on laboratory supply chain tools; how to review the monthly LMIS reports for data quality and how to provide feedback to health facilities. SIAPS also provided technical assistance to SCCU to strengthen implementation of the laboratory Logistics Management Information Systems (LMIS) at all 18 hospital laboratories. Furthermore, SIAPS mentored 17 laboratory technologists (8 males and 9 females) in inventory management, compiling laboratory LMIS reports and completing laboratory requisition forms. As a result of this technical assistance and support, 94% of laboratories (17 out of 18) submitted the LMIS reports. Only 6% of the hospital laboratories experienced stock-out of HIV RTKs in this reporting period.

**Constraints to progress**

mHealth operationalization has been delayed by the failure of data synchronization technology. SIAPS has begun the development of an alternative technology to ensure transfer of data from health facilities to DHMT commences. The technology is expected to be implemented in the first month of the following quarter.

Two laboratories were not adhering to LMIS protocol due to staff turnover (new staff were not competent in laboratory LMIS). SIAPS continues to work with the SCCU to train newly engaged staff in Laboratory LMIS.

**Partner contributions**

There was no partner contribution toward this objective in this reporting period.

**Objective 3: Pharmaceutical services improved to achieve desired health outcomes**

SIAPS conducted 135 supportive supervision and mentoring visits to health facilities in the SIAPS-supported districts (Berea, Botha-Bothe, Mafeteng, Maseru and Mohale's Hoek,

Leribe, Qacha's Nek, Mokhotlong, and Thaba Tseka). A total of 331 health care workers (264 females & 67 males) were mentored in inventory management and pharmaceutical management information systems using both the cluster and health facility visit approaches. SIAPS achieved the following results due to its support to the district:

- 92% (144 out of 156 health facilities assessed) use country-appropriate tools to report logistic and patient data (the target is 90%).
- 95% (111 out of 117 of health facilities assessed) keep complete patient information as per national standards (the target is 90%).
- 3% (4 out of 155 of SIAPS supported sites assessed) have ARVs stocked according to plan, i.e. within the two months minimum and three months maximum stock levels.
- 10% of health facilities (7 out of 71 assessed health facilities) experienced stock-outs of ARVs for more than three days.

### *Constraints to progress*

In this quarter, only 4 of the 155 facilities had commodities (in particular ARVs) stocked according to plan. This is because the NDSO was supplying health facilities with two months of stock instead of three months of stock as in the standard operating procedure. (Two months is equal to the minimum stock level and three months is maximum level.) NDSO did this because of inadequate stock of ARVs in the country, resulting from the nationwide scale-up of the ART CD4 threshold to 500 350 cell/mm<sup>3</sup> since December 2014, up from 350 cell/mm<sup>3</sup>. The stock was budgeted and procured based on the old algorithm for starting ART.

### *Partner contributions*

SIAPS worked with NDSO to compile monthly stock status reports

## Mali

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

SIAPS Mali supported the MoH and its stakeholders to strengthen pharmaceutical governance, build the pharmaceutical management capacity of individuals and institutions, make logistics data available for decision making, and improve pharmaceutical services.

To improve pharmaceutical governance, SIAPS supported the Directorate of Pharmacy and Medicine (DPM) to organize three meetings to validate HIV commodities quantification results (January 23, 2015), analyze essential medicines stock status (March 20, 2015), and update malaria and family planning commodities supply plans (March 27, 2015). Participants from MOH, USAID implementing partners, UN agencies, and civil society organizations (CSOs) attended these meetings. The number of CSOs that participated in and/or monitored pharmaceutical management decision making and operations increased from 12 to 17. Participants at regional meetings came from health districts, regions, and USAID partners such as ASSIT, USAID/Nutrition, and WASH. CSOs, such as the Millennium Village Project, Strengthening Decentralized Health System Project, and the Community Health Regional Federation, also attended.

To improve governance in the pharmaceutical public sector, SIAPS supported the DPM, Direction Régionale de la Santé (DRS), and districts to disseminate LMIS SOPs, the stock management reporting tool (Compte Rendu de Gestion de Stock), and medicine stocks cards to health facilities. The number of health facilities that benefited from management tools increased from 562 to 835 (including 102 health facilities in the Kayes Region, 57 health facilities in the Koulikoro Region, 237 health facilities in the Sikasso Region, 209 health facilities in the Segou Region, 173 health facilities in the Mopti Region, and 57 health facilities in Bamako).

As part of capacity-building efforts in pharmaceutical management, SIAPS supported 12 local institutions that subsequently completed 30 technical assignments. SIAPS also supported MOH to conduct supportive supervision at the national and regional levels, covering 48 (out of 50) health districts in Kayes, Koulikoro, Sikasso, Segou, Mopti, and Bamako. Coaching sessions were conducted in four health districts and indicated that the percentage of trained professionals who successfully completed their post-training action plan increased from 19% to 36%. To improve the pharmaceutical management capacity of the Central Medical Stores (PPM), their strategic plan for 2015-2019 was validated during a MOH-led consensus workshop that was attended by many stakeholders involved in medicines supply chain. As the strategic plan that was validated will help PPM envision a long-term objective in the five next years, SIAPS started supporting a review of the main PPM supply chain operations, SOPs manuals, and other interventions, such as development of a staff training plan and an improved PPM management information system.

To render available data for decision making, SIAPS assisted the MOH in developing and submitting one PPMRm and one PPMRc and to conduct one end user verification survey. From the various reports, recommendations were made for a continuous availability of malaria and

contraceptive commodities. Additionally, SIAPS continued to track commodities information through the LMIS. The percentage of health facilities that completed and submitted an LMIS report for the most recent reporting period increased from 32% to 40%. At the same time, the percentage of stock records that corresponded with physical counts for a set of indicator medicines in regional warehouses and district and local health facility increased from 43% to 52%. The percentage of health facilities that used consumption data to inform ordering increased to 70%. These results showed a noticeable improvement of evidence-based decision making and a significant reduction of three-day stock outs for the tracer drugs, from 66% to 31% in warehouses and from 84% to 48% in health facilities.

Finally, SIAPS and the NMCP disseminated results from a feasibility survey that was conducted to determine the possibilities of involving private pharmacies in the management of malaria commodities, thereby improving access per the national malaria case management policy. The study showed that access to antimalarial medicines could be improved through private pharmacies that daily see 50–200 clients, 1/5 of them having been prescribed an antimalarial medicine. (However, data also showed that only 40% of pharmacies were inspected by a medicines regulatory authority in the last two years.)

### ***Objective 1: Pharmaceutical sector governance strengthened***

To improve pharmaceutical governance, SIAPS supported the DPM to organize their quarterly supply chain coordination meetings to discuss and address issues related to health commodities management.

During this quarter, two meetings of the national committee were held on January 23, 2015, and March 20, 2015, to validate HIV quantification exercise results and discuss malaria, family planning, and MCH commodities' stock status, respectively.

Following up on recommendations from these meetings, Malaria and Family Planning Technical Working Groups (TWGs) subsequently organized their respective meetings on March 27, 2015, to update their supply plans based on medicines consumption and inventory replenishment data by using Pipeline software. These TWGs reiterated that donors should respect their commitments to maintain supply plans and the delivery calendar.

### ***Constraints to progress***

During this quarter, SIAPS found that the involvement of all stakeholders in the process of decision making on pharmaceutical management was insufficient. Other constraints included a lack of operations standardization for medicine supply at all levels of the national supply chain system, including an insufficient CMS operations performance.

### ***Partner contributions***

- Malaria, HIV and AIDS, and Family Planning TWGs
- DPM, PPM, PNLP, DSR, CSLC/MSHP, HCNLS
- Donors: USAID, PSI, UGP/PNUD, UNFPA, Global Funds

- OSC: Projet village du millénaire, FERASCOM, PSI, ASDAP, Projet de développement décentralisé, Marie Stop International, ESTHER AID, PSI, Futurs Group, USAID ASSIT

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

As part of capacity building efforts in pharmaceutical supply management, SIAPS supported 12 local institutions thereby enabling professionals from these local partners to complete 30 technical assignments. The number of professionals trained in pharmaceutical management did not change during this quarter, maintaining the record of 836.

Additionally, SIAPS supported the regional directorates of health in Kayes, Koulikoro, Sikasso, Segou, Mopti, and Bamako to organize their quarterly meetings to analyze and validate data on malaria. MCH, HIV and AIDS, and family planning commodities stock status were collected from the district level and aggregated. These meetings also offered the opportunity to address any pharmaceutical management issues that were identified during the joint supportive supervision and coaching sessions. Validated data showed that the percentage of health facilities that completed and submitted required LMIS reports increased from 32% to 40%. They will be considered and subsequently submitted to DPM for decision making.

Finally, in collaboration with its global partner IHS, SIAPS supported the validation process of the PPM's five-year strategic plan, along with the preparatory phase of PPM's SOPs assessment that will drive improvement of supply chain management operations.

***Constraints to progress***

It appeared from supervision visits that some health professionals previously trained on pharmaceutical management were still struggling to properly implement their post-training action plans.

***Partner contributions***

- Regional health directorates of Kayes, Sikasso, and Segou Regions
- Health districts
- PPM, DPM, NMCP, Health Reproductive Directorate, HIV Program, HCNLS, Catholic Relief Service (CRS), National Pharmacists Council (CNOP)
- USAID, PSI, UNDP, UNFPA, Global Fund

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

To render available medicines data for decision-making, SIAPS supported the MoH in developing and submitting 1 PPMRm, 1 PPMRc and to conduct 1 end user verification survey. Recommendations were made for a continuous availability of malaria and contraceptives commodities. Additionally, SIAPS continued its support to health districts and health facilities to track commodities information through the Logistic Management Information System (LMIS).

SIAPS worked closely with the DPM, PPM, NMCP, PSI, and USAID/PMI to produce a quarterly PPRMm and PPMRc that made recommendations on supply and distribution for malaria and family planning commodities. SIAPS subsequently assisted the DPM, NMCP, and PPM to implement the recommendations, particularly adherence to the national supply plan by stakeholders and implementation of distribution plans by the PPM.

The PPRMc recommended that donors commit to their medicines procurement and delivery calendars so that the national supply plan could be maintained. This report advocated also for a quick transfer of 3,000 UNFPA-donated intrauterine device kits from DPM to PPM for immediate distribution.

In collaboration with SIAPS, NMCP conducted an end user verification survey in February 2015, according to a sampling protocol and revision that was introduced by PMI in 2011. The findings of this exercise will be disseminated at the national and regional levels during the next quarter so that corrective actions could be taken.

#### *Partner contributions*

- PPM, PSI, DPM, DSR, USAID, and UNFPA attended meetings on analysis and validation of collected pharmaceutical management data
- DRS, PPM, and regional warehouses and health districts of Kayes, Koulikoro, Sikasso, Segou, and Mopti Regions and Bamako participated in quarterly review meetings

#### **Objective 4: Pharmaceutical services improved to achieve desired health outcomes**

To improve the availability of commodities at all levels of the country health system and to assist stock managers in their day-to-day tasks, SIAPS supported DPM, DRS, and districts to conduct supportive supervisions. Among other, these supervisions contributed to strengthening the capacity of field-based health workers to use pharmaceutical management tools to improve availability of medicines and increase the number of patients that can be treated at the health-center level. Approximately 120 sites, including 5 PPM regional warehouses, 5 regional health directorates, 48 health-facility depots, and 42 district warehouses were visited.

#### *Constraints to progress*

Stakeholders have not consistently adhered to the country family planning and malaria commodities supply plans.

#### *Partner contributions*

NMCP, DPM, Private Sector Pharmacists Association (SYNAPO), National and Regional Pharmacists Councils (CNOP, COPD), Community Health Regional Federation (FENASCOM, FERASCOM Bamako), DRS Bamako, CRS, PSI, TB Program, PPM, National Directorate of Health (DNS).



## **Mozambique**

**Goal: To ensure access to safe, effective, high-quality pharmaceutical products and effective pharmaceutical services to help achieve desired health outcomes.**

SIAPS continued to work with the Mozambique Pharmaceutical Department (PD) to finalize the Essential Medicines List (EML) using the expertise of both a local and an international consultant. SIAPS provided technical support and facilitated the EML workshop. Several meetings were held with the technical team from SIAPS headquarters to finalize the installation of the Pharmadex electronic tool for medicines registration.

The draft statement of work (SOW) for the IT support needed at the country level was also developed. It was determined that IT support for in-country troubleshooting will be outsourced. The previously developed SOPs and guidelines to streamline the medicines registration will be reviewed to ensure that it fits well with Pharmadex.

### ***Objective 1: Governance in the pharmaceutical sector strengthened***

The final draft of the EML was reviewed by a group of 74 health professionals from different health disciplines in a four-day high level workshop which was officially opened by the minister of health. The next step is to review and finalize the list with recommendations from the SIAPS technical team and consultants. The funding for the workshop came from SIAPS and WHO. WHO was also represented at the workshop and provided technical support.

With the support of SIAPS, and with the use of the developed performance indicator reference sheets (PIRS), the new focal point collected the possible data and produced the PD annual monitoring and evaluation report for 2014.

#### *Constraints to progress*

The main constraint in the process of preparing the national EML workshop was the varying availability of the committee members, and the late confirmation of the workshop dates. The monitoring and evaluation data collection was difficult for some PD staff because they do not have any system that can generate information on their activities.

#### *Partner contributions*

- Clinical areas and health programs gave input on EML medicines selection.
- PD secretariat of the committee for EML review, as well as other PD staff, have provided significant assistance.
- WHO supported the first two days of the workshop.

### ***Objective 2: Capacity in pharmaceutical management increased and enhanced***

No progress has been made on this objective.



*Constraints to progress:*

This is a new activity and awaited the approval of the FY15 workplan for work to begin.

***Objective 3: Pharmaceutical services to achieve desired health outcomes improved***

During this period, SIAPS worked in collaboration with the Department of Hospital Pharmacy (DFH) and reviewed the recommendations of the 2nd National DTC Workshop, which required implementation support. The next step is to schedule a meeting and finalize the implementation timeline according to the matrix of recommendations.

*Constraints to progress:*

Staff to support competing activities.

*Partner contributions:*

The Department of Hospital Pharmacy (DFH) staff reviewed the recommendations of the 2nd National DTC Workshop that was supported by SIAPS.

## **Namibia**

**Goal: To ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes.**

### ***Overall Quarter Progress***

SIAPS continued to support the Namibia Medicines Regulatory Council (NMRC) in mentoring technical staff and providing technical assistance in the evaluation of applications for the registration of essential medicines. This helps ensure availability of safe and high-quality medicines to manage treatment of HIV/AIDS, TB, and other infectious diseases, and to support maternal, newborn and child health (MNCH). Through SIAPS technical assistance, 42 medicine registration applications which were received in 2013 were evaluated by trained evaluators. The backlog of 550 applications from the period 2010-13 was reduced by 49.1% in 2014. SIAPS also supported the upgrade of the NMRC website to host the medicine registration tool Pharmadex.

In collaboration with the Division of Pharmaceutical Services (Div:PhSs), SIAPS technical advisors visited all district and referral hospitals, selected primary health care (PHC) facilities offering ART services, and two medical depots in the 14 regions of Namibia to offer onsite support and mentorship. Technical assistance (TA) was given to nursing and pharmacy staff at all the 52 ART sites using the ART Electronic Dispensing Tool (EDT) to improve pharmaceutical services and access to quality ART services to the Namibian population. SIAPS assessed the implementation of ART decentralization activities, including the mobile electronic dispensing tool (m-EDT), to PHC facilities during the visits.

SIAPS continued to work with the University of Namibia School of Pharmacy (UNAM-SoP) to strengthen the Pharmaceutical Management Module by developing course materials on Pharmaceutical regulatory affairs. SIAPS supported the UNAM-SoP in the introduction of the Pharmaceutical technician course which was launched in February 2015. A total of 30 students have been enrolled in this course.

SIAPS provided TA to the Div:PhSs in organizing for the Pharmacist Assistant (PA) Forum. The Pharmacist Assistant Forum brought together PAs from all regions, as well as policy makers at Div:PhSs. At the forum, SIAPS disseminated findings and recommendations on various SIAPS supported activities, including the rollout of EDT mobile in Nurse-Initiated and -Managed Antiretroviral Therapy (NIMART) sites, the STG post implementation assessment, Pharmacy Management Information Systems (PMIS), and ART PMIS reports. Discussion of these technical activities with the health facility managers and national level policy makers enabled SIAPS-recommended interventions to be agreed upon at this forum.

SIAPS worked with the MoHSS Therapeutics Information and Pharmacovigilance Center (TIPC) and University of Washington to write an abstract and a manuscript on the results of sentinel surveillance carried out at the Katutura Intermediate Hospital and Windhoek Central Hospital, which concluded in December 2014. The abstract was submitted for presentation at the International Society for the Pharmacoeconomics and Outcomes Research (ISPOR) conference in May 2015. SIAPS held meetings with the TIPC to plan and adapt curriculum and materials for

the 2nd Medicine Safety Surveillance Training of Trainers (ToT), which was conducted on 4-6 March 2015. The training drew a total of 13 participants—pharmacists and medical doctors from district hospitals and regional offices in the Southern, Central, Eastern and Western regions of Namibia.

**Objective 1: Pharmaceutical regulatory system strengthened for better ART services**

SIAPS provided TA and mentorship to the NMRC dossier evaluation team on the evaluation of applications for the registration of essential medicines to ensure availability of safe and high-quality medicines for people living with HIV/AIDS and other diseases. Ten trained technical assessors from MoHSS and the private sector participated in a five-day dossier evaluation session, and 42 medicine registration applications received by NMRC in 2013 were evaluated.

SIAPS provided TA to the NMRC to analyze medicine registration data for the period of January-December 2014. Although the analysis showed an increase in processing time from 34 days in 2013 to 48 days in 2014, it was mainly due to NMRC's focus on reducing the 2010-13 backlog of over 550 applications. This number was reduced by 49% in 2014, with the help of training, mentoring, and prioritization of earlier applications.

In collaboration with MoHSS and Intrahealth, SIAPS developed the draft version of the upgraded NMRC website to host the medicine registration tool -Pharmadex. The tool was presented to NMRC staff and discussions were held on the key features to be included on the website. Feedback was obtained from the stakeholders/users for further improvement. The recommendations will be incorporated in various parts of the website upgrade. This will enable NMRC disseminate timely information pertaining to medicine regulatory activities in Namibia for better transparency and accountability.

SIAPS supported the MoHSS's Div:PhSs in planning and conducting the annual support supervisory visits (SSVs), and provided TA in revising the tools for the SSVs. Checklists for hospitals, multi-regional medical depots (MRMDs) and primary health care (PHC) facilities were reviewed for use in the SSVs. New sections were added to the hospitals SSVs checklists for assessing implementation of ART decentralization activities using the mobile EDT at PHC facilities and a section on assessing the quality of dispensing to patients on ART. SSVs were conducted in all district hospitals in the 14 regions, as well as all referral hospitals, the two MRMDs, and selected PHC facilities in each district. Formal feedback was given to 13 of the regions visited in which recommendations were discussed and action plans for improvement were developed for each region for improving service delivery.

MoHSS, with support from SIAPS and SCMS, has implemented strategies aimed at strengthening ART pharmaceutical systems in Namibia, including the roll-out of ART services to PHC facilities and the implementation of nurse-initiated management of ART services (NIMART). SIAPS drafted a manual on processes and procedures for conducting national-level SSVs, the first draft of which has been circulated for technical and peer review by MoHSS. The manual was compiled to standardize the processes and procedures for conducting SSVs. This is part of SIAPS efforts to transition the management of SSVs wholly to the MoHSS. Following a

service quality assessment (SQA) at ART sites in the first quarter of FY15, SIAPS supported MoHSS in compiling the SQA report and drafting an article on SIAPS' role in an assessment of service quality at ART sites in selected regions in Namibia. The assessment was to identify site barriers to providing high-quality clinical care and identify areas for further assessment and improvement in HIV care. The article was published in the MSH quarterly newsletter.

### *Partner contributions*

- 1) NMRC provided the medicines dossiers for the evaluation session held in February 2015, and coordinated the dossier evaluation activity.
- 2) The Directorate(s) of Primary Healthcare, Special Programs and Policy Planning and Human Resources Department of the MoHSS provided logistical support for the annual Pharmaceutical Services SSVs in 2015.

### *Constraints to progress*

- Delayed implementation of web-based Pharmadex at NMRC attributed to the NMRC's busy schedule. SIAPS will continue to pursue convenient time for NMRC to train and start testing the tool
- The SSVs team that visited Oshana region was unable to give a formal feedback presentation to the Regional Management Team as the members of the RMT were unavailable. The feedback presentation was shared with the regional pharmacist, who was tasked with giving feedback to the region.

### *Lessons learnt*

Site visits for activities such as SSVs can be used to follow up on other activities to utilize resources effectively. In this case SSVs for Pharmaceutical services were used to follow up on implementation of EDT mobile at PHC facilities, an activity that is being piloted by SIAPS in Kavango and Zambezi regions

### ***Objective 2: Capacity of pharmaceutical HR and local institutions in managing the pharmaceutical system and supply chain in delivery of sustainable ART and other pharmaceutical services strengthened.***

SIAPS continues to support UNAM-SoP to develop course materials for the Pharmaceutical Management Module. SIAPS conducted meetings with UNAM to discuss the process of developing Pharmaceutical Regulatory Affairs pre-service training course materials for UNAM. The team determined the number of lecture hours assigned to the module to guide the team on the depth of the materials to be developed. Materials have been collected and with support from the HQ team, a course outline is being developed. This will be shared with the UNAM-SOP staff prior to developing the training materials.

SIAPS submitted an abstract on strengthening pre-service pharmacy training on rational medicine use (RMU)—with particular regard to antimicrobial resistance (AMR) in Namibia—to the American Public Health Association. This abstract is based on SIAPS support to UNAM-

SOP in developing modules for the pharmacy course curriculum. UNAM-SOP reformed its undergraduate pharmacy course to adequately address RMU and AMR topics in an effort to integrate topics of practical, clinical, and public health importance, such as RMU and AMR in pre-service training courses.

SIAPS is a technical resource to the UNAM School of Medicine's project on infection control and hospital hygiene in Namibia, funded by the German government. SIAPS participated in a stakeholders meeting to plan for a workshop on hospital hygiene and infection control, and provided TA in the development of presentations on RMU and antimicrobial resistance (AMR) in Namibia. The presentation was made by MoHSS representatives from Namibians Against Antimicrobial Resistance (NAAR) and Windhoek Central Hospital, and included the role that SIAPS has played in developing Namibia's AMR advocacy strategy.

SIAPS participated in the launch of the pharmaceutical technician (PT) curriculum on February 16, 2015. The curriculum was developed with support from SIAPS in FY14. A total of 30 working PAs were enrolled in the program, mainly drawn from the public sector. The development of a competency framework for a PT in Namibia informed the curriculum for the course. The PT course will be offered by the institution on a part-time basis for two years, enabling PAs to progress academically and creating a career path for them. Pharmaceutical Technicians will enhance provision of ART services in Namibia once they graduate from UNAM.

#### *Partner contributions*

1. UNAM-SoP helped lead discussions for the development of pharmaceutical regulatory affairs course materials for pharmaceutical management module.
2. UNAM-SOP helped to launch the pharmaceutical technician course.

#### *Constraints to progress*

Inadequate human resources, high staff turnover, limited follow-up for on-the-job support, and/or awareness at health facilities make it difficult to implement programs that MoHSS staff had been trained in. These challenges have an impact on pharmaceutical practices such as inventory management and medicine use evaluations, which are among the activities of the therapeutics committees.

Compilation of an aggregate report from medicine use indicator data collected by UNAM-SoP students is delayed as the UNAM opted to assign students to compile the report, which is necessary for capacity enhancement of both the B.Pharm students and UNAM-SoP. The absence of the aggregate report made it difficult to report on the annual indicators, but SIAPS is working with UNAM-SoP lecturers to support students to compile the report.

**Objective 3: Pharmaceutical metrics developed, the availability and use of data for making strategic decisions on ART program improved**

SIAPS continues to support the MoHSS Directorate of Special Programs (DSP) HIV Case Management and Div:PhSs in utilizing HIV data for decision making. In February, SIAPS held a planning meeting with the WHO consultant based at Tufts University to plan for the 2015 HIV-DR EWI study, as well as the implementation of the defaulter tracing study. The meeting was held with SIAPS on the 13th February in Windhoek.

In collaboration with the DSP and Tufts University, SIAPS wrote an abstract on monitoring Early Warning Indicators of HIV drug resistance and implementing a national strategy to improve ART services in Namibia. The abstract was submitted for presentation at the APHA Conference in November 2015.

At the request of US Centers for Disease Control and Prevention (CDC) and Response Monitoring and Evaluation (RM&E) sub-division of the Directorate of Special Programs (DSP), SIAPS provided technical assistance for abstracting data from the National Database (NDB) for all patients on ART until December 2014. This data will be used for comparison with e-PMS data and inform the Spectrum modeling. Data from Spectrum is used by the program to forecast future ART needs for the country. As of December 2014, there were 130,331 active patients registered in the EDT.

SIAPS is supporting the implementation of NIMART by strengthening ARV stock, patient and data management using the EDT and its mobile version at PHC facilities. The visits covered all Namibia's 14 regions. During the SSVs SIAPS also conducted follow up visits to support the implementation of the EDT mobile in Rundu district. Support on EDT mobile data uploading was given to the main ART site at Rundu ART pharmacy. Seven PHC sites, including three clinics and four health centers (HC) were visited. Nine nurses, four PAs (two from Nkarapamwe HC, and two from the main EDT site) and one pharmacist were trained. In addition, two health assistants and one community counsellor were also trained. In total 17 healthcare workers were trained on the use of the EDT Mobile. In the Zambezi region support including training on EDT mobile was provided to four nurses in charge at the four PHC facilities visited.

SIAPS submitted an abstract on the SIAPS-supported implementation of EDT Mobile in Namibia's Kavango and Zambezi Regions for the American Public Health Association's 2015 conference. This activity was part of SIAPS TA to MoHSS in decentralizing ART services to PHC facilities through use of mobile technology for data capture. The Electronic Dispensing Tool (EDT) is a portable, hand-held scanner that enables non-pharmaceutical staff to record patient data off-site. EDT mobile prompts users to enter "real-time" patient data in a clear and concise format, minimizing errors and data gaps. During the visits to these two regions 43 nurses and five pharmacists were trained, and nurses began using EDT mobile at 41 outreach sites. In the Zambezi region, 2,979 patients—representing 37% of ART patients in the region—are now being directly managed at PHC facilities through EDT mobile devices. This has contributed to increased access to ART by hard-to-reach populations while preserving the accuracy and completeness of ART data in Namibia.

SIAPS provided TA to the Div:PhSs in organizing the PA forum, which brought together representatives of PAs from all regions as well as policymakers at Div:PhSs. In the forum, SIAPS disseminated findings and recommendations on various SIAPS-supported activities, including the rollout of EDT mobile in nurse-initiated and -managed antiretroviral therapy (NIMART) sites; the standard treatment guidelines (STG) post-implementation assessment; and pharmacy management information systems (PMIS) and ART PMIS reports. Discussion of these technical activities with the health facility managers and national level policy makers enabled SIAPS-recommended interventions to be agreed upon at this forum.

### *Partner contributions*

- 1) The NMPC subdivision of the MoHSS Div: PhSs supported facilities using the EDT
- 2) MoHSS-DSP provided support to PHC facilities using the EDT mobiles for ART data capture
- 3) Tufts University in the compilation of the 2014 HIV-DR EWI report

### *Constraints to progress*

Transitioning of the EDT Helpdesk to MoHSS has been a challenge due to the absence of a dedicated IT support technical person in the ministry.

### ***Objective 5: Pharmaceutical services delivery strengthened to improve adherence to HIV/TB treatment, enhance achievement of health outcomes, and contain AMR***

SIAPS, in collaboration with the DSP, wrote an abstract on the implementation of the EDT-Mobile at primary healthcare (PHC) facilities in the Kavango and Zambezi regions in. The abstract was submitted for presentation at the International AIDS Society (IAS) conference. In addition, SIAPS compiled a related article which is available on the SIAPS website: [http://siapsprogram.org/wp-content/uploads/2015/02/Namibia\\_EDTmobile\\_SS1.ef\\_.pdf](http://siapsprogram.org/wp-content/uploads/2015/02/Namibia_EDTmobile_SS1.ef_.pdf)

SIAPS worked with the Therapeutics Information and Pharmacovigilance Center (TIPC) of the MoHSS and the University of Washington to write an abstract and a manuscript on the results of sentinel surveillance carried out at the Katutura Intermediate Hospital and Windhoek Central Hospital, which concluded in December 2014. The abstract was submitted for presentation at the International Society for Pharmacoconomics and Outcomes Research (ISPOR) conference in November. SIAPS held meetings with the TIPC to plan and adapt curriculum and materials for the 2nd Medicine Safety Surveillance Training of Trainers (ToT), which was conducted on March 4-6, 2015. The training drew a total of 13 participants—pharmacists and medical doctors from district hospitals and regional offices from the Southern, Central, Eastern and Western regions of Namibia.

SIAPS continues to support the Health Professions Council of Namibia (HPCNa) in distributing the STGs to practitioners and covering costs of reprinting. In February, professionals and interns registering as nurses, pharmacists, medical doctors and allied health professionals procured the STGs at a fee determined by HPCNa. This was the first time the STGs were distributed under a cost recovery mechanism.

In February, SIAPS Namibia held a meeting with the SIAPS Arlington and Harvard University teams to provide feedback on the feasibility report for a systematic process for the review and use of EDT data elements and queries to assist in the strengthening of ART EWI data use for decision making. During the meeting SIAPS Namibia provided details for the next phase—in particular with regard to the approval process for local collaborators—and a work plan and budget for the activity.

SIAPS participated in a forecasting exercise for pharmaceutical commodities. The SCMS-led activity provided support to the MoHSS in determining the extra resources (ARV commodities) required to increase ART coverage to at least 90% in high-prevalence regions.

SIAPS assisted the Khomasdal Health Center with presenting on the role of Therapeutics Committees (TCs) in combating antimicrobial resistance, including resistance to ARVs and the TC's role in managing medicine use in health facilities. Twenty-five participants, including medical doctors, pharmacy staff, nurses and administrators, attended the TC meeting. Awareness creation among health care workers on their role in monitoring early warning indicators (EWIs) of ARV resistance and promoting rational use of ARVs and other medicines is an important strategy that can be used by TCs to conserve the effectiveness of currently used antimicrobials including ARV medicines.

SIAPS participated in a meeting with clinical mentors who supervise the management of ART patients in the Khomas, Rundu, Zambezi, Omusati, Kunene and Oshana regions, all of which have high HIV burdens. This meeting is held on a quarterly basis to review treatment options for ART patients on salvage regimens. Effective consultative management of these patients is important for saving their lives and for reducing resistance to ARVs, as such patients are already showing documented resistance to more than one type of ARV medicine. Three cases of patients showing resistance to second-line regimens were reviewed and new regimens were prescribed for each.

### *Partner contributions*

- i) MoHSS (TIPC) on pharmacovigilance activities – active surveillance and community pharmacovigilance
- ii) MoHSS- HIV Case management unit and the DSP on ART adherence and retention initiatives
- iii) Harvard University to develop a systematic process for review of EDT data elements and queries to assist in the strengthening of ART EWI data use for decision making

### *Constraints to progress*

Div: PhSs is often not attending or represented at crucial meetings such as the HIV-DR panel meeting. SIAPS is regularly seen as a de-facto representative of PhSs in such meetings. SIAPS held discussions with Div:PhSs and USAID-Namibia to rectify the situation.



## Philippines

**Goal: Strengthen key institutions in reducing the TB burden through increased access to quality and effective pharmaceutical and laboratory services**

### ***Overall Quarter Progress:***

In this quarter, SIAPS continued to assist the National Tuberculosis Control Program (NTP) and the National TB Reference Laboratory (NTRL) to improve laboratory management systems by providing technical input to NTRL management and its Technical Units (TUs) on the development of the 2014 annual report, the 2015 annual work plan and the 2015 monitoring and evaluation (M&E) plan.

SIAPS is also supporting the NTRL in the development of the laboratory network training program and the national laboratory training plan to enhance current laboratory trainings and have the trainings certified by the Philippine Regulatory Commission (PRC). SIAPS and the NTRL have begun assessing the training needs of TB laboratory staff to inform the process.

Additionally, SIAPS continues to support the Barangay Health Management Council (BHMC) of Quezon City. SIAPS gave technical assistance in the development of the implementing rules and guidelines for BHMC expansion to three additional barangays: E. Rodriguez, Ermin Garcia and Libis.

SIAPS contributed to the improvement of pharmaceutical management at the central level by providing technical inputs in addressing issues in supply chain through the regular meetings of the Drug Supply Management (DSM) sub-technical working group, composed of NTP, NTRL, the Philippine Business for Social Progress (PBSP), and other implementing partners. Medicines forecasting and quantification for the bedaquiline study and nine-month MDR-TB treatment regimen, as well as 2016 Global Fund targets, were also developed based on QuanTB outputs.

SIAPS is also collaborating with Department of Health (DOH) regional offices and the Innovations and Multisectoral Partnerships to Achieve Control of Tuberculosis (IMPACT) Project in the roll-out of the Practical Guide for the Management of Pharmaceuticals and other Health-related Commodities (PGMP). During this quarter, 17 and 27 regional and provincial health staff were trained on PGMP in Regions I and VIII, respectively.

To support the preparations for two operational research studies—the nine-month MDR-TB treatment regimen and the bedaquiline trial—SIAPS provided training on good pharmacovigilance practices to 23 participants from the NTP, the Food and Drug Administration (FDA) of the Philippines, the National Center for Pulmonary Research of the Lung Center of the Philippines (NCPR- LCP), the National Center for Pharmaceutical Access and Management (NCPAM), the World Health Organization (WHO) Philippines, IMPACT, and the Technical Assistance Support to Countries (TASC) Project.

SIAPS continues to support the NTP and FDA of the Philippines in the registration process for second-line drugs (SLDs) for TB by securing medicine dossiers and other requirements for the

approval of the two studies through close coordination and regular collaboration with STOP TB-Global Drug Facility and International Dispensary Association (IDA). SIAPS and its partners have also drafted the pharmacovigilance standard operating procedures (SOPs) for cohort event monitoring, which are currently being reviewed by the NTP and FDA of the Philippines.

**Objective 1: Capacity for Pharmaceutical and Laboratory Leadership, Governance and Management Improved**

To support the NTP and NTRL in the improvement of laboratory management systems and services, SIAPS assisted NTRL management and its TUs in the development of the 2014 Annual Report, which documents the institution's accomplishments over the previous year. SIAPS also assisted the NTRL in developing the 2015 work plans for both NTRL management and the five TUs, including their M&E plan. Inputs from the assessment of the 2014 accomplishments refocused the plans of the NTRL to ensure that it will be able to focus its activities and achieve its objectives.

SIAPS is helping NTRL's Training and Development Unit (TDU) identify the training needs of TB laboratory staff at the national, intermediate and peripheral levels. Initial findings revealed that there is a shared need to improve technical skills in recording and reporting and in laboratory data analysis and report writing, as well as in management skills, such as planning and M&E. SIAPS will continue its support to NTRL TDU to conduct the training needs assessment.

SIAPS continues to support Quezon City (QC) in the rollout of the Barangay Health Management Council (BHMC) approach. SIAPS gave inputs to the QC government to finalize the local ordinance, and will extend the assistance to the development of the implementing rules and guidelines for BHMC expansion to other barangays. Currently, SIAPS is providing technical assistance to three other barangays, bringing the total number of assisted barangays to 6. With the recent request of the QC health officer-in-charge for SIAPS to expand its assistance in the creation of the BHMC in the seventh area, Barangay Commonwealth, SIAPS Program's reach will increase in the near future. Barangay Commonwealth is a big, urban, poor community, and has the highest population among all barangays in the city.

SIAPS is working closely with the NTP to strengthen the overall pharmaceutical management of the TB supply chain at the national level. SIAPS has mentored the new NTP DSM staff in forecasting and quantification of SLDs using QuanTB. Based on these forecasting assumptions, PBSP has prepared the SLD procurement form for 2015-16.

SIAPS facilitated the Drug Supply Management (DSM) sub-technical working group meeting, attended by representatives from the NTP and PBSP, to discuss and address issues in the pharmaceutical sector. During this reporting period, the group: (1) reviewed the delivery and stock status of first-line drugs (FLDs) and SLDs, and facilitated the procurement of medicines with critically low stock levels; (2) reviewed the medicine requisition and performance of treatment centers for the allocation list of the nine-month MDR-TB Treatment Regimen study; and (3) started drafting the policy guidelines on the disposal of expired and damaged medicines and supplies. QuanTB outputs were also utilized in the forecasting and quantification of the

medicine requirements for the bedaquiline study and the nine-month MDRTB treatment regimen study, and for 2016 Global Fund (GF) targets.

Further progress was made in supporting the efforts of NTP and regional offices in strengthening the capacities of regional, provincial and peripheral health staff in the management of TB medicines and supplies. In Region IV A, the regional DSM working group, which was established in the previous quarter, continues to enhance the coordination mechanisms and improve the requisition practices of facilities in the region. For this quarter, 149 out of 164 (91%) of the RHUs used their actual facility consumption data as basis for their requisition of TB medicines (up from 44 out of 60 RHUs, or 73%, in the previous quarter). SIAPS also supported Rizal PHO in the conduct of the DSM monitoring visits in the province.

In Region VIII, the provincial NTP coordinator of North Samar, who attended the PGMP training of trainers, rolled out the training to 27 RHU staff in the province with technical inputs from SIAPS and IMPACT. Training test results showed that the participants on average scored 56% in the pretest and 86% in the post-test.

### *Partner contributions*

IMPACT provided logistics support in roll out of PGMP training in North Samar, Region VIII, and facilitated the monitoring of supply chain management in North Samar, Region VIII and Rizal, Region IV A. DOH Region IV A provided the venue for the meeting of the DSM sub-technical working group.

### *Constraints to progress*

Conflicting schedules of NTRL TUs delayed several activities, including finalization of the 2014 Annual Report, the 2015 Annual Plan and the 2015 M&E Plan.

### ***Objective 2: Capacity for Transparent and Evidence-Based Decision Making Improved***

The continued technical assistance from SIAPS to the NTRL has improved ability of the Monitoring and Evaluation Unit (MEU) and other technical units to perform its functions. The framework for internal collaboration for reporting and the SOPs developed by SIAPS have been implemented, and are now being enhanced by NTRL management and the TUs. The MEU is leading all efforts on laboratory information management and reports generation. Internal NTRL quality indicators to measure management and TU performance were developed with SIAPS' assistance and are now being adopted to assess the performance of NTRL TUs. The staff takeaways from the Laboratory Information Utilization Training conducted by SIAPS in the previous quarter are being applied in analyzing laboratory performance and developing reports.

SIAPS continues to assist the Quezon City (QC) District 3 health staff to improve recording and monitoring of stock utilization through the use of the TB Supply Tracking tool. With SIAPS support, an inventory management meeting was also facilitated by QC District 3 Health office to

address issues on stock-outs and overstock of TB medicines by redistributing them between the nine facilities in the district.

Additionally, SIAPS conducted a group discussion with QC District 3 Health Center nurses to gather insights regarding supply management support, including the use of the inventory tracking tool. The key findings included the convenience provided by the automatic computation of stock balances, and the early warning signal of the color-coded columns; however, the challenges reported are the: (1) difficulties in recording the quantities of medicines converted from CAT I to CAT II stocks, (2) the duplication of nurse duties in the submission of both paper-based and TB tracking tool Excel-based reports, (3) encoding of reports at home due to unavailability of computers in the facility; and (4) lack of utilization of information generated by the tracking tool. A feedback session with QC District 3 program managers and supervisors will be organized by SIAPS to discuss these findings and identify the next steps in the implementation of the tracking tool for supply management.

SIAPS participated in the year-end PMDT and Integrated Tuberculosis Information System (ITIS) Program Implementation Review and gave inputs in the development of 2015-16 regional action plans for ITIS implementation. SIAPS helped the Knowledge Management Information Technology Services (KMITS) in the review of the 2015 work and financial plan for ITIS implementation.

SIAPS also contributed in the enhancement of the ITIS drug inventory module and continues to provide assistance in the development of the laboratory module.

### *Constraints to progress*

The lack of functional computers in some of the health centers in QC District 3 makes the implementation of the TB Supply Tracking Tool more difficult as the health staff needs to do the encoding at home. The issue of “double recording” from the health center nurse’s perspective is staff workload-related and needs further investigation to be resolved. The lack of utilization of information provided by the tracking tool indicates the need to further promote a paradigm shift in information management. This observation is generally true for all levels of the NTP and the health system.

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

The main activities for this quarter focused on supporting NTP, PBSP and NCPR-LCP in the preparation for the nine-month MDR-TB treatment regimen and bedaquiline operational research studies.

In close coordination with the FDA of the Philippines, the Global Drug Facility (GDF) and IDA, SIAPS continues to assist NTP to register all SLDs; however, challenges were encountered on the non-English medicine dossiers from the manufacturers and dossiers of off-label drugs.

For the off-label drugs, the NTP and partners including NCPR-LCP, TASC, PBSP and WHO-Philippines are pooling related literature on the intended drug use for MDR-TB, which will be submitted to FDA of the Philippines and WHO Headquarters for appraisal.

A training on pharmacovigilance cohort event monitoring was conducted by SIAPS for 23 partners from NTP, FDA of the Philippines, NCPR-LCP, NCPAM, WHO, PBSP, IMPACT and TASC. The training topics included cohort event monitoring, pharmacovigilance systems strengthening, causality assessment; and pharmacovigilance data interpretation and reporting. Action plans developed by partners focused on strengthening the pharmacovigilance units of FDA of the Philippines and NTP, and the organization of a National Drug Advisory Committee for causality analysis. SIAPS also worked with partners to develop the SOPs for cohort event monitoring, which will be used in the two studies: a nine-month MDRTB treatment regimen and bedaquiline use.

SIAPS submitted a preliminary draft of the national TB supply chain assessment to USAID-Philippines and presented the results and options to other USAID cooperating agencies.

Data collection activities were started in 16 public NTP culture laboratories as part of the assessment of the NTP laboratory network's capacity to support the implementation of the 2015 National TB Prevalence Survey. This activity was requested by the NTP to inform its planning process for the survey. The assessment will continue this coming quarter.

SIAPS helped to review and revise the PMDT implementing guidelines and also contributed in the enhancement of PMDT monitoring tools, particularly on supply chain management sections. SIAPS participated in the SIAPS Global TB Conference held in Bangkok, Thailand in March 2015, and facilitated the attendance of two staff from NTP and National Center for Pharmaceutical Access and Management (NCPAM). During this conference, SIAPS shared the activities, challenges and future plans of FDA of the Philippines' pharmacovigilance unit; and discussed the country's experience on the pharmacy DOTS initiatives implemented by Philippine Pharmacists Association (PPhA).

### *Partner contributions*

The Global Fund supported part of Day 1 of the "Pharmacovigilance Cohort Event Monitoring" Training.

### *Constraints to progress*

The registration process of SLDs is delayed due to challenges in the translation of non-English medicine dossiers of Kanamycin from the manufacturers, and securing dossiers for off-label drug use medicines such as clofazimine. Hence, the implementation of the nine-month MDR-TB regimen study is also delayed.

## **South Africa**

**Goal: Strengthen the capacity of pharmaceutical systems at all levels to support the South African Government priority health programs and initiatives to improve health outcomes.**

### ***Overall Quarter Progress***

The National Strategic Framework for Antimicrobial Resistance (AMR) 2014-2024 and the AMR background document developed with SIAPS assistance were signed by the minister of health and the director general of the National Department of Health (NDOH). This brings to 13 the number of key pharmaceutical sector governance documents developed with SIAPS assistance.

Five districts and one provincial depot team completed the Pharmaceutical Leadership Development Program (PLDP) in Limpopo (LP) province during this quarter. Some of the challenges addressed by the teams included improving the correlation between stock records and physical stock from 56% in September 2014 to 86% in February 2015 at seven healthcare facilities in the Capricorn district and improving compliance of prescriptions with legal requirements from 70% to 89% in six months at three hospitals in Mopani District. In addition, 24 facility and pharmacy managers from 12 health facilities in the Northern Tygerberg sub-structure (NTSS) of Metro District Health Services in the Western Cape (WC) presented results achieved in sustaining and scaling-up quality improvement projects initiated in 2012 as part of the Leadership Development Program facilitated by SIAPS.

The Master Procurement Catalogue (MPC) which forms part of the draft National Pharmaceutical Management Information System (PMIS) was finalized and published on the NDOH website. The MPC, which includes an inventory of all items on pharmaceutical contracts, is expected to facilitate alignment and aggregation of procurement data from the provinces that use a standard coding system.

SIAPS and Supply Chain Management Systems (SCMS) are both providing assistance to the NDOH in implementing the direct delivery (DDV) procurement model. To optimize synergy for the benefit of the counterpart, an SCMS/SIAPS Shared Enterprise Workshop was held to clarify the roles and responsibilities of both parties in providing technical assistance. Subsequently, the two programs have embarked on a process to align activities through the development of a project charter and joint plans.

SIAPS completed the academic detailing for 21 sections of the draft version of the primary healthcare (PHC) standard treatment guidelines and essential medicines list (STG/EML) 2014. These are a set of slides that explain the changes to the STGs. In addition, SIAPS supported NDOH in developing an implementation and roll-out strategy for the PHC guidelines.

SIAPS presented a poster entitled “Strengthening Infection Prevention and Control Systems in Resource-Limited Settings by using a Self-Assessment and Continuous Quality Improvement Approach” to the 15th International Congress of the International Federation of Infection Control in New Delhi, India.

**Objective 1: Pharmaceutical sector governance strengthened (IR 1)**

To date, SIAPS has facilitated the development, review, and revision of several policy documents, such as the criteria for issuing pharmacy licenses and the National Contraception Clinical Guidelines. The NDOH has identified additional needs to strengthen the policy framework for pharmaceutical services at national and provincial levels.

During the quarter, the National Strategic Framework for Antimicrobial Resistance (AMR) 2014-2024 and the AMR background document developed with SIAPS assistance were signed by the minister of health and the director general of NDOH. SIAPS also assisted with the finalization of the Implementation Plan for Antimicrobial Stewardship in South Africa-Post-Summit Commitments, which was circulated for comment among the AMR working group members. The implementation plan identified the establishment of the Ministerial Advisory Committee (MAC) on AMR as a priority intervention in the implementation of the first objective of the strategy which is “to strengthen, coordinate and institutionalize interdisciplinary efforts through national and health establishment level governance structures.” It is proposed that MAC will have representatives from the Departments of Health, Agriculture, Forestry and Fisheries, and Science and Technologies. SIAPS worked closely with NDOH to develop a project plan for the establishment of the MAC. Technical support was also provided in the drafting of the terms of reference (TORs) which were subsequently shared with the AMR working group for comment. The TORs are expected to be submitted to the National Health Council (NHC) during the next quarter.

To prepare for the submission of the National Policy for the Establishment and the Functioning of Pharmaceutical and Therapeutics Committee in South Africa to the NHC, SIAPS worked with NDOH to write the foreword and introduction for the policy, which were signed by the Minister of Health and Director General of NDOH, respectively. The policy is expected to be submitted to the NHC during the next quarter. SIAPS engaged NDOH to discuss development of a national policy on pharmaceutical waste management as contained in the FY15 work plan. Because of competing priorities, NDOH decided to put the development of this policy on hold until further notice.

During this quarter, the Business and Market Intelligence Unit within the Affordable Medicines Directorate (AMD) of NDOH was established and the deputy director appointed. The unit collects, analyses, and disseminates quantitative market information to inform decision making for various units within the directorate. The unit was established as a culmination of SIAPS’ technical assistance, through a consultant who was engaged from May 2013 to January 2015. In this way, SIAPS provided technical assistance to strengthen the capacity of NDOH on contract and tender management, in the utilization of market and business intelligence, improving efficiency of the bid evaluation process, strengthening price negotiation for tenders, and implementing reforms for price adjustment of products on contract.

SIAPS continued to provide technical assistance to the NDOH with the coordination of tenders for medical-related items. During the quarter SIAPS assisted with the alignment of the tender specifications with the standards from the South African Bureau of Standards (SABS) for

bandages and dressings, crutches and walking aids, and surgical sundries and administration accessories. The alignment of the specifications with the SABS standards is expected to improve the quality of medical-related items procured for public healthcare facilities.

SIAPS committed to supporting the development of a master set of standard operating procedures (SOPs) for pharmaceutical services for the NDOH. During this quarter, a meeting was held with the director of Affordable Medicines to agree on the plan for developing these SOPs. Subsequently, SIAPS has begun identifying and categorizing relevant SOPs according to the specific functions performed in a hospital pharmacy. This work is ongoing.

South Africa has a high burden of drug-resistant tuberculosis (DR-TB). SIAPS is supporting the NDOH in its efforts to decentralize the management of DR-TB patients. SIAPS provided input for the development of a policy framework for the management of DR-TB initiated by the MDR-TB Directorate of the NDOH. Feedback is awaited from NDOH on the draft policy framework.

SIAPS facilitated a strategic planning meeting for the Northern Cape (NC) provincial pharmaceutical services directorate. A draft action plan which includes proposed indicators for the directorate was developed and reviewed with SIAPS assistance. Follow-up support will be provided in finalizing the plan in the following quarter. SIAPS also participated in a strategic planning workshop organized by the LP DOH: Pharmaceutical Services. The aim of the workshop was to align the provincial strategic objectives and indicators with the National Medium-Term Strategic Framework 2014-2019 and the National Development Plan 2030. SIAPS assisted with development and alignment of indicators for the work planned in the province.

Support was also provided to NDOH to facilitate a stakeholder consultation meeting for private sector service providers of centralized dispensing services and the provinces on the review and revision of Board Notice 49 of 2015 of the South African Pharmacy Council, which relates to Good Pharmacy Practice (GPP) rules published in terms of the Pharmacy Act. The board notice proposes several amendments to rules regulating the provision of pharmacy services which have implications for NDOH initiatives, such as collection of medicines from alternate collection points through the Centralized Chronic Medicine Dispensing and Distribution (CCMDD) Program.

SIAPS provided support for the KwaZulu-Natal (KZN) district pharmacist's quarterly review meeting. During this meeting, indicators and the data dictionary were revised to accommodate shifting priorities in the province as well as the NDOH norms and standards for pharmaceutical services.

In FY13, SIAPS supported the NDOH to establish a set of norms and standards for the delivery of pharmaceutical services and for routine monitoring utilizing a dashboard. During this quarter, SIAPS provided support in the collation of provincial reports in preparation for the NHC sub-committee meeting. SIAPS is providing technical assistance to two provinces to improve their score related to one of the measures which requires evidence of a current provincial medicines formulary. SIAPS is working with LP and Gauteng (GP) provinces to finalize their formularies and ensure their alignment with the newly awarded contracts. Once the contracts have been



finalized for this period, formularies can be completed and submitted to the provincial Pharmacy and Therapeutic Committees (PTCs) for approval. As the first step to support the revitalized North West (NW) PTC to comply with the dashboard standards, SIAPS facilitated an induction workshop in collaboration with the AMD of NDOH. The purpose of the workshop was to assist the provincial PTC to strengthen their support for rational medicines use (RMU) in the province.

**Objective 2: Capacity of personnel for the provision of pharmaceutical services enhanced (IR 2)**

Building on the initiative from 2013, SIAPS worked with the University of Western Cape (UWC), Schools of Public Health and Pharmacy, and Boston University to develop an online RMU elective module for the master of public health program. The material developed during 2013 for the UWC winter school formed the basis of this new online module. SIAPS was responsible for development of the following modules: investigating the underlying reasons for medicine use problems, evidence-based medicine, value for money, RMU, PTC and RMU, and AMR.

SIAPS assisted Nelson Mandela Metropolitan University (NMMU) with updating training material for the PTC and medicines supply management courses. As part of the focus on ensuring sustainability, SIAPS has transitioned training materials to NMMU where these courses will be offered as core modules for third-year BPharm students. SIAPS worked with Sefako Mkgatho Health Sciences University (previously University of Limpopo, Medunsa Campus) and UWC on the finalization of memoranda of understanding (MOUs) outlining the support provided to these universities. The annexure to the existing MOU between SIAPS and NMMU was updated to reflect activities for 2015. SIAPS provided training on the RxSolution dispensing module for a lecturer at NMMU.

Since its inception, SIAPS has supported 623 public sector facilities in applying an approach for participatory and continuous performance improvement through the PLDP and the Adopt-a-Clinic Project in LP. Since the inception of the PLDP in South Africa, 51% of the 55 measurable results addressed using the Challenge Model were achieved. Six teams from LP (five district and one provincial team from the provincial depot) completed the program in February and submitted abstracts, presentations, and posters. Final reports are being reviewed and finalized. Team projects included:

- Reducing time taken to pay supplier invoices and improving compliance with the Public Finance Management Act at LP Pharmaceutical Depot
- Improving stock record accuracy at seven healthcare facilities in the Capricorn district
- Improving RMU and compliance of prescriptions with legal requirements at three hospitals in Mopani District
- Improving compliance with National Core Standard (NCS) at ten PHC clinics in Sekhukhune District
- Improving efficiencies of the CCMDD Program in Vhembe District
- Implementing RxSolution for stock management at Mokopane and Warmbaths Hospital pharmacies in the Waterberg District

A final technical report is being developed for provincial pharmaceutical services management. The Leadership Development Program (LDP) was completed by 24 participants in the WC-NTSS in 2013. These teams of facility and pharmacy managers from 12 PHC facilities used the LDP approach to develop and implement a quality improvement plan to address a specific workplace challenge. Results achieved by these initiatives were presented to senior management in May 2013. SIAPS assisted the sub-structure management to develop an approach to scale up successful initiatives at all 12 facilities and sustain them for a year. Four key outputs were identified and incorporated into the performance plan for both the facility and pharmacy managers. A monitoring tool was developed by the director of Pharmaceutical Services in NTSS and used by the district office to monitor progress toward achieving and sustaining the quality improvement initiatives identified. Results achieved during the period May 2014 to February 2015 were shared with senior management from Metro District Health Services, Provincial Pharmacy Services, and universities within the province in March. The four key initiatives sustained were:

- Reducing waiting times for patients receiving a chronic medicine parcel at the pharmacy to less than 30 minutes
- Instituting procedures so that 15% of patients receiving chronic medicine parcels can collect them off-site or at an alternate site
- Ensuring 100% compliance with applicable norms and standards per NCS
- Sustaining a quality improvement initiative unique to each facility

The director of Pharmaceutical Services in NTSS shared the gains made and successes from the sub-structure at the South African Association of Hospital and Institutional Pharmacists (SAAHIP) Conference held in the Drakensberg in March 2015. This presentation was made as part of a two-hour workshop facilitated by SIAPS entitled “Pharmacy leaders for the future – Are we doing enough?” During this workshop, delegates deliberated on how, as a collective, the pharmacy profession in South Africa is nurturing the leadership mindset; developing a pipeline of leaders; and how the baton of leadership can be passed onto the new generation.

Following the success of the LDP in the NTSS, a similar process started for 27 participants from the Khayelitsha Eastern Sub-structure in the same province. The first workshop was held for facility, clinical, and pharmacy managers from 11 facilities.

In KZN, 13 teams are involved in sustaining and scaling up PLDP quality improvement initiatives and using the LDP approach to deal with challenges in pharmaceutical services. Two workshops and one coaching visit have already been held in the province to assist the district teams in conceptualizing the process, identifying challenges and developing measurable results to be achieved. All teams have identified a challenge at the district or facility level and developed an M&E plan and key indicators. The majority of the teams have completed their baseline assessment; key actions have been identified and teams are in the process of implementing these interventions. The province has requested assistance with a plan to measure the impact of the PLDP. The next coaching visit for the province is scheduled for May 2015.

**Objective 3: Use of information for decision making for pharmaceutical services improved (IR 3)**

SIAPS continued to support the implementation of information systems to support two key NDOH initiatives, namely the DDV procurement model and management of tenders.

The MPC, which was developed from all items on pharmaceutical contracts, has been signed off by the NDOH, loaded on the NDOH website, and is being used by all provinces to monitor and report on availability of medicines which appear on the Essential Medicines List and are used in each province. The process of identifying non-standardized codification is ongoing. The item databases of LP, Mpumalanga (MP), and the Free State (FS) are currently being reviewed by the NDOH with the provincial counterparts.

As reported previously, SIAPS contributed to the development of a framework for the MPC which will form part of the National PMIS. The draft framework was revised and disseminated to NDOH and SCMS for comments. Once finalized, the document will be submitted to NHC for adoption.

In an effort to streamline the process for receiving bids on tenders, SIAPS contributed to the development of editable pdf forms for two tenders (condoms [HM01] and administrative accessories [HM10]), which were published in February 2015. The forms enable potential suppliers to capture and submit electronic bids which can be exported into the tender module (RxTender), thus saving time and reducing data capturing errors. The tender module was developed by SIAPS and is being updated for implementation at NDOH. The two tenders have closed, and SIAPS is supporting the extraction of information from the electronic submissions into the tender module.

RxPMPU, a customized version of RxSolution, has been implemented at the NDOH for management of orders and monitoring of supplier performance in the DDV model. The DDV model is currently being used to facilitate procurement of antiretrovirals and other medicines in GP and LP. During the quarter, the pilot was initiated for the interface developed between RxPMPU and one of the supplier's systems to facilitate easier exchange of information, such as purchase orders. The standard order form used by facilities to place orders on RxPMPU was updated to show voucher numbers and allow for four signatures. Updating the signatures ensures that the forms meet legal requirements.

SIAPS is currently in the process of testing the latest version of RxSolution, which is expected to be rolled out this year.

SIAPS supported the implementation of Infomaker<sup>®</sup>, an off-the-shelf commercial report-building software in the FS depot and at Ermelo Hospital. Support included advanced training and customization of reports. Training was also provided to GP and Eastern Cape (EC) provincial office staff.

A SCMS/SIAPS Shared Enterprise Workshop was held to clarify the roles and responsibilities of both parties in providing technical assistance for PMPU activities at the NDOH and provincial

departments of health (PDOHs). The following expectations were charted to reach a common goal with regard to collaboration and implementation of PMPU activities:

- Clarify understanding around the two projects working together
- Ensure that roles and responsibilities of both parties are clear
- Identify required capabilities and agree on execution of joint activities
- Determine how the two projects can work together to lay the basics for the NDOH control tower
- Ensure alignment with NDOH plans
- Develop a joint project plan
- Facilitate synergy among projects and sub-projects

The two projects are now holding joint meetings on a weekly basis. The initial focus after the workshop is the development of a project charter, activity plan, and communication strategy. Provincial steering and technical committee meetings for the implementation of RxSolution were held in the EC, KZN, and NC. The project charter for RxSolution implementation in the FS has been revised and is waiting sign-off.

RxSolution is currently installed in 354 public healthcare facilities across South Africa. SIAPS continued to provide technical support to all these sites. The support comprised in-service training on medicine supply management, assistance in stock-taking at facilities, electronic ordering processes using RxPMPU, interfacing with the remote demander module, demand planning using consumption data extracted from the medical depot (mainly in GP), and facility usage reports for both GP and LP. Staff employed by Health Systems Trust (HST) to implement RxSolution in the NC (Pixley Ka Seme District) as well as ANOVA staff (LP) were trained. On-site training at facilities is provided as part of ongoing support.

As part of quality assessment activities for the roll-out and implementation of RxSolution, 164 facilities where RxSolution has been installed were contacted during this quarter to determine the level of usage of the system and the support given thus far by SIAPS and partners. A questionnaire was sent to pharmacy managers to obtain their perspectives. So far, responses have been received from 52 facilities. Any reported challenges and/or comments were shared with the implementation team for further action.

A technical progress report on the implementation of RxSolution in GP was compiled and submitted to NDOH. Another report on the technical assistance provided to Chris Hani Baragwanath Academic Hospital was also prepared and forwarded to NDOH.

Following the minister of health's announcement in 2014 that RxSolution would be rolled out countrywide, there has been an unprecedented increase in demand for the program; 7 sites in the NC have been earmarked for assessment and 36 sites prioritized for RxSolution implementation in the EC. SIAPS and the Foundation for Professional Development (FPD), a PEPFAR-funded partner, have started the process of assessing 51 clinics in Tshwane District for implementation of RxSolution. An exploratory visit was made to King Edward Hospital in KZN with a view to install RxSolution at this facility. SIAPS assisted the pharmacy in calculating stock levels using historic consumption data. In addition, SIAPS has been requested to install RxSolution in 700

National Health Insurance (NHI) clinics across the provinces. Discussions between NDOH and SIAPS on mobilizing resources to achieve this task are underway. NDOH also requested SIAPS strengthen the procurement of medicines of port health clinics by implementing RxSolution. SIAPS will develop an implementation plan for Port Health Clinics and share the plan with the NDOH.

#### Partner contributions

- SCMS: Currently managing the NDOH PMPU
- HST: Ongoing technical support to facilities with RxSolution implementation
- FPD: Started implementation of RxSolution in Tshwane District clinics; also contributed to the review of the product list at the LP pharmaceutical depot to align it with the MPC
- BroadReach: Procured 25 workstations to be used for RxSolution in community health centers, clinics, and at the Central Dispensing Unit in Ekurhuleni

#### Constraints to progress

MOUs for RxSolution have not been signed for all the provinces where the system is implemented. SIAPS is continuing to engage stakeholders to facilitate the finalization and signing of MOUs.

#### ***Objective 4: Financial mechanisms strengthened to increase access to medicines (IR 4)***

The Central Procurement Unit (CPU) of the NDOH submits quarterly reports to the Global Fund, as well as updates on the pharmaceutical supply management plan. SIAPS provided strategic technical support to the NDOH Global Fund cluster to facilitate the reporting process and improve the quality of reporting, with a particular focus on completeness.

SIAPS assisted with monitoring of expenditures on items procured with Global Fund resources. Strengthening the CPU reporting system to comply with Global Fund requirements will ultimately help broaden CPU's authority. TORs were confirmed for assistance that would be required by the Global Fund-NDOH from SIAPS in 2015. Support included updating the procurement supply management (PSM) plan, reviewing quarterly dashboard submissions to the country coordinating mechanism, and reviewing the work plan. SIAPS was responsible for developing a work plan of procurement activities for the Global Fund-NDOH that SIAPS would support. SIAPS facilitated meetings with Global Fund-NDOH and CPU. In preparation for meeting with the Global Fund, SIAPS supported the Global Fund-NDOH unit in recommending a way forward for updating the product quality reporting tool. In March 2015, SIAPS took the initiative to start an update on the PSM plan to meet the April deadline. The draft document has now been shared with the Global Fund-NDOH, and SIAPS is awaiting information to update the document further.

SIAPS advised NDOH on management of expired stock. This included reviewing the contractual requirements with the Domestic Distribution Centre where Global Fund stock is warehoused to show how expired stock should be handled. The Global Fund would like to promote a mapping

of procurement activities for inclusion in a Global Fund concept note. SIAPS supports the majority of procurement activities in country and has offered assistance in this regard. A summary report outlining the Global Fund activities in South Africa was developed for inclusion in a broader report to USAID.

**Objective 5: Pharmaceutical services improved to achieve desired health outcomes**

SIAPS completed the academic detailing for 21 sections of the PHC STGs/EML 2014. Currently SIAPS is helping with the final review of the first seven chapters of the first draft of the PHC book. In addition, SIAPS supported NDOH in developing an implementation and roll-out strategy for the PHC guidelines based on previous experience in implementing the pediatric STGs in 2014. SIAPS has recommended that the PHC roll-out be in the form of training sessions conducted in each of the nine provinces by representatives of the Essential Drugs Program (EDP) unit of NDOH. A pamphlet and flow diagram showing the cascade approach for implementation of the PHC STGs and EML was shared with the heads of Pharmaceutical Services. SIAPS facilitated the obtaining of permission from the Medicines for Malaria Venture (from Switzerland) to use material in the PHC implementation, and drafted the foreword and introduction to the PHC STGs and EML 2014 for signature by the minister of health and director general of health of NDOH, respectively. SIAPS identified and created a database of key stakeholders that NDOH can use to ensure effective dissemination of EML chapters for comment and distribution once finalized.

To promote understanding of the changes in the PHC STGs, SIAPS drafted three summaries for potential publication in the *South African Pharmaceutical Journal* (SAPJ). SIAPS also provided input on an introductory article written for the SAPJ by NDOH in collaboration with an EML committee member.

SIAPS assisted WC Pharmacy Services with training 46 healthcare professionals in RMU. The training focused on pharmacists, doctors, and nurses who are responsible for medicine management. During the training, participants were required to develop criteria for the evaluation of aspirin use within the province. This tool will be developed further to allow a province-wide medicine use evaluation. SIAPS trained members of two district PTCs in KZN. The eThikwini District PTC was established as a result of the PLDP offered by SIAPS in KZN.

SIAPS provided ongoing technical support to the NDOH Pharmacovigilance Centre (NPC) in implementing the decentralized pharmacovigilance (PV) system nationally. SIAPS facilitated the roll-out of the NPC decentralized PV system in 24 clusters (comprising 266 feeder clinics) that are currently reporting adverse drug reactions (ADRs) in MP. A further 20 clusters were formed from 294 facilities in NW. Phase 2 implementation training was completed in the previous quarter. This phase seeks to stimulate reporting and improve the quality of reports received. Approximately 20 clusters are actively reporting and 4 clusters have regular meetings. SIAPS customized-support visits were undertaken for Potchefstroom and Nic Bodenstein clusters in January and February 2015. During this quarter, 137 ADRs were reported from MP (29) and NW (108). NC was identified as being the next province in the national roll-out. Phase 1 implementation training was done in February 2015 and planning took place for phase 2 training

and cluster formation in the province. SIAPS is currently involved in the planning phase of a new concept related to developing a “PV district support team” for monitoring and support of the clusters in each district. This team will be comprised of nurses, doctors, and pharmacists from different clusters and will also act as a link to the district PTC.

SIAPS provided ongoing technical assistance in interpretation of data collected from sites where NPC has been rolled out.

Current data sets presented for this quarter from the NW include the proportion of ART patients who reported grade II to IV ADRs (suspected) segregated by the specific antiretroviral drug regimens and the association of significant ADRs reported in patients on ART with the specific ART regimens and age.

This data is currently being prepared for a publication entitled Reported Incidence of Adverse Drug Reactions in Patients on Antiretroviral Therapy in North West Province of SA. SIAPS chaired a session at the Symposium on Clinical Research in Africa where PV systems throughout East, Central, and Southern Africa were discussed.

In the current work plan, SIAPS has planned to work with Gauteng PDOH, the Dr. George Mukhari Academic Hospital (DGMAH), and the Sefako Makgatho Health Sciences University to build a hospital pharmacy model at DGMAH that can serve as a center of excellence for pharmaceutical services. The aims of this model, which can be replicated in other tertiary hospitals, are to ensure the availability of quality essential medicines for HIV, TB, and non-communicable diseases, serve as a learning site for students and health personnel, and support quality patient care. During this quarter, a stakeholder engagement workshop was conducted, a steering committee was established, and a needs assessment conducted to identify priority interventions. Four project teams were established and an implementation plan developed. The goals of each project team are to:

- Ensure the functionality of the Infection Control Committee and the hospital PTC (governance and management)
- Set minimum and maximum stock levels on RxSolution and conduct ABC analyses (pharmaceutical supply)
- Improve compliance with the three phases of dispensing as per GPP and implement the RxSolution dispensing module (dispensing and supply to individuals)
- Improve monitoring and reduction of adverse drug events and medication errors (safe, appropriate, and cost-effective use)

Work has commenced with the pharmaceutical supply team. Minimum/maximum stock levels have been set and staff trained. Orders are being placed and received using RxSolution. Work with the other teams will continue in the next quarter.

Technical assistance was provided to the GP Pharmaceutical Services Directorate on the calculation of maximum stock factors to ensure proper ordering at the facility level. This is a follow-up to the medicine supply management training of trainers’ workshop conducted by SIAPS in partnership with SCMS.

SIAPS attended the NDOH-initiated expert consultative meeting on TB regimens. The purpose of the meeting was to focus on the effectiveness of the current TB treatment regimen used to treat drug-sensitive TB. SIAPS made two presentations on the pharmaceutical management assessments for TB and HIV conducted in provincial health facilities and health centers of the Department of Correctional Services (DCS). The first presentation focused on the supply chain component, while the second one focused on adherence to STGs. SIAPS will continue to provide technical assistance to both NDOH and DCS as planned in the current work plan. Technical assistance in DCS is subject to signing of a MOU between the two parties, a draft of which has been submitted to DCS.

In LP, induction workshops were held for community service pharmacists (CSPs). The induction included lessons learned from the Adopt-a-Clinic initiative which focused on supporting pharmaceutical services at clinics. SIAPS supplied training manuals and PowerPoint presentations for medicine supply management training that will be conducted by district pharmacists and district CSP coordinators. With SIAPS support, two podium presentations were made at the 2015 SAAHIP conference on work done by CSPs in 2014 as part of Adopt-a-Clinic.

The NDOH assigned 37 CSPs to the DCS. The DCS Pharmaceutical Services Sub-Directorate organized a two-day induction and orientation workshop for 46 CSPs and newly appointed pharmacists and pharmacist's assistants in the EC. SIAPS was invited to facilitate a session on medicine supply management. An electronic version of the guidelines for the implementation of PTCs in GP and MDS-3 were also shared.

SIAPS was invited by the KZN DOH to conduct a refresher course on the Infection Control Assessment Tool. An activity on hand hygiene was conducted with the involvement of all 19 participants. At the request of the NDOH-Quality Assurance Directorate, SIAPS provided the FS DOH with 1,250 copies of the hand hygiene poster to support IPC activities.

SIAPS presented a poster entitled Strengthening Infection Prevention and Control Systems in Resource-Limited Settings by using a Self-Assessment and Continuous Quality Improvement Approach at the 15th International Congress of the International Federation of Infection Control in New Delhi, India.

#### *Partner contributions*

- I-TECH: Sponsored training, audio-visual material for PV training
- Right to Care: Employed a PV coordinator in MP
- FPD: Facilitated sessions during the induction of CSPs in Capricorn and Sekhukhune Districts and ANOVA-facilitated sessions in Vhembe and Mopani Districts in LP

#### *Constraints to progress*

- Inadequate monitoring of cluster meetings in the NW because a provincial PV coordinator has not been hired



- Differences in the document format used by the communications unit of the NDOH and the EDP, resulting in delays in the finalization of the PHC STGs; SIAPS is working with the EDP to finalize the document

## South Sudan

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

### ***Overall Quarter Progress***

SIAPS continues to support USAID-approved activities within the two states of Western (WES) and Central Equatoria (CES). SIAPS works within the USAID operational framework of ensuring that critical areas of the pharmaceutical sector are improved while maintaining the developmental gains achieved over the period with focus on the two states of WES and CES. SIAPS continues to collaborate and leverage resources with partners to expand the pharmaceutical and malaria interventions across the whole country.

During quarter 2, SIAPS supported the distribution of essential medicines/EMF commodities to facilities in various states including CES. These commodities include oral rehydration salts, antibiotics, antimalarials (ACTs), and sulphadoxine pyrimethamine (SP) for intermittent preventive treatment in pregnancy and oxytocin for reduction of maternal and child deaths.

SIAPS supported USAID | DELIVER in reviewing and completing the standard operating procedures (SOP) for the Central Medical Store (CMS). These SOPs will help CMS staff improve the management of the commodities in the warehouse and ensure warehouse standard practices. It also forms part of the capacity-building efforts by USAID | DELIVER to the CMS. These SOPs will strengthen commodities management and improve the general supply chain for drug storage and distribution in the country.

SIAPS led the development of the malaria newsletter (to be distributed on 2015 World Malaria Day) through solicitation and review of articles from program leads within the NMCP, WHO, and partners. This newsletter publicizes the progress of the Malaria Programme in South Sudan and is also an advocacy and resource mobilization tool for malaria control in the country. SIAPS has written four articles on the following topics: the South Sudan Malaria Programme Review (MPR), 2013; the second South Sudan Malaria Strategic Plan, 2014/15-2020/21; the second South Sudan Malaria Indicator Survey (MIS), 2013-14; and support of SIAPS to South Sudan's National Malaria Control Programme.

During this period the SIAPS country program director, SIAPS management based in Arlington, and USAID South Sudan had a number of strategic discussions and interactions by email, Skype, and phone to revise and agree on the broad directions for the SIAPS program.

Some of the indicators that we are reporting on include:

- 1) Number of pharmaceutical management trainings conducted in WES and CES: 5/16 roll out trainings
- 2) Number of counties submitting monthly stock status report (16): stock status reports for 6 counties collected in CES; activities in WES limited by absence of technical staff, which will improve after recruitment of a technical advisor and a data officer for the state

- 3) Number of constituted Pharmaceutical Technical Working Groups (PTWGs): the program has initiated four PTWG meetings this quarter, which exceeds the expected four meetings for the year

**Objective 1: Pharmaceutical services improved to achieve desired health outcomes**

SIAPS worked with CES MOH to deliver ACTs received under EMF Lot-7 to all six counties. SIAPS stepped in for USAID | DELIVER to support the distribution based on a request from the State MOH (SMOH) and USAID. With SIAPS technical support, the ACTs have currently been shipped to the various counties.

SIAPS provided technical and logistical support to Morobo County in CES in the distribution of EMF commodities to health facilities that had been requested earlier but could not be delivered because of logistic challenges. These health facilities included Aboroto, Payume, Lujulo, and Aloto Primary Health Care Centers (PHCCs) and Yaribe and Kendila Primary Health Care Units (PHCUs). SIAPS engaged the county's implementing partners in the process.

To ensure correct and uninterrupted supply of medicines to improve the maternal mortality indicators, SIAPS prepared labels for misoprostol tablets for three counties in CES (Kajokeji, Terekaka, and Lainya). These were delivered to the respective counties in preparation for the upcoming introduction of Home Health Promoters programs. This will ensure proper management and track the use of misoprostol and ultimately ensure that pregnant women are protected from death. SIAPS continues to provide technical assistance in the management of the CES medical store (which also holds supplies for Juba County) to ensure smooth operation, appropriate medicine storage, and proper inventory management practices (e.g., store arrangement of medicines, stock card update, receipt and issue of medicines). Currently, supplies are issued based on requests from facilities as part of the pull system. Condoms and ARVs from PEPFAR are also stored at the CES medical store.

SIAPS, as part of support to the National HIV Department through PEPFAR, carried out an HIV commodities quantification on January 21, 2015. SIAPS facilitated the process and compiled the quantification of OI commodities, e.g., co-trimoxazole. The updated quantification document was shared with the quantification team. This activity ensures that partners (MOH and PEPFAR) can initiate procurement in a timely manner to avoid stock-out of OIs and contribute to the AIDS-Free Generation agenda.

SIAPS prepared a commodity procurement information request for procurement of antimalarial commodities to support WES and CES. In all, 400,000 LLINs, 630,000 doses of ACTs, and 250,000 doses of SP are to be procured through USAID | DELIVER and stored at the state warehouse for distribution to the various counties in the two states. These supplies will help prevent and treat malaria-related ailments and save lives.

SIAPS facilitated a de-junking exercise for Nagero County (WES), following a request by Integrated Services Delivery Program (ISDP) (supports the county in implementing primary

health care services). SIAPS de-junked the county store of expired commodities from previous Multi-Donor Trust Fund supplies and freed up space to receive the current EMF supplies.

### *Partner contributions*

The project has collaborated with ISDP, Health Pool Fund, and USAID | DELIVER to ensure that issues related to drug supply and pharmaceutical management are addressed.

### *Constraints to progress*

The general insecurities continue to greatly affect drug supply and management in the county, with certain areas very difficult to reach due to the conflict.

In CES and WES, some counties do not have store keepers and pharmacists who can be accountable for the management of drugs. This affects the management of the drug supply and capacity-building efforts by the program.

Selected counties and health facilities have challenges with shelves and pallets, which results in poor storage and management of EMF supplies. The program has initiated procurements of pallets to reduce the problem.

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

To increase and enhance the capacity for pharmaceutical supply management and services, SIAPS continues to provide technical assistance in the day-to-day management of the CES medical store, ensuring smooth operation and appropriate medicines storage and inventory practices, including arrangement of medicines in the store, stock card update, and receipts and issues of medicines.

SIAPS conducted supportive supervision of Yei, Morobo, and Terekeka Counties in CES, with the objective of improving facilities with poor stock status reports and drug requisitions. In Morobo County, SIAPS and the Action African Help-International (AAH) facility supervisor visited Yondu, Lujulo, and Yogufe PHCUs and Kaya PHCC. In Yei County, SIAPS, in partnership with the county assistant administrator and AAH facility supervisor, visited Pisak, Logo, and Wadupe PHCUs and Mugwo and Payawa PHCCs. In Terekeka County, SIAPS, in collaboration with the county M&E staffs, visited Lojora and Jobem PHCUs. In all, SIAPS provided on-the-job training to 11 male and 2 female staff.

SIAPS provided introductory training on computer use and its application to CES warehouse staff (3 male and 1 female). This is to capacitate warehouse managers to prepare them for future computer-based management of commodities to improve efficiency and reduce workload.

SIAPS conducted on-the-job training on the use of pharmaceutical tools and store arrangement for facility staff in Kogulu, Kimba, Rodoba, Yaribe, and Moiyo PHCUs and Lasu, Aboroto, and Payume PHCCs to improve pharmaceutical management. In all, 18 staff was trained (12 male

and 6 female). These trainings will ensure that data on drug use and management at facilities is improved so that it can be used for decision making and quantification.

SIAPS facilitated a three-day pharmaceutical management training in Nimule (CES) as part of support to other partners in strengthening pharmaceutical management activities. The training focused on best practices and standards for handling and storage of pharmaceuticals so that they can apply these standards in their health facilities. Participants received materials to guide implementation in their various facilities. All from Nimule Hospital, 20 participants (5 males and 15 females), were trained.

SIAPS, as part of the roll out of pharmaceutical management training after the TOT in the first quarter, conducted three days of pharmaceutical management training in Kajokeji (CES). The training focused on inventory management through proper use of stock cards, dispensing registers, issue and receipt vouchers, and storage management. In all, 24 participants (12 male and 12 females) were trained. These trainings are so critical to also ensure that the current distribution of EMF commodities reach the intended beneficiaries to save lives and ensure good storage practices.

#### *Partner contributions*

The project has collaborated with ISDP and Health Pool Fund to ensure that pharmaceutical management trainings are rolled out throughout the country.

#### *Constraints to progress*

Human resources are a challenge at the facilities, and the capacity to undertake pharmaceutical management tasks is minimal. This leads to difficulty in rolling out program activities.

#### ***Objective 3: Pharmaceutical management information made available for decision making at different levels of the health system***

To ensure that information for decision making is enhanced, SIAPS continued to provide monthly stocks status reports through the Logistic Management Unit for CES. During the monthly report data collection and feedback to the counties, the team noted that there has been a continuous decline in the rate of stock-outs of tracer medicines in all counties. This can be attributed to the effective distribution of EMF throughout the country. In general, CES stock-outs reduced from 29% in September 2014 to 14% in December 2014. SIAPS continues to provide emergency support to facilities that are stocked out in CES and WES.

SIAPS carried out an assessment at the ART center in Juba Teaching Hospital (JTH) as part of plans to install the Electronic Dispensing Tool (EDT). The SIAPS team conducted the assessment using a questionnaire to identify the gaps in the facility's supply system. SIAPS has also developed various SOPs for HIV supply chain management for JTH; they were developed from the tools currently being used to manage commodities. The EDT, once established, will provide the needed solutions to improve the supply chain system for ART management at JTH and contribute toward an AIDS-Free Generation.

SIAPS compiled the fourth quarter PPMRm, which includes the national antimalarial stock status as of December 31, 2014. The data is used globally for the early warning system to monitor countries' antimalarial stock status including information on drug selection, procurement, and distribution. The report showed that most of the antimalarials have approximately 4-5 months of stock, which is consistent with the current pipeline and procurements in the country.

As part of inventory management and strengthening of data collection, SIAPS visited the PHCUs at Gurei, Malakia, Secrete Heart, Mahad, Kator, Gumbo, Hai Jebel, Gudele, St. Kizito, Gudele Block 4, and PHCCs at Nyokuron and Munuki.

### *Partner contributions*

Human resources are a challenge at the facilities, and the capacity to undertake inventory management tasks is minimal. This leads to delays in receiving prompt and accurate reports for analysis. The program has only one data officer to cover both WES and CES, which has made it impossible to get information from WES.

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

Due to changing focus of the program in pharmaceutical sector governance, SIAPS role is limited in supporting the review and update of the STG/EML. Currently, SIAPS is collaborating with WHO to establish the committees and partner discussions for this process to begin, using the PTWG as the forum for discussion and implementation of this review. WHO is taking the lead for this entire process and will engage a consultant until completion. It is expected that, after the review, partners will support the printing and dissemination of the document in their various states.

### *Constraints to progress*

The newly established Drug and Food Control Authority is lacking enough human resource to engage in fruitful discussions in the EML/STG.

### ***Objective 5: Scale-up of malaria interventions accelerated, better coordinated, and documented***

A Malaria Technical Working Group (MTWG) met to finalize the Malaria Annual Operational Plan (AOP) for 2015–2016. This document will guide the NMCP to prioritize its activities and ensure effective implementation of malaria interventions. Following finalization of the consolidated AOP by NMCP and partners, SIAPS supported CES and WES in the development of their AOPs. Working from a crude draft received from the state malaria coordinator for CES, SIAPS prepared a draft plan based on a Roll Back Malaria generic template. The refined draft was sent to the state coordinator for review and feedback.

A Malaria Case Management TWG meeting was held to discuss country malaria updates, seasonal malaria chemoprevention, finalization of malaria case management and training guideline, and the summary NMCP plan for 2015. SIAPS participated in discussions and prepared and gave a presentation on the malaria situation in South Sudan. The meeting recognized the need for more research and documentation regarding adaption of seasonal malaria chemoprophylaxis. On review and finalization of the guidelines, a number of items were suggested for incorporation.

A District Health Information System (DHIS) training for malaria grant implementing partners including NMCP staff was conducted. The DHIS consultant will update the malaria DHIS system including sentinel indicators, which will simplify analysis and reporting of sentinel site data.

A MTWG meeting was held to discuss kick-off of the therapeutic efficacy testing (TET) study. A TET technical committee was formed. A detailed schedule of activities and timelines was drawn to ensure timely protocol submission and implementation. The study will monitor efficacy of currently used first-line antimalarials (including ASAQ) to enable early detection of resistance. SIAPS participated in drafting the schedule of preparatory activities, TORs for the TET technical committee, TET site assessment tool, and a road map for the 2015 TET implementation. With the threat of resistance to ACTs spreading from South East Asia, this study is important. The first TET commenced in 2013, but stopped due to war outbreak. SIAPS staff worked with the NMCP during an integrated disease surveillance and response (IDSR) review meeting, funded by WHO, to review the overall achievements, challenges, and way forward for the IDSR system in the country. This is to improve IDSR performance including the malaria sentinel surveillance system.

SIAPS participated in a Global Fund country team meeting to review the various stages of the malaria application and the steps to grant signing. Following guidance from the Global Fund team, NMCP will identify key activities within the costed extension work plan (January to March 2015) that the program is capable of completing before March 31.

April 25 is World Malaria Day (WMD). Careful planning for the occasion was initiated, involving SIAPS and all partners. Key activities and events were identified. A roadmap to the event was drawn and available resources were mapped. SIAPS provided a tentative budget to support the activity. A WMD technical committee was formed.

The MTWG, in consensus with the Global Fund HQ, drew up a plan for the grand launch of the Global Fund's new funding model grant implementation. The launch (April 1, 2015) will also recognize the award presented to the president of the republic by the African Leaders Malaria Alliance in recognition of South Sudan as the "most improved national malaria control program."

*Partner contributions*

The Global Fund, through PSI, WHO, and USAID, has been supporting malaria activities through the engagement of technical assistance/consultants and advisors. USAID has also contributed to the procurement of antimalarials for case management.

*Constraints to progress*

The human resource capacity at the national, state, and county levels to fully implement malaria interventions is limited. This has limited the ability of the malaria program to fully roll out its strategies at the lower levels. Embedded advisors from SIAPS and WHO are supporting the national program to develop the necessary policies and tools for effective implementation of malaria activities. The Global Fund has also provided resources for the recruitment of key technical personnel such as M&E and logistics officers to support the program.



## Swaziland

### **Goal: Assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes for HIV, tuberculosis, and family planning**

Swaziland continues to adapt global recommendations to scale up treatment access to children, pregnant and lactating women using WHO ART treatment guidelines and the recently launched Swaziland integrated HIV management guidelines (2014). SIAPS continues to support interventions intended to assure the availability of quality pharmaceutical products and effective pharmaceutical services in the management of HIV. SIAPS has supported the MOH and demonstrates results in areas of governance, capacity building, information, service delivery, and financing in the pharmaceutical sector.

SIAPS supported the Office of the Chief Pharmacist in developing Swaziland's medicines donation guidelines to help with importing donated pediatric third-line ARVs, including supporting documents to help plan introducing bedaquiline and delamanid into extensively drug-resistant XDR-TB treatment in Swaziland. SIAPS also provided technical input for the quality control activities for essential medicines imported into Swaziland.

SIAPS coordinated the convening of the supply chain technical working group (SCTWG), which deliberated on the procurement, storage, and distribution of health products including condoms and laboratory commodities. The SCTWG's key activities in this reporting period were contributing to the grant making exercise of the HIV/TB Global Fund grant 2015–2018. SIAPS worked with the principal recipient to develop the procurement and supply management component. To ensure competitive bidding in the health sector, SIAPS supported tender adjudication exercises for ARVs, essential medicines, laboratory commodities and family planning commodities.

SIAPS provided mentorship to 56 health facilities across the country and reaching 62 health care workers on topics such as; warehouse management, inventory management, ARV dispensing and adverse events monitoring. Most facilities have shown improvement in updating stock card and labeling medicines.

The laboratory LMIS recorded a 100% reporting rate and timeliness of reports for the second quarter in a row. SIAPS also recorded improvements in the use of RxSolution after mentoring in the last quarter based on the RxSolution gap assessment conducted in FY14. Moreover, the SIAPS supported Patient Information system Redesign Project (Client Management Information System) is being piloted.

With introduction of new integrated HIV management guidelines, SIAPS prioritized active adverse drug reaction monitoring interventions at all treatment sites. The active surveillance for HIV/TB is going ahead with three new facilities added to the five facilities reported in the previous quarter. After several sensitization exercises, there have been notable improvements in the number of reports received by the MOH pharmacovigilance unit from facilities. SIAPS has also shared its progress on establishment of TB/HIV active surveillance and involving the private sector in TB control in both local and international forums.

Swaziland continues to face challenges in maintaining required levels of health commodities at facilities and the central level. Only 18% of supported ART sites were able to maintain required minimum-maximum stock levels for ARV tracer drugs. Furthermore, 17% of these ART sites reported to have had a stock-out of tracer products for at least three days or more in the last three months. Condom stock levels have also declined in this reporting period. SIAPS continues to support the Central Medical Store and health facilities to rationalize the distribution of ARVs, TB and family planning commodities so as to ensure that treatment is not interrupted. Support has also been provided to help get the budget from the Ministry of Finance supplemented, as well as explore USAID assistance in supplying an emergency condoms and ARVs stock.

### **Objective 1. Strengthen Governance in the Pharmaceutical Sector**

SIAPS continued to provide support to the MOH in strengthening governance of pharmaceuticals to support the HIV management initiatives.

SIAPS supported the Office of the Chief Pharmacist in advocating for the enactment of the Medicines and Related Substances Control Bill and the Pharmacy Bill. SIAPS participated in a meeting with private sector pharmacists to encourage their involvement in the bill's advocacy activities. In addition, SIAPS participated in a meeting between the chief pharmacist and the health parliamentary Portfolio Clerk to strategize on the best approach for the next steps and to map up timelines towards the enactment of the Bills. A briefing note on the bills was also prepared and distributed to pharmacists in an effort to ensure uniformity in the advocacy messages.

SIAPS also supported MOH in maintaining control of the quality of medicines imported into Swaziland. A process has been established to issue tax exemption letters to all registered importers. These letters are used by the Swaziland Revenue Authority to exempt the importers on all prescription medicines. This is an effort to restrict medicines importers to only those registered with the MOH and curb the importation of substandard, restricted, or prohibited medicines. In the next quarter, SIAPS will continue supporting the activities towards establishing the MRA, including the maintenance of medicines registration system.

In addition, SIAPS supported drafting guidance papers to inform the importation of donated new drug molecules into Swaziland. These will inform the decisions to be made by MOH senior management on handling the donation and importation of products such as bedaquiline and delamanid for MDR and XDR-TB treatment in Swaziland.

In this quarter, SIAPS continued facilitate the convening of SCTWG meetings, to deliberate on pressing supply chain issues impacting the availability of ARVs, family planning including condoms, essential medicines, laboratory and malaria commodities. In addition to the support provided to the SCTWG, SIAPS continues to support weekly supply chain meetings organized by the Swaziland Health Laboratory Services (SHLS) in which stakeholders and partners get an opportunity to advise the SHLS management on supply chain-related matters. SIAPS also participated in the condom TWG meeting.

### *Constraints to Progress*

The Office of the Chief Pharmacist did not convene a public sector pharmacists' meeting this quarter because of other conflicting activities including the tender adjudication and CMS's annual stock taking activities. Thus the SPSP M&E framework could not be presented at this forum for finalization.

The poor attendance by key players within the supply chain of health commodities, pharmacists responsible for ARVs, TB, and essential medicines is a challenge that has been faced by the TWG even in this quarter. However, there has been an improvement in that at this quarter's meeting there were presentations for ARVs and essential medicines although the pharmacists responsible were not present.

### **Objective 2. Increase Capacity for Pharmaceutical Supply Management and Services**

SIAPS continued to build capacity of health care workers in pharmaceutical management. During this quarter, SIAPS planned to continue conducting mentorships as well as onsite and off-site trainings targeting health workers responsible for stock management and ARV dispensing.

SIAPS conducted a training for Mbabane Government Hospital and Mankayane Government Hospital on setting up Pharmaceuticals and Therapeutics Committees (PTC)—30 participants (20 females, 10 males) were trained over two days. These hospitals are expected to have their first meeting of establishing a PTC in their facilities in the next quarter and terms of reference have been drafted for the PTC.

Fifty six health facilities were visited for supportive supervision across all the regions of the country, i.e., Hhohho—12 sites, Lubombo—17 sites, Manzini—16 sites, Shiselweni—11 sites, and 62 health care workers (HCW) were mentored on topics such as warehouse management, inventory management, dispensing, and pharmacovigilance. There has been a general improvement in areas of stock card updating and good dispensing of medicines.

As a follow-on to last year's SIAPS and the SHLS training program on implementing the two-tier LMIS, SIAPS visited 12 mini-laboratories and 2 main laboratories to observe improvements in stock management and to provide mentorship and support the laboratory staff on commodity management. At these facilities, 15 HCWs were mentored with the aim of ensuring that they are well equipped with appropriate laboratory commodity management skills.

Moreover, SIAPS in collaboration with SHLS and the University Research Council to provide training to 35 laboratory personnel from mini-laboratories on Point of Care (ISO 22870) and quality training.

### *Constraints to Progress*

Because of the large volume of patients and staff shortages at certain facilities, the provision of adequate mentorship continues to be compromised. The technical advisors continue to work with the regional health management teams to identify the best time and method to conduct mentorship at health facilities. SIAPS continues to prioritize the large volume facilities and their feeders to receive mentorship and supportive supervision.

### **Objective 3: Address Information Utilization for Pharmaceutical Management Decision making**

During this reporting period, SIAPS conducted routine site visits and mentorship on RxSolution as informed by the assessment exercise conducted in the last quarter targeting level of use for RxSolution in all sites countrywide. Ten health facilities and nine health workers were mentored on good inventory management practices for requisitioning, storage, distribution, and dispensing of pharmaceuticals and medical supplies using RxSolution. In the next quarter, SIAPS will increase mentorships and support to other sites in Shiselweni and Manzini regions, ensuring that sites can optimally management inventory through RxSolution.

SIAPS also continued to support the rollout of the web-based Commodity Tracking System (CTS) at the CMS to capture ARV, SRH, and TB. SIAPS successfully completed the system development phase with the contracted vendor. All deliverable materials were submitted and approved by project team, including system documentation, source code, application, and data migration tools. SIAPS, in collaboration with MOH Strategic Information Department, developed an implementation plan for making the system operational at central level.

SIAPS also supported the central warehousing in improving reporting of logistics data from facilities. During the quarter, 87% ART sites managed to complete and submit an ART LMIS report for the quarter ending March 2015, illustrating a 2% decrease in performance from the quarter ending December 2014. The laboratory LMIS recorded a 100% reporting rate for quarter ending March 2015 consistent with the previous quarter. of Reports timeliness continues to be a challenge with this quarter with only recording a 56% of ART sites being on time—a 10% decrease in performance for the quarter ending March 2015. On the other hand, the lab LMIS stream of data reports were 100% on time. The consistent good performance of the SHLS can be attributed to their use of the CTS and the presence of a dedicated data entry clerk to receive and capture the reports from facilities. In the next quarter, SIAPS will support MOH to conduct a data quality exercise to ascertain the sites' challenges with reporting and maintaining quality data outputs. The importance of receiving quality reports continues to be emphasized during site supportive visits as this is essential to stock management and making decisions on procurement and distribution. SIAPS works with CMS and SHLS in using the reports from facilities to identify areas that need attention and supports health workers to mentorship and supportive visits to facilities.

#### **Objective 4. Financing Strategies and Mechanisms Strengthened to Improve Access to Medicines**

After the approval of the concept note by the Global Fund, the country moved on to the grant making process. SIAPS provided technical support to NERCHA and Central Medical Stores (CMS) in the development of the grant. As a department of the MOH responsible for the procurement, storage, and distribution of health commodities, CMS had been tasked with integrating the supply chain of all health commodities. CMS identified integration of storage and distribution as the key strategy towards operational efficiency in health products warehousing and distribution.

Storage constraints are not a new challenge to CMS despite efforts to increase storage capacity. Through SIAPS support, CMS developed a plan to improve warehousing and distribution of health commodities. The warehouse plan described the steps that government was undertaking to improve the warehousing of all health commodities to accommodate the scale-up of ART treatment after the adoption of the 2013 WHO guidelines which led to the development of the Swaziland ART guidelines for 2014. The plan states how the storage and distribution of medicine, medical supplies, and laboratory commodities would be integrated so that government would be able to efficiently store and distribute health commodities because the SHLS and CMS share customers and have common products which they procure.

As the warehouse stock levels climb to more desirable levels, SIAPS has assisted the SHLS in requesting additional space at the CMS to contain additional stock that has recently arrived. SIAPS has supported the SHLS in developing a warehouse process flow between the two warehouses, one being the National Reference Laboratory main warehouse, which is operational and keeps the majority of the stock, and a “spillover” warehouse at the CMS. The process flow ensures that stock management principles are properly followed at both warehouses and all stock is accounted for and can be traced throughout the chain. The process flow design shows stock movement from the main warehouse to the spillover warehouse both physically as well as electronically through an inventory management system (RxSolution). SIAPS has further trained the warehouse personnel on the process flow as well as managing the spillover warehouse stock on the warehouse management system.

SIAPS has also continued to assess health facility storerooms with an aim of assisting facilities staff to utilize the available space efficiently.

#### ***Constraints to Progress***

Although the members of the TWG were made aware of a consultative meeting which would be convened to discuss the PSM plan but when the meeting was called not all the regular members were able to attend. Efforts were made to contact some of the members on their mobiles to improve the attendance of the meeting. Representatives from CMS, Global Fund principal recipient (NERCHA), MOH and development partners were able to attend and give input. The comments received were incorporated and the document was filed to be submitted to Global Fund as part of the grant making documents.

This quarter, SIAPS supported the SHLS in evaluating tenders for the supply of reagents and supplies for FY2015–2017. The weeklong exercise aimed to ensure that quality laboratory reagents and supplies are sought from reliable suppliers while ensuring that value for money is achieved.

As part of the tender evaluation committee, SIAPS provided technical support to the MOH Procurement Unit for the evaluation of tenders for ARV, TB, family planning medicine, and other essential medicines and medical supplies. The MOH procures health commodities through an open tender which is floated once a year. However, the current tender will be for two years. This will prevent suppliers from increasing the prices when the contract is for one year and then Government extends.

### **Objective 5. Improve Pharmaceutical Services to Achieve Desired Health Outcomes**

Swaziland has been faced with challenges in maintaining required levels of health commodities at facilities and central levels. During the quarter ending March 2015, only 18% (N = 133) of ART supported sites were able to maintain required minimum-maximum stock levels for ART tracer drugs. Furthermore, 17% (133) of these ART sites reported to have had a stock-out of tracer products for at least 3 days or more in the last 3 months. The CMS also recorded tracer medicines out of stock in the same period. Moreover, the CMS had 67% of tracer products within required storage levels in for the quarter under review. Lopinavir/ritonavir 125 mg tablets were the most stocked-out item at all levels of the health care system.

The knowledge, attitudes and, practices survey report, was disseminated to the National TB Control Programme (NTCP) in a meeting for the all national and regional NTCP staff members.

Swaziland also participated in the SIAPS Global TB conference held in Thailand. Representatives from SIAPS Swaziland and MOH participated in the conference and shared experiences in involving the private sector in TB control, and the Swaziland approach to establishing the TB/HIV active surveillance system and lessons learned. SIAPS continued to support five health facilities implementing TB/HIV active surveillance by sharing presentations on active surveillance activity with all relevant stakeholders including ART doctors, senior nurses, pharmacists, and data clerks at implementing sites. Furthermore, facilities currently implementing and those scheduled to begin TB/HIV medicine active surveillance were visited. SIAPS installed the SSASSA database at one additional site and also conducted re-sensitization meetings at three health facilities.

SIAPS also continued to provide guidance in introducing new medicines such as anti-malarials and the active surveillance required to monitor the ADEs caused by these medicines. SIAPS also supported the second stakeholder feedback forum to disseminate the findings from the causality assessment of 30 ADE reports. The next steps will include the development of a risk management strategy based on the results. SIAPS also received approval from the MOH Strategic Information Department to print additional ADE reporting forms. SIAPS continues advocating for the active ADR reporting at all health facilities, as part of the rollout of the new

HIV management guidelines.

SIAPS' supported the MOH to convene a National Essential Medicines Committee meeting to discuss amendments to the list of medicines availed to clinics, with particular focus on MNCH medicines to help achieve the PMTCT goals and Ending Preventable Maternal and Child Deaths initiative. A list of MNCH priority medicines were considered and approved for inclusion in the tracer commodities list, and categorized as vital medicines. This meeting also received and deliberated on results of the STG post-implementation survey.

SIAPS has been monitoring the progress of the Quality Improvement Projects implemented by health facilities. Three sites submitted results of their quality improvement projects which will help them make informed decisions on antimicrobial resistance advocacy. Moreover, five health facilities reported to have held at least one pharmaceutical and therapeutics committees meeting.

SIAPS contributed in the Non-Communicable Diseases (NCD) TWG's Stepwise Approach to Surveillance report writing and analysis. SIAPS also worked with the TWG on listing medicines for the Diabetes Mellitus Algorithm Rapid Assessment Tool to be implemented in health facilities. SIAPS supported the implementation of tender adjudication exercises for the ARVs, essential medicines, laboratory commodities, and reproductive health commodities.

SIAPS will provide training to pharmacists on implementation of the HIV Guidelines of the country in the next quarter.

### *Constraints to Progress*

As part of monitoring the health products availability, SIAPS supports the MOH in producing a supply plan for ARVs and TB and family planning commodities every quarter, but no planning occurred during this quarter. The medicines tenders evaluation took the majority of the time this quarter; this and other urgent matters prevented supply planning. The supply plan meetings have now been scheduled for April 2015 to inform the government 2015/16 procurement cycle based on the new tender prices.

## Tajikistan

**Goal: To strengthen the TB control system to address the increased threat of MDR-TB**

### ***Overall Quarter Progress***

SIAPS continues to provide technical assistance in tuberculosis (TB) pharmaceutical management to the National TB Program (NTP) of Tajikistan. The early warning and quantification system, facilitated by QuanTB, is used countrywide, and the supply needs for the second quarter of 2015 was calculated with QuanTB. In addition, QuanTB helped identify the danger of medicines expiry and wastage under the current national order of second-line medicines from the Global Drug Facility (GDF). SIAPS also developed final drafts of the TB pharmaceutical management manual and training materials as part of the curriculum for the post-diploma education of TB specialists and nurses. SIAPS also developed an outline to facilitate the use of electronic forms for anti-TB medicines stocks reporting and monitoring.

### ***Objective 1: Increase and enhance capacity for pharmaceutical management of the NTP of Tajikistan***

The draft TB pharmaceutical management manual and training materials (PowerPoint presentations) for post-diploma education curriculum developed in the previous quarter were translated to Russian. The manual and training materials were presented to the NTP and the chief TB specialist of the Ministry of Health (MoH). Now the manual and training materials are being reviewed by National TB Program and the Chief TB specialist in Tajikistan. After their comments, the documents will be finalized and presented for approval as a part of the existing in-service trainings for TB doctors and nurses. SIAPS will provide follow-up technical support and monitoring.

SIAPS continued to provide technical assistance to NTP in various aspects of pharmaceutical management. During her visit in Q1 2015, SIAPS consultant Maia Kavtaradze was asked to provide quantification assistance for second-line anti-TB medicines to the NTP and its partner organizations, Project HOPE and the UNDP (the Principal Recipients of the Global Fund TB Grants). Ms. Kavtaradze supported the national TB pharmaceutical management coordinator in the quantification and analysis of the current supply needs. It was found that the current high medicines stocks created an urgent need for corrections to be made to the last order of second-line medicines placed by UNDP to Global Drug Facility (GDF) to avoid potential wastage of medicines due to expiry. Ms Kavtaradze assisted in developing several possibilities for the GDF and Global Fund to rectify the situation. A final decision on a plan has yet not been made yet and negotiations with the Global Fund, GDF and the country teams are ongoing. SIAPS continues to work remotely with the country to provide appropriate expertise.

### ***Partner contributions***

SIAPS worked in close collaboration with the UNDP and Project Hope on quantification the needs and correction of the last order by UNDP's Global Fund project.



**Objective 2: Increase the use of information for decision-making in TB pharmaceutical management**

Based on the assessment and discussion with the NTP and partner organizations in Tajikistan in the previous quarters, it was decided that SIAPS will assist the NTP in developing and implementing of eForms for anti-TB medicines stocks reporting and monitoring of rayon levels. The system will allow for electronic Excel forms to be sent by email; LMIS quarterly reports from rayon and summary reports will be generated automatically based on the Excel reporting forms.

These forms are currently filled manually, and the NTP pharmaceutical coordinator enters the information manually in the Excel sheet for all the rayons. The forms are sent irregularly, and the entry process may take up to four weeks. This is a drain on the pharmaceutical manager's time and resources. When the electronic system is developed and implemented, as soon as the reports are received from the rayon of TB services through email, the summary report can generated immediately. This would save time for the TB pharmaceutical manager and enable her to focus on other managerial tasks. It is also expected that the system would improve the quality and completeness of reports. SIAPS developed an outline of the system, which will be discussed with NTP and the counterparts during the visit of SIAPS team to Tajikistan in April 2015.

*Partner contributions*

SIAPS collaborates with Project Hope and KNCV to ensure coordination the efforts for the implementation of this activity, as well as to ensure the sustainability of the results after SIAPS program finishes.

*Constraints to progress*

A lack of internet connection in some TB facilities, and the fact that the corresponding staff in some TB facilities do not use email, could present a problem. The ways to overcome these problems will be discussed with counterparts during the SIAPS team's visit to Tajikistan in April 2015.

**Objective 3: Strengthen Supply system of anti-TB medicines**

SIAPS continued to provide technical support to the NTP in setting up a system for early warning and quantification of anti-TB medicines through use of QuanTB. Now NTP uses QuanTB for the quantification of orders and supply planning on a regular basis: in January 2015, the national PM coordinator used QuanTB for the quantification of regular quarterly supply needs of second line anti TB medicines to the regions and also those 13 district TB facilities that are under the direct responsibility of the national TB center. Data collected and analyzed with QuanTB at the national level contributed to early detection of potential upcoming problems in second-line anti-TB medicines supply. In particular, analyses carried out with QuanTB showed that stock on hand and on order from the GDF exceeded country needs—a situation that would

likely lead to medicines wastage due to expiry. Based on the calculation that was done with the use of QuanTB, Tajikistan has requested changes in the expected orders, including proposing desired expiry dates for all medicines to avoid waste or stock-outs.

### *Partner contributions*

Project Hope and KNCV are willing to contribute to the implementation of QuanTB as an early warning and quantification tool, as well as to take over technical assistance to the NTP after the completion of the SIAPS program in Tajikistan.

### *Constraints to progress*

During the piloting the system in June–December 2014, information for QuanTB was collected on a monthly basis. The data was collected by regional TB pharmaceutical management coordinators, but currently there is not sufficient capacity to enter and analyze the data in QuanTB at the regional level; rather, this is done by the National TB pharmaceutical manager, creating an enormous additional workload for her. Based on the evaluation of the pilot period, and discussions held with the national PM coordinator and the NTP manager, it was decided that the data would be collected and analyzed on a quarterly basis in line with the LMIS reporting period. In parallel, there will be focus on increasing the capacity of the regional TB pharmaceutical managers to enter data in QuanTB, analyze it, and take remedial actions on the regional level.

## **Turkmenistan**

**Goal: To strengthen the TB control system of Turkmenistan to address the increased threat of MDR-TB.**

### ***Objective 1: Strengthen the Turkmenistan NTP by improving the TB management information system***

In March 2015, SIAPS consultant Maia Kavtaradze was requested by the WHO Regional Office for Europe to conduct an evaluation of the anti-TB medicines management in Turkmenistan as part of the National TB Program (NTP) review. During her visit, she looked at procurement and supply management practices and anti-TB medicines availability and use. She also participated at the national TB conference dedicated to the International TB Day on March 24, where she made a presentation “e-TB Manager: a Comprehensive Web-Based Tool Conceived for Strengthening TB programs.” Using e-TB manager was discussed with the representatives of the national TB program, the Ministry of Health (MOH), and WHO Regional Office for Europe and WHO Country office. Even though the NTP and the MOH still express their interest to use e-TB manager at pilot sites, nothing has been done to start piloting the system. Same time NTP requested WHO and SIAPS consultant to plan and conduct training on use of QuanTB for quantification and supply planning of anti-TB medicines by the NTP staff. SIAPS is considering this request.

#### *Partner contributions*

WHO Europe together with WHO Country Office participates in preparation of the pilot of e-TB Manager providing logistical and financial support.

#### *Constraints to progress*

No clear explanation is given as to what the reasons are for the delay of starting eTB Manager pilot. Instead, there is a promise that the NTP will start entering the data soon.

## **Ukraine**

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

### ***Overall Quarter Progress***

In the second quarter of its fourth project year, SIAPS Ukraine has advanced in all fields of activities, both supported through PEPFAR and anti-corruption funding. For Objective 1, the ownership of e-TB Manager was successfully transferred to the government entities and SIAPS assisted in building their capacity to operate the system. The final version of Transfer Memorandum is tabled to Ukrainian Center for Disease Control (UCDC) for signing. The State Penitentiary System (SPS) is actively rolling out e-TB Manager, reaching a remarkable 72% of compliance to paper-based reporting forms.

At the same time, efforts were directed towards maintaining the functionality of e-TB Manager and implementing new features and functions. After the implementation of the new treatment guideline, the Users' Guide is being updated. Presentation of the capabilities of the data analysis tool of e-TB Manager was delivered to the regions by UCDC. Regional facilities got support during field visits.

For Objective 2, the protocol for Drug Utilization Review (DUR) was approved by the ethics committee, and the data collection was performed in TB facilities. Following this success, the DUR is now being initiated in AIDS facilities. Furthermore, under this objective, progress was made in implementation of Pharmacovigilance Automated Information System (PAIS) progressed and, by the end of March, 41 cases were entered into the system.

For the Objective 3, visible progress was made in establishing new National Essential Medicines List (EML) as a basis for public procurement and reimbursement. The support was received from three parliamentary committees, and as of end of March 2015, the first draft of the Decree of the Cabinet of Ministers for approval of EML has been developed.

Activities aimed at building the capacity of Civil Society Organizations (CSOs) to perform the price referencing are also moving forward, and the scope of work for software developers is close to be finalized.

For Objective 4, the work on amending the remarkable progress is achieved in activities related to Framework Contracts—Amending the Order of the Ministry of Economic Development and Trade that now allows health care facilities in the oblasts to draw on the advantages of framework contract procurement proceeded quite rapidly. The Procurer-in-Chief was officially named in Poltava oblast by local administration decree, which is regarded as a significant milestone being a formal prerequisite for framework contracting pooled procurement.

**Objective 1: Strengthen Pharmaceutical Management Information Systems to Support the HIV and AIDS and TB Programs**

The major targets in reporting period continued to be (1) advancing transition of the ownership of e-TB Manager to Government of Ukraine, and (2) continuing to provide technical support in countrywide roll-out of the e-TB Manager.

1. The final version of Transition Memorandum was created, agreed upon with UCDC, and provided to them for signature. By the end of March 2015, the Transition Memorandum is still in UCDC, and we expect it to be signed before the end of April.

Additionally, a scope of work was developed for a consultant who will assess the piloting of medicines management module and provide technical assistance in further implementation of the Medicines Management Module and Quantification tool. The position of the consultant has been advertised, and we expect to approve the candidate on April 1. SIAPS continued to provide TA to National TB Institute and State Penitentiary System in the further deployment of e-TB Manager.

Good progress has also been made in the State Penitentiary System (SPS). In pursue of the decisions made in Q1, SPS has assigned staff responsible for acting as national administrator of the system, received the access keys to e-TB Manager from UCDC, and sent a letter to penitentiary facilities in regions requesting to improve/start entering cases in e-TB Manager. The compliance to paper-based reporting forms is now 72%. Additionally, a discussion of the overall status of e-TB Manager implementation in SPS was the main topic of the February 4 stakeholders' meeting. As a follow up to this meeting, SPS approved the 2015 e-TB Manager implementation plan, has assigned staff responsible for acting as regional administrators of the system, and developed internal operation procedures on entering data to the system and disseminated them among regional administrators and users.

2. SIAPS-Ukraine continued to provide technical support to the national level users in countrywide roll out of the e-TB Manager.

- Following the implementation of the new treatment guideline in e-TB Manager, work began on updating the User's Guide.
- The drugs management module of e-TB Manager (QuanTB) is continuing to be adapted to the current treatment guideline. During Q1 in 2015, 51 facilities were entering data on TB medicines to e-TB Manager.
- Following the successful implementation of the tool for data analysis in Ukrainian version of e-TB Manager and UCDC staff training on this tool for the, the presentation was delivered by UCDC staff to all regional e-TB Manager administrators on March 19. A follow-up cascade training has been scheduled. Moreover, UCDC started using the tool for data analysis to support the decision-making process. The data the global TB report was prepared with use of the data analysis tool and submitted to WHO.
- The visit to Kirovohrad oblast TB facilities was conducted on March 5 and 6. During this field trip, three facilities which were seen by UCDC as problematic were visited. As a result of the trip, one facility was found to be working properly but feedback was provided

regarding the wish for additional functionality. The second facility had a problem with their internet connection and no one was available to fix it; SIAPS helped to establish a connection with e-TB Manager. The third facility had a problem with internet speed, so a list of alternative providers was offered for consideration, with follow-up being that they will select another internet service provider and will find money to pay for new modem and an internet connection.

- Continuous support was provided by routine maintenance, fixing bugs, and minor features development.

### *Partner contributions*

The major contributing partner for this objective remains UCDC, which in the reporting period continued to provide SIAPS with specifications of technical requirements for updates, how to fix computer bugs, and new features needed for e-TB Manager.

### *Constraints to progress*

Several major challenges are linked to UCDC, particularly human resources availability. As of now, UCDC cannot afford having even a part-time Java programmer who would fix bugs and other minor problems, so still SIAPS-Ukraine is providing this support. Another critical position is not filled yet — UCDC still didn't decide on SOW for backup administrator. This person will have different responsibilities from both the programmer (currently supported by SIAPS-Ukraine) and the system administrator (currently UCDC staff member). This position must be filled to ensure the uninterrupted performance of the system. However, hosting expenses have increased fourfold. UCDC cannot afford it and has addressed USAID for support.

Another major challenge remains in advancing the e-TB Manager roll-out in State Penitentiary System. The over-bureaucratized nature of this government body makes it sometimes resistant to innovation changes. Despite the resolution of the problem with assigning staff and relevant job descriptions for e-TB Manager National Administrator level users, the State Penitentiary System is still in the process of setting internet connection for e-TB Manager clients, utilizing money of the grant of Global Fund to Fight AIDS, Tuberculosis and Malaria.

## ***Objective 2: Improve Pharmaceutical Services for the TB and HIV and AIDS Programs***

Based on the preliminary successful results of the drug utilization review (DUR) pilot in TB facility and in regards to the priorities set by the PEPFAR program in Ukraine, SIAPS has started moving towards implementing DUR in HIV facilities as well.

In the reporting period, the DUR TB ethics committee was established within Kyiv Oblast TB Dispensary (by the dispensary internal order dated January 15, 2015). The new DUR protocol was submitted for the ethics committee, and was approved in January 2015. SIAPS provides technical assistance to facilitate this process and enable data collection.

In February, the data collection was performed as planned, and a total of 70 patients' records were reviewed. As a result, by the end of March 2015, SIAPS has received the completed data collection forms and has entered the next DUR phase, the data analysis, which is expected to be finalized in April. Then DUR report will be developed.

To support the implementation of DUR HIV in HIV facilities, the action plan was developed and agreed with SIAPS HQ senior technical advisor. Later, a request for proposals was announced to select a vendor for DUR protocol development. Only one proposal was received, so the deadline for submission of proposals was extended until April 17. The development of the protocol will start in Q3 FY15.

The list of possible sites for DUR was compiled, and preliminary negotiations were held with two HIV facilities. By the end of March 2015, SIAPS reached an agreement with Kyiv city AIDS center to be a site for DUR. The relevant memorandum of understanding is now being developed and is expected to be signed in April.

Based on the results of the first training on use of Pharmacovigilance Automated Information System (PAIS) conducted for State Expert Center (SEC) in Q1 (December 29, 2014), SEC has submitted their comments and suggestions regarding using the system on the national level (data analysis). The developer used these comments and suggestions to improve the system. The next training on the system was conducted for doctors and regional PV representatives of SEC, who have approved the further implementation of the system. Later the improved version of the system was tested and it was decided that it is ready to be used, so SIAPS continued piloting PAIS in AIDS centers. The data entry on adverse reactions started on March 13. By the end of March, 41 cases were entered in the system.

It was anticipated that doctors may resist implementing the system as they were not convinced of its use. Thus it was rather unexpected when this number of reports was submitted through the system during such short time. After the trainings and field visits, the doctors are showing great interest and readiness to work with the system. This is an unexpected success which SIAPS-Ukraine will be building upon in the next quarters.

Field visits were conducted in Kyiv city and Kyiv oblast AIDS centers and Hromashevsky Institute of Epidemiology. Additionally, the video conference was conducted with Zhytomyr, Vinnytsia, and Chernivih AIDS centers. They included shared screens on both sides, observation of operations and performance improvement through correction of errors and suggestions on how to avoid them.

After the additional funding was approved by USAID for the data protection system, SIAPS continues to work with the developer, and now the amendment to the original contract is being prepared. This will allow starting the development of data protection system in the next quarter.

In the last days of the previous period, PAIS became available for usage from SEC-owned web address. In the reporting period, the Secure Socket Layer certificate was received for the SEC web server.

*Partner contributions:*

Major contributors to the DUR pilot in the TB facility are the SEC and the facility itself (Kyiv Oblast TB Dispensary). Both are participating in review of patients records, filling the data collection forms and in setting the thresholds for the DUR indicators to allow the data analyzing later.

SEC contributed to PAIS by providing their comments and suggestions to the system's current version, which led to its improvement and data collection launch.

**Objective 3: Improve Pharmaceutical Management Governance**

The work on PV guidelines was suspended in previous quarter because the server of the SEC (where the data and draft documents were stored) was damaged in a fire. In the reporting quarter, the SEC has restored its server, which enabled the continuation of the work on PV guidelines. The first four modules of the national PV guidelines were submitted to the Ministry of Health of Ukraine by the State Expert Center, to be approved by the order of the Ministry.

As a result of multiple meetings held with stakeholders in the reporting period, it was decided that, given the current political situation, the only support for developing and accepting the new National Essential Medicines List (EML) would be the Parliament of Ukraine, particularly the heads of the three parliamentary committees— health care, entrepreneurship, and international relations.

This decision was justified as SIAPS has received the envisioned support from Members of Parliament regarding the legal approval of National EML and relevant regulations around it by the Decree of the Cabinet of Ministers of Ukraine. The essential advice was provided to SIAPS on the proper mechanism of the Decree adoption through the parliamentary committees' hearings (a saving time as compared to the alternative way—through the Ministry of Health).

Based on the situation analysis performed in Q1, and based on the received support from the Members of Parliament, SIAPS has started to develop the national EML. The MOU was signed with the National Medical University which will provide local experts to help develop the guidelines. The law company was selected to support the development and implementation of the legislation on the National EML.

As of end of March 2015, the first draft of the decree of the Cabinet of Ministers is developed. By this Decree the following pieces will be adopted: the National EML and provision, which will regulate the medicines selection process based on the National EML.

In the reporting period, the stakeholders were requested to review the scope of work for development of the web-based price monitoring tool and provide their comments/input. The scope of work was finalized on March 31. CSOs committed to specific roles related to hosting links to price referencing tool.



*Partner contributions:*

The modules of the national PV guidelines were compiled by the working group, while the draft Ministry order was submitted to the Ministry by the SEC.

The National Medical University provided assistance in developing the draft National EML.

CSOs were involved in developing the medicines price monitoring tool. Particularly, they provided their comments to the SOW for development of the tool and committed to hosting links to price referencing tool on their sites.

*Constraints to Progress*

Obtaining approval of the first four modules of the PV Guidelines may be slow because the Ministry is engaged in urgent procurement procedures as well as in structural and functional organizational change.

The envisioned changes to EML (the one list instead of multiple, with significant changes in a scope) remains politically sensitive, even with a support from the MPs.

***Objective 4: Improve Management of Supply Chain Services***

This quarter, interventions to influence the country's regulatory policy yielded quick results leading to rationalization of the list of products eligible for procurement through framework contracts (Ministry of Economic Development and Trade Regulation No. 503). This intervention allowed for wider range of products to be procured through framework contracts. As a result, the health care facilities in the oblasts are entitled now to draw on the advantages of this cutting-edge procurement technique at the site and oblast levels.

SIAPS-Ukraine continued to systemically improve pharmaceutical procurement practices through capacity building efforts. The new oblast, which signed an MOU at the end of the previous quarter, benefitted from the training curriculum developed by the Framework Contracting task force. Eighty-five people from health care facilities, 2 ministries, 3 health administrations, and 1 regional pharmaceutical warehouse belonging to the oblast had a chance to master framework contracting and develop relevant practical skills. In the Dnepropetrovsk oblast, trainings were well received by both local and central authorities. The head of Health Administration not only expressed his support of framework contracting during trainings but also went out to the press to announce that this year they would advertise public tenders through this mechanism. The framework contracting team also set up an oblast stakeholder meeting and conducted two public-private partnership events. As a result, key regional authorities and 33 pharmaceutical manufacturers/suppliers had a chance to learn what framework contracts are.

In the Poltava oblast, the local administration decreed that a general procuring entity for pooled procurement be established, which is regarded as a significant milestone. Naming a Procurer-in-Chief is a formal prerequisite for FC pooled procurement. The general procurement entity started collecting requests from the health facilities it would procure for and should continue in the next

quarter to compile and analyze the requests sent in, which will form a basis for the tendering documentation.

### *Partner Contributions*

Dnepropetrovsk Oblast Health Administration had an active role in and substantially contributed to the conduct of three FC trainings.

The stakeholders' meeting was co-chaired by Deputy Head of Dnepropetrovsk Oblast Council and Head, Health Administration. Both administrators were interested in and stated their support of the framework contracting activities. They see a great potential in framework contracting in the field of anticorruption and view it as an efficient tool for streamlining procurement practices in their oblast. Hence, their gratitude to the task force, which brought to the oblast and implemented the framework contracting trainings.

### *Constraints to Progress*

Pharmaceutical suppliers and distributors have poor motivation for participation in public tenders as the substantial portion of the pharmaceutical market in Ukraine falls into the category of the out-of-pocket expenses (about 85%). Pharmaceutical price registration is another setback as in the environment of rapid inflation this mechanism does not allow for quick response to market changes.

Unfortunately, the reasons mentioned above led to failure of the first round of tendering. Only one participant registered, while the minimum number of participants is three for tender to be legally valid.

## **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 NTP of Uzbekistan in setting up of the early warning and quantification system with use of QuanTB. SIAPS, in close collaboration with the National TB Pharmaceutical Management Working Group, developed a process and tools for data collection and data entry in QuanTB, trained the users in four pilot regions on using QuanTB analyze data and detect potential problems in supply of anti-TB medicines. The pilot regions have started using QuanTB as an early warning and quantification tool. SIAPS also supports visits of the members of the National TB Pharmaceutical Management Working Group to the pilot regions to provide to the regional staff on-the-job support and supervision. The results of using QuanTB have been reported to the working group and SIAPS.

Also, SIAPS provided assistance to the National TB program of Uzbekistan to pilot Drug Use Review (DUR) in three TB facilities in Tashkent City. The DUR plan was developed, DUR criteria were agreed upon, and the data collection forms were elaborated. Then trained data collectors collected the data by reviewing of 105 patients' cards. Currently, the collected DUR data is being analyzed and will be put into a report in the next quarter. The results of DUR and an improvement plan will be communicated to the staff of the pilot TB facilities.

### ***Objective 1: Strengthen Pharmaceutical Sector Governance***

The Russian version of the report of the *Assessment of TB Pharmaceutical System in Uzbekistan* has been finalized. It will be translated in English. SIAPS is working on developing an abstract to be submitted on the World Lung Conference organized by the International Union against TB and Lung Diseases in November 2015.

### ***Objective 2: Strengthen Pharmaceutical Services for the NTP of Uzbekistan***

SIAPS provided assistance to Uzbekistan's national TB program to pilot a Drug Use Review (DUR) program—an ongoing, systematic process designed to ensure rational and effective use of medicines. In March, SIAPS facilitated Pharmaceutical Management working group meeting to plan the pilot DUR program in three facilities of Tashkent City: Republican Scientific Institute of Pulmonology and Tuberculosis, Tashkent City TB dispensary, and Tashkent City TB Hospital. As result of the meeting, the DUR plan was developed, DUR criteria and thresholds were selected, and data collection forms were developed. Then three medical doctors were trained in DUR data collection. Overall, 105 patient cards were reviewed in three TB facilities. Currently, the collected data is being analyzed. In the next quarter, the report on the DUR will be developed. The report will contain not only results of the DUR, but also improvement plan for each pilot site. The results of DUR and improvement plan will be communicated with the staff of the pilot TB facilities.

### *Partner Contributions*

The national TB pharmaceutical management working group is a main partner for this activity. All steps of this activity were managed by the working group with the technical guidance and support of SIAPS.

### **Objective 3: Strengthen Supply System of Anti-TB medicines**

SIAPS is working with the NTP of Uzbekistan on setting up the early warning and quantification system with use of QuanTB. In January 2015, SIAPS supported a meeting of the National TB Pharmaceutical Management working group on planning the implementation of the system. The group discussed piloting the system, and it was decided that in the first quarter of 2015, the system will be piloted in 3 regions (Samarkand, Khorezm, and Fergana oblasts) and Tashkent City, which will be managed and coordinated by the central level. Rollout of the system is expected to start in June 2015, based on the experience from the pilot regions to be discussed on the post-pilot workshop in May 2015.

A workshop was held on January 26–29, 2015, to set up an early warning and quantification system. There were 16 participants on the workshop representing the national TB pharmaceutical management working group and 4 pilot regions. The participants were trained on use of QuanTB and Excel tool for data collection. Workshop attendees also, agreed on what processes should be on the place for data collection and entry in QuanTB, and conducting analyzes to detect the problems in supply of anti-TB medicines on the oblast and the rayon levels and using it for decision making for avoiding stock-outs or expiration of medicines. The monthly reporting forms on use QuanTB as an early warning tool were developed, as was a schedule for supportive supervision visits by the members of the National TB pharmaceutical management working group.

After the workshop, the pilot oblasts started collecting the data from the respective rayons that was analyzed using QuanTB. Supportive supervision visits to the oblast were conducted by the members of the National TB Pharmaceutical Management working group.

### *Partner contributions*

SIAPS is working in close collaboration with the National TB Pharmaceutical Management working group.