

Systems ^{for} Improved Access to Pharmaceuticals ^{and} Services

Improved Access. Improved Services.
Better Health Outcomes.



Annual Report: Program Year 1

October 2011–September 2012



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SIAPS 
Systems for Improved Access
to Pharmaceuticals and Services

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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

ACT	artemisinin-based combination therapy
ADR	adverse drug reaction
AIDS	acquired immunodeficiency syndrome
AMI	Amazon Malaria Initiative
AMR	antimicrobial resistance
ART	antiretroviral therapy
ARV	antiretroviral
CCM	community case management
CDC	US Centers for Disease Control and Prevention
CRPHF	Hélio Fraga National TB Reference Center (Brazil)
DGFP	Directorate General of Family Planning (Bangladesh)
DNME	National Directorate of Medicines and Equipment (Angola)
DMP/MT	Direction de la Pharmacie du Médicament et de la Médecine Traditionnelle (Haiti)
DRC	Democratic Republic of the Congo
DTC	Drug and Therapeutics Committee
DTP	diphtheria, tetanus, pertussis
EDT	Electronic Dispensing Tool
EPI	Expanded Program on Immunization
EUV	end-user verification (survey)
FDA	US Food and Drug Administration
FMHACA	Food, Medicines and Health Care Administration and Control Authority (Ethiopia)
FY	fiscal year
HIV	human immunodeficiency virus
M&E	monitoring and evaluation
MDR	multidrug resistant
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
NGO	nongovernmental organization

NMCP	national malaria control program
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 program (Burundi)
PNLS	national AIDS control program (DRC)
PNME	Program for Essential Medicines (Angola)
RDT	rapid diagnostic test
SAIDI	South American Infectious Disease Initiative
SCMS	Supply Chain Management System (project)
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems (Program)
SUGEMI	national pharmaceutical management system (Dominican Republic)
TB	tuberculosis
TIPC	Therapeutics Information and Pharmacovigilance Center (Namibia)
UNAM	University of Namibia
UNICEF	United Nations Children's Fund
USAID	US Agency for International Development
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

PROGRAM INFORMATION



The **SIAPS GOAL** is to assure the *availability of quality* pharmaceutical products and *effective* pharmaceutical services to achieve desired health *outcomes*.

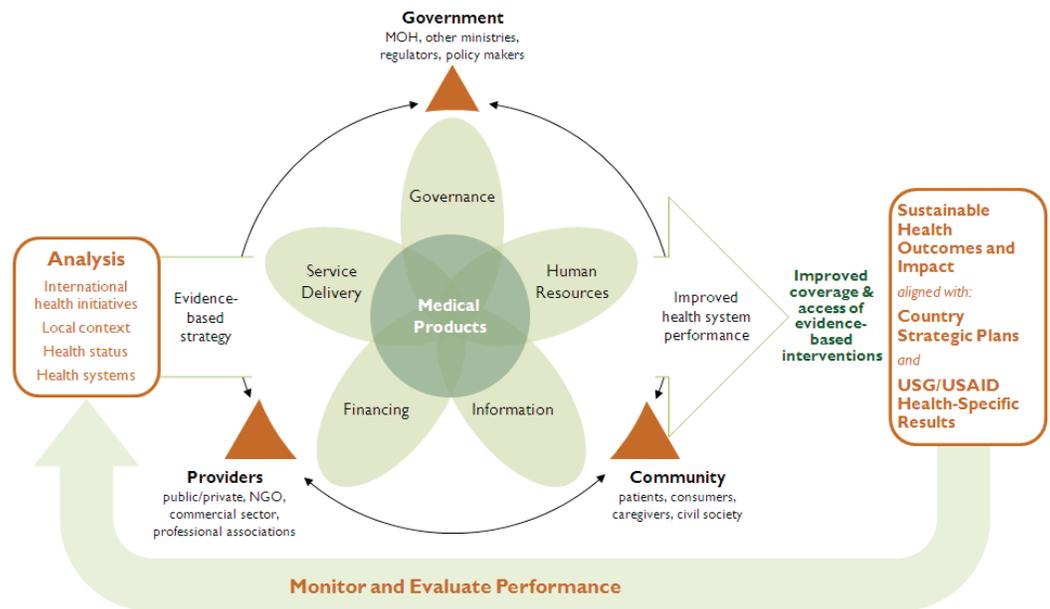
The **SIAPS OBJECTIVE** is to promote and use a *systems-strengthening* methodology that will result in a positive and sustainable *health impact*.

The US Agency for International Development (USAID) awarded the Management Sciences for Health (MSH) a five-year \$197.9 million Co-Operative Agreement, Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, which is a follow-on to the Strengthening Pharmaceutical Systems (SPS) Program. The program works to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes for the period September 2011 and through September 2016.¹

¹ <http://www.msh.org/global-presence/siaps.cfm>

The program applies a systems-strengthening approach consistent with the Global Health Initiative (GHI) intended to result in improved and sustainable health impact. The SIAPS' approach emphasizes GHI principles, especially improving metrics, monitoring and evaluation; empowering local governments and organizations and increasing country ownership. Toward this end, the SIAPS framework and result areas reflect the dynamic relationships among five health systems building blocks, with a pharmaceutical product overlay that guides technical content.

SIAPS Pharmaceutical System Strengthening Framework



The specific SIAPS results areas include:

- Strengthening pharmaceutical sector **governance**
- Building individual, organizational, and institutional capacity **for pharmaceutical supply management and services**
- Addressing the **information** for decision-making challenge in the pharmaceutical sector
- Strengthening **financing strategies** and mechanisms to improve **access to medicines**
- Improving **pharmaceutical services** to achieve desired health outcomes

Implemented by a team lead by MSH, the SIAPS core partner team includes the Accreditation Council for Pharmacy Education, Harvard Pilgrim Health Care Institute, Harvard School of Public Health, Logistics Management Institute, and the University of Washington's Department of Global Health. In addition to these core partners, MSH is joined by a select group of organizations who serve as specialized resource partners for SIAPS. They include the African Medical and Research Foundation, Ecumenical Pharmaceutical Network, Results for Development, RTT Group, Village Reach, and William Davidson Institute at the University of Michigan.

PROGRESS TOWARD RESULT AREAS



PHARMACEUTICAL SECTOR GOVERNANCE STRENGTHENED

The SIAPS approach to improving governance and accountability focuses on building capacity of national counterparts to establish transparent management systems grounded in policies based on best practices, legislation supported by the rule of law, and regulation supported by appropriate technology and capacity.

National medicine regulatory authorities in developing countries are often confronted with systematic challenges; for example, backlogs of drug registration applications wait for review, and regulatory activities are not conducted transparently or with accountability. SIAPS provides support to national medicine regulatory authorities to improve pharmaceutical sector governance and strengthen regulatory systems to ensure timely access to medicines and other health supplies.

Determining the appropriate technical assistance involves a review of the existing regulatory system, legislation, and policies, and an assessment of a country's regulatory capacity and operations. Those results then form the basis of a strategic framework and plan to strengthen the regulatory system. To bolster the policy and regulatory environment, SIAPS helps countries apply appropriate technological and capacity-building initiatives to create efficient and sustainable

drug registration systems, monitor medicine quality, and fulfill other regulatory mandates. The result is better access to quality, safe, and effective health products.

Progress made in Year 1 of SIAPS implementation:

Good governance principles embodied across health systems components:

- » SIAPS conducted an evaluation of the organizational structure of the national malaria program (PNILP) in **Burundi**, using MSH's MOST evaluation tool. From the evaluation, recommendations were made to strengthen the PNILP structure by revising its legal status to upgrade the institution to an autonomous entity with an updated organogram, capacitating the staff by providing local trainings, and equipping the PNILP with information technology equipment.
- » SIAPS supported 24 pharmacy managers in **South Africa** to complete the Pharmaceutical Leadership and Development Program. The managers presented their achievements to senior management and other stakeholders in Eastern Cape Province. All five teams achieved their measurable results, with three teams addressing challenges relating to National Core Standards; SIAPS also launched the Pharmaceutical Leadership and Development Program in North West province for 19 pharmacy managers and held an introductory workshop for facility managers and responsible pharmacists from 12 facilities in the Western Cape Province.
- » In collaboration with the World Health Organization (WHO) and **DRC's** Department of Pharmacies, Medicines, and Traditional Medicine, SIAPS put in place a new approach to revise the National Essential Medicines List. The approach focuses on making the revision process more transparent and efficient, and addresses issues such as conflict of interest of persons involved in the review process.
- » SIAPS facilitated the establishment of a Forecasting Working Group in **Bangladesh** to serve as a central coordination mechanism to ensure accurate national-level forecasting, quantification, and supply planning of reproductive health commodities.
- » SIAPS facilitated the Supply Chain Management Technical Working Group meetings in **Lesotho**, resulting in improved coordination of supply chain activities and partner assistance. Information from pharmaceutical and logistics management information systems is now regularly shared among key stakeholders through this forum.
- » SIAPS participated in the inaugural Postpartum Hemorrhage Technical Working Group meeting on the introduction of misoprostol in two counties (Mvolo and Mundri East) of South Sudan; SIAPS also helped to finalize the postpartum hemorrhage prevention implementation plan and coordinated the product supply chain management aspects of the ongoing USAID-funded prevention of postpartum hemorrhage program in Mvolo and Mundri East. This included facilitating custom clearance, receipt, and storage at the Central

Medical Stores, distribution to the counties, and pre-packaging for dispensing of misoprostol.

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

- » SIAPS provided technical assistance to revitalize the National Drugs Regulatory Authority in the **Democratic Republic of the Congo (DRC)**, which is functional now and meets every quarter. In less than two years, the number of medicines registered in the country reached more than 700 from almost zero (target 1,000).
- » SIAPS supported the Ministry of Health in **Haiti** to identify major gaps and issues in the pharmaceutical sector affecting access to and appropriate use of essential medicines and key public health products that would need to be considered in the revision of National Medicine Policy. Following this, SIAPS supported the conduct of key stakeholder engagement workshops related to the policy revision and worked with the Direction de la Pharmacie du Médicament et de la Médecine Traditionnelle (DPM/MT) team to revise the draft National Medicine Policy based on stakeholder and WHO recommendations and recent global trends.
- » In **Namibia**, SIAPS provided support that contributed to 156/428 (36%) of application dossiers for registration of medicines being processed and 223/309 (73%) of medicine samples tested for quality. Of the 223 samples, 103 (46%) were tested within two weeks of submission.
- » In **Rwanda**, SIAPS assisted in the development of a strategic document on how to systematically revise the Clinical Protocol and Treatment Guidelines. The strategic document was finalized and shared with the Rwanda Ministry of Health (MoH).
- » SIAPS helped the MoH in **South Sudan** to draft a concept paper on setting up an autonomous Central Medical Store, to review and update key regulatory guidelines and tools, and to promote licensing of private pharmaceutical practitioners in Eastern Equatorial state.
- » SIAPS supported the drafting, passage, and publication of the **South Sudan** Food & Drug Control Authority Bill which provides policy parameters for ensuring drug safety. SIAPS also supported the Kaya office to detect illegal imports and substandard medicines. This resulted in an official complaint being submitted by MoH to the Uganda National Drug Authority.

Transparent and accountable pharmaceutical management systems:

- » An auditable pharmacy transaction system to establish a transparent and accountable transaction and service system was finalized in Ethiopia. This system creates a means to maximize the use of available resources and reduce wastages; SIAPS also developed a three-day curriculum/course outline and organized training for 132 participants.

National pharmaceutical sector development plans are strategic and evidence-based:

- » SIAPS worked with **South Sudan's** NMCP to reactivate monthly malaria technical working group meetings, coordinated in-country malaria missions, improved malaria planning at the state level, drafted guidelines and tools to guide scale-up malaria interventions; planned a malaria program review, and initiated activities aimed at strengthening systems to monitor antimalaria drug efficacy and key malaria indicators; supported NMCP to update the national malaria treatment guidelines and finalize/submit the therapeutic efficacy testing protocol and request the study medicines from WHO.
- » A policy framework for private providers of health care services was developed on behalf of the provincial Department of Health in the Western Cape, **South Africa**, which was adopted and implemented.
- » SIAPS supported the MoH in **South Sudan** to complete the EPI review; develop the 2012-2016 comprehensive multi-year plan for immunization systems development in South Sudan; finalized the 2012 vaccination week implementation plan; revised standard case definitions; and provided technical assistance to capacity building for EPI in South Sudan. SIAPS's support contributed to an increase of DTP-3 coverage by 20% (against a 19% target); 37% of the counties attained the annualized DTP-3 target of 80%. The large number of counties reaching high rates for the quarter is a result of immunization defaulter tracing campaigns implemented during the vaccination week.

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. SIAPS helps countries engage in comprehensive workforce planning to address challenges such as increasing demands, resource constraints, and health workforce policy reforms. This involves collecting and reporting data to help determine workforce needs, matching workforce and educational outcomes, and building a compelling case for funding posts in the public sector.

To increase pharmaceutical sector efficiency, SIAPS works with stakeholders to assess a country's or program's capacity to manage pharmaceuticals—from facility to national level. Then, using a stakeholder consensus approach, we identify areas for improvement and develop long term interventions to strengthen the system.

Progress made in Year 1 of SIAPS implementation:

Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened

- » SIAPS assisted in drafting training materials aimed at improving the knowledge and skills of pharmacies and accredited drug outlet dispensers to increase TB case detection in Tanzania; developed and finalized supporting

New Pharmacy Assistant Program in Swaziland

With a population of over a million, landlocked Swaziland faces a shortage of skilled healthcare workers, including pharmacy personnel. There are 64 registered pharmacists, with the majority of them belonging to the private sector as an increasing portion of the population battles several communicable diseases such as malaria, tuberculosis, and the most prevalent – HIV and AIDS.

The lack of pharmacy personnel has led to an increase in the number of facilities that use non-pharmaceutical staff to handle medicines and medical supplies, resulting in inefficient pharmaceutical supply management. It can also lead to reduced efficiency, due to heavy workloads, and eventually compromises the quality of pharmaceutical services offered in these facilities.

As a way to counter the scarcity of pharmacy staff, the Swaziland Ministry of Health (MOH) requested support from the SIAPS Program to establish a pharmacy assistant training program.

Earlier this year, SIAPS helped develop a new educational curriculum for approval by the University of Swaziland (UNISWA) and the Southern African Nazarene University (SANU) Senates – two main universities offering health science graduate programs, specifically for nurses. The new training

program is a certificate program comprising of two years of full time classroom learning with the second year consisting largely of on-site field training.

As of May, the UNISWA Faculty Board approved the curriculum and is now awaiting final approval from the university Senate. The training program is scheduled to commence in August 2012 with an initial intake of about 25 candidates.

SIAPS is concurrently working with the MOH on finalizing the Pharmacy Bill 2012, which will officially recognize the Pharmacy Assistant position as one of the cadres in the delivery of pharmacy services. This cadre is already recognized in the country's task-shifting framework documents and has been approved for registration by the Medical and Dental Council – the registration body for most health professionals including pharmacy personnel. The MOH is also working with the Ministry of Public Service to establish posts for this cadre within the public service.

A larger and stronger pharmacy workforce will be better able to manage pharmaceuticals, help ensure improved access to high quality medicines and pharmaceutical services for patients, and ultimately help improve their health outcomes.

tools including TB symptoms checklist, cough register, and reporting and referral forms; trained 595 dispensers from Morogoro region.

- » Under the Amazon Malaria Initiative (AMI), SIAPS helped to introduce guidelines and manuals to improve regional malaria pharmaceutical management, and conducted result/impact evaluations after the implementation of these tools. The revised criteria for programming and distribution of medicines in low-incidence areas were immediately used to redistribute regional antimalarial stock in two countries. Peru drafted a ministry decree to institutionalize this practice nationwide. To transfer SITETB system ownership, SIAPS trained participants from all 27 **Brazilian** states. All states are currently following new guideline and treatment recommendations and using fixed-dose combinations for first treatment.
- » SIAPS provided human resource support to the University of **Namibia** (UNAM) and the National Health Training Center, which enabled them to enroll 49 pharmacy students and 35 pharmacist assistants, respectively.
- » In **Ethiopia**, 46 DTCs were established; SIAPS trained the newly established hospitals using the monitoring-training-planning approach that involves: gap assessment using a standard checklist, orientation based on the gap assessment and planning, and support in implementing the plans. Additionally, SIAPS carried out in-service training on clinical pharmacy/pharmaceutical care to **Ethiopian Hospital Reform Implementation Guidelines**-implementing

sites in collaboration with Jimma University. The main purpose of this activity was to train pharmacists on clinical pharmacy in an effort to initiate clinical pharmacy services in 21 selected hospitals. Almost 800 professionals attended different training events.

Local institutions and organizations provide pharmaceutical services and TA in pharmaceutical system strengthening.

- » SIAPS worked closely with the Extending Service Delivery Project to follow-up on a community case management of malaria pilot in two districts in **Burundi**; organized supervision visits in health centers to ensure that artemisinin-based combination therapies (ACTs), rapid diagnostic tests (RDTs), and other commodities needed by community health workers are available; held meetings for workers to give refresher training on the management of commodities and reporting tools; taught staff at 25 health centers to calculate the average monthly consumption to avoid stock-outs.

Innovative and proven approaches for human resource capacity building adopted and implemented.

- » SIAPS collaborated on the collection of procurement and supply management and other supply chain curricula from various universities (not just in Vietnam) and created a comparative analysis of their various components; used a method of self-administered questionnaire and open discussions with key informant groups to help identify the supply management-related competencies expected of today's pharmacy graduates at undergraduate and postgraduate levels; the program also helped to draft, finalize, and disseminate the resulting technical report entitled, Pre-service Curriculum Reform on Pharmaceutical Supply Management at the Hanoi University of Pharmacy: Technical Assistance for Curriculum Review and Competency Assessment; collaborated with the Department of Pharmaceutical Management and Economics to develop detailed curriculum drafts of the nine modules for postgraduate and undergraduate courses; obtained wider consultation and feedback through a workshop attended by stakeholders representing the university, government, and non-government entities.

INFORMATION FOR DECISION-MAKING CHALLENGE IN THE PHARMACEUTICAL SECTOR ADDRESSED

SIAPS activities focus on building capacity for the aggregation, analysis, presentation, and dissemination of the information to support evidence-based decision making. Through our tools, software solutions, and pharmaceutical management information system activities, SIAPS helps ensure that quality pharmaceutical 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 mobile phone and other technology in designing tools; harmonizing tools to help integrate pharmaceutical management information systems; and strengthening local organizations to customize,

maintain, and take ownership of the tools and also 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.

Progress made in Year 1 of SIAPS implementation:

Pharmaceutical management information system (PMIS) support both products and patients

- » SIAPS carried out End User Surveys that provided stock status and supply plans and information on other malaria related commodities that enabled the President's Malaria Initiative (PMI) to make key procurement decisions. Three countries (Angola, DRC, and Liberia) were able to address different challenges that were identified through the end-user-verification (EUV) surveys. For example—
 - **Angola.** Completed EUV surveys in 8 provinces covering 36 health facilities; collaborated with USAID|DELIVER to provide technical assistance to the National Directorate of Medicines and Equipment (DNME)/ Program for Essential Medicines (PNME) to facilitate receipt of PMI-funded malaria commodities (1,800,840 Coartem treatments and 862,150 RDTs). Once completed, SIAPS collaborated with USAID|DELIVER and the NMCP in coordinating distribution of the ACTs and RDTs to the country's 18 provinces, following an agreed upon distribution plan.
 - **DRC.** Assisted both national and provincial Ministries of Health to obtain and interpret pharmaceutical management data through active collection of data using mechanisms such as the Procurement and Performance Management Review for malaria and contraceptives and the EUV survey. Information generated contributed to recommendations to the US government on health product procurement.
 - **Liberia.** Implemented the EUV survey in four counties to monitor the use and availability of malaria commodities for decision making purposes; visited 41 health facilities and compiled and submitted reports to NMCP and partners. Findings were used to carry out an emergency supply of ACTs to Gbarpolu County.
 - SIAPS worked with partners to conduct EUV surveys at 63 health facilities in 17 provinces in **Burundi**. The survey showed an improvement in laboratory diagnostics, case management, and supply chain management.
- » SIAPS took the lead in collecting data on a quarterly basis for the Procurement Planning and Monitoring Report for Malaria in Angola, Benin, Burundi, Ethiopia, Kenya, Mali, Malawi, Senegal, and Uganda. Data were collected on the stock status of malaria medicines from these countries and shared with USAID|DELIVER for collation and sharing with USAID/PMI team to guide procurement decisions.

- » In **Ethiopia**, SIAPS supported the collection, compilation, and report of patient uptake data and cumulative regimen broken down bi-monthly from 613 health facilities. The information generated was shared with USAID, CDC, Supply Chain Management System (SCMS), regional logistic associates, regional health bureaus, I-TECH Ethiopia, the Clinton Health Access Initiative and Johns Hopkins-Ethiopia. As a result, the national antiretroviral therapy (ART) technical working group is being reactivated to play an active role in monitoring ART. SIAPS alerted partners that an unacceptably large percentage of new patients were being put on stavudine-based regimen as opposed to tenofovir-based regimens.
- » In **Lesotho**, SIAPS provided support for the management of the logistics management information system to ensure continuous availability of essential laboratory commodities. This support has included monitoring routine reporting and data quality assessments, resulting in the reporting rate improving from 44% to 76% in one quarter. The quality of the data submitted also improved significantly, with timeliness, accuracy, and completeness of reporting improving by 41%, 12%, and 29% respectively.
- » In **Namibia**, SIAPS provided technical support for the expansion of the pharmaceutical management information system (PMIS) to cover the performance measurement of the public pharmaceutical sector, including completion of indicators for the Central Medical Stores and Pharmaceutical Control and Inspection.

Innovative and proven tools broadly available and used

- » The Electronic Dispensing Tool (EDT) was adopted and implemented by the **DRC** National AIDS Control program (PNLS). It was included in its five-year strategic plan 2011-2015 (with a tool from WHO and another tool from the US Centers for Disease Control and Prevention [CDC]) as the only tool that provides information on patients and medicines at the same time.
- » SIAPS finalized the electronic application used to consolidate and report on the national inventory and consolidate the information/requisition forms (SUGEMI-1) generated by health facilities in the **Dominican Republic**. Currently 90% of regional health services are regularly reporting the consumption and availability of medicines in the system.
- » SIAPS helped implement RxSolution, an integrated pharmaceutical management system developed by MSH, at 11 hospitals in **Lesotho** and rolled out the dispensing and inventory module of RxSolution as well as trained users. SIAPS continued to support the use of RxSolution at 216 sites across South Africa; enhanced service delivery at facility level through the introduction of electronic batch management capability linked with dispensing. SIAPS supported the implementation of the RxSolution software at all ART sites in Swaziland. In addition, the store module of the software has been implemented at the National Medical Warehouse and the Laboratory Warehouse. SIAPS continues to work with the local MoH team in building their capacity to support the users of the RxPMIS and RxSolution.

- » In **Namibia**, SIAPS developed an electronic tool to facilitate the documentation of complementary medicines. The entry of 4,000 complementary medicine products in the electronic database will enable the National Medicines Regulatory Authority to better regulate and track complementary medicine products ensuring that the public has access to quality and safe products on the market.
- » SIAPS developed a draft of a methodology for estimating “unmet need” for maternal health commodities. Both qualitative and quantitative data were collected and global and country specific reports were reviewed.
- » SIAPS provided technical assistance to the registration team at **Mozambique’s** Pharmacy Department to develop essential tools to evaluate products for registration; identified tools needed to establish and standardize improved criteria and procedures for registering pharmaceutical products; developed drafts of two of the tools; conducted a seven-day training on the evaluation of medicine dossiers for pharmaceutical product registration, which was attended by all 10 members of the Pharmacy Department registration team as well as a member of the pharmacovigilance unit and the head of FARMAC (public retail pharmacies); discussed and revised the SOPs for receiving and evaluating applications for the registration dossier with the registration head of the department. These procedures and evaluation list were translated to English and presented in dual language format for easy access for both the applicants and the Pharmacy Department staff.

Strategic information on pharmaceutical systems strengthening available and used

- » In **Ethiopia**, the Debre-Markos hospital implemented the auditable pharmacy transaction system and recorded the following outcomes: zero expiry of medicines during the budget year (2011–2012); the cost of slow-moving items decreased by 80% from US \$33,000 to US \$6,700; the number of slow moving medicines decreased 60% from 32 to 13.

FINANCING STRATEGIES AND MECHANISMS STRENGTHENED TO IMPROVE ACCESS TO MEDICINES

Traditionally, pharmaceutical financing has been perceived as relating to funding pharmaceutical purchasing, and initiatives such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and US President’s Emergency Plan for AIDS Relief (PEPFAR) has focused heavily on funding for procurement. However, even countries that have adequate funds to procure medicines cannot always manage the flow of funds and assure availability of health supplies. Financing, therefore, broadly covers resource mobilization and maximizing efficiencies, resource pooling, payment and purchasing.

SIAPS helps countries conduct analyses to improve decisions regarding cost containment, greater efficiency, and options for mobilizing financing. Examples of this work may include evaluation of alternate supply chain systems; analysis of financial flow and sustainability; identification of options to remove roadblocks; development and implementation of systems for tracking, monitoring, and

controlling pharmaceutical spending; and analysis and evaluation of pricing policy options. Our health management expertise combined with SIAPS partners' knowledge and experience in innovative financing strategies allows countries to maximize their pharmaceutical resources.

Progress made in Year 1 of SIAPS implementation:

Financial barriers reduced

- » Contributed technical expertise to a group of **TB** stakeholders with the Second-Line Drug Access Improvement Initiative, which is focusing on interventions aimed at shaping the market through expanding the number of manufacturers of quality assured medicines, providing incentives to manufacturers through better forecasting and quantification, streamlining procurement process for better prices, and improving the demand side through more efficient diagnosis of multidrug-resistant (MDR)-TB and rational use of medicines.
- » SIAPS supported the generation of evidence to bridge the gap for the financing of antiretrovirals (ARVs) and medicines and supplies for other diseases in **Dominican Republic**. The written evidence of the gaps created transparency and accountability.

More efficient use of existing resources

- » SIAPS supported the Drafting a concept paper to study distribution costs for **Malaria** commodities.
- » SIAPS provided technical assistance to Drug and Therapeutics Committees (DTCs) in 22 **Ethiopian** hospitals to conduct ABC/VEN analysis to evaluate their resource utilization, identify gaps, and design intervention through developing more cost-efficient systems for proper selection, quantification, procurement, distribution and use of drugs.

Additional financial resources are generated

- » SIAPS initiated a standardized assessment of the 10 regional pharmaceutical warehouses and the central medical stores in **Cameroon**, with the goal of using the data to develop an action plan for addressing weaknesses; helped the government complete all the objectives related to meeting Global Fund's condition precedents including the development of—
 - An action plan based on the standardized assessment that is a condition precedent to the disbursement of funds to Cameroon from the Global Fund Round 10 HIV/AIDS grant.
 - A revision of the National AIDS Control Program's procurement manual to comply with Global Fund policies.
 - A plan for improving storage and distribution capacity to ensure that conditions are adequate for handling the volume of the products beings managed through the National HIV/AIDS program.

- A strategic plan to upgrade and improve systems to manage patient and commodity management data in the national HIV/AIDS program.
- In **South Sudan**, SIAPS provided a technical analysis of the performance of the Expanded Program on Immunization (EPI) for the period January to June 2012 and used the results to advocate for financial support to 16 priority counties selected on the basis of the highest number of missed diphtheria, tetanus, pertussis (DTP)-3 immunizations.

PHARMACEUTICAL SERVICES IMPROVED TO ACHIEVE DESIRED HEALTH OUTCOMES

Pharmaceutical services comprise the activities that pharmaceutical staff carry out to support patient care and treatment. Beyond the supply of pharmaceutical products, pharmaceutical services include educating and training staff, providing medicine information and counseling, monitoring medicine use to assure patient safety and achieve desired health outcomes, formulating policies and regulations to improve pharmaceutical care, and disseminating information and educational materials to promote public health.

SIAPS improves pharmaceutical services by using strategies, approaches, tools, and activities to support rational medicine use and AMR advocacy and containment. Our technical focus areas include medication adherence; standard treatment guidelines, essential medicines lists, formularies, and clinical algorithms; facility and community-based case management; medicine and therapeutics information; and infection control.

Progress made in Year 1 of SIAPS implementation:

Availability of pharmaceuticals improved

- » To support **Maternal Child Health**, SIAPS conducted a maternal health assessment to provide the MoH in Rwanda with the information needed to develop an action plan for assuring access to maternal health commodities. The report included a finalized action plan for improving access to maternal health medicines and supplies in **Rwanda**.
- » A rapid analysis of the unmet need for oxytocin in **Rwanda** based on theoretical need and amounts procured and distributed was also conducted with support from SIAPS.
- » In **Brazil**, the country quantified medicine needs for 81 different TB/DR-TB treatment units to avoid stock-outs, overstocks, and losses due to expiration with support from SIAPS. SIAPS developed the second-line drug inventory model (standard operating procedures [SOPs] and tracking tool), which was then approved by the National TB Program and implemented in 10 DR-TB reference centers.
- » SIAPS provided technical assistance to MoH and USAID in **South Sudan** and other donors to expedite product selection and emergency procurement for essential medicines and medical supplies to avoid stock-outs in 2013.

SIAPS Assists UN Commission Inquiry on Lifesaving Medicines for Mothers and Children

Globally, pregnant women still continue to suffer and die from postpartum hemorrhage and pre-eclampsia/eclampsia – when a woman has dangerously high blood pressure levels (pre-eclampsia) which can lead to fatal seizures (eclampsia) – even though there are proven therapies that can prevent and treat these conditions.

In 2010, the United Nations (UN) first launched the **Every Woman, Every Child** initiative to help save the lives of 16 million women and children by 2015 – in accordance with the Millennium Development Goals (MDGs). As a part of this initiative, the UN will soon commence a special Commission focused on overlooked life-saving commodities for women's and children's health.

SIAPS took part in planning meetings convened by UNICEF, WHO and UNFPA to prepare for the UN Commission inquiry. Ad hoc working groups were formed to prepare background documentation to analyze existing information on potential barriers to access of maternal and child health medicines including policy and regulatory frameworks, manufacturing issues, procurement, supply chain management and use.

At the request of **USAID**, SIAPS reviewed documentation submitted by other members of the group and synthesized findings. The documents reviewed

included assessments from several countries, journal articles, and reports from various USAID-funded projects. Through this review, several problems in health systems worldwide were identified.

Although prevention and treatment policies for postpartum hemorrhage and pre-eclampsia/eclampsia existed, these policies were often not put into practice appropriately or at all. National medicine regulatory authorities who are supposed to ensure the quality of medicines often lack the capacity to monitor and evaluate maternal health commodities sufficiently. Inadequate storage conditions of medicines lead to severely degraded products that cannot be used to help pregnant women in physical distress. Even data needed to quantify the true supply needs of these medicines are absent.

These findings have been synthesized by the maternal health working group in a report to be presented to a soon-to-be launched UN Commission – a diverse group of leaders and experts invited to catalyze changes in the way overlooked commodities are made, distributed and used in order to prevent the leading causes of death among women. The Commission will advocate at the highest levels to build consensus around priority actions for increasing the availability, affordability, accessibility and rational use of selected commodities for maternal health

- » In **South Africa**, SIAPS provided support to the Gauteng provincial conference to develop strategies and a model to ensure 98% availability of medicines at all levels of care.

Patient safety and therapeutic effectiveness assured

- » Using funding from USFDA, SIAPS
 - Completed and published the report, *Safety of Medicines in sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance*. A dissemination conference and workshop to develop pharmacovigilance tools to address some of the assessment findings was also held in Nairobi for 110 participants from 32 countries. The meeting included 110 participants from 32 countries and brought together partners from the global regulatory and pharmacovigilance community, including the World Health Organization, Bill and Melinda Gates Foundation, European Medicines Agency, U.S. Centers for Disease Control and Prevention, U.S. Food and Drug Administration, U.S. Agency for International Development, and national regulatory authorities and public health programs. The meeting also included training conducted by the US Food and Drug Administration (FDA) Center for Biologics Evaluation & Research on active surveillance for vaccine pharmacovigilance.

- Conducted the Asia pharmacovigilance assessment in five study countries: Bangladesh, Cambodia, Nepal, the Philippines, and Thailand. In all countries, local consultants appointed by the national regulatory authorities collected assessment data and drafted individual country reports.
- » SIAPS provided support to the Therapeutics Information and Pharmacovigilance Center (TIPC) in **Namibia** to carry out patient safety monitoring activities. A total of 250 adverse medicine reaction reports were received and processed by the TIPC. Additional support included the public health evaluation of compliance to switching guidelines, investigation of risk of nevirapine associated skin and liver reactions, and the risk of renal failure associated with tenofovir.

Medication Use improved

- » In **DRC**, SIAPS completed baseline studies in collaboration with the National Centre for Pharmacovigilance in nine DTCs. Following the baselines, SIAPS collaborated with the University of Kinshasa to help each hospital select interventions to address problems with medicines use and to develop action plans for implementing the interventions.
- » SIAPS supported the four **Jordanian** hospital teams as they implemented Continuous quality improvement (CQI) system protocol aimed at improving antibiotic prophylaxis in cesarean sections the protocol and carried out monitoring and evaluation through a continuous quality improvement process; worked with responsible MoH departments to assure that cefazolin, the protocol antibiotic for all three MoH hospitals, became available. As a result, Prince Faisal Hospital's department of pharmacy utilized strategies from "Identifying Drug Use Problems" and "Drug Use Evaluation" (presented and exercised during a SIAPS workshop) to quantify and control the number and amount of antibiotic prescriptions through its outpatient pharmacy. There was dramatic improvement in the cesarean section log capture rate, increasing steadily from 21% in January to 94% in May.
- » 315 rural drug vendors in **Ethiopia**, were trained to build their capacity in the areas of rational dispensing, patient counseling and proper management of pharmaceutical supplies in the private sector

Pharmaceutical services standards defined, adopted and implemented

- » SIAPS helped critically analyze a drug sensitivity test proficiency program for 17 public health labs (27 labs have been evaluated but 17 were chosen to participate) in **Brazil**; drafted recommendations and defined corrective measures in a final report submitted to the National TB Reference Lab for approval and dissemination.
- » With support from SIAPS, **Bangladesh** introduced an effective disposal system of unwanted items for Directorate General of Family Planning (DGFP), which contributed to increased available storage space and improved warehousing and logistics management; 70% of unwanted commodities were properly disposed.

- » SIAPS worked closely with the MSH Integrated Health System Strengthening Project and MoH Clinical Services to conduct an internal review of the Clinical Protocols/Treatment Guidelines; shared the draft with professional bodies such as the medical association for inputs; the final version was approved by the **Rwanda** MoH.
- » SIAPS supported **South Africa's** National Essential Drug List Committee in the development of the Adult Hospital Level Essential Medicines List, which was published by the National Department of Health (NDoH).

Emergence of antimicrobial resistance (AMR) slowed:

- » In **Ethiopia**, SIAPS trained 37 journalists on the prevention and containment of antimicrobial resistance (AMR) and rational medicines use. The objectives of the training were to increase public awareness of AMR and rational use through the media.

COMMON AGENDA



Background

The Common Agenda portfolio is made up of a proportion of all the separate health elements, and with this funding and guidance from USAID, SIAPS is expected to identify overarching pharmaceutical management issues that have emerged as key technical areas for SIAPS, but are not limited to any particular health element. The Common Agenda portfolio also supports activities that recur each year and are essential to the programmatic expansion of SIAPS.

Objectives

- Improve capacity for pharmaceutical systems strengthening
- Improve data for decision-making
- Financial mechanisms strengthened to improve access to medicines
- Improve pharmaceutical services
- Contribute to dissemination of evidenced-based approaches and best practices

Progress

- Developed a roadmap for the establishment of a framework for accrediting in-service education programs targeted to pharmaceutical personnel, including pharmacists, pharmacy technicians and pharmacy assistants in resource-limited settings.
- Participated and presented on: “Global Programs and Access to Medicines” at the annual forum of The Ecumenical Pharmaceutical Network (EPN in Addis Ababa, from March 21 to 23, 2012.
- Continued to participate in initiatives that promote workforce development in supply chain management through meetings and conferences. For example, SIAPS participated in the International Federation of Pharmacists (FIP) Education Initiative’s External Stakeholders Meeting held at the Centennial FIP Congress in Amsterdam in October 2012, at which the Initiative launched its Global Competency Framework for Services. It also participated in *People that Deliver* initiative which aims at improving supply chain management through “professionalization” of health logistics.
- Developed a roadmap for the development of a framework and metrics for measuring pharmaceutical systems strengthening interventions. An initial literature review has been completed and synthesis is well underway to examine existing approaches that have attempted measurement of systems strengthening.
- Updated and published various manuals and technical guidance resources including: “How to Investigate Antimicrobial Use in Hospitals: Selected Indicators”; “Infection Control (Self) Assessment Tool for Primary Health Care Facilities”; “Revising Pre-service Curriculum to Incorporate Rational Medicine Use Topics: A Guide”.
- Defined the scope for updating the WHO essential medicines Knowledge Management (KM) portal and expanding its use in collaboration with WHO. Systems modifications that are needed for the portal were also established. In addition, SIAPS developed the criteria and process by which documents will be uploaded into the system in order to expand the portal collection with relevant reports of work supported by USAID. Documents are currently being screened for suitability and uploaded to the portal. SIAPS also reviewed the WHO draft tool on “Country Situation Analysis on Antimicrobial Resistance (AMR)” and provided appropriate comments and suggestions.
- Through coordination with donors and participation in conferences/seminars/networks to identify and address bottlenecks (WHO/AMDS and the Global Fund), formulate priority health system research agenda (Alliance for Health Policy and Systems Research); share supply chain updates, challenges, innovations and various ways to improve SCM (USAID Supply Chain Advisors workshop); develop tools (AMDS) and champion advocacy efforts aimed at increasing access to medicines (Inter Agency Task Team on HIV Prevention and Treatment of Women and their Children, Child Survival Working Group, and Clinton Health Access Initiative (CHAI).

GLOBAL PROGRAMS



MALARIA

Background

SIAPS collaborates with national malaria control programs and central medical stores to develop and implement strategies to strengthen pharmaceutical management for malaria prevention and case management. SIAPS also supports the Roll Back Malaria Partnership Secretariat and the regional Roll Back Malaria networks. In addition, SIAPS supports the Global Fund in proposal design, the development of procurement and supply management plans, and addressing grant implementation bottlenecks.

Objectives

- Pharmaceutical sector governance strengthened
- Increase capacity for pharmaceutical supply management and services
- Increase utilization for information for decision-making
- Strengthen financing strategies and mechanism to improve access to medicines

Saving Lives Through Emergency Distribution of Anti-malarial Medicines



A supervisor from the National Malaria Control Program explains emergency distribution and the new reporting system to the chiefs of health centers in a district of Conakry.

In Guinea, malaria is a common threat year-round, especially during the rainy season that lasts from May to October. It affects everyone, but for children under five years of age, appropriate and immediate treatment could mean the difference between life and death.

Malaria accounts for 31% of consultations, 25% of hospitalizations, and 14% of deaths in health facilities among children according to Guinea national statistics. Unfortunately, Guinea struggles with an inconsistent supply of anti-malarial medicines, test kits, and preventive products, relying heavily on donors for obtaining such products. Even when the products arrive in country, financial and operational challenges often lead to delays in distribution to the various regions' public health centers and hospitals.

Every day that a health facility spends without malaria treatment drugs, lives are put at risk.

Following an initial request from the National Malaria Control Program (NMCP), the [U.S. President's Malaria Initiative](#) (PMI) and [USAID](#) funded the first emergency distribution of artemisinin-based combination therapies (ACTs) in late 2011. ACTs such as AS-AQ (artesunate-amodiaquine) are the first-line treatment for uncomplicated cases of malaria.

In response to new stock-outs in 2012 of medicines at many public health facilities, NMCP requested once again support from PMI and USAID in re-supplying the country with ACTs as well as rapid diagnostic test (RDT) kits which can be used to diagnose malaria not only in health centers but also at the community level.

SIAPS worked closely with the NMCP, the Central Pharmacy of Guinea (PCG), USAID partners MCHIP and Faisons Ensemble, Peace Corps volunteers and the regional health directors, ensuring a country-wide distribution in November 2012, even to the most remote areas. PCG arranged the advanced shipment of products to its regional warehouses and ensured delivery to all 38 health districts, where the chiefs of health facilities met to collect the products.

Over 400 centers, hospitals and some military clinics benefited directly from ACTs and RDTs. Estimates of medicines and products needed had been collected in advance of the emergency distribution through workshops and by phone. The quantity given to each facility depended on its average use of ACTs over time, and its remaining stock.

In order to avoid future stock-outs of products, this distribution was used as an opportunity to introduce monthly reporting forms and tools that would ensure a more consistent flow of information from the health facility to the district level and from there to the central level.

Moving forward, health facilities will be resupplied with malaria products after sending monthly reports detailing the number of medicines given to patients. The data will allow NMCP and the Ministry of Health to better plan for the proper quantity of products that should be sent to the local level, and how much to acquire for the country in general, reducing the risk of shortages.

Not only did the emergency distribution provide a short-term solution, but it started a longer-term procurement and supply solution. SIAPS is working with the PNLN and PCG to ensure the regular delivery of medicines and commodities to the regions, especially as a significant amount of additional products funded by PMI and USAID have arrived in Guinea or are expected shortly. In total, 755,000 doses of ACTs for all age groups, 1.1 million RDTs, 375,000 doses of sulfadoxine-pyrimethamine (SP) for preventive treatment of pregnant women, and 40,000 doses of injectable quinine for severe malaria will be provided to beneficiaries (many of them children) at no cost over the next year – helping advance PMI's goal of reducing malaria deaths by 50% in Guinea by the end of 2015.

Progress

- SIAPS continued to promote good governance principles through the implementation of a set of three PMI monitoring tools in close collaboration with USAID/DELIVER and PMI/W. The tools included the Information on commodity supply plans for malaria commodities; End Use Verification

(EUV) tool; and the Procurement Planning and Monitoring Report for Malaria (PPMRm). These tools aim at improving the availability of quality malaria medicines and commodities through the establishment of a regular stock tracking system which monitors availability and contributes to the detection and prevention of commodity leakages and stock outs in PMI programs. In collaboration with USAID/DELIVER, SIAPS organized the EUV summit on July 26, 2012. EUV methodology and main findings per country were presented to senior USAID/PMI staff. USAID/PMI found that the EUV tool was very useful in improving access to medications and also agreed that its implementation should continue in all PMI countries.

- SIAPS supported the local coordination and collaboration among MOHs and partners in five (5) countries including Burundi, DRC, Guinea, Mali, and South Sudan with the aim of improving pharmaceutical management in these countries.
- SIAPS provided support to a number of SIAPS PMI supported countries, using field and core funds, to strengthen the capacity of their National Regulatory Authorities with the aim to improving medicines policies, legislation, regulations, norms and standards:
 - In Guinea, SIAPS worked with the National Regulatory Authority to set up a national essential medicine list revision committee for the very first time. SIAPS will support Guinea regulatory authority to revise the EML and to make sure that artesunate injectable is included for severe malaria treatment as recommended by WHO.
 - With support from SIAPS, the South Sudan Drug & Food Control Authority Bill was passed into law and the Act was published in the gazette. SIAPS supported the MOH to review/update the concept paper on the establishment of an autonomous Central Medical Warehouse. A Cabinet Memo to support the submission of the concept paper to the Council of Ministers was developed, as well as the job descriptions for health facilities in Eastern Equatoria State (EES).
 - In Liberia, SIAPS provided support to the National Regulatory Authority to disseminate STG and EML developed under SPS project in the entire country. The dissemination of these policy documents will serve rational procurement according to country need and will also improve prescribing practices at the facility level.
 - In Ethiopia, with technical support of SIAPS, the Food, Medicines and Health Care Administration and Control Authority (FMHACA) finalized the Medicines Waste Management and Disposal Directives and the National Strategic Framework on Medicines Waste Management to ensure prevention of environmental hazards and for infection control a key strategy for the containment of antimicrobial resistance. SIAPS also collaborated with Pharmaceutical Fund and Supply Agency (PFSA) to support hospital Drug and Therapeutic Committees (DTCs) to develop, print and launch facility-specific essentials drug lists.
- SIAPS supported the improved coordination of partners in procurement and

distribution of antimalarial commodities by leveraging core and field support funds in the following PMI supported countries:

- In Angola, SIAPS facilitated the signing of exemption documents for PMI shipment of ACTs and RDTs. SIAPS also collaborated with USAID/DELIVER in providing TA to the MOH/DNME to process documents to facilitate arrival, receipt and distribution of PMI-funded commodities to 18 provinces.
- SIAPS assisted the MOH in Guinea to receive, store and distribute USAID-funded commodities to be used in the entire country.
- In Mali, in collaboration with USAID/DELIVER, SIAPS assisted the MOH with the reception, storage and transportation of USAID-funded commodities from the central warehouse to the district warehouses.
- SIAPS supported PMI countries to strengthen Pharmaceutical Management Information Systems (PMIS) for better management of malaria commodities:
 - In Mali, Guinea, and Ethiopia, SIAPS supported country National Malaria Control Programs to implement measures to improve the communication capacity of key actors in the pharmaceutical sector, to conceptualize a Pharmaceutical Management Information System that allows stock levels and consumption data to flow from health centers to the Central level, and to establish and support a regional mechanism for collecting, analyzing and transmitting pharmaceutical management data.
- SIAPS supported countries to collect information on the stock status of malaria medicines through the quarterly implementation of the Procurement Planning and Monitoring Report for Malaria (PPMRm) in Angola, Burundi, DRC, Ethiopia, Guinea, Kenya, Mali, Uganda, and South Sudan. Data were shared with USAID/DELIVER for collation and sharing with USAID/PMI team to facilitate procurement decisions. At the country level, data was used by decision makers to identify, analyze and anticipate problems of stock-out or expiries.
 - SIAPS supported the quarterly implementation of the EUV tool. At the end of each implementation of EUV, a feedback meeting with MoH program partners was held as a platform to share and disseminate the results of the EUV exercise, highlighting the issues affecting the supply chain and LMIS from the provincial level down to the health units. The EUV report has given MoH partners the opportunity to assess and take steps to correct and improve pressing issues and challenges in the field.
 - SIAPS collected information on supply plans for malaria commodities in Angola, Burundi, DRC, Ethiopia, Guinea, Kenya, Liberia, Mali, and South Sudan. Data was shared with USAID/DELIVER for collation and sharing with the USAID/PMI team and the ACT Supply Task Force. Any impending stock issues were alerted to the team to facilitate procurement decisions as well as corrective actions to avert stock outs.
- A concept paper on identifying distribution costs for ACTs, RDTs, and Nets from Central Medical Store to facility in two PMI countries (Benin

and Kenya) was developed by SIAPS. The concept paper was approved by USAID/PMI on July, 2012. The concept paper was sent to USAID/Kenya and USAID/Benin to seek individual USAID mission approval. SIAPS received approval from both USAID missions in September 2012. We are presently waiting for USAID/Washington contract office approval for the signature of the sub contract with WDI to start field work to start the field study.

- SIAPS participated in the WARN meetings during which SIAPS approaches on pharmaceutical management were shared with West Africa regional partners.
- SIAPS participated in the ACTWatch Advisory Committee meeting in Geneva in September 2012. The role of the Advisory Committee for ACTWatch2 was discussed. SIAPS provided advice on the design of ACTWatch survey and reviewed the finding study.
- SIAPS developed a manual for Quantification of Malaria Commodities in collaboration with a number of partners including USAID/PMI, CDC, USAID/DELIVER, Roll Back Malaria, Clinton Health Access Initiative, William Davidson Institute, and Medicines for Malaria Venture. The manual is designed to provide users, especially those at the malaria program level including malaria program managers, procurement officers, warehouse managers, implementing partners, donor agencies and others, with practical steps and guidance on how to carry out a national level quantification of artemisinin-based combination therapies (ACTs) and rapid diagnostic tests (RDTs) for the diagnosis and treatment of uncomplicated malaria.

MATERNAL AND CHILD HEALTH

Background

The goal of the maternal and child health portfolio is to assure availability and appropriate use of quality medicines and supplies and effective pharmaceutical services to reduce maternal and child mortality. SIAPS works toward this goal through increasing global awareness of the importance of good pharmaceutical management of maternal and child health supplies and coordinating efforts with other USAID implementing partners and with regional and country-level initiatives. Since access to quality maternal, newborn, and child health services demands a strong health system, SIAPS focuses on systems-strengthening approaches that increase the capacity of health workers to appropriately manage maternal and child health supplies, increase availability and use of information for decision-making, and improve availability and use of medicines and supplies for maternal and child health.

Objectives

- Capacity for maternal and child health pharmaceutical supply management increased and enhanced
- Utilization of information for decision-making increased
- Pharmaceutical services for maternal and child health improved

Progress

- Conducted a maternal health assessment to provide the MoH in Rwanda with the information needed to develop an action plan for assuring access to maternal health commodities. The survey report was finalized, incorporating comments and recommendations from stakeholder workshop participants. The report, Rapid Assessment of Pharmaceutical Management of Medicines and Supplies for Preventing and Managing Emergency Obstetric and Newborn Conditions in Rwanda: September 2012; Final Report, is awaiting the signature of the Minister of Health.
- Conducted a rapid analysis of the unmet need for oxytocin in Rwanda based on theoretical need and amounts procured and distributed.
- Developed and finalized the action plan for improving access to maternal health medicines and supplies in Rwanda was developed and finalized as well as the Rwanda maternal health assessment.
- Contributed to a report on essential maternal health commodities and a country strategy for Ethiopia for child health for the United Nations Commission on life-saving commodities.
- Continued to be active in the Maternal Health Supplies Working Group and the Pneumonia and Diarrhea Working Group as well as remaining engaged in the Community Case Management (CCM) Task Force and with external partners.
 - Developed a draft version of the methodology for estimating “unmet need” for maternal health commodities. Both qualitative and quantitative data was collected and global and country specific reports were reviewed.

TUBERCULOSIS

Background

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

Objectives

- Pharmaceutical governance for TB strengthened at global level and country level

- Capacity for TB pharmaceutical supply management and services increased and enhanced
- Improved utilization of information for TB control decision making
- Improved financing strategies for expedited access to new TB tools and pharmaceutical services
- Improved pharmaceutical services and access to TB products to achieve TB goals

Progress

- Worked with the Global Drug Facility on the development of a global TB medicines quantification tool and mechanisms for data collection.
- Contributed technical expertise to a group of stakeholders with the Second-Line Drug Access Improvement Initiative, which is focusing on interventions aimed at shaping the market through expanding the number of manufacturers of quality assured medicines, providing incentives to manufacturers through better forecasting and quantification, streamlining procurement process for better prices, and improving the demand side through more efficient diagnosis of MDR-TB and rational use of medicines.
- Conducted a desk review of TB tools, TB financing, financial barriers, and financing options.
- With the USAID TB team, developed a strategy to strengthen the Global Drug Facility that includes both short- and long-term specific technical assistance through a seconded technical specialist and manager.
- Supported e-TB Manager including carrying out updates and modifications to both the generic tool as well as country-specific versions; finalized the updated User's Guide for e-TB Manager Generic Version 2.0.
- Completed the analysis to categorize TB medicines according to their level of risk and mapped out the TB system flow for implementation of active surveillance. Consequently, risk management draft protocol and draft active surveillance implementation plans were crafted.
- Drafted training materials aimed at improving the knowledge and skills of pharmacies and accredited drug outlet dispensers to increase TB case detection in Tanzania; developed and finalized supporting tools including TB symptoms checklist, cough register, and reporting and referral forms; trained 595 dispensers from Morogoro region.

US FOOD AND DRUG ADMINISTRATION

Background

In 2010, the FDA and USAID signed an interagency agreement implemented through the SPS program. The objective was to foster collaboration on the task of strengthening those systems that ensure the quality and safety of FDA-regulated products. The FY10 funding of the agreement was used to conduct an assessment of pharmacovigilance systems and their performance in sub-Saharan Africa. FY11

Africa 2012 Pharmacovigilance Meeting



While access to new essential medicines in Africa continues to increase, a lack of proper monitoring and promotion of safe, good quality, and effective medication is also on the rise. With such weak pharmacovigilance systems, adverse drug reactions, poor product quality and medication errors become a hazard to health care systems.

During three days in April, the 2012 Pharmacovigilance Meeting, which was hosted by the Ministry of Health, Kenya; the Pharmacy and Poisons Board; SIAPS Program; and the USAID-funded Health Commodities and Services Management (HCSM) Program brought together partners from the African Regulatory Authorities, WHO, BMGF, EMA, CDC, FDA, USAID, and other key stakeholders to disseminate study findings of pharmacovigilance systems and performance in sub-Saharan Africa and facilitate a dialogue around common needs and opportunities.

The meeting was held in Nairobi, Kenya from April 18-20 and included a one-day launch of the study publication, *Safety of Medicines in Sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance*, followed by a two-day intensive workshop where countries shared their current practices and collectively identified operational tools and guidelines needed to implement pharmacovigilance activities with a systems perspective.

The full agenda and presentations can be found [here](#).

funding was used to: (1) assess pharmacovigilance systems and their performance in Asia and disseminate findings; (2) hold a conference to disseminate findings of the sub-Saharan Africa study and a workshop to identify needs related to the development of pharmacovigilance tools; and (3) develop and disseminate a framework and tools for pharmacovigilance systems.

Objectives

- Assess and disseminate findings on the pharmacovigilance and post-market surveillance systems performance in the Asia/Pacific region
- Conduct a workshop for the development of pharmacovigilance tools and conduct a conference for the dissemination of findings of the Africa study
- Develop and disseminate framework and tools for pharmacovigilance system

Progress

- Completed and published, *Safety of Medicines in sub-Saharan Africa: Assessment of Pharmacovigilance Systems and their Performance*.
- Organized a dissemination conference and workshop to develop pharmacovigilance tools to address some of the assessment findings. The meeting also included training conducted by the FDA Center for Biologics Evaluation & Research on active surveillance for vaccine pharmacovigilance.
- Conducted Asia pharmacovigilance assessment in five study countries: Bangladesh, Cambodia, Nepal, the Philippines, and Thailand. In all countries, local consultants appointed by the national regulatory authorities collected assessment data and drafted individual country reports.

REGIONAL PROGRAMS



USAID BUREAU FOR THE LATIN AMERICA AND CARIBBEAN REGION—AMAZON MALARIA INITIATIVE

Background

SIAPS is supporting pharmaceutical management activities to follow-up on activities initiated with SPS resources. Focus is on the institutionalization of activities promoted by AMI and the development and implementation of strategies to improve pharmaceutical management in low-malaria incidence settings. These proposed activities follow the 2010–2015 AMI Strategic Orientations on Drug Access and Use.

Objectives

- Coordinate joint activities with AMI partners to strengthen the governance of the pharmaceutical sector
- Support evidence-based decision making on malaria pharmaceutical management
- Provide technical assistance to institutionalize best practices on malaria pharmaceutical management to provide desired outcomes

Progress

- Completed the final reports of the following studies: (1) “adequacy” evaluation of malaria control strategies in Brazil, Nicaragua, and Panama; (2) dissemination and use of malaria pharmaceutical management information; (3) “bottle neck” analysis in the procurement of malaria medicines.
- Supported the integration of the Bolivian malaria program into a unified pharmaceutical system.
- Carried out an evaluation of the introduction of malaria pharmaceutical guidelines in Madre de Dios, Peru.
- Conducted a regional workshop with the participation of Pan American Health Organization. Regional AMI activities to support the improvement of malaria pharmaceutical management were agreed on during this meeting.
- Supported the dissemination of the quarterly bulletin on malaria medicines stock in AMI countries and in-depth assessments on specific issues. That information has been the basis of the donation/exchange of medicines and reorientation of malaria control strategies.
- Helped introduce guidelines and manuals to improve malaria pharmaceutical management, and conducted result/impact evaluations after the implementation of these tools. The revised criteria for programming and distribution of medicines in low-incidence areas were immediately used to redistribute regional antimalarial stock in two countries. Peru drafted a ministry decree to institutionalize this practice nationwide.

USAID BUREAU FOR THE LATIN AMERICA AND CARIBBEAN REGION—SOUTH AMERICAN INFECTIOUS DISEASE INITIATIVE

Background

The central focus of the South American Infectious Disease Initiative (SAIDI) is rational use of antimicrobials and AMR control, with a special emphasis on preventing the emergence of MDR-TB. Since 2004, Rational Pharmaceutical Management Plus and SPS Programs and the other SAIDI international partners have been working with national counterparts in Bolivia, Peru, and Paraguay to create a new, evidence-based and stepwise approach to local solutions for containing AMR. In FY10, SAIDI partners decided to concentrate all the technical assistance and resources in the control of TB and MDR-TB in the jurisdiction of Madre de Dios, Peru. Limited resources were still used to document the impact of previous interventions and to transfer capacities to national institutions.

Objective

- TB treatment outcomes in Madre de Dios improved

Progress

- Supported the introduction of TB pharmaceutical guidelines in Madre de Dios.
- Completed remodeling of selected warehouses using affordable technology; completed and distributed a technical report with the results of the baseline assessment and cost of the intervention.

HIGHLIGHTS FROM SIAPS HEADQUARTERS



Organization and Staffing

All key Program positions were filled or transitioned into during the first quarter. The Project Director, Technical Deputy Director, and Deputy Director for Finance and Operations all transitioned into their SIAPS roles, from first day of the program. The Deputy Director for Country Programs also started during the course of the quarter. The Monitoring and Evaluation (M&E) Advisor was hired under the Center for Pharmaceutical Management prior to program start and hence was available from the start.

Work Planning

SIAPS developed a new template to guide the work planning process for all program portfolios. The template emphasizes the relation between activities and SIAPS intermediate results and highlights M&E as a key section, while also capturing portfolio-specific knowledge management activities. By the end of the quarter, all workplans for which SIAPS had received obligations were completed and submitted to the respective Missions and to USAID/Washington.

Program Management Systems

SIAPS explored options for procuring or adapting new software solutions to help better manage specific program aspects. These include work planning and reporting; managing technical assistance and training needs; and managing program documentation and reports. Several tools were identified and examined. A web-based tool, Central Desktop, was identified as a suitable platform for managing technical assistance and training resources.

To replace the Strategic Monitoring System used during the Strengthening Pharmaceutical Systems (SPS) Program, staff researched and evaluated several M&E and project management tools. After detailed reviews and demonstrations from three different software companies, SIAPS determined that the Newdea software best met the program's requirements. An on-site customization meeting was held with a Newdea representative who travelled to Arlington and spent three days with SIAPS staff, customizing the tool and developing a detailed implementation plan.

Capacity Building and Performance Management

All SIAPS Technical staff and Portfolio Managers attended a day-long meeting to learn about new processes and provide SIAPS technical staff at headquarters with the same guidance that field staff received during the Regional Launch Meetings held in January/February 2012.

With funding from the SPS Afghanistan program, the Capacity Building and Performance Improvement Unit launched the pilot phase of the *Literature Search Skills Course* in summer 2012 to participants in these SIAPS and SPS Associate Award countries: Afghanistan, Ethiopia, Kenya, Rwanda, and South Africa.

The Unit drafted and disseminated the strategy for on-boarding newly hired Country Project Directors and building the capacity of seasoned Country Project Directors. The strategy consists of three major parts: a two-week participatory on boarding program, an anticipated day-long session at the SIAPS 2013 Global Meeting, and an online platform for ongoing training and performance improvement opportunities.

The Unit coordinated the adaptation and revitalization of a Quantification Training. The Unit coordinated the process of making the two-week training more participatory and based on learner's needs and worked with facilitators and technical staff to ensure program success.

Knowledge Management

The Center for Pharmaceutical Management's Knowledge Management team implemented the new Wordpress platform for the SIAPS website, including site design, content mapping, and plug-in development.

Conferences and Meetings

In collaboration with the Ministry of Health in Kenya, SIAPS hosted a pharmacovigilance meeting in Nairobi from April 18–20, 2012. The new report on: "Safety of Medicines in Sub-Saharan Africa: Assessment of

Pharmacovigilance Systems and their Performance” published by SPS was launched during the meeting. Many partners from the African Regulatory Authorities, WHO, the Bill & Melinda Gates Foundation, European Medicines Agency, CDC, FDA, USAID, and other key stakeholders attended. This was followed by a two-day workshop to discuss experiences and priority for regulatory system tools.

Key Documentation

The program developed a draft concept paper on SIAPS Support for Strengthening Regulatory Systems and Governance in Developing Countries. It also published an article on “Pharmacovigilance and global HIV/AIDS” in the *Journal of Current Opinion in HIV and AIDS*. SIAPS updated and finalized the manual entitled *How to Investigate Antimicrobial Use in Hospitals: Selected Indicators*. SIAPS also translated and finalized the French and Spanish versions of this manual. All three versions are now published.



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