

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

Improved Access. Improved Services.
Better Health Outcomes.



Annual Report: Program Year 5

October 2015–September 2016



USAID
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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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CONTENTS

| | |
|--|-----------|
| Acronyms and Abbreviations..... | 7 |
| Introduction..... | 9 |
| Health Areas | 17 |
| Malaria | 18 |
| Maternal, Newborn, and Child Health..... | 20 |
| Neglected Tropical Diseases..... | 26 |
| Tuberculosis..... | 29 |
| Cross Bureau | 37 |
| Intermediate Results..... | 47 |
| Pharmaceutical Sector Governance Strengthened | 48 |
| Technical Highlight..... | 60 |
| Capacity for Pharmaceutical Management and Services Increased and Enhanced.. | 63 |
| | 63 |
| Technical Highlight..... | 69 |
| Information for Decision Making in the Pharmaceutical Sector Addressed..... | 72 |
| Technical Highlight..... | 78 |
| Financing Mechanisms Strengthened to Improve Access to Medicines..... | 81 |
| Technical Highlight..... | 85 |
| Supply Management Improved to Achieve Desired Health Outcomes | 89 |
| Technical Highlight..... | 94 |
| Pharmaceutical Services Improved to Achieve Desired Health Outcomes | 96 |
| Technical Highlight..... | 106 |

| | |
|------------------------------------|------------|
| Countries..... | 109 |
| Angola..... | 110 |
| Bangladesh..... | 112 |
| Benin..... | 114 |
| Burundi..... | 116 |
| Cameroon..... | 118 |
| Central Asia..... | 120 |
| Dominican Republic..... | 122 |
| Democratic Republic of Congo..... | 124 |
| Ethiopia..... | 126 |
| Guinea..... | 129 |
| Haiti..... | 131 |
| LAC Amazon Malaria Initiative..... | 132 |
| Mali..... | 134 |
| Mozambique..... | 136 |
| Namibia..... | 138 |
| Niger..... | 140 |
| Philippines..... | 141 |
| Sierra Leone..... | 143 |
| South Africa..... | 145 |
| South Sudan..... | 147 |
| Swaziland..... | 149 |
| Ukraine..... | 151 |
| West Africa Regional Project..... | 153 |

ACRONYMS AND ABBREVIATIONS

| | |
|-------------|---|
| ACPE | Accreditation Council for Pharmacy Education |
| ACT | artemisinin-based combination therapy |
| ADE | adverse drug event |
| AMR | antimicrobial resistance |
| APTS | Auditable Pharmacy Transactions and Services |
| ART | antiretroviral treatment |
| ARV | antiretroviral |
| CCM | community case management |
| CHW | community health worker |
| CPD | country project director |
| DGFP | Directorate General Family Planning |
| DGHS | Directorate General Health Services |
| DOT | directly observed treatment |
| DTC | Drug and Therapeutic Committee |
| EML | Essential Medicine List |
| ECSA | East, Central, and Southern Africa [region] |
| EUV | end use verification |
| EWS | early warning system |
| FDA | US Food and Drug Administration |
| FMHACA | Food, Medicine and Health Care Administration and Control Authority |
| FP | family planning |
| GDF | Global Drug Facility |
| Global Fund | Global Fund for AIDS, Tuberculosis and Malaria |
| GHI | Global Health Initiative |
| HMIS | Health Management Information System |
| IPTp | Intermittent Prevention Treatment during Pregnancy |
| LCP | Lung Center of the Philippines |
| LFA | local fund agent |
| LLITN | long-lasting insecticide treated net |
| LMIS | Logistics Management Information System |
| M&E | monitoring and evaluation |
| MCH | maternal and child health |

| | |
|---------|--|
| MCNH | maternal, child, and neonatal health |
| MDR-TB | multidrug-resistant tuberculosis |
| MOF | Ministry of Finance |
| MoH | Ministry of Health |
| MOHFW | Ministry of Health and Family Welfare |
| MOHSS | Ministry of Health and Social Service |
| MRA | Medicines Regulatory Authority |
| NDP | National Drug Policy |
| NDRA | National Drug Regulatory Authority |
| NHTC | National Health Training Center |
| NMCP | National Malaria Control Program |
| NMRC | Namibia Medicines Regulatory Council |
| NTDs | Neglected Tropical Diseases |
| NTP | National Tuberculosis Program |
| PEPFAR | President's Emergency Plan for AIDS Relief |
| PMDT | programmatic management of drug-resistant TB |
| PMI | President's Malaria Initiative |
| PMTCT | prevention of mother to child transmission |
| PR | primary recipient |
| PTC | Pharmaceutical and Therapeutics Committee |
| RDT | rapid diagnostic test |
| RH | reproductive health |
| RMU | rational medicine use |
| SACU | South African Customs Union |
| SADC | South African Development Community |
| SANU | Southern Africa Nazarene University |
| SCM | supply chain management |
| SCMP | Supply Chain Management Portal |
| SIAPS | Systems for Improving Access to Pharmaceuticals and Services [Program] |
| SOP | standard operating procedure |
| SPS | Strengthening Pharmaceutical Systems [Program] |
| TB | tuberculosis |
| TDF | Tropical Disease Foundation |
| TOR | terms of reference |
| TOT | training of trainers |
| UNITAID | global health organization for increased funding for HIV and AIDS, TB, and malaria drugs |
| VPP | Voluntary Pooled Procurement |
| WHO | World Health Organization |
| XDR | Extensively drug-resistant tuberculosis |

INTRODUCTION



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Systems thinking is now a widely accepted concept in global health.^{1,2} Governments, donors, and other actors in global health recognize that guaranteeing the availability of medicines is a necessary, but insufficient component to improving health outcomes. Rather, medicines availability must be bolstered by other components, such as ensuring that quality medicines are available and prescribed and dispensed appropriately by health care workers; patients must also use medicines properly. In order to achieve improvements in health for their populations and address health inequities, governments and donors must invest in strengthening health systems. A health system depends on its subcomponent, a pharmaceutical system, for the continuous availability of safe, effective, and affordable essential medicines and other health technologies of assured quality to deliver effective health interventions that improve health outcomes. This is in alignment with USAID's Vision for Health Systems Strengthening (2015-2019). To this end, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program focuses on achieving positive health outcomes by assuring the availability of quality pharmaceutical products and effective pharmaceutical services.

1 Adam, T., & de Savigny, D. (2012). Systems thinking for strengthening health systems in LMICs: need for a paradigm shift. *Health Policy and Planning*, 27(suppl 4), iv1-iv3.

2 WHO 2014. *Medicines in Health Systems: advancing access, affordability and appropriate use*. Ed. Maryam Bigdeli, David H Peters, Anita K Wagner.

SIAPS partners convened to agree on the definitions of a pharmaceutical system and its strengthening as follows: ³

A pharmaceutical system consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.

Pharmaceutical systems strengthening is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to enhance responsive and resilient system performance for achieving better health outcomes.

SIAPS Program objectives are to help countries:

- Strengthen pharmaceutical sector **leadership** and **governance** and establish sound policies and legislation;
- Build **human resource** and **institutional capacity** for more sustainable organizations;
- Address **information** needs to support decision making in pharmaceutical systems;
- Improve **financing** strategies and mechanisms to assure adequate funding and effective use of resources; and
- Provide effective pharmaceutical **services** that help meet the needs of the patient and the achievement of desired health outcomes.

Ensuring access (defined as availability, affordability, accessibility, and acceptability⁴) to quality essential pharmaceuticals and related services that support their safe, appropriate, and cost-effective use is the key objective of a pharmaceutical system and a core function of the health system it supports. Essential medicines and health technologies are required for the achievement of desired health outcomes and many disease-specific targets. As they constitute a key component of **Universal Health Coverage (UHC)**, countries and their development partners, such as USAID, are working to build stronger systems to produce sustainable improvements in access to and appropriate use of quality products. As Windisch et al. note, “Sustained access to health commodities will depend on the strength of the health system,” not solely the strength of the supply chain.⁵

Strengthening the entire pharmaceutical system addresses systemic deficiencies, going beyond the selection, procurement, and distribution of pharmaceutical

3 Defining and Measuring Pharmaceutical Systems Strengthening. Report of the SIAPS Partners Consultative Meeting, September 11-12, 2014.

4 Management Sciences for Health 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health

5 R. Windisch, P. Waiswa, F. Neuhann, et al. Scaling up antiretroviral therapy in Uganda: using supply chain management to appraise health systems strengthening. *Globalization and Health* 2011, 7:25

products to include the provision of pharmaceutical services, which includes dispensing of pharmaceuticals combined with providing medication-related information, counseling, and support for self-care.⁶

It also includes slowing the emergence of drug resistance and ensuring that medications are safe and do not cause unintended harm to patients. This approach ensures equitable access to and appropriate use of effective pharmaceutical technologies and medicines for diagnosis and treatment of major public health threats, including malaria, HIV/AIDS, maternal and child deaths, tuberculosis (TB), neglected tropical diseases (NTDs), and more recently, Ebola. The systems approach underlying the SIAPS implementation strategy to help countries meet disease-specific targets strengthens pharmaceutical systems to provide a wider range of medicines and pharmaceutical products, ultimately producing improved health outcomes.

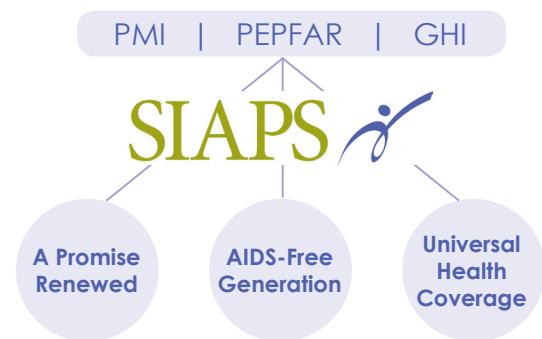
SIAPS seeks to strengthen the pharmaceutical system in its totality, by addressing five interrelated health systems core functions as defined by the World Health Organization (WHO) — governance, human resources, information, financing, and service delivery — to ultimately address disease-specific, in-country needs. The systems-based approach differs from providing isolated inputs to the pharmaceutical system, such as procuring and distributing pharmaceutical products or upgrading infrastructure of health facilities, which may improve services only in the short term.

SIAPS remains committed to President’s Malaria Initiative (PMI) and the President’s Emergency Plan for AIDS Relief (PEPFAR) goals and is a strategic partner supporting additional USG Global Health initiatives— **Universal Health Coverage (UHC)**, **Ending Preventable Child and Maternal Deaths (EPCMD)**, **an AIDS-free Generation (AFG)**, and **Protecting communities from Infectious Diseases (PCID)**. SIAPS uses platforms presented by PMI, PEPFAR, and other USAID funding streams to accelerate advancement of these goals.

SIAPS provides technical leadership and assistance to developing countries in pharmaceutical system strengthening (PSS) with a deliberate focus on patient-centered services and health outcomes for health areas, including family planning, HIV/AIDS, malaria, maternal and child health, tuberculosis, and neglected tropical diseases. This systemic technical assistance (TA) from SIAPS enables comprehensive changes to organizational structure and institutional capacity, policy and regulations, and relationships among the pharmaceutical system’s components.

All interventions are designed to focus on sustainable systemic improvements in pharmaceutical management and pharmaceutical services through capacity building of institutions and individuals. Furthermore, the SIAPS Program recognizes that sustainable improvements in all pharmaceutical system components are critical for responsive, resilient system performance that can

All interventions are designed to focus on sustainable systemic improvements of pharmaceutical management and pharmaceutical service provision through capacity building of institutions and individuals.



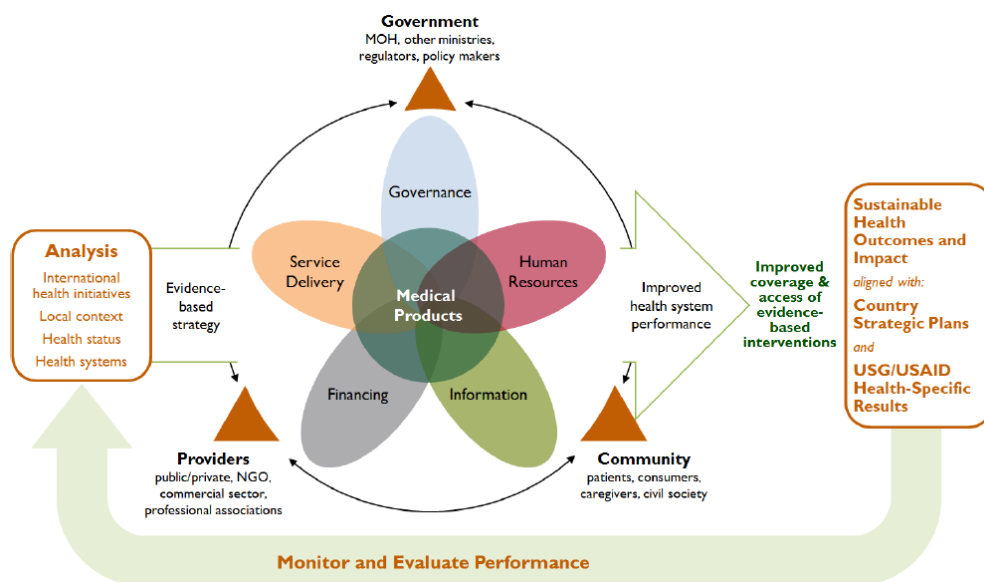
⁶ Systems for Improved Access to Pharmaceuticals and Services (SIAPS). Enhancing Health Outcomes for Chronic Diseases in Resource-Limited Settings by Improving the Use of Medicines: The Role of Pharmaceutical Care. Submitted to the U.S. Agency for International Development by the SIAPS Program. Arlington, VA: Management Sciences for Health.

meet the test of epidemics, such as the recent Ebola outbreaks in West Africa, and ensure uninterrupted access to life-saving commodities.

The SIAPS Approach to Pharmaceutical System Strengthening

The SIAPS pharmaceutical systems strengthening framework (also referred to as the “daisy wheel”) is the program’s conceptual framework that guides the design, implementation, and monitoring of program activities. By focusing on sustainable systemic improvements of pharmaceutical management and pharmaceutical service provision through capacity building of institutions and individuals in five areas, the SIAPS pharmaceutical systems strengthening framework (Figure 1) comprehensively integrates the medical products function at the center of the set of interacting building blocks. Also depicted are the key stakeholders categorized as government, providers, and community and the expected outcomes, as the pharmaceutical system contribution to health outcomes. This complex systems approach to its design is essential to improving global health.^{7,8} By strengthening the pharmaceutical systems of LMICs to ensure the accessibility of quality pharmaceutical products and services, countries are better positioned to meet the USG global health goals and presidential initiatives. When priorities or funding are focused on a single disease or condition, the approach’s underlying implementation strategy is to help countries meet disease-specific priorities and targets, while strengthening the pharmaceutical system for a wider range of medicines and pharmaceutical products.

Figure 1.
SIAPS framework
for pharmaceutical
systems strengthening



Even with widespread availability of medicines, inappropriate, irresponsible, and irrational use of medicines is a serious risk with major implications, including the development of antimicrobial resistance. First-line TB medicines, for example, are now widely available in nearly all countries; however, persistent challenges around medication adherence and rational use continue to perpetuate drug resistance, leading to more complicated and expensive treatment regimens. Antimicrobial drug resistance (AMR) is a multi-faceted problem that requires a

7 Julio Frenk. 2010. The Global Health System: Strengthening National Health Systems as the Next Step for Global Progress. PLOS Medicine, 7(1); e1000089.

8 David H Peters. 2014. The application of systems thinking in health: why use systems thinking? Health Research Policy and Systems, 12:51.

comprehensive solution including medicines availability, therapeutic substitution based on product availability, strengthened quality assurance in the supply chain to assure product quality, rational use to avoid overuse as it relates to stock-outs and supply imbalances. Therefore, SIAPS strives to build capacity for comprehensive, patient-centered pharmaceutical care practices, anchored by effective informational systems, tools, and capacity to help promote rational medicines use, improve medication adherence, and slow the development of drug resistance.

Working to Strengthen Pharmaceutical Systems

SIAPS has worked toward supporting the attainment of USAID health goals by focusing on innovative, viable strategies to promote pharmaceutical systems strengthening. SIAPS achieves all its work through its global network of staff in the United States and country offices, along with core and resource partners. To promote and use a system strengthening approach that will result in positive and sustainable health impact, the SIAPS technical strategy incorporates the Global Health Initiative (GHI) principles.⁹ Given the diversity of country needs and contexts, country teams work directly with USAID Missions and local partners to contextually model the SIAPS approach to align with specific USG priorities and goals, as well as pre-identified gaps of host governments as articulated in national health strategic plans, and thus deliver results that are locally appropriate and sustainable.

Country teams continue to be supported by a program management team at the headquarters office in Arlington, Virginia that ensure that quality work plans and reports are delivered on time, mobilize technical and other resources, and liaise with USAID/Washington, other MSH technical units, and other partners to ensure that country programs have the required resources to achieve their goals. SIAPS' core technical team provides cross-cutting and specialized technical support to all country and health element portfolios that assure the program-wide application of best practices and lessons learned. They also focus on operational research and comparative analysis that contribute to our body of knowledge and enhance technical leadership. Our health element focal persons and their staff liaise directly with the health element leads for malaria, TB, maternal, neonatal and child health (MNCH), HIV/AIDS, and neglected tropical diseases (NTDs) in USAID/Washington to ensure that the SIAPS Program focuses on interventions that will help achieve US government targets, while ensuring uniformity and consistency of technical approaches at global, regional, and country levels.

Our core and resource partners bring a mix of skills and expertise in pharmacy education and training, pharmaceutical health insurance, cost-effectiveness evaluations and research, logistics management, pharmacovigilance, pharmaco-economics and epidemiology, laboratory strengthening, mission sector coordination, research and evaluation, operations research, and management information systems. Core partners include: the **Accreditation Council for Pharmacy Education (ACPE)**, **Harvard University**, the **Logistics Management Institute (LMI)**, and the **University of Washington**. Specialized resource partners include the **African Medical Research Foundation (AMREF)**, **Ecumenical Pharmaceutical Network (EPN)**, **Results for Development (R4D)**, **Imperial Health Sciences (IHS)**, **VillageReach**, and the **William Davidson Institute**.

9 "Principles." US Global Health Programs, Global Health Initiatives. Web, 15 Nov. 2016
<https://www.ghi.gov/principles/>

The SIAPS program's ultimate objective is to institutionalize its PSS interventions to ensure the sustainability of activities beyond the life of the program.

The SIAPS program's ultimate objective is to institutionalize its PSS interventions to ensure the sustainability of activities beyond the life of the program. Consequently, central to the execution of the SIAPS PSS framework is involving key local stakeholders: local governments, service providers, and the community. Lessons learned from the past five years of operationalizing the SIAPS PSS framework, as guided by the **SIAPS core operating principles**, are described below.

Build on and Strengthen Existing Systems

USG and recipient nations alike work to create sustainable health systems that are eventually owned, managed, and operated by host governments and their citizens. SIAPS technical assistance is designed to simultaneously address countries' most pressing needs in the short term, while building on existing systems and local capacity to increase country ownership, and therefore sustainability of USAID investments, in the long term. As such, SIAPS activities are developed in alignment with in-country health goals, and designed, implemented, and monitored in close collaboration with in-country stakeholders. Advocacy has been critical to SIAPS' success in securing necessary commitment and facilitating effective and sustainable improvements in pharmaceutical systems and as such, SIAPS has continued matching advocacy strategies to governments' needs.

Integrate Public Health Programs and National Supply Systems

SIAPS activities are integrated with existing public health programs and supply systems, as interventions that address systems are more powerful in ensuring sustainability and bringing about longer-term impact. An integrated pharmaceutical system improves efficiency and has a sustained positive impact on the availability of medicines and commodities used by disease-control programs. A holistic approach that strengthens all functional areas of pharmaceutical management and builds human resource capacity significantly contributes to the reliable supply of medicines and other health commodities.

Build the Capacity of Local Organizations and People

SIAPS' capacity building efforts help countries to improve their ability to manage pharmaceuticals at all levels. All SIAPS country programs use MSH's two-part approach to capacity building: individual and organizational. This systematic approach to strengthening the capacity of local institutions significantly enhances country ownership and increases the health system's ability to sustain the improvements in the long run. Further, SIAPS takes advantage of relevant tools and job aids, which are critical for helping newly trained workers to apply their skills in the workplace and institutionalizing system-level practices. For example, in-service training and task shifting are effective strategies for increasing access to medical products and services, improving health outcomes for patients, and improving the morale of existing health workers. In Ethiopia, the introduction of clinical pharmacy services has substantially improved early identification and prevention of medication errors, drug interactions, adverse drug reporting, and adherence to treatment.

Engage in In-Country Coordination of Support from Various Stakeholders

SIAPS helps to capacitate governing bodies to create and use mechanisms for in-country stakeholder collaboration to optimize donor resources, coordinate pharmaceutical management planning, and harmonize tools and approaches. In this regard, SIAPS endeavors to enlist various stakeholders, including civil society, that have an interest in or are affected by SIAPS-supported activities and to build the capacity of partners who will take over leadership and oversight of these efforts. This approach is tripartite: strong working relationships with government counterparts; active engagement and coordination with other donors, implementing agencies, and development partners; and involvement of the private sector.

Continuously and Objectively Self-Assess Using a Set of Defined Metrics

Continuously monitoring and evaluating program progress using defined metrics is critical to informing course correction in order to attain program success. SIAPS has a defined Performance Monitoring Plan (PMP) to track program progress. In Cameroon, the review of SIAPS indicators during program implementation of a capacity building intervention revealed a risk of decreased performance on some post-training indicators. This prompted SIAPS/Cameroon to reshape the supervision activities and feedback methodology in a bottom-up approach. Stock-outs at facility level declined from 100% in PY2 and PY3 to 9% in PY5 as a result.

Facilitate Consensus-Building on Definition of Pharmaceutical Systems Strengthening and of a Monitoring Framework

SIAPS convened a consultative meeting of its partners to identify definitions of a pharmaceutical system and PSS, and components to be included in a measurement framework for systems strengthening. The meeting brought together SIAPS core and resource partners, experts from USAID, the Pan American Health Organization (representing WHO), and Boston University School of Public Health. SIAPS used the results to develop a draft measurement framework with associated indicators for PSS and finalized a manuscript that was submitted to the Health Policy and Planning journal. The manuscript reviews the literature on pharmaceutical systems and its strengthening and proposes definitions and the components deemed critical for tracking progress in PSS.

Harmonize Information Systems to Improve Patient Care

SIAPS has addressed the challenge of the lack of pharmaceutical data through the revision and roll-out of appropriate data collection tools (paper-based and electronic). Across SIAPS country programs, information management has been “revolutionized” by health workers adopting the use of computers to manage pharmaceutical information. Pharmaceutical data have been used for monthly reports, commodity forecasts, research activities, and funding proposals, including Global Fund proposals. With SIAPS support, countries have developed more efficient systems for collecting, collating, and processing ART data. In the process, SIAPS has shown that:

- Even in resource-constrained settings, well-organized, dispensing-based pharmacy data can provide insight into patient uptake and prescribing patterns. This information can serve as a basis for taking timely actions to rectify deviations from treatment guidelines, as well as for program monitoring and quantification for essential medicines.

- Dissemination and feedback loops for collected data are critical for generating action that can help improve health systems and outcomes, as witnessed in Angola, DRC, Mali, Namibia, Swaziland, and Ethiopia.

Share Lessons Learned and Best Practices Widely

SIAPS' knowledge management strategy ensures that USAID Missions, other US agencies, implementing organizations, host-country governments, other donors, multinational organizations, and international stakeholders receive the information they need to monitor program progress, avoid duplication of efforts or conflicting plans, and use the lessons learned and best practices to improve complementary activities. SIAPS has developed a tailored end-of-program joint knowledge management and communications work plan so that best practices and innovative solutions for improving access to and appropriate use of medicines through a PSS approach will be widely disseminated.

Advancing the SIAPS Goal in Program Year Five

In fiscal year 2016 (FY16), SIAPS continued to advance its goal of assuring the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes by working with local counterparts and partners in 47 countries, with field support in 15 countries. This fiscal year SIAPS provided technical assistance to regional programs in West Africa, Central Asia, and Latin American and the Caribbean.

The SIAPS Program Award was initially \$197,926,458 over five years. In the tail end of FY15, the program was granted an extension of twelve months, until September 22, 2017 and the Program Award increased to \$225,926,458.

This implementation year, SIAPS began supporting some West African countries in their post-Ebola recovery efforts. SIAPS opened a country office in Sierra Leone and is using Ebola funding to provide further bolster support in some countries already supported by SIAPS, Guinea, Mali, and Benin.

While the SIAPS Program has been extended to September 2017, several country programs will close-out prior to then. During FY16, country programs in Angola, Burundi, Cameroon, Dominican Republic, Democratic Republic of Congo, Haiti, South Africa, South Sudan, Swaziland and LAC AMI, and Central Asia completed their technical assistance and transitioned ongoing activities to their respective host governments and other partners. As the SIAPS Program comes to a close, a final report, summarizing the achievements and lessons over the life of SIAPS, will be produced.

The SIAPS Program's annual report presents SIAPS' accomplishments during program year five (PY5). The highlights presented are due to the cumulative nature of pharmaceutical systems strengthening efforts over the past five years. Results are also presented here by our core portfolios - health program areas that demonstrate SIAPS' contributions to the health goals of the USG and Cross Bureau that demonstrates contributions to USAID/W Office of Health Systems (OHS) priority objectives. Lastly, the report presents results by SIAPS intermediate result areas, representing the multiple countries and regions where we work.

HEALTH AREAS

MALARIA



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Countries Supported by the Malaria Core Portfolio in Year 5

| |
|------------------------|
| Angola |
| Burundi |
| DRC |
| Ethiopia |
| Guinea |
| Kenya |
| Mali |
| Niger |
| South Sudan |
| Latin America Regional |

THE CHALLENGE

Many President's Malaria Initiative (PMI)-supported countries continue to face challenges in ensuring an uninterrupted supply and appropriate use of high-quality malaria medicines and commodities. Factors contributing to these challenges include poor planning and coordination among country partners; a lack of strategic information for decision making (leading to frequent stock-outs of key health commodities at all levels); and weak human resources capacity to perform key pharmaceutical management functions, resulting in irrational medicine prescribing, dispensing, and use.

ACHIEVEMENTS DURING PROGRAM YEAR FIVE

Global-level Engagements

To document how pharmaceutical systems strengthening approaches and activities support efforts to control malaria, a desk review of documented activities and results across eight countries (Angola, Burundi, DRC, Ethiopia, Guinea, Kenya, Mali, and South Sudan) was conducted. The review was followed by key informant interviews with project staff, government stakeholders, other

SIAPS Strategy

The USAID/PMI-funded SIAPS Program endeavors to improve pharmaceutical governance and build national-level capacity to manage malaria products, improve the quality of information systems, strengthen financing strategies, and improve the quality of pharmaceutical services provided to malaria patients. At the country level, SIAPS collaborates with national malaria control programs (NMCPs) and central medical stores to develop and implement strategies to strengthen pharmaceutical management that will prevent malaria and improve case management.

implementing partners, and beneficiaries. The data were triangulated with other relevant sources to support evidence of SIAPS' achievements, and the document is undergoing external review.

SIAPS held regular meetings with PMI/Washington staff to discuss the implementation of activities in PMI-supported countries. The discussions included the project's transition plan for malaria activities which was shared with PMI. SIAPS also participated in meetings to discuss the transition of PMI tools, such as the End Use Verification (EUV) and the Procurement Planning and Monitoring Report for Malaria (PPMRm), from SIAPS to the USAID-funded Global Health Supply Chain-Procurement, Supply, and Management (GHSC-PSM) project).

Regional-level Engagements

SIAPS participated in an annual meeting to promote regional coordination between USAID-funded Leadership, Management, and Governance (LMG) and SIAPS projects. The meeting also aimed to identify and document good practices for providing capacity-building assistance to NMCPs, exchange information and experiences among senior technical advisors, and discuss strategies for ensuring the sustainability of applied interventions. Senior technical advisors from the NMCPs of Burundi, Cameroon, Cote d'Ivoire, Guinea, Laos, Liberia, Niger, and Sierra Leone attended the meeting.

Country-level Engagements

SIAPS continued to support the implementation of the PPMRm and EUV tools to facilitate procurement decisions, avert stock-outs of life-saving commodities, and monitor their appropriate use. PPMRm findings have allowed countries to mobilize resources, accelerate procurement of commodities, and revise forecasts and distribution plans. The EUV process has enabled countries to assess and take steps to improve the availability and use of malaria commodities.

MATERNAL, NEWBORN, AND CHILD HEALTH



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BACKGROUND

As the Millennium Development Goals came to an end in 2015, the global community reaffirmed its commitment to ending preventable child and maternal deaths through the Sustainable Development Goals (SDGs) and set new, more ambitious commitments to reduce maternal, newborn, and child mortality rates that required more intensified efforts and holistic, systems strengthening approaches.

Despite the progress made in reducing maternal and child mortality rates, both still remain high. Alarmingly, a large proportion of these deaths could be avoided if women and children were to have access to adequate health services where necessary quality medicines and supplies are available and skilled health providers are present. The preventative and curative measures for the major causes of maternal and child deaths are well known, but access to them remains elusive for many.

To address these issues, the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) was launched in 2012 to focus on 13 essential reproductive, maternal, newborn, and child health (RMNCH) commodities and develop a set of recommendations aimed at increasing access to and availability of these commodities. Two years later, recognizing the need for heightened attention for RMNCH, USAID and the global RMNCH community renewed their

SIAPS Strategy

Achieving the EPCMD targets will require a focused systems strengthening approach.

SIAPS works with global and in-country partners to improve access to and use of lifesaving medicines for women and children, thereby contributing to EPCMD. By promoting a pharmaceutical systems strengthening approach, SIAPS activities go beyond addressing supply chain challenges and incorporate interventions to positively affect the system as a whole, from strengthening pharmaceutical legislation, regulations, and policies to supporting appropriate community case management and patient-centered care.

SIAPS strategies implemented at the global and country levels include improving governance of pharmaceutical systems, strengthening supply chain management capacity, increasing the availability of pharmaceutical information for decision making, developing appropriate pharmaceutical financing strategies, and promoting the rational use of medicines and supplies.

commitment to ending preventable child and maternal deaths (EPCMD) by setting new targets (fewer than 50 maternal deaths per 100,000 live births and fewer than 20 child deaths per 1,000 live births) to be achieved by 2035.

Five strategic shifts were proposed to achieve these targets: (1) increase efforts in the countries that account for the largest share of deaths under the age of five; (2) reach the most underserved populations; (3) target priority causes of mortality with innovative efforts and interventions that can be scaled up; (4) in addition to health programs, invest in empowering women and supporting an enabling environment; and (5) create transparency and mutual accountability at all levels through a strengthened commitment to common metrics for tracking progress.¹

As the SDGs were launched, the UN and World Bank launched the Global Financing Facility to support Every Woman Every Child, which is a platform designed to better leverage financing to support country-led investment plans aimed at improving RMNCH.

THE CHALLENGE

Many essential MNCH medicines and supplies are generic products that are widely available in both the public and private sectors. However, ensuring access to and availability of these medicines and supplies in-country requires improving pharmaceutical policy; enforcing compliance with policies and procedures, particularly in procurement; and addressing regulatory components of the health system. In addition, several key MNCH products are often only authorized for administration by highly skilled providers despite evidence that administration by less skilled providers is both feasible and effective. The availability of quality MNCH medicines and supplies is often limited by weaknesses in public-sector systems, including inaccurate quantification of requirements; inappropriate pharmaceutical procurement mechanisms; procurement of products that do not meet the necessary technical specifications; weak distribution systems; inadequate storage facilities; and limited inventory tracking systems, especially to the community. In the private sector, the

¹ USAID. Acting on the Call: Ending Preventable Child and Maternal Deaths Report, June 2014, Available from: <http://www.usaid.gov/what-we-do/global-health/acting-call-ending-preventable-child-and-maternal-deaths-report>

quality of available MNCH medicines is often questionable because weak regulatory authorities are unable to consistently implement quality assurance measures.

Limited information for decision making at all levels is also a barrier to access to MNCH commodities. The scarcity of reliable morbidity data and the lack of personnel skilled in analyzing and using those data make it difficult to accurately estimate the demand for procurement purposes and to identify gaps in coverage. Financial obstacles can also impede access. Public-sector procurements for MNCH commodities are generally funded through public-sector health budgets and are subsequently reliant on perceived national priorities and limitations in funding mechanisms. The funding allocated for the purchase of pharmaceutical products is often insufficient to meet the demand. A complicating factor is that several key medicines and supplies are used for multiple indications and are not necessarily limited to MNCH conditions. Changing provider and client behavior to prioritize the use of these medicines for MNCH conditions will help to ensure that they are available when needed.

An additional challenge for the global MNCH community is how to maintain momentum after UNCoLSC ends in 2016. It is crucial that RMNCH commodities remain high on countries' agendas and that they prioritize access to and availability of commodities for women and children.

ACHIEVEMENTS DURING PROGRAM YEAR FIVE

Global-Level Contributions

UN Commission on Life-Saving Commodities for Women and Children

SIAPS has been actively engaged in supporting UNCoLSC since its creation in 2012. SIAPS participated in the planning meetings during which the 13 commodities prioritized by the UNCoLSC were defined and a set of recommendations was identified. SIAPS continued to provide support through its participation in many of the Commission's technical resource teams (TRTs) during this final year of UNCoLSC, and many of the TRTs focused on finalizing deliverables and documenting the work that has been done. SIAPS staff played an active role in the TRT conveners meeting in New York, in the launch of the Lifesaving Commodities Practitioners Network in Geneva, and through regular participation in TRT meetings and teleconferences. Table 1 provides a brief summary of SIAPS' contributions to UNCoLSC TRTs during PY5.

Other Global Partnerships and Initiatives

SIAPS works closely with global partners and actively participates in standing technical communities of practice in both maternal and child health.

In the area of child health, SIAPS has been fully engaged with the Integrated Community Case Management (iCCM) Financing Task Team's (FTT) Procurement and Supply Management (PSM) sub-group throughout the year. During this final year of the iCCM FTT, SIAPS contributed to the planning and organization of a meeting for countries scaling up iCCM under the Global Fund, which took place February 16–18, 2016, in Nairobi, Kenya. The SIAPS

Table 1. SIAPS support to UNCoLSC, FY 2015–2016

| Technical Resource Team | Key Contributions and Products |
|-------------------------------|---|
| Maternal Health | <ul style="list-style-type: none"> Documented the options analysis with national stakeholders in Mali that resulted in the decision to integrate oxytocin into the Expanded Program on Immunization (EPI) cold chain at the district and community levels Finalized the guidance document on integrating oxytocin in the EPI cold chain Facilitated the merger of the Maternal Health TRT (MHTRT) and the Maternal Health Supplies Caucus of the Reproductive Health Supplies Coalition (RHSC), which is chaired by SIAPS Contributed to the MHTRT legacy document Contributed to a literature review on universal health coverage for reproductive health commodities |
| Supply Chain | <ul style="list-style-type: none"> Updated the companion guide on the quantification of 13 priority RMNCH commodities in English and French and disseminated it at the International Conference of Family Planning, RHSC annual meeting, Global Maternal and Newborn Health Conference, and USAID Mini-University and through two webinars (one in English and one in French) Drafted the Supply Chain TRT (SCTRT) “legacy document” summarizing the progress the group has made since the beginning of UNCoLSC |
| Chlorhexidine | <ul style="list-style-type: none"> Contributed to development of a note on the appropriate use of chlorhexidine (CHX) that was posted on the chlorhexidine working group website Provided support to Afghanistan and DRC in implementing CHX and developing a CHX introduction strategy Provided technical support to DRC to conduct a survey on the use of CHX and to facilitate its registration Supported the team from the DRC Ministry of Health to prepare for participation in the regional CHX sustainability meeting in Ethiopia |
| Diarrhea and Pneumonia | <ul style="list-style-type: none"> Conducted a study in DRC on the use of amoxicillin DT job aids and dispensing envelopes (co funded by UNICEF) and presented the results at the working group meeting in New York June 8–10, 2016. The report is available in French and English. Contributed to the development of a lessons learned document on zinc/oral rehydration solutions |
| Injectable Antibiotics | <ul style="list-style-type: none"> Conducted the landscape analysis of antibiotics for newborn sepsis in DRC, disseminated the results in DRC and to the TRT (under an award from Save the Children through the Injectable Antibiotics TRT as a cost-sharing initiative). The report is available in French and English. Reviewed the implementation guidelines of the newborn sepsis management recommendations at WHO’s request |

principal technical advisor for MNCH contributed to preparing, presenting, and facilitating the session. During the meeting, countries identified weaknesses in PSM that needed strengthening and submitted technical assistance requests to the organizers, which SIAPS later reviewed.

SIAPS continues to chair the Supply Chain Management (SCM) subgroup of the iCCM Taskforce. In addition to organizing meetings and planning activities, SIAPS mapped nongovernmental organizations working in PSM for iCCM, planned and participated in two webinars (SCM in private-sector approaches for iCCM and waste management), set up an “Ask the Expert” page on the CCM Taskforce website, and contributed to discussions on monitoring and evaluation indicators.

In maternal health, SIAPS was active in the Reproductive Health Supplies Coalition (RHSC), chaired the Maternal Health Supplies (MHS) Caucus, and participated in the RHSC annual and semiannual meetings. At these meetings, SIAPS actively led activities on RMNH supplies in the Systems Strengthening Working Group session, the MHS Caucus session, and a panel on the MHTRT. SIAPS was actively involved in planning the 2017 annual meeting and facilitated a session on commodities at the post-partum hemorrhage meeting organized by the Maternal and Child Survival Program.

SIAPS also attended the Women Deliver conference and the Global Maternal and Newborn Health (GMNH) conference in Mexico, where staff presented at four sessions.

SIAPS finalized the data analysis and drafted an article on the review of current pharmaceutical management policies and systems that affect access to essential RMNCH medicines and supplies across countries. This activity is in collaboration with the Countdown Health Systems and Policy working group. The work was presented in the GMNH conference and at a Countdown meeting. Final feedback was received from all authors, and the article will be finalized and submitted to the working group chairs for their approval and submission to a journal.

SIAPS works to develop tools to assist countries in ramping up efforts to decrease maternal and child mortality, thereby contributing to EPCMD.

- **Intervention Guide for the Management of Childhood Illnesses.** This was disseminated widely among the CORE group and the Diarrhea and Pneumonia working group of the UN Commission, on the SIAPS website, and to country offices and UNICEF.
- **Guidance for Planning the Introduction of New Reproductive, Maternal, Newborn, and Child Health Medicines and Supplies.** The purpose of this document is to provide guidance to program managers in ministries of health at the national and sub-national levels as well as other stakeholders on actions to take and factors to consider when expanding access to essential RMNCH commodities. It addresses several pharmaceutical management issues (pharmaceutical policies, effective medicine management, strengthening regulatory systems, information needs, and product quality and safety practices) that are often overlooked when considering the introduction of new products.
- **Assessment of the Medicines Benefit Program of the Ghana National Health Insurance Scheme.** The purpose of this assessment was to assess how MNCH medicines are managed under the National Health Insurance Scheme in Ghana.

Finally, this year SIAPS participated in the annual USAID Mini-University, where staff presented on “Building Systems for Access and Appropriate Use of iCCM Medicines” and “Increasing Access to Lifesaving Commodities for Women and Children: Getting the Numbers Right!”, and at the American Public Health Association conference, presenting on the importance of systems strengthening for the implementation of iCCM.

Tools and Innovations

SIAPS made significant progress in developing tools for assessing sub-national procurement of MNCH medicines in Kenya and mapping financial flows for those medicines. SIAPS adapted the sub-national procurement assessment tools that were implemented in Bangladesh to the context of Kenya. An analysis of the results is being finalized and will be shared with key stakeholders during FY17. The tools for mapping financial flows for MNCH commodities were implemented in Nepal, and the information collected in Nepal was submitted and presented to USAID to be used at the November Global Financing Facility meeting. Financial flow information was also collected in Kenya through the sub-national procurement assessment and is being collected in Bangladesh and Uganda.

Country-Level Contributions

To assist countries in their efforts to end preventable child and maternal deaths, SIAPS supports the development of innovative approaches to addressing barriers to access using a systems strengthening approach. Previously, the SIAPS MNCH Core supported activities in Bangladesh, DRC, Guinea, and Mali; however, this year these activities were funded by the Mission in country and will be reported accordingly. The country support provided by the MNCH Core was provided through UNCoLSC activities (described above).

Lessons Learned and Way Forward

During the last year of implementation, SIAPS will continue to provide global technical leadership on pharmaceutical systems issues related to MNCH, develop and validate guidance and essential tools in pharmaceutical management that will help ensure access to quality MNCH commodities, and work to enhance the evidence base for effective strategies to increase access to medicines and services for MNCH.

To achieve the global targets set for ending preventable child and maternal deaths, the appropriate medicines and supplies must be available when and where women and children need them, and acquiring these products and the services through which they are provided must not represent a financial hardship for women and their families. This requires a strong pharmaceutical system in which the quality of medicines in circulation is ensured, appropriate medicines and supplies are provided, strong supply chains ensure the availability of quality products at service delivery points, and service providers are able to administer the products and counsel patients on their appropriate use. However, as global initiatives work to accelerate progress to end preventable child deaths, country ownership and participation are essential.

NEGLECTED TROPICAL DISEASES



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BACKGROUND

Neglected tropical diseases (NTDs) comprise 14 parasitic and bacterial infections. They are the most common afflictions of humankind. The seven most prevalent NTDs (ascariasis, hookworm infection, trichuriasis, lymphatic filariasis, onchocerciasis, schistosomiasis, and trachoma) affect more than one billion individuals, or one-sixth of the world's population. Ninety percent of the NTD disease burden is in Africa, with the majority of those victims infected with two or more NTDs.

Supply chain constraints also plague current NTD prevention and treatment programs. Inadequate NTD drug (NTDD) management in many countries has resulted in excess stocks that lead to wastage from drug expiry and stock-outs, which cause treatment interruptions that affect the NTD problem globally.

Through its NTD program, SIAPS continues to enhance NTD program managers' capacity for supply chain management (SCM) to improve storage and transportation, rational medicine use, drug forecasting, and adverse event (AE) reporting to promote NTD commodity security and safety. Collaboration with partners ensures that capacity building and improved forecasting will be carried out effectively and efficiently, enabling maximum results with minimum expenditures.

SIAPS Strategy

The main objective of the SIAPS NTD core portfolio is to strengthen pharmaceutical management systems to achieve global NTD goals. SIAPS provides technical input to USAID, the World Health Organization (WHO), the TFGH, global NTD networks, national NTD programs, and other relevant bodies to address technical leadership issues related to NTD medicine policy, including donations, medicine regulation, SCM, serious adverse event (SAE) reporting, and patient safety.

SIAPS provides technical assistance to develop and disseminate comprehensive NTD product management training and an operational manual that includes tools and procedures to manage NTD products and related data at different levels of the supply chain system. The SIAPS approach also aims to integrate, wherever possible, data collection, processing, and reporting across programs to help reduce the staff burden for these tasks. Tools are developed in a consultative manner that involves host-country programs, the TFGH, WHO, and other stakeholders and provides information to cover receipt, issue, return of unused products, tracking expiries, consumption, stock levels, shipment status, and reporting adverse drug effects. The tools are customizable to country needs.

SIAPS activities contribute to USAID objectives through health system strengthening approaches and experiences in improving SCM globally. Based on the identified weakness in the pharmaceutical management of NTDs, a number of manageable, targeted investments aimed at strengthening the systems have been proposed, including:

- Strengthening NTDD management at all levels of the supply chain system by providing technical expertise on SCM at working group meetings and scientific conferences that focus on forecasting, quantification, and ordering; customs clearance, logistics, and inventory management; storage; management of AEs; reporting; and waste disposal
- Collaborating with national drug regulatory authorities in USAID-supported countries to build their capacity for SCM and for improving AE management and reporting
- Developing, testing, and disseminating training and operational manuals, including information management tools at the global and country levels to collate and provide timely information on stock status, pipelines, and deliveries of NTDs at all levels
- Conducting a technical assessment of NTD SCM and capacity and providing technical assistance to improve systems

In discussions throughout the year with the Task Force for Global Health (TFGH), RTI International (RTI) and Family Health International 360, several issues were raised as gaps or voids in the current supply chain guidelines from numerous endemic countries. The proper disposal of waste is often overlooked during trainings of community health workers and medicine distributors. In addition, the proper disposal of expired or damaged (questionable quality) medicines was described as a problem by many donation programs. This is an aspect of the supply chain that would benefit from a comprehensive guideline that program managers can refer to following mass drug administrations (MDAs).

CHALLENGE

A 2011–2012 assessment conducted by the USAID-funded Strengthening Pharmaceutical Systems Program (the predecessor of SIAPS) in Cameroon, Mali,

Tanzania, and Uganda showed marked weaknesses in the capture, transmission, aggregation, and analysis of data related to NTD products, particularly during MDAs carried out by community health workers. Even when available, aggregated NTD reports do not reach program managers at the national level in time to allow them to develop accurate forecasts and prepare timely and comprehensive donation applications and procurement requests for manufacturers. In addition, there is no system at the global level that collates supply pipelines and tracks the stock status of these commodities in priority countries. Improvements are needed to address identified weaknesses, including poor in-country coordination among NTD programs in forecasting, quantification and ordering, customs clearance, logistics and inventory management, management of AEs, and waste disposal.

ACHIEVEMENTS DURING PROGRAM YEAR FIVE

The SIAPS NTD program is addressing the challenges identified through assessments and consultations with key stakeholders. The activities defined below are in accordance with USAID's approach to large-scale implementation of integrated treatment programs for NTDs, focusing on the scale-up of MDAs. Strengthening the pharmaceutical management of NTD programs contributes to USAID and WHO goals of controlling and eliminating the seven preventive chemotherapy-treatable NTDs.

Since October 2015, SIAPS has participated in and presented at selected meetings, groups, and conferences contributing to the work of NTD advisory and technical working groups, particularly supply chain, SAE/adverse drug reaction reporting, and M&E working groups. These meetings included the American Society for Tropical Medicine and Hygiene Annual Meeting, the NTD Supply Chain Forum, and the NTD Non-governmental Development Organizations Forum. Participation at these meetings has promoted proper supply chain and pharmacovigilance coordination with the USAID NTD program and implementing partners.

SIAPS facilitated SCM workshops directed at national-level supply chain and NTD program managers in Accra, Ghana; Lagos and Abuja, Nigeria; Cotonou, Benin; and Conakry, Guinea. These workshops included more than 160 participants from Ministries of Health (MoHs), WHO, and implementing non-governmental organization representatives (RTI) from Ghana, Sierra Leone, Nigeria, Benin, Cote d'Ivoire, Mali, Niger, Guinea, and Senegal.

SIAPS worked with country program managers for RTI ENVISION and the Senegal MoH NTD and drug supply operational staff to disseminate and develop action plans based on the assessment and recommendations of their supply chain and pharmaceutical management systems.

SIAPS worked with partners to develop clear guidelines and standard operating procedures on the rational use of NTDDs and how to dispose of or recycle, if appropriate, waste following MDAs. This document addresses returning NTDDs that have expired or are of questionable quality to the central medical stores for appropriate documentation and disposal; disposal or proper cleaning of used NTDD bottles; and disposal of other supplies and diagnostics used during MDAs, M&E, and surveillance activities.

TUBERCULOSIS



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BACKGROUND

Despite the availability of highly effective treatment, tuberculosis (TB) remains a critical global health problem. In 2015, approximately 1.4 million people died of TB, including 0.4 million who were HIV-positive (WHO, 2016). Of the 10.4 million cases of TB estimated to have occurred in 2015, national TB programs (NTPs) were notified of only 6.1 million, leaving a gap of approximately 4.3 million people who were either not diagnosed or not reported (WHO, 2016).

Adding to the challenge is the rapid emergence of drug-resistant (DR) forms of TB. In 2015, approximately 480,000 people worldwide developed multidrug-resistant (MDR) TB, with less than a quarter of these enrolled in treatment in 2015 (WHO, 2016).

Three key approaches in the USG TB Strategy (2015-2019) are in line with the WHO End TB Strategy for reducing the burden of TB on individuals and communities:

- Supporting countries with the highest TB, DR-TB, and/or TB-HIV burdens

Countries Supported by the Tuberculosis Core Portfolio in Year 5

| |
|-------------|
| Bangladesh |
| DRC |
| Ethiopia |
| Kenya |
| Mozambique |
| Myanmar |
| Nigeria |
| Pakistan |
| Philippines |
| South Sudan |
| Swaziland |
| Tajikistan |
| Tanzania |
| Uganda |
| Ukraine |
| Uzbekistan |
| Zambia |

- Leveraging interagency strengths and innovative approaches
- Supporting multilateral and international global programs, policies, and research for TB prevention, care, and treatment

CHALLENGE

A number of pharmaceutical management issues hinder TB control. First, there is a notable gap between evidence-based pharmaceutical management improvement practices and their application in global initiatives. This discrepancy results in inefficient global TB medicines supply mechanisms and highlights the need to strengthen governance, leadership, and coordination within and between global initiatives. A second challenge is leadership and human resource capacity for pharmaceutical supply management and services within TB programs, specifically with regard to forecasting and quantification, inventory management, and supply planning. Without institutional improvements in capacity, short-term gains in pharmaceutical management will not be sustained.

Besides human resources, other health systems building functions in many high-burden TB countries require individual strengthening and improved synergy, particularly in management information systems (including data quality assurance and impact assessment), the definition of standards, and the delivery of pharmaceutical services. Without a concerted effort to bolster these foundational elements, global investments in the development and promotion of new tools for TB control may be used ineffectively. Adding to these issues is that there is a dearth of research documenting the outcomes and impacts of pharmaceutical interventions in low- or middle-income settings with the greatest burden of TB. This gap may result in part from limited pharmaceutical research expertise at the country level, lack of supportive infrastructure, or limited funding for research in the face of competing priorities. However, such research promotes inclusivity in the design and implementation of interventions and is necessary to generate data for strategic decision making.

In addition, the first new TB medicines in more than 40 years—bedaquiline and delamanid—were recently released onto the market for the treatment of MDR-TB. Since then, these medicines have also been used to treat TB patients who have experienced life-altering side effects or developed intolerance or resistance to some second-line TB medicines. In 2015, USAID and Janssen Pharmaceuticals announced a donation of 30,000 treatments of bedaquiline to treat DR-TB patients. WHO also issued guidance documents to help countries quickly introduce these medicines. However, uptake has been slow by countries

SIAPS Strategy

The primary goal of the SIAPS TB Core portfolio is to ensure the availability of quality pharmaceutical products and support the implementation of effective pharmaceutical services for achieving global and USG TB program targets also represented in the USG health goals, namely protecting communities against infectious diseases, fostering an AIDS-free generation, and strengthening health systems. SIAPS builds on many years of experience, methodologies, and tools developed and tested by Management Sciences for Health, and its different USAID programs. As a result, SIAPS has at its disposal an array of instruments to address TB pharmaceutical management gaps within the health system.

for a myriad reasons, including a lack of expertise, infrastructure, and appropriate systems to monitor the efficacy, safety, and potential adverse effects of these medicines. Consequently, there is increased demand from countries for knowledge on how to manage patients on these new TB medicines and regimens and for technical assistance on overall programmatic implementation.

These challenges are compounded by limited access to and improper use of quality assured TB medicines in many high-burden countries. Limited access to medicines stems in part from a lack of valid quantification information and supply chain bottlenecks at the country level. In addition, access to quality TB diagnosis, treatment, and pharmaceutical services in the private sector remains limited and is often substandard. With regard to improper use of TB and DR-TB medicines, a lack of monitoring of drug utilization and management of adverse reactions can result in poor treatment outcomes and foster the development of drug resistance. Patient-centered TB diagnosis and treatment relies on the capacity of health staff to track and assess patient data and ensure the implementation of evidence-based care. Concurrent treatment of co-morbidities, such as TB/HIV and TB/diabetes, results in greater risk of adverse events, which may contribute to treatment interruptions and poor patient outcomes. With the introduction of new tools in the fight against TB, including bedaquiline and delamanid, pediatric formulations, short-course treatment regimens, and new diagnostic tools, SIAPS is building country capacity to improve access to lifesaving medicines and technologies for TB patients.

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ACHIEVEMENTS DURING PROGRAM YEAR FIVE

Pharmaceutical governance for TB strengthened at global and country levels

SIAPS has targeted improved pharmaceutical governance for TB by collaborating with key global partners, in particular the Stop TB Partnership and the Global Drug Facility (GDF). The GDF is an international mechanism that provides access to quality assured, first- and second-line TB medicines and consumables for rapid diagnostic tests. During program year five (PY5), SIAPS provided support to the GDF to review, update, and, where necessary, develop SOPs, forms, and documents for various GDF teams during the transition from WHO to the United Nations Office for project services. In total, approximately 94 documents were updated, written as new procedures, embedded in other documents, or combined to clarify their use. SIAPS also provided technical support to the GDF for the development of the first draft of their strategic rotating stockpile concept note for second-line TB medicines. This year, SIAPS participated in five GDF monitoring missions/joint program reviews in Mozambique, Ethiopia, Philippines, Zimbabwe and Kenya.

The 45th Union conference held during the first quarter of PY5 and SIAPS was highly involved in sharing technical expertise and best practices in TB pharmaceutical management. During the conference,

SIAPS co-hosted three workshops and three symposia, in addition to presenting at workshops and in post-graduate courses. SIAPS attended the meeting of the WHO Global Task Force on Digital Health for TB to define next steps of

To expand access to QuanTB training and build capacity in quantification, forecasting, and early warning systems, SIAPS developed a free online e-course on QuanTB, which will be released on LeaderNet by the end of 2016.

implementing the target products profile, where both the e-TB Manager and QuanTB tools were highlighted as examples of dashboard development. SIAPS also attended a follow-up meeting for the project on improving quantification and access to quality-assured second-line TB drugs funded by the Eli Lilly MDR-TB Foundation. The project implemented by KNCV and partners aims to introduce QuanTB and an early warning system (EWS) for DR-TB medicines in 10 countries to prevent stock-outs and reduce wastage of TB medicines.

In addition, SIAPS contributed technical expertise to multiple global-level meetings. SIAPS staff traveled to Cairo, Egypt, to participate in the workshop mHealth for TB-Tobacco in February 2016. SIAPS participated in the WHO Guideline Development Group that worked to revise and update the DR-TB treatment guidelines, participated in the WHO's active drug-safety monitoring and management strategy meeting, and presented the SIAPS-developed Pharmacovigilance Monitoring System (PViMS) tool, contributing to global best practices and development of new tools in support of the introduction of new drugs for TB.

Capacity for TB pharmaceutical supply management and services increased and enhanced

SIAPS works on a number of levels to improve pharmaceutical management capacity. On a global level, SIAPS facilitated sessions at the WHO Collaborating Centre for Tuberculosis and Lung Diseases in Cepina, Italy, focusing on improving skills for pharmaceutical management for TB, MDR-TB, and TB/HIV and quantification and EWS. This year, SIAPS facilitated several trainings for more than 140 participants on a variety of topics, such as WHO courses, TB control strategies, and pharmaceutical management focusing on introducing new TB medicines and novel regimens.

Efforts in building capacity in quantification and forecasting have continued throughout the year. During PY5, SIAPS trained more than 120 NTP drug management staff from 18 countries, other organizations, and independent consultants on how to use QuanTB to quantify and track TB medicines. To build capacity in quantification and forecasting in Latin America, SIAPS, along with PAHO, trained participants from 14 countries on the use of QuanTB.

Working to expand access to QuanTB training and build capacity in quantification, forecasting, and EWS, SIAPS developed a free online e-course on QuanTB. SIAPS staff created, reviewed, and loaded the course content and design onto the LeaderNet platform where it will be hosted in preparation for its release by the end of 2016. In April 2016, SIAPS conducted a GDF consultant training on QuanTB in Marrakesh, Morocco, building the capacity of 44 participants who attended the workshop to effectively use the tool for quantification and EWS for TB medicines.

Improved utilization of information for better decision making

SIAPS works to improve information for decision making through the availability and interoperability of electronic tools combined with systems strengthening. SIAPS has improved e-TB Manager, a web-based tool for managing key information needed by NTPs, through regular updates and new features for

enhanced and expanded use. e-TB Manager integrates data across a variety of aspects of TB control, including information on patients, suspected patients, medicines, laboratory testing, diagnosis, treatment, and outcomes. e-TB Manager is currently used in 1,619 active sites in 10 countries. Globally, more than 2,903 active users are managing 620,345 TB cases, DR-TB cases, and presumptive TB individuals by using e-TB Manager. Over the course of the year, use of e-TB Manager expanded to manage 150,000 more cases than the previous year. A new generic desktop version (local case management application which syncs with the internet) was finalized. This version was implemented in Bangladesh and adapted to fit specific country needs identified during during PY5. In addition, TB LMIS (a customized drug management module of e-TB Manager) at the central level in Bangladesh was implemented with plans for scale up. An improved e-TB Manager, version 3.0, was developed to provide the user with enhanced functionalities and the ability to run on portable devices. Final release of this version is expected during the next fiscal year.

During PY5, a multi-country, e-TB Manager user satisfaction survey was conducted. SIAPS received 1,753 responses with a completion rate of 86% from 9 participating countries. The average response rate of 76% among the 9 countries significantly exceeded expectations. Key results of the survey show that 81% of users agree that e-TB Manager improves patient case management, 80% find e-TB Manager reliable, and 75% agree that they have the capacity to use all of e-TB Manager's features. A blog published in [The Lancet](#) offers further analysis on e-TB Manager and survey results.

Continuing to help countries improve utilization of information for decision making, a new version of QuanTB, an electronic forecasting, quantification, and EWS tool designed to improve procurement processes, ordering, and planning for TB treatment, was released. QuanTB has been adopted by the GDF as its standard tool for quantifying TB medicines and monitoring medicines availability in client countries. QuanTB has been downloaded more than 1,650 times. Fifteen countries report the use of QuanTB data for medicines tracking and decision making.

Improved pharmaceutical services and access to TB products

Our endeavors to improve access to TB diagnosis and treatment include three primary components. The first is to provide technical assistance to USAID-priority high-burden countries to strengthen access to TB medicines by implementing EWSs for stock-outs/waste of TB medicines. SIAPS has done this through a regional technical assistance mechanism combined with QuanTB implementation; together, these allow staff sufficient time to address supply problems by providing alerts for medicines expiries, stock-outs, the need for emergency medicine orders. It also allows monitoring of pharmaceutical systems, including identifying improvements and gaps in the systems.

During a recent in-depth review of five countries (Ethiopia, Nigeria, Tanzania, Kenya, and Zimbabwe) that received technical assistance from SIAPS regional advisors, stocks-outs of TB medicines decreased from 38% to 0% for first-line medicines and from 17% to 0% for second-line medicines between February 2014 and December 2015. SIAPS regional advisors worked with NTPs on using tools, such as QuanTB, and to take action to prevent imminent stock-outs, minimize wastage, and ensure adequate stock levels. More than USD \$10 million was saved

An e-TB Manager user satisfaction survey found that:

81% of respondents agree that e-TB Manager improves patient case management

80% of respondents find e-TB Manager reliable

75% of respondents agree that they have the capacity to use all of e-TB Manager's features

in these five countries alone between December 2014 and June 2016 as a result of the SIAPS technical assistance.

The second component of SIAPS' efforts to improve the quality and accessibility of TB diagnosis and treatment is by strengthening linkages between the public and private sectors. In accordance with the global strategies of the Stop TB Partnership and the USG, SIAPS developed a strategic approach that begins with compiling in-country information on the TB/DR-TB situation in the private sector. SIAPS then collaborates with key stakeholders to design environment-specific interventions based on the collected data.

SIAPS has piloted a unique public-private partnership activity in Pakistan to explore the potential of increasing TB diagnosis. SIAPS spearheaded assessments of knowledge, attitudes, and practices of private pharmacies and medicine shops and then used the findings to develop interventions to establish referral mechanisms between private retail outlets and TB diagnostic centers under the leadership of the respective NTPs; 502 pharmacies in six major cities were part of the pilot. Trained staff referred 1,071 presumptive TB cases to public-private mix general practitioners and public-sector basic health units over a period of eight months. Of these, 829 (77%) were traceable and 198 (18%) of the total referred were confirmed as having TB. As a result of the pilot study the NTP decided to include private pharmacies in the 2020 national strategic plan for TB control. SIAPS supported developing the plan's concept note and budget. With support from the Global Fund, the NTP, the provincial TB control program, and partners have begun implementing the project on a national scale.

The third component of SIAPS efforts to improve access to TB diagnosis and treatment is supporting improved patient outcomes by promoting the monitoring of medicines use, employing risk management algorithms, and undertaking active surveillance. Monitoring the use of medicines can be done through a drug use review, a systematic process designed to promote the safe and effective use of TB treatment. Risk management algorithms have been designed to help health care workers (HCWs) identify and promptly address known side effects of TB treatment, while active surveillance activities allow health systems to proactively identify and manage side effects that result from the combination of medicines for TB and HIV.

To improve patient safety, SIAPS works with NTPs and appropriate national regulatory bodies to establish or strengthen active surveillance systems to determine the real-life frequency, risk factors, and impact of clinically significant adverse medicine events on treatment outcomes. In PY5, SIAPS developed PVIMS, a web-based application used by clinicians, regulatory bodies, and implementing partners to monitor the safety and effectiveness of medicines, including the new TB medicines. This system, the first of its kind, was implemented in Georgia and formally handed over to the National Center for Tuberculosis and Lung Diseases to collect data from sites across the country and support adverse event monitoring.

SIAPS developed PVIMS, a web-based application used by clinicians, regulatory bodies, and implementing partners to monitor the safety and effectiveness of medicines, including the new TB medicines.



Rapid Introduction and Adoption of New TB medicines and regimens

During PY5, SIAPS provided technical assistance to Georgia, Kenya, Philippines, Uganda, and Swaziland to implement the new medicines and their regimens and

train NTP and MOH staff, and 491 HCWs. As a result, more than 200 patients in Georgia, 68 patients in Swaziland, and 42 patients in the Philippines have begun treatment with bedaquiline.

SIAPS also developed resources and training materials for the introduction of new TB medicines, including a website (www.newTBdruginfo.org), targeted at program managers, MOH staff, and HCWs. An upcoming e-course on the use of new TB medicines and regimens will be available on LeaderNet.org.

LESSONS LEARNED AND WAY FORWARD

The main challenges in improving pharmaceutical management for TB are shifting donor priorities, which result in reallocation of resources and staff. However, through USAID, SIAPS has been able to fund direct technical assistance to high-burden countries via regional and in-country technical advisors. This approach proved efficient for SIAPS, although identifying and training such advisors has been a challenge in some countries.

Through the implementation of TB-related activities, SIAPS recognized that when properly implemented and with follow-up, the EWS incorporated in QuanTB provides immediate results and is able to prevent treatment interruptions, improve procurement and ordering practices, and minimize waste, resulting in saving of over USD \$10 million.

Another lesson learned is that ordering medicines without a comprehensive plan for uptake is ineffective, so it takes coordinated efforts and system strengthening to make sure the medicines introduced are used efficiently. Delays to implementation can be avoided by making sure government-allocated funds are accessible when needed during bedaquiline donation program implementation in-country.

An important emerging technical area for SIAPS is active pharmacovigilance for new medicines and regimens. SIAPS has developed an electronic system to consolidate and analyze pharmacovigilance data for more evidence-based decisions to promote patient safety. SIAPS is supporting global capacity in this area by contributing towards the development of global policies for new TB medicines and building in-country capacity.

Managing adverse events without an electronic system can be challenging in settings with low statistical capacity. Leading the way in helping countries introduce new medicines and technologies in the fight against TB, SIAPS learned there is a need for country champions to drive the process and the importance of coordinating key stakeholders at the beginning of the process of implementing new TB medicines. By laying this groundwork, rolling out new TB medicines, ensuring medicines access, and patient safety has a higher likelihood of successfully improving TB treatment and care and, most importantly, ensuring better health outcomes.

CROSS BUREAU

CROSS BUREAU



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THE CHALLENGE

The Office of Health Systems (OHS) serves as USAID’s center of excellence and focal point for providing worldwide leadership and technical expertise in health systems strengthening (HSS).¹ It is responsible for three core functional roles:

- Technical leadership and strategic direction
- Knowledge and talent generation and management
- Field support and program implementation

With OHS cross bureau funds, SIAPS provides cross-cutting activities at the global and regional levels that contribute to strengthening availability of medical products, vaccines, and technologies, thus ensuring that people have sustained access to and make appropriate use of essential medical products that are safe, effective, and of assured quality.

¹ Users Guide to USAID/Washington Programs (June 2015) <https://www.usaid.gov/sites/default/files/documents/1864/2015-Complete-Users-Guide.pdf>

Using Cross Bureau funding, SIAPS priorities are to:

- Strengthen pharmaceutical sector governance to promote transparency and accountability through appropriate laws, regulations, policies, and standard operating procedures (SOPs)
- Increase and enhance human and institutional capacity to regulate and manage pharmaceutical systems and services
- Develop and support the use of pharmaceutical management information systems (PMIS), embracing both products and patients, including information systems for procurement, logistics, services, and regulatory systems
- Reduce financial barriers to access through more efficient and effective use of financial resources and support for innovative financing strategies and approaches
- Strengthen pharmaceutical systems to ensure product availability and quality, protect patient safety, and contain the emergence of antimicrobial resistance

These priority objectives in turn contribute to USG goals of ending preventable child and maternal deaths (EPCMD), AIDS-free generation, protecting communities against infectious diseases, and universal health coverage (UHC). SIAPS' key activities and achievements using OHS cross bureau funds in PY5 are described below.

GLOBAL TECHNICAL LEADERSHIP

This year, SIAPS continued with development of a framework and corresponding indicators for monitoring and measuring whether investments in pharmaceutical systems strengthening (PSS) are contributing to the development of stronger, more sustainable systems. In this respect, SIAPS completed the selection of indicators through an iterative process. Specific criteria were used to select the indicators for measuring PSS that had been identified through a literature search. SIAPS applied these criteria and scored the different indicators that were pulled from the various pharmaceutical system assessment tools. SIAPS, in collaboration with its partner, the Boston University School of Public Health (BUSPH), also developed a prototype assessment tool addressing these indicators that will be piloted in four EPCMD countries. The results of the pilot will inform the finalization of the measurement framework and metrics, as well as the assessment tool, which may then be applied in all EPCMD countries. During the course of the year, SIAPS also finalized a manuscript that was submitted to the *Health Policy and Planning* journal. The manuscript reviews the literature on pharmaceutical systems and its strengthening and proposes definitions and the components deemed critical for tracking progress in PSS. These components were defined on the basis of consensus inputs from external stakeholders and formed the foundation for the development of the assessment tool. SIAPS is currently preparing to present this body of work to the health systems strengthening global community at the Fourth Global Symposium on Health Systems Research in Vancouver, November 2016.

To further support knowledge sharing through the WHO Essential Medicines and Health Products (EMP) Information Portal, SIAPS continued to provide financial support to the WHO IT contractor responsible for the software platform. The documentation upload process continued to expand in PY5 with the size

SIAPS is leading the effort to develop a pharmaceutical systems measurement framework and indicators to assist country health planners and donors to identify weaknesses and vulnerabilities in pharmaceutical systems and to strategically plan targeted interventions and investments as part of an overall sector development plan.

of the collection increasing from 5,112 to 5,543 documents over the past year. Based on a user survey conducted this year, various changes to the portal were implemented, including an updated search function, an import and export feature for batches of publications in CSV and XML formats, and the development of a mobile version, which will enhance access to information particularly in low- and middle-income countries (LMICs).

Also this year, SIAPS conducted a thematic gap analysis of the portal to identify what type of information is missing. The analysis was instrumental in the development of a set of recommendations to help WHO strategize on how to improve the function, content, and utility of the portal.

To maintain close coordination and collaboration with other donors, global initiatives, and international and regional organizations in PSS, SIAPS represented USAID and contributed to discussions in a number of global and regional forums:

- » SIAPS presented the Indicator-based Pharmacovigilance Tool (IPAT) developed by SIAPS' predecessor program, Strengthening Pharmaceutical Services, at the African Pharmacovigilance San Frontières consultants meeting and at the African Society of Pharmacovigilance 2015 conference, both held in Accra, Ghana, November 23-26, 2015. The global IPAT provided an excellent opportunity and a platform to inform regional efforts for the harmonization of pharmacovigilance (PV) metrics. To present a united front, SIAPS and WHO will draft a joint communiqué as well as an article for the Drug Safety Monitor on the use of IPAT and the recently published WHO PV indicator manual.
- » As part of SIAPS technical assistance provided to the East Central and Southern Africa Health Community (ECSA-HC) Secretariat to strengthen TB commodity and data management, SIAPS participated in the ECSA-HC TB experts meeting, held in Mauritius November 28–29, 2015, and the health ministers' conference held the following week. SIAPS presented a proposed ECSA-HC TB data and commodity management strategy, developed in collaboration with ECSA TB experts, and a TB supply chain dashboard to improve access to data for decision making. The strategy was endorsed by ECSA member states and ECSA is now working toward funding this strategy.
- » At the 8th Global Health Supply Chain Summit held in Dakar, Senegal from November 11-13, 2015, SIAPS shared its Ukraine experience and achievements in promoting transparency and accountability by establishing a web-based price monitoring tool that informs both the public and decision makers on how prices of medicines vary within Ukraine, how they compare with international benchmarks, and how they evolve over time.
- » At the International Pharmaceutical Federation (FIP) World Congress, which took place September 29–October 3, 2015, SIAPS gave oral presentations and presented posters entitled *Implementation of National Standard Treatment Guidelines Leads to Small Improvements in Prescribing Patterns in Swaziland* and *Practical Difficulties of Delivering Medicines Where Infrastructure Does Not Exist*. Discussions around the latter presentation highlighted the need to explore collaboration between global health supply chain and humanitarian logistics professionals and to define the role of pharmacists in supply chain management of health commodities.

- » SIAPS staff conducted an outreach to the BUSPH Pharmaceuticals Program in March 2016. Students in this program are uniquely qualified for engaging in global pharmaceutical management upon graduation. At BUSPH's request, SIAPS presented on-campus on approaches to PSS, with an emphasis on the SIAPS PSS approach and achievements thus far. Students and staff expressed interest in future collaboration.
- » At the Women Deliver Conference held in Copenhagen, Denmark, May 16–19, 2016, SIAPS presented to a panel briefing for congressional staff on the broader, global context of reproductive, maternal, neonatal, child, and adolescent health needs of women's and girls' health and development successes and challenges globally and in key regions of the world. SIAPS provided an overview of the impact of SIAPS' work on women's and girls' health in South Asia and how pharmaceutical management and services improve the health of women and girls worldwide. SIAPS also presented the program's successes and lessons learned at two other side events.
- » At the WHO Department of Essential Medicines and Health Products' Technical Briefing Seminar held in Geneva May 9-13, 2016, SIAPS shared its experience in strengthening PMIS in West Africa (i.e., use of data for decision making). SIAPS' presentation raised a lot of interest from seminar participants, all of whom requested that they be granted access to SIAPS' web-based commodity dashboard OSPSANTE.²

TECHNICAL PRODUCTS TO SUPPORT NATIONAL HEALTH SYSTEMS

Using cross bureau funds this year, SIAPS produced and disseminated a number of technical publications that are of global interest in strengthening pharmaceutical systems in LMICs. Key publications include:

- *Continuing Pharmaceutical Education: Guide to Establishing Quality Assured and Accredited Programs*, accessible at <http://siapsprogram.org/publication/continuing-pharmaceutical-education-guide-to-establishing-quality-assured-and-accredited-programs/>
- e-Learning course entitled *Good Governance in the Management of Medicines*, accessible at <https://www.globalhealthlearning.org/course/good-governance-management-medicines>
- e-Learning course entitled *Antimicrobial Resistance (Part 2)*, accessible at <https://www.globalhealthlearning.org/course/antimicrobial-resistance-part-2>
- *Analyzing Options for Strengthening Pharmaceutical Systems*, accessible at <http://siapsprogram.org/publication/analyzing-options-for-strengthening-pharmaceutical-systems/>
- *Improving Infection Prevention and Control Practices at Health Facilities*

in Resource-Limited Settings: SIAPS Technical Report, accessible at <http://siapsprogram.org/publication/improving-infection-prevention-and-control-practices-at-health-facilities-in-resource-limited-settings-siaps-technical-report/>

- Technical brief entitled *Improving Health Outcomes through Delivery of Patient-Centered Pharmaceutical Care by Pharmacists in Low- and Middle-Income Countries*, accessible at <http://siapsprogram.org/publication/technical-brief-improving-health-outcomes-through-delivery-of-patient-centered-pharmaceutical-care-by-pharmacists-in-low-and-middle-income-countries/>

GLOBAL ENGAGEMENT

Assessment Tools

- » SIAPS continued to play a key role in the WHO Good Governance for Medicines (GGM) working group. The objective of the working group is to update and expand the scope of the GGM assessment instrument for measuring transparency in the public pharmaceutical sector. SIAPS has contributed to multiple iterations of the tool, which has been revised and expanded to assess accountability in addition to transparency.
- » SIAPS was invited by the Health Finance and Governance Project to collaborate in revising the Health Systems Assessment Approach Manual version 2.0 to align health system functions with opportunities to advance toward UHC objectives (depicted in the WHO's three dimensions of UHC)³. SIAPS proposed revisions to module 6 on medical products, vaccines, and technologies, in collaboration with the Promoting the Quality of Medicines Project implemented by United States Pharmacopeia.
- » Much deliberation took place this year on the regulatory system assessment tool that was developed by SIAPS in response to immediate needs for assessing and monitoring regulatory systems in less developed countries. Key features of the tool include the ability to rapidly implement it with few financial and human resources. However, in response to a newly developed regulatory system Global Benchmarking Tool (GBT) by WHO, SIAPS in consultation with USAID, determined that it was not prudent to pursue this activity any further. Subsequently, SIAPS agreed to be part of a coalition of

E-Learning Courses

In support to global pharmaceutical systems workforce development, SIAPS used cross bureau funds to develop two courses hosted on the USAID Global Health e-Learning Portal entitled *Good Governance in the Management of Medicines* and *Antimicrobial Resistance (Part 2)*, both with links provided above. Thus far, the courses have been taken by health care professionals around the world including MOH officials, USAID staff, students, consultants, among others.

interested parties, which uses common standards, tools, and indicators to help countries strengthen their regulatory systems. This coalition approach was presented and discussed at a meeting convened by WHO in Washington DC in early September 2016. Based on the agreed upon recommendations arising from the meeting, SIAPS will serve on the working group mandated to refine the coalition approach.

Global Advocacy to Combat AMR

SIAPS contributed throughout the year to USG and global efforts to contain the emergence and spread of antimicrobial drug resistance (AMR). SIAPS supported information sharing to make the case for combating AMR at various forums, namely:

- A poster presentation entitled *Strengthening Preservice Pharmacy Training on Rational Medicine Use, Antimicrobial Resistance, and Pharmacovigilance* at the FIP 76th World Congress of Pharmacy and Pharmaceutical Sciences 2016 in Argentina
- A plenary session on *Containing Antimicrobial Resistance to Realize the Goals of Universal Health Coverage* at the Ecumenical Pharmaceutical Network (EPN) Forum 2016 in Germany
- Two oral presentations were given at the 143rd American Public Health Association Annual Meeting and Expo (October 31–November 4, 2015) with the titles *Country and Regional-Level Advocacy and Coalition-Building Against Antimicrobial Resistance* and *Ensuring Access to and Appropriate Use of Medicines for iCCM: It Takes a System*
- SIAPS collaborated with the EPN and the ReAct Group to develop, print, declare, and distribute a call to action document

REGIONAL ENGAGEMENT

- » In PY5, SIAPS used cross bureau funds to strengthen regional-level capacity for antimicrobial stewardship and AMR. SIAPS collaborated with its partner EPN to support AMR advocacy and containment activities for three of its constituency members. These included the Christian Health Association of Malawi, which conducted a baseline assessment of hand hygiene practices at Likuni and Daeyang Luke Hospitals, established hand-washing committees, and conducted trainings on proper hand hygiene guidelines. Second, it also included the Zimbabwe Association of Church Related Hospitals, which provided training to 23 journalists and has been following up with each participant to establish a plan of action for tracking publication of articles related to AMR. As of September 2016, 16 articles have been published. Third, in Kenya, Gertrude's Children's Hospital conducted an assessment of staff adherence to STGs, and, based on the findings trainings were conducted for physicians and pharmacy staff on appropriate use of STGs and impact on AMR.
- » SIAPS provided technical assistance to the New Partnership for Africa's

Development (NEPAD) Agency's African Medicines Regulatory Harmonization (AMRH) Program to achieve one of its strategic objectives related to increasing the capacity of the pharmaceutical regulatory workforce in Africa. To this end, SIAPS provided support for the selection of regional centers of regulatory excellence (RCOREs) in PV that are designated by a selection committee to be the go-to institutions (or the partnership of institutions) with specific regulatory science expertise and training capabilities on the continent. Once designated as an RCORE, the institution or partnership of institutions adopts strengthening pharmaceutical regulatory workforce in Africa as its mission.

- » In conjunction with work to support AMRH, SIAPS participated in the Second Biennial Scientific Conference on Medicines Regulation in Africa, Regulatory Systems Strengthening for Advancing Research, Innovation, and Local Pharmaceutical Production in Africa in Addis Ababa, Ethiopia, November 30-December 1, 2015, organized by the NEPAD Agency, the African Union Commission, and WHO in collaboration with partners. SIAPS presented a poster on promotion of local production of malaria medicines in DRC through RSS, and made three oral presentations in a session on strengthening product registration through the introduction of electronic information systems in conjunction with associated process improvements, which drew upon results from Ethiopia and Mozambique.
- » Also in support of AMRH, SIAPS participated in the planning meeting that was held in early March 2016 in Nairobi with two RCOREs in PV, the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance in Accra, Ghana, and the Pharmacy and Poisons Board of Kenya. Proposed activities were discussed, including the mapping of the PV infrastructure in Africa and creation of a database of Africa PV experts.
- » At the request of the NEPAD/AMRH team, SIAPS helped develop a scope of work for a consultancy to guide selection of RCOREs by AMRH. The expected outcomes of this work in early PY 6 include (1) an RCORE monitoring framework, (2) a list of key performance indicators for RCOREs, (3) a document outlining RCORE eligibility and selection criteria, including evaluation tools, (4) a revised selection and renewal procedure for the designation of RCOREs.
- » The second steering committee meeting and the validation workshop for the Common Technical Document (CTD)⁴ of the Economic Community of West Africa States (ECOWAS) Medicines Regulatory Harmonization (MRH) Initiative were co-sponsored by SIAPS and the World Bank. SIAPS provided technical assistance represented in the review of the draft medicine registration guidelines. The workshop was a first step toward development of harmonized CTD guidelines in ECOWAS member countries.

⁴ CTD is a document filed usually by the manufacturers or market holders to register a product in a country in order to be granted market authorization.

EAST AFRICAN COMMUNITY MEDICINES REGULATION AND HARMONIZATION PROGRAM PORTFOLIO

In line with SIAPS' agreed upon work plan for the East African Community (EAC) PV grant, which is part of the EAC's larger regional MRH initiative, SIAPS supported and facilitated a workshop November 9-13, 2015, in Nairobi, Kenya, to draft a harmonized PV assessment tool that will be used for conducting baseline assessments and eventually for the continuous monitoring of the countries in the region; 22 participants, including members of the expert working group (EWG) (two representatives from each of the six EAC member states) and staff from the EAC, World Bank, and SIAPS, attended the event, which was co-facilitated by the University of Washington.

Using two existing assessment tools—the IPAT and WHO's Practical Manual for the Assessment of Pharmacovigilance Systems—workshop participants selected a unique set of appropriate indicators and corresponding assessment questions that specifically reflect the EAC's PV goals both at the country and regional levels. The workshop produced a first draft of the EAC's harmonized PV assessment tool, which underwent another round of revision by the EWG at a subsequent workshop in Kigali, Rwanda. SIAPS also reviewed and provided technical input to a concept note that the EAC secretariat sent to the national medicines regulatory authorities of the EAC member states describing the approach and methodology for carrying out a pilot PV system baseline assessment, which includes the newly agreed upon set of harmonized EAC PV indicators. The PV assessments are expected to take place next year.

INTERMEDIATE RESULTS

IR1 PHARMACEUTICAL SECTOR GOVERNANCE STRENGTHENED



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Low- and middle-income countries spend on average about 25% of their total health budget on medicines and other pharmaceutical products.¹ In some low-income countries, pharmaceutical expenditures constitute as much as 68% of total health expenditures.¹ Misuse or inefficient management of scarce resources can lead to financial losses for governments and institutions, as well as inflated prices and decreased access to needed medicines for individuals. Transparency International estimates that corruption siphons off 10–25% of global public procurement spending.² Public sector pharmaceutical procurement is likely to be plagued by similar problems. Furthermore, corrupt practices and mismanagement can lead to the distribution and use of ineffective or substandard, falsely labeled, falsified, and counterfeit medicines that can harm patients. Poor governance allows opportunities for corruption to occur and enables mismanagement to go unnoticed.

Key developments in the policy environment in project year (PY) 5 include the launch of the Sustainable Development Goals (SDGs) which replaced the Millennium Development Goals at the start of 2016. Notably, the SDGs highlight

1 Lu Y et al. 2011. *The World Medicines Situation 2011: Medicine Expenditures*. 3rd ed. Geneva: WHO.

2 Transparency International. 2006. *Handbook for Curbing Corruption in Public Procurement*. Berlin: Transparency International.

the importance of governance in achieving development goals (SDG targets 16.6 and 16.7) and call for reductions in corruption and bribery across all sectors, including health (SDG target 16.5). Also, regulatory system strengthening (RSS) in low- and middle-income countries continues to gain greater attention from the international community as regional regulatory harmonization efforts—such as those launched for the African continent and its regional economic communities—focus their efforts on building regulatory capacity to support the expansion of pharmaceutical manufacturing. As a result of this increased attention, WHO and its partners, including SIAPS, committed in PY5 to pursuing a coalition approach that helps coordinate resources toward the attainment of common goals, as defined at the country level.

SDG 16 “Promote peaceful and inclusive societies for sustainable development, provide access to justice for all, and build effective, accountable, and inclusive institutions at all levels” includes the following targets:³

- **Target 16.5** - Substantially reduce corruption and bribery in all their forms.
- **Target 16.6** - Develop effective, accountable, and transparent institutions at all levels.
- **Target 16.7** - Ensure responsive, inclusive, participatory, and representative decision-making at all levels.

In PY5, SIAPS continued to help countries address governance issues that impact key pharmaceutical management functions and the supporting management systems (human resources, information, and financial), as well as to improve the adoption of and adherence to good governance principles, such as transparency, accountability, and participation. SIAPS’ technical leadership activities and collaboration with global initiatives and partners working in governance and RSS have been especially pertinent, given the increasing attention to health system governance, corruption, and regulatory constraints at the global level. The following is a summary of our work and achievements in governance and RSS in PY5.

SIAPS Approach for Strengthening Governance in Pharmaceutical Systems

The SIAPS approach for strengthening governance in pharmaceutical systems focuses on assisting countries to establish policies and legislation supported by rule of law; organizational structures that are able to exercise 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. SIAPS uses approaches that facilitate skills transfer, build capacity for good governance, and engage multiple stakeholders, including civil society, to promote ownership and participation.

3 <https://sustainabledevelopment.un.org/sdg16>

ACHIEVEMENTS DURING PROGRAM YEAR FIVE

In this year SIAPS continued to provide technical inputs to assist the World Health Organization (WHO) to update and expand the scope of Good Governance for Medicines Program assessment instrument for measuring transparency in the public pharmaceutical sector, which is currently being piloted.

Technical Leadership

On December 2, 2015, the eLearning course “Good Governance in the Management of Medicines” developed by SIAPS using Cross Bureau funding, was launched on USAID’s Global Health eLearning Center (GHeL). The course, developed with assistance from the Knowledge for Health (K4Health) Project, was added to the certificate program, “Governance and Health,” and complements the three health governance courses prepared by the USAID-funded Leadership, Management, and Governance (LMG) Project. As of September 30, 2016, 188 learners from 50 countries have completed the SIAPS-developed course, including 54 people from Sudan’s Ministry of Health (MOH) National Medical Supplies Fund (NMSF), which is the national center for procurement and distribution of medicines in Sudan. The NMSF director made the course compulsory and part of performance evaluations for pharmacists working at the institution. In July 2016, a video developed by K4Health of four user case studies entitled “Hear How GHeL Is Impacting the Lives of Our Learners!”, which featured an interview with the director about the SIAPS-developed course, was posted on the GHeL website.

In July 2016, SIAPS collaborated with the authors of the three LMG-developed courses and K4Health to host a two-week, facilitated, online study group to allow learners the opportunity to share experiences on practical application of governance practices and challenges encountered; 105 participants from 35 countries who had started or completed one of the four courses signed up for the study group, of which 31% contributed actively to discussions which is the highest participation rate of any of the five GHeL study groups held to date. In the month following the study group, the completion rate of the SIAPS-developed course increased by 18%.

In this year SIAPS continued to provide technical inputs to assist the World Health Organization (WHO) to update and expand the scope of Good Governance for Medicines Program assessment instrument for measuring transparency in the public pharmaceutical sector, which is currently being piloted.

SIAPS’ technical leadership in RSS during PY5 contributed to the advancement of several regional medicines regulatory harmonization programs in Africa and improved the coordination of international partners working in RSS. SIAPS worked with the New Partnership for African Development (NEPAD) agency and other technical partners in the region to strengthen the Regional Centers of Regulatory Excellence designated for the African Medicines Regulatory Harmonization Initiative, including the development of monitoring and evaluation tools to measure their performance and inform the next selection process. SIAPS also attended four stakeholder meetings on regional harmonization in the East and West Africa regions to provide technical input into their respective strategies for implementation of the African Union Model Law, product registration, pharmacovigilance, and post-marketing surveillance. In addition, SIAPS contributed to a new “coalition of interested parties” approach to RSS, which WHO presented to key international partners for discussion at the end of PY5, based on its experience collaborating with SIAPS and other organizations in Bangladesh earlier in the year.

Policies, Legislation, and Contractual Agreements

Pharmaceutical products and the entities that manage them must be carefully regulated because products that are unsafe, of poor quality, or used incorrectly are potentially harmful. Policies and legislation provide the framework for the regulation of pharmaceutical products, personnel, and establishments in a country and must be supported by guidelines, standard operating procedures (SOPs), effective contractual agreements, and monitoring systems. Effective medicines registration, licensing of pharmaceutical establishments, and control of promotion, availability, prescribing, and dispensing of products rely on appropriate and enforceable legislation and policies. Successful management of contractual agreements for delivery of pharmaceutical services depends on the development of robust contracts and the establishment of systems and indicators to monitor their implementation. The following are examples of our work in PY5 to help countries develop or revise, adopt, and monitor adherence to pharmaceutical policies, legislation, and contractual agreements that support health sector priorities and promote good governance in pharmaceutical systems.

- » SIAPS concluded its long-term technical assistance to **Haiti's** Ministry of Public Health and Population in support of the development, launch, and implementation of the country's first-ever national medicines policy (NMP) this year with a workshop that provided guidance to departmental pharmacists on how to implement the NMP. Launched in June 2015, the NMP established a framework for pharmaceutical regulation.
- » In **Guinea**, SIAPS worked with international and local partners to assist the national medicines regulatory authority (DNPL) in revising the existing national pharmaceutical law, which dates from 1994. SIAPS assisted the national committee mandated by DNPL with updating the legislation to review relevant local and regional documents to identify changes needed; draft the bill; convene stakeholder, partner review, and validation meetings; and complete revisions. The drafting of the bill is now complete and it has been submitted for judiciary review. The next steps are for the bill to be submitted to the government secretary general, the ministerial council, and parliament for approval.
- » **Swaziland** made significant progress toward approval and enactment of the Medicines and Related Substances Control Bill and the Pharmacy Bill, which were developed with the support of SIAPS and its predecessor project. The Medicines and Related Substances Bill, which provides for the establishment of Swaziland's first medicines regulatory authority, was approved by both houses of Parliament for presentation to the king for his endorsement. SIAPS assisted the Chief Pharmacist's office and the Health Portfolio Committee prepare for the parliamentary debates and will now help prepare a report for submission to the king for enactment of the bill. SIAPS will also support the Chief Pharmacist's office in preparing for a joint House sitting on the Pharmacy Bill, which is expected to occur before the end of 2016.
- » SIAPS has received anticorruption funding to assist the Government of **Ukraine** in establishing a national essential medicines list (NEML) that will be used nationwide as the sole list for public procurement and potentially for reimbursement. In PY5, SIAPS helped draft and advocate for the approval

Three SIAPS-supported countries have developed or updated their national medicines policy.

Six SIAPS-supported countries have developed or updated pharmaceutical laws and regulations.

17 SIAPS-supported countries/regions have developed or updated pharmaceutical and disease-specific guidelines and SOPs

9 countries have updated national medicines, device, and equipment lists with assistance from SIAPS

of two regulations in support of this activity, as well as one amendment to a Cabinet of Ministers of Ukraine decree to address a regulatory hurdle. The approval of the two regulations, which regulate the NEML's development and adoption process and provide for the foundation and functioning of the competition committee that will be responsible for conducting the competition-based selection of candidates for the Expert Committee, mark important milestones toward establishing a NEML. The process of selecting members began in May 2016. This makes for the fifth legislative instrument drafted/amended and approved with assistance from SIAPS in support of this activity.

- » A contract approved in PY5 between the **Dominican Republic** National Health Service and the government logistics agency, PROMESE/CAL, requires the agency to report monthly on differences between medicine products and quantities requisitioned by health facilities and those dispatched. The contract, developed with assistance from SIAPS, denotes an important advance in strengthening monitoring and oversight of PROMESE/CAL.
- » In **South Africa**, several policy documents, developed or updated with assistance from SIAPS to improve processes for making and implementing decisions and to support good governance in the country's pharmaceutical sector, were finalized and submitted for approval in PY5. These included: 1) a pharmaceutical services policy for the Department of Correctional Services; 2) the policy for issuing authorizations to nurses to perform functions listed in Section 56(6) of the Nursing Act 33 of 2005 (including the prescribing of medicines); and 3) a policy document for the establishment and management of pick-up points where patients can collect antiretrovirals (ARVs) and medicines for other chronic diseases dispensed under the Central Chronic Medicines Dispensing and Distribution Program.

Standards, Guidelines, and Procedures

A challenge that many low- and middle-income countries confront is a lack of robust guidelines and SOPs that define norms and standards for performing pharmaceutical functions. In this program year, SIAPS supported 11 countries to develop, revise, or update a variety of guidelines (pharmaceutical and disease-specific), product lists (essential and specialty medicines, devices, equipment, product catalogues) and SOPs based on international guidance and best practices that provide the foundation for good governance and sound practices in pharmaceutical systems. Some examples are set out below.

- » In the **Philippines**, the Department of Health secretary signed and endorsed "The Practical Guide for the Management of Pharmaceuticals and Health-Related Commodities," which was developed by SIAPS and the National TB Program.
- » In **South Africa**, SIAPS used a guidance document that the project developed in PY4 to develop/update the terms of reference (TORs) for three committees. With assistance from SIAPS, the contracting unit of the National Department of Health (NDOH) revised and finalized TORs for the committee responsible for evaluating bids for pharmaceutical and medical product tenders; the NDOH updated the TORs of the NEML committee; and, staff from the

Department of Correctional Services drafted TORs for the pharmaceutical and therapeutics committees that they plan to establish in six regions.

- » In the **Dominican Republic**, SIAPS developed guidelines for quantification and programming of medicines and supplies to assist country counterparts to perform these tasks independently after SIAPS closes.
- » **Bangladesh's** Ministry of Health and Family Welfare (MOHFW) approved the standardized table of medical equipment for 500-bed hospitals that was developed with assistance from SIAPS and issued a government order that provides for its use as a reference document for procurement. SIAPS also helped the MOHFW's Procurement and Logistics Management Cell review and revise the draft pricing guide and submit it for approval.
- » **Mozambique's** Pharmacy Department (PD), with support from SIAPS, developed the specialty medicines list to complement the essential medicines list that was prepared in PY4, also with assistance from SIAPS.
- » SIAPS supported **Mali's** central medical stores (PPM) in updating 18 SOPs for ordering, validation, storage, and shipping of pharmaceutical products.

Transparency and Accountability

Good governance requires effective organizational structures and transparent procedures that support appropriate decision making, authority, and oversight; hold entities and individuals accountable for their performance; and, enable greater participation of stakeholders, including civil society. The following are examples of SIAPS' activities in PY5 to strengthen transparency and accountability in structures and systems across program countries, thereby improving efficiency, effectiveness, and responsiveness in the performance of core pharmaceutical functions and reducing vulnerability to corruption.

- » SIAPS developed a tool—the **Ukraine** Medicines Price Observatory (UMPO)—to enable civil society organizations (CSOs) to monitor prices as part of efforts to increase transparency in medicines pricing in Ukraine. The web-based price monitoring tool allows users to investigate causes of differences in prices and availability of medicines at central and regional levels in the country and to compare those prices with ones available on the international market; the tool was officially transferred to the All Ukrainian Network of People Living with HIV in June 2016. During the first five months of operation (May 11 to September 30, 2016) the tool was accessed 544 times by 404 users.
- » In **Cameroon**, SIAPS helped Positive-Generation, a local CSO that publishes reports on the availability of ARVs and diagnostics at health facilities throughout the country in its weekly newsletter, develop a dashboard that enables the CSO to generate weekly reports more easily, securely store data, and improve dissemination of information.
- » SIAPS continued its long-term support to help institutionalize the Auditable Pharmaceutical Transactions and Services (APTS) regulations in **Ethiopia**, which was introduced to achieve greater transparency and accountability

As a result of the Auditable Pharmaceutical Transactions and Services (APTS) initiative in Ethiopia, 67 health facilities are experiencing greater transparency and accountability in pharmaceutical and financial management and have benefitted from significant reductions in medicines wastage, increased revenue, and improvements in the availability of essential medicines.

In Ethiopia, 10 of 11 regional health bureaus have enacted APTS regulations.

In 5 SIAPS-supported countries, CSOs now play a greater role in monitoring and oversight in pharmaceutical systems.

7 SIAPS-supported countries and regions are using dashboards for monitoring and oversight.

in the management of pharmaceuticals and related finances. In PY5, four regional health bureaus enacted regulations that support the further expansion and sustainability of this initiative. This brings the number of regions that have enacted APTS regulations to 10; only one region—Harari—has yet to approve APTS regulations. APTS is now being implemented in 67 health facilities throughout the country; significant reductions in medicines wastage, increased revenue, and improvements in the availability of essential medicines have been reported as benefits.

- » **Bangladesh** introduced the e-Government Procurement (e-GP) system as part of efforts to enhance transparency and promote good governance in public procurement. The Directorate General of Health Services (DGHS), with assistance from SIAPS, completed its registration in the national e-GP system in PY5. Beginning in FY 2016-17, all DGHS national competitive bidding processes will be conducted through the e-GP system, and SIAPS will provide technical assistance to build capacity and support implementation of the system.
- » In June 2016, **Namibia** launched the Ministry of Health and Social Services (MOHSS) Pharmaceutical Information Dashboard at 15 state hospitals. In addition to providing managers with information on the number of patients on antiretroviral therapy (ART) and ARV stock status, the dashboard, which was developed with assistance from SIAPS, features an early warning system to alert managers to potential stock-outs. This brings the number of SIAPS-supported countries and regions that are using a dashboard for monitoring and oversight to seven.

Coordination, Partnership, and Advocacy

In PY5, SIAPS countries continued to support partnership and coordination efforts that promote more informed and collaborative decision making, foster transparency and accountability, streamline supply chain management and service delivery, and improve the efficiency of planning, allocation, and mobilization of government and donor resources. Some examples include—

- » In the **Philippines**, SIAPS continued to support the Quezon City Health Department in scaling up the Barangay Health Management Council (BHMC) Initiative in all six city districts. The initiative brings together community groups, officials, and health providers to improve TB program management and service delivery in urban poor settlements (barangays). In PY5, SIAPS conducted capacity building workshops for district health office staff and helped them develop district-level scale up plans; assisted five new BHMCs develop annual work plans for their first year of operation; and drafted a guide for establishing BHMCs which will be handed over to the Quezon City Health Department and other stakeholders to support the scale up of BHMCs in the city and other areas of the country. As of June 2016, 15 BHMCs have been established in Quezon City directly with SIAPS assistance covering 30% of the city's 142 barangays and a population of almost 1.1 million (34% of the city population).
- » SIAPS helped **Mali's** Directorate of Pharmacy and Medicines and the central

medical stores convene a three-day annual review meeting of public supply chain stakeholders to discuss progress made and future priorities. The 83 attendees, who included representatives from government, UN agencies, donors, and CSOs, heard presentations from regions on bottlenecks and solutions and learned about OSPSANTE, the web-based portal developed with support from SIAPS to track, aggregate, and disseminate reported logistic data. In addition, SIAPS supported routine coordination meetings at the central and regional levels to discuss and address supply chain issues and to validate forecasts and supply plans for malaria, MCH, HIV, TB, and family planning commodities.

- » After the **Democratic Republic of Congo (DRC)** restructured its health provinces, thereby increasing the number of provinces from 11 to 26, SIAPS helped the new provincial health divisions in USAID-supported provinces establish provincial medicine committees to ensure that MOH's partners' support is well coordinated. SIAPS also supported a two-day workshop that brought together partners supporting the national malaria program as part of efforts to reduce diversion and illegal sales of subsidized antimalarial products. The partners discussed strategies for addressing these problems and finalized a memorandum of understanding (MOU) to facilitate partner collaboration for agreed-on actions.
- » SIAPS assisted **South Sudan's** MOH in convening meetings of the pharmaceutical technical working group and the emergency medicines fund throughout PY5, including during a period of violence and civil unrest. These partner coordination meetings provide a platform for sharing pharmaceutical information to support more informed decision making and are a critical component of the country's efforts to address gaps in essential medicines stock management.

Strategic Planning

Long-term strategic plans guide the implementation of approaches, methods, and mechanisms to help achieve priorities and goals set out in national policies and promote good governance in the pharmaceutical sector. In PY5, SIAPS primarily focused its efforts on assisting national governments in finalizing the products of strategic planning exercises and tools for their implementation.

- » In **South Africa**, the national strategy for improving the availability of health products, which SIAPS has been working on with the NDOH and the USAID-funded Supply Chain Management System project, was finalized and presented to the National Health Council Sub-Committee on Pharmaceutical Services.
- » The final strategic paper for **Bangladesh's** next Sector-Wide Program (2016-2021) recognized the contribution of the SIAPS Program to the development of the procurement and supply management component and results framework.
- » SIAPS assisted the Faculty of Pharmaceutical Sciences (FOPS) at the University of Kinshasha in developing its first-ever strategic plan, operational plan, and competency framework. The strategic plan was presented in

13 countries have established and/or strengthened mechanisms to improve coordination in pharmaceutical or laboratory systems with assistance from SIAPS.

3 SIAPS-supported countries have developed and approved long-term national pharmaceutical sector strategic plans that provide a roadmap for pharmaceutical services development.

10 SIAPS-supported countries have developed/revised strategic plans for central medical stores, national regulatory authorities, laboratories, training institutes, supply chain management, pharmacovigilance, and national disease programs.

Chicago to members of the US Accreditation Council for Pharmacy Education, academics, and curriculum experts. FOPS, with help from SIAPS, incorporated feedback into the strategic plan.

Regulatory Systems Strengthening

When a country's regulatory system lacks transparency and accountability, or the processes are not based on best practices and international standards, its key functions may not be executed effectively, efficiently, or ethically, thereby limiting the population's access to safe, quality-assured medicines. SIAPS provides support to national medicines regulatory authorities to assess their systems, strengthen their legal frameworks, build their technical capacity, develop and revise processes, and upgrade information management systems across all regulatory functions.

Nine SIAPS-supported countries have improved product registration through advocacy, process reform and restructuring, capacity building, and the introduction of new information systems. **Six** countries have implemented electronic information systems for registration, **four** of which adapted and launched the SIAPS-developed software, Pharmadex.

Four SIAPS-supported countries have strengthened inspection of pharmaceutical establishments, **four** have improved licensing of pharmaceutical establishments and professionals, and **five** have addressed quality control of pharmaceuticals.

Two countries have developed and implemented pre-service curricula for regulatory sciences/regulatory affairs to build the capacity of pharmacy students to become regulators.

Three regional medicines regulatory harmonization programs have enlisted technical support from SIAPS in legislation, registration, pharmacovigilance and post-marketing surveillance, and M&E.

Highlights of SIAPS' work in RSS during PY5 are presented below. Results for SIAPS-supported pharmacovigilance activities are presented under IR5.

In **Angola**, SIAPS supported the National Directorate of Medicines and Equipment's (DNME) efforts to become a stronger institution with greater authority to regulate pharmaceuticals by advocating for the necessary legislative change which is pending approval, and building the capacity of the product registration unit. With assistance from SIAPS, the DNME organized formal discussions with key stakeholders, including the General Inspectorate of Health, Criminal Investigation Unit, Ministry of Commerce, Customs and representatives from the private sector. These discussions resulted in agreements to strengthen and expedite import controls for pharmaceutical products at the MOH, starting with priority diseases, and to allocate more resources to the implementation of a formal medicine registration process. As a starting point for establishing a formal medicine registration process, SIAPS helped DNME's registration unit develop a plan for identifying and collecting data on all medicines imported in the last three years. SIAPS also assisted DNME staff in developing product registration tools that are aligned with the South African Development Community (SADC) requirements and guidelines. Finally, as part of closeout activities, SIAPS

developed a road map for product registration for the DNME and stakeholders to review and consider for adoption.

SIAPS continued its support for the Directorate General of Drug Administration (DGDA) in **Bangladesh** in its ongoing efforts to improve the medicine registration system through implementation of the Common Technical Document (CTD) application format and new electronic software, Pharmadex, to manage the application review process. The DGDA's adoption of CTD was advanced this year primarily through training workshops to build the knowledge and capacity of DGDA officers and pharmaceutical industry applicants on the format and review process. As part of a strategy to sustain CTD implementation and institutionalize capacity, SIAPS and the DGDA designated and oriented 15 representatives from the DGDA and pharmaceutical companies as master trainers. To advance the implementation of Pharmadex, SIAPS conducted a series of user acceptance testing and training workshops to demonstrate software functions, delineate roles of users, and provide hands-on practice on how to review CTD-based medicine dossiers using the system. In addition, SIAPS assisted the DGDA in finalizing the revised templates and forms used in product registration, developing SOPs for applicants and DGDA staff, and updating the Pharmadex Users' Manual.

Recognizing that successful implementation of both CTD and Pharmadex depends on support and uptake by the national pharmaceutical industry, the DGDA and SIAPS brought together the company heads of the top 40 pharmaceutical companies to discuss the new registration system, and as a result, secured their commitment to using it. SIAPS also brokered a three-year partnership between DGDA and the Korean International Cooperation Agency to have the Korean Ministry of Food and Drug Safety provide training for DGDA officials to build their capacity to regulate medicines in accordance with international standards. Fifteen DGDA officials attended the first two-week training in Korea in PY5. Finally, SIAPS partnered with WHO, the World Bank, and other implementing partners, including the USAID-funded Promoting Quality of Medicines (PQM) Program, to form a coalition of partners supporting RSS in Bangladesh. The coalition will assist the DGDA in developing a five-year strategic plan in the coming year. As a first step, SIAPS worked with PQM and DGDA to identify and prioritize the technical assistance needs of the National Control Laboratory as it works toward achieving WHO accreditation.

SIAPS continued to work with the Food, Medicines, and Health Care Administration and Control Authority (FMHACA) in **Ethiopia** to develop and implement its electronic information system for medicine registration and associated process improvements. With assistance from SIAPS, FMHACA established a team of experts to serve as the change management team and developed an organizational change management document to support the process. Three new sets of SOPs for medicines registration were drafted, and legacy medicines registration data were reviewed and cleaned in preparation for inclusion in the new database. Also, 42 industry applicants were trained on the new software, which was finalized and will be officially implemented at the beginning of the next year. In addition, SIAPS provided support to the School of Pharmacy of Addis Ababa University (SOP/AAU) and FMHACA as they made preparations to launch the new post-graduate regulatory sciences program. SIAPS helped them conduct a situation analysis to identify capacity building needs of

the intended instructors and then set up a study tour enabling four officials from FMHACA and SOP/AAU to visit 14 institutions in South Korea and the United States. As a result, the SOP/AAU signed a MOU with the Women's University School of Pharmacy in Korea and is expected to sign additional MOUs with other teaching institutions.

In **Mozambique**, the use of the electronic medicine registration tool, Pharmadex, launched in 2015 with assistance from SIAPS was lower than expected in the first half of PY5. In response, SIAPS and the PD held a workshop to assess the current situation of Pharmadex, identify barriers and root causes of low usage, and define interventions and next steps to address them. SIAPS conducted a follow-up training workshop with staff from the medicine registration unit to go over the process for generating review reports using the new system and assisted the PD to plan for the changes needed to harmonize Mozambique's guidelines for product registration with SADC guidelines. SIAPS also worked with the PD to transfer data on 4,232 products registered prior to the implementation of the electronic registration system into the new electronic archive, so that variation and renewal applications for these can now be processed electronically, thereby reducing the registration time. Finally, to promote sustainability of Pharmadex, SIAPS trained PD IT staff, developed two instruction manuals, and strengthened the capacity of selected super users to enable them to manage Pharmadex without remote support from SIAPS headquarters. Collectively, these activities in medicine registration positively contributed to a reduction in the number of days to approve a product registration application from 275 days in December 2015 to 176 days in June 2016. Also in PY5, SIAPS helped the PD establish an M&E framework and system, which is now functional. The PD is now able to monitor their performance and progress—for example, changes in the number of days to register products—and use this information to define priorities and plan appropriate actions to address gaps.

In **DRC**, SIAPS assisted the national regulatory authority (DPM) in convening all four of its planned quarterly product registration sessions. In PY5, the registration committee received 1,002 dossiers and approved 404 products. This brings the total number of medicines that have been registered in DRC to 4,606, up from 400 in 2011 when SIAPS began supporting quarterly application evaluations. Furthermore, 1,392 products were de-registered during the year due to expiry of their marketing authorizations without renewal, which brings the number of registered products in the country to 3,027 as of September 2016. DPM now has full ownership of the quarterly registration sessions, and other partners are providing financial support to the institution to ensure the sessions continue after SIAPS ends. Also in PY5, SIAPS helped the DPM install and set up new registration software (Integrated System of Computerized Management of Regulatory Process in a Drug Regulatory Authority [SIGIP-ARP]), migrate the legacy data for previously registered products, and brought in two experts to train 25 staff on the use of the new software.

SIAPS continued its long-term technical assistance to the **Namibia** Medicines Regulatory Council (NMRC) to strengthen medicines registration by providing support to the quarterly dossier review sessions, addressing emerging issues with the new online version of its electronic tool for registration, Pharmadex, and updating the registration status of over 100

medicines. Analysis of data generated by Pharmadex shows that the average number of days taken to evaluate and approve a medicine registration application decreased from 34 days in 2013 to 26 days in 2016. This improvement can be attributed to an increase in human resources at NMRC, the regularity of the dossier evaluation team's review sessions, and continued SIAPS technical assistance to improve the efficiency of product registration. Additionally, there is now at least one registered product available for 78% of the items listed in Namibia's official National Medicine List used for public sector procurement, up from 61% in 2011. SIAPS also helped the NMRC strengthen the system for post-marketing surveillance of medicines, established in PY4, by assisting with the sensitization and training of ART staff on the importance of submitting product quality reporting forms to the Quality Surveillance Laboratory and by supporting sampling and testing activities in accordance with the medicine quality monitoring guidelines. Also in PY5, SIAPS continued to work with the University of Namibia's School of Pharmacy to solicit stakeholder input to finalize the pharmaceutical regulatory affairs module for the BPharm course.

In **Swaziland**, SIAPS assisted the MOH with reviewing the implementation plan for the new medicines regulatory authority, which is pending enactment of new pharmaceutical legislation, and with improving the regulation of imported medicines. SIAPS helped update the medicines listing database and the registration status for all medicines used in the public sector, develop the medicines quality control laboratory action plan, and set up procedures for monitoring the importation, consumption, and supply of narcotics. In addition, SIAPS provided input on the African Union Model Law on the Harmonization of Medicines Regulation on behalf of Swaziland and the SADC at a meeting led by the NEPAD agency of the African Union.

TECHNICAL HIGHLIGHT

STRENGTHENING POST-EBOLA RECOVERY AND RESILIENCY IN FOUR COUNTRIES



OVERVIEW

A strong pharmaceutical management system is critical for responding to and preventing public health emergencies. The US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health (MSH), is helping four countries affected by Ebola—Sierra Leone, Guinea, Mali, and Benin—recover and rebuild essential drug management and delivery services and to increase their capacity and sustainability. The two-year project began in 2015.



STRENGTHENED SYSTEMS

The pharmaceutical sectors in these countries face challenges that worsened during and after the Ebola crisis. All four target countries have fragile supply chain systems. Weak information management led to a lack of timely, reliable medicine consumption and morbidity data for effective planning and decision making. There is an overall shortage of qualified pharmaceutical personnel at all levels. Efforts shifted to controlling the Ebola epidemic, and basic health services stopped or operated at a very low level. This cut into delivery of services for other public health priorities, such as antiretroviral drugs for HIV, maternal health, and malaria control.

Outdated policies and guidelines for medicines and medical supplies continue to hamper regulatory agencies that were already lacking the legislation and enforcement capacity to ensure the safety and effectiveness of pharmaceuticals. Further, the high

volume of unusable Ebola donations is clogging already tight medicine storage spaces and hampering quality control.

Note: MSH is also assisting Liberia through the USAID-funded leadership, Management, and Governance (LMG) program.

APPROACH

Working with USAID, partners, and host governments, SIAPS is strengthening these countries' national central medical store systems, medicine regulatory agencies, and pharmacy departments to help them adopt and enforce adequate policies, guidelines, and norms. SIAPS is also building the capacity of regional, district, and health facility groups, such as district health management and drug and therapeutic

committees, to carry out these advances and sustain health system performance.

Specific interventions include assessing each country's ability to address pharmaceutical supply chain and service delivery challenges. They also include promoting transparency and accountability, training and mentoring, stock status monitoring and reporting through adequate information systems to help ensure product availability, storage and inventory control improvements, and improving rational medicine use and safety.

SIERRA LEONE: TRACKING PROGRESS

In Sierra Leone, SIAPS is supporting key pharmaceutical government entities, including the Directorate of Drugs and Medical Supplies, the Pharmacy Board of Sierra Leone, district health management teams, and last mile health facilities, through a new country office. The program helped update the national medicines list to inform purchasing and selection; formed a national committee to handle quantification and introduce the automated SIAPS tools (Quantimed, QuantTB, and Pipeline); implemented a bi-monthly, countrywide continuous results monitoring and support system (CRMS) to ensure availability, inventory management, and rational use of pharmaceuticals; and helped build capacity at all levels to ensure sustainability. The CRMS has been implemented in 11 of the country's 13 districts as of October 2016.

SIAPS also assisted in the revision of the report, request and issue voucher (RR&IV), Sierra Leone's logistics management information system (LMIS), and designed a daily and monthly treatment/pharmacy register for use in approximately 1,200 public peripheral health units and 21 district hospitals. The treatment register captures patient uptake; prevalence of priority diseases; and consumption and stock status data of key pharmaceuticals, including selected Ebola-related commodities.

GUINEA: STRENGTHENING LEADERSHIP AND INFORMATION SYSTEMS

In Guinea, SIAPS is building on its experience of implementing the USAID-funded President's Malaria Initiative for the last four years, including developing an LMIS to strengthen the supply chain. The SIAPS post-Ebola recovery plan

focuses on scaling up interventions nationwide. It includes helping the Ministry of Health maximize its resources for capacity building, accountability, and quality assurance, including the national medical store parastatal Pharmacie Centrale de Guinee (PCG) and the Direction Nationale de la Pharmacie et des Laboratoires (DNPL) of the Ministry of Health. SIAPS is strengthening the country's LMIS to include the inventory and distribution of Ebola products to help ensure that they are safe and available.

Another key goal in Guinea is an automated pharmaceutical information management system to support decision making. With technical and financial support from SIAPS, the DNPL has developed a testing environment for a new, automated, electronic logistics management information system (eLMIS). Once the test phase is complete, the DNPL will roll out the new system nationwide.

MALI: RISK MANAGEMENT

With Ebola still present in Guinea, which shares a border with Mali, and large population shifts within West Africa, there is a risk of new Ebola cases in Mali. In this country, SIAPS supports the Ministry of Health's Department of Pharmacy and Medicines (DPM) in improving management of Ebola products and related information systems to help combat an outbreak. SIAPS helped the Ebola national coordination committee finalize an inventory of infection prevention and control products, job aids and posters, and a list of essential items that the national medical stores and partners involved in supply chain management will follow for procurement. SIAPS provided technical assistance in Ebola commodities quantification and incorporated the data into a web-based dashboard, OPSANTE, introduced with SIAPS support. SIAPS is also collaborating with the USAID-funded Advancing Newborn, Child and Reproductive Health program to design LMIS tools, including standard operating procedures and training materials. At the request of the Ministry of Health, SIAPS is also helping to develop a national Ebola strategic plan and establish a national logistics committee for Ebola.

BENIN: DISTRIBUTING SUPPLIES

Benin shares a border with Nigeria, where Ebola took hold, so preventing and preparing for an occurrence of the virus in Benin is critical. That

Boosting pharmaceutical supply and delivery resilience contributes to the preparedness for, prevention and detection of, and response to emerging disease threats.

includes effectively managing Ebola-related medicines and equipment and related information systems. Working with other organizations to promote a cohesive response, SIAPS is supporting the Ministry of Health's DPMED efforts to inventory, forecast the need for, purchase, store, and distribute Ebola-related products nationwide, including basic infection control items and communications materials. The program helped the Ministry of Health compile a list of necessary Ebola products and establish a quantification working group to assess stock. To strengthen the LMIS, the program is helping to develop tools and training materials and standardize operating procedures. Information captured includes stock movement and status reporting. The program is also advising

health workers at all levels on safe and secure product storage, handling, and distribution.

NEXT STEPS

Boosting pharmaceutical supply and delivery resilience contributes to the preparedness for, prevention and detection of, and response to emerging disease threats. For example, Benin's bolstered system improved its response to the recent outbreak of Lassa fever. Each country brings strengths to its challenges and uses them to test system improvements, such as the CRMS in Sierra Leone, the eLMIS in Guinea, the product inventory in Mali, and distribution systems in Benin. Improved automation, computer hardware and networks, and more advanced technology and data sharing will be important to improvement and to cross-pollinating best practices to all countries in the region. SIAPS will continue to promote knowledge sharing and best practices among all four countries and hopes to bring key partners together to share experiences and lessons learned in person.

IR2 CAPACITY FOR PHARMACEUTICAL MANAGEMENT AND SERVICES INCREASED AND ENHANCED



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The development of stronger pharmaceutical systems that allow for greater and more equitable access to medicine hinges on the availability of people with the appropriate knowledge and skills to effectively implement pharmaceutical management. It also requires that organizations have sufficient capacity to lead, manage, and effect positive change within the pharmaceutical sector. SIAPS engages with a broad spectrum of stakeholders—from governments and universities to health facilities and health care workers—to address pressing human resource capacity challenges, such as health care worker shortages, resource constraints, and policy-level issues. Using a participatory approach, we identify areas and opportunities for capacity improvement and develop strategies to strengthen the system in the long-term, while also working to develop solutions to immediate or short-term threats to medicines availability and access.

ACHIEVEMENTS DURING PROGRAM YEAR FIVE

Strengthening Capacity of Individuals, Institutions, and Organizations

A key area where SIAPS focuses its efforts is on pre- and in-service trainings for health care professionals through local institutions. Designing and implementing

training curricula, courses, and programs for pharmacists, physicians, nurses, and other health care workers helps strengthen the cadre of professionals ready to effectively manage, prescribe, and monitor the use of medicines.

Pre-Service Trainings

In collaboration with local universities and other training institutions, SIAPS enhances pharmacists' and health care workers' knowledge by developing more robust training curricula, courses, and programs. This year alone, SIAPS helped develop or reform three professional pre-service training curricula in medicines supply management, rational medicine use (RMU), and pharmacovigilance. SIAPS also collaborated with a number of university training programs to build pharmaceutical education capacity and produce pharmaceutical professionals locally.

- » In **Dominican Republic**, SIAPS finalized the educational modules for the certified course (diploma) on RMU, which was implemented in partnership with the Universidad Central del Este. In December 2015, SIAPS conducted a workshop to train the facilitators of the course, prior to its implementation. During the third quarter, 31 students completed the course. A group of 32 students also initiated the course in August 2016 where the tuition fees of 20 students were sponsored by USAID. A revised and updated version of the educational modules is available on the SUGEMI "tool box kit"/National Health Service website.
- » In **Namibia**, during the second quarter, SIAPS supported the development of a second pre-service health curriculum for the National Health Training Center pharmacy assistants' course, reaching the country's life-of-project target of two pre-service training curricula. In addition, SIAPS provided technical assistance to the University of Namibia's (UNAM) School of Pharmacy (SoP) to develop course materials for a pre-service training in medicines regulation. This training is part of the curriculum for the UNAM Bachelor of Pharmacy and will ensure that pharmacists graduating from UNAM are equipped with the fundamental knowledge and skills to improve the quality, safety, and efficacy of medicines. As of June 2016, the cumulative number of health care workers who graduated from a pre-service training institution or program reached 163 (life-of-project target of 164).
- » In **South Africa**, SIAPS worked with five tertiary institutions (Nelson Mandela Metropolitan University, Sefako Makgatho Health Sciences University (SMU), University of Fort Hare, University of KwaZulu-Natal, and the University of the Western Cape [UWC]). SIAPS support included the development of training and materials to address course gaps in pharmaceutical management. During this year, two additional pre-service health professional training curricula were developed, for a total of six training curricula, surpassing the life-of-project target of four. During year 4 of the program, SIAPS provided technical assistance to deliver the first distance-learning course aimed at strengthening RMU in Africa. This year, the course was finalized and handed over to UWC, demonstrating the sustainability of SIAPS pre-service capacity building efforts.

As of September 2016, SIAPS developed or revised 39 in-service training curricula in 10 countries (figure 1), exceeding the life-of-project target of 36 training curricula; during this year, six in-service training curricula were developed or revised in Bangladesh (2), Ethiopia (2), Namibia (1), and South Africa (1).

In-Service Trainings

SIAPS works to improve in-service training opportunities for practicing pharmaceutical and health professionals. As of September 2016, SIAPS developed or revised 39 in-service training curricula in 10 countries (figure at right), exceeding the life-of-project target of 36 training curricula; during this year, six in-service training curricula were developed or revised in **Bangladesh (2), Ethiopia (2), Namibia (1), and South Africa (1)**. In addition, about 9,000 pharmaceutical staff in over 20 countries were trained in various aspects of pharmaceutical management, including financing, leadership, regulatory systems, quality assurance, pharmaceutical care, medicine safety, antimicrobial resistance (AMR), and supply chain management (quantification, inventory management, and information management, among others).

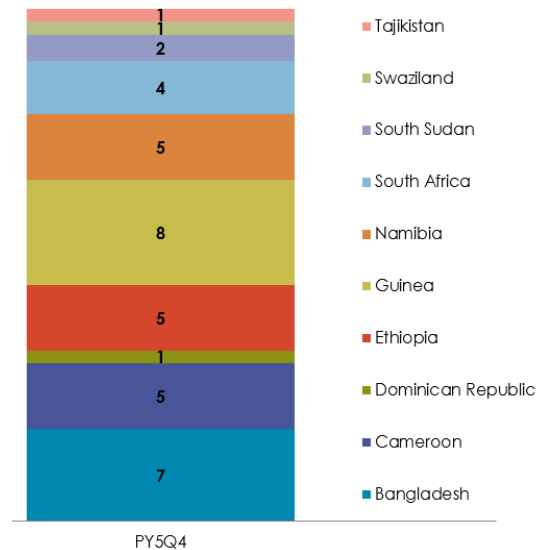


Figure 1. Number of SIAPS-supported revised/developed in-service training curricula

In **Burundi**, SIAPS assisted the National Malaria Control Program (PNILP) in conducting an orientation session for a national team on intermittent preventive treatment in pregnancy (IPTp) policy implementation in six health districts. This orientation session aimed to update the team on IPTp, review training materials, and develop the timeline for a training of trainers (TOT) at the provincial and district levels, and to cascade training to health care providers. As for the TOT at the provincial and district levels, during the second quarter, SIAPS assisted the PNILP in training 34 trainers from six health districts in three health provinces. The output of the training was the coordinated development of specific IPTp implementation plans for the six health districts. In addition, during the third quarter, SIAPS supported the PNILP and the National Reproductive Health Program in training 103 trainers on IPTp policy. These trainers assisted in the training of 846 health care providers on IPTp policy implementation in 18 health districts. As result, all health districts planned for FY16 were trained, for a total of 30 health districts.

In **Ethiopia**, over 1,800 professionals attended FY16 trainings on the APTS, the standard operating procedures (SOPs) for the Pharmacy ART Information Management Manual, Electronic Dispensing Tool (EDT), Drug and Therapeutics Committees (DTCs), AMR, and reproductive, maternal, newborn, and child health.

In **South Africa**, during the second quarter, SIAPS exceeded the life of program targets of persons trained in pharmaceutical management (1,206 persons were trained against the target of 1,104) and new health care workers graduating from a program that includes pre-service training (499 graduates against the target of 340). In addition, SIAPS worked with the Pharmaceutical Services Directorate in the Free State to finalize and implement the Pharmaceutical Leadership and Governance Initiative, which helped address challenges related to medicine supply management identified by the auditor general. By the end of the fourth quarter, all capacity building efforts to enhance the skills of pharmaceutical service personnel were closed and handed over to stakeholders. Aspects of the Leadership Development Program (LDP) course content and facilitation material were transitioned to SMU, and technical reports on all LDP and pharmaceutical leadership development program (PLDP) activities were completed.

About 9,000 pharmaceutical staff in over 20 countries were trained in various aspects of pharmaceutical management.

To ensure sustainable improvements in pharmaceutical management, SIAPS successfully transitioned the leadership programs to stakeholders.

Building Institutional Capacity to Strengthen Pharmaceutical Systems

SIAPS strives to ensure its capacity building efforts to address immediate country needs but also take into account long-term goals that promote local ownership and sustainability. Toward this end, SIAPS works to build on existing systems and strengthen capacity of local organizations to provide pharmaceutical technical assistance and support. Highlights from this year include the following.

To improve the pharmaceutical regulation capacity of the DGDA in Bangladesh, SIAPS facilitated a three-year capacity building partnership between the DGDA and the Korea International Cooperation Agency.

- » In **Bangladesh**, SIAPS continues to provide technical assistance to the Directorate of General Drug Administration (DGDA) to improve the performance of their regulatory systems. Specifically, SIAPS is building the capacity of DGDA and pharmaceutical manufacturers on how to develop and regulate medicines according to international standards. To achieve national ownership and sustainable results, SIAPS has facilitated a partnership between the DGDA and the Korea International Cooperation Agency for over three years. This year, 15 DGDA officials participated in the first training on biopharmaceutical regulation. As a result of the training, DGDA officials finalized their action plans, helping Bangladesh identify and propose possible solutions to the country's current issues and major challenges. In addition, in the second quarter, SIAPS trained close to 500 DGHA logistics officials from 10 districts on the standard inventory tools (stock register, issue voucher, bin card, etc.) with the objective of providing information on general logistics issues and the newly developed inventory tools for timely reporting.
- » During the third quarter, SIAPS conducted training on quantification techniques and tools for the procurement and supply management technical working group members. The training was a first of its kind in **Guinea** and laid the foundation for developing accurate national forecasts and supply plans for antimalarial commodities by using best-practice tools (i.e., Quantimed and Pipeline). Eight staff from the national malaria control program (PNLP), the national medicines regulatory authority, the Pharmacie Centrale de la Guinée, and Catholic Relief Services participated in the trainings. Building on the training outcomes, SIAPS supported the PNL in carrying out a multi-year forecast of antimalarial commodities by using both consumption and morbidity/service statistics data. Preliminary forecast results will be used to develop subsequent supply plans and help the program identify the financial resources required to support malaria program activities through 2022.
- » To facilitate training on stock management and LMIS for 30 correctional services and defense force health workers, in the first quarter, SIAPS/**Swaziland** collaborated with the UN Office on Drugs and Crime. These trainings aimed to assist the security force health workers conform to the supply chain system in the country, as they report and order from Central Medical Stores and receive health products at the right time and in the right condition.
- » During the fourth quarter, a two-day training session was conducted by the **West Africa Regional Program** for selected West Africa Health Organization (WAHO) staff at their headquarters in Bobo-Dioulasso, Burkina Faso. The goal of the training was to familiarize and make WAHO staff comfortable with

management of OSPSIDA. Since WAHO is not an executive body and their main task is to assist country-level/local organizations, WAHO is currently exploring the possibility of transferring OSPSIDA management and related activities to the Central Medical Stores of Cote d'Ivoire.

Other Approaches for Capacity Building

Supportive supervision

The SIAPS approach to building human resource capacity goes beyond traditional capacity building methodologies. Supportive supervision promotes effective and equitable health care through measured improvements in the procedures, personal interactions, and management of primary health care facilities and pharmacies while focusing on meeting staff needs for management support, logistics, training, and continuing education. SIAPS assists governments and in-country counterparts to design and implement a supportive supervision plan and helps conduct mentoring and supportive supervision visits.

For example, in **Mali**, SIAPS supported 13 public institutions in organizing 18 trainings and mentoring sessions. SIAPS also continued to support the Regional Directorate of Health to conduct coaching visits to trainees in five regions (Kayes, Koulikoro, Sikasso, Segou, and Mopti); 238 (45 female and 193 male) trainees in five regions and six districts were mentored. Such activities had significant impact on the number of trainees successfully completing a post-training action plan—77% of trainees successfully completed post-training action plans (out of 71% planned as the program target).

In **Mozambique**, a SIAPS Pharmadex programmer trained the Pharmacy Department (PD) IT team on system management and configuration and provide first-line support to maintain Pharmadex (because the Pharmadex IT expert can only provide support remotely). In addition, SIAPS hired one consultant to support the implementation of Pharmadex at the PD site and strengthen the capacity of system administrators to submit and review registration dossiers. This activity positively contributed to the number of days to approve a product registration application, with a decrease from 275 days during the first quarter to 176 days during the third quarter.

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

By strengthening the capacity of Pharmadex super users in Mozambique, the number of days to submit and review registration dossiers decreased by nearly 100 days, from 275 days in the first quarter to 176 days in the third quarter.

In Sierra Leone, SIAPS developed and introduced a Continuous Results Monitoring System to improve pharmaceutical management at the district level and is providing supporting supervision to ensure to ensure sustained improvements in acquired skills.

Tools for Capacity Building

SIAPS' multifaceted approach to capacity building recognizes the growing importance of electronic tools and new media to support its work of strengthening pharmaceutical systems. For example, during this year, a selected team of 13 staff from the National HIV and AIDS Control Institute, the Central Procurement Agency for Medicines and Medical Supplies, USAID/**Angola**, and SIAPS participated in a 9-day intensive training on quantification, data collection and validation, and the application of electronic tools for the quantification of health products, with specific attention given to HIV/AIDS and malaria commodities. Participants were able to apply electronic forecasting tools (Quantimed and PipeLine) to supply planning and stock-level monitoring.

During the third quarter, SIAPS/**Burundi**, in collaboration with SCMS and the Directorate of Pharmacies, Medicines and Laboratories, trained 24 trainers (at the district level) on new LMIS procedures and tools. These trainers collaborated with those trained in the prior quarter to train 121 health managers and stock managers at facility level. A total of 409 health managers and stock managers from 12 health districts were trained on the new LMIS procedures and tools, which is 96% of targeted participants.

In **Sierra Leone**, to ensure proactive supportive supervision by district health management teams to health facilities, SIAPS developed and introduced a Continuous Results Monitoring System (CRMS). CRMS uses a checklist to monitor stock availability, expiry, use of information system tools, storage conditions, and capacity building of staff managing pharmaceuticals. The checklist tracks tracer and key medicines, including ARV, TB, malaria, and reproductive products and is used to monitor performance and results on a bimonthly basis. Reports from these continuous exercises allow key stakeholders to provide feedback and address identified challenges in real-time.

In **South Africa**, the web-based national pharmaceutical services management dashboard was finalized and successfully migrated to a new domain (www.perseus.org.za) which went live in August. This significant innovation replaces the Excel-based tool developed in 2014. Provincial and national users were trained on use of the system, providing an opportunity for users to provide input on the system and strengthen their sense of ownership. Involvement of the NDOH staff in the development and training process has been critical in facilitating country ownership.

TECHNICAL HIGHLIGHT

STRENGTHENING THE NATIONAL MALARIA CONTROL PROGRAM IN SOUTH SUDAN



PROJECT DESCRIPTION

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program works to ensure access to quality pharmaceutical products and effective pharmaceutical services through systems strengthening approaches that achieve positive and lasting health outcomes. SIAPS, which is funded by the US Agency for International Development (USAID) and implemented by Management Sciences for Health (MSH), is providing technical assistance at the national level and in South Sudan's former Central and Western Equatoria states to strengthen pharmaceutical services.



to their weak immune systems. According to the 2013 Malaria Indicator Survey (MIS) from the country's Ministry of Health (MoH), only 17 % of children under the age of five years received treatment within 24 hours of fever onset, and only 50% sleep under long lasting insecticide-treated nets (LLINs). Only 32% of pregnant women received two or more sulphadoxine-pyrimethamine intermittent preventive treatments for malaria during pregnancy². Access to malaria treatment and prevention services remains limited due to poor planning and coordination, particularly at the state and county levels.

The Government of South Sudan expends significant resources in the fight against malaria. With support from development partners, it has invested in personnel, infrastructure, and the procurement and distribution of malaria commodities in the country. As one of the key partners supporting government efforts to control malaria, SIAPS has been working to build the capacity of the National Malaria Control Program (NMCP), a government organization responsible for the planning, coordination, and general oversight of all malaria prevention and control activities, including fulfilling Roll Back Malaria and MIS requirements.

BACKGROUND

Malaria is an endemic disease that accounts for 40% of outpatient consultations, 30% of hospital admissions, and 20% of health facility deaths in South Sudan¹. Children under the age of five and pregnant women are most vulnerable to malaria due

APPROACH

SIAPS seeks to build the capacity of the NMCP to perform its core functions, including planning, coordinating, and implementing malaria interventions. With a senior malaria technical advisor and a senior monitoring and evaluation advisor embedded within the NMCP, SIAPS helps to build the capacity of public

1 South Sudan Ministry of Health 2013 Malaria Indicator Survey Report.

2 Ibid.

health workers by providing on-the-job training and conducting routine supportive supervision for the NMCP and its partners. The SIAPS team coordinates with other USAID and global health partners and provides malaria case management training to build local capacity and ensure effective management of essential antimalaria commodities in the country.

PROJECT IMPLEMENTATION

Building Capacity within the NMCP

SIAPS technical support to the NMCP included providing on-the-job training, conducting malaria technical working group meetings, improving malaria surveillance, and updating the malaria epidemic preparedness and response plan. SIAPS continued to coordinate the Pharmaceutical Technical Working Group as the secretariat and provided a national-level update of malaria commodities security.

Training in Malaria Case Management and Rational Medicine Use

The MoH issued revised Malaria Case Management Guidelines in 2016. In response, SIAPS organized malaria case management trainings to build local capacity for effective treatment and rational medicine use per the guidelines. Working with national- and state-level trainers of trainers from the NMCP and key national public hospitals, SIAPS staff delivered three trainings, one in Western Equatoria State and two in Central Equatoria State. The goal of these trainings was to build the competencies of health workers to understand the risks associated with complicated severe falciparum malaria; take histories and make appropriate diagnoses; administer emergency treatment to severely ill patients, including children and pregnant women; and keep appropriate records.

By May 2016, SIAPS had trained 107 health workers, including medical officers, clinical officers, nurses, midwives, dispensers, nursing assistants, storekeepers, laboratory assistants, and community health workers from 10 counties in the Western and Central Equatoria states³. All 107 trained health workers developed two post-training action plans to be implemented and reviewed during supportive supervision visits.

Supporting the 2013 and 2016 MIS

As recommended by the Roll Back Malaria Partnership, which is the platform for a coordinated global effort against malaria, the NMCP conducts an MIS every two to three years to evaluate the outcomes and impact of malaria interventions using population-based indicators. The MIS is a national survey that examines the prevalence of core malaria control interventions; the prevalence and type of malaria parasites in children under the age of five and pregnant women; the prevalence of anemia among pregnant women; and the knowledge, attitudes, and practices regarding malaria in the general population⁴.

As part of the core planning team for the 2013 MIS in South Sudan, SIAPS worked closely with the NMCP and its partners to provide technical oversight, including budgeting, protocols, and data collection. During the implementation phase, SIAPS provided logistical support and training to field teams; oversaw data entry, analysis, and compilation; and assisted with the publication and dissemination of the final report. Despite challenges due to conflict in South Sudan, SIAPS has provided similar support to the NMCP and its partners in preparing the protocol and tools for the 2016 MIS.

Conducting Supportive Supervision in Health Facilities

SIAPS conducted quarterly joint supportive supervision visits with NMCP staff, along with state malaria coordinators and malaria monitoring and evaluation officers, to counties in the Western and Central Equatoria states to provide guidance and mentor health workers. The visits gave SIAPS the opportunity to assess the capacity of health workers and technical staff working in the target malaria sentinel sites; the availability of laboratory services, such as malaria microscopy and rapid diagnostic testing; and the training needs, reporting tools, and conditions that influence the performance of health workers. The visits also helped the team gather information on supply chain management in general and gauge the availability of antimalaria medicines in health facilities. After conducting each visit, SIAPS developed recommendations and coordinated trainings to improve the management of malaria patients at health facilities.

3 Central Equatoria State Malaria Case Management Training Report. April 2016.

4 South Sudan Ministry of Health 2013 Malaria Indicator Survey Report.

Distributing Malaria Commodities

As the lead agency supporting the MoH in ensuring effective management of pharmaceuticals and services in South Sudan, SIAPS provided safe storage for USAID-procured malaria commodities, including LLINs and artemisinin-based combination therapy (ACT) in the Western and Central Equatoria states. SIAPS supported NMCP partners in conducting a gap analysis for malaria commodities, developing a distribution plan for existing commodities to ensure coverage, and increasing the availability of antenatal care services.

In the Western and Central Equatoria states, SIAPS distributed 250,000 doses of sulphadoxine-pyrimethamine to pregnant women, 635,650 doses of ACT to health facilities, and 400,000 LLINs through routine distribution in eight states per the World Health Organization's Expanded Program on Immunization and antenatal care clinic recommendations. SIAPS worked with the USAID-funded DELIVER project and the NMCP to finalize the commodities procurement information request forms for these antimalarial commodities for the Western and Central Equatoria states. SIAPS, with additional funding from USAID, also supported the NMCP to procure one million rapid diagnostic tests to be distributed as a stop

gap for fiscal year 2017 in eight Health Pooled Fund 2-supported states. The tests are expected to be distributed in November 2016.

CHALLENGES

Insecurity: Many counties in Western Equatoria State have suffered from ongoing insecurity that hindered supportive supervision visits. As a result, some targets were not achieved. Insecurity further affected commodities distribution, with some LLIN consignments looted while en route to Kuajok, Warrap State. Conflict in July 2016 led to a scaling down of project activities across many sites in South Sudan, and SIAPS has had to provide remote support from outside the country.

Infrastructure: Many counties still lack adequate infrastructure, such as medicine stores, electricity, and roads, making supportive supervision visits a challenge.

Staff turnover and morale: Nearly 50% of essential staff left the NMCP between March and August 2016. This was partly due to delayed salary payments from the Global Fund malaria grant principal recipient in South Sudan, as well as a desire to look for job opportunities outside the NMCP.

RECOMMENDATIONS

| Project Activity | Recommendation |
|--|---|
| Malaria case management trainings | Malaria case management trainings should be continued on the job and via continuing medical education at health facilities. Copies of printed guidelines should be available to all health facility workers; one copy per facility is not sufficient. |
| Technical support to USAID partners on the storage and distribution of malaria commodities | Before shipping medical commodities to their destinations, an assessment of storage needs must be completed and gaps costed. Medical commodities destined for remote field locations may be dispatched in batches to minimize loss and storage challenges at the receiving end. |
| Development of malaria policy documents | As part of the policy development process, consensus building on draft policy documents among key technical working group members should be prioritized before seeking approval from senior management at the MoH. An external consultant should be hired to help with activities that require a significant level of effort. |
| Technical assistance to the NMCP to conduct the 2016 MIS | It is critical that the country continue conducting the 2016 MIS even after the SIAPS project concludes, as it provides important planning information to the MoH and donors. |
| Supportive supervision | Supportive supervision should be continued because it provides the NMCP with information on training needs for health workers and issues of availability of essential medicine in health facilities, particularly antimalaria medicines. |

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IR3

INFORMATION FOR DECISION MAKING IN THE PHARMACEUTICAL SECTOR ADDRESSED



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The collection, analysis, and use of health and logistics data drive better decision making at all levels of a health system. This data, when used through efficient systems, contributes to ensuring a steady supply of medicines; providing insights into the factors that enables patients to adhere to treatment regimens; developing and revising national treatment protocols; facilitating more accurate quantification, procurement, and costing for medicines and other health supplies; and ultimately contributing to stronger health systems and better health outcomes. SIAPS emphasizes stakeholder buy-in and ownership and advocates for effective information systems and long-term sustainability of interventions.

SIAPS has supported the integration of pharmaceutical data collection, analysis, and presentation of information to help staff at all levels of a country's health system make evidence-based decisions to improve the management of health commodities and pharmaceutical services. Through our tools, SIAPS has helped ensure that quality pharmaceutical information is available across the health systems—from formulating pharmaceutical policy and plans, to monitoring supply chain systems and pharmaceutical services. SIAPS' work to strengthen pharmaceutical management information systems (PMIS) embodies the SIAPS systems strengthening approach by relying on cross-cutting interactions with governance, capacity building, financing, supply chain, and pharmaceutical services to make longer term, sustainable improvements.

At the beginning of SIAPS, three main themes relating to information and information systems were identified as the keys to improving decision making. These were data availability and use, data quality, and system design/use of tools. To address these topics, SIAPS applied several strategies, including assessing local information needs, leveraging mobile and Internet technologies, integrating multiple PMIS platforms, and strengthening the capacity of local organizations to customize, maintain, and take ownership of PMIS tools and data. SIAPS also worked with countries to improve data quality, ensure that information systems capture data on both product and patient-focused parameters, and disseminate data in a timely manner to stakeholders through appropriate reporting channels. Data generated from SIAPS-supported systems now allow in-country decision makers to access critical information, including for example, treatment regimens, consumption rates, and stock data. During PY5, the priority was to strengthen the systems already in place and handing over the tools to in-country counterparts to ensure their sustainability.

Through our tools, SIAPS has helped ensure that quality pharmaceutical information is available across the health systems.

ACHIEVEMENTS DURING PROGRAM YEAR FIVE

Information Systems support both Patients and Pharmaceutical Management

SIAPS has developed, and supported continued implementation of existing pharmaceutical management tools to meet the needs of countries. SIAPS has also facilitated the introduction, implementation, and scale-up of PMIS tools through trainings, effective support mechanisms, and bolstering the skills of program managers to successfully launch, establish, and manage PMIS tools. SIAPS has worked to ensure these tools are effective, locally appropriate, and sustainable.

| SIAPS-supported tool | Where it's used | Achievements in PY5 |
|----------------------|---|--|
| RxSolution | South Africa, Lesotho, Namibia, Swaziland, and Uganda | Rolled out to 135 new sites around South Africa, bringing the total to 577 sites; 36 additional sites began the installation of RxSolution in quarter four |
| Pharmadex | Ethiopia, Bangladesh, Mozambique, and Namibia | Implemented in Mozambique and Ethiopia during PY5Q4 |
| QuantTB | Bangladesh, Zimbabwe, Zambia, Nigeria, DRC, Mozambique, Philippines, South Sudan, Myanmar, Ethiopia, Uzbekistan, Sierra Leone, Guatemala, Honduras, Venezuela, Colombia, Brazil, Uruguay, Mexico, Dominican Republic, and Nicaragua | Version 4, which now includes a supply planning module, was completed and launched QuantTB was rolled out by 9 Latin American countries and is being used as of PY5Q4 |
| e-TB Manager | Operating at more than 1,550 sites in 10 countries Globally, managing over 550,000 TB and MDR-TB cases | Managed 154,218 additional TB cases, DR-TB cases, and presumptive TB individuals Development of e-TB Manager version 3.0, with enhanced functionalities and is compatible with portable devices |

| SIAPS-supported tool | Where it's used | Achievements in PY5 |
|--|---|--|
| Quantimed | Bangladesh, Cameroon, South Sudan, Ethiopia, Swaziland, Mali, Afghanistan, Angola, and Sierra Leone | <p>Deployed in Angola and Sierra Leone for quantification of HIV/AIDS and malaria commodities</p> <p>Used to quantify RMNCH commodities and essential medicines</p> |
| Electronic Dispensing Tool (EDT) | Ethiopia, Guyana, Haiti, Kenya, Namibia, Rwanda, Tanzania, and Zambia | <p>More than 700 sites in 12 countries, supporting approximately 800,000 ART patients each year</p> <p>10 sites in Namibia piloted EDT short message service (SMS) patient adherence reminder in the third quarter</p> |
| Pharmacovigilance Monitoring System (PViMS) | <p>Georgia</p> <p>Philippines - In process of adoption</p> | <p>Performed system testing in the Philippines during PY5Q4</p> <p>Developing implementation guidelines for use of PViMS</p> |

These and other tools, including SIAPS-supported PMIS dashboards, have been successfully used to organize data across vertical health programs, from health facilities to national-level databases, and between the private and public sectors.

Through the use of these tools, the number of SIAPS-supported facilities appropriately reporting patient and logistics data has increased from 735 health facilities in PY1, to 2,603 by the end of PY4, to 2,776 facilities by the end of PY5 (96% of the goal set for the end of the program), (see Figure 1).

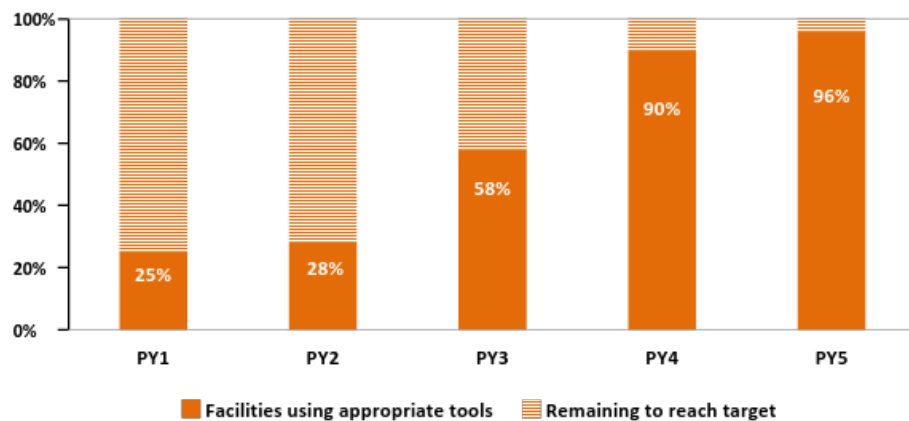


Figure 1. Percentage of SIAPS-supported facilities appropriately reporting patient and logistics data

Increasing the Availability and Use of Innovative and Proven Tools

SIAPS has used a comprehensive PMIS approach covering the pharmaceutical system, from monitoring adherence, pharmacovigilance, and other patient-related data to supporting centralized and integrated national information systems that

guide informed decisions on procurement, warehousing, and distribution. SIAPS has worked to ensure that data are not just available, but are presented in easy-to-access and understandable ways, including online portals, dashboards, and other platforms that increase ease of use.

Dashboards Enhance Access to and Use of Key PMIS Data

During PY5, SIAPS supported the Ministry of Health and Social Services (MOHSS) in **Namibia** to launch the MOHSS Pharmaceutical Information Dashboard, a web-based tool that improves supply chain decision making by enabling the MOHSS to actively monitor the availability of essential medicines, vaccines, and clinical supplies at the central, regional, and health facility levels.

For the efficient flow of stock status information to the Pharmaceutical Information Dashboard, SIAPS supported the MOHSS in developing a facility electronic stock card (FESC) to replace the paper-based stock cards used at district and referral hospitals. FESCs provide real-time stock status, reducing the time pharmacy staff devote to record keeping and allowing them to devote more time to patient care.

After the launch of the dashboard and FESCs during PY5, the percentage of facilities using consumption data to inform ordering has increased from 20% in PY4 to 57%, surpassing the life- of-project target for the country (50%).

Scaling up Tools That Work

In July 2016, with the collaboration of the Pan-American Health Organization (PAHO) and the Global Drug Facility (GDF), QuanTB was introduced to 12 **Latin American countries** during a one-week workshop in Guatemala. Of the 12 attending countries, 9 have adopted the tool and are rolling it out with the help of PAHO, GDF, and SIAPS since PY5Q4.

As a result of this regional implementation of QuanTB, SIAPS has been invited to provide technical support on TB pharmaceuticals management by applying QuanTB through an online community of practice initiated by PAHO and the **Strategic Fund**.

Improving the Availability and Use of Strategic Information on Pharmaceutical Systems Strengthening

SIAPS aims to meet the needs of a country and empower decision makers at all levels to take action based on accurate and reliable data. To make that happen, the right data needs to be available to the right stakeholders at the right time. SIAPS has worked to ensure that PMIS data are available when and where they are needed most, whether it is an electronic system replacing paper-based reporting and recording forms, a user-friendly tool for forecasting medicine supplies, an early warning tool, or a logistics management information system (LMIS).

In the fifth year of project implementation, there has been a substantial increase in the availability of accurate logistics data. The percentage of health facilities that completed and submitted LMIS reports has mushroomed, from 5% at the

After the launch of the Pharmaceutical Information Dashboard and facility electronic stock cards in Namibia this year, the percentage of facilities using consumption data to inform ordering has increased from 20% in PY4 to 57% in PY5.

The percentage of health facilities that completed and submitted LMIS reports has mushroomed, from 5% at the beginning of SIAPS to 95% at the end of PY5.

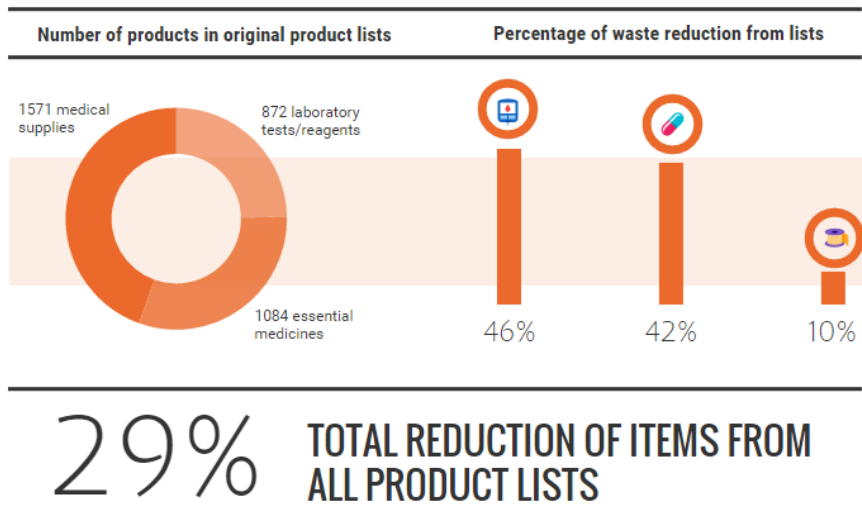
beginning of SIAPS to 95% at the end of PY5. In **Cameroon**, for example, the percentage of surveyed health facilities that completed and submitted an LMIS report for the most recent reporting period increased from 59% at the end of PY4 to 72% in at the end of this year. Additionally, in **Mali**, 93% of health facilities used consumption data to inform ordering of supplies during the fourth quarter, in contrast to the 79% that accomplished this by the end of PY4.

Strategic Information Helps Drive Better Decisions and Avert Risks

In collaboration with the Pharmacie Populaire du Mali (PPM), SIAPS/Mali worked to improve supply chain visibility by focusing on eliminating information waste, designing unique product codes for all the commodities carried by the central medical stores, and creating a product catalog to be used by the PPM’s customers for ordering.

An analysis of the PPM’s product lists found that products were being repeatedly registered, sometimes with the same exact names, sometimes with variations. This caused several issues in terms of data collection, aggregation, and analysis for quantification, procurement, inventory management, and order fulfillment. Through waste reduction activities that included careful examination of product lists to identify repetition of products, correction of input errors, and rationalization of products on the basis of demand history and expert opinion, SIAPS and the PPM were able to remove 1,019 products from the PPM’s three product lists. For example:

- Laboratory supplies/reagents were reduced by 46% to 468 products
- Essential medicines were reduced by 42% to 632 products
- The medical supplies list was reduced by 10% to 1,408 products



The strategic importance of this intervention (reduction of waste, design of product codes and product catalog) will allow the PPM to improve visibility and traceability of products, streamline supply chain operational efficiency (including simplification of order preparation and fulfillment for PPM’s customers), rationalize procurement and quantification processes, and improve vendor/customer relationship management, among other benefits.

Fostering the Development of Stronger Pharmaceutical Systems

In addition to providing critical data on products and patients to inform more effective pharmaceutical systems, SIAPS, in collaboration with its key partners, aims to strengthen pharmaceutical systems by applying the Continuous Results Monitoring System (CRMS) approach. The CRMS is a dynamic and comprehensive indicator-based supportive supervision and performance improvement approach developed by SIAPS that tracks key pharmaceutical management indicators for strengthening pharmaceutical management, improving health outcomes, and promoting ownership through a stakeholder review process. In PY5, CRMS was implemented country-wide in **Sierra Leone** to aid in the process of rebuilding the country's health system post-Ebola and to make it more resilient to future epidemics.

TECHNICAL HIGHLIGHT

CONTINUOUS RESULTS MONITORING AND SUPPORT SYSTEM TRACKS POST-EBOLA RECOVERY IN SIERRA LEONE



AN EPIDEMIC FURTHER WEAKENS SUPPLY CHAIN MANAGEMENT

The catastrophic Ebola epidemic that began in 2014 aggravated Sierra Leone's already weak pharmaceutical supply system. The country's pharmaceutical storage, handling, distribution, and waste disposal programs were in dire need of improvement. A "push system" of standardized medicine deliveries without reliable use data compromised inventory control and accurate forecasting, leading to frequent stock-outs or overstocks. Cost recovery also functioned poorly, potentially impacting future health care resources.

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health (MSH), received two years of funding in September 2015 from the US Agency for International Development (USAID) to provide technical assistance for rebuilding and strengthening the post-Ebola pharmaceutical supply chain management system in Sierra Leone. A country's ability to respond to and contain infectious disease outbreaks depends greatly on its competency in mobilizing appropriate staff and providing and resupplying its health system with select, essential infection prevention and control commodities during public health emergencies.

The project covers health management teams, medical stores, hospitals, and peripheral health units in all 13 districts and involves the country's Directorate of Drugs and Medical Supplies (DDMS), which is responsible for coordinating and providing pharmaceutical services (including promoting rational medicine use) in Sierra Leone; the National Pharmaceutical Procurement

Unit, which is being restructured; and the Pharmacy Board of Sierra Leone.



Figure 1. The 13 districts of Sierra Leone

TRACKING PERFORMANCE IMPROVEMENT

SIAPS uses a systems strengthening approach that supports and integrates all core functions of a country's health systems for greater impact and for global health security and emergency preparedness, including governance; human resources; information; financing; service delivery; and medical products (supplies, vaccines, and technology). SIAPS established a field office in Sierra Leone in April 2016 and recruited technical and support staff to help strengthen the country's pharmaceutical system, with a focus on supply chain management.

To that end, SIAPS helped the country institute a continuous results monitoring and support system (CRMS) to assess baseline challenges in pharmaceutical management and regularly track and support improvement in key areas. The CRMS uses a series of indicators to track and monitor factors that influence medicine availability and disease case management. Developed in Ethiopia in 2009 to bolster malaria treatment, the CRMS has proven valuable in tracking performance trends so that partners and stakeholders can come together to address service gaps. Its use has helped countries identify product delivery challenges, strengthen supply systems, improve operations, ensure the availability of resources, and improve data quality. It also allows health leaders to regularly measure progress in these areas.

For example, in the USAID-funded SIAPS/President’s Malaria Initiative project in Ethiopia, a CRMS helped the country shift overstocked products to health facilities that were stocked out of them, thereby preventing the products’ expiration and sending lifesaving medicines where they were needed. Analyzing the quantity of key medicines dispensed versus the number of patients treated has led to more accurate needs forecasting and cost-effective procurement. Further, tracking expired products has helped facilities locate unusable products, helping them declutter and organize storage spaces for active medicines.

Sample performance indicators:

- Availability of medicines
- Availability of forms/tools
- Use of inventory control/management information system tools
- Testing, positivity, and treatment correlation
- Availability and practice of proper storage:
 - Adequate storage available
 - Drug boxes stacked on pallets
 - Boxes stacked away from wall
 - Loose drug containers shelved
 - Store organized
 - Expired drugs segregated for disposal
 - Expired drugs disposed
- Availability of staff
- Staff training and supervision/mentoring status
- Adverse drug reaction reporting

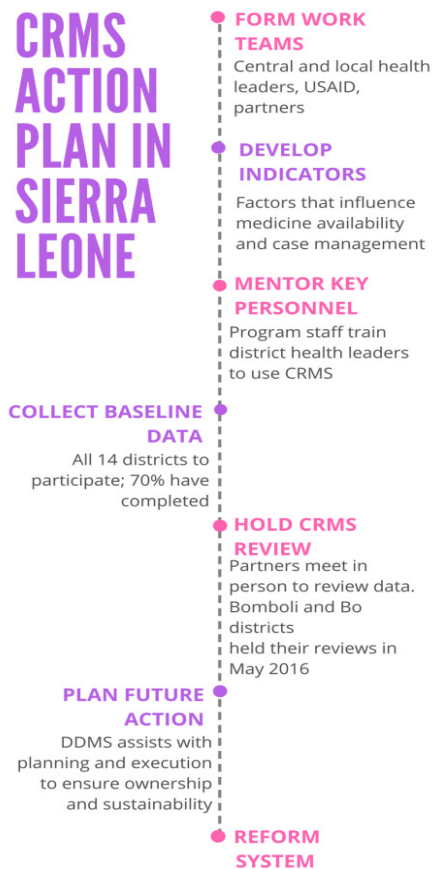


Figure 2. Implementing CRMS emphasizes engaging with central and local health leaders, one-on-one training, and in-person meetings to plan future activities

CRMS data are updated every two months, and the implementing facility or district shares a summary analysis of key indicators with stakeholders and partners. These groups then meet for a CRMS review to discuss the report, analyze gaps, and develop solutions for progress.

IMPLEMENTATION AND EXPECTED RESULTS

SIAPS has developed and introduced checklists for conducting bi-monthly CRMS checks on health facility performance and results. The program has been implemented in 11 out of the 13 districts in Sierra Leone, which include approximately 1,000 health facilities. In the first round of CRMS data reporting, SIAPS staff trained 268 district- and central-level staff in its principles and practices. Bombali and Bo districts conducted CRMS exercises and collected baseline data from 201 health facilities in May 2016. SIAPS, DDMS, and district health management teams will present results during CRMS review forums, and findings will be used to plan performance improvement in targeted health facilities. Bombali and Bo officials

held a review meeting in September to discuss several areas of improvement identified by the CRMS, including challenges with oversupply, stock-outs, and expiration; reliable treatment registers; and adequate storage conditions.

The tracking system aims to help ensure the pharmaceutical supply system's accountability and efficiency, leading to timely and accurate reporting. Medicine distribution will be based on consumption and need to help facilities order the correct medicines in the right quantities and ensure uninterrupted supplies. Training data will help ensure that district medical store and health facility staff involved in managing medicines and medical supplies will have the basic knowledge and skills to better manage and report on stock status and consumption issues.

Implementing a CRMS will help ensure continuous performance monitoring and promote increased transparency and rational medicine use. Meetings and status reviews also offer a first-of-its-kind platform to bring partners together and learn about national guidelines; harmonize their activities; and address challenges in procurement, warehousing, distribution, and waste disposal. It also provides a reliable mechanism for peer monitoring and knowledge sharing.

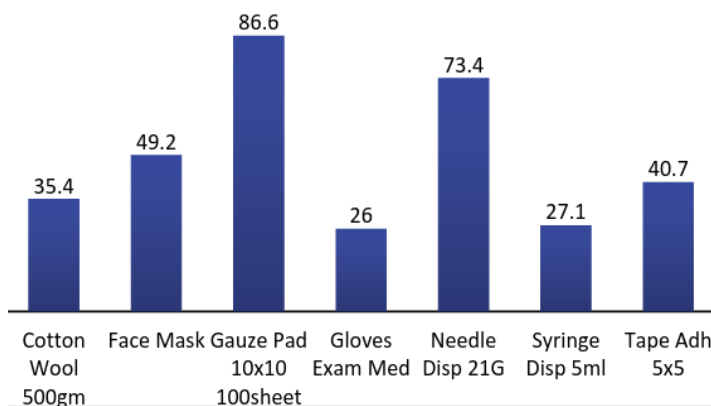


Figure 3. Percentage of PHUs with stock-out of medical supplies; data from first bi-monthly CRMS report for Bombali District, April 2016

CHALLENGES

Sierra Leone's current information system faces a number of hurdles, including poor data quality, a lack of user-friendly tools, weak reporting mechanisms, and a lack of accountability. Documentation is often weak, with delayed revisions of some manuals and guidelines and limited accessibility. There is also a severe shortage of skilled pharmaceutical staff at all levels, and volunteers run and

work in many public health facilities. Poor storage and inventory management are persistent and pervasive.

SUCCESS FACTORS

The SIAPS program objectives are in line with the key results areas of the government's National Ebola Recovery Strategy and support a coordinated, systemic effort and national impact. The DDMS intends to assign four senior pharmacists to serve as regional pharmaceutical management system coordinators. Further, programs for specific health areas, such as human immunodeficiency virus, tuberculosis, and malaria, have dedicated pharmacists in each district, which strengthens local leadership. SIAPS and its partners have positive and collaborative working relationships with central-level pharmacy units as well as district pharmacists.

NEXT STEPS

SIAPS works to bolster local capacity in general, and for this project focuses especially closely on the district level. Local resources, such as vehicles and venues, are used as much as possible to help ensure sustainability. SIAPS' technical efforts include mentoring district health leaders one-on-one to ensure that they understand and know how to apply CRMS methodology. This approach has helped encourage adoption of the system. Working closely with the central and regional governments to coordinate SIAPS events with leaders' schedules has made the work flow much more efficient. The CRMS has also been a reality check on health facilities' status and service levels versus government records and expectations.

GOING FORWARD

MSH and its country partners aim to implement systemwide changes that include stronger leadership in health; more strategic planning; and clear targets, expectations, and deadlines, as well as regular performance monitoring and increased transparency to help Sierra Leone develop a robust pharmaceutical supply chain management system. A comprehensive approach will increase the health system's sustainability and resiliency and help to prevent future outbreaks of Ebola and other communicable diseases.

IR4 FINANCING MECHANISMS STRENGTHENED TO IMPROVE ACCESS TO MEDICINES



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Financial resources are essential for ensuring that a pharmaceutical system is responsive to the needs of its target population. Adequate financial resources must be available and appropriately allocated. Adopting context-relevant mechanisms for mobilizing and allocating financial resources and providing oversight to the pharmaceutical supply chain can contribute to cost savings in countries where funding for health services and commodities is inadequate, which allows for the sustainability of health programs. In addition, because medicines benefit programs are designed in the context of universal health coverage (UHC), they should be cost effective and structured to allow maximum benefit for subscribers to promote equitable access to medicines.

SIAPS Approach for Strengthening Financing to Improve Access to Medicines

The SIAPS approach to pharmaceutical financing includes identifying, analyzing, and increasing the sources of financing and revenue within the context of the country architecture, policies, laws and regulations, human resources, and information systems and supporting decision making regarding the allocation, mobilization, and cost containment of funds.

The SIAPS approach to pharmaceutical financing includes identifying, analyzing, and increasing the sources of financing and revenue within the context of the country architecture, policies, laws and regulations, human resources, and information systems and supporting decision making regarding the allocation, mobilization, and cost containment of funds. SIAPS encourages efficient use of existing financial resources, advocates for donor support, and reduces financial barriers that limit the availability of medicines through innovative strategies and mechanisms. Appropriate, evidence-based financing interventions, such as Auditable Pharmacy Transaction Services (APTS), are designed to improve both technical capacity and resource allocation in pharmaceutical services and supply chain systems.

ACHIEVEMENTS DURING PROGRAM YEAR FIVE

Mobilizing Additional Financial Resources

Building on strong relationships with partners, SIAPS has strengthened countries' medicine quantification plans and built greater capacity for tracking stock status and medicine usage. Analytics from such exercises informed SIAPS' recommendations as it aided countries in developing proposals for emergency procurements and concept notes to the Global Fund, the President's Malaria Initiative, the US President's Emergency Plan for AIDS Relief, and other funders. Once funds are committed and deliveries are received in country, SIAPS continues providing support to ensure that products reach health facilities by outlining distribution plans and their implementation. For example, in **Angola**, a SIAPS-led stock monitoring exercise informed the National Malaria Control Program's request to the Global Fund for additional quantities of artemisinin-based combination therapy (ACT) tablets and rapid diagnostic tests. After the order was received in country from the Global Fund, SIAPS participated in high-level meetings to plan the distribution of the commodities and provided a series of supportive supervision visits to hospitals and provincial health offices after distribution. In response to the country's HIV/AIDS and reproductive health commodity needs, SIAPS provided the results of a quantification exercise to the Instituto Nacional de Luta Contra a Sida to identify additional funding gaps and inform emergency procurements to the World Bank and the Global Fund, and the program assisted the National Reproductive Health Program to receive, distribute, and inventory commodities.

Despite security concerns and violence in Burundi, SIAPS updated the Global Fund and USAID/Burundi on the current stock status of malaria commodities. Close monitoring of stock status led to the National Malaria Program engaging SIAPS to update the supply plan and forecasting of malaria commodities for two years.

During the fifth program implementation year of SIAPS, requests and concept notes to the Global Fund required revisions to ensure a minimal stock-out rate. In partnership with **Cameroon's** National AIDS Control Committee (NACC), SIAPS made significant contributions to the development and revision of grant-making documents after the approval of a Global Fund HIV/TB concept note. After identifying targets for treatment coverage, the SIAPS quantification exercise highlighted the need to revise the budget for the procurement of commodities. SIAPS was engaged to assist the NACC in revising the budget and responding to questions from the Global Fund related to the quantification and management of requested products. Despite security concerns and violence in Burundi, SIAPS updated the Global Fund and USAID/**Burundi** on the current stock status of malaria commodities at Centrale d'Achat des Medicaments Essentiels

au Burundi (CAMEBU). Close monitoring of stock status led to the National Malaria Program (Programme National Integre de Lutte contre le Paludisme [PNILP]) engaging SIAPS to update the supply plan and forecasting of malaria commodities for two years. SIAPS has worked closely with CAMEBU to receive deliveries of ACTs as they arrive in country. In addition, SIAPS worked with the **Swaziland** Health Laboratory Services to forecast needed quantities of HIV rapid test kits (RTKs) and pediatric antiretrovirals (ARVs). A funding gap analysis was submitted to USAID/Swaziland to support the emergency request for a 10-month supply of HIV RTKs.

SIAPS uses financial management and electronic logistics management tools to supplement and inform its assistance to countries in quantification, preparing emergency requests, and contributing to Global Fund applications. In **Burundi**, PNILP staff were trained on how to use the TOMPRO financial management software to configure, generate, and print required Global Fund financial reports. SIAPS/**West Africa Regional Program** used OSPSIDA to generate quantification and procurement reports to identify potential stock-outs and expires that would influence medicine availability within Togo's National AIDS Control Program. SIAPS' analysis informed a request to the Global Fund for additional stock of efavirenz 600mg and nevirapine 10mg/ml.

Increased Efficiency in the Use of Existing Resources

SIAPS supported the responsible use of existing financial resources by contributing to interventions that emphasize the importance of transparent financial transactions at health facilities and monitor drug prices to improve financial decision making at all levels of the health system. SIAPS also conducted ABC/VEN analyses, examined budgetary constraints, and participated in critical discussions regarding pharmaceutical and health system reforms. In **Ethiopia**, hospitals in the Amhara, SNNP, and Oromia regions conducted ABC/VEN analyses with SIAPS guidance using three years of medicine-purchasing data. The results of the analyses informed interventions by the hospital drug and therapeutics committees, such as prescription audits and medicine use evaluations. In the **Dominican Republic**, SIAPS revised the Ministry of Health's (MOH) procurement plan after identifying a financial gap, which will inform how budgetary limitations will affect ARV procurement. In Ukraine, SIAPS advised working groups on health care financing and medicine procurement reforms. SIAPS also developed a web-based price-monitoring tool, performed user acceptability testing, and installed it on the MOH's server. The tool encourages informed decision making related to the pricing of pharmaceutical products during active procurement cycles.

In addition, SIAPS has developed a unique approach to tracking medicine expenditures and increasing revenue from the sale of medicines in **Ethiopia**. APTS, SIAPS' intervention for improved financial accountability of medicine expenditures and availability, is now operational in 67 facilities throughout Ethiopia. After receiving onsite training and mentoring, personnel at health facilities are using the system to track the sale of medicines and provide regular reports to regional authorities and the Federal Ministry of Health (FMOH). APTS produces daily and monthly reports on pharmaceutical transactions and services to be used in decision making. SIAPS has also used APTS as a platform to make recommendations on how to improve pharmacies' appearance and storage

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capacity. The success and widespread adoption of APTS can be attributed to its inclusion in the FMOH's Health Sector Transformation Plan and the enactment of regulations in 10 regions and at the federal level. In addition, a national assessment of APTS concluded that the intervention has contributed to significant improvements in health facility-level indicators, indicating that APTS has had an impact far beyond solely tracking medicine expenditures.

Reducing Financial Barriers for Patients in Accessing Medicines

As many countries work to rollout or expand UHC initiatives, SIAPS has advocated for the inclusion and evaluation of medicine benefit programs. This year, SIAPS conducted broad assessments of pharmaceutical benefit programs in **Ghana** and **Ethiopia** to inform the countries' implementation practices of national health insurance and contribute to the global dialogue on medicine benefit programs within national health insurance schemes. In Ghana, SIAPS supported the National Health Insurance Authority (NHIA) in initiating a retrospective medicine utilization review using data from the NHIA e-claims system for antimalarials. SIAPS sought input for its assessment from the MOH, USAID/Ghana, and the NHIA and conducted various site visits to insurance claims centers. One year of electronic claims data for malaria was provided by the NHIA from selected facilities and disaggregated by dosage form, prescriber type, and age. In partnership with LMI, SIAPS submitted a draft report of the Ghana National Health Insurance Authority Medicine Utilization Analysis to USAID and the NHIA for comment. The study will inform strategic purchasing of medicines under the country's national health insurance scheme. SIAPS served on the Ethiopian Health Insurance Agency's technical working group for advisement on health insurance schemes and led a nationwide assessment of the Government of Ethiopia's health insurance initiatives and the pharmaceutical supply chain, pharmacy benefit management practices, and systems in the public and private sectors. Data were collected related to rational medicine use, pharmaceutical financing, and benefit management through site visits, stakeholder interviews, and document review. A draft report entitled "Ethiopia National Health Insurance Scale-up Assessment on Medicines Financing, Use and Benefit Management: Findings, Implications and Recommendations" was submitted to key stakeholders for review.

TECHNICAL HIGHLIGHT

ECONOMIC COST OF NON-ADHERENCE TO TB MEDICINES RESULTING FROM STOCK-OUTS AND LOSS TO FOLLOW-UP IN THE PHILIPPINES



INTRODUCTION

One of the key elements of successful tuberculosis (TB) control programs is adherence to treatment, and this is a cornerstone of most international and national policies and guidelines. Non-adherence is often due to patient-related factors, but can also be a result of provider issues, such as stock-outs of TB medicines. Non-adherence results in increases in length and severity of illness, deaths, disease transmission, and drug resistance. These have economic consequences in terms of costs and loss of income for patients and their families and also costs to the health system.

Non-adherence is commonly due to treatment interruption, which may be for short intermittent periods of a few days or for longer periods of weeks or months, and may even end up as complete discontinuation of treatment. Interventions to prevent treatment interruption are aimed at both patients and providers. On the provider side, actions include ensuring proper prescribing practices and management of side effects, providing good quality medicines, and preventing stock-outs. On the patient side, these include interventions to encourage patients to continue treatment even when they feel better, use medicines as directed, and remove barriers such as transport costs. These actions are believed to be a good investment, but the economic savings have not been well and clearly defined. The Philippines is among 22 countries considered to have a high burden of TB, including multidrug-resistant (MDR) TB. The Philippines Department of Health (DOH) has an extensive TB program with directly observed treatment short (DOTS) courses for TB and programmatic management of drug resistant TB for MDR-TB. In addition, the DOH has

strategies and procedures in place to ensure and improve treatment adherence, including supervised treatment, patient compliance incentives, and supply chain management strengthening. This is not always easy, however, especially in a large, decentralized country where health care services are largely managed at local levels and stock-outs and loss to follow-up (LTFU) have been challenges.

In recent years, National Tuberculosis Control Program (NTP) data and several studies have indicated problems with stock-outs of some TB medicines and with LTFU. Both of these problems result in treatment interruption.

At the request of the NTP and USAID, a study was conducted to determine the health, mortality, and economic impact of stock-outs and LTFU to justify greater investment in addressing these challenges.



Child with MDR-TB undergoing treatment in the Philippines. (photo: WHO/HM Dias)

METHODOLOGY

Three case studies were selected on the assumption that these would probably have had the greatest impact: stock-outs of drug-sensitive TB (DS-TB)

category 1 medicines; LTFU of DS-TB patients; and LTFU of MDR-TB patients.

Data were obtained from three sources: a global literature review, a review of NTP documents and records, and interviews with an expert panel of doctors, pharmacists, and NTP staff. Algorithms were developed based on the information received (figure 1), and these were modeled in a spreadsheet-based tool developed by SIAPS to analyze the impact.

The models quantify the likely impact of the treatment interruption in terms of subsequent treatment or non-continuation of treatment and in terms of provider costs, household out-of-pocket costs, and productivity losses. The models show the additional health and cost outcomes of each specific type of treatment interruption, excluding the health and cost outcomes that would have been incurred if treatment had not been interrupted.

RESULTS

DS-TB medicine stock-outs

Based on the results of a sample patient survey conducted in early 2014, as many as 2,663 DS-TB patients may have been unable to obtain medicines from the public sector for a month or more. The likely impact of these stock-outs is that 266 of these patients would have developed MDR-TB because of poor-quality private sector treatment, poor adherence, or discontinuation of treatment (table 1). And these 266 patients are likely to have infected an additional 63 people with MDR-TB. In addition, 588 patients and persons infected by those patients are likely to have died.

The total additional economic cost resulting from the stock-outs is likely to have been as much as USD 21 million, comprised of USD 1.5 million for additional service delivery costs and USD 19.5 million for additional household costs (out-of-pocket costs and productivity losses) (table 2). This works out to a cost of approximately USD 8,000 per patient who interrupted treatment, meaning that an investment of up to that amount to prevent the stock-out for one patient would have resulted in a net saving to society.

DS-TB patients lost to follow-up

In 2014, 8,870 DS-TB patients were reported by the NTP as lost to follow-up. The likely impact of

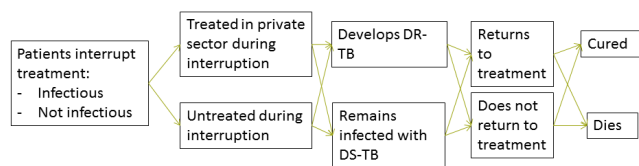


Figure 1. Conceptual framework for treatment interruption

this LTFU is that 887 of these patients would have developed MDR-TB through poor-quality private sector treatment, poor adherence, or discontinuation of treatment. And those 887 patients are likely to have infected an additional 245 people with MDR-TB. In addition, 1,958 patients and persons infected by those patients are likely to have died.

The total additional economic cost resulting from this LTFU is likely to have been as much as USD 72.2 million, comprised of USD 5.8 million for additional service delivery costs and USD 66.4 million for additional household costs. This works out to a cost of approximately USD 8,000 per patient who interrupted treatment, meaning that an investment of up to that amount to prevent LTFU for one patient would have resulted in a net saving to society.

MDR-TB patients lost to follow-up

A study of a 2012 cohort of MDR-TB patients found that 29% were lost to follow-up. We applied that percentage to the 2,680 MDR-TB patients treated in 2014, which gave an assumption that 777 MDR-TB patients would have been lost to follow-up. The likely impact for the 777 patients is that 330 would have developed XDR-TB through poor-quality private sector treatment, poor adherence, or through discontinuation of treatment. And those 330 patients are likely to have infected an additional 19 people with XDR-TB. In addition, the MDR-TB patients who were still infectious at the time of interruption are likely to have infected an additional 474 persons with MDR-TB. Plus, 233 people are likely to have died as a result of the LTFU.

The total additional economic cost resulting from this LTFU is likely to have been as much as USD 12.9 million, comprised of USD 4.5 million for additional service delivery costs and USD 8.4 million for additional household costs. This works out to approximately USD 17,000 per patient who interrupted treatment, meaning that an investment of up to that amount to prevent the LTFU for one patient would have resulted in a net saving to society.

Table 1. Impact of treatment interruption on morbidity and mortality

| Number of | DS-TB stock-outs of 1 month | DS-TB LTFU of 3 months | MDR-TB LTFU of 5 months |
|---|-----------------------------|------------------------|-------------------------|
| Patients whose treatment was interrupted | 2,663 | 8,870 | 777 |
| Patients who develop MDR-TB as a result of the interruption | 266 | 887 | 0 |
| Patients who develop XDR-TB as a result of the interruption | Not estimated | | 330 |
| Additional persons who develop DS-TB as a result of the interruption* | 0 | 0 | 0 |
| Additional persons who develop MDR-TB as a result of interruption | 63 | 245 | 474 |
| Additional persons who develop XDR-TB as a result of interruption | Not estimated | | 19 |
| Persons who die as a result of the interruption | 588 | 1,958 | 233 |

*In both of the DS-TB case studies, the opinion of the expert group was that none of the patients with DS-TB should be infectious at the time of the treatment interruption and, therefore, no additional people would be infected as a result of the interruption.

Table 2. Estimated economic impact of treatment interruption

| | DS-TB stock-outs of 1 month | DS-TB LTFU of 3 months | MDR-TB LTFU of 5 months |
|---|-----------------------------|------------------------|-------------------------|
| Number of patients whose treatment was interrupted | 2,663 | 8,870 | 777 |
| Total estimated additional cost | | | |
| Provider cost | \$ 1.5 million | \$ 5.8 million | \$ 4.5 million |
| Household cost | \$ 19.5 million | \$ 66.4 million | \$ 8.4 million |
| Total | \$ 21.0 million | \$ 72.2 million | \$ 12.9 million |
| Estimated additional cost per affected patient | | | |
| Provider cost | \$ 573 | \$ 655 | \$ 5,733 |
| Household cost | \$ 7,309 | \$ 7,485 | \$ 10,875 |
| Total | \$ 7,882 | \$ 8,141 | \$ 16,608 |

CONCLUSIONS

The results of the three case studies show that TB treatment interruption can have a significant impact on morbidity and mortality, causing many people to develop MDR-TB and XDR-TB, resulting in many new infections and deaths. The economic impact on the health services, families, and society in general is equally devastating, running into many millions of US dollars.

These results are only approximate estimates because some of the assumptions were based on estimates provided by an expert panel in the absence of data. However, it is likely that

the above figures are actually underestimated, partly because we did not take into account that some patients who had become non-infectious before interrupting treatment but did not return to treatment would have become infectious again at some stage. We also did not take into account that some of the persons who would have developed MDR-TB would have later developed XDR-TB.

The global literature review found that little research has been done on the impact of treatment interruption, and additional research would, therefore, be highly beneficial, both in the Philippines and globally to provide a more robust evidence base.



The results of the analysis indicate that prioritization should be given to improving supply chain management to prevent stock-outs; reduce DS-TB patient LTFU through better education and case management, especially in regions where it is high; and reduce MDR-TB LTFU through improved case management, including better management of medicines, because adverse side effects are a major reason for LTFU.

It is clear from these case studies that the cost of treatment interruption in the Philippines is significant and that investing additional resources to resolve the causes of these problems is likely to be extremely worthwhile.

Further Reading

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IR5a SUPPLY MANAGEMENT IMPROVED TO ACHIEVE DESIRED HEALTH OUTCOMES



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To address supply inefficiencies and frequent stock-outs of medicines and laboratory reagents, vertical supply chains for different public health programs that are set up to facilitate the delivery of particular treatments, and human resource capacity issues in developing countries, SIAPS collaborates with Ministries of Health (MOHs) and in-country stakeholders to strengthen the responsiveness of national pharmaceutical supply chains to the demands of target populations seeking care from the public health system. Better health outcomes can only be achieved when prescribed medicines are available at health service delivery points.

SIAPS-supported interventions for addressing the above issues include human resource capacity building; streamlining logistics systems; timely redistribution and ordering plans; improving warehouse processes; and standardizing logistics management tools, such as standard operating procedures (SOPs), manuals, and guides. To strengthen the capacity of supply chain managers at multiple levels, SIAPS conducted formal training on best practices, structured routine mentoring, and supportive supervision programs and developed tools to assist in decision making. Working closely with government stakeholders, SIAPS supported the identification of funding gaps through quantification and stock status updates, which informed procurement and distribution plans and mitigated stock-outs and expiries. During the past year, SIAPS also provided critical technical assistance

In the Dominican Republic, the availability of ARVs and essential medicines in health facilities remains high at 93% and 92%, respectively.

to improve processes and systems pertaining to product selection, quantification, procurement, warehousing, distribution, and inventory management.

ACHIEVEMENTS DURING PROGRAM YEAR 5

Improved organizational structures for more effective quantification and supply of medicines and other health commodities

SIAPS has provided technical assistance to country MOHs and their partners to reinforce the governance structure of supply chain systems to ensure timely and continuous product availability for patients. SIAPS has supported a number of technical working groups (TWGs) to make informed decisions on future procurements through accurate quantifications of medicines needed in **Angola, Mali, Bangladesh, Ethiopia, Philippines, Guinea, Mali, Sierra Leone, and South Sudan**. During a national quantification workshop in **Sierra Leone**, SIAPS oversaw the establishment of the country's National Quantification Committee and seven program-specific TWGs. In collaboration with Angola's National Directorate of Medicines and Medical Equipment, SIAPS was a leader and cofacilitator of bimonthly meetings of the Logistics, Operations, and Procurement subcommittee, which encourages participants to identify and solve challenges that influence the availability of medicines. SIAPS has also developed terms of reference for the diffusion of TWGs from the national to regional level. For example, plans are in place to establish regional malaria commodity TWGs in Ethiopia.

SIAPS has provided training to TWG members on how to quantify medicine needs using epidemiological data, past rates of consumption, and forecasting tools. In Guinea, the Procurement and Supply Management TWG conducted multiyear forecasts of antimalarial commodities with assistance from SIAPS. The TWG has predicted the need for antimalarials in the country based on consumption and morbidity through 2022, which has allowed greater awareness for funding. Despite ongoing political unrest in **South Sudan**, SIAPS coordinated meetings of the Pharmaceutical TWG to discuss the procurement of malaria commodities.

When all stakeholders are involved, accurate and evidence-based quantification exercises result in better coordination of medicine procurement and supply management, improved access to medicine, and cost savings. SIAPS has used existing forums, such as disease-specific TWGs, to develop consensus on quantities of medicines to be procured. To support **Angola's** National Quantification TWG, SIAPS conducted forecasting and supply planning exercises for January 2016–December 2018 to inform emergency requests to the Global Fund and World Bank to mitigate future stock-outs. In addition, SIAPS provided training this year to build the capacity of supply chain managers in quantification. At the national level, SIAPS held a three-phase, two-week quantitation workshop in **Sierra Leone** that trained 53 supply chain personnel on general quantification principles, processes, methodologies, and tools. In some instances, training at lower levels of the supply chain resulted in greater ownership of quantification activities. For example, in **Ethiopia**, more than 97% of Drug and Therapeutic Committees participated in quantification activities overseen by SIAPS to estimate the needs of their health facilities.

SIAPS has engaged with government stakeholders and partners to develop multiyear supply plans and national supply chain strategies. This year, SIAPS assisted **Swaziland's** Health Laboratory Services to conduct quarterly supply plan reviews for laboratory reagents and supplies. A major milestone was achieved when SIAPS supported **Angola's** MOH to develop the country's first comprehensive national supply chain strategy for health commodities. A multistakeholder workshop was held to develop a strategic plan, outline priorities, and recommend interventions for strengthening the supply chain system. In **Mali**, SIAPS provided input to the malaria supply plan during a quarterly meeting of the Comite National de Coordination. In **Burundi**, SIAPS assisted CAMEBU in reviewing stock status and figures associated with supply planning to address identified funding gaps.

Key SIAPS-developed interventions have proven highly influential in ensuring the availability of medicines, such as systems implemented in the **Dominican Republic** and **Ethiopia**. The SUGEMI pharmaceutical management system in the Dominican Republic continues to encourage health facilities to report their stock status and receive feedback, thereby ensuring that medicine availability remains high. During the final quarter of the year, health facilities reported that adult antiretroviral (ARV) availability was 93%, while essential medicines availability was 92%. Auditable Pharmacy Transaction Services (APTS), the SIAPS-supported intervention for improved financial accountability of medicine expenditures and availability, is now operational in 67 facilities throughout Ethiopia. APTS has been successful in tracking commodity stock status and reducing the percentage of health facilities experiencing stock-outs of antimalarials.

More efficient supply systems with capabilities to better track medicine consumption and manage inventory

Logistics management tools, such as SOPs, manuals, and guides, were developed in **Angola, Bangladesh, Benin, Cameroon, Ethiopia, Mali, Philippines, Sierra Leone, South Sudan, Swaziland, Tajikistan, and Uzbekistan**. Collaborations between the **Swaziland** Procurement Regulatory Agency, the MOH's Procurement Unit, and SIAPS have resulted in a draft procurement procedure manual and procurement systems strengthening plan. In **Bangladesh**, SIAPS incorporated feedback from the Central Medical Stores Depot (CMSD) and the newly created TWG to finalize CMSD's first warehouse SOP manual. With new standards implemented, 86% of health facilities are now using standardized checklists to monitor medicine storage. New stock management SOPs were developed in **Mali** and were complemented by SIAPS-facilitated training on the country's new logistics management information system (LMIS).

SIAPS responds to requests by MOHs, central medical stores, and donors to assist with the distribution of commodities to health facilities and stock redistribution to reduce product expiry. In **Mali**, SIAPS worked with the National Malaria Control Program and PPM to finalize distribution plans for multiple cycles of malaria commodities to health facilities. In **Angola**, SIAPS worked with government stakeholders and other implementing partners to redistribute medicines and other health products from overstocked health facilities to facilities that were at risk of stock-outs of selected medicines. In collaboration with **Burundi's** National Malaria Control Program and Central Medical Stores, SIAPS coordinated

SIAPS-supported interventions for addressing the above issues include human resource capacity building; streamlining logistics systems; timely redistribution and ordering plans; improving warehouse processes; and standardizing logistics management tools, such as standard operating procedures (SOPs), manuals, and guides.

SIAPS supports quantification activities at the central, regional, and facility level, which results in improved coordination of supply management, increased access to medicines, and cost savings.

In Cameroon, SIAPS worked with civil society organizations to ensure timely data entry into the OSPSIDA dashboard, a web-based HIV/AIDS data collection tool. As a result, data for decision making has become more accessible and is informing procurement decisions.

several deliveries and distributions of President's Malaria Initiative-donated pharmaceutical products, including rapid diagnostic tests and artemisinin-based combination therapy treatments for adults and children. SIAPS has also worked with country MOHs to evaluate and implement alternative systems for medicine distribution, particularly when relevant to the country context. Working collaboratively with the National Malaria Commodities TWG, the Pharmaceuticals Fund and Supply Agency (PFSA), and the Federal Ministry of Health of **Ethiopia**, SIAPS contributed to the planning for substantial changes to the supply chain structure for malaria commodities, including transitioning the responsibility for the distribution of malaria commodities from regional health bureaus to the PFSA.

SIAPS has provided onsite interventions related to inventory management and guided facility-level performance improvement, emphasizing increased efficiency and accountability for stock status and availability. SIAPS-led training on inventory management and supportive supervision visits in **Swaziland** contributed to reducing commodity stock-outs to low levels at warehouses and health facilities this year. In **Benin**, SIAPS collaborated with the Pharmacy and Medicines Department of the MOH and the USAID-funded Advancing Newborn, Child and Reproductive Health Program to perform a physical inventory of Ebola-related products in warehouses and health facilities in 10 health zones across four health districts. In **Sierra Leone**, SIAPS introduced the Continuous Results Monitoring System (CRMS) in two districts. CRMS is a comprehensive, indicator-based, supportive supervision and performance improvement approach that tracks key pharmaceutical management indicators and encourages performance improvement through stakeholder feedback.

Integrated supply services allowing programs to leverage resources and share capacity-building costs

Through a structured and consultative assessment process, SIAPS examined supply chains and their warehouse storage systems to inform its recommendations on improving medicine availability at the health facility level. SIAPS provided technical assistance to carry out supply chain assessments in **Bangladesh, Benin, Mali, Ukraine, and countries in the West Africa Regional Program**. In **Mali**, SIAPS conducted a situational analysis of PPM, the country's Central Medical Store. The analysis performed informed the development of a five-year strategic plan and a product catalog. In addition, SIAPS provided recommendations to PPM regarding the need to make structural and operational changes to the design of its warehouse to ensure optimal storage conditions. SIAPS also provided recommendations on warehouse and waste management in **Bangladesh**. After providing guidance to health facilities under Bangladesh's Directorate General of Family Planning and Directorate General of Health Services (DGHS), approximately 94,040 cubic feet of space was freed in health facilities, highlighting how immediate action was taken after pharmaceutical waste disposal and good warehousing practices were emphasized by SIAPS.

Throughout the past year, SIAPS has developed and implemented electronic pharmaceutical and logistics management tools to encourage accurate reporting and track medicines in the supply chain. These tools have also been influential in improving the use of supply chain information for decision making by serving as key data sources from which MOHs and other agencies can make supported

decisions. In **Bangladesh**, the DGHS received SIAPS support to develop and implement an electronic LMIS (eLMIS). In an effort to decrease reliance on paper-based LMIS tools, SIAPS trained 955 staff members in four districts in Bangladesh on eLMIS. SIAPS/**Mali** routinely submitted procurement planning and monitoring reports for antimalarials and contraceptives using stock status data from OSPSANTE from the central and facility levels. In **South Sudan**, SIAPS piloted a pharmaceutical dashboard in three counties of the Central Equatoria State in close collaboration with the Logistics Management Unit to generate stock status reports for tracer medicines.

SIAPS tools, which contain valuable information on medicine availability and use, have been used to support civil society, avert stock-outs, and inform donor procurements. In **Cameroon**, SIAPS worked with civil society organizations to ensure timely data entry into the OSPSIDA dashboard, a web-based HIV/AIDS data collection tool. As a result, data for decision making has become more accessible and is informing procurement decisions. For example, using OSPSIDA, SIAPS assisted the MOH to avert stock-outs of HIV/AIDS commodities at more than half of their health facilities by recognizing that an emergency ARV procurement was needed. Moreover, SIAPS tools, such as QuanTB and e-TB Manager, have informed the quantification of first- and second-line TB medicines to be requested and management of medicines received by the Global Fund in **Bangladesh** and the **Philippines**.

TECHNICAL HIGHLIGHT

ENSURING THE QUALITY OF TUBERCULOSIS MEDICINES BY IMPROVING STORAGE CONDITIONS



CONTEXT

According to the World Health Organization (WHO), poor-quality medicines and inadequate storage conditions¹ are among the contributing factors that result in poor tuberculosis (TB) treatment outcomes and multidrug-resistant tuberculosis. The recommended temperature to retain the quality of TB medicines is below 25°C², but at the peripheral level in Bangladesh, most TB medicines are stored at the Directly Observed Treatment Short-Course (DOTS) centers of the upazila (subdistrict) health complexes (UHCs) or in the implementing nongovernmental partners' facilities, where the storage facilities consist of wood or steel lockable cabinets. These cabinets cannot ensure the ideal storage temperature and therefore put expensive and sensitive TB medicines at risk of degradation. In 2012, the US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health, conducted a rapid assessment of TB pharmaceutical management in Bangladesh. One recommendation in the assessment report was that options should be considered for lowering the storage temperature at facilities at the upazila level. Both the fifth and sixth Joint Monitoring Missions of the National Tuberculosis Control Program (NTP), conducted in 2010 and 2014, respectively, put forth

recommendations to improve storage standards at the upazila level; however, due to a lack of funding, the NTP could not implement these recommendations.

APPROACH

In 2014, SIAPS conducted a cost-benefit analysis and found that at the upazila level, renovating store rooms or air conditioning at all drug stores might impose a significant cost burden. However, installing a medicine refrigerator in each DOTS center would be a cost-effective solution to having a temperature-controlled, secured storage area that would require minimum space. To improve storage conditions and maintain the temperature within acceptable limits for TB medicine, SIAPS and NTP began commissioning medicine refrigerators for DOTS centers at UHCs on a limited basis in 2015. First, SIAPS discussed the plan with NTP, conducted a short survey to assess feasibility, and identified UHCs in which to implement the intervention. One refrigerator was given to an upazila that averaged between 70 and 100 TB patients per quarter, and two refrigerators were given to upazilas with more 100 patients per quarter. In total, 102 medicine refrigerators for 94 DOTS centers in 14 districts were commissioned by August 2015. A temperature-monitoring chart was provided to each site to ensure that the recommended temperature is maintained. NTP also instructed the facilities to use the refrigerators for TB medicines only.

¹ Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis

² Technical Specifications / Product List by Global Drug Facility



Before: Medicine stored in a steel cabinet



After: Medicine stored in refrigerators

Installing a medicine refrigerator in each DOTS center would be a cost-effective solution to having a temperature-controlled, secured storage area that would require minimum space.

RESULTS AND IMPLICATIONS

After the refrigerators were commissioned, SIAPS and NTP conducted joint monitoring visits to assess the functionality of the equipment and identify the immediate results of the intervention.

- UHC DOTS centers are now able to store TB medicines within the recommended temperature range, even during the summer (March to September), when the room temperature ranges from 25°C to more than 40°C. Therefore, the risk of gradual degradation of medicine efficacy is minimized.
- Storekeeper can organize different medicines according to expiry dates and easily apply first expiry first out principles during distribution.
- The TB medicines are secured.

At the intervention sites, DOTS providers are now taking a two-week supply at a time, rather than requesting a month's supply, as was their previous practice, because they feel that medicines are maintained in good condition in the refrigerators.

CONCLUSION

Poor storage facilities will invariably lead to medicine damage and loss of medicine quality. The introduction of these medicine refrigerators has improved the storage condition for TB drugs, and the intervention has received interest from development partners, particularly the Global Fund, as an innovative and effective storage solution at the peripheral level. Therefore, the viability of a country-wide roll out of this intervention through NTP should be explored.

IR5b PHARMACEUTICAL SERVICES IMPROVED TO ACHIEVE DESIRED HEALTH OUTCOMES



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Making medicines available to populations with little or no access to them is critically important, but availability alone is not sufficient to ensure improved health outcomes. The World Health Organization (WHO) estimates that 50% of medicines are used inappropriately, which can ultimately result in medicine waste or shortages, fiscal inefficiencies, poor health outcomes, and the development of antimicrobial resistance (AMR).¹

Ensuring that the medicines being prescribed are safe and effective, treatment regimens are standardized and current, and medicine use is optimized helps to create an environment in which patients can attain the best possible health

SIAPS Approach for Improving Pharmaceutical Services

SIAPS uses a pharmaceutical system strengthening approach that is rooted in the WHO health systems framework and the key principles of the Global Health Initiative to help build local capacity in low- and middle-income countries to improve pharmaceutical services. The approach focuses on improving patient safety, optimizing medicine use, and containing AMR.

outcomes. By focusing not only on strengthening supply chains but also on the pharmaceutical systems through which medicines are provided, SIAPS helps to ensure that availability is accompanied by equitable, ethical, and responsible access and use.

ACHIEVEMENTS DURING PROGRAM YEAR FIVE

Patient Safety and Therapeutic Effectiveness Assured

SIAPS works to ensure the safety and continued effectiveness of medicines by supporting countries in adopting or strengthening both active and passive medicine surveillance mechanisms and supporting pharmacovigilance (PV) tools that facilitate better reporting and more effective use of data for decision making.

This year, SIAPS actively worked to support the implementation of the Pharmacovigilance Monitoring System (PViMS) in the **Philippines** to strengthen the capacity of the National TB Program (NTP) for monitoring medicine safety and effectiveness. PViMS is a web-based application that streamlines and simplifies data collection and analysis for active surveillance. SIAPS facilitated several workshops with the NTP, Food and Drug Administration (FDA), and other TB stakeholders to plan for the implementation of the PV tool at additional facilities. SIAPS also supported the FDA in standardizing the data to be collected for active PV surveillance of TB patients.

In **Swaziland**, SIAPS supported the Pharmacovigilance Unit in managing the country's seven active surveillance sentinel sites and continued to issue the Medicines Safety Watch newsletter to disseminate important PV-related updates to stakeholders. To support improved treatment of patients with extensively drug-resistant TB, SIAPS supported the National TB Control Program in rolling out and integrating bedaquiline into treatment programs. The SIAPS-developed PViMS was adapted to include the bedaquiline implementation guidelines, an adaptation that is expected to be useful to other countries introducing bedaquiline. In support of the "Test and Start" initiative in Swaziland, SIAPS is continuing to integrate the pharmacovigilance system into the national AIDS program as a routine part of monitoring treatment quality and patient safety. Currently, 4,176 patients are enrolled in the active surveillance program (52% female, 48% male), and 1,212 adverse drug reactions have been reported by clinicians (68% related to anti-TB medicines and 32% related to antiretrovirals (ARVs) since the program began. The sentinel surveillance system is currently being implemented at seven hospitals and health facilities.

In **Bangladesh**, in collaboration with the Adverse Drug Reaction Monitoring (ADRM) cell of the Directorate General of Drug Administration, SIAPS has supported 30 public and private hospitals and pharmaceutical manufacturers in the past two years. This year, SIAPS organized a one-day workshop for 60 representatives to review PV activities at these sites, refresh previous trainings, and share best practices that are being adopted. While the reporting rate for adverse drug events (ADEs) has increased more than four-fold in the past two years, SIAPS and the ADRM cell have continued to work toward greater understanding and awareness of the importance of PV systems through visits to local institutions, including the National Institute of Ophthalmology, National

In South Africa, SIAPS fully transitioned responsibility for an online course on RMU to the University of the Western Cape. This year, the university is offering the course as an elective or module for the Master of Public Health degree.

Institute of Cardio Vascular Diseases, and National Institute of Orthopedic and Traumatology Rehabilitation.

Similarly, in **Ethiopia**, SIAPS conducted face-to-face discussions at health facilities regarding ADE reporting to increase commitment and create awareness of PV among health providers. As a result, SIAPS saw the cumulative number of health facilities reporting ADEs increase by 16.4% (from 152 to 177), and the number of reports has increased by 8.1% (from 844 to 912) during the first quarter of this reporting year. SIAPS also helped disseminate ADE reporting forms, allergy cards, and newsletters to encourage further reporting. The reporting of ADEs has resulted in several regulatory actions, including recall, production stops, or quality investigations for select ringer lactate, chloroquine, paracetamol syrup, iodine tincture, and hydrogen peroxide products.

In **DRC**, SIAPS supported the NTP in implementing its active surveillance PV program for patients on second-line TB treatment across 14 health facilities in Kinshasa and five other USAID-supported provinces. SIAPS/**South Africa** supported the National Pharmacovigilance Centre in the capture and review of 92 ADE reports from the Tuberculosis Electronic Drug Resistance register. SIAPS also worked to improve the management and data quality for the national sentinel surveillance system for birth defects in high volume maternity units.

Medication Use Improved

SIAPS is building local capacity for rational medicine use (RMU) through the development and revision of pre-service curricula, targeted trainings on treatment standards and good prescribing practices, and the promotion of pharmaceutical care approaches that are patient centered rather than product centered.

During this project year, SIAPS finalized “*Systems-based Approaches to Improving Medication Adherence*,” which describes strategies and tools that help to address adherence in a systems strengthening manner. The document is slated for dissemination next quarter.

In **South Africa**, SIAPS fully transitioned responsibility for an online course on RMU to the University of the Western Cape. This year, the university is offering the course as an elective or module for the Master of Public Health degree. In Dominican Republic, 31 students completed the certified course (diploma track) on RMU during its first offering and 32 were enrolled for the second iteration. The updated course modules have been made available on the SUGEMI/National Health Service website.

In an effort to monitor and promote RMU, SIAPS/**Swaziland** collaborated with Swaziland Christian University to host a workshop on medicines use research, with support from the Nelson Mandela Metropolitan University’s Medicine Utilization Research in Africa initiative. This workshop was aimed at developing the skills of pharmacy and therapeutic committee representatives, National Essential Medicines Committee members, public- and private-sector pharmacists, and pharmacy students on methods for conducting medicine research to contribute to the country’s health research agenda. Thirty health care workers participated in the training.

In **Ethiopia**, SIAPS worked to improve rational dispensing and use of reproductive, maternal, newborn, and child health (RMNCH) medicines and reinforce appropriate referral processes through a training-of-trainers workshop for stakeholders from universities, regional health bureaus, the Pharmaceuticals Fund and Supply Agency, and the Ethiopian Pharmaceutical Association. SIAPS also supported nine health facilities in the Oromia, Dire Dawa, and Amhara regions in conducting medicine use training sessions. Topics included antibiotic resistance; multiple drug administration; and medicine use considerations for chronic diseases, RMNCH, diabetes, and antiretroviral therapy (ART).

In **South Sudan**, SIAPS conducted multiple training workshops for health care workers in the former Western Equatoria State and in the former Central Equatoria State on pharmaceutical management, malaria case management, and RMU. Participants were provided with copies of the training materials and developed post-training action plans.

To support improved access to ARVs in **Namibia**, SIAPS collaborated with the Ministry of Health and Social Services (MOHSS), Project HOPE, IntraHealth, and the CDC to support the implementation of community-based ART dispensing programs in Nyangana and Engela. SIAPS helped to adapt dispensing tools to the new scheme, including making modifications to the Electronic Dispensing Tool (EDT). Nurse mentors and pharmacy staff involved in delivering ART services in these facilities were trained on the process flow and dispensing of ARVs to community-based ART groups. SIAPS, along with other partners, is also supporting the MOHSS Directorate of Special Programs to implement Namibia's adherence strategy. SIAPS developed the adherence strategy and presented it to the adherence technical working group for adoption. Based on the group's recommendation, SIAPS supported the implementation of the EDT SMS reminder system at 10 sites in Namibia following a smaller pilot project.

To decrease barriers to ART in **Angola**, SIAPS supported a shift in dispensing practices. SIAPS helped to implement changes that enabled dispensing of ART, which was previously available only at the hospital level, at health facility pharmacies. This has helped to reduce patient burden at the hospital level and the stigma associated with patients visiting HIV-specific facilities for each refill.

SIAPS/**Philippines** also initiated a nine-month multidrug-resistant TB regimen operations research study at multiple TB treatment centers. Staff members from participating treatment facilities were oriented on the study protocol and began enrolling patients in the study.

In **Ethiopia**, where the increasing prevalence of chronic and noncommunicable diseases combined with the high burden of infectious disease has increased the need for patient-centered pharmacy services, SIAPS continues to advance the practice of clinical pharmacy services in collaboration with in-country stakeholders, including the Federal Ministry of Health (FMOH). This year, 14 new hospitals in seven regional states started providing clinical pharmacy services, bringing the number of health facilities implementing these services to more than 75. In addition, SIAPS provided support to implement clinical pharmacy services in 10 health facilities where mothers and children are treated.

In Ethiopia, SIAPS worked to increase pharmacovigilance reporting and as a result, the reporting of adverse drug events has led to in several regulatory actions, including the recall, production stops, or quality investigations of certain products.

SIAPS/**Burundi** assisted the newly created communication unit within the National Malaria Control Program (PNILP) to validate a malaria prevention behavior change communication guide. The guide explains appropriate communication methods and key messages on malaria prevention. SIAPS helped the PNILP train 30 central-level trainers, 20% of whom were women, and supported the PNILP central trainers to train an additional 340 trainers (26% women) on malaria prevention communication guidelines, including methods and messages. SIAPS also supported the MOH to produce and disseminate messages on malaria prevention, early diagnosis, and treatment through radio and newspaper outlets. To support the PNILP in scaling up intermittent preventive treatment in pregnancy and integrated community case management (iCCM) of childhood diseases, SIAPS collaborated with CARITAS to assist the PNILP and Direction d'Offre et Demande de Soins (Directorate of Offer and Demand of Health Services) to introduce malaria community case management for children under the age of five as part of iCCM efforts in five new health districts. This year, iCCM was initiated in the health districts of Mutaho and Giteranyi, and more than 150 community health workers have been trained to implement the new guidelines.

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

SIAPS worked with drug and therapeutics committees (DTCs) in several countries to strengthen the mechanisms for supporting medicine management and rational use at hospitals and health facilities. Key activities this year include:

- » Supporting the Rational Medicine Utilization Subcommittee of the Gauteng Pharmaceutical and Therapeutics Committee (PTC) in **South Africa** to assess the implementation of the 2014 standard treatment guidelines (STGs) for primary health care facilities. A key result showed that only 21% of medicines were prescribed in accordance with the STGs, indicating a need to continue raising awareness on the STGs and RMU.
- » SIAPS/**Mozambique** continued to strengthen the capacity of the Hospital Pharmacy Department in improving DTCs at the central and provincial levels. During this reporting quarter, SIAPS conducted supervisory visits to the Lichinga Hospital and Pemba Hospital DTCs. SIAPS worked to train hospital pharmacists on how to collect, analyze, and report data on prescription indicators, medication errors, and aggregate consumption. Three province-level and two central-level hospitals then collected the data and analyzed the results. Key results indicated that at least one antibiotic was prescribed during most patient visits to health facilities (51%–88% of patient encounters) and that antibiotics have the highest consumption rate of any therapeutic group among the health facilities (32%–50%).
- » SIAPS supported the MOHSS in **Namibia** in successfully receiving approval from the Global Fund to fund a national training of therapeutic committees for the next calendar year.

- » In **DRC**, SIAPS supported the Health Provincial Division to conduct medicine use studies at 10 facilities in five provinces to draw comparisons between hospitals with and without a DTC. Among the findings on prescribing practices, patient knowledge, and use of treatment guidelines, the study revealed that:
 - On average, only two medicines were prescribed per patient encounter in hospitals with a DTC, while up to four medicines were prescribed in hospitals without a DTC
 - The percentages of generic medicines prescribed were 70% and 58% in hospitals with and without a DTC, respectively
 - The percentage of outpatient prescriptions with at least one antibiotic was higher (59%) in hospitals without a DTC than in those with a DTC (47%)
 - In hospitals with a DTC, 60% of malaria cases were treated as per the recommended malaria treatment guidelines, while only 40% were in hospitals without a DTC.

SIAPS also supported in-country stakeholders in conducting a range of activities to support drug use reviews (DURs) and drug use evaluations (DUEs). Key activities included:

- » **SIAPS/South Africa** provided technical assistance to the Western Cape Provincial PTC to capture data received from 254 facilities for a DUR of aspirin. Approximately 4,500 aspirin cases were captured using the data collection forms. Preliminary results indicate that more than two-thirds of patients given aspirin were treated inappropriately. SIAPS also provided technical assistance to the Essential Drugs Program (EDP) Unit to carry out pharmaco-economic evaluations and technical medicine reviews to support the decision-making process in the review of the STGs and essential medicines list (EML). In addition, SIAPS presented the benefits of using the ABC/VEN Matrix as a routine monitoring tool to eleven institutions that worked with their respective PTCs to conduct DUEs, resulting in improved use for the 13 identified items with an estimated 51% decrease in spending per month. Three institutions presented their results at the Gauteng Pharmacy Managers Conference in September.
- » In **Ukraine**, the data collection for a DUR in the HIV sector was conducted and the technical reports and presentations were finalized for dissemination. SIAPS held a stakeholder meeting on April 6, 2016, to present final DUR results in both the HIV and TB sectors. Stakeholders approved the reports and expressed an interest in expanding DUR implementation to other health facilities (e.g., AIDS centers and TB dispensaries).
- » **SIAPS/Uzbekistan** supported the NTP to pilot a DUR program in three hospitals.
- » In **Namibia**, SIAPS supported the Therapeutics Committee (TC) in the Kunene region to compile the results from a DUR into a final report. Results from the review show high (83%) compliance to STGs. SIAPS also developed a DUE manual to encourage TCs to assess medicine use and encourage compliance with Namibia's STGs and ART guidelines.

- » In **DRC**, SIAPS provided technical and financial support to the MOH to evaluate the use of chlorhexidine digluconate 7.1% for umbilical care. The evaluation is being conducted in 29 health facilities in eight health zones.
- » In **Ethiopia**, SIAPS supported the DTC at Hiwot Fana Hospital in conducting a DUR of crystalline penicillin use in the pediatric ward. A total of 114 patient records were reviewed and assessed by indication, frequency of administration, contraindications, and drug interactions.

During its fifth year of implementation, SIAPS intensified its focus on assessing, collecting, and documenting program results; disseminating implementation experiences and lessons learned; and empowering in-country stakeholders to continue making progress in the area of pharmaceutical services. This year, SIAPS and its partners presented nearly 20 conference posters or presentations related to IR 5B, including the following on RMU and AMR:

- » *Ensuring access to and appropriate use of medicines for iCCM: It takes a system.* Oral presentation at the 143rd American Public Health Association (APHA) Annual Meeting and Expo, Chicago, IL, USA. November 3, 2015.
- » *Country and regional level advocacy and coalition-building against antimicrobial resistance.* Oral presentation at the 143rd American Public Health Association (APHA) Annual Meeting and Expo, Chicago, IL, USA. November 3, 2015.
- » *Assessment of the World Health Organization early warning indicators of HIV drug resistance in Namibia for public health action, 2015.* Poster presentation at AIDS 2016, Durban, South Africa. July 18–22, 2016.
- » *Drug Use Review Program in Uzbekistan: Pathway to Improved Rational Use of Anti-Tuberculosis Medicines.* Poster presentation at the 46th UNION World Conference on Lung Health, Cape Town, South Africa. December 2–6, 2015.
- » *Containing antimicrobial resistance to realize the goals of universal health coverage.* Oral presentation at the Ecumenical Pharmaceutical Network (EPN) Forum 2016, Tübingen, Germany. May 18–21, 2016.
- » *Comparison of selected prescribing indicators measured before and after implementation of standard treatment guidelines in Swaziland.* Oral presentation at the 2nd Medicines Use Research in Africa Conference, Gaborone, Botswana. July 25–27, 2016.
- » *Strengthening preservice pharmacy training on rational medicine use, antimicrobial resistance, and pharmacovigilance.* Poster presentation at the 76th FIP World Congress of Pharmacy and Pharmaceutical Sciences, Buenos Aires, Argentina. August 28–September 1, 2016.

Pharmaceutical Service Standards are Defined, Adopted, and Implemented

During this project year, SIAPS supported multiple countries in advancing pharmaceutical standards, revising and implementing treatment guidelines, and assessing medicines for inclusion in EMLs and formularies. SIAPS supported the

following achievements during the reporting period:

- » The Diagnostic and Therapeutic Guidelines and the Pharmaceutical Formulary were launched at a SIAPS-supported event in **Dominican Republic**, where the Vice President delivered remarks.
- » With SIAPS support, a national-level committee in **Mozambique** has adopted a new focus and terms of reference for future monitoring and review of the EML.
- » SIAPS/**Namibia** supported the Division of Pharmaceutical Services and the EML Committee in proposing changes to the Namibia EML to the Policy Management and Development Review Committee, which accepted all of the proposed changes. The new changes align the EML with new WHO recommendations.
- » Multiple new medicine formulations were included in the **Philippines'** National Drug Formulary to support improved pediatric TB management. The new formulations enable easier administration of medicines to children. In addition, standard operating procedures (SOPs) were developed for PV surveillance of bedaquiline that align with the drug safety monitoring and management framework and the bedaquiline study protocol.
- » SIAPS/**South Africa** assisted the EDP Unit in conducting workshops in the Western Cape and Kwazulu-Natal to support the roll-out of the updated edition of the Primary Health Care STGs and the EML smart phone application. With SIAPS supporting medicine reviews and the publications process, the fourth editions of the South Africa Adult Hospital-Level EML and STGs were finalized and published on the National Department of Health website.
- » Also in **South Africa**, the Essential Medicines List Tool was renamed the Essential Medicines Electronic Access (EMeA) and was migrated to a new domain (www.emela.org.za). STGs will also be moved to the new site, and SIAPS is adapting the guidelines to the new digital format.
- » SIAPS supported the printing and dissemination of STGs in **DRC** and developed a dissemination and training plan that is being piloted in referral hospitals with an established DTC.
- » In **Sierra Leone**, SIAPS supported the Directorate of Drugs and Medical Supplies in developing a revised draft of the national EML, which has been approved and signed by the MOHSS and the Chief Medical Officer and is expected to help harmonize the types of medicines and supplies procured for the government's free health care initiative.
- » In **Swaziland**, SIAPS supported the finalization, printing, and dissemination of the bedaquiline and delamanid clinical and pocket guidelines. In addition, to improve reporting and assessment of ADEs, SIAPS developed standard definitions and severity grading scales as job aids and an ADE reporting cascade.
- » In **Ethiopia**, SOPs were produced and disseminated to standardize and guide the establishment of drug information services at the health facility level.

Emergence of AMR Slowed

SIAPS is working to support global, regional, and local efforts to combat AMR by raising awareness, supporting the development of national AMR action plans, building capacity for RMU, and assessing and monitoring antibiotic use.

This year, SIAPS published two courses on AMR through the Global Health eLearning (GHeL) Center with the support of K4Health. Part 2 of the course was published in November 2015, and the previously published Part 1 was revised, updated, and republished in September 2016. Within the first few weeks of publication, 46 people from 18 countries earned a certificate for the newly revised AMR Part 1 course. Part 2 of the course has been successfully completed by 345 people from 48 countries.

As a regional capacity strengthening effort, SIAPS worked with the Ecumenical Pharmaceutical Network (EPN) to support the management of results-oriented proposals from EPN's member organizations on topics related to antimicrobial stewardship and AMR. The projects were implemented by the Christian Health Association of Malawi, the Zimbabwe Association of Church-related Hospitals, and Gertrude's Children's Hospital in Kenya. Activities completed by the projects team included trainings on proper hand hygiene guidelines, the publication of 16 articles on AMR following a training for journalists, and an assessment of adherence to STGs. In collaboration with the EPN, SIAPS helped to develop, print, declare, and distribute a Call to Action (CTA) document as one of the key outputs of the EPN's Biannual Forum 2016. The CTA was published on the SIAPS website and shared externally through social media channels and the MSH newsletter. Also during the forum, SIAPS presented at a plenary session on "Containing Antimicrobial Resistance to Realize the Goals of Universal Health Coverage."

In **Ethiopia**, SIAPS supported a training for journalists on topics related to prevention and containment of AMR, RMU, RMNCH and medicine use, drug and substance abuse and the consequences, and medicines safety. A total of 23 participants from different mass media agencies and outlets attended the training, which resulted in three additional publications on AMR containment. SIAPS also supported AMR Containment Commemoration Day on June 18, 2016, in Hawassa in collaboration with the Ethiopian Pharmaceutical Association, the Southern Nations Regional Health Bureau (RHB), the Nationalities and Peoples Region RHB, the Ethiopian Pharmaceutical Students Association, the FMOH, FMHACA, PFSA, and WHO. The theme of the 2016 AMR day was "Preserve Antimicrobials: Contain AMR!"

In **Namibia**, SIAPS is a member of the national steering committee on the containment of AMR and the prevention of hospital-acquired infections, which is helping to advocate for the establishment of antibiotic stewardship committees in the regions. Also in Namibia, SIAPS supported data abstraction for the 2016 HIV-DR Early Warning Indicator (EWI) analysis. The five EWIs included ontime pill pick up, retention in care, pharmacy stock-outs, dispensing practices, and viral load suppression.

As in previous years, SIAPS/**South Africa** supported the Pharmacy Council and EDP to finalize the theme for Pharmacy Week, "Use Medicines Safely." SIAPS

also supported the Gauteng and KwaZulu-Natal provinces in the development and operationalization of provincial AMR plans that align with the National AMR Strategy Framework and National AMR Implementation Plan. SIAPS also conducted a research project entitled “Using Electronic Pharmacy Dispensing Data for Surveillance of Outpatient Antibiotic Consumption and Monitoring of Antibiotic Prescribing Practices at District and Provincial Hospitals in the South African Public Sector: A Feasibility Study in North West Province.” The study’s key findings include:

- During the two-year study period, 39% of patients received a prescription for an antibiotic
- One-third of patients receiving an antibiotic prescription received two or three antibiotics
- Some patients were prescribed up to eight antibiotics at one time, including two penicillins and two quinolones prescribed simultaneously

In **Swaziland**, SIAPS supported the MOH in forming and establishing the terms of reference for the National Antimicrobial Resistance Containment Committee, the mechanism through which the National Antimicrobial Resistance Containment Plan/Strategy will be drafted. In April 2016, the first committee members were appointed. The MOH and SIAPS are partnering with WHO in development of the strategy, and an initial draft is expected to be finalized in the coming months.

TECHNICAL HIGHLIGHT

STRENGTHENING BANGLADESH'S NATIONAL PHARMACOVIGILANCE SYSTEM: LESSONS LEARNED AND OPPORTUNITIES



What is Pharmacovigilance?

The World Health Organization (WHO) defines pharmacovigilance (PV) as the science and activities concerned with the detection, assessment, understanding, and prevention of adverse reactions to medicines. The ultimate goal of PV is to improve the safe and rational use of medicines, thereby improving patient care and public health.

CONTEXT

The pharmaceutical sector of Bangladesh has positioned itself well in the international and domestic markets over the last few decades. More than 97% of the local demand for medicines is met by Bangladeshi pharmaceutical companies, and roughly 30 companies export a significant quantity of medicines to 113 countries¹. For pharmaceutical companies, it is relatively easy to obtain marketing authorization for the sale of medicines in Bangladesh, but it is becoming increasingly crucial for the Directorate General of Drug Administration (DGDA) to strengthen regulations and surveillance systems to ensure that medicines and commodities provided to patients and the public are safe and effective and that they meet approved quality standards. Although PV started in Bangladesh in 1999, several factors contributed to it going dormant, including a lack of legislation and strategic leadership, limited motivation, no common understanding among DGDA staff about PV, and coordination and communication

gaps among stakeholders. As a result, many adverse drug reactions were not reported correctly.

APPROACH

In 2012, the US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health, started working with the DGDA and conducted a comprehensive assessment of the DGDA's regulatory systems and capacity. As part of the recommendations made in the assessment, SIAPS provided technical support to the DGDA to revive the national PV program and establish an Adverse Drug Reaction Monitoring (ADRM) cell. This cell, which is responsible for collecting adverse event reports from health care facilities, hospitals, and pharmaceutical companies, maintains and analyzes adverse event databases, including data entry and quality assurance, and shares adverse event information with WHO's International Drug Monitoring Center (WHO-UMC) at Uppsala.

In September 2013, the Ministry of Health and Family Welfare named the ADRM cell the National Drug Monitoring Centre (NDMC) of Bangladesh and officially launched the National Pharmacovigilance

1 2015 Annual Report of the Directorate General of Drug Administration (<http://www.dgda.gov.bd/index.php/downloads/annual-information/143-annual-report-2015>); <http://www.dhakatribune.com/long-form/2015/feb/13/prescription-growth>

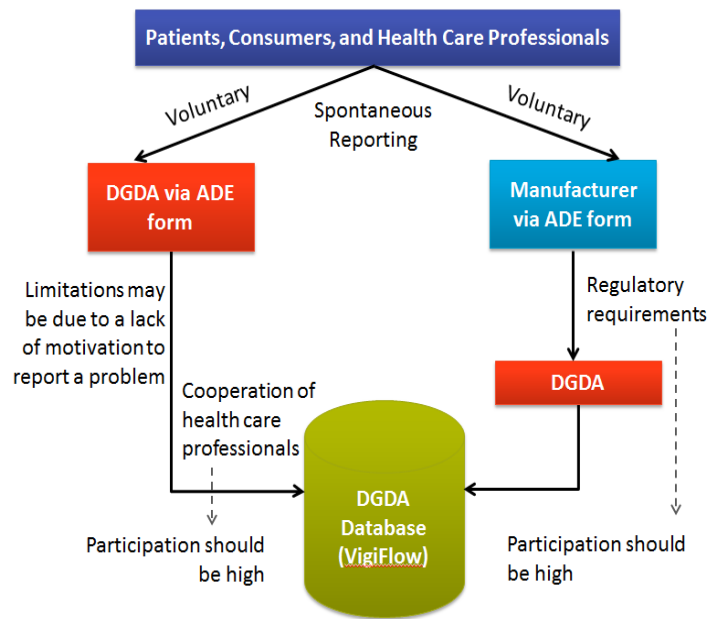
Program. The PV program was initially introduced at 20 private and public hospitals and 13 pharmaceutical companies. With technical assistance from SIAPS, the DGDA formed an Adverse Drug Reaction Advisory Committee (ADRAC) and trained its members to evaluate, analyze, and make recommendations on adverse drug events (ADEs). SIAPS also helped the DGDA develop PV guidelines; tools; and information, education, and communication training materials to support an ADE reporting a team comprising DGDA officials and SIAPS technical advisors made regular monitoring visits to selected hospitals, while staff from the ADRM cell sent biweekly e-mails and made follow-up phone calls to key personnel at the hospitals and pharmaceutical companies where the PV program was being introduced. SIAPS also facilitated a series of workshops and capacity building trainings for DGDA officials and pharmaceutical industry representatives to increase PV awareness and knowledge.

RESULTS

The system-oriented approaches used by SIAPS to keep the national PV program functional and effective yielded some significant results:

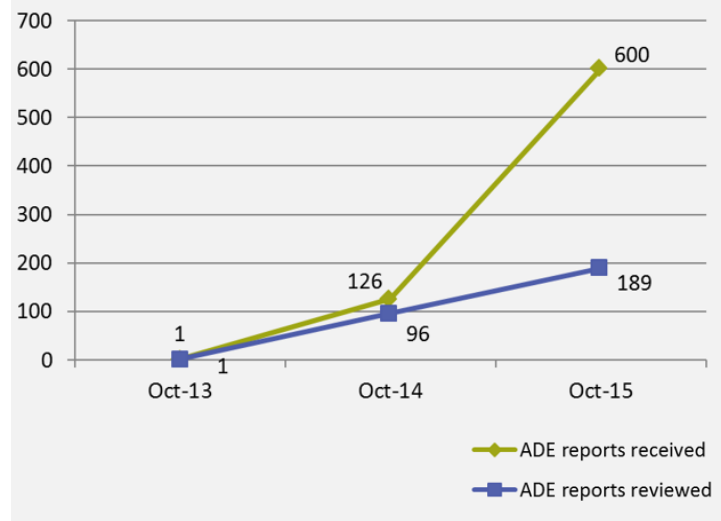
- In December 2014, Bangladesh became a full member of WHO-UMC.
- A total of 30 hospitals and pharmaceutical companies with designated PV focal points are currently working as “sentinel surveillance sites” to implement PV interventions. The DGDA also extended the PV program to two divisional teaching hospitals (Chittagong and Rajshahi Medical Colleges). As of March 2016, 48% and 56% of these hospitals and pharmaceutical manufacturers, respectively, are regularly reporting adverse events.
- The DGDA received 600 ADE reports between October 2013 and October 2015, and of these, 189 had complete data and were reviewed by the committee and uploaded into the VigiFlow database. Figure 1 shows a four-fold increase in the number of reports received and a two-fold increase in the number of reports reviewed by the ADRAC during this time period. An additional 171 ADE reports that were received by the DGDA between November 2015 and March 2016 are currently being reviewed.

PV framework: How adverse drug event reports reach the DGDA



The DGDA received 600 ADE reports between October 2013 and October 2015, and of these, 189 had complete data and were reviewed by the committee and uploaded into the VigiFlow database.

Figure 1: Cumulative number of ADE reports received and reviewed



- Related training on PV was provided to 460 health care providers and pharmaceutical industry representatives.
- A DGDA executive order has been sent to all public medical college hospitals and local pharmaceutical manufacturing companies, including pharmaceutical importers, that asks these sites to monitor the ADEs of their

products through their own channels and to report the findings to the NDMC².

CHALLENGES AND LESSONS LEARNED

The DGDA faces several significant challenges, including a lack of public awareness on ADE reporting and inadequate experience of DGDA and other officials working in health facilities as well as policy makers on PV. Concerted efforts are needed from all stakeholders to increase public awareness and build the capacity of both DGDA officials and health care providers to increase the number and quality of ADE reports. Frequent staff changes have slowed down PV implementation in the public and private hospitals selected for this program.

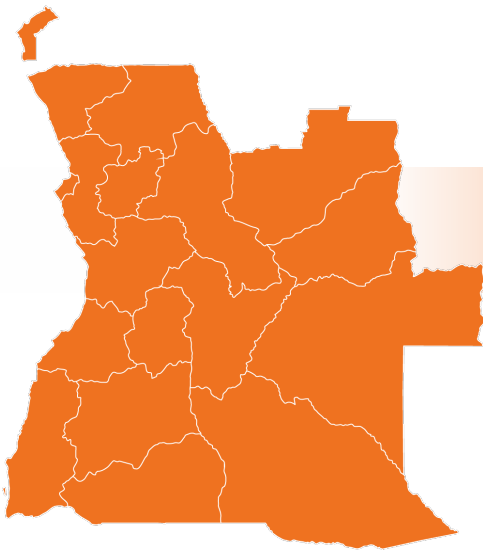
CONCLUSION

PV activities currently operate on a limited scale in Bangladesh, but to ensure an optimal public health impact and safety in relation to medicine use, it is essential to expand these activities nationwide. In addition, engaging a broader range of stakeholders (e.g., patients, health care providers, academics, and researcher institutes and universities) and promoting country ownership are imperative if the effectiveness of the PV program in Bangladesh is to be sustained.

COUNTRIES

SIAPS worked in 20 countries and 3 regions during program year five. SIAPS has provided innovative technical assistance over the last five years to foster sustained improvements in pharmaceutical systems.

The following section presents a snapshot of accomplishments during FY16.



ANGOLA

SIAPS STRATEGY

SIAPS/Angola endeavors to improve the availability of essential health commodities for sustainable and uninterrupted access to quality health products that will improve outcomes at all levels of the health care system. This is achieved by strengthening the coordination of pharmaceutical supply chain management planning and implementation and ongoing performance monitoring for the rational use of resources; increasing and enhancing individual and institutional capacity for pharmaceutical supply management; strengthening information collection and management for effective decision making in supply chain logistics management; and contributing to the improved availability of pharmaceutical products and services at the service delivery point level.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Strengthening governance by launching the first comprehensive national supply chain strategy

This year, SIAPS supported Angola's Ministry of Health (MOH) to develop its first comprehensive national supply chain strategy for health commodities. In June 2016, a multistakeholder workshop was held to develop a strategic plan that outlined priority gaps and recommended appropriate interventions. Participants selected priority areas and established a committee to finalize the strategic plan to improve the availability and use of safe, efficacious, quality, and cost-effective medicines and other health products in Angola for the next five years.

Strengthening the MOH's ability to effectively regulate imported pharmaceuticals

SIAPS continued supporting the National Directorate of Medicines and Equipment's (DNME) efforts to become a stronger institution with greater autonomy and building the capacity of the product registration unit. The DNME organized meetings with multi-institutional stakeholders to advocate for the need to strengthen and expedite import controls for pharmaceutical products. As a result, stakeholders approved the allocation of additional resources to begin the formal process of medicine registration. SIAPS helped DNME's registration unit develop a plan to identify and collect data on medicines imported over the last

three years. SIAPS also assisted DNME staff in developing product registration tools that are aligned with the South African Development Community requirements and guidelines. Finally, as part of closeout activities, SIAPS developed a road map for product registration for the DNME and stakeholders to review and consider for adoption.

Mentoring pharmaceutical staff in the pharmaceutical management of HIV/AIDS commodities

During the fifth program year, SIAPS successfully designed and implemented a mentorship program to increase the capacity of pharmaceutical staff at nine health facilities and provincial warehouses in Luanda and to address identified issues in the pharmaceutical management of HIV/AIDS commodities. SIAPS and a team of consultants led trainings on stock management and dispensing antiretrovirals (ARVs), and pharmaceutical staff are now better able to record quality stock data. Some health facilities have begun dispensing ARVs at the pharmacy level, which has resulted in more client satisfaction because of the significant reduction in wait time at the clinic and has helped mitigate the stigma associated with patients going to an HIV treatment facility to refill their ARVs.



BANGLADESH

SIAPS STRATEGY

SIAPS/Bangladesh focuses on good governance, procurement, logistics, institutional capacity building, and improving the regulatory system, with the aim of ensuring continuous availability of quality commodities to support quality health care delivery and patient safety, and the timely availability of reliable data to support evidence-based decision-making.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Sustaining supply chain coordination within the Ministry of Health and Family Welfare

SIAPS has assisted in establishing and with the functioning of several national-level coordination bodies within the Ministry of Health and Family Welfare (MOHFW) and its key directorates to strengthen pharmaceutical procurement and supply. SIAPS introduced the Procurement and Logistics Management Cell (PLMC) in 2012, which serves as the overarching coordinating body within the MOHFW to monitor and supervise procurement and supply chain functions. Yet, the challenge remained to create permanent staff positions for the PLMC to ensure sustainability in the gains achieved since 2012. With robust advocacy by SIAPS, the MOHFW successfully lobbied the Ministry of Public Administration to approve seven permanent positions within the PLMC for the continuation of MOHFW-level coordination among key entities and implementation of the Health, Population, and Nutrition Sector Development Plan.

Aligning information systems to boost transparency and data for decision making

In program year five, SIAPS assisted the Directorate General of Health Services (DGHS) in establishing an electronic logistics management information system (eLMIS) dashboard for 25 life-saving priority MNCH medicines using the DHIS2 platform. SIAPS trained health officials of health facilities on quality reporting using the system and released a beta version into the Supply Chain Management Portal (SCMP), a procurement tracker and dashboard that is available to the MOHFW, stakeholders, and the public. Including the eLMIS in the SCMP will increase transparency and evidence-based decision making. As part of a

sustainability plan, SIAPS prepared a technical guide and user manual. As of July 2016, the percentage of health facilities reporting in the eLMIS increased to 80%.

Streamlining sub-national procurement documents to ensure dietary services for the poor

The procurement of food/diet for patients is an important issue, particularly at local-level hospitals, but procurement has been conducted without consulting the public procurement rules or acts. To address this issue, SIAPS customized procurement documents for sub-national level procurement that were validated in a workshop headed by the MOHFW health secretary in July 2016. SIAPS is planning the nationwide training for sub-national level procurement officials, which will take place next year. The customized documents and training are intended to make the procurement system in the MOHFW more effective and more efficient.

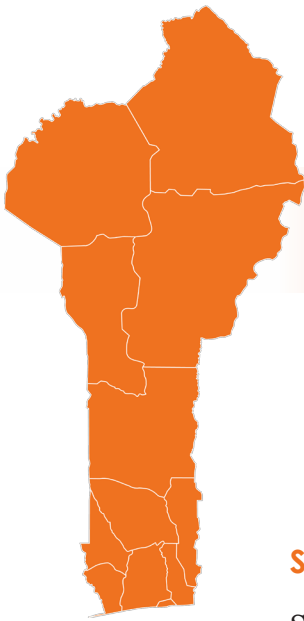
Family planning commodities remain at the optimal level of stock countrywide

Countrywide roll-out of the service delivery point dashboard module, part of the SCMP, has widened the scope of the electronic logistics reporting system for the Directorate General for Family Planning, thereby ensuring the availability of commodities at the service delivery level. Through capacity building and troubleshooting assistance by the pool of master trainers, stock-outs at the sub-district level and service delivery points have decreased to less than 1%.

Establishing a medicine registration system to increase the availability of quality, safe, and efficacious medicines

SIAPS developed a country-specific online drug registration system, Pharmadex, which is being prepared for piloting. Pharmadex will be used as a platform for the effective implementation of common technical documents (CTDs) by tracking the process of drug registration, licensing, and overall regulatory management. SIAPS developed the CTDs and provided training to Directorate General of Drug Administration (DGDA) and pharmaceutical manufacturing officials on medicine registration and reviewing CTD-based medicine dossiers through Pharmadex. SIAPS also developed a user/applicant request form to test the system with 40 pharmaceutical companies.

Subsequently, SIAPS facilitated a three-year partnership between DGDA and the Korea International Cooperation Agency (KOICA) that permits the Ministry of Food and Drug Safety (MFDS) of Korea to conduct training/workshops for DGDA officials on regulatory affairs and patient safety. By introducing Pharmadex into the regulatory process, Bangladesh will ensure that medicines of proven quality, efficacy, and safety are available to the public and thus contribute to improving health outcomes.



SIAPS STRATEGY

SIAPS supports the Ministry of Health (MOH) to ensure availability, accessibility, and rational use of efficacious, safe, and good quality commodities, including Ebola-related and other health technologies, at affordable prices by strengthening the national pharmaceutical management system. SIAPS provides technical leadership and assistance to MOH through the National Directorate for Pharmacy and Laboratories (DPMED) to strengthen capacity in the pharmaceutical management system.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Enhancing capacity for effective pharmaceutical management of Ebola- and other hemorrhagic fever-related commodities

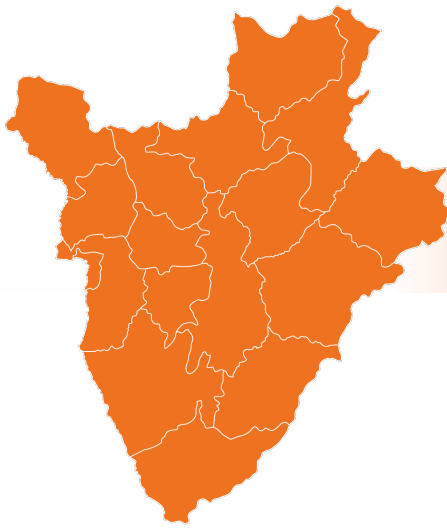
SIAPS provided technical assistance to the MOH Ebola Commission by quantifying Ebola and other hemorrhagic fever commodities, including Lassa fever. This quantification exercise was coupled with capacity building for members of the national quantification committee and the results from the exercise included an official list of Ebola- and other hemorrhagic fever-related products to serve as a reference document during the procurement process. At the facility level, SIAPS built the capacity of managers to improve the completeness and quality of health management information system (HMIS) and the logistics management information system (LMIS) data.

Assessing the regulatory system to improve the availability of safe and high quality commodities

SIAPS received a request from USAID/Benin to support the DPMED in implementing an electronic tool to strengthen the registration system of medicines and health products. SIAPS proposed the next step of conducting a situational analysis of the regulatory information management system and processes of the DPMED. Based on the findings, SIAPS will then develop appropriate recommendations and an action plan. SIAPS worked closely with DPMED to develop the scope of work and timeline to conduct this assessment.

Coordinating stakeholders to improve governance in supply management

SIAPS provided technical assistance to the DPMED in organizing the semi-annual National Procurement and Supply Management Committee (*Comite National d'Approvisionnement des Produits de Sante* [CNAPS]) workshop. The event, which is a high-level platform to discuss supply chain-related issues in Benin, enabled SIAPS to obtain approval from CNAPS for its national supply chain assessment and strategic planning. Committee members validated the key findings and recommendations of the assessment and the 2016–2020 strategic plan.



BURUNDI

SIAPS STRATEGY

SIAPS/Burundi contributes to increasing access to malaria diagnostic and treatment services, thereby significantly reducing mortality due to malaria. In doing so, SIAPS provides technical assistance to the Programme National Intégré de Lutte contre le Paludisme (National Malaria Control Program [PNILP]) to implement successful interventions to strengthen key institutions in reducing mortality and morbidity through strong case management and the availability of malaria commodities.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Improving Malaria Services for Pregnant Women

Beginning in 2014, SIAPS has been working with the PNILP, the Programme National de Santé de la Reproduction (National Reproductive Health Program [PNSR]), WHO, and UNICEF to develop and implement a national policy for intermittent preventive treatment in pregnancy (IPTp). The IPTp policy was introduced in Burundi to reduce the prevalence of severe maternal anemia and cases of low childbirth weight due to placental malaria, and thus decrease maternal and neonatal deaths. It was launched in 2015 and during program year five (PY5), SIAPS has actively been engaged in the nationwide scale-up. Activities included training 1,246 health care providers and trainers on IPTp policy and sensitizing local authorities on prevention measures against malaria, such as the correct use of long-lasting insecticide treated nets, hygiene, and indoor residual spraying. Due to these efforts and the partnership with the MOH, IPTp has been implemented nationwide.

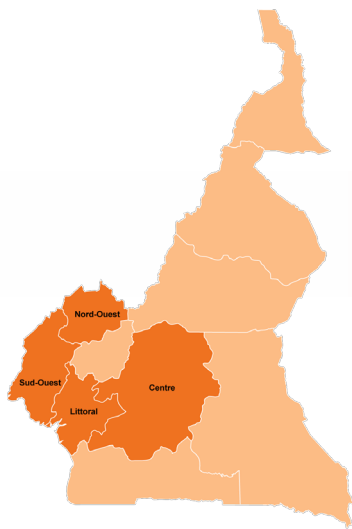
Increasing children's access to quality malaria services

To promote early detection and treatment of malaria cases among children under five, SIAPS continued its collaboration with partner CARITAS Burundi in assisting the PNILP to scale up the integrated community case management of children's diseases. The objective was to train community health workers (CHWs) from five districts to diagnose and treat malaria, diarrhea, and pneumonia and to detect acute malnutrition among children ages 2 to 59 months. In PY5, SIAPS assisted in training 17 trainers at the central level and 270 CHWs in diagnosing

and treating malaria in children under 5. To support these endeavors, SIAPS assisted the PNILP in distributing 690,300 malaria treatments for children ages 1 to 5 and 979,150 treatments for newborns (2 to 11 months old) purchased by the President's Malaria Initiative (PMI).

Enhancing commodity security through capacity building and improving stakeholder coordination

To increase capacity for commodities quantification, SIAPS assisted the MOH and partners to form a National Commodity Security Committee this project year, whose objective is to ensure the optimal supply of commodities to meet the country's goals for priority public health programs. The committee, the PNILP, and SIAPS evaluated the stock levels of malaria commodities, resulting in a gap in malaria commodities of 53%. Using updated figures, SIAPS worked with partners, including the Global Fund, to ensure the timely delivery of an emergency ACT procurement. SIAPS also worked closely with PMI and the MOH to ensure that the PMI-donated malaria commodities restored stock levels until additional quantities were received from the Global Fund.



CAMEROON

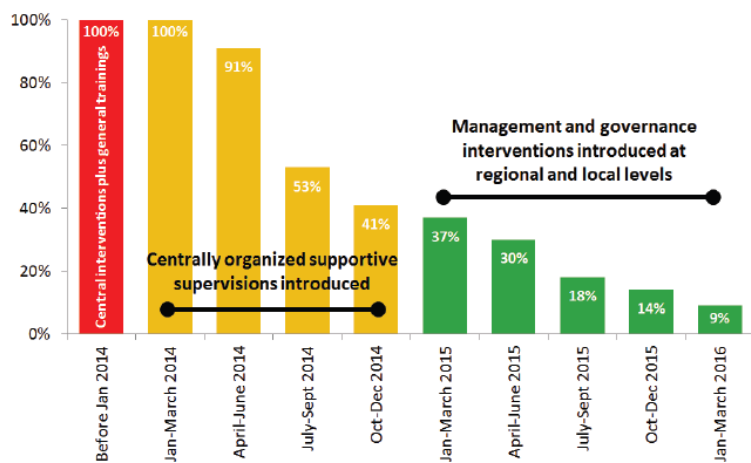
SIAPS STRATEGY

SIAPS/Cameroon’s objective of improving access to HIV and related pharmaceutical services, evolved over the five-year project from emergency response to a systems strengthening approach and from investments prioritizing centrally based activities to interventions aiming at enhancing management capacity at the regional and health-facility levels.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Improved pharmaceutical management at the central, regional, and facility levels resulting in increased availability of ARVs

The availability of ARVs at the central level improved significantly, thanks to restoring the financial flow for ARV procurement through the Global Fund, capacity building, and the improvements in centrally organized supervision,



Percentage of health facilities experiencing stock-outs (HFESO)

forecasting, and quantification. These efforts of eradicating ARV stock-outs at the central level contributed directly to a decrease in health facilities experiencing stock-outs (HFESO).

The introduction of management and governance interventions at the regional and facility levels, as well as placing SIAPS technical advisers in regions to more easily provide support, contributed to reduced stock-outs of all six tracer ARVs. The percentage of HFESO has significantly declined from 100% in 2014 to 9% in March 2016.

Increased transparency and accountability to support good governance

SIAPS has been collaborating with Positive Generation, a local civil society organization, to leverage advocacy, monitoring, and reporting efforts to increase

transparency and accountability, and ultimately improve patients' access to HIV commodities. In 2015 and 2016, SIAPS worked closely with Positive Generation to jointly analyze barriers to access to HIV services and contrast indicators. SIAPS also assisted Positive Generation in developing a web-based version of the Treatment Access Watch magazine.

Strengthened capacity to improve the availability of HIV commodities and the management of pharmaceutical services

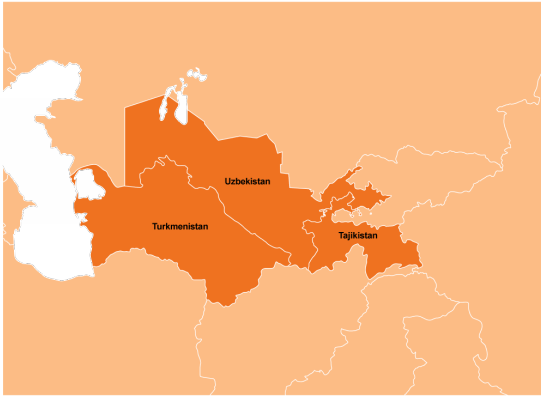
Most improvements in human capacity to manage and provide oversight of HIV commodities and pharmaceutical services were achieved at the regional and health-facility levels and are attributed to a continuous improvement methodology. Qualitative interviews and feedback from administrators of the regional warehouses, ART site coordinators, dispensers, and store keepers, demonstrated a high degree of satisfaction of the skills acquired.

At the central level, the capacities of both the National AIDS Coordination Committee and the Quantification Committee have increased such that they are able to conduct quantification exercises using the tools Quantimed and ForLab.

Improved availability, quality, and use of data at 129 ART and PMTCT sites

Prior to 2012, the HIV program in Cameroon lacked a record keeping and reporting system to capture patient and pharmaceutical information. SIAPS and other partners assisted with developing and disseminating tools for data capture and implementing training and supervision strategies to ensure appropriate use of those tools at the regional and facility levels and thus improve national stock monitoring exercises. Results from this year include:

- 98% of health facilities keep complete patient information, as per the national standards (September 2016)
- 79% of the health facilities (June 2016) were monitoring and maintaining suitable stock levels of all ARVs, an increase from 15% in 2013
- More than 82% of the 104 SIAPS-supported health facilities report monthly logistics information (September 2016)
- OSPSIDA, an HIV pharmaceutical management information dashboard, had complete information (98%) on ART sites in the four PEPFAR-supported regions in June 2016
- ART site coordinators of 69% of health facilities were conducting regularly internal supervision of pharmaceutical services, verifying stock levels, and ensuring consistency of data reported across registers and reports as of June 2016



CENTRAL ASIA

SIAPS STRATEGY

SIAPS employs four essential strategies in its support of Central Asian countries: 1) strengthening pharmaceutical governance for TB at the global and country levels; 2) increasing capacity for TB pharmaceutical supply management and services; 3) improving the use of information for decision making in TB control; and 4) improving pharmaceutical services and access to TB products.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

TAJIKISTAN

Increasing the use of information for decision making in Tajikistan for TB pharmaceutical management

This year, SIAPS assisted the National TB Program (NTP) in optimizing reporting and developed an automated tool to monitor and manage the logistics management information system (LMIS). The electronic LMIS is designed to receive and automatically aggregate quarterly LMIS reports on consumption and stock levels. The system helps ensure that reports are being submitted on time, improves their accuracy, and reduces the time needed for aggregating data received from different facilities. In addition, transitioning to an electronic system is important for improving supply planning of anti-TB medicines and minimizing stock-outs or expired medicines. SIAPS worked closely with the NTP to customize the LMIS, which includes a feature that allows stock data to be exported to QuanTB. The new version of the LMIS has been piloted in six districts.

Strengthening the supply chain system in Tajikistan to better manage anti-TB medicines

Since its installation, information from QuanTB has been used in quarterly reports. These reports are used to create, update, and revise supply plans for anti-TB medicines and their quantification. SIAPS supported QuanTB's manager and the pharmaceutical management coordinator of the NTP in the review process. Project HOPE, the principal recipient of the Global Fund TB grant, and the KNCV Tajikistan Branch implementing USAID-funded TB programs took over support of QuanTB after SIAPS closed out in Tajikistan.

UZBEKISTAN

Supporting the nationwide scale up of QuanTB to improve TB program management

QuanTB was piloted as an early warning and quantification system in four regions of Uzbekistan in 2015. By the end of the year, USAID/Uzbekistan requested that SIAPS support the NTP in scaling up QuanTB and drafting national guidelines on pharmaceutical management, which would include guidance on use of QuanTB. Scale up efforts to 10 regions began in January 2016, and in February, the Ministry of Health (MOH) accepted the NTP's request to require using QuanTB for reporting from the regions to the central level, which was a prerequisite for system's nationwide rollout. SIAPS provided trainings at the regional and central levels and was part of the team providing supervision visits to the regions.

Developing pharmaceutical management guidelines to ensure sustained improvement in the TB sector

To ensure sustained improvement in the pharmaceutical management of TB, SIAPS organized a meeting of the Pharmaceutical Management Working Group to review a draft, developed by SIAPS, of the TB pharmaceutical management manual and instructions for organizing the reporting, collecting, and processing of data for QuanTB. These documents are expected to be finalized and then introduced to the MOH for endorsement and incorporation into the ministry's 2014 Universal Order, which regulates the prevention, diagnosis, and treatment of TB and drug-resistant TB patients in Uzbekistan but does not yet include TB pharmaceutical management aspects.



DOMINICAN REPUBLIC

SIAPS STRATEGY

SIAPS collaborates with stakeholders in the Dominican Republic to increase the availability of critical medicines, including antiretrovirals and diagnostic materials, through the consolidation and sustainability of the Integrated System for Medicine and Supply Management (SUGEMI). National counterparts will have the capacity to effectively and efficiently operate SUGEMI, which will have a positive impact on the morbidity and mortality of non-communicable and communicable diseases, including HIV/AIDS.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Ensuring sustainable financing for the procurement of pharmaceuticals

Since 2012, SIAPS has assisted in implementing a coordinated national exercise for the estimation of needs using a standardized methodology. This year, SIAPS contributed to revising the 2016 procurement plans for Ministry of Health (MOH) hospitals and primary health facilities to be aligned with the budget. SIAPS supported the 2017 national pooled procurement process by conducting gap analyses and identifying alternative financial sources, followed by lobbying for additional MOH resources. SIAPS further developed guidelines for the quantification and programming of medicines and supplies, which include links to all electronic applications for data entry and analysis. These guidelines will facilitate future quantification exercises without the need for external technical assistance.

Enhancing pharmaceutical services by improving pharmaceutical staff's knowledge of rational use

SIAPS finalized the educational modules for the certified course on rational medicine use, which was implemented in partnership with the Universidad Central del Este. In December 2015, SIAPS conducted a workshop to train course facilitators, and by the end of the third quarter, 31 students had completed the course. In August 2016, 32 students began the second iteration of the course. A revised and updated version of the educational modules is available on the SUGEMI “Toolbox Kit”/National Health Service website.

Increasing transparency and accountability within the pharmaceutical sector

In program year five (PY5), the Dominican Republic National Health Service and the government logistics agency, PROMESE/CAL, signed a service contract that included a requisition and dispatch report and required PROMESE/CAL to submit monthly reports on differences between medicine products and quantities requested by health facilities and those dispatched. SIAPS developed three standard operational procedures for PROMESE/CAL and helped implement the plan. The contract, developed with assistance from SIAPS, is an important step forward in strengthening the monitoring and oversight of PROMESE/CAL.

Institutionalizing a national tool to improve the availability and use of data for decision making

SIAPS continued supporting the implementation of SUGEMI in hospitals. To scale up the implementation of SUGEMI to the rest of the hospital network, SIAPS led a training of trainers course with the intention to cascade trainings. SIAPS assisted in integrating laboratory reagents and materials into SUGEMI. By the end of the implementation year, 21% (8/38) of laboratories made their requests using SUGEMI forms. At the same time, SUGEMI continued to operate as expected, with more than 90% of health facilities reporting their data and receiving feedback by the end of PY5.



DEMOCRATIC REPUBLIC OF CONGO

SIAPS STRATEGY

SIAPS/DRC is committed to improving maternal and child survival and as part of that commitment will scale up the community distribution of lifesaving commodities. SIAPS continues to provide technical assistance to the three national control programs—malaria, HIV/AIDS, and TB—at all levels to ensure the availability of pharmaceutical commodities. At the central level, SIAPS focuses on supporting the Ministry of Health to continue improving policies and regulations targeting the pharmaceutical system.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Institutionalizing a training curriculum to meet current public health needs

SIAPS provided technical and financial assistance to the University of Kinshasa Faculty of Pharmaceutical Sciences (FOPS) to develop a strategic plan in response to an evaluation that determined that training institutions were neither responding to the public health concerns of the country nor addressing the supply chain issues faced by the pharmaceutical sector. SIAPS' technical assistance focused on creating a FOPS five-year strategic plan, a FOPS operational plan, and a FOPS competency framework for pharmacists. FOPS and SIAPS presented and received constructive feedback, and the plan is currently being finalized. FOPS is the first training institution in DRC to have a strategic plan and has received accolades from the Minister of High Education, who recommended that all other DRC training institutions adopt this model and use the FOPS strategic plan as a reference.

Supporting the regulatory authority to improve governance and leadership

Since 2012, SIAPS has provided comprehensive institutional capacity building support to the Drug Regulatory Authority to streamline and better coordinate the registration process. SIAPS' technical support helped strengthen the capacity of the national registration committee. SIAPS also developed a registered medicines directory to track unregistered and unauthorized medicines that has been disseminated nationwide. As a result of these efforts, the national registration committee now has independent funding and is fully functional.

Other results include:

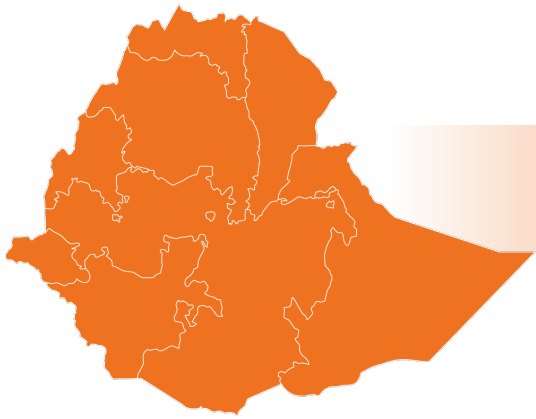
- The number of registered medicines increased from 200 in 2010 to more than 4,600 by September 2016.
- Of the medicines currently included in the national essential medicines list, 72% have at least one product registered, an increase from 44% in 2011.
- The number of days to process a new application decreased from a peak of 82 days in 2013 to 58 days by September 2016.

Supporting efforts to improve storage conditions and stock availability at the facility level

Improving storage conditions has been an ongoing supply chain management activity for SIAPS for the last five years. SIAPS provides technical assistance to central regional medical stores, warehouses, and health facilities in USAID-supported provinces to address the gaps identified. The assistance has been centered on pharmaceutical management trainings, supply distribution, implementing data collecting tools, and updating standard operating procedures.

Results include:

- Among SIAPS-supported health facilities, 75% use a standardized checklist to monitor storage conditions, an increase from zero in December 2011.
- The percentage of SIAPS-supported health facilities with stock-outs of a preselected group of medicines for three days or more in the last three months decreased from 100% in December 2011 to 36% by July 2016.
- The percentage of SIAPS-supported warehouses with stock-outs of a preselected group of medicines for three days or more in the last three months decreased from 100% in December 2011 to 13% by July 2016.



SIAPS STRATEGY

SIAPS/Ethiopia provides “next generation” technical assistance and leadership to the Ethiopian health sector in pharmaceutical systems strengthening, with a deliberate focus on patient-centered services and health outcomes for all program areas. SIAPS supports the Government of Ethiopia in aligning the long-term goals of country ownership and sustainability. Immediate needs are continuing to scale up and expand prevention and treatment programs without adversely affecting health outcomes.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Expanding the Auditable Pharmaceutical Transaction and Services initiative

The Auditable Pharmaceutical Transaction and Services (APTS) regulations are a package of interventions designed to address issues of accountability, transparency, and quality of service at the health facility level. In PY5, four regional health bureaus enacted regulations that support the further expansion and sustainability of APTS. This brings the number of regions that have enacted APTS regulations to 10; only one region—Harari—has yet to approve the regulations. APTS is now being implemented in 67 health facilities throughout the country. The introduction of new cadres, such as pharmacy accountants and cashiers, has transformed access to financial information related to medicine sales, reduced leakage, and contributed to a substantial reduction in waiting time and patient convenience.

In PY5, SIAPS conducted a national assessment of APTS in collaboration with the Federal Ministry of Health and the Ethiopian Pharmaceutical Association. The assessment showed that APTS has contributed to significant improvements in health facility-level indicators, such as patient satisfaction, medicine availability, medicine revenue, waste reduction, and overall improvement in the use of the medicine budget. Other results include:

- On average, 82.3% of sampled hospitals made structural changes to adhere with APTS requirements.
- Among APTS sites, 93.8% produce monthly financial and service reports.

- Wastage at APTS sites averages 1.1%, which falls below the national target of 2%.
- The availability of key tracer medicines was higher at APTS sites than at non-APTS sites.
- Stock-out duration is shorter at APTS sites than at non-APTS sites.

Increasing awareness of pharmacovigilance to improve patient safety

This implementation year, SIAPS met with health facility managers and providers regarding adverse drug event (ADE) reporting to increase commitment and create awareness of pharmacovigilance among health providers. As a result, SIAPS saw the cumulative number of health facilities reporting ADEs increase by 16.4% (from 152 to 177) and the number of reports increase by 8.1% (from 844 to 912) during the first quarter of PY5. SIAPS also helped disseminate ADE reporting forms, allergy cards, and newsletters to encourage further reporting. The reporting of ADEs has resulted in several regulatory actions, including recalls; production stops; and quality investigations for select ringer lactate, chloroquine, paracetamol syrup, iodine tincture, and hydrogen peroxide products.

Implementing a new online registration system to speed access to quality medicines

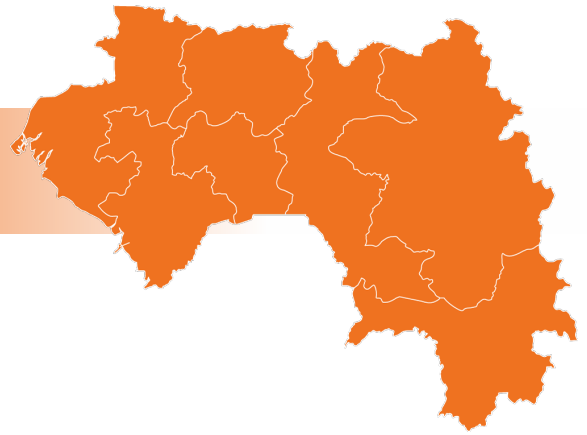
SIAPS has been assisting the Food, Medicine and Health Care Administration and Authority (FMHACA) in developing and implementing the Medicine Information Registration System (MIRS), an online pharmaceutical product registration information system, to increase the efficiency, transparency, and accountability of the marketing approval process. SIAPS supported the development and testing of the web-based software as well as its deployment to the FMHACA server to be used both internally and by industry applicants. Further, FMHACA staff trained more than 70 industry applicants and uploaded 96.7% of all previously registered medicines into the system. Applicants are now submitting their applications online, and FMHACA staff are reviewing and issuing certificates successfully. Over the coming months, SIAPS will support revisions of standard operating procedures and completion of all necessary documentation in preparation for the handover to FMHACA staff, which will help to ensure successful ownership of the registration system.

Supporting the national coordination of and raising awareness of antimicrobial resistance

To increase public awareness and advocacy of antimicrobial resistance (AMR) and rational medicine use (RMU), SIAPS, the FMHACA, regional health regulators, and mass media agencies conducted two trainings on AMR and RMU in the Amhara and SNNP regions for 37 and 41 journalists, respectively, who are producing and disseminating messages in print and electronic media in the public and private sectors. Journalists trained by SIAPS have written and disseminated 221 articles on AMR this year. To further increase awareness, SIAPS also supported AMR Containment Commemoration Day on June 18, 2016, in Hawassa, in collaboration with stakeholders.

Finally, SIAPS drafted an implementation plan for the national AMR strategy that is used as a working document by the national advisory committee and also provided input for planning work at committee members' institutions. An antimicrobial resistance surveillance network stakeholders meeting was organized by the Ethiopian Public Health Institute (EPHI) in collaboration with the Centers for Disease Control and Prevention and the American Society for Microbiology. SIAPS has been working with the EPHI to collect, compile, analyze, interpret, and use culture and sensitivity data for decision making.

GUINEA



SIAPS STRATEGY

SIAPS/Guinea works to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, SIAPS has partnered with the Ministry of Health (MOH) to improve pharmaceutical sector governance, transparency, policy, legislation, and capacity building and to strengthen supply chain management, data management, and reporting.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Scaling up the MOH's post-Ebola recovery plan

This year, SIAPS began working with the MOH on its post-Ebola recovery plan, which focuses on scaling up interventions nationwide. One intervention is strengthening the country's logistics management information system (LMIS) to include the inventory and distribution of Ebola products to help ensure that they are safe and available. With technical and financial support from SIAPS, the national medicines regulatory authority (DNPL) developed a testing environment for a new, automated, electronic LMIS. Once the test phase is completed, the DNPL will roll the system out nationwide.

Strengthening governance by updating the national pharmaceutical law

SIAPS worked with international and local partners to assist the DNPL in revising the existing national pharmaceutical law, which dates from 1994. SIAPS assisted the national committee mandated by the DNPL in updating the legislation, including reviewing relevant local and regional documents to identify needed changes; drafting the bill; convening stakeholder, partner review, and validation meetings; and completing revisions. The draft bill is complete and has been submitted for judiciary review. The next steps are for the bill to be submitted to the government secretary general, the ministerial council, and parliament for approval.

Using data to inform improvements in the procurement and supply planning processes

During the third quarter, SIAPS conducted training on quantification techniques and tools for procurement and supply management technical working group

members. The training was the first of its kind in Guinea and laid the foundation for developing accurate national forecasts and supply plans for antimalarial commodities using best practice tools, such as Quantimed and Pipeline. Eight staff from the national malaria control program (PNLP), the national medicines regulatory authority, the Pharmacie Centrale de la Guinée, and Catholic Relief Services participated in the trainings. Building on the training outcomes, SIAPS supported the PNLN in carrying out a multi-year forecast of antimalarial commodities by using both consumption and morbidity/service statistics data. Preliminary forecast results will be used to develop subsequent supply plans and help the program identify the financial resources required to support malaria program activities through 2022.

HAITI



SIAPS STRATEGY

SIAPS supports the Government of Haiti (GOH) in ensuring the availability of HIV/AIDS and family planning commodities. As such, SIAPS provides assistance to the Direction de la Pharmacie, du Médicament et de la Médecine Traditionnelle (DPM/MT) of the Ministry of Public Health and Population (MSPP) in identifying priority pharmaceutical sector policy gaps to which USAID may provide assistance.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Supporting the implementation of the national medicines policy

During the previous year, SIAPS revised and assisted in the launch and dissemination of the national medicines policy. This year, SIAPS provided guidance to departmental pharmacists on how to implement the national medicines policy and develop a plan for their respective departments.

Strengthening National Supply Chain System

To date, the MSPP has solely relied on donor assistance and NGOs to provide essential medicines and other health technologies to public health sector facilities. This assistance includes procurement, storage, and distribution and has led to the creation of multiple parallel supply chain networks. To address the multiplicity of supply networks and improve coordination, the GOH, as part of its health sector strategy, decided to establish an integrated health supply chain network, the *Système National d'Approvisionnement et de Distribution des Intrants* (SNADI).

SIAPS has been supporting the DPM/MT in analyzing several supply network options to generate information that GOH/MSPP may use for this strategy. SIAPS finalized and presented the results of the options analysis to the SNADI Technical Committee who expressed satisfaction with the results, which will be used to develop the SNADI strategy.



LAC AMAZON MALARIA INITIATIVE

SIAPS STRATEGY

SIAPS supports Amazon Malaria Initiative (AMI) countries in having institutionalized and sustainable national and regional mechanisms to ensure a continuous supply of antimalarials as the key malaria control strategy, particularly in low-incidence areas and remote areas where underserved populations live and work.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Addressing AMI countries' unmet need in malaria commodities

Because of the decrease in malaria incidence, most AMI countries are facing a lack of national suppliers for antimalarials. The problem is even more critical for artemisinin monotherapy (which is no longer recommended by WHO, though still used in Peru) and therapy for severe cases. This implementation year, SIAPS assisted regional workshops and coordination meetings with the Pan American Health Organization (PAHO) strategic fund to implement a pooled procurement of antimalarials and a regional scheme for the donation of medicines for severe cases, which will increase the availability in countries that are still facing problems with local procurement of antimalarials.

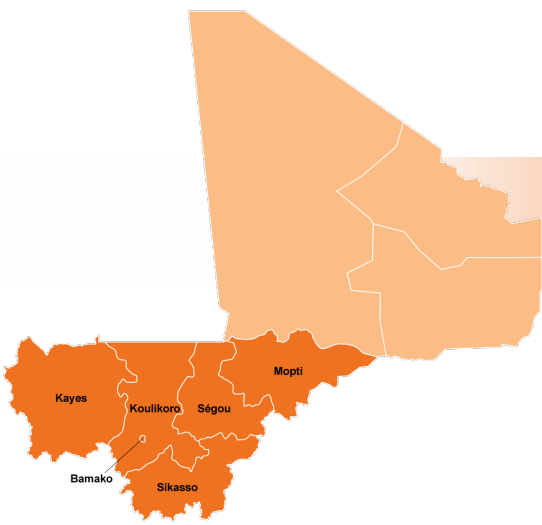
Designing interventions for difficult to reach locations in Brazil

SIAPS worked with local counterparts in Pará and Roraima (Brazil) on the systematization of interventions to improve access to malaria diagnosis and treatment in gold mining areas. SIAPS finalized a technical report on the topic, specific to the Pará region, and included a proposal for results monitoring. In Roraima, SIAPS completed a rapid assessment on the situation of access to malaria treatment in underserved communities. Based on the situation analysis, SIAPS analyzed the results with the Roraima team and identified the most feasible interventions to confront the lack of access to malaria diagnosis and treatment in gold mining areas.

Scaling up a malaria intervention to increase the availability of mefloquine + artesunate fixed-dose combination in Peru

This year, SIAPS provided technical assistance to Peru to assess the introduction of mefloquine + artesunate fixed-dose combination (FDC). The situation was

critical because mefloquine is in short supply, thereby increasing the risk of monotherapy, which in turn, increases the risk of drug resistance. The Peruvian Medicine Directorate and SIAPS implemented the nationwide scale-up of evidence-based malaria pharmaceutical management, including the introduction of FDC. Currently, SIAPS is drafting SOPs for malaria pharmaceutical management and will later provide an assessment of implementation of good storage practices to reduce the temperature in local pharmacies.



SIAPS STRATEGY

In Mali, the SIAPS strategy places specific emphasis on malaria, family planning (FP), and maternal, newborn, and child health (MNCH) commodities. To meet Ministry of Health (MOH) and stakeholder priorities and expectations, SIAPS/Mali focuses on 1) strengthening pharmaceutical sector governance, 2) improving human and institutional capacities, and 3) establishing a functional LMIS.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Improving supply chain management by promoting good governance principles

In 2013, SIAPS aided the MOH in founding a national coordination mechanism, the National Technical Committee for the Coordination and Monitoring of Health Commodities (CNC) to coordinate stakeholders in supply chain management and, in particular, to unify existing program-focused quantification and coordinating committees. This year, SIAPS has supported capacity building through training CNC members and technical working groups (TWGs) on supply planning, OSPSANTE, quantification, and its relevant tools. The active engagement of civil society organizations grew to 26, who have not only increased inclusiveness and transparency, but also enhanced accountability by prompting donors and the MOH to maintain their commitments.

CNC members are now able to use appropriate tools to collect and analyze information for decision making, coordination, and planning. As of August 2016, CNC TWGs had updated 17 malaria and FP supply plans, and the malaria TWG has developed 23 malaria commodity distribution plans. Lastly, the success of the CNC has resulted in the replication of similar coordination mechanisms in six regions.

Informing decision making with quality data

SIAPS assisted the MOH in developing and implementing the information dashboard OSPSANTE (Outil de Suivi des Produits de la Santé), which captures, aggregates, and tracks information on malaria, FP, and MCH commodities. This year, SIAPS continued coaching and mentoring CNC members and facility and district-level managers on OSPSANTE. The general reporting rate by facilities and warehouses has now reached 98%. There has been a reduction in stock-outs in

warehouses from 50% (2013) to 28% (2016) as the central, district, and facility-level staff use OSPSANTE to manage and relocate stock to prevent stock-outs and use commodities before they expire. To further promote supply management for all priority health programs, SIAPS assisted the Directorate of Pharmacy and Medicines in including nutrition and HIV commodities in OSPSANTE.

Building a resilient health system to respond to Ebola

This year, SIAPS began providing technical assistance to the Ebola Emergency Operations Center at the request of the USAID Mission. SIAPS supported the MOH in conducting an assessment and inventory of equipment and infection prevention and control (IPC) commodities in the health facilities of regions located on the border with Guinea and assisted the Ebola quantification TWG in a quantification exercise of IPC commodities. As a result of that exercise, an agreed-upon list of Ebola-related products is now available to all stakeholders. SIAPS is also working with the MOH to include Ebola-related commodities in OSPSANTE.



MOZAMBIQUE

SIAPS STRATEGY

SIAPS/Mozambique works with partners in the pharmaceutical sector and in priority health programs to improve services so that pharmaceutical products are available at service delivery points, prescribed and dispensed appropriately, used correctly by patients, and monitored for safety and efficacy, with the aim of achieving desired health outcomes.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Assisting with the development of an online registration system to improve access to quality medicine

SIAPS continued to support the MOH's Pharmacy Department (PD) in fully implementing Pharmadex, a computerized information system, with the goal of improving the efficiency, accountability, and transparency of the country's national drug registration process. While Pharmadex was launched in 2015, usage was lower than expected in the first half of program year five (PY5). In response, SIAPS conducted a situational analysis to monitor system usage and convened a workshop to review those results, identify obstacles, and develop solutions. SIAPS conducted a follow-up training workshop with staff from the medicine registration unit to go over the process for generating review reports using the new system and assisted the PD to plan for the changes needed to harmonize Mozambique's guidelines for product registration with South African Development Community guidelines. In addition, 4,232 product files containing the primary information needed to process market authorization renewals and variations were converted from paper to electronic format.

These activities positively contributed to the number of days required to approve a product registration application, decreasing from 275 days in December 2015 to 176 days by June 2016. Also in PY5, SIAPS helped the PD establish an M&E framework and system, which is now functional. The PD is now able to monitor its performance and progress and use this information to define priorities and plan appropriate actions to address gaps.

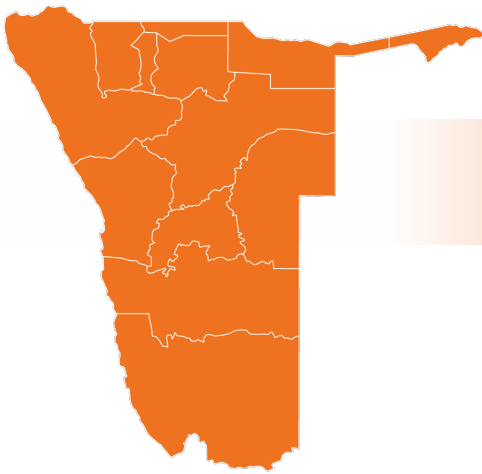
Strengthening governance in the pharmaceutical sector

SIAPS continued to support the Ministry of Health (MOH) by submitting a guide for future revisions of the national essential medicines list (EML), including a

monitoring plan and updates to the terms of reference and the national medicines formulary. Boosted by Pharmadex use, data showed a steady decrease in the average number of days needed to register a pharmaceutical product and a 4% increase in the number of EML products registered, to 68%.

Supporting the capacity of drug and therapeutics committees

In PY5, SIAPS conducted seven supportive supervision visits and one national drug and therapeutics committee (DTC) workshop. The supportive supervision visits were intended to strengthen hospitals' DTC capacity to continuously improve the safe use of medicines at the health facility level. At the workshop, each DTC presented its quality improvement project, collected insights from other committees, and shared success factors. At the end of the workshop, DTCs were able to harmonize therapeutic performance and clarify issues regarding medicine use studies. These activities positively impacted two indicators: the number of people trained in implementing DTCs, at 557 (81% of the life of project target) and the number of sites assisted by SIAPS that implements medicine safety activities and pharmacovigilance, at 13 (162.5% of the life-of-project target).



NAMIBIA

SIAPS STRATEGY

SIAPS/Namibia strives to improve the quality and safety of pharmaceutical services to achieve sustained control over the HIV epidemic. Over the past five years, SIAPS Namibia has focused on interventions that increase the availability of quality antiretrovirals (ARVs), other essential medicines, and services to sustain antiretroviral therapy (ART) coverage to more than 80% of patients in need. SIAPS activities have also contributed to building the capacity of the pharmaceutical workforce for ART service delivery; using routinely collected patient information to make programmatic decisions, such as achieving patient retention in ART to prevent drug-resistant HIV; designing and analyzing financing options for universal health coverage to ART services; and strengthening the Ministry of Health and Social Services' (MoHSS) governance and leadership of ART services.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

During the second quarter, SIAPS supported the development of a second preservice health curriculum for the National Health Training Center pharmacy assistant's course and achieved the country's life-of-project target of two preservice training curricula.

In addition, SIAPS provided technical assistance to the University of Namibia's (UNAM) School of Pharmacy to develop course materials for a preservice training in medicine regulations. This training is part of the curriculum for the UNAM Bachelor of Pharmacy and will ensure that pharmacists graduating from UNAM are equipped with the fundamental knowledge and skills to improve the quality, safety, and efficacy of medicines. As of June 2016, the cumulative number of health care workers who graduated from a preservice training institution or program reached 163 (the life-of-project target is 164).

Enhancing transparency and improving hospitals' capability to monitor and order commodities

With support from SIAPS, Namibia's MoHSS developed a facility electronic stock card (FESC), installed it in 15 hospitals, and scaled it up to all 35 district-level hospitals. SIAPS oriented 30 health workers on the FESC during a five-day, facility-based, on-the-job training. The FESC will automate the ordering process on the basis of consumption and is expected to enhance the visibility of facility-

level stock status data to improve decision making for pharmaceutical services in health facilities. Since its launch in June 2016, the percentage of facilities using consumption data to inform ordering has increased from 20% to 57%, surpassing the life-of-project target of 50%.

Expanding ARV dispensing

SIAPS continued to ensure optimal availability of data in Namibia by providing routine IT support to the MoHSS' 50 primary electronic dispensing tool (EDT) sites. This support was extended to the Intermediate Hospital Oshakati's RxSolution platform and to the e-TB Manager and national database servers.

SIAPS conducted a data quality audit and compared EDT and ePMIS ART active patient and enrollment data for October in nine facilities from five PEPFAR priority regions. Gaps in data from the two tools were identified, and an implementing partner meeting was held with staff from SIAPS, the MoHSS, and IntraHealth at the Onandjokwe District Hospital to identify strategies that would help to reduce those gaps.

Capacity building exercises continued in Namibia, where SIAPS supported the training of second-year National Health Training Centre Pharmacist's Assistant students on the use of the EDT through practical simulations at the training center. A total of 40 students acquired skills on dispensing ARVs to patients, compiling monthly ART reports, and ordering medicines using the EDT.



SIAPS STRATEGY

SIAPS works to improve the management of malaria commodities to increase the availability of products, build the capacity of National Malaria Control Program (NMCP) supply chain staff, mobilize financial resources, and provide technical assistance to improve health outcomes by reducing the negative impact of malaria.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Strengthening the pharmaceutical system to manage seasonal malaria chemoprevention efforts

SIAPS worked closely with the Ministry of Health (MOH) to conduct the 2015 and 2016 seasonal malaria chemoprevention distribution campaigns. A SIAPS technical advisor has been assisting with stakeholder coordination, quantification, procurement, supply planning, and distributing malaria commodities. With efforts by the MOH, SIAPS, and other stakeholders, approximately 75% of the targeted children received antimalarials during the 2015 campaign. Approximately 83% of targeted children aged 3 to 59 months received antimalarials during the first round of the 2016 campaign.

Boosting coordination to improve malaria supply chain management

This year, the NMCP developed its 2016–2020 strategic plan. SIAPS contributed to the plan by drafting the supply chain component. SIAPS provided technical assistance to the malaria supply chain committee by revising malaria data collection tools and reviewing the reporting system and information flow. SIAPS also advocated for the placement of an emergency order through the Global Fund’s procurement mechanism in December 2015, which avoided widespread stock-outs of malaria commodities.

Long-lasting insecticidal net mass distribution campaign in Niamey

This year, the NMCP and its partners prepared for a long-lasting insecticidal net (LLIN) mass distribution campaign targeting the Niamey region. LLINs were procured by both the government (30%) and the Global Fund (70%). During the five-day distribution campaign, 571,311 LLINs were distributed to 174,298 families (for approximately 1,028,000 individuals with a ratio of 1 LLIN for 1.8 people), resulting in a coverage rate of 89%. Because some LLINs have not yet been distributed, the distribution continues at health facilities.

PHILIPPINES



SIAPS STRATEGY

Using a systems strengthening approach, SIAPS/Philippines builds the capacity of TB stakeholders at all levels—national, regional, provincial, city, and barangay (grassroots)—to help reduce the TB burden through increased access to quality and effective pharmaceutical and laboratory services.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Supporting operational research on bedaquiline and its effectiveness in treating MDR-TB

The National TB Program (NTP), in collaboration with SIAPS and other TB partners, began an operational research study to monitor the safety and effectiveness of the nine-month MDR-TB treatment regimen and bedaquiline, the first anti-TB medicine to be approved by the US Food and Drug Administration in more than 40 years. Bedaquiline is considered a particularly significant development in the fight against MDR-TB. The study has been initiated at multiple TB treatment centers. Staff from participating treatment facilities have been oriented on the study protocol and have begun enrolling patients in the study.

Introducing an active pharmacovigilance surveillance system to increase patient safety

SIAPS supported the Food and Drug Administration (FDA) in the Philippines on the adoption of the PharmacoVigilance Monitoring System (PViMS), a web-based application that streamlines and simplifies data collection and analysis of pharmacovigilance (PV) information. In preparation for the adoption of PViMS, SIAPS assisted with several activities, including participating in a workshop with the FDA, NTP, and other stakeholders to develop implementation guidelines for PViMS use.

Further PV support includes working closely with the FDA to improve capacity in active PV surveillance. SIAPS has provided assistance to strengthen adverse event reporting and produce guiding documents for the FDA PV unit to ensure its ability to work effectively during the introduction of bedaquiline.

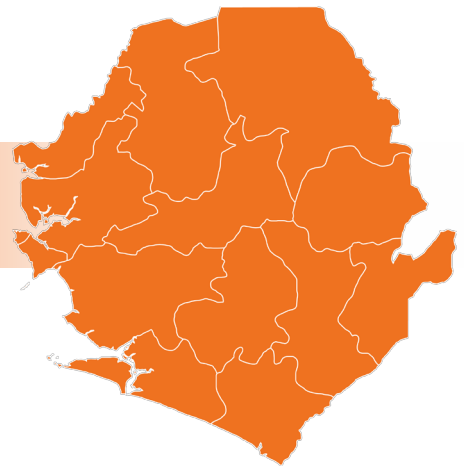
Facilitating the process to introduce a new pediatric TB formulation in the Philippines

During the first quarter of the implementation year, the new pediatric fixed-dose combination TB formulation was included in the Philippine National Formulary, the country's essential medicines list. The new formulation is a dispersible, flavored tablet that dissolves in water. It can be easily administered to children, and it reduces the logistics management burden of the previous bottles of suspension. SIAPS contributed to this success by facilitating collaboration among the NTP, the Pharmaceutical Division, the World Health Organization, and the Global Drug Facility and assisting the NTP in the application process. The NTP, with assistance from SIAPS, quantified the needs and submitted a USD \$2 million procurement order to cover an estimated 55,712 patients from April 2016 to December 2017.

Scaling up community-level TB program management and service delivery

SIAPS continued to support the Quezon City Health Department in scaling up the Barangay Health Management Council (BHMC) Initiative in all six city districts. The initiative brings together community groups, officials, and health providers to improve TB program management and service delivery in poor urban settlements (barangays). This implementation year, SIAPS conducted capacity-building workshops for district health office staff to help scale up district-level plans. The success of the BHMCs also led SIAPS to assist in creating five new BHMCs and drafting a guide for establishing additional BHMCs. The Quezon City Health Department and other stakeholders will use this guide to scale up BHMCs in the city and throughout the country. As of June 2016, 15 BHMCs were established in Quezon City as a direct result of SIAPS' assistance. They covered 30% of the city's 142 barangays with a population of almost 1.1 million (34% of the city's population).

SIERRA LEONE



SIAPS STRATEGY

The SIAPS/Sierra Leone strategy is to contribute to the post-Ebola recovery of the health system as it relates to pharmaceutical management. It is taking a phased approach to addressing functions that were affected by Ebola and rebuilding the system with logistics management, capacity building, and system strengthening initiatives. Interventions that seek to strengthen pharmaceutical management include supply chain governance and coordination; demand planning (quantification); capacity building through trainings, mentorships, and supportive supervision; storage and inventory control; stock status monitoring and reporting; and rational medicine use.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Coordinating government stakeholders to improve governance in the pharmaceutical sector

SIAPS identified the Directorate of Drugs and Medical Supplies (DDMS), which is the Ministry of Health and Sanitation (MOHS) directorate responsible for oversight and support in the pharmaceutical sector, as the primary beneficiary of capacity building and the entry point to district health management teams (DHMTs) and health facilities. SIAPS provided technical assistance in the development of terms of references and with a DDMS organogram that is awaiting endorsement by the MOHS.

SIAPS/Sierra Leone has quickly established itself as a credible collaborator on a number of common issues requiring coordination between the three pharmaceutical entities of the MOHS: the DDMS, The National Pharmaceutical Procurement Unit, and the Pharmacy Board of Sierra Leone (PBSL). This promotes consensus building, sharing information, and harmonizing roles to help ensure access to quality and safe medicines and promote rational use.

Capacity building at the central level to improve governance and enhance the procurement process

Because capacity building is an associated component of SIAPS's technical assistance for strengthening DDMS governance and leadership, SIAPS has initiated plans to provide leadership training through the leadership development program for DDMS managers, including district pharmacists, and potentially

PBSL officials. Technical assistance this year included significant technical and advocacy support toward finalizing the 2016 National Essential Medicines List, which is now being printed.

A two-week workshop on quantification, designed to build capacity in the principles of forecasting and supply planning, was attended by 53 health professionals at all levels. This resulted in the MOHS approving and establishing a National Quantification Committee. SIAPS also assisted in conducting a parallel training on multi-year TB medicine quantification. Electronic quantification tools (Quantimed, Pipeline, and QuanTB) have now been installed on two dedicated computers provided by SIAPS.

Developing a system to track supply chain recovery and resilience in district health facilities

To ensure proactive supportive supervision for health facilities, SIAPS introduced a Continuous Results Monitoring and Support System (CRMS), which uses a checklist to track stock availability, expiries, the availability and use of information system tools, and the status of storage conditions. The checklist tracks tracer and key medicines, including health program products such as antiretroviral, TB, malaria, and reproductive products, and is used to monitor performance and results on a bimonthly basis. The data collected through the CRMS process and other sources will be used to quantify the procurement of health care supplies for 2017. The first round of CRMS was rolled out in 11 districts and 927 health facilities, covering 80% of peripheral health units.

SIAPS also provided technical guidance and support to the Department of Planning Policies and Information to design and validate a new treatment register for use at the health facility level to track conditions treated and medicines dispensed. This tool, along with ongoing use of CRMS, will bolster effective data management and supply chain decision making. Three facilities have begun piloting the register.

SOUTH AFRICA



SIAPS STRATEGY

SIAPS/South Africa aims to strengthen pharmaceutical sector governance; enhance the capacity for pharmaceutical supply management and services; and improve the use of information for decision making for pharmaceutical services, access to medicine, the availability of medical products, rational medicine use, and patient safety.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Assisting in the expansion of nursing functions to improve access of pharmaceutical services

This year, SIAPS assisted in finalizing a policy as part of South Africa's Nursing Act of 2005, which authorizes nurses to perform clinical and prescribing functions. SIAPS was part of the team that assisted the National Department of Health (NDOH) to implement this policy, which addressed the uncertainty related to the authority of a nurse to examine a patient, make a diagnosis, or prescribe medicine. Activities included describing the competencies of nurses to perform these functions and developing software to support the process.

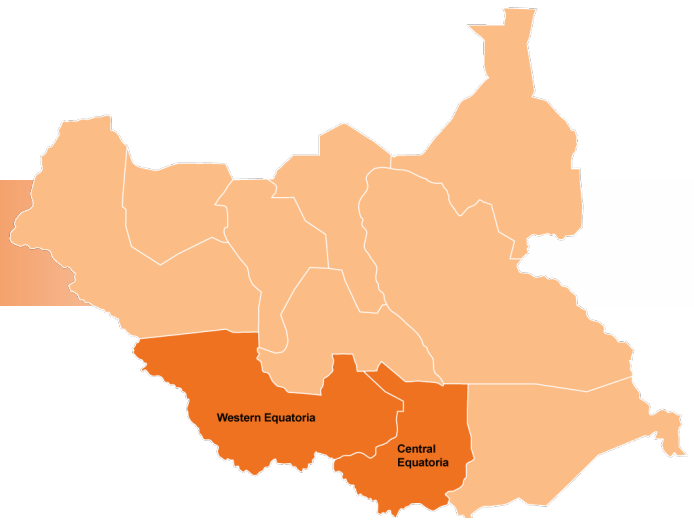
Successfully supporting pharmaceutical leaders through innovative pre- and in-service trainings

SIAPS/South Africa exceeded the life of project targets for persons trained in pharmaceutical management (1,206 people against the target of 1,104) and new health care workers graduating from a program that includes preservice training (499 graduates against the target of 340). In addition, SIAPS worked with the Pharmaceutical Services Directorate in the Free State to finalize and implement the Pharmaceutical Leadership and Governance Initiative, which helped address challenges related to medicine supply management identified by the auditor general. By the end of the implementation year, all capacity-building efforts to enhance the skills of pharmaceutical service personnel were closed and turned over to stakeholders. Aspects of the leadership development program (LDP) course content and facilitation materials were transitioned to Sefako Makgatho University, and technical reports on all LDP and pharmaceutical LDP activities were completed.

Integrating RxSolution to facilitate comprehensive pharmaceutical service delivery

In 2014, the NDOH endorsed RxSolution as a tool for managing pharmaceutical inventory. To ensure its full function, SIAPS supported RxSolution's interfacing with six other information systems, including the National Hospital Dashboard. Through interfacing, RxSolution monitors medicines from ordering to dispensing to patients, and the information can be stored in a central database. To support the sustainability of RxSolution in public health facilities, SIAPS partnered with higher learning institutions and integrated training on RxSolution into the preservice curricula for pharmacists and mid-level pharmacy personnel. By September 2016, 453 facilities were using RxSolution for stock management and dispensing medicine to patients, exceeding the target of 435 facilities.

SOUTH SUDAN



SIAPS STRATEGY

SIAPS/South Sudan aims to ensure the availability of quality pharmaceutical commodities, such as artemisinin-based combination therapy, antiretrovirals, family planning, and other essential products, and effective pharmaceutical services to achieve desired health outcomes, such as preventing maternal and child deaths and malaria deaths, as well as contributing to an AIDS-free generation. The long conflict in South Sudan disrupted the health system and caused considerable weaknesses and gaps in all areas of the pharmaceutical system. In response to the conflict, SIAPS remains flexible, adapting its technical assistance within the context of a fragile state.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Boosting information availability for improved pharmaceutical management and service delivery

This year, SIAPS piloted a pharmaceutical dashboard in three counties of the former Central Equatoria State (CES) in close collaboration with the Logistics Management Unit (LMU) to generate stock status reports for tracer medicines. SIAPS provided support to the LMU to install and customize the pharmaceutical dashboard, an online platform for managing stock levels of essential medicines, including antiretroviral therapy (ART)-related commodities, to provide more accurate information. SIAPS has been working with the LMU to generate reports that will inform decision making.

The electronic dispensing tool (EDT) was installed at the Juba Teaching Hospital ART Center this year and is now functioning well with minimal support from SIAPS staff. The EDT now has a database of more than 3,000 patient records and generates monthly stock status and patient usage reports. The IT support has been an effective means of ensuring that technical issues are resolved as soon as they are identified, which has enhanced efficient operations at the site.

Increasing the skills of pharmaceutical staff through supportive supervision and in-service training

SIAPS conducted training workshops in pharmaceutical management, rational medicine use, and malaria for health care workers in both the former Western Equatoria State and the former CES. SIAPS disseminated copies of the training

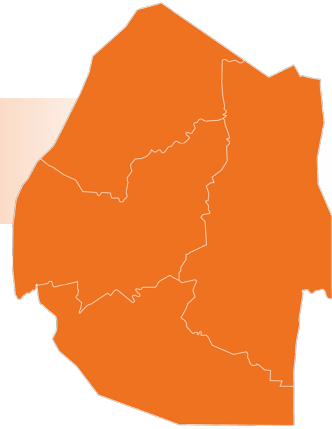
manuals, tools, and handouts. As a result of the trainings, post-training action plans were developed.

SIAPS conducted supportive supervision visits to several counties in the CES. As part of the activity, SIAPS and other supervision team members collected continuous results monitoring system data and provided on-the-job training to improve the capacity of health workers at health facilities.

Coordinating stakeholders to guarantee medicine availability during civil unrest

SIAPS assisted South Sudan's Ministry of Health in convening meetings of the pharmaceutical technical working group and the emergency medicines fund throughout program year five, including during a period of violence and civil unrest. These partner coordination meetings provide a platform for sharing pharmaceutical information to support more informed decision making and are a critical component of the country's efforts to address gaps in essential medicine stock management.

SWAZILAND



SIAPS STRATEGY

SIAPS/Swaziland endeavors to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes for HIV/TB care and treatment. The program objectives include strengthening pharmaceutical sector governance, increasing the capacity for pharmaceutical supply management and services, improving the use of pharmaceutical information for decision making in supply chain, improving product availability and rational use of HIV/TB commodities, and promoting patient safety. All interventions are designed and implemented as guided by Swaziland government policy documents and strategies for the health sector.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Supporting legislative efforts to better enable the MOH to respond to public health needs

Swaziland has made significant progress toward the approval and enactment of the Medicines and Related Substances Control Bill and the Pharmacy Bill, which will replace existing legislation that dates back to 1929. Both bills, which were developed with support from SIAPS and its predecessor project, were presented to the House of Assembly for final deliberations, and the Medicines and Related Substances Control Bill was approved by both houses of parliament for presentation to the king for endorsement. SIAPS is assisting the Chief Pharmacist's Office in preparing a report for submission to the king for the enactment of the Medicines and Related Substances Control Bill, which provides for the establishment of Swaziland's first medicines regulatory authority. SIAPS will also support the Chief Pharmacist's Office in preparing for a joint house sitting on the Pharmacy Bill, which is expected to take place by the end of 2016.

Establishing Swaziland's first medicines regulatory authority

SIAPS assisted the Ministry of Health (MOH) with reviewing the implementation plan for the new medicines regulatory authority, which is pending enactment of new pharmaceutical legislation, and with improving the regulation of imported medicines. SIAPS helped update the medicines listing database and the registration status for all medicines used in the public sector; develop the medicines quality control laboratory action plan; and establish procedures for monitoring the importation, consumption, and supply of narcotics. In addition,

SIAPS provided input on the African Union Model Law on the Harmonization of Medicines Regulation on behalf of Swaziland and the South African Development Community at a meeting led by the New Partnership for African Development of the African Union.

Expanding pharmacovigilance activities to include the use of PViMS

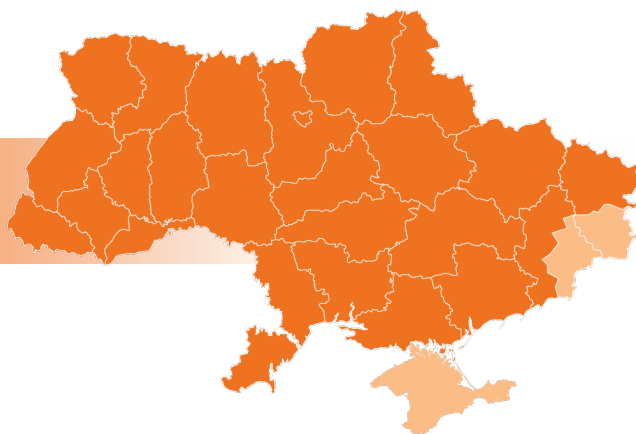
This year, SIAPS continued its support to the Pharmacovigilance (PV) Unit in managing the country's seven active surveillance PV sentinel sites and continued to issue the Medicines Safety Watch newsletter to disseminate important PV-related updated to stakeholders. To support improved treatment of patients with XDR-TB, SIAPS supported the National TB Control Program in rolling out and integrating bedaquiline into treatment programs. The SIAPS-developed, web-based PViMS was adapted to include the bedaquiline implementation guidelines, which are expected to be useful to other countries introducing bedaquiline.

In support of the "Test and Start" initiative in Swaziland, SIAPS is continuing to integrate the PV system into the national AIDS program as a routine part of monitoring treatment quality and patient safety. Currently, 4,176 patients are enrolled in the active surveillance program (52% females, 48% males), and 1,212 adverse drug reactions have been reported by clinicians (68% related to anti-TB medicines and 32% related to antiretrovirals) since the program's inception.

Strategizing to contain antimicrobial resistance in Swaziland

To halt the spread of antimicrobial resistance, SIAPS supported the MOH in drafting the terms of reference for the National Antimicrobial Resistance Containment Committee, which will be responsible for drafting the Antimicrobial Resistance Containment Plan/Strategy. Committee members have been appointed, and the MOH and SIAPS are partnering with the World Health Organization to create the strategy. The first draft is anticipated to be finalized in the coming months.

UKRAINE



SIAPS STRATEGY

SIAPS/Ukraine focuses on improving access to and rational use of medicines and on developing policies and frameworks that enable the pharmaceutical system in Ukraine to function with transparency and accountability. Specifically, SIAPS/Ukraine provides technical assistance to the Ministry of Health and other stakeholders to identify and implement strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system that will enhance responsive and resilient system performance and ultimately achieve better health outcomes.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Advocating for streamlined regulation in the procurement process

During the fifth implementation year, SIAPS has been assisting the Government of Ukraine in establishing a national essential medicines list (NEML) to be used as the country's sole list for public procurement and potentially for reimbursement. SIAPS helped draft and advocate for the approval of two regulations in support of this activity, as well as an amendment to a Cabinet of Ministers of Ukraine decree to address a regulatory obstacle. These two regulations will control the NEML's development and adoption process and provide the foundation and guidance for the Competition Committee responsible for conducting the competition-based selection of candidates for the Expert Committee. With the approval of these regulations, the Government of Ukraine has achieved an important milestone toward establishing a NEML. The Essential Medicines List Expert Committee has since been formed and is currently drafting the NEML.

Increasing transparency with a medicines pricing tool to compare medicine pricing and availability

The Ukraine Medicines Price Observatory is a SIAPS-developed tool that increases transparency in medicine pricing in Ukraine by allowing users to investigate the causes of price differences, determine the availability of medicines at the central and regional levels, and compare prices with those on the international market. To further increase the tool's accountability and transparency, it was officially transferred to the All Ukrainian Network of People Living with HIV, a civil society organization, in June 2016. During the first five months of operation (May–September 2016), the tool was accessed 544 times by 404 users.

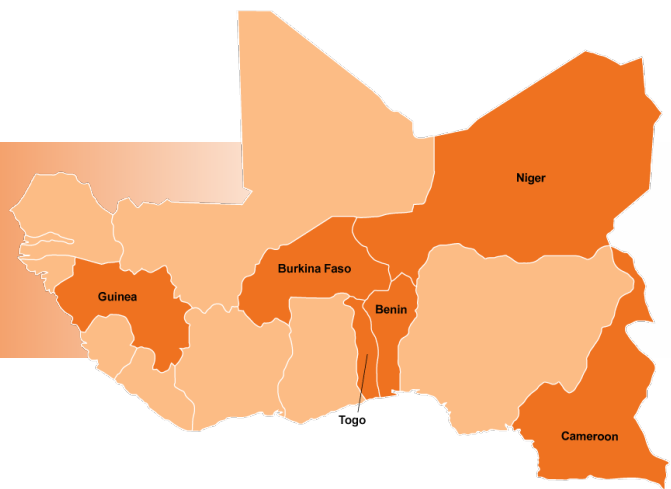
Evaluating pharmaceutical services for better service provision in the HIV and TB sectors

SIAPS collected data for a drug utilization review (DUR) in the HIV and TB sectors to evaluate medicine prescribing, administration, and use. SIAPS' assistance included drafting technical reports and presentations. In April 2016, SIAPS hosted a stakeholder meeting to present the final results in both the HIV and TB sectors. Stakeholders approved the reports and expressed an interest in expanding the DUR to other health facilities, such as AIDS centers and TB dispensaries. The final Ukrainian version of the DUR report for the HIV sector is being prepared for electronic publication, and the executive summary of the English version is being finalized.

Assessing the national supply chain and identifying opportunities to strengthen the system

SIAPS conducted a national supply chain assessment to systematically review existing gaps in the supply chain and prioritize them according to their impact if and when they are addressed. SIAPS organized a working group, provided technical assistance on the methodology, and trained data collectors. In September 2016, the assessment report was finalized and is expected to be presented to stakeholders by the end of October 2016.

WEST AFRICA REGIONAL PROJECT



SIAPS STRATEGY

SIAPS/West Africa Regional Project facilitates the availability of quality pharmaceutical products, especially those related to HIV/AIDS, to achieve high level, desirable health outcomes in targeted West Africa countries.

SIAPS provides support to six target countries in the West and Central Africa region—Benin, Burkina Faso, Cameroon, Guinea, Niger, and Togo—to address recurrent pharmaceutical supply management issues.

HIGHLIGHTS FROM PROGRAM YEAR FIVE

Transitioning the management of OSPSIDA in a sustainable manner

SIAPS developed an HIV/AIDS commodities tracking tool, Outil de suivi des produits du VIH/SIDA en Afrique de l'Ouest (OSPSIDA), a web-based system that provides an early warning system dashboard to monitor HIV/AIDS commodity availability and related information. SIAPS has deployed OSPSIDA in all six focus countries and is in the process of transitioning management to the West Africa Health Organization (WAHO). A proposal establishing a transition committee and its roles and responsibilities was presented to WAHO, and SIAPS conducted a training to familiarize WAHO staff with OSPSIDA management. However, given that WAHO is not an executive body to make final decisions on OSPSIDA, WAHO and SIAPS will also explore options to transfer OSPSIDA management-related activities to the Central Medical Stores (CMS) of Cote d'Ivoire, as the CMS currently hosts and manages the WAHO security stock.

Averting stock-outs in Togo by using OSPSIDA's early warning system

SIAPS supported the National AIDS Control Program of Togo (PNLS) to use OSPSIDA to incorporate patient and commodity data to assess the impact of potential stock-outs on patients receiving ARVs. Updating OSPSIDA with 2014 data revealed that 71% of ARVs in use in Togo were at high risk of stock-out at the national level, putting 96% of patients at high risk of treatment interruption. However, this 96% was reduced to less than 1% in November 2015 with close support from SIAPS. Deploying OSPSIDA in Togo has significantly enhanced the visibility of supply chain data for timely and evidence-based decisions that have contributed to the increased availability of HIV/AIDS products within a year.

Generating quality data to improve pharmaceutical services and patient care

The Togo's PNLs has identified the need to improve the management of patient and commodity data at ARV dispensing sites to have reliable data for resupply, forecasting, and quantification. Best practices learned from the Electronic Dispensing Tool (EDT) implementation in five pilot sites during the fourth program year were used to support the development of a concept note for a nationwide roll out, which has been approved by the Global Fund. This year, SIAPS installed the new version of EDT at four of the pilot sites, and the results of a field visit showed that the concordance between EDT records and prescriptions at each of the four dispensing sites was still 100%. SIAPS is now working with the PNLs on a nationwide roll out of EDT.



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