



# **TOWARD BUILDING RESILIENT PHARMACEUTICAL SYSTEMS:** SIAPS FINAL REPORT



**USAID**  
FROM THE AMERICAN PEOPLE

**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 ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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# ACRONYMS AND ABBREVIATIONS

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ACT	artemisinin-based combination therapy
ADE	adverse drug event
ADR	adverse drug reaction
aDSM	active drug safety monitoring and management
AFG	AIDS-free Generation
AIDS	acquired immunodeficiency syndrome
AMI	Amazon Malaria Initiative
AMR	antimicrobial resistance
AMRH	African Medicines Regulatory Harmonization Program
APTS	Auditable Pharmaceutical Transactions and Services (Ethiopia)
ART	antiretroviral therapy
ARV	antiretroviral
BHMC	Barangay Health Management Council
CASG	community adherence support group
CBART	community-based ART
CHW	community health worker
CMS	central medical store
CRMS	Continuous Results Monitoring System
DGDA	Directorate General of Drug Administration (Bangladesh)
DGFP	Directorate General of Family Planning (Bangladesh)
DGHS	Directorate General of Health Services (Bangladesh)
DOH	Department of Health
DPMED	Department of Pharmacy (Benin)
DRC	Democratic Republic of the Congo
DR-TB	drug-resistant tuberculosis
DTC	Drug and Therapeutics Committee
EAC	East African Community
EDT	Electronic Dispensing Tool
EHRIG	Ethiopian Hospital Reform Implementation Guideline
EML	essential medicines list
EPMCD	Ending Preventable Child and Maternal Deaths
EUV	end-use verification (survey)
FDA	Food and Drug Administration
FP	family planning
GDF	Global Drug Facility
GHeL	Global Health eLearning Center
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
iCCM	integrated community case management
LAC	Latin American and Caribbean
LMIC	low- and middle-income country



LMIS	logistics management information system
M&E	monitoring and evaluation
MDR-TB	multidrug-resistant tuberculosis
MNCH	maternal, newborn, and child health
MOH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare (Bangladesh)
MSH	Management Sciences for Health
NEML	national essential medicines list
NEPAD	New Partnership for African Development Agency
NHTC	National Health Training Centre (Namibia)
NMCP	National Malaria Control Program
NMRC	Namibia Medicines Regulatory Council
NTP	National TB Program
PAHO	Pan American Health Organization
PCID	Protecting Communities from Infectious Diseases
PEPFAR	US President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PMIS	pharmaceutical management information system
PNLP	National Malaria Control Program (Guinea)
PNLS	National AIDS Control Program (Togo)
PSM	procurement and supply management
PSS	pharmaceutical systems strengthening
PV	pharmacovigilance
PViMS	Pharmacovigilance Monitoring System
RMU	rational medicine use
RDT	rapid diagnostic test
RSS	regulatory systems strengthening
SCM	supply chain management
SCMS	Supply Chain Management System (Program)
SDG	Sustainable Development Goal
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	standard operating procedure
STG	standard treatment guideline
TB	tuberculosis
TOR	terms of reference
TWG	technical working group
UHC	universal health coverage
UNAM	University of Namibia
UNCoLSC	UN Commission on Life-Saving Commodities
USAID	US Agency for International Development
USG	United States Government
WAHO	West Africa Health Organization
WARP	West African Regional Program
WHO	World Health Organization





## A MESSAGE FROM THE SIAPS PROGRAM DIRECTOR

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One of the most thrilling aspects of SIAPS for me has been watching the evolution of pharmaceutical systems strengthening activities and having the satisfaction of seeing work that began in many countries more than a decade ago with SIAPS predecessors take root, grow, and impact health systems and the lives of many—both patients and health workers. These are not one-off projects, because our work is never done. It moves forward on a continuum, building on progress, expanding to take advantage of new opportunities. We began with a focus on the product; now we focus on the patient and health outcomes. I think about Namibia, where we started with basic supply chain improvement and are now helping implement mobile technology for patient management, or Ethiopia, where we started with the distribution of ARVs and ended up assisting with the establishment of an electronic medicine registration system.

The capacity building work we've done will endure, to the benefit of country systems, other projects, and future activities. This is due in great part to our most valuable asset: the people who have worked with SIAPS, mostly chosen from the countries in which we work. They come from all levels and walks of life: project staff, government leaders, partners, educators, health workers. We have all been part of this grand effort, sharing a vision and a mission.

Our staff are a cadre of talented, dedicated professionals with a wealth of technical knowledge. Skilled people are vital to any functioning pharmaceutical system, and even as SIAPS closes, these colleagues continue their work to transfer their knowledge all over the world. For example, our country lead in Liberia now heads the medicines and health products regulatory authority there, carrying the torch of our work and helping make sure that the population has access to lifesaving medicines.

Thanks to this community—you—the future of our work is bright. I'm excited to see the next chapter, when we collectively continue to shine a light on all components of the pharmaceutical system and not just the supply chain to ensure improved access, improved services, and the attainment of desired health outcomes.

— Francis Aboagye-Nyame, SIAPS Program Director



# SIAPS PARTNERS

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Management Sciences for Health



Accreditation Council for Pharmacy Education



Harvard University  
— Pilgrim Institute  
— School of Public Health



Logistics Management Institute



University of Washington's Department of Global Health



Boston University



African Medical and Research Foundation



Ecumenical Pharmaceutical Network



Results for Development



Imperial Health Sciences

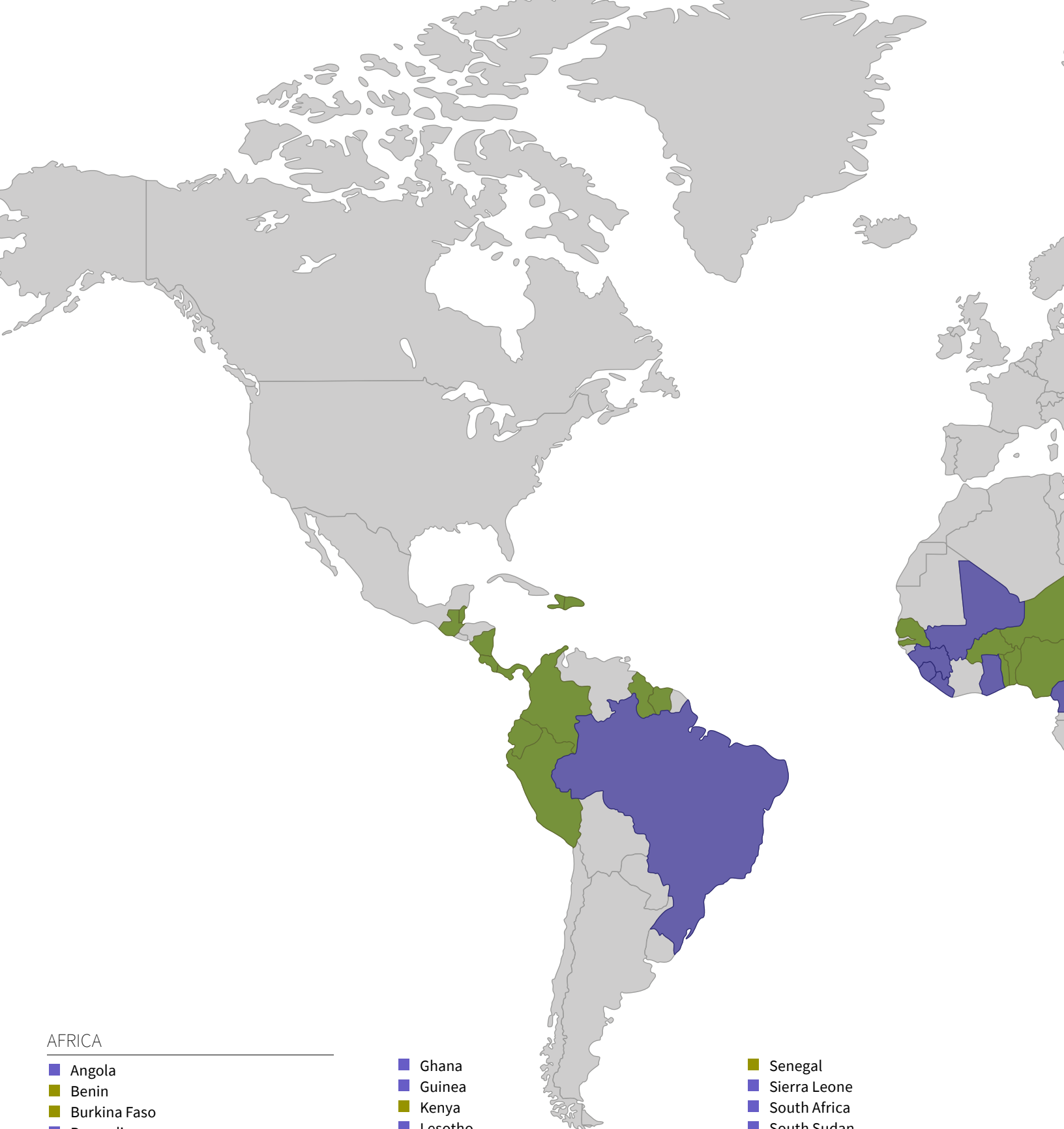


VillageReach



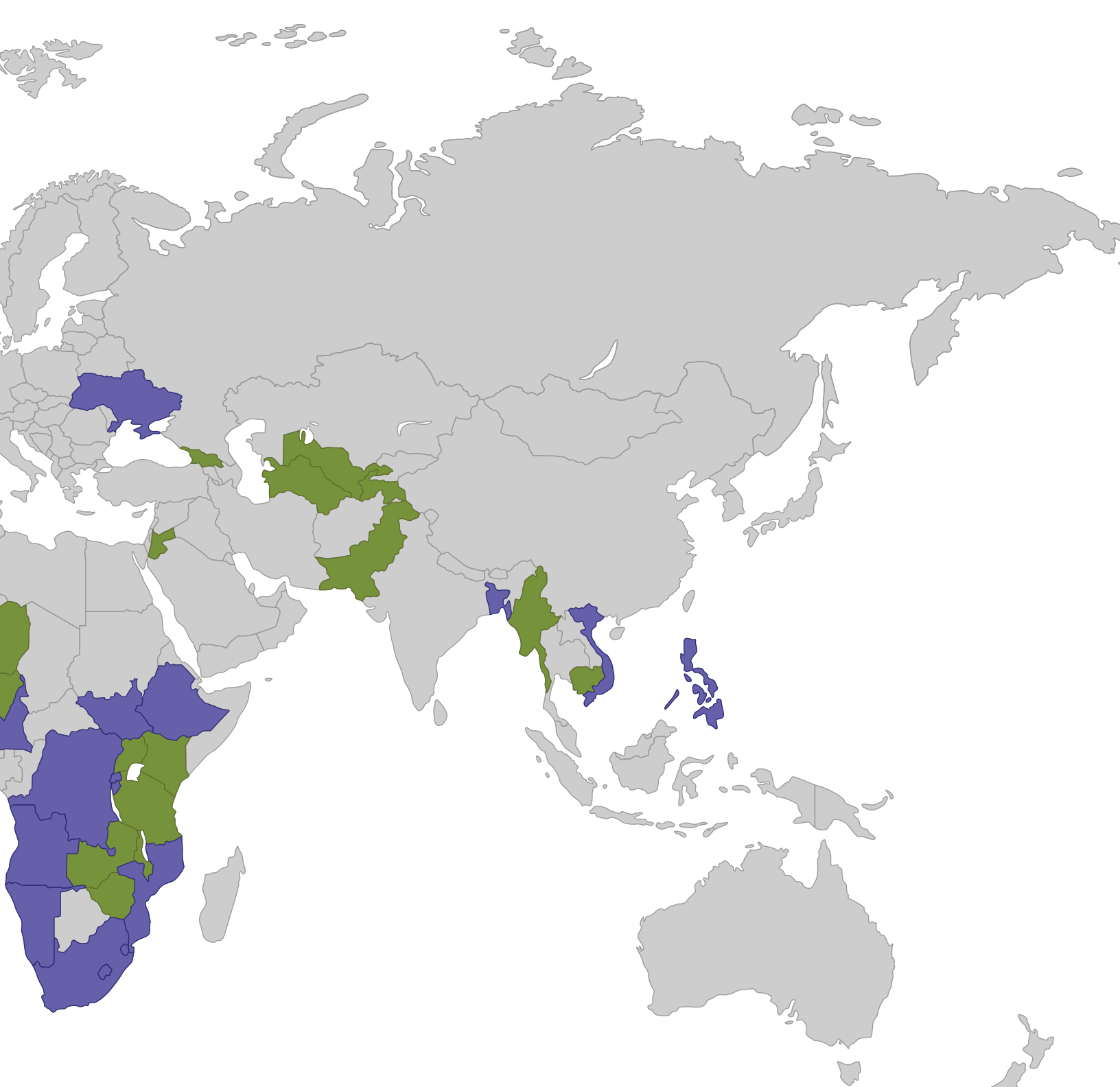
William Davidson Institute





AFRICA

- |   |              |   |
|---|--------------|---|
| ■ Angola  | ■ Ghana      | ■ Senegal   |
| ■ Benin   | ■ Guinea     | ■ Sierra Leone  |
| ■ Burkina Faso  | ■ Kenya      | ■ South Africa  |
| ■ Burundi   | ■ Lesotho    | ■ South Sudan   |
| ■ Cameroon  | ■ Liberia    | ■ Swaziland   |
| ■ Democratic Republic of the Congo  | ■ Malawi     | ■ Tanzania  |
| ■ EAC (East African Community) – Burundi, Kenya, Rwanda, Tanzania, and Uganda                                   | ■ Mali       | ■ Togo  |
| ■ ECSA-HC (East Central and Southern Africa Health Community) – Malawi, Swaziland, Tanzania, Uganda, and Zambia | ■ Mozambique | ■ Uganda  |
| ■ Ethiopia  | ■ Namibia    | ■ WARP (West African Regional Program) – Benin, Burkina Faso, Cameroon, Guinea, Niger, and Togo |
|   | ■ Niger      | ■ Zambia  |
|   | ■ Nigeria    | ■ Zimbabwe  |
|   | ■ Rwanda     |   |



ASIA

- Bangladesh
- Burma
- Cambodia
- Pakistan
- Philippines
- Vietnam

EASTERN EUROPE & CENTRAL ASIA

- Georgia
- Ukraine
- Tajikistan
- Turkmenistan
- Uzbekistan

LATIN AMERICA & CARIBBEAN

- Amazon Malaria Initiative (LAC/AMI)  
– Belize, Brazil, Colombia, Costa Rica,  
Ecuador, Guatemala, Guyana, Nicaragua,  
Panama, Peru, and Suriname
- Brazil
- Colombia
- Dominican Republic
- Haiti
- Peru

MIDDLE EAST

- Jordan

■ SIAPS Field Offices

■ SIAPS TA Countries







# OVERVIEW OF THE SIAPS PROGRAM

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## Introduction

Essential medicines are indispensable for improving the health and saving the lives of people who need them. However, to be fully effective, safe, available, and affordable, medicines must be correctly prescribed and appropriately used. Achieving these benchmarks requires a strong, responsive pharmaceutical system working within and in support of a functioning health system. Strengthening the entire pharmaceutical system addresses systemic deficiencies, going beyond the selection, procurement, and distribution of pharmaceutical products to include the provision of pharmaceutical services (i.e., dispensing and supplying pharmaceuticals to individuals and providing medication-related information and counseling and support for self-care).

Strengthening efforts demand a commensurate legal and policy foundation coupled with good governance practices to minimize and mitigate opportunities for inefficiencies and corruption. By doing so, pharmaceutical systems are well positioned to respond to health challenges such as controlling the costs of medicines and services, which cannot be ignored as countries move along the path toward universal health coverage (UHC).<sup>1</sup>

From 2011 to 2018, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program worked with local counterparts and partners in 46 countries to comprehensively strengthen pharmaceutical systems by addressing five interrelated health systems functions—governance, human resources, information, financing, and service delivery—to ultimately address disease-specific and country needs.<sup>2</sup> The SIAPS pharmaceutical systems strengthening (PSS) approach ensured equitable access to and appropriate use of effective pharmaceutical technologies and medicines for diagnosis and treatment of major

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<sup>1</sup> World Health Organization. 2014. *Medicines in Health Systems: Advancing access, affordability and appropriate use*. Maryam Bigdeli, David H. Peters, Anita K. Wagner (Eds).

<sup>2</sup> World Health Organization. 2007. *Everybody's business: strengthening health systems to improve health outcomes: WHO's framework for action*. Geneva: WHO

public health areas, including malaria; HIV/AIDS; family planning; maternal, newborn, and child health (MNCH); tuberculosis (TB); neglected tropical diseases (NTDs); and, more recently, Ebola. By helping countries meet disease-specific targets, the SIAPS implementation strategy strengthened pharmaceutical systems to provide a wider range of medicines and pharmaceutical products, ultimately producing improved health outcomes.

The SIAPS PSS approach aligned with USAID's Vision for Health Systems Strengthening (2015–2019). SIAPS also remained committed to the President's Malaria Initiative (PMI) and the President's Emergency Plan for AIDS Relief (PEPFAR) goals and was a strategic partner supporting additional US Government (USG) global health initiatives—UHC, Ending Preventable Child and Maternal Deaths (EPCMD), achieving an AIDS-free Generation (AFG), and Protecting Communities from Infectious Diseases (PCID). SIAPS used platforms presented by PMI, PEPFAR, and other USAID-funding streams to accelerate advancement of these goals.

## SIAPS Operations and Funding

SIAPS was implemented by Management Sciences for Health (MSH) together with a host of core and resource partner organizations. Over the life of the program, SIAPS worked in 46 countries, with field offices in 22 countries. The SIAPS program ceiling was initially \$197,926,458 over five years. At the end of fiscal year 2015, SIAPS was granted an extension of 12 months until September 30, 2017, and the program ceiling increased to \$225,926,458. In September 2017, SIAPS received an additional program ceiling increase to \$244,424,225 through March 22, 2018.

To achieve the program's goals, SIAPS fostered its collaboration with a number of partnering organizations. The partnership with a consortium of core partners and specialized resource partners brought a wide-ranging mix of skills and expertise to SIAPS.

- Core Partners: Accreditation Council for Pharmacy Education (ACPE), Harvard University (Harvard Pilgrim Health Care (HPHC) and Harvard School of Public Health (HSPH)), Logistics Management Institute (LMI), and the University of Washington (UW)
- Specialized Resource Partners: African Medical and Research Foundation (AMREF), Ecumenical Pharmaceutical Network (EPN), Research for Development (R4D), Imperial Health Sciences (IHS) (formerly RTT Group), VillageReach, and William Davidson Institute (WDI)

Country teams were supported by a program management team at the SIAPS headquarters in Arlington, Virginia. This ensured that quality work plans and reports were delivered on time and that technical and other resources were mobilized. In addition, the program management team was in close proximity to liaise with USAID/Washington, other MSH technical units, and partners to guarantee that country programs had the required resources to achieve SIAPS' goals.

## How SIAPS Worked: A Systems Strengthening Framework to Guide Activities

To plan, coordinate, and implement its comprehensive approach, SIAPS followed a PSS framework (figure 1) that supported the design, implementation, and monitoring of program activities in five areas, which mirror the program's intermediate result (IR) areas:

1. Strengthening pharmaceutical sector **leadership and governance** and establishing sound policies and legislation
2. Building **human resource** and **institutional capacity** for more sustainable organizations
3. Addressing **information** needs to support decision making in pharmaceutical systems

4. Improving **financing** strategies and mechanisms to ensure adequate funding and effective use of resources
5. Providing effective **pharmaceutical services** that meet the needs of the patient and achieve desired health outcomes

The framework also integrated the medical products function at the center of these foundational elements. Key stakeholders were government, providers, and the community. Strengthening through this framework helped ensure that pharmaceutical systems made a full contribution to a health system's performance—ultimately increasing access to medicines and leading to better health outcomes.

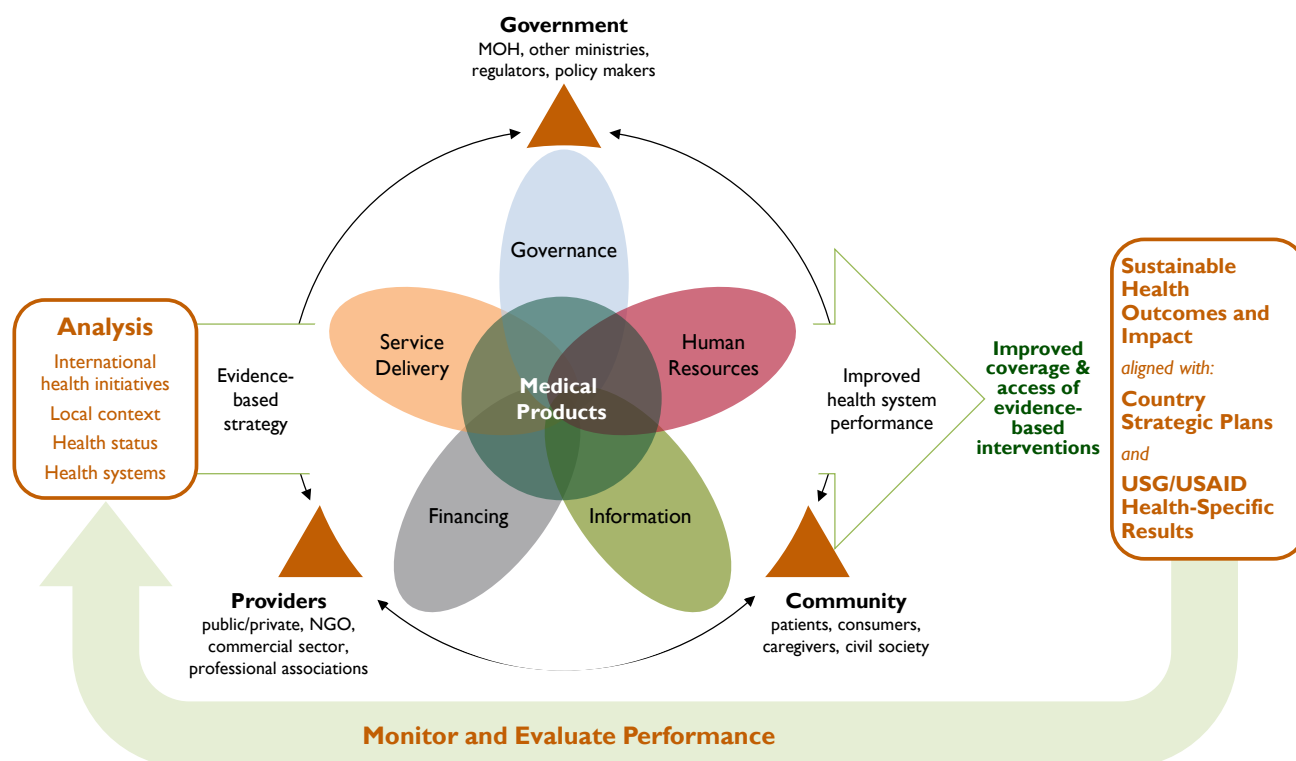


Figure 1. SIAPS framework for PSS

The SIAPS approach involved a systematic, analytical, and evidence-based process to achieve results. This approach required the availability of relevant, validated, and reliable data to represent the country context, the health status of the target community, and the performance of the health system. Ultimately, the results framework was designed to demonstrate a change in pharmaceutical system performance that is linked to SIAPS activities.

USAID Mission-approved country activities were implemented in a multipronged manner that incorporated up to five of the health systems functions. This technical focus was reflected in the expected intermediate results for the SIAPS program (figure 2).

SIAPS incorporated a monitoring and evaluation approach that effectively integrated quantitative and qualitative evidence as gauges of progress toward stated program objectives and intermediate results that assessed progress across the health system functions. By tracking progress against identified outcome targets and assessing these results against activities conducted (by using output/process indicators), SIAPS technical advisors and their government counterparts could access evidence needed to make informed decisions. These decisions affected activity implementation, resource allocation, and geographic targeting.



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

IR1	IR2	IR3	IR4	IR5
Pharmaceutical sector governance strengthened	Capacity for pharmaceutical supply management and services increased and enhanced	Information for decision making challenges in the pharmaceutical sector addressed	Financing strategies and mechanisms strengthened to improve access to medicines	Pharmaceutical services to achieve desired health outcomes improved
<p><b>1.1</b> Good governance principles embodies across all health systems components.</p> <p><b>1.2</b> Improved medicines, policies, legislation, regulations, norms, and standards.</p> <p><b>1.3</b> Transparent and accountable pharmaceutical management systems.</p> <p><b>1.4</b> National pharmaceutical sector development plans are strategic and evidence based.</p>	<p><b>2.1</b> Pharmaceutical management capacity of individuals, institutions, organizations and networks strengthened.</p> <p><b>2.2</b> Local institutions and organizations provide pharmaceutical services and TA in pharmaceutical system strengthening.</p> <p><b>2.3</b> Innovative and proven approaches for human resource capacity building adopted and implemented.</p>	<p><b>3.1</b> Pharmaceutical management information systems (PMIS) support both products and patients.</p> <p><b>3.2</b> Innovative and proven tools broadly available and used.</p> <p><b>3.3</b> Strategic information on pharmaceutical systems strengthening available used.</p>	<p><b>4.1</b> Financial barriers reduced.</p> <p><b>4.2</b> More efficient use of existing resources.</p> <p><b>4.3</b> Additional financial resources are generated.</p>	<p><b>5.1</b> Availability of pharmaceuticals improved.</p> <p><b>5.2</b> Patient safety and therapeutic effectiveness assured.</p> <p><b>5.3</b> Medication use improved.</p> <p><b>5.4</b> pharmaceutical services standard defined, adopted and implemented.</p> <p><b>5.5</b> Emergence of antimicrobial resistance (AMR) slowed.</p>

Figure 2. SIAPS results framework

## SIAPS Legacy

The work done between 2011 and 2018 solidified important technical concepts and advanced and consolidated systems strengthening work, with many countries achieving important milestones. The ultimate goal of SIAPS was to institutionalize interventions so that pharmaceutical systems prosper under country ownership. To this end, the program endeavored to responsibly transition projects to implementing partners and governments.

While SIAPS has closed, the work in PSS is not finished. Pharmaceutical systems must be consistently strengthened in conjunction with sustaining effective health systems. SIAPS is a model in building resilience through strengthening the foundational components of pharmaceutical systems, thereby improving access and services to achieve better health outcomes.

## Core Operating Principles for Resilient, Sustainable Pharmaceutical Systems

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Throughout its six years of operation, SIAPS established and was guided by the following core principles in support of implementing the PSS framework globally.

**Build On and Strengthen Existing Systems:** SIAPS' technical assistance was designed to address countries' most pressing needs while building on existing systems and local capacity to promote sustainability.

**Integrate Public Health Programs and National Supply Systems:** The program's activities were integrated with existing public health programs and supply systems because interventions that address systems are more powerful in ensuring sustainability and bringing about longer-term impact than are one-off activities.

**Build the Capacity of Local Organizations and People:** Individual and organizational capacity building efforts helped countries improve their ability to manage pharmaceuticals at all levels.

**Engage in In-country Coordination of Support from Various Stakeholders:** Supporting governing bodies and in-country stakeholder collaborations optimized donor resources and enabled coordinated pharmaceutical management planning and harmonized tools and approaches.

**Continuously and Objectively Self-assess by Using a Set of Defined Metrics:** SIAPS defined and used a Performance Monitoring Plan (PMP) to track program progress.

**Facilitate Consensus Building on the Definitions of PSS and a Monitoring Framework:** SIAPS proposed definitions of a pharmaceutical system and PSS (see Cross Bureau).

**Harmonize Information Systems to Improve Patient Care:** SIAPS improved pharmaceutical data for decision making by developing and supporting the roll-out of appropriate data collection tools, both paper-based and electronic.

**Widely Share Lessons Learned and Best Practices:** SIAPS implemented a knowledge management and communications work plan to disseminate PSS best practices and innovative solutions to USAID Missions, other US agencies, implementing organizations, host-country governments, other donors, multinational organizations, and international stakeholders.

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This report showcases SIAPS' achievements across 46 countries. Interventions are described by intermediate results and health areas (i.e., malaria, MNCH, NTDs, and TB) and demonstrate how SIAPS successfully worked with a range of stakeholders, including Ministries of Health, to bolster pharmaceutical systems and address country-specific needs.







# CROSS BUREAU

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## Global Technical Leadership

Health and pharmaceutical systems are constantly evolving, either through planned reforms to meet a country or global health agenda or in response to unplanned system shocks, which may be sudden (e.g., Ebola, floods, civil strife) or chronic (e.g., stock-outs of products, limited qualified human resources).

The SIAPS/Cross Bureau portfolio supported USAID's Office of Health Systems' role as USAID's center of excellence and as the hub for health systems strengthening initiatives by providing leadership and technical expertise in strengthening pharmaceutical systems. In doing so, SIAPS' efforts implicitly recognize that pharmaceutical systems are embedded in and influenced by broader health systems.

Numerous low- and middle-income countries (LMICs) have embraced the global health agenda, specifically universal health coverage (UHC) and the Sustainable Development Goals (SDGs). Working to achieve UHC and SDG goals, many LMICs are strengthening their health systems by embedding the principles of equity, efficiency, and sustainability. Cross Bureau funds allowed SIAPS to leave a legacy of knowledge products and tools in support of national health and pharmaceutical systems. SIAPS has produced a number of global technical leadership products that define and conceptualize various interrelated notions and provide guidance for countries to take action to strengthen their pharmaceutical systems and monitor their progress.

### *Defining and Measuring Pharmaceutical Systems Strengthening*

Clear definitions and reliable measures of pharmaceutical systems strengthening (PSS) are needed to guide the design of interventions that will improve the performance and resilience of pharmaceutical systems. Despite an extensive body of work on access to and use of medicines and myriad tools that measure elements of pharmaceutical systems, there has been little attempt to conceptualize a pharmaceutical system as an entity.

As a crucial first step and through iterative discussions, SIAPS and its partners—USAID, the Pan American Health Organization (representing the World Health Organization (WHO)), and the Boston University School of Public Health—developed definitions of a pharmaceutical system and pharmaceutical systems strengthening.<sup>3</sup>

*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 make it more responsive and resilient and to enhance its performance for achieving better health outcomes.*

The narrow focus of existing tools on distinct parts of the pharmaceutical system limits their value in ascertaining which interventions might result in stronger, more sustainable systems. Based on the above definitions, SIAPS developed and piloted a measurement framework and corresponding indicators to enable countries to monitor progress toward stronger, more resilient pharmaceutical systems.

Figure 3 illustrates the critical system components, attributes, and outcomes that SIAPS identified for measuring PSS. This activity culminated in the web-based tool, *PSS Insight*, available at [pssinsight.org](http://pssinsight.org). It is anticipated that countries will use PSS Insight to assess their pharmaceutical systems, identify areas for improvement, and track progress.

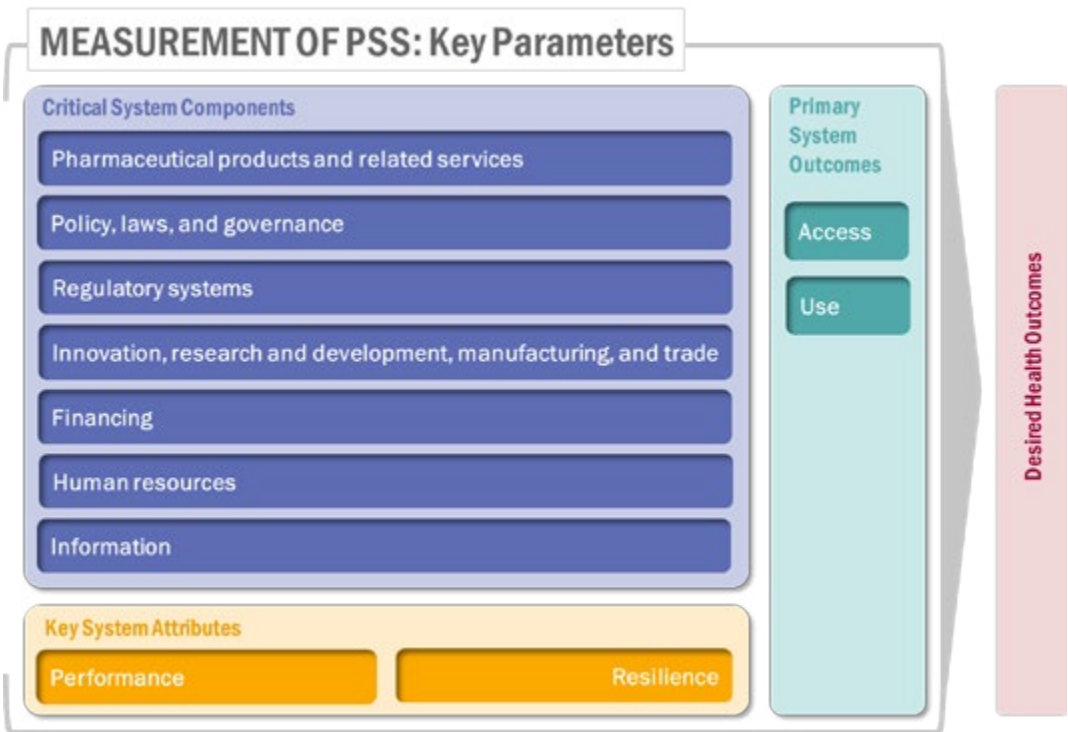


Figure 3. Key parameters of measuring progress towards pharmaceutical system strengthening

<sup>3</sup> Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F. Defining pharmaceutical systems strengthening: concepts to enable measurement. Health Policy and Planning, Volume 32, Issue 4, 1 May 2017, Pages 572–584, <https://doi.org/10.1093/heapol/czw153>

## *The Role of Strengthening Pharmaceutical Systems in Achieving UHC*

Through its seminal publication, “*Pharmaceutical Management Considerations for Expanded Health Coverage of Essential Health Services and Financial Protection Programs*,” SIAPS challenges the skewed discourse on financial protection for UHC by providing practical guidance to pharmaceutical system stakeholders (policy makers, health insurance and financial protection managers, development partners, and implementers). The publication makes the case for decision makers to take a holistic and inclusive view of the role of pharmaceutical system functions, such as regulations and governance arrangements and human, financial, and information resources, and the processes that ensure access to and appropriate use of medicines. Access encompasses four dimensions: affordability, (cultural) acceptability, (geographical) accessibility, and availability.<sup>4</sup> SIAPS recognized that tailoring pharmaceutical management efforts to meet UHC objectives can be complex and may follow different trajectories depending on country-specific needs and contexts. The guidance therefore provides steps to inform priority setting in resource-limited environments.

The SIAPS/Cross Bureau portfolio developed a number of knowledge products that are of global interest in strengthening pharmaceutical systems in LMICs (table 1).

**Table 1. Key SIAPS Knowledge Products**

<b>PSS Knowledge</b>	<b>Title</b>	<b>Synopsis</b>
PSS case studies	Compendium of global PSS case studies, available at <a href="http://www.pharmasystems.org">www.pharmasystems.org</a>	This compendium demonstrates global PSS approaches implemented in LMICs by USAID and other stakeholders and shows how a systems approach is necessary to transform the landscape of pharmaceutical systems.
<b>PSS Process</b>	<b>Title</b>	<b>Synopsis</b>
Stakeholder engagement and evidence-informed decision making	<a href="#">Analyzing Options for Strengthening Pharmaceutical Systems</a>	This guidance document describes an evidence-based approach for the critical and systematic analysis of intervention options in pharmaceutical systems, supported by practical examples and technical annexes that can be used to tailor the approach to a variety of technical areas and problems.
<b>PSS Functional Area</b>	<b>Title</b>	<b>Synopsis</b>
Governance	Strengthening Governance in Pharmaceutical Systems: SIAPS Country Case Studies	This compendium explains the importance of governance in pharmaceutical systems, presents eight case studies on SIAPS’ work in enhancing good governance in pharmaceutical systems, summarizes challenges commonly encountered and lessons learned, and closes with some reflections on the utility of SIAPS’ governance framework.
Workforce Development	<a href="#">Continuing Pharmaceutical Education: Guide to Establishing Quality Assured and Accredited Programs</a>	This document outlines the rationale and framework for establishing continuing education/continuing professional development programs as well as the necessary elements for these programs to be effective.
Information for Decision Making	<a href="#">Decreasing the Data Burden at the Last Mile to Improve Data Management and Use for Stronger Pharmaceutical Systems</a>	This brief defines and quantifies the data burden facing health workers in LMICs and provides recommendations for Ministries of Health, donors, and implementing partners to improve data management and health service delivery.

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



<b>PSS Functional Area</b>	<b>Title</b>	<b>Synopsis</b>
Financing	Pharmacoeconomics Training Course and Facilitators Guide	Targeted to government staff, regulators, and medicine selection committee members, this course builds attendees' capacity to improve the medicine and health technologies selection process in resource-limited settings, thereby maximizing effectiveness, reducing costs, and improving health outcomes.
Pharmaceutical Services	<a href="#">Developing, Implementing, and Monitoring the Use of Standard Treatment Guidelines: A SIAPS How-To Manual</a>	This manual guides health professionals through the systematic process of establishing, implementing, and monitoring the use of standard treatment guidelines in LMICs by addressing issues such as strength of evidence, transparency, conflicts of interest, and effective implementation.

The SIAPS/Cross Bureau portfolio also supported the development of eLearning courses that are accessible through the USAID Global Health eLearning Center to bolster knowledge of PSS students, practitioners, and stakeholders.

<b>Course</b>	<b>Number of participants completing the course (as of September 2017)</b>
<a href="#">Antimicrobial Resistance (Part 1)</a>	1,454
<a href="#">Antimicrobial Resistance (Part 2)</a>	1,168
<a href="#">Good Governance in the Management of Medicines</a>	363

### ***USG and Global Efforts to Contain the Emergence and Spread of Antimicrobial Resistance***

Antimicrobial resistance (AMR) is a fundamental threat to expanding UHC and meeting US Government (USG) health goals. SIAPS and its predecessor projects contributed to the AMR action-related objectives of the Global Health Security Agenda (GHSA) through multiple resources, tools, and publications that support key aspects of AMR containment. SIAPS' key AMR publications include:

- [Building country- and regional-level advocacy and coalitions to combat antimicrobial resistance: Multi-country examples and lessons learned](#)
- [Systems-based Approaches to Improving Medication Adherence](#)
- [Combating Antimicrobial Resistance with Stronger Health Systems](#)

Collectively, these guidance documents are intended to streamline efforts and emphasize the need for multidisciplinary action to adequately address the multidimensional drivers of AMR.

In addition, SIAPS designed an *AMR Monitoring Framework* to facilitate the process of harmonizing methods for tracking results, making constructive comparisons, and synthesizing and disseminating experiences and lessons learned. The results framework will serve as a management tool for both USAID and partner countries that are implementing the GHSA/AMR actions.

## *Synergizing Resources and Efforts to Strengthen Health and Pharmaceutical Systems*

To leverage resources, SIAPS collaborated with other USAID-funded programs, including the Health Finance and Governance Project, to buttress the pharmaceutical systems perspective and increase access to medical products, vaccines, and technologies through the following guidance documents:

- [Pharmaceutical Expenditure Tracking Guide](#)
- [Health Systems Assessment Approach Manual version 3.0](#) (in collaboration with the Promoting the Quality of Medicines Project)

## *Regional and Global Engagement to Strengthen Health and Pharmaceutical Systems*

Consistent engagement with regional and global health actors is critical to bringing PSS concepts into action. As such, Cross Bureau funds enabled the development of technical products and supported key activities initiated by global and regional entities (table 2).

Table 2. Examples of SIAPS Regional and Global Engagement

Organization	SIAPS Contributions
New Partnership for Africa's Development's (NEPAD)/ African Medicines Regulatory Harmonisation Programme (AMRH) Initiative	<ul style="list-style-type: none"><li>• African Union (AU) Model Law on Medical Products Regulation</li><li>• Selection of Regional Centers of Regulatory Excellence (RCOREs) to increase Africa's regulatory workforce capacity</li><li>• Defined priority areas for strengthening pharmacovigilance (PV) functions and defined mechanisms for PV coordination and governance among RCOREs</li><li>• Monitoring and evaluation framework for RCORE activities</li></ul>
East African Community (EAC)	<ul style="list-style-type: none"><li>• Lead technical partner on PV harmonization efforts:<ul style="list-style-type: none"><li>– Regional PV assessment tool and member state support during its implementation</li><li>– Defined regional PV priorities</li><li>– Draft business plan for PV harmonization</li></ul></li></ul>
Economic Community of West Africa States (ECOWAS)/ West African Health Organization (WAHO)	<ul style="list-style-type: none"><li>• AU Model Law and the launch of the subregional regulatory harmonization initiative</li></ul>
World Health Organization (WHO)	<ul style="list-style-type: none"><li>• Essential Medicines and Health Products Information Portal</li><li>• WHO Good Governance for Medicines Assessment Instrument</li><li>• Coalition of Interested Parties Regulatory Framework</li></ul>

Finally, over the last six years, the SIAPS/Cross Bureau portfolio contributed to numerous discussions in global and regional forums, with a view to better coordinate efforts, improve allocation of resources, develop consensus on global/regional strategies to be pursued and replicated, harmonize tools and approaches, document technical approaches, and increase the introduction and mainstreaming of best practices.

Joint stakeholder efforts are necessary beyond the life of SIAPS to strengthen pharmaceutical systems to meeting both USG and global health goals.







## REFLECTIONS OF A COUNTRY PROGRAM DIRECTOR

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When I arrived in Ukraine in November 2013, it was the height of the Euromaidan protest. There was a huge public uprising; people were demanding change in many areas, including the health sector. The upheaval had traumatic consequences, but it opened the door to change. Typically, people are used to the status quo, and nobody wants to rock the boat. In Ukraine, though, there was a sense that anything was possible. With SIAPS, we had an opportunity to support top-down change in the system, including legislation to establish different mechanisms for strengthening the country's pharmaceutical system.

We were the only project working on pharmaceutical management in the country, so it was important to gain trust by involving a wide range of stakeholders to collaboratively design interventions. The Ministry of Health was amenable to reform, which led to progress in establishing an essential medicines list and revamping the national procurement process. We worked with patient organizations, which have a big political voice in the country, and with the private sector, including the American Chamber of Commerce; the European Business Association; and local pharmaceutical manufacturers, distributors, and associations.

SIAPS worked hard to develop relationships with Ukrainians, and the program also had close working relationships with the World Health Organization and with the charitable organizations Renaissance Foundation and Patients of Ukraine. We had support from regional health providers for projects such as establishing a national TB patient registry, which greatly improved the management of TB patients, and a reimbursement system to improve access to medicines for patients with hypertension, type 2 diabetes, and asthma. As a result, we were able to significantly contribute to health system reform in the country, with results that are sustainable and are a stable foundation for future progress.

—Juanita Folmsbee, Country Program Director, Ukraine







## INTERMEDIATE RESULTS

### IR1 Pharmaceutical Sector Governance Strengthened

Good governance helps protect pharmaceutical systems from corruption and mismanagement, which can diminish access to medicines and lead to the use of unsafe, ineffective, or poor quality products that may harm patients. These issues can also cause wastage and misuse of scarce resources as well as inflated prices for medicines, which has financial consequences for governments, institutions, and individuals. The SIAPS approach for strengthening governance in pharmaceutical systems focused 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 and accountable systems and processes that are based on best practice norms and guidelines; and human resource management systems that promote effective performance and ethical practices. This approach further recognized that sustaining improvements in the pharmaceutical sector necessitates engaging with stakeholders, including civil society, to promote ownership and participation.

#### *Policies and Legislation*

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. During the program, SIAPS helped develop or revise, adopt, and monitor adherence to pharmaceutical policies and legislation that provide the framework for the regulation of pharmaceutical products, personnel, and establishments in a country;





support its health sector priorities; and promote good governance in pharmaceutical systems. These interventions engaged a broad range of stakeholders, including Ministries of Health and Finance, civil society organizations (CSOs), professional associations, and advocacy groups, to generate commitment, active participation, and transparency for sustained country ownership.

A national medicines policy (NMP) articulates a government's political commitment and constitutes a guide for action for providing safe, quality, and effective medicines for a country's citizens. SIAPS provided technical assistance to Haiti's Ministry of Public Health and Population to develop the country's first NMP and supported the revision of NMPs in Namibia and Guinea.

During the life of the program, SIAPS helped eight countries develop or revise and submit 32 pharmaceutical laws and regulatory instruments for approval. SIAPS collaborated with the national medicines regulatory authority and partners in Guinea to update the 1994 national pharmaceutical law, which is just one example of the program's work in this area. The law is awaiting review and endorsement by the Minister of Health and adoption by the national assembly.

In Swaziland, the Medicines and Related Substances Control Bill was enacted into law in November 2016. The new law, which replaces legislation dating back to 1929, provides for the establishment of the country's first national medicines regulatory authority. SIAPS assisted the Ministry of Health (MOH) to develop this bill and also the Pharmacy Bill, which provides for the creation of a Pharmacy Council to regulate the pharmacy profession. The program also helped the Chief Pharmacist's Office conduct seminars and prepare briefs to educate legislators on the importance and content of draft bills and advocate for their enactment.

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

A challenge that many low- and middle-income countries confront is a lack of robust guidelines and standard operating procedures (SOPs) that define norms and standards for performing pharmaceutical functions. To address this issue, SIAPS supported 23 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. These guidelines, lists, and SOPs provide the foundation for good governance and sound practices in pharmaceutical systems.



In Bangladesh, for example, SIAPS helped the Ministry of Health and Family Welfare produce a suite of manuals, guidelines, and SOPs to help streamline, standardize, and improve the efficiency of family planning and other medicine procurement processes. These efforts, along with other SIAPS-supported activities, contributed to reducing procurement lead times of contraceptives from 78 weeks in 2010 to 33 weeks in 2013.

The selection of medicines has a considerable impact on quality of care and cost of treatment, making it one of the most cost-effective areas for intervention.<sup>5</sup> SIAPS supported 13 countries in updating national medicines, device, and equipment lists, including Ukraine, where the program provided technical assistance to harmonize the various medicine lists used to guide public procurement and establish a robust and transparent process for

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<sup>5</sup> Management Sciences for Health. 2012. MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health.

developing a unified national essential medicines list (EML). The program collaborated with MOH and country experts to develop a transparent process for selecting expert committee members and create an evidence-informed and inclusive methodology for determining the initial EML and performing subsequent revisions. SIAPS also helped to prepare the legislative instruments to institutionalize the process. The Decree of Cabinet of Ministers, approved in March 2017, mandates the EML as the sole list for publicly funded procurement and reimbursement at the regional level as of July 2017. The EML and decrees are anticipated to make regional procurements less vulnerable to duplication, inefficiencies, and conflicts of interest.

### ***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 interventions 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.

In South Africa, SIAPS helped to formulate a guidance document for developing or reviewing terms of reference (TOR) for all types of pharmaceutical sector committees and used it to help the Department of Health revise the TOR for the committee responsible for evaluating bids for pharmaceutical product tenders. In Guinea, SIAPS assisted the central medical stores to successfully launch its first competitive tender in 2014, which culminated in a more transparent and competitive process. SIAPS/Cameroon collaborated with Positive Generation, a local CSO that reports weekly on antiretroviral medicine availability at health facilities, to compare the CSO's monitoring data with that generated by the public system; analyze barriers to HIV treatment access; and, together with other partners, advocate for reforms to address constraints.

In Ethiopia, the implementation of Auditable Pharmaceuticals Transactions and Services (APTS), a package of system-strengthening interventions, has helped the government achieve greater transparency and accountability in the management of pharmaceuticals, related finances, and delivery of services at public health facilities. APTS regulations have been enacted in all 11 regions of the country. In 2017, 77 health facilities, 72 hospitals, and 7 health centers were implementing APTS. A 2016 assessment of APTS-implementing facilities showed improvements in quality of service, patient satisfaction, waiting time at pharmacies, and patients' knowledge of medicines dispensed to them. In most hospitals, the availability of key medicines increased from 65% to more than 95% and wastage from expiries decreased from 8% to less than 2%.

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

Throughout the project, SIAPS supported partnership and coordination efforts in 16 countries to promote more informed and collaborative decision making, foster better planning, mobilization, and management of government and donor resources; and streamline supply chain activities. In Mali and South Sudan, SIAPS assisted in planning and coordination efforts during periods of severe civil unrest to maintain uninterrupted access to essential medicines and services.

In the Philippines, SIAPS supported the Quezon City Health Department to institute Barangay Health Management Councils (BHMCs), which bring together community groups, government officials, and health providers to improve tuberculosis (TB) program management and service delivery in poor urban settlements (barangays). SIAPS helped design, pilot, and scale up the initiative, which provides a platform for information sharing, consensus building, and joint planning and also enables the community to participate and take ownership in managing

the TB program. Through this initiative, there is more effective coordination between stakeholders who now develop a single, unified plan and budget. Improved coordination and stakeholder engagement has spurred political commitment and increased funding and community resources for TB case finding and treatment in many barangays. By June 2016, 17 BHMCs were established as a direct result of SIAPS’ assistance, reaching 45 (32%) of Quezon City’s 142 barangays with a population of almost 1.3 million (40% of the city’s population).

### *Strategic Planning*

Long-term strategic plans guided the implementation of approaches, methods, and mechanisms to help achieve priorities and goals set out in national policies. SIAPS worked with Ministries of Health in Angola, Guinea, Namibia, South Africa, South Sudan, and Swaziland to prepare long-term national pharmaceutical sector strategic plans that provide a roadmap for pharmaceutical services development. In addition, 13 countries developed or revised strategic plans for central medical stores, national regulatory authorities, laboratories, training institutes, supply chain management, pharmacovigilance, and national disease programs with assistance from SIAPS. For example, following a fire in Guinea that destroyed medicines and supplies valued at millions of dollars, SIAPS helped develop a contingency plan that identified immediate actions needed, such as emergency procurements, as well as a mid-term strengthening plan for addressing the central medical store’s warehouse capacity and safety constraints. To support efforts in training the future pharmaceutical workforce, SIAPS assisted the University of Kinshasa’s Faculty of Pharmaceutical Sciences to develop its first-ever strategic plan, operational plan, and competency framework.

### *Regulatory Systems Strengthening*

In resource-limited countries, national medicines regulatory authorities (NMRAs) often do not have sufficient capacity or effective systems to oversee and implement key regulatory functions to ensure the safety, efficacy, and quality of pharmaceuticals. These functions include product registration, the inspection and licensing of pharmaceutical establishments, product quality testing, and medicine safety monitoring (see IR5 page 35). Over the course of the program, SIAPS supported 16 countries in strengthening regulatory systems. This work included helping NMRAs assess their systems, strengthen legal frameworks, build institutional and human resource capacity, improve processes, and upgrade their information management systems.

#### **SIAPS support in regulatory systems strengthening**



- Product registration in 10 countries
- Inspection practices in 5 countries
- Licensing practices in 4 countries
- Pharmaceutical quality control in 6 countries

SIAPS conducted regulatory systems assessments using the SIAPS-developed Regulatory Systems Assessment Tool (RSAT) in Angola, Bangladesh, Mozambique, and Namibia, and in Mali using WHO’s Global Benchmarking Tool.

SIAPS technical assistance improved processes for product registration in 11 countries through advocacy, process restructuring, capacity building, and introducing or updating information systems. NMRAs in six countries (Bangladesh, Benin, DRC, Ethiopia, Mozambique, and Namibia) implemented electronic information systems for registration. SIAPS worked with these NMRAs to adopt international standards and best practices in medicines registration, such as the use of the Common Technical Document (CTD) for registration applications in some countries, and to implement process improvements as a prerequisite for automation of the information systems. In Ethiopia, all product applications are now processed electronically, increasing



efficiency and transparency. Mozambique and Namibia experienced reductions in the average number of days needed to evaluate and reach a decision on product applications and increases in the percentage of registered products on their respective EMLs.

Finally, SIAPS participated in three regional regulatory harmonization initiatives—the African Medicines Regulatory Harmonization program and initiatives of the East African Community and the Economic Community of West Africa States. These initiatives promote the standardization of regulatory practices across countries and improve the efficiency, effectiveness, and rigor of regulatory processes (see table 2 in Cross Bureau, page 11).


In recognition of the interdependence of key regulatory functions and the need to address the regulatory system as a whole to achieve greater effectiveness and sustainability, SIAPS worked to provide technical support across multiple regulatory functions. In 2012, for example, SIAPS led an assessment of Bangladesh's Directorate General of Drug Administration (DGDA)'s regulatory systems and capacity and provided follow on support in the following areas:

**Pharmacovigilance:** SIAPS trained DGDA officials in adverse event reporting and helped establish the Adverse Drug Reaction Monitoring Cell to oversee nationwide adverse event reporting. These efforts culminated in launching the National Pharmacovigilance Program in 2013 and in Bangladesh becoming a full member of the WHO Collaborating Centre for International Drug Monitoring.

**Medicines registration:** SIAPS helped the DGDA introduce CTDs for registration applications; customized Pharmadex, a web-based product registration tool; and provided extensive training for DGDA officials and applicants from the pharmaceutical industry. SIAPS also facilitated a three-year partnership between the DGDA and the Korea International Cooperation Agency to have the Ministry of Food and Drug Safety of Korea conduct training workshops for DGDA officials on regulatory affairs and patient safety.

**Inspections and quality assurance of medicines:** SIAPS assisted the DGDA to develop and update guidelines and tools for conducting Good Manufacturing Practice inspections at manufacturing sites, provided training for inspectors, and expanded the website to enable more efficient submission of reports. Bangladesh's National Control Laboratory (NCL) performs quality control testing of pharmaceutical products prior to registration and marketing authorization and tests all post-marketing samples. SIAPS, in collaboration with the USAID-funded Promoting Quality of Medicines (PQM) Program, assisted the DGDA in identifying and prioritizing technical needs for strengthening the standards and technical capabilities of the NCL as it works toward achieving WHO accreditation.

**Coordination:** To achieve better coordination, efficiency, and outcomes in regulatory system activities, SIAPS partnered with WHO, the World Bank, and PQM to form a coalition. This coalition approach was piloted in Bangladesh, where the partners assisted the DGDA to develop a five-year strategic plan for the regulatory system. Since its launch in June 2017, SIAPS has been among the lead partners promoting the coalition approach and contributing to its design for implementation in other countries.

A photograph of two young children lying under a white mosquito net. The child on the left is wearing a red shirt and is smiling broadly, looking up at the net. The child on the right is wearing a yellow shirt and is also looking up, with a slight smile. The background is a plain, light-colored wall.

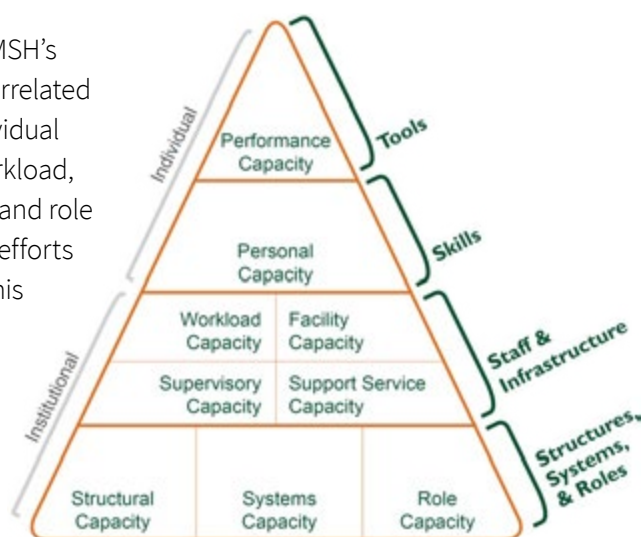
SIAPS' collaboration with DRC's regulatory authority increased the number of registered medicines from 200 (2010) to more than 4,400 (2016). The list of registered medicines is now used by government inspectors to control medicines at ports of entry.

SIAPS helped Swaziland's MOH operationalize the national regulatory authority established under the 2016 Medicines and Related Substances Control Act.

# IR2 Capacity for Pharmaceutical Management and Services Increased and Enhanced

Successful pharmaceutical systems hinge on cadres of skilled health care workers, program managers, and leaders—people with up-to-date knowledge, skills, and competency-based training to effectively implement pharmaceutical management activities. These successful systems also require that institutions and organizations have sufficient capacity to lead, manage, and effect positive change within the pharmaceutical sector. During the life of the program, SIAPS has engaged with a broad spectrum of stakeholders—country governments, universities, health facilities and health care workers, professional associations, and private-sector entities—to address pressing human resource capacity challenges, including health care worker shortages, resource constraints, competency gaps, outdated curricula, and policy-level issues. Using a participatory approach, SIAPS worked with these stakeholders to identify areas and opportunities for capacity improvement and develop strategies for long-term systems strengthening while also working to resolve immediate or short-term problems related to medicine availability and access.

The SIAPS approach to capacity building was guided by MSH's capacity building framework, which emphasizes nine interrelated components. These components are categorized as individual (performance and personal capacity) or institutional (workload, facility, supervisory, support service, structural, systems, and role capacity) (figure 4). All were vital considerations in SIAPS' efforts to strengthen the capacity of pharmaceutical systems. This approach emphasized strengthening the pharmaceutical management capacity of individuals, institutions, and networks through participatory methodologies and innovative approaches. Recognizing the value and importance of partnerships, SIAPS leveraged its working relationships with local and global institutions to design and implement collaborative interventions that are both locally relevant and sustainable.



\*Adapted from Potter, C., and R. Brough. 2004. Systemic Capacity Building: A Hierarchy of Needs. Health Policy and Planning, 19(5):336-345.

Figure 4. MSH's capacity building framework\*

## Strengthening Individual and Institutional Capacity through Pre- and In-service Training

### *Pre-service Curriculum Reform*

SIAPS worked with local universities and other training institutions to strengthen the pharmaceutical training that future pharmacists and other health care workers receive by developing more robust training curricula, courses, and programs. By the end of the program, SIAPS helped develop or reform 11 health professional pre-service training curricula in the areas of supply chain management, pharmacy law ethics, rational medicine use, and pharmacovigilance. Four of these programs in Swaziland, Namibia, and Democratic Republic of the Congo (DRC) were accredited by in-country governing bodies. SIAPS also supported the placement of pharmacy personnel in underserved and rural areas of DRC, Lesotho, Namibia, South Africa, Swaziland, and Vietnam.

Consistent with its approach to building sustainable cadres of personnel, SIAPS also worked with a number of university training programs to build their capacity to enhance pharmaceutical education and produce pharmaceutical professionals locally as a key mechanism to sustain the system.



## Meeting the Demands of Namibia's Pharmaceutical Sector and Workforce

To assist Namibia in meeting the demand for a strong health workforce, SIAPS helped initiate two pre-service training programs—one at the University of Namibia (UNAM) for pharmacists and the other at the National Health Training Centre (NHTC) for pharmacy assistants (PAs). Collaboration included developing frameworks and standards for accreditation, which enabled the establishment of the UNAM's School of Pharmacy (SoP). SIAPS helped design coursework for the UNAM-SoP's Bachelors in Pharmacy curriculum in pharmaceutical management, rational medicine use, pharmacoeconomics, pharmacovigilance, and regulation.

Pharmaceutical management tools, including the Electronic Dispensing Tool (EDT) and the facility electronic stock card, were installed in the training laboratories of both UNAM-SoP and NHTC, offering students hands-on experience prior to encountering these tools at health facilities. New graduates also benefitted from onsite mentorship and supportive supervision from licensed and accredited professionals.

Between 2012 and 2016, 140 PAs graduated from NHTC and 138 pharmacists from UNAM-SoP. The SoP dean acknowledged that the strategic plan, developed with SIAPS, was pivotal in guiding the direction of the school. As part of the strategic plan, UNAM-SoP introduced a two-year pharmacy technician diploma, which began in 2015. The following year, the university launched a Masters of Pharmacy program and implemented several continuing professional development programs, offering additional opportunities for pharmaceutical students and personnel to build their skills.

A series of supportive supervision visits by the government found that all of the 35 district hospitals visited had at least one certified pharmacy staff member providing services, an increase of 25% from the beginning of the SIAPS technical assistance.<sup>6</sup> A 2016 assessment showed an increase in patient satisfaction with information received about their medication, and a tracer study confirmed employer and supervisor satisfaction with PA performance.<sup>7</sup> The majority of PAs work in the public sector, many at antiretroviral therapy (ART) clinics where the need for pharmaceutical personnel is great, further demonstrating the program's success in addressing the demand for qualified pharmaceutical personnel.

### *In-service Training*

In addition to pre-service training, SIAPS worked to improve in-service training opportunities for practicing pharmaceutical and health professionals. SIAPS aimed to build not only technical skills among practitioners but also the capacity for leadership, management, and mentoring. Since SIAPS' inception, 40 in-service training curricula have been developed or revised in 11 countries, exceeding the program's target of 30 curricula. During the program, more than 51,000 pharmaceutical staff from more than 20 countries were trained in various aspects of pharmaceutical management, including financing, leadership, regulatory management, quality assurance, pharmaceutical care, medicine safety, antimicrobial resistance, and supply chain management.



<sup>6</sup> Fults E. 2016. Strengthening Namibia's Pharmacy Sector and Workforce. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health. <http://siapsprogram.org/publication/altview/technical-brief-strengthening-namibias-pharmacy-sector-and-workforce/english/>

<sup>7</sup> Ibid.

## Deploying Clinical Pharmaceutical Services in Ethiopian Hospitals

Although the 2010 Ethiopian Hospital Reform Implementation Guidelines included pharmaceutical clinical guidelines as a key service component, pharmacy staff at the time were trained using an outdated curriculum and lacked the requisite knowledge and skills to provide clinical services in hospitals. To overcome this obstacle, SIAPS supported the development and implementation of an in-service training program to build the clinical knowledge and skills of hospital pharmacists and helped train 200 pharmacists from 65 hospitals between 2012 and 2014. In 2016, SIAPS conducted a cross-sectional study at 43 hospitals that took part in the in-service training program and found that ward-based clinical pharmaceutical services had been taken up in 95% of hospitals; clinical teams accepted 88% of pharmacists' recommendations; and these services were highly regarded by most hospital CEOs (97%), doctors (95%), nurses (100%), and pharmacists (97%).<sup>8</sup>

### *Institutional Capacity Building*

Institutional capacity building includes establishing and incorporating frameworks and processes into the workplace while simultaneously increasing individuals' skillsets to lead, manage, and implement changes that promote the application of best practices, standards, and guidelines. To this end, SIAPS used its systems approach to build institutional capacity with the intention of aiding countries in achieve their long-term goals.

## Strengthening Pharmaceutical Leadership and Management

SIAPS leveraged work from its predecessor program to develop and implement the pharmaceutical leadership development program (PLDP) in South Africa, Lesotho, and Sierra Leone, which was adapted from the MSH Leadership Development Program (LDP). PLDP/LDP is customized for each country and combined pharmaceutical management knowledge and sound leadership practices to better equip pharmacy managers to respond to challenges in their workplace. Workplace-based teams used information gained during the workshops to address real workplace challenges and produce measurable results.

The PLDP has not only built individual capacity of health care providers but also strengthened institutional capacity at the health service delivery level. The interventions resulted in a wide range of individual, organizational, and health service delivery outcomes, including improved quality of service provision, medicine availability and accessibility, patient safety and adherence, and patient experience; increased rational medicine use; and enhanced organizational capacity (table 3). During the program, 546 health care professionals were trained in PLDP/LDP in South Africa (274), Lesotho (255), and Sierra Leone (17).

Table 3. Examples of District-level PLDP/LDP Achievements in South Africa

District/Province	Target	Baseline	Endline
eThekweni South District, Kwa-Zulu Natal (KZN) Province	100% reporting on stock-out and expired medicine data elements by 15 primary health care (PHC) clinics	67% of PHC clinics reporting on stock-outs (2013)	100% reporting on medicine stock-outs (TB, tracer, and ART medicines) (2014)
uMgungundlovu District, KZN Province		33% reporting on expired medicines (2013)	100% reporting on expired medicines (2014)

cont...

<sup>8</sup> PFSA and SIAPS. National assessment on the implementation status of clinical pharmacy service at public hospitals in Ethiopia. Addis Ababa: PFSA and SIAPS; 2016.

District/Province	Target	Baseline	Endline
uMgungundlovu District, KZN Province	Reduce the percentage of chronic repeat prescription cards containing inappropriately prescribed items to less than 40%	76% of chronic repeat prescriptions cards had inappropriately prescribed medication (2012)	26% of chronic repeat prescriptions cards had inappropriately prescribed medication (2013)
Gugulethu CHC, Western Cape Province	Turnaround time is < 3 hours for 75% of the chronic diseases of lifestyle (CDL) patients on appointment date	54% of CDL patients spend > 3 hours in the facility on their appointment date (2014)	90% of CDL patients were leaving the facility within 3 hours (2014)
Dr. Ruth Segomotsi Mompati, North West Province	Increase the number of patients initiated on isoniazid preventive therapy per month	Average of three patients per month (Apr–Aug 2012)	Average of eight patients per month (Sep 2012–Jan 2013)
Ngaka Midiri Molema District, North West Province	Improve compliance with NCS measures in 10 PHCs from 33% to 60%	33% average compliance with NCS in 10 PHCs (2012)	77% average compliance with NCS in 10 PHCs (2013)

### *Supportive Supervision*

The SIAPS approach to building human resource capacity complemented traditional trainings with additional proven and innovative capacity building methodologies. One such methodology was supportive supervision, which promotes effective and equitable health care through measured improvements in procedures, personal interactions, and management while focusing on meeting staff needs for support and continuing education. Throughout the program, SIAPS assisted and conducted supportive supervision visits in 15 countries.

## Reinforcing Skills on the Job through Supportive Supervision

To address the shortage of staff capacity in supply chain and logistics management in Lesotho, SIAPS placed district logistics officers (DLOs) on district health management teams (DHMTs) to improve the logistics management information system through supportive supervision and mentoring. As a result, 94% of health facilities (171 of 182) used country-appropriate antiretroviral therapy (ART) requisition forms to report logistics and patient data in 2015. The percentage of health facilities that received feedback from the DHMTs and DLOs on the previously submitted report or data steadily increased from 74% in December 2014 to 88% by September 2015.

In Togo, SIAPS supported the National AIDS Control Program (PNLS) in conducting supportive supervision at five pilot ART sites using the EDT to build the capacity of EDT users and identify issues affecting the use of the EDT prior to the nationwide roll-out. The PNLS team visited each ART site once a week for four weeks. Four of the pilot sites had already abandoned the paper-based dispensing register, as EDT had improved the completeness and timeliness of reporting by these facilities.





In Swaziland, SIAPS collaborated with Southern Africa Nazarene University to establish the country's first pre-service pharmaceutical training program. SIAPS supported the development of two curricula—Certificate in Pharmacy and Diploma in Pharmacy—eliminating the need for pharmaceutical personnel to seek training outside the country.

As part of Guinea's post-Ebola recovery activities, SIAPS helped produce the Medicines for All training module to ensure the rational management of pharmaceutical commodities in health facilities through improved inventory management.

# IR3 Utilization of Information for Decision Making Increased

The collection, analysis, and use of health and logistics data drive better decision making at all levels of a health system. These data, when used within efficient systems, help ensure a steady supply of medicines; provide insights into the factors that enable patients to adhere to treatment regimens; contribute to developing and revising national treatment protocols; facilitate more accurate quantification, procurement, and costing for medicines and other health supplies; and ultimately contribute to stronger health systems and better health outcomes.

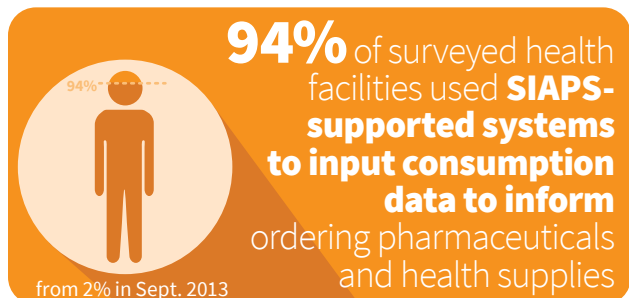
SIAPS supported the integration of pharmaceutical data collection, analysis, and presentation to help staff at all levels of a country's health system make evidence-informed decisions to improve the management of health commodities and pharmaceutical services. Through its tools, SIAPS helped increase the availability of quality pharmaceutical information across 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 focusing on cross-cutting interactions—governance, capacity building, financing, supply chain, and pharmaceutical services—and stakeholder engagement to ensure that improvements in the health system and health outcomes are sustainable.

SIAPS identified three main themes relating to information and information systems as the drivers to improving decision making: data availability, data quality, and system design that are conducive to the use of tools, including interoperability. 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 ensure that information systems capture data on both product and patient-focused parameters and disseminate data in a timely manner through appropriate reporting channels. Data generated from SIAPS-supported systems now allow decision makers to access critical information, including treatment regimens, consumption rates, and stock data. To ensure sustainability, SIAPS prioritized the responsible hand over of the tools to country counterparts to ensure their continued use.

## Improving Data Availability

SIAPS 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 worked not only to make data available but also to present them in easy-to-access and understandable ways, including online portals, dashboards, and other platforms that increase ease of use.

SIAPS worked with 13 countries to strengthen or institutionalize PMIS and logistics management information systems (LMIS) using innovative tools. Through capacity building and improved processes for data collection and analysis, 94% of SIAPS-supported health facilities were submitting LMIS reports in a timely manner. With increased data availability, the percentage of SIAPS-supported health facilities using consumption data to inform ordering increased from 2% at baseline to an impressive 94% in 2017.







## Designing Platforms to Enhance Patient Treatment and Pharmaceutical Management

Throughout the program, SIAPS has used its knowledge and understanding of information gaps to develop a suite of electronic tools for health care workers, managers, government officials, and policy makers to monitor supplies and services and make better informed decisions.

SIAPS partnered with country stakeholders to customize these tools to their needs, harmonize and integrate them within the health system, and use them appropriately to support evidence-based decision making.

## Increasing Functionality through Interoperability

Beyond simply designing tools to be used for a particular health program or at only one level of the pharmaceutical system (i.e., facility, district, or central level), SIAPS prioritized increasing the functionality of its tools through interoperability with other PMIS. Interoperability eases the exchange and use of information across organizational boundaries through software design that follows certain standardized formats and protocols. Of the tools in table 4, e-TB Manager, EDT, RxSolution, QuanTB, and Pharmacovigilance Monitoring System (PViMS) are interoperable with other software.

## Ensuring Public Access to SIAPS Tools for Sustainable Impact

In 2017, SIAPS began releasing all SIAPS-developed electronic tools to the public in open source code format. These tools, along with relevant documentation for users and programmers, can be accessed by anyone through GitHub, a web-based version control repository hosting service.

After SIAPS helped install and scale up the facility electronic stock card in Namibia, the Intermediate Hospital Oshakati **decreased ordering time from about two weeks to two days and waiting time from one to two days to approximately 30 minutes**, allowing staff to devote additional time to pharmaceutical care.



Table 4. Electronic PMIS Tools Developed by SIAPS

Tool	Functions	Global Reach	Highlights
 RxSolution	Used to manage inventory and purchase orders, issue stock, and dispense medication	Lesotho, Namibia, South Africa, Swaziland, and Uganda	<ul style="list-style-type: none"> <li>• Rolled out to 613 sites</li> <li>• Installed in a simulation laboratory at the National University of Lesotho to prepare preservice health care workers prior to workplace deployment</li> </ul>
 Pharmadex	Used to organize, compare, and analyze supplier and product information; track product applications; and trace data on cost, usage, and safety	Bangladesh, Ethiopia, Mozambique, and Namibia	<ul style="list-style-type: none"> <li>• In Mozambique, the average time to approve a registration application decreased by 36% from 429 days (2012) to 275 days (2016)</li> <li>• Source codes were handed over to Bangladesh government officials for full ownership</li> </ul>
 QuanTB	Quantification, case management, and early warning system designed to improve procurement processes, ordering, and supply planning for TB treatment	136 countries, including Bangladesh, Brazil, Colombia, DRC, Dominican Republic, Ethiopia, Guatemala, Honduras, Mexico, Mozambique, Myanmar, Nicaragua, Nigeria, Philippines, Sierra Leone, South Sudan, Uruguay, Uzbekistan, Venezuela, Zambia, and Zimbabwe	<ul style="list-style-type: none"> <li>• Since 2014, there have been 2,269 downloads</li> <li>• QuanTB became the official procurement tool of the Global Drug Facility</li> </ul>
 e-TB Manager	Integrates data across all aspects of TB control, including information on suspected cases, patients, medicines, laboratory testing, diagnosis, treatment, and outcomes	Armenia, Azerbaijan, Bangladesh, Brazil, Cambodia, Indonesia, Namibia, Nigeria, Ukraine, and Vietnam	<ul style="list-style-type: none"> <li>• Manages more than 650,000 TB and multidrug-resistant TB (MDR-TB) cases</li> <li>• Installed at more than 1,550 sites</li> <li>• Version 3.0 has enhanced functionalities and operates on mobile devices</li> </ul>
 Quantimed	Facilitates the calculation of commodity needs using either a single method or a combination of any of the three primary quantification methods: past consumption, morbidity patterns, and proxy consumption	Afghanistan, Angola, Bangladesh, Cameroon, Ethiopia, Mali, Sierra Leone, South Sudan, and Swaziland	<ul style="list-style-type: none"> <li>• Used to quantify reproductive, maternal, newborn, and child health commodities and essential medicines</li> <li>• Deployed in Angola and Sierra Leone for quantifying HIV and malaria commodities</li> </ul>
 Electronic Dispensing Tool (EDT)	Helps accurately dispense medicines by managing and generating data on patient profiles and medicine history, medicines inventory, and patient statistics	Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Morocco, Namibia, Nepal, Rwanda, Tanzania, Togo, and Zambia	<ul style="list-style-type: none"> <li>• Installed at more than 700 sites in 12 countries</li> <li>• Supports approximately 800,000 antiretroviral (ARV) treatment patients per year</li> <li>• A mobile version is used at outreach and primary health care facilities in Namibia</li> </ul>
 Pharmacovigilance Monitoring System (PViMS)	Enables active surveillance in low- and middle-income countries by addressing the entire data collection, data analysis, and reporting process	Georgia, Philippines, and Swaziland	<ul style="list-style-type: none"> <li>• Provides case management for patients using new TB medicines and regimens (bedaquiline or delamanid) to treat MDR-TB</li> <li>• Institutionalized for TB drug safety monitoring and management in Georgia, Philippines, and Swaziland</li> <li>• Adopted as the national pharmacovigilance tool in Philippines</li> </ul>

# Institutionalizing Comprehensive Information Systems in Bangladesh

To enhance procurement systems at the central level in Bangladesh, SIAPS assisted the Ministry of Health and Family Welfare (MOHFW) in the design, implementation, and hand over of the Supply Chain Management Portal (SCMP), a comprehensive online procurement tracker and management dashboard. The SCMP receives data from the Directorate General of Family Planning and the Directorate General of Health Services through a series of interoperable platforms that relay information from health facilities to the central level, and government officials use these data to make procurement decisions.

Through the institutionalization of information management systems (figure 5), government officials and health care workers are no longer purely in a data producing role, but are also active users of those data. Government officials successfully analyze information captured in the SCMP to determine and prepare procurement packages. Because SCMP data are publicly accessible, stakeholders can more easily work with MOHFW officials to routinely use data to identify where stock-outs and overstocks occur and plan measures to make additional procurement orders or redistribute commodities.

In 2017, 99% of health facilities submitted reports on time, and there have been no countrywide stock-outs of family planning/reproductive health commodities since 2012. SIAPS technical assistance also contributed to the MOHFW saving USD 6.38 million from improved quantification of family planning and reproductive health, MNCH, and TB commodities (as of 2015).

Improvements in central-level procurement spurred advocacy for the MOHFW to establish a permanent unit to oversee procurement processes. In 2016, the Procurement and Logistics Cell was funded to have dedicated staff to continue overseeing procurement throughout the MOHFW. This is a milestone for Bangladesh's health sector strategic plan.

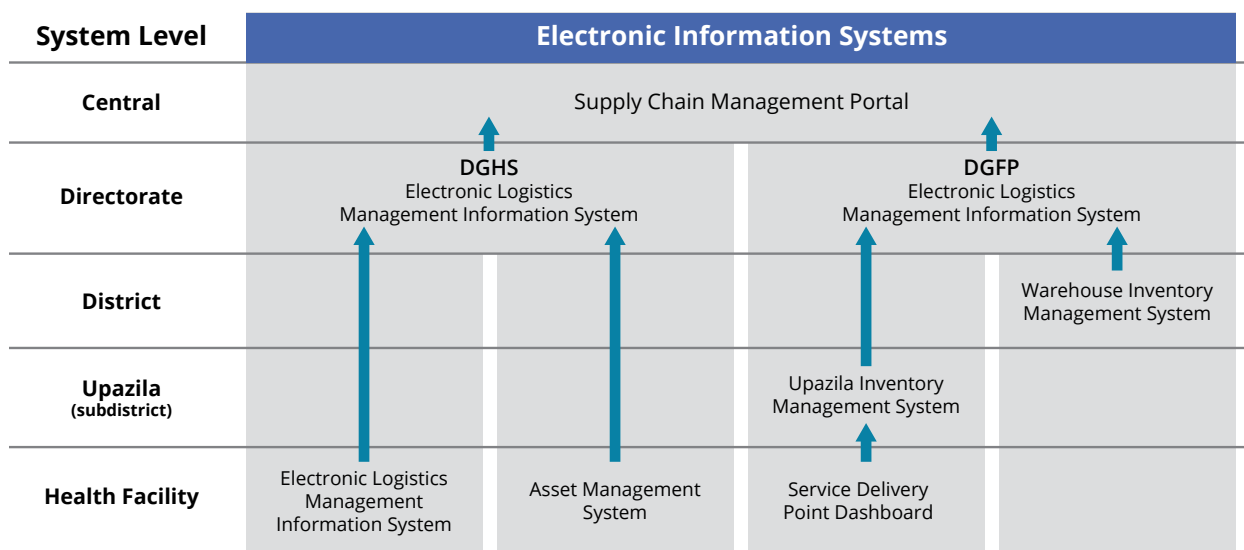



Figure 5. Interconnecting e-tools to promote better procurement and supply management in Bangladesh

A close-up, side-profile photograph of a man with dark skin and a mustache, wearing a white lab coat over a light-colored collared shirt. He is focused on his work, holding a small glass vial in his right hand and a pipette in his left hand, dispensing liquid into a test tube. The background is a plain, light-colored wall. The lighting is soft, highlighting the texture of his lab coat and the concentration on his face.

In Namibia, the EDT and mobile EDT are used as part of the newly implemented community-based antiretroviral therapy program to increase access to ARVs by making it easier for people to obtain medicines without traveling long distances and waiting in long lines.



# IR4 Financing Strategies and Mechanisms to Improve Access to Medicines Strengthened

A pharmaceutical system can only function effectively when there are adequate financial resources, efficient allocation of funding, and well-designed and effective pharmaceutical programs, all of which promote equitable access to medicines. Global spending on medicines in 2014 and 2015 increased by 9%, overtaking the overall health expenditure and economic growth rates.<sup>9</sup> Simultaneously, 20–40% of health expenditures are estimated to be wasted, and in the pharmaceutical system this is seen in the form of expired or damaged medicines due to poor procurement and distribution practices, corruption, and leakage.<sup>10,11</sup> For consumers, out-of-pocket payments accounted for approximately 36.2% of health expenditures in low- and middle-income countries (LMICs) in 2014, compared to 13.6% in Organisation for Economic Co-operation and Development countries.<sup>12</sup> Medicines alone comprise roughly 30% of health spending in LMICs.<sup>13</sup> Therefore, catastrophic health events can lead families and individuals into poverty, and those already in poverty cannot access quality health services and medicines due to the lack of affordability.

Because financial resources are finite for individuals and governments, the onus is on governments to accurately estimate the financial need, develop creative mechanisms for funding, and ensure prudent use of those finite resources. Without serious efforts to finance the pharmaceutical subsector, health systems will continue to be hampered. The SIAPS approach to strengthening financing to improve access to medicines first required analyzing the sources of financing and revenue within the country financing architecture and assessing policies, laws and regulations, human resources, and information systems. In a second step, SIAPS and country counterparts designed interventions to optimize the use of existing resources, mobilize additional resources, and reduce barriers to equitable access to medicines through innovative strategies and mechanisms.

## *Mobilization of Additional Financial Resources*

SIAPS supported countries by identifying funding gaps and advocating for the redistribution of resources and stock. SIAPS strengthened country capacity in quantification, supply planning, and tracking stock inventory and medicine usage, resulting in more accurate procurements. Once funds were committed and deliveries received, SIAPS ensured that products reached the correct health facilities by drafting and monitoring distribution plans.

Between 2011 and 2017, SIAPS assisted seven countries with the development of 20 Global Fund applications that collectively amounted to more than USD 500 million (figure 6). By developing Global Fund grant proposals and ensuring compliance to donor requirements for additional funding requests, SIAPS-supported countries have been able to access critical funding for malaria, TB, and HIV/AIDS.



<sup>9</sup> Moon S. Powerful Ideas for Global Access to Medicines. 2017. The New England Journal of Medicine. Available at: [www.nejm.org/doi/10.1056/NEJMp1613861](http://www.nejm.org/doi/10.1056/NEJMp1613861)

<sup>10</sup> World Health Organization. WHO Global Health Expenditure Atlas, 2014. Available at: <http://www.who.int/health-accounts/atlas2014.pdf>

<sup>11</sup> Management Sciences for Health. 2012. MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health.

<sup>12</sup> World Bank. Out-of-pocket health expenditure (% of total expenditure on health). Available at: <https://data.worldbank.org/indicator/SH.XPD.OOPC.TO.ZS>

<sup>13</sup> Lu Y, Hernandez P, Abegunde D, Edejer T. 2011. Medicine expenditures. The world medicines situation 2011. Geneva: World Health Organization. Available at: [http://www.who.int/health-accounts/documentation/world\\_medicine\\_situation.pdf](http://www.who.int/health-accounts/documentation/world_medicine_situation.pdf)

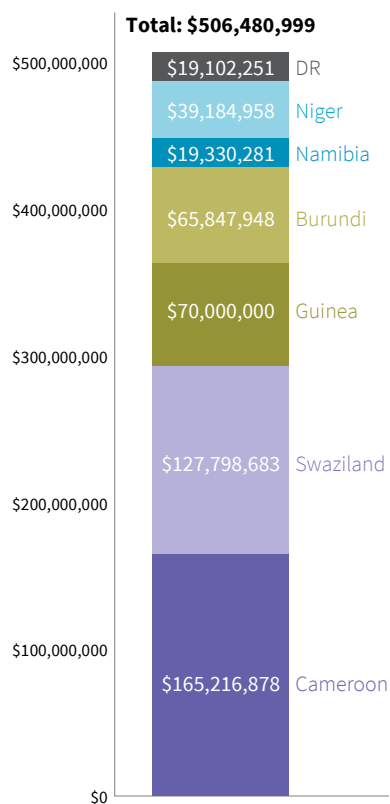


Figure 6. Value of Global Fund grants and proposals developed with assistance from SIAPS

## Enhanced Financial Accuracy through Gap Analyses

Four countries—Cameroon, Dominican Republic, South Sudan, and Swaziland—conducted financial gap analyses with SIAPS assistance to preempt funding gaps related to the purchase of medicines.

In Dominican Republic, SIAPS provided technical assistance to improve quantification and procurement processes. SIAPS helped develop a presidential decree to support pooled procurement and a standardized methodology to revise the procurement process. Between 2012 and 2017, SIAPS supported the pooled procurement process by conducting gap analyses and identifying alternative financial sources, followed by advocating for additional Ministry of Health resources when necessary. To facilitate future quantification exercises without the need for external technical assistance, SIAPS also drafted guidelines for the quantification and programming of medicines and supplies, with links to all electronic applications for data entry and analysis.

With assistance from SIAPS, Dominican Republic saved USD 53 million as a result of improvements to pooled procurement. Further, revision of the high-cost medicines list saved an additional USD 62 million, which was then invested in the procurement of antiretrovirals and other essential medicines.

## Increased Efficiency in the Use of Existing Resources

SIAPS supported the responsible use of existing financial resources with interventions that emphasize the importance of transparent financial transactions at health facilities and by monitoring drug prices to improve financial decision making at all levels of the health system. SIAPS contributed to more than USD 120 million in savings across four countries through improved pharmaceutical management practices, including improved quantification and procurement; revised national essential medicines lists; and revised hospital formularies and stock redistribution (table 5).



Table 5. Savings from Improved Pharmaceutical Management Practices

Portfolio	Approx. Amount Saved (USD)	Action
Bangladesh	6,380,000	Quantification support for tuberculosis; reproductive health/family planning; and maternal, newborn, and child health commodities
Ethiopia	186,678	Stock redistribution to reduce expiries
South Africa	2,043,520	Revised formulary
Dominican Republic	53,000,000 62,000,000	Pooled procurement Revised high-cost medicines list
Total	123,610,198	

## Reduced Financial Barriers to Patients in Accessing Medicines

As many countries work to rollout or expand universal health coverage initiatives, SIAPS advocated for the inclusion and evaluation of medicine benefit programs within national health insurance schemes. SIAPS conducted broad assessments of pharmaceutical benefit programs to inform the implementation practices of national health insurance authorities in Ghana and Ethiopia and to inform the design strategies for the pharmaceutical benefit component for the planned national health insurance schemes in South Africa and Namibia.

In Mozambique and Democratic Republic of the Congo, SIAPS collaborated with health ministries to contain the costs of medicines and health services by revising and standardizing prices. SIAPS also supported the development of equity-enhancing national medicine pricing policies in Angola and Ukraine. SIAPS/Ukraine further contributed to the roll-out of the reimbursement program called Affordable Medicines. The program provides essential medicines for cardiovascular diseases, type 2 diabetes, and asthma, either at no cost or for a small copayment.

### Innovating Pharmaceutical Services in Ethiopia through Auditable Pharmaceutical Transactions and Services

SIAPS developed a unique approach to tracking medicine expenditures and increasing revenue from the sale of medicines in Ethiopia. Auditable Pharmaceutical Transaction and Services (APTS) is a package of interventions designed to improve the quality of pharmaceutical services at public health facilities. This intervention for improved financial accountability of medicine expenditures and availability was approved in all 11 regions of the country and is operational in 77 health facilities, 72 hospitals, and 7 health centers throughout Ethiopia.

Health personnel use 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 also used APTS as a platform to make recommendations on how to enhance pharmacies' appearance, storage capacity, and privacy for patients. The results span a range of areas—from increased availability in medicines to patient satisfaction to budget utilization (table 6). The success and widespread adoption of APTS across Ethiopia's regional health bureaus can be attributed to its inclusion in the FMOH's Health Sector Transformation Plan and the enactment of regulations in all regions and at the federal level. 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.<sup>14</sup>

Table 6. Improvements in Surveyed Health Facilities Implementing APTS, 2011–2015

Indicators	2015*
% of hospitals that measure affordability of medicines on a monthly basis	73
% of hospitals that use unique identifying codes for each medicine	73
% of hospitals that conducted transaction auditing	71
% of hospitals that took measures based on audit findings	31
% of hospitals that report product, finance, and service-related data	75

\*APTS baseline was zero in 2011

<sup>14</sup> Fenta TG, Teshome D, Gulelat B, Assefa T. 2016. Outcomes of Auditable Pharmaceutical Transactions and Services (APTS) Implementation: Assessment Report. Submitted to the Federal Ministry of Health (FMOH), Ethiopian Pharmaceutical Association (EPA), and Systems for Improved Access to Pharmaceuticals and Services (SIAPS). Addis Ababa: FMOH, EPA, and SIAPS.



The SIAPS-developed Supply Chain Management Portal increases financial transparency during the procurement process in Bangladesh as it is prepopulated with the national medicines list and price guide and includes standardized descriptions of commodities and equipment, thereby eliminating the possibility of giving preference to any particular brand.



# IR5 Pharmaceutical Services to Achieve Desired Health Outcomes Improved

## Availability of Pharmaceuticals Improved through Stronger Supply Chain Systems

Despite many positive changes in the global health supply-chain landscape, many countries still face several challenges with the availability of medicines and other health products. Underlying operational challenges include inaccessibility to quality data throughout the supply chain; inefficiencies in the management of procurement, storage, and transportation; and inadequate workforce numbers and capabilities.

In response to these challenges, SIAPS led targeted interventions to address them, including capacity building in supply management and standardizing and streamlining logistics systems, processes, and 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 trainings on best practices, structured routine mentoring, and supportive supervision and developed tools to assist in evidence-informed decision making. SIAPS also supported the identification of funding gaps through quantification and stock status updates to inform procurement and distribution plans and mitigate product stock-outs and expiries.

### *Assessing Supply Chain Capability and Performance to Inform Action*

SIAPS used a structured and consultative assessment process to examine pharmaceutical supply systems, identify and analyze bottlenecks, and propose intervention options for system strengthening. Importantly, stakeholders endorsed most of these intervention options for implementation. SIAPS provided technical assistance for supply chain assessments in 11 countries: Angola, Bangladesh, Benin, Cameroon, Guinea, Mali, Philippines, Swaziland, Togo, Ukraine, and Uzbekistan.

## Innovating to create additional commodity storage capacity in Mali

Recommendations from a situational analysis of Mali's Central Medical Store (PPM) informed both its five-year strategic plan and product catalog. In addition, SIAPS advised the PPM on structural and operational changes to optimize storage capacity and conditions. Accordingly, SIAPS helped the PPM in designing and building prefabricated warehouses, namely, Warehouse-in-a-Box (WiB). This innovative structural development cuts the costs associated with traditional new construction and is rapidly deployable to meet the country's pressing commodity storage needs. By the end of the program, WiB construction had launched centrally in Bamako and in the regions of Kayes, Koulikoro, and Mopti.

## Pharmaceutical Services to Achieve Desired Health Outcomes Improved

SIAPS conducted assessments of the pharmaceutical supply system in Guinea and Benin by using the national supply chain baseline assessment toolkit. This comprehensive toolkit was collaboratively developed by SIAPS, USAID-funded Supply Chain Management System, and the USAID | DELIVER Project. It consists of two tools that assess the supply system's capability maturity and operational performance. Key performance indicators and capability maturity scales are used to measure system performance and identify inefficiencies. Findings from this assessment are being used as the baseline to monitor performance. The tool can be used by Guinea's

[cont...](#)

and Benin's Ministries of Health for future assessments, enabling policy makers and supply chain managers to develop strategic and operational plans and more easily monitor whether system strengthening interventions are achieving desired progress.

The results of this assessment guided the supply chain strategic-planning process of Benin's National Directorate of Pharmacy and Laboratories (DPMED). It also spurred the DPMED to solicit USAID's support to strengthen the country's medicine registration system. Consequently, SIAPS supported procurement of a high-capacity server to enhance the existing electronic medicine registration tool. SIAPS further assisted DPMED in processing the backlog of medicine registration application dossiers.

The Global Fund has since created an assessment tool that is modeled after the capability maturity assessment toolkit for its own assessments of supply chain systems in countries receiving Global Fund grants.

### *Efficient Quantification of Health Commodities*

Accurate and evidence-based quantification exercises involving all stakeholders contribute to better coordination of medicines procurement and supply management, cost savings, and improved access to medicines. SIAPS provided technical and capacity-building assistance to institutionalize effective quantification systems, improve accuracy in estimating procurement needs, and help stakeholders in the planning and solicitation of financial resources.

SIAPS helped establish forecasting and supply planning coordination committees in 16 countries, with respective terms of reference, across health programs to create more streamlined, horizontal, and reliable quantification systems. Quantification interventions implemented by SIAPS have contributed to increased availability of commodities at the central warehouse and health-facility levels in many SIAPS-supported countries, such as Mali (figure 7), and aided countries in applying for financing. In Sierra Leone, for instance, SIAPS oversaw the establishment of the country's national quantification committee and seven disease-specific technical working groups (TWGs). In 2017, SIAPS guided the HIV TWG in finalizing a three-year (2018–2020) quantification that was part of a Global Fund grant request proposal.

## Coordinating Stakeholders to Streamline the Quantification Process in Mali

In 2013, Mali's Ministry of Health requested SIAPS assistance in establishing a national coordination mechanism for health commodities supply management, Comité National de Coordination et de suivi de la Gestion des Médicaments Essentiels (CNC). SIAPS helped CNC members setup a quantification subcommittee to oversee seven disease-specific TWGs responsible for quantification exercises and supply planning. SIAPS trained and supported TWG members during annual quantification exercises, which use data from the SIAPS-developed commodity management dashboard, OSPANTE, as well as appropriate forecasting tools (PipeLine and Reality Check). There is now has one national quantification process for key commodities and one national country supply plan per health program that accounts for donor commitments. Better skills and tools have enabled TWGs to perform quantification exercises and generate supply plans quicker and more reliably. As a result, there has been a reduction in stock-outs in warehouses, from 89% (2013) to 19% (2017), and in health facilities, from 51% (2013) to 27% (2017) (figure 7), as the CNC and its subgroups have relocated stock as necessary. Furthermore, success of the CNC prompted the setup of similar coordinating mechanisms in six regions to continue the work of ensuring the availability of medicines at all levels of the health system.



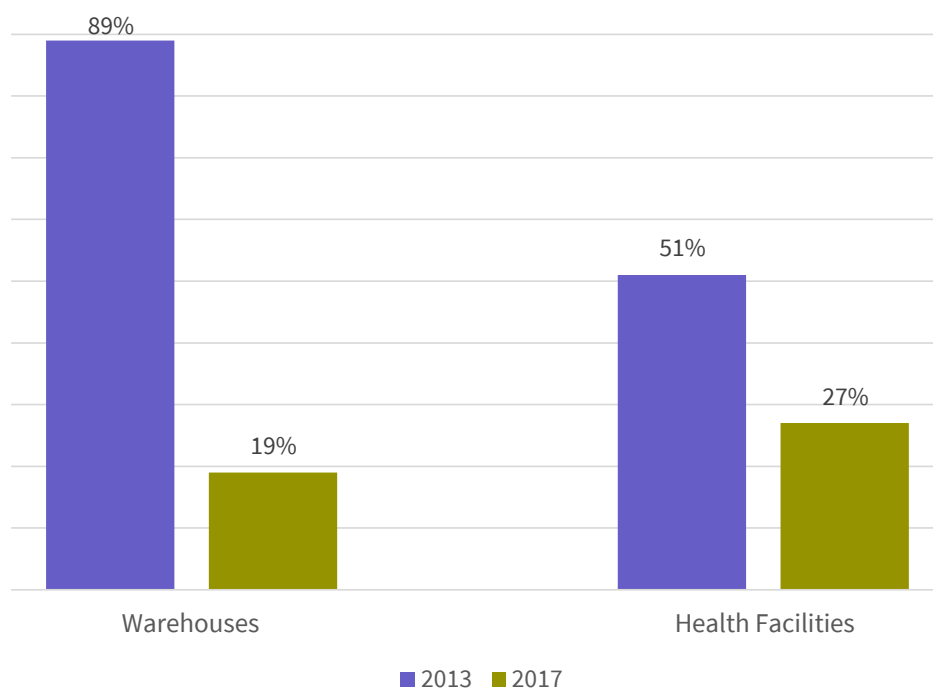


Figure 7. Percentage of warehouses and health facilities in Mali with stock-outs of a preselected group of medicines for 3 days or more in 2013 and 2017

### *Tracking Medicine Consumption and Inventory*

Logistics management tools, such as SOPs, manuals, and guides, were developed in several SIAPS-supported countries to facilitate adherence to pharmaceutical management standards and best practices. 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 at warehouses from 21% (2013) to 5% (2017). In Sierra Leone, SIAPS introduced a Continuous Results Monitoring System (CRMS), a supportive supervision and performance-improvement approach that tracks key pharmaceutical management indicators and encourages performance improvement.

## Introducing the Service Delivery Point Dashboard Module in Bangladesh

In Bangladesh, SIAPS has helped develop a series of manuals, guidelines, and SOPs in supply management that have contributed to more accurate pharmaceutical procurement and improved supply management performance within the Ministry of Health and Family Welfare. The introduction of the service delivery point dashboard module, as a component of the national-level procurement tracker and commodity dashboard, has enabled the capture of stock and consumption data at health facilities. Through capacity building and creating a pool of master trainers, stock-outs at the subdistrict level and service delivery points were reduced from 7% and 2% (2014), respectively, to 0 and less than 1% (2017). This has resulted in no stock-outs of family planning commodities countrywide since 2011.

## *Improving Information Quality and Availability for Decision Making*

An effective health system depends on high-quality pharmaceutical information, from supply inventory records to patient data. SIAPS improved the quality and availability of information with a suite of electronic tools that help pharmaceutical managers develop sound policies and monitor supplies and services. These tools are used globally, for example, QuanTB has been downloaded in 136 countries, and many have demonstrated positive impact in supply chain systems. QuanTB has received global recognition and is now the official tool of the Stop TB Global Drug Facility for procurement and as an early warning system.

### Using e-Tools to Prevent Health Product Stock-out and Improve Patient Services

In 2014, the early warning system in Togo's HIV/AIDS commodities tracking tool, Outil de suivi des produits du VIH/SIDA en Afrique de l'Ouest (OSPSIDA), revealed that 71% of antiretrovirals (ARVs) were at high risk of stock-out, putting 96% of patients at high risk of treatment interruption. SIAPS supported the MOH in mobilizing an emergency procurement and, by November 2015, this 96% had been reduced to less than 1%.

As Namibia implements community-based antiretroviral therapy (ART), the SIAPS-developed Electronic Dispensing Tool (EDT) has been an important component in managing patient and inventory information. SIAPS supported decentralization efforts with technical assistance to health workers on using EDT and its mobile version to dispense ARVs through community adherence support groups. SIAPS also presented the tools, SOPs, and process flows for group dispensing. By November 2017, 55 groups with more than 650 stable patients had benefited from these newly introduced community support groups. Patients reported improved adherence and satisfaction with reduced waiting time and travel to obtain ARVs.

## **Pharmaceutical Services Improved to Achieve Desired Health Outcomes**

While critically important, making medicines available to populations is by itself not sufficient to ensure improved health outcomes. The World Health Organization (WHO) estimates that 50% of medicines are used inappropriately, which can result in poor health outcomes, medicine waste or shortages, financial losses, and the development of antimicrobial resistance (AMR).<sup>15</sup>

Ensuring that medicine selection, prescribing, dispensing, and use are optimized creates an environment in which patients can attain the best possible health outcomes. By focusing not only on strengthening supply chains but also on the pharmaceutical systems, SIAPS helped ensure that availability is accompanied by rational use to improve patient safety, optimize medicine use, and contain AMR.

### ***Patient Safety and Therapeutic Effectiveness Ensured***

SIAPS worked 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.

SIAPS worked with national stakeholders in 12 countries, including Bangladesh, Democratic Republic of the Congo (DRC), Ethiopia, Namibia, South Africa, Swaziland, and Ukraine, to support active or passive

<sup>15</sup> World Health Organization. 2010. Medicines: Rational Use of Medicines, Fact Sheet No. 338.

surveillance systems. SIAPS/Ethiopia's support to 168 health facilities led to an increase in adverse drug event (ADE) reporting, from 79 (2011) to 683 (2016). In addition, two regulatory decisions were made based on ADE reports: an investigation on a fixed-dose ARV medicine and two product-quality defect reports. At the central level, SIAPS/Bangladesh's technical assistance supported significant progress in improving the reporting system managed by the Adverse Drug Reaction Monitoring Cell and contributed to Bangladesh becoming a full member of the WHO Collaborating Centre for International Drug Monitoring.<sup>16</sup>

In Burundi, Namibia, and Swaziland, SIAPS supported the introduction of sentinel site-based active surveillance systems, which monitor medicine safety at the facility level. Since 2013, the active surveillance system in Swaziland has monitored more than 4,000 patients, and it had collected data on more than 1,200 adverse events as of September 2016. As a result of improvements in reporting adverse drug reactions, Swaziland was made a full member of the WHO Collaborating Centre for International Drug Monitoring.

## Ensuring Safety Monitoring with the Introduction of New TB Medicines

Philippines, Swaziland, Georgia, Kenya, and Uganda were among the first countries to treat tuberculosis (TB) patients with bedaquiline and delamanid, which are the only new TB medicines released to the market in more than 40 years and are used to treat multidrug resistant-TB (MDR-TB). Critical to introducing these new medicines is monitoring drug safety, and SIAPS provided technical assistance to strengthen the capacity of National TB Programs (NTPs) to monitor the safety and effectiveness of bedaquiline and other medicines. SIAPS assistance included training national counterparts and international partners on good PV practices, developing PV SOPs and guidelines, visiting facilities, and offering on-site mentoring. SIAPS/Philippines provided technical assistance to the nine-month MDR-TB treatment regimen operations research study on bedaquiline. In Georgia and Swaziland, SIAPS served as a member of the active drug safety monitoring (aDSM) working groups.

Philippines, Swaziland, and Georgia also began implementing the SIAPS-developed Pharmacovigilance Monitoring System (PViMS), a web-based application that streamlines and simplifies data collection and analysis for active surveillance. SIAPS facilitated several workshops for NTPs and TB stakeholders to implement PViMS at TB treatment centers, monitor drug safety, and provide case management for patients taking bedaquiline or delamanid. In Philippines, PViMS has been adopted as the national aDSM database.

### *Improving Medication Use*

A number of social, behavioral, and financial considerations intertwine to influence how patients ultimately take their medicines. When providers dispense unnecessary or inappropriate medicines, do not provide adequate treatment counseling, or fail to understand the driving forces behind non-adherence, patients often receive sub-optimal care and experience negative health outcomes that can further exacerbate the spread of AMR. SIAPS addressed this by implementing patient-centered pharmaceutical care programs, developing or improving the use of standard treatment guidelines (STGs) and essential medicines lists (EMLs), supporting the effective use of diagnostics, and improving patient counseling and adherence.

SIAPS/Ethiopia helped institutionalize clinical pharmacy services in 65 hospitals by training 200 pharmacists and introduced tools and SOPs to promote patient-centered pharmaceutical care. A 2015 assessment showed that 8,257 drug therapy problems (DTPs) had been identified by pharmacists in 31 hospitals since the initiation of

<sup>16</sup> The WHO Uppsala Monitoring Center provides a forum for WHO member states to collaborate in pharmacovigilance. Countries must demonstrate a certain administrative structure and technical competence in PV for full membership. As of January 2018, there were 130 full members. <https://www.who-umc.org/>



services in August 2012. Pharmacists were able to intervene in 87% of the 8,257 DTPs, with an 88% acceptance rate of their recommendations by multidisciplinary teams. Pharmacists at six hospitals identified 79 treatment errors at point of service between October and December 2016, all of which were immediately corrected.

### Global Technical Leadership

As a global technical and thought leader in strengthening pharmaceutical services in low- and middle-income countries (LMICs), SIAPS published the following seminal documents:

- *Enhancing Health Outcomes for Chronic Diseases in Resource-Limited Settings by Improving the Use of Medicines: The Role of Pharmaceutical Care* provides a framework, scope, and standards for implementing pharmaceutical care in LMICs.
- *Systems-based Approaches to Improving Medication Adherence* describes strategies and tools that help to address adherence using a systems strengthening approach.
- *Developing, Implementing, and Monitoring the Use of Standard Treatment Guidelines* is a how-to-manual that provides practical guidance on the various aspects of STG development and management and includes multiple tools, templates, examples, and country/local-level case studies.
- *Revising Preservice Curriculum to Incorporate Rational Medicine Use Topics* details how to incorporate rational medicine use and AMR components in health professional training programs and includes several tools and templates to facilitate the process.

### Case Management

Proper case management of a disease or health condition helps ensure effective treatment and medication safety, promotes high-quality care and cost-effective outcomes, and helps contain drug resistance. SIAPS supported community case management (CCM) for malaria in Burundi, CCM for TB in Tanzania, and integrated CCM for pneumonia, diarrhea, and malaria in Mali, DRC, and Guinea. SIAPS/Burundi trained more than 500 community health workers (CHWs) and attained impressive results for the overall implementation period—caregivers of 88% of children under the age of five sought care from CHWs within 24 hours of the onset of the child’s fever. Of those children who tested positive for malaria with a rapid diagnostic test, 91% were treated with artemisinin-based combination therapies within 24 hours of the onset of fever.

### Drug and Therapeutics Committees

Drug and therapeutics committees (DTCs) manage the selection of medicines, evaluate medicine use, and implement strategies to improve use throughout the health care system. SIAPS provided support to DTCs in seven countries—DRC, Ethiopia, Jordan, Mozambique, Sierra Leone, South Africa, and Swaziland. Collaborating with country stakeholders, SIAPS provided 57 trainings to more than 1,555 participants as well as ongoing technical support, including onsite technical assistance and supportive supervision. Following the trainings and technical assistance, 451 DTCs were created and 52 revitalized. DTCs helped conduct 45 medicine use studies or evaluations; develop or implement five treatment/prophylaxis guidelines and four formularies; develop five rational medicine use policies; conduct 27 in-service trainings on rational medicine use; and revise two pre-service curricula to include DTC-related topics.



## Medication Adherence

Support for medication adherence is essential for empowering patients to better manage their therapies. To decrease barriers to antiretroviral therapy (ART) in Angola and Namibia, SIAPS supported the transition to decentralized dispensing practices. In Angola, SIAPS helped implement changes that enabled dispensing of ARVs at health facility pharmacies, which had previously been available only at hospitals. SIAPS/Namibia contributed to the implementation of community-based ART (CBART) dispensing programs by training nurse mentors and pharmacy staff on the CBART model. SIAPS also helped develop Namibia's adherence strategy and modified the Electronic Dispensing Tool by adding an SMS reminder for patients to pick up their pills on time. In collaboration with other partners, SIAPS/Namibia supported the Ministry of Health and Social Services to apply the WHO-recommended early warning indicators to monitor patients' medication adherence.

## Setting Standards for Pharmaceutical Services

SIAPS supported multiple countries in advancing pharmaceutical standards, revising and implementing treatment guidelines, and assessing medicines for inclusion in EMLs and formularies. SIAPS assisted 13 countries in revising and/or updating EMLs and 23 in developing pharmaceutical and disease-specific guidelines and SOPs. To help encourage widespread use of hospital-level STGs and the EML, SIAPS worked with government partners in South Africa to make the documents available through a smart phone application and to optimize the online versions of both.

## Emergence of AMR Slowed

SIAPS worked at the global, regional, and country levels to slow the spread of AMR and promote rational medicine use. Activities included building awareness of the threat of AMR, advocating for a coordinated response, and implementing interventions that support the goals of WHO's Global Action Plan on AMR. SIAPS' practical guidebook, "Building Coalitions for Containing Antimicrobial Resistance," is included as a resource in the national action plan toolkit references in WHO's Manual for Developing National Action Plans. The guide describes SIAPS' experiences and lessons learned in building coalitions against AMR at the country and regional levels and includes user-friendly implementation tools and templates.

SIAPS collaborated with Knowledge for Health to develop a two-part e-Course on AMR, which is available on the Global Health eLearning Center. Between September 2016 and September 2017, 1,454 individuals from 83 countries earned certificates for completing part 1 of the course. Between its publication in November 2015 and September 2017, 1,168 individuals from 80 countries earned certificates for completing part 2 of the course (table 7).

Table 7. Number of Participants Completing SIAPS-developed AMR Courses

eCourse	Timeframe	# Countries Represented	# Participants Earning Certificates			
			Male	Female	Unknown	Total
AMR Part 1	2016–2017	83	669	782	3	1,454
AMR Part 2	2015–2017	80	582	584	2	1,168

SIAPS provided technical assistance to develop national AMR strategies in Ethiopia, Namibia, Sierra Leone, South Africa, and Swaziland. In Namibia, SIAPS helped mobilize a wide range of stakeholders and sectors against AMR through a call-to-action and collaborated with the University of Namibia to integrate AMR and rational medicine use topics into the school's pre-service pharmacy curriculum. SIAPS/Ethiopia raised public awareness of AMR by building the capacity of journalists to disseminate AMR-related information via print and electronic media. Through this effort, 286 journalists were trained on AMR prevention and containment and published 368 stories on AMR and rational medicine use between 2012 and 2015.

Using an infection control self-assessment tool (ICAT), SIAPS helped country stakeholders develop, implement, and monitor infection prevention and control (IPC) practices in hospitals. In Namibia and South Africa, the ICAT was institutionalized and adapted as an official tool to improve IPC practices. SIAPS also adapted the ICAT for more basic health care settings and published “Infection Control Assessment Tool for Primary Health Care Facilities.”

SIAPS helped introduce chlorhexidine (7.1%) for newborn cord care in DRC, Pakistan, and Afghanistan by developing an introduction strategy that took appropriate regulatory frameworks into account. For example, in DRC, SIAPS supported product registration and the revision of the EML and treatment guidelines to include chlorhexidine, which is now used in all regions.

## Reducing the Use of Prophylactic Antibiotics during Cesarean Section in Jordan

SIAPS worked with Jordan’s Ministry of Health (MOH) to strengthen national and institutional capacity to improve antimicrobial stewardship and patient outcomes and contain AMR. SIAPS helped pilot a continuous quality improvement (CQI) system in three hospitals to improve the prophylactic use of antibiotics for cesarean sections. SIAPS assisted hospital teams in developing customized protocols and procedures for the prophylactic use of antibiotics in cesarean section, and teams agreed on the general principles of CQI plans for their hospitals.

SIAPS supported hospital teams to develop, use, and refine tools to facilitate monitoring indicators on protocol adherence, timing and use of prophylactic antibiotics, rates of surgical site infection, and cost savings. At the end of the pilot period, all three MOH hospitals had demonstrated success in decreasing both the number of doses of antibiotic prophylaxis given and the prescribing of other, unnecessary antibiotics, which amounted to significant cost savings (table 8).

Table 8. Improvements in Antibiotic Use at Three Pilot Hospitals in Jordan

Result Area	2012
Correct antibiotic use (cefazolin)*	86%**
Correct timing of first dose*	92%**
Correct number of doses*	88%**
Average cost for antibiotic prophylaxis per case	79% decrease compared to baseline
Cesarean section surgical site infection rate	1.59 % (within international rate benchmark) <sup>17</sup>

\* Baseline: 0% (2010)

\*\*in log-captured cases (log capture rate = 81%)

Finally, the MOH leveraged the experience and lessons learned from the pilot to develop and mandate the use of uniform standard protocols and procedures for antibiotic prophylaxis during cesarean section in all government-run obstetric and gynecologic hospitals.

<sup>17</sup> Ghuman M et al. Post-caesarean section surgical site infection: rate and risk factors. The New Zealand Medical Journal 2011; 124





## HEALTH ELEMENTS

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### Malaria

Since 2000, there has been substantial progress in the fight against malaria. Between 2000 and 2015, malaria case incidences declined by 37% and malaria mortality rates by 60%.<sup>18</sup> Despite this remarkable progress, approximately 216 million cases of malaria occurred globally in 2016, resulting in an estimated 445,000 deaths, most of which were children under the age of five in Sub-Saharan Africa.<sup>19</sup> Sustained reductions in malaria-related mortality and morbidity will only be achieved through a systems strengthening approach to improve access to and the appropriate and safe use of quality-assured malaria medicines.

The US President's Malaria Initiative (PMI) has invested heavily in procuring malaria commodities, ensuring their safe and effective use, and strengthening local supply chains. Many countries supported by PMI continue to face challenges in ensuring an uninterrupted supply of high-quality malaria medicines and commodities as well as their appropriate use. Factors contributing to these challenges include poor planning and coordination among country partners; a lack of strategic information for decision making, leading to stock-outs at all levels; and weak human resource capacity to perform key pharmaceutical management functions, resulting in irrational medicine prescribing, dispensing, and use.

Working closely with PMI, SIAPS improved the availability of quality antimalarial products and their effective use to achieve desired health outcomes in support of PMI objectives. Using the systems strengthening approach, the SIAPS malaria portfolio ensured that approaches, strategies, and tools were based on and informed by country-level needs and priorities; identified opportunities at the global, regional, and country levels to use new and existing tools; and coordinated the implementation of activities.

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<sup>18</sup> World Health Organization. Fact Sheet: World Malaria Report 2015. Available at: <http://www.who.int/malaria/media/world-malaria-report-2015/en/>

<sup>19</sup> World Health Organization. World Malaria Report: 2017. Available at: <http://apps.who.int/iris/bitstream/10665/259492/1/9789241565523-eng.pdf>

# Global Technical Leadership

The SIAPS malaria portfolio contributed to the global malaria body of knowledge and policy dialogue by taking a lead role in a variety of Roll Back Malaria working and technical advisory groups, presenting at conferences, and producing publications. A key success in this area is “[The Multi-Partners Manual for Quantification of Malaria Commodities](#),” which was developed by SIAPS and other partners and provides step-by-step guidance for carrying out national-level quantification of artemisinin-based combination therapies and rapid diagnostic tests (RDTs). This manual has been used across all SIAPS- and USAID | DELIVER-supported countries that also receive PMI support and has been adopted by Roll Back Malaria as its official quantification manual.

## Strengthening Coordination among Partners

SIAPS supported good governance and coordination in the supply chain by facilitating pharmaceutical supply management working groups in Angola, Burundi, Democratic Republic of the Congo (DRC), Guinea, Mali, and South Sudan. To improve efficiency, SIAPS strengthened country-level coordination among in-country malaria partners through regular malaria coordination meetings and the development of joint work, operational, and strategic plans.

Also in the aforementioned countries, SIAPS coordinated and facilitated a malaria implementing partners meeting, during which the national malaria control programs (NMCPs) and their main partners shared and analyzed data for malaria commodities to improve decision making.

## Securing Additional Financing for Malaria Control

SIAPS played a key role in the financing and sustainability of national malaria programs. SIAPS collaborated with NMCPs and malaria partners in Angola, Burundi, Niger, and South Sudan to develop concept notes for Global Fund malaria grants. As a result of this assistance, the Global Fund approved Burundi’s concept note for USD 24,921,561 to support NMCP activities for three years. In Niger, the technical review panel approved the concept note for USD 36,735,493 and an additional USD 2,449,465.

## Improving Availability of Information for Decision Making

SIAPS supported countries to implement a set of three PMI commodity monitoring tools: information on supply plans for malaria commodities; the End Use Verification (EUV) tool; and the Procurement Planning and Monitoring Report for Malaria. SIAPS supported the implementation of more than 70 EUV surveys in eight PMI countries: Angola, Burundi, DRC, Ethiopia, Guinea, Kenya, Liberia, and Mali. At the end of each survey, Ministries of Health and partners met to share and disseminate results and highlight the issues affecting the availability and use of malaria commodities. NMCPs then took corrective actions to improve the availability and use of malaria commodities (table 9).

Table 9. NMCP Actions Based on EUV Survey Findings from Select Countries

Country	Evidence-informed Actions
Burundi	The NMCP streamlined the requisition process for malaria commodities, leading to a reduction in the requisition time from two weeks to two days.
DRC	The NMCP adopted the EUV survey as one of its monitoring and evaluation tools.
Guinea	A new malaria reporting system was created that achieved a 90% reporting rate in 2015, which was an increase from 30% in 2012.
Liberia	The NMCP and country health teams were prompted to organize trainings after findings showed a lack of formal training in case and commodity management.
Mali	The Ministry of Health made free RDTs available for the entire population, with no cost recovery.

## Highlights of Country-level Contributions

SIAPS provided technical assistance for country-level activities to ensure that systems strengthening interventions in support of malaria control programs were of the highest technical quality and were consistent with PMI objectives and SIAPS's mandate. Some key achievements are highlighted in table 10.

Table 10. Select Country-level Achievements

Country	Key SIAPS Achievements
Angola	Supported the NMCP to develop and distribute pharmaceutical management tools to all facilities. Of the 778 facilities, 672 (86%) are currently using appropriate tools for malaria logistics data.
Burundi	Helped develop a policy document and implement intermittent preventive treatment in pregnancy (IPTp). <sup>20</sup> SIAPS also supported the quantification and delivery of IPTp commodities.  Helped implement community case management activities to strengthen malaria case management at the facility and community levels.
DRC	Helped revitalize the national procurement and supply chain management working group that assesses national antimalarial supplies; SIAPS participated in the first nationwide quantification in 2016.  Assisted in establishing provincial-level medicines coordination committees that would enable partners to share and analyze information regularly at the national and provincial levels.
Guinea	Supported the NMCP in carrying out a five-year forecast and a three-year procurement plan for malaria commodities, which helped secure more than 98% of the funding required for the procurement of malaria commodities between 2016 and 2018.
Niger	Collaborated with the NMCP to launch a supply chain technical working group for malaria commodities.
South Sudan	Supported the development the National Malaria Control Policy, updated malaria case management and training guidelines, and revised the national malaria strategic plan.  Trained and mentored central-level NMCP staff.

<sup>20</sup> IPTp is a proven cost-effective intervention for preventing malaria during pregnancy.





## Maternal, Newborn, and Child Health

Many essential maternal, newborn, and child health (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 (especially in procurement), and addressing regulatory components of the health system. The availability of quality MNCH medicines and supplies is often subject to the weaknesses in public sector supply chain systems, including inaccurate quantification, poor procurement and distribution practices, inadequate storage, and limited information management systems. 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. Financial issues can also be an obstacle to access to essential reproductive, maternal, newborn, and child health (RMNCH) medicines.

SIAPS worked with global and country partners to improve access to and use of life-saving medicines for women and children, thereby contributing to the US Government goal of ending preventable child and maternal deaths. By promoting a pharmaceutical systems strengthening approach, SIAPS activities went beyond solely addressing supply chain challenges, but rather incorporated 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.

### Global Technical Leadership

SIAPS actively supported the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) and participated in several of the commission's technical resource teams (TRTs), beginning in 2012 (table 11). SIAPS participated in identification of the 13 life-saving RMNCH commodities prioritized by the UNCoLSC and developed documents that informed the commission's recommendations.

SIAPS developed tools and conducted assessments to assist countries in expanding efforts to lower maternal and child mortality. Highlights are as follows:

*The Estimation of Unmet Need for Maternal Health Medicines.* SIAPS designed and validated a tool to assist countries in planning for better quantification and procurement. The tool has been used extensively in forecasting demand for maternal health medicines.

*Guidance for Planning the Introduction of New Reproductive, Maternal, Newborn, and Child Health Medicines and Supplies.* This document guides program managers at the national and subnational levels, as well as other stakeholders, on actions and considerations 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 during the introduction of new products.

*Mapping financial flows in four countries.* SIAPS mapped financial flows related to MNCH commodities in [Bangladesh](#), [Kenya](#), [Nepal](#), and [Uganda](#) to document how decisions regarding financing for these commodities are made and therefore assist the donor community in making smarter investments and assisting countries in mobilizing additional resources.

*Subnational procurement assessment.* This assessment in Bangladesh and Kenya provided a snapshot of the procurement practices at the subnational level and identified options for the government to increase access to RMNCH commodities through improved procurement practices and more efficient use of financial resources.

*Intervention Guide for the Management of Childhood Illnesses.* This guide assists district managers in developing interventions to improve availability and use of medicines for childhood illnesses. It was successfully validated in three districts in Zambia and presented to the School of Public Health at the University of Zambia.

Table 11. Highlights of SIAPS support to UNCoLSC, 2012–2017

Technical Resource Team	Key Contributions and Products
Maternal health	Options analysis with national stakeholders in Mali, to consider the integration of oxytocin into the Expanded Program on Immunization (EPI) cold chain at district and community levels  Guidance document on integrating oxytocin into the EPI cold chain  Maternal health TRT legacy document
Supply chain	Guidance on quantification of 13 life-saving RMNCH commodities in English and French, which were presented in many different forums and validated in several countries  Program briefs on promising supply chain practices  Supply chain TRT legacy document
Chlorhexidine	Introduction of chlorhexidine in Afghanistan, Democratic Republic of the Congo, and Pakistan  Guidance documents for chlorhexidine introduction
Diarrhea and pneumonia	Study in DRC on the use of amoxicillin dispersible tablets job aids and dispensing envelopes  Lessons learned document on zinc/oral rehydration solutions
Injectable antibiotics	Landscape analysis of antibiotics for newborn sepsis in DRC  Reviewed the WHO implementation guidelines for newborn sepsis management

Lastly, SIAPS participated in the following technical communities of practice:

- Reproductive Health Supplies Coalition
- Community Case Management (CCM) Task Force–SIAPS served as co-chair of the supply chain management subgroup and helped revitalize it
- Integrated Community Case Management (iCCM) Financing Task Team–SIAPS and other partners supported countries scaling up iCCM through Global Fund support
- Countdown Health Systems and Policy Working Group–SIAPS analyzed the pharmaceutical management policies and systems that affect access to essential RMNCH medicines and supplies across countries and submitted an article for publication in a peer-reviewed journal

## Country-level Contributions

To assist countries in their efforts to end preventable child and maternal deaths, SIAPS supported the development of innovative approaches to addressing barriers to access by using a systems strengthening approach. SIAPS efforts are summarized in table 12.

Table 12. Highlights of SIAPS/MNCH country-level achievements

Country	Key Achievements
Angola	<ul style="list-style-type: none"> <li>• Supported the national commodity security working group</li> <li>• Conducted a national quantification exercise</li> </ul>
Bangladesh	<ul style="list-style-type: none"> <li>• Finalized an assessment of pharmaceutical management practices at the district level</li> <li>• Developed a five-year forecast for essential RMNCH commodities</li> <li>• Created a technical working group to support the development and pilot of a Logistics Management Information System (LMIS) for the Directorate General of Health Services</li> <li>• Included RMNCH commodities in the pharmacovigilance system</li> </ul>
Burundi	<ul style="list-style-type: none"> <li>• Developed tools and job aids for CHWs to strengthen supply chain management as well as quality of care</li> <li>• Conducted an evaluation of CCM of malaria with a costing study resulting in the recommendation to expand an integrated CCM package</li> </ul>
DRC	<ul style="list-style-type: none"> <li>• Revised the essential medicines list to include key MNCH medicines, such as chlorhexidine and misoprostol</li> <li>• Revised national MNCH guidelines to align with the revised essential medicines list</li> <li>• Developed a national plan for introduction of chlorhexidine</li> <li>• Supported all in-country UNCoLSC efforts</li> </ul>
Guinea	<ul style="list-style-type: none"> <li>• Supported the Ministry of Health in planning the scale-up of CCM</li> <li>• Strengthened commodity management by CHWs through the use of job aids highlighting procedures</li> <li>• Conducted a quantification exercise for CCM medicines and supplies</li> <li>• Developed a community LMIS</li> </ul>
Mali	<ul style="list-style-type: none"> <li>• Developed a new LMIS that includes information from the community level</li> <li>• Developed training materials, tools, and job aids for the new LMIS</li> </ul>
South Sudan	<ul style="list-style-type: none"> <li>• Provided pharmaceutical management support for the introduction of misoprostol</li> <li>• Supported the development of an LMIS to increase visibility of data on availability of MNCH medicines</li> </ul>





## Neglected Tropical Diseases

Neglected tropical diseases (NTDs) produce a devastating level of chronic disability in developing countries. 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; 90% of the NTD disease burden is in Africa, with the majority of those victims infected with two or more NTDs.<sup>21</sup>

The World Health Organization (WHO) has targeted the seven most prevalent NTDs for elimination or control by 2020. Medicines donated by the pharmaceutical industry are now available to target these diseases and to help reach those WHO goals. However, supply chain constraints hamper prevention and treatment programs, often due to inadequate management that results in stock-outs or excess stock that lead to wastage from drug expiry.

The primary objective of SIAPS' NTD portfolio was to strengthen pharmaceutical management systems to achieve global goals. SIAPS provided technical input to USAID, WHO, the Task Force for Global Health, global networks, national NTD programs, and other relevant bodies to address technical leadership issues related to medicine policy, including donations, medicine regulation, supply chain management, serious adverse event (SAE) reporting, and patient safety.

### NTD Tools, Guides, and Manuals

SIAPS provided technical assistance to develop and disseminate comprehensive NTD management trainings, standard operational manuals, and tools to manage NTD commodities across all levels of the supply chain. The SIAPS approach also sought to integrate data collection and reporting across programs to help reduce staff burden whenever possible. SIAPS customized a comprehensive supply chain management tool to document and track receipt, issue, return of unused products, expiries, consumption, stock levels, and shipment status and to report adverse events related to NTD products. The tool was originally developed in consultation with country programs, the Task Force for Global Health, WHO, and other stakeholders.

<sup>21</sup> World Health Organization. Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation, 2012. Available at: [http://apps.who.int/iris/bitstream/10665/70809/1/WHO\\_HTM\\_NTD\\_2012.1\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/70809/1/WHO_HTM_NTD_2012.1_eng.pdf)



## **Supply Chain Assessments**

SIAPS also conducted pharmaceutical management assessments in high-endemic USAID priority countries, namely Senegal and Ethiopia, to identify priority issues and advise ministries of health and NTD staff on priority actions to promote access to and improve use of NTD commodities. In Ethiopia, the assessment exercise conducted with funding from and collaboration with the International Trachoma Initiative also resulted in SIAPS-led NTD supply chain management workshops, in partnership with the Federal Ministry of Health.

## **Building NTD Management Capacity**

SIAPS also held a series of regional training workshops in Ethiopia, Ghana, Guinea, Benin, and Nigeria on supply chain management for national NTD program managers. The workshops built capacity of national and district program managers and pharmacy professionals in improving supply chain management skills, integrated supply chain, more efficient use of all NTD medications, and better management of NTD medication tracking. This will lead to reduced overstocks in warehouses and facilities and an overall higher quality of treatment in programs.



## Tuberculosis

Inefficient tuberculosis (TB) medicine supply mechanisms highlighted the need to strengthen health system building blocks in many high-burden TB countries, as well as governance, leadership, and coordination within and among global initiatives. Without a concerted effort to bolster these foundational elements, global investments in TB control and institutional improvements may be ineffective and unsustainable.

The primary goal of the SIAPS/TB portfolio was to ensure access to quality pharmaceutical products and support the implementation of effective pharmaceutical services for achieving global and US Government TB program targets. SIAPS/TB employed four key pharmaceutical systems strengthening strategies to achieve these goals: strengthen pharmaceutical governance for TB at the global and country levels; increase and enhance capacity for TB pharmaceutical supply management and services; improve utilization of information for TB control decision making; and improve pharmaceutical services and access to TB products.

## Global Technical Leadership

SIAPS made considerable contributions to global TB policies by providing technical leadership in pharmaceutical management to the StopTB Global Drug-Resistant TB Initiative and the World Health Organization (WHO) during the development of key policy documents and TB guidelines, particularly related to the introduction of new TB medicines and regimens. These documents include:

- [WHO Policy Implementation Package for New TB Tools](#) (2014), for which SIAPS contributed a chapter entitled “Systems approach for ensuring uninterrupted supply of new and existing quality-assured medicines”
- [Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis](#) (2014)
- [WHO Treatment Guidelines for Drug-Resistant Tuberculosis, 2016 Update](#)
- [Digital Health for the End TB Strategy: An Agenda for Action](#) (2015)
- [Active Tuberculosis Drug-Safety Monitoring and Management \(aDSM\): Framework for Implementation](#) (2015)
- [Implementing the end-TB Strategy: The Essentials](#). WHO 2015

During the life of the program, the SIAPS/TB portfolio developed several products demonstrating thought leadership in strengthening pharmaceutical systems to improve the availability of TB medicines and pharmaceutical care. The following are highlights of this work.

### ***Strengthening Global TB Supply Mechanisms***

SIAPS global and regional engagement centered on developing organizational capacity of global donors and initiatives, including the Global Drug Facility (GDF) and WHO, to improve global pharmaceutical supply management (PSM), develop interventions for accelerated uptake of new medicines, and prevent stock-outs and treatment interruptions.

One of the SIAPS/TB portfolio's most significant achievements was its continuous technical support to the StopTB/GDF, an international procurement and supply mechanism for all TB medicines and diagnostic products that also provides technical assistance to countries. SIAPS/TB's technical support was multifaceted and included strategy development; drafting more than 90 position papers, concept notes, and other documents; operational management assistance; and establishing and leading advisory boards and technical working groups. SIAPS built capacity through trainings and workshops on quantification and using QuanTB, which is now the GDF's official quantification tool. GDF staff and consultants subsequently led similar trainings in GDF-supported countries.

### ***Pharmaceutical Management Information Systems***

SIAPS/TB worked to improve information for decision making through the availability and interoperability of electronic tools that would facilitate connecting and exchanging information with other software programs, thereby improving data availability for patient care and supply management. A significant achievement of the SIAPS program was the development and global use of three information systems—e-TB Manager, QuanTB, and the Pharmacovigilance Monitoring System (PViMS).



#### ***e-TB Manager***

SIAPS/TB and its predecessor programs designed e-TB Manager for managing data across most aspects of TB prevention and care. e-TB Manager has been successfully implemented in 10 countries and used at more than 2,500 sites to manage more than 650,000 TB cases. Peer-reviewed studies reported that selected countries using e-TB Manager:<sup>22, 23</sup>

- Improved the quality, timeliness, and completeness of data by reducing supervision visits by 70%
- Improved treatment adherence with built-in alerts by maintaining a DR-TB cure rate of approximately 60% while doubling case reporting
- Promoted countrywide TB monitoring and surveillance by identifying high- and low-performing TB sites and helping to target interventions



#### ***QuanTB***

To meet the evolving needs of national TB programs (NTPs) as they introduce new medicines or guidelines and scale up treatment, SIAPS/TB developed QuanTB as an electronic quantification, supply planning, and monitoring system. QuanTB was designed to improve PSM processes and access to TB treatment. When used regularly, QuanTB serves as an early warning system by providing information on actual versus planned consumption, medicine needs, impending expiries, and stock-outs.

<sup>22</sup> "User experience analysis of an eHealth system for tuberculosis in resource-constrained settings: A nine-country comparison", International Journal of Medical Informatics, 2017, <http://www.sciencedirect.com/science/article/pii/S1386505617300783>

<sup>23</sup> "User experience analysis of e-TB Manager, a nationwide electronic tuberculosis recording and reporting system in Ukraine", European Respiratory Journal Open Research, 2017 <http://openres.ersjournals.com/content/3/2/00002-2017>

SIAPS/TB trained NTP medicine management staff from 32 countries, other organizations, and independent consultants to use QuanTB for quantification and tracking of TB medicines. The tool has been implemented in additional countries by partners such as the GDF, KNCV, the UNION, and Project HOPE. As of September 2017, QuanTB had been downloaded more than 2,500 times in 136 countries. SIAPS also developed the eCourse, “Using QuanTB,” to teach health care professionals how to use QuanTB for forecasting, quantification, and early warnings of TB medicines.



### **PViMS**

Patient safety is at risk when lengthy TB treatment regimens are used. SIAPS invested in the development of guidance and an electronic tool that address this problem.<sup>24</sup> PViMS is a web-based application that enables aDSM and management in low- and middle-income countries by addressing the entire data collection and causality analysis process to identify and report signals for improving patient safety. For this reason, PViMS is a highly suitable platform to support the safe introduction and use of new TB medicines and regimens. PViMS was adopted by and handed over to NTPs in Georgia, Swaziland, and the Philippines, where it also serves as a national pharmacovigilance platform.<sup>25</sup>

## **Regional Approach to Technical Assistance**

SIAPS/TB provided continuous technical assistance through regional advisors to more than 30 countries in Africa, Asia, and Eastern Europe to ensure an uninterrupted supply of all TB medicines. Regional advisors assisted NTPs and partners to strengthen drug management practices, build local capacity, ensure the availability of quality pharmaceutical products, and support the implementation of effective pharmaceutical services and new TB treatment tools for achieving global TB program targets. As part of these efforts, SIAPS/TB trained more than 3,700 people, including representatives from NTPs and Ministries of Health from 32 countries, the Global Fund, GDF, WHO, and local and international partner organizations.

An in-depth review of five countries (Ethiopia, Nigeria, Tanzania, Kenya, and Zimbabwe) receiving assistance from SIAPS/TB regional advisors found that 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/TB regional advisors worked with these NTPs on preventing imminent stock-outs or minimizing wastage and implemented order postponement, splitting of shipments, and in-country redistribution to enable cross-border transfer of stock. As a result of this assistance, these five countries saved USD 8.5 million by preventing expiries through shipment postponements and the cross-border transfer of excess stock.

## **Public-private Partnerships**

Despite private-sector retail pharmacies often being the first point of care for people with TB-like symptoms in many high-burden TB countries, these private-sector services were often disconnected from the NTP and did not aid in case detection. To address this challenge, SIAPS/TB collaborated with stakeholders to design and pilot country-specific public-private partnerships in Tanzania and Pakistan to establish referral mechanisms between private retail outlets and TB diagnostic centers.

<sup>24</sup> “Preventing and Minimizing Risks Associated with Anti-tuberculosis Medicines to Improve Patient Safety” SIAPS. 2013 <http://siapsprogram.org/wp-content/uploads/2014/02/14-033-Min-Risk-Anti-TB-Meds-final.pdf>

<sup>25</sup> Adopting the Pharmacovigilance Monitoring System for the Philippines National Tuberculosis Program. SIAPS. February 5, 2018. <http://siapsprogram.org/publication/adopting-the-pharmacovigilance-monitoring-system-for-the-philippines-national-tuberculosis-program/>



The pilot in Tanzania involved 588 outlets and resulted in 81 of 587 clients (14%) who were referred for follow up testing confirmed as having TB. In Pakistan, 502 pharmacies referred 1,071 presumptive TB cases for further testing over an eight-month period. Of these, 198 (18%) were confirmed as having TB. As a result of the pilot studies, the Tanzanian NTP decided to scale up the intervention, and in Pakistan, private pharmacies were included in the 2020 national TB strategic plan, which began national scale up in 2016.

## Drug Use Reviews

NTPs in resource-limited settings do not always systematically monitor the use of MDR-TB medicines, which may result in patients not complying with their medicine regimen and can worsen the disease or increase the spread of MDR-TB. Drug use reviews (DURs) are used to identify common problems in medicine management, and when applied to TB medicines, DURs can help prevent the development of antimicrobial resistance, optimize patient outcomes, and ensure patient safety.

SIAPS/TB developed “[Drug Use Reviews—A Practical Strategy to Ensure the Rational Use of Anti-Tuberculosis Medicines](#),” which describes the steps required to conduct a DUR; suggests criteria for reviewing medicines; and offers performance benchmarks or targets. SIAPS/TB provided training and supported DUR programs in Bangladesh, Kenya, Swaziland, Ukraine, and Uzbekistan.

## New TB Medicines

The first new TB medicines in more than 40 years—bedaquiline and delamanid—were released onto the market for the treatment of MDR-TB in 2013 and 2014, respectively. In March 2015, USAID and Janssen Therapeutics signed an agreement to donate 30,000 free treatment courses of bedaquiline through the Bedaquiline Donation Program. SIAPS was tasked with providing technical assistance to Georgia, Kenya, Philippines, Swaziland, and Uganda to adopt, expedite the introduction and use of, and monitor the effects of bedaquiline and other new TB medicines and regimens. To do so, SIAPS used a system strengthening approach that involved establishing stewardship for pharmaceutical governance; engaging and coordinating stakeholders; building on existing systems; and strengthening human resources for efficient forecasting, quantification, phase-in supply planning, and early warnings. Special attention was given to improving patient safety through the introduction of PViMS.

With SIAPS support, Georgia was one of the first countries that benefited from the Bedaquiline Donation Program, enrolling 290 patients on bedaquiline, and 125 on delamanid treatment between October 2015 and September 2017. Swaziland was the first country to field test and adopt PViMS as an aDSM tool. As of September 2017, the country had received 235 treatment courses of bedaquiline and was steadily enrolling eligible patients. In the Philippines, SIAPS supported the development of guidelines and standard operating procedures for active patient safety monitoring via PViMS in 10 MDR-TB treatment facilities with more than 100 patients on bedaquiline treatment as of September 2017. None of these five SIAPS-supported countries experienced stock-outs of these vital products or delays in the enrollment of patients because of unavailability of medicines.

To make the SIAPS experience and expertise in the introduction of new TB medicines available to a broad audience, SIAPS developed a resource website (<http://newtbdruginfo.org/>) and an eCourse on the use of new TB medicines and regimens, which is available on MSH’s <https://leadernet.org/>.



For country-specific final reports, visit [siapsprogram.org](https://siapsprogram.org) and [dec.usaid.gov](https://dec.usaid.gov)





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