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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.

Recommended Citation

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<tr>
<td>ACT</td>
<td>artemisinin-based combination therapy</td>
</tr>
<tr>
<td>ADE</td>
<td>adverse drug event</td>
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<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
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<tr>
<td>aDSM</td>
<td>active drug safety monitoring and management</td>
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<tr>
<td>AFG</td>
<td>AIDS-free Generation</td>
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<tr>
<td>AIDS</td>
<td>acquired immunodeficiency syndrome</td>
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<tr>
<td>AMI</td>
<td>Amazon Malaria Initiative</td>
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<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
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<td>AMRH</td>
<td>African Medicines Regulatory Harmonization Program</td>
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<tr>
<td>APTS</td>
<td>Auditable Pharmaceutical Transactions and Services (Ethiopia)</td>
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<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
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<tr>
<td>ARV</td>
<td>antiretroviral</td>
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<tr>
<td>BHMC</td>
<td>Barangay Health Management Council</td>
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<tr>
<td>CASG</td>
<td>community adherence support group</td>
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<tr>
<td>CBART</td>
<td>community-based ART</td>
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<tr>
<td>CHAI</td>
<td>Clinton Health Access Initiative</td>
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<tr>
<td>CHW</td>
<td>community health worker</td>
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<tr>
<td>CMS</td>
<td>central medical store</td>
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<tr>
<td>CRMS</td>
<td>Continuous Results Monitoring System</td>
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<tr>
<td>DDMS</td>
<td>Directorate of Drugs and Medical Supplies (Sierra Leone)</td>
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<tr>
<td>DGDA</td>
<td>Directorate General of Drug Administration (Bangladesh)</td>
</tr>
<tr>
<td>DGFP</td>
<td>Directorate General of Family Planning (Bangladesh)</td>
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<tr>
<td>DGHS</td>
<td>Directorate General of Health Services (Bangladesh)</td>
</tr>
<tr>
<td>DIGEMID</td>
<td>General Directorate of Drugs and Medical Supplies (Peru)</td>
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<tr>
<td>DNPL</td>
<td>national medicines regulatory authority (Guinea)</td>
</tr>
<tr>
<td>DNPM</td>
<td>Directorate of Family Planning (Guinea)</td>
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<tr>
<td>DOH</td>
<td>Department of Health</td>
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<tr>
<td>DPMED</td>
<td>Department of Pharmacy (Benin)</td>
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<tr>
<td>DRA</td>
<td>drug regulation authority</td>
</tr>
<tr>
<td>DRC</td>
<td>Democratic Republic of the Congo</td>
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<tr>
<td>DR-TB</td>
<td>drug-resistant tuberculosis</td>
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<tr>
<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
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<tr>
<td>EAC</td>
<td>East African Community</td>
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<tr>
<td>EDT</td>
<td>Electronic Dispensing Tool</td>
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<tr>
<td>EHRIG</td>
<td>Ethiopian Hospital Reform Implementation Guideline</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>EML</td>
<td>essential medicines list</td>
</tr>
<tr>
<td>EPMCD</td>
<td>Ending Preventable Child and Maternal Deaths</td>
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<tr>
<td>EUV</td>
<td>end-use verification (survey)</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FMHACA</td>
<td>Food, Medicines and Health Care Administration and Control Authority (Ethiopia)</td>
</tr>
<tr>
<td>FP</td>
<td>family planning</td>
</tr>
<tr>
<td>FY</td>
<td>fiscal year</td>
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<tr>
<td>GDF</td>
<td>Global Drug Facility</td>
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<td>GHeL</td>
<td>Global Health eLearning Center</td>
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<tr>
<td>Global Fund</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<tr>
<td>HPD</td>
<td>Hospital Pharmacy Department</td>
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<tr>
<td>iCCM</td>
<td>integrated community case management</td>
</tr>
<tr>
<td>LAC</td>
<td>Latin American and Caribbean</td>
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<tr>
<td>LMIC</td>
<td>low- and middle-income country</td>
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<td>LMIS</td>
<td>Logistics Management Information System</td>
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<tr>
<td>M&amp;E</td>
<td>monitoring and evaluation</td>
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<tr>
<td>MCH</td>
<td>maternal and child health</td>
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<tr>
<td>MDR-TB</td>
<td>multidrug-resistant tuberculosis</td>
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<tr>
<td>MNCH</td>
<td>maternal, neonatal, and child health</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MOHFW</td>
<td>Ministry of Health and Family Welfare</td>
</tr>
<tr>
<td>MOHS</td>
<td>Ministry of Health and Sanitation (Sierra Leone)</td>
</tr>
<tr>
<td>MOHSS</td>
<td>Ministry of Health and Social Services</td>
</tr>
<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
</tr>
<tr>
<td>NEML</td>
<td>national essential medicines list</td>
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<tr>
<td>NEPAD</td>
<td>New Partnership for African Development agency</td>
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<tr>
<td>NHTC</td>
<td>National Health Training Centre (Namibia)</td>
</tr>
<tr>
<td>NMCP</td>
<td>national malaria control program</td>
</tr>
<tr>
<td>NMRC</td>
<td>Namibia Medicines Regulatory Council</td>
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<tr>
<td>NTP</td>
<td>national TB program</td>
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<tr>
<td>PAHO</td>
<td>Pan American Health Organization</td>
</tr>
<tr>
<td>PCG</td>
<td>central medicine store (Guinea)</td>
</tr>
<tr>
<td>PCID</td>
<td>Protecting Communities from Infectious Diseases</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>US President’s Emergency Plan for AIDS Relief</td>
</tr>
<tr>
<td>PMI</td>
<td>President’s Malaria Initiative</td>
</tr>
<tr>
<td>PMIS</td>
<td>pharmaceutical management information system</td>
</tr>
<tr>
<td>PNLP</td>
<td>national malaria control program (Guinea)</td>
</tr>
<tr>
<td>PNLS</td>
<td>national AIDS control program (Togo)</td>
</tr>
<tr>
<td>PPMRc</td>
<td>procurement planning and monitoring report for contraceptives</td>
</tr>
<tr>
<td>PPMRm</td>
<td>procurement planning and monitoring report for malaria</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
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<td>---------</td>
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<tr>
<td>PrEP</td>
<td>pre-exposure prophylaxis</td>
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<tr>
<td>PSM</td>
<td>procurement and supply management</td>
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<tr>
<td>PSS</td>
<td>pharmaceutical systems strengthening</td>
</tr>
<tr>
<td>PTCs</td>
<td>Pharmaceutical and Therapeutics Committees</td>
</tr>
<tr>
<td>PV</td>
<td>pharmacovigilance</td>
</tr>
<tr>
<td>PViMS</td>
<td>Pharmacovigilance Monitoring System</td>
</tr>
<tr>
<td>PY</td>
<td>program year</td>
</tr>
<tr>
<td>RMU</td>
<td>rational medicine use</td>
</tr>
<tr>
<td>RDT</td>
<td>rapid diagnostic test</td>
</tr>
<tr>
<td>RSS</td>
<td>regulatory systems strengthening</td>
</tr>
<tr>
<td>SCM</td>
<td>supply chain management</td>
</tr>
<tr>
<td>SCMS</td>
<td>Supply Chain Management System (Program)</td>
</tr>
<tr>
<td>SDG</td>
<td>Sustainable Development Goal</td>
</tr>
<tr>
<td>SIAPS</td>
<td>Systems for Improved Access to Pharmaceutical Services</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
<tr>
<td>SPS</td>
<td>Strengthening Pharmaceutical Systems (Program)</td>
</tr>
<tr>
<td>STG</td>
<td>standard treatment guideline</td>
</tr>
<tr>
<td>SUGEMI</td>
<td>national pharmaceutical management system (Dominican Republic)</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>TIPC</td>
<td>Therapeutics Information and Pharmacovigilance Center (Namibia)</td>
</tr>
<tr>
<td>TOR</td>
<td>terms of reference</td>
</tr>
<tr>
<td>TOT</td>
<td>training of trainers</td>
</tr>
<tr>
<td>TWG</td>
<td>technical working group</td>
</tr>
<tr>
<td>UCDC</td>
<td>Ukrainian Center for Disease Control</td>
</tr>
<tr>
<td>UHC</td>
<td>Universal Health Coverage</td>
</tr>
<tr>
<td>UNAM</td>
<td>University of Namibia</td>
</tr>
<tr>
<td>UNCoLSC</td>
<td>UN Commission on Life-Saving Commodities</td>
</tr>
<tr>
<td>UNFPA</td>
<td>United Nations Population Fund</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
</tr>
<tr>
<td>USAID</td>
<td>US Agency for International Development</td>
</tr>
<tr>
<td>USG</td>
<td>United States Government</td>
</tr>
<tr>
<td>WAHO</td>
<td>West Africa Health Organization</td>
</tr>
<tr>
<td>WARP</td>
<td>West African Regional Program</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>XDR-TB</td>
<td>extensively drug-resistant tuberculosis</td>
</tr>
</tbody>
</table>
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, responsible pharmaceutical system working within and in support of a functioning health system. Further, a pharmaceutical system is not simply a collection of supplies of medicines and products, warehouses and waiting rooms. Rather, it is a broad, coordinated network of people and activities working collaboratively with these tools to help people get and stay healthy.

Now in its sixth year, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program works to ensure the availability of quality-assured pharmaceutical products and effective pharmaceutical services. Realizing the interrelated nature of pharmaceutical system components, SIAPS takes a comprehensive approach to improving them, planning interventions that support each building block of the system, and creating sustainable results. This approach aligns with USAID’s Vision for Health Systems Strengthening (2015-2019).

Following this approach, the program’s technical assistance aims to support systemic changes to a pharmaceutical system’s organizational structure and institutional capacity; policies and regulations; and relationships among various components. It encompasses goals in critical health areas, including family planning, HIV/AIDS, malaria, maternal and child health, tuberculosis, and neglected tropical diseases. The program also seeks to support responsive, resilient performance in the face of potential and occurring epidemics.
Defining Systems and Activities to Measure Progress
As part of its project deliverables, SIAPS collaborated with core and resource partners in 2014 to identify definitions of a pharmaceutical system and pharmaceutical systems strengthening (PSS). The activity’s purpose was to conceptualize a pharmaceutical system as an entity—a relatively new endeavor—and to construct a framework for measuring results of PSS activities. The group produced the following definitions:

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

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

A Systems Strengthening Framework Guides Activities
To plan, coordinate, and implement its comprehensive approach, SIAPS follows a PSS framework (figure 1) that supports the design, implementation, and monitoring of program activities in five 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 integrates the medical products function at the center of these foundational elements. Key stakeholders are government, providers, and the community. Strengthening through this framework helps ensure that a pharmaceutical system makes 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

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Even with widespread availability of medicines, inappropriate, irresponsible, and irrational use of medicines is a serious risk with major implications, including the development of antimicrobial resistance (AMR). First-line TB medicines, for example, are now widely available in nearly all countries; however, persistent challenges around medication adherence and rational use continue to perpetuate drug resistance, leading to more complicated and expensive treatment regimens. AMR is a multi-faceted problem that requires a comprehensive solution including medicines availability, therapeutic substitution based on product availability, strengthened quality assurance in the supply chain to ensure product quality, and rational use to avoid overuse as it relates to stock-outs and supply imbalances.

Therefore, SIAPS acts to build capacity for comprehensive, patient-centered pharmaceutical care practices, anchored by effective information systems, tools, and capacity to promote rational medicines use and improve medication adherence and slow the development of drug resistance.

### Core Operating Principles for Resilient, Sustainable Pharmaceutical Systems

Throughout its six years of operation, SIAPS has established, been guided by, and refined the following core principles in support of its PSS action framework.

**Build On and Strengthen Existing Systems:** SIAPS' technical assistance is 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 are 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 one-off activities.

**Build the Capacity of Local Organizations and People:** Individual and organizational capacity-building efforts help 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 optimizes donor resources and enables coordinated pharmaceutical management planning and harmonized tools and approaches.

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

**Facilitate Consensus-Building on the Definitions of PSS and a Monitoring Framework:** This activity resulted in the proposed definition (box, above) of both a pharmaceutical system and PSS.

**Harmonize Information Systems to Improve Patient Care:** SIAPS supports 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 developed a knowledge management and communications work plan to disseminate best practices and innovative solutions that use a PSS approach to USAID Missions, other US agencies, implementing organizations, host-country governments, other donors, multinational organizations, and international stakeholders.

### Collaborating with Countries, Programs, and Partners

Country teams continue to be supported by a program management team at SIAPS headquarters in Arlington, Virginia. This ensures that quality work plans and reports are delivered on time and that technical and other resources are mobilized. In addition, the team liaises with USAID/Washington, other MSH technical units, and partners to ensure that country programs have the required resources to achieve their goals.

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

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

**SIAPS Year 6: Advancing and Transitioning Programs and Activities**

The program’s annual report presents SIAPS’ accomplishments during program year six (PY6), its final full year of program implementation. The SIAPS Program ceiling was initially $197,926,458 over 5 years. In the tail end of fiscal year 2015, the program was granted an extension of 12 months until September 22, 2017, and the program ceiling increased to $225,926,458. In September 2017, the program received an additional program ceiling increase to $243,926,458 through March 22, 2018.

The work done in fiscal year 2017 (FY17) advanced and consolidated systems strengthening work complete throughout the program’s tenure. SIAPS worked with local counterparts and partners in 46 countries, with field support in 22 countries. This fiscal year, SIAPS also provided technical assistance to regional programs in West Africa, Central Asia, and Latin American and the Caribbean. SIAPS continued to support Sierra Leone in its post-Ebola recovery and is using Ebola funding to further bolster Ebola recovery and support in Guinea, Mali, and Benin, which SIAPS had already been supporting via other programming.

The ultimate goal of the SIAPS Program is to institutionalize interventions so that pharmaceutical systems prosper under country ownership. To this end, the program carried out its plans to transition projects to implementing partners and governments. Country programs in Dominican Republic, Ethiopia, Guinea, Niger, and Ukraine completed their technical assistance in FY17, and transitioned ongoing activities to their respective host governments and other partners.

This report highlights cumulative results of PSS efforts over the past six years, activities that have solidified pharmaceutical system foundations and advanced progress in comprehensive reform. Results are presented here by our core portfolios, health program areas that demonstrate SIAPS’ contributions to the health goals of the USG and Cross Bureau, and to the USAID Office of Health Systems’ (OHS) priority objectives. Last, the report presents results by SIAPS intermediate result areas, representing the multiple countries and regions where we work. As SIAPS comes to a close, the program will produce a final report summarizing its achievements and lessons.
CROSS BUREAU
The Office of Health Systems (OHS) serves as USAID’s center of excellence and focal point for providing worldwide leadership and technical expertise in health systems strengthening (HSS). It is responsible for three core functional roles:

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

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

Using cross bureau funding, SIAPS priorities are to:

- Strengthen pharmaceutical sector governance to promote transparency and accountability through appropriate laws, regulations, policies, and standard operating procedures
- Increase and enhance human and institutional capacity to regulate and manage pharmaceutical systems and services
- Develop and support the use of Pharmaceutical Management Information Systems (PMIS), embracing both products and patients, including information systems for procurement, logistics, services, and regulatory systems
- Reduce financial barriers to access through more efficient and effective use of financial resources and support for innovative financing strategies and approaches

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Strengthen pharmaceutical systems to ensure product availability and quality, protect patient safety, and contain the emergence of antimicrobial resistance

Contribute to the generation of new knowledge and dissemination of evidenced-based approaches and best practices

These priority objectives in turn contribute to USG goals of ending preventable child and maternal deaths, AIDS-free generation, protecting communities against infectious diseases, and expansion of health care coverage. SIAPS’ key activities and achievements using OHS cross bureau funds in PY6 are described below.

Global Technical Leadership

Efforts to measure progress in pharmaceutical systems strengthening (PSS) have been hampered by the lack of clear definitions and widely accepted, reliable measures. Through its work, SIAPS aims to fill this gap through development of definitions of pharmaceutical systems and PSS, accompanied by a framework and metrics for PSS measurement. In PY6, the manuscript prepared by SIAPS that reviews the literature on and proposes definitions for pharmaceutical systems and PSS was published in the peer-reviewed journal, *Health Policy and Planning*, as an open access article. The publication also identifies pharmaceutical system components and attributes that are deemed critical for measurement of PSS. These components and attributes, together with the definitions, provide the foundation for measuring a system’s performance. In November 2016, SIAPS delivered an oral presentation based on the publication at the Fourth Health System Research Global Symposium in Vancouver, Canada.

In PY6, SIAPS finalized the PSS measurement framework and the list of component indicators for piloting in USAID Global Health priority countries for HSS, developed the data collection and management tool PSS Insight, and drafted the user manual. A targeted literature review was conducted to verify that relevant domains and sub-domains of health system performance and resilience were accounted for in the pharmaceutical system attribute metrics selected for piloting. Next, performance indicator reference sheets (PIRS) were prepared that clearly define the indicators; describe how to calculate each indicator; identify each indicator’s purpose, issues, and limitations; and guide data collectors to likely data sources. The indicators and PIRS were reviewed by SIAPS subject area experts, and SIAPS’ partner, Boston University School of Public Health (BUSPH), before being incorporated into a data collection and management tool and user manual for piloting.

After receiving the required approvals from both the USAID Mission and the Ministry of Health and Family Welfare in Bangladesh, SIAPS conducted the first in-country pilot of the selected indicators and the PSS Insight tool and user manual. Data collectors provided feedback on the tool and process, as well as the collected data. The data from Bangladesh are currently being analyzed by BUSPH to inform data interpretation and potential modifications to PSS Insight. An additional country pilot is planned to take place early in PY7. SIAPS currently plans to finalize the tool and accompanying user manual in PY7.

SIAPS recognizes that published evidence of PSS is limited, and the documentation that does exist is neither well known nor widely shared. SIAPS therefore initiated a global call for case studies to highlight successful strategies and actions that have been used to improve access to and use of pharmaceutical products and services around the world. SIAPS used an aggressive communications campaign to raise awareness and attract applicants via the HSS network, e-Drug, IBP Initiative, Reproductive Health Supply Chain, Global Health Knowledge Collaborative, HIPNET, as well as through MSH’s global newsletter and social media channels, including Facebook and Twitter. The call for case study specifications included descriptions of a pharmaceutical or health systems challenge, technical approach, and specific actions implemented to strengthen the pharmaceutical system. Case studies were also to include indication of evidence-based improvements in the health
system’s performance and/or health outcomes in addition to lessons and recommendations. Out of 46 submitted case studies, 32 met the basic eligibility to move through external review. SIAPS’ partners Harvard School of Public Health and Harvard Pilgrim Institute completed a rigorous review using seven key criteria elements and scoring rubric. SIAPS will publish and disseminate the final case studies in PY7.

In the pharmaceutical sector, numerous governance structures (e.g., committees) make crucial decisions about selection, procurement, distribution, and use of medicines, diagnostics, and other pharmaceutical products. One of the underlying causes of poor functioning of such committees is the absence of robust or weak terms of reference (TOR) that define their roles and responsibilities and provide the framework within which they must function. In this year, SIAPS developed a technical brief entitled Developing Better Terms of Reference to Improve the Performance of Pharmaceutical Sector Committees: Case Studies from South Africa that provides guidance and a template for developing or updating TOR for councils, committees, and boards that make decisions or provide oversight in the pharmaceutical sector. The brief provides three case examples of the use of the TOR guidance and template in South Africa and summarizes the lessons learned. This brief is intended for those charged with developing TOR for all types of pharmaceutical sector committees and for committee members that want to review and bolster existing TOR.

With the increasing focus on strengthening governance in health systems comes greater attention to learning how governance as well as leadership and management interventions impact health and pharmaceutical systems. However, data on the impact of these interventions is often difficult to collect and measure, and the evidence base for guiding the selection of interventions is lacking. In this year, SIAPS collaborated with USAID’s Leadership, Management, and Governance (LMG) Project to examine and document the evidence that exists regarding the role and governance, leadership, and management in strengthening health system performance—specifically pharmaceutical systems—in low- and middle-income countries (LMICs). The chapter on pharmaceutical systems is one of five that constitute the compendium that documents the evidence of leadership, management, and governance influence and impact on health service delivery and performance. To prepare the chapter, SIAPS worked with LMG Project staff to scan peer-reviewed and gray literature using a rapid assessment methodology. The resulting compendium is not intended to be a systematic or exhaustive review of the literature, but rather a formative evaluation of the state of the evidence to stimulate discussion and inform further research and study. The compendium will be published early in PY7.

Since 2011, the SIAPS Program has used the Regulatory System Assessment Tool (RSAT) to conduct assessments of regulatory systems in five countries. On the basis of multiple reviews of WHO’s Global Benchmarking Tool (GBT), in-depth discussions with WHO, and observations at international partner meetings, SIAPS made the decision in October 2016 to significantly reduce the scope of its planned revision of RSAT to avoid producing an assessment tool that would duplicate GBT without adding significant value and potentially undermining the shift in regulatory system strengthening (RSS) toward a global coordinated approach with standard metrics. On the basis of that revised scope, SIAPS edited problematic assessment questions and quantitative indicators in the original version of RSAT—rewording, reordering, adding or deleting them, as needed—to ensure comprehension and technical accuracy, and subsequently reworked the instructions. At the end of PY6, the revised tool was submitted to the editorial team for finalization. The final product will include instructions, assessment questions, and a list of suggested indicators. Although a finalized version of RSAT will be made available, it is expected that its use will be limited to special circumstances where a particular user deems GBT to be inappropriate or insufficient for their intended purpose.
In line with SIAPS’ agreement to encourage countries to adopt GBT as the recommended and preferred tool for RSS assessments in LMICs, SIAPS collaborated with WHO at the end of PY6 to use GBT to conduct a regulatory assessment in Mali. In preparation for the assessment, the SIAPS team participated in two virtual training sessions provided by WHO via Webex, in addition to participating in an online training module, which provided an in-depth orientation to the tool, including its functions and use. SIAPS agreed to compile feedback on its experience using GBT, as well as its desktop technical review of the indicators and reference sheets, and submit it to WHO for discussion following the Mali assessment (expected early in the next project year).

In an era of shrinking funds for health and a growing emphasis on maximizing value for money, it has become even more important for countries, donors, and other partners to better understand where funding for pharmaceuticals is coming from and who spends how much on what and to develop a systematic and comprehensive methodology for tracking and estimating these expenditure flows.

SIAPS has partnered with USAID’s Health Finance and Governance Project (HFG), whose expertise in widely implementing and adapting the national health accounts is being leveraged with SIAPS’ expertise in the field of pharmaceutical management to develop an approach with key indicators to track pharmaceutical expenditures. In PY6, SIAPS developed a matrix to map a list of pharmaceutical policy questions and appropriate indicators that would inform policy makers in LMICs in the planning and monitoring of medicine financing policies. SIAPS drafted the description of the selected indicators, detailing indicator definition, policy relevance, relevance to WHO-OECD’s systems for health accounts, potential data sources, and calculation methods. The indicators were reviewed for their relevance and feasibility for data collection. Also, a draft outline for a pharmaceutical expenditure tracking guidance was developed. The ministries of health and finance of LMICs; UN agencies; donors, such as USAID, Department for International Development, and the Global Fund; and key implementing agencies are expected to be the target audience for this guidance. As a next step, SIAPS will collaborate with HFG to review the indicators and develop the guidance.

With universal health coverage (UHC) gaining global momentum, there is a need to ensure that it is accompanied by adequate mechanisms and approaches that can promote equitable access to affordable, essential medicines. Balancing the objective of UHC with the realities of limited resources in developing countries requires that national health programs take special attention, not only to increasing the investments in UHC, but also to establish key sub-systems and mechanisms that promote efficacy and efficiency within the system, hence creating opportunities for increased coverage and access. For example, having a mechanism for appropriate product selection is critical to ensuring that selected medicines and technologies are not only safe and effective, but also cost effective, to ensure value for money in maximizing coverage and reducing out-of-pocket expenses.

To support LMICs in recognizing opportunities for establishing mechanisms for sub-systems within the pharmaceutical sector, SIAPS finalized a policy paper on “Pharmaceutical management considerations for financial protection programs”. The paper is aligned with the critical pharmaceutical system components—pharmaceutical products and services; policy, laws, and governance; regulatory systems; financing; human resources; information; and innovation, research, and development. As a next step, a webinar will be conducted to advocate for the importance of including medicines and strengthening pharmaceuticals systems in LMICs’ efforts to attain UHC.

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

At the Fourth Health System Research Global Symposium held in Vancouver, Canada, in
November 2016, SIAPS delivered an oral presentation entitled *Defining Pharmaceutical Systems Strengthening: Concepts to Enable Measurement* as part of an oral session grouping on the topic of strengthening the supply of pharmaceuticals and other commodities. SIAPS summarized the work done by the program to advance the current thinking on pharmaceutical systems by building on existing approaches to address the lack of consensus on what constitutes a pharmaceutical system and the absence of a clearly defined framework or agreed approach to measure progress toward stronger, more resilient pharmaceutical systems. The presentation highlighted the explicit, newly developed definitions of the pharmaceutical system and PSS and the identified system components/attributes for guiding the measurement as well as the methodology for developing them.


SIAPS participated in the AMRH partners workshop organized by the World Bank and NEPAD in Midrand, South Africa, in February 2017. The workshop aimed to re-examine the strategic vision for medicines regulatory harmonization on the African continent. The meeting addressed the emergence of new partners and new technical areas within the AMRH Program and the need to incorporate and coordinate with them within the overall strategy. The meeting also called for a revised governance framework for AMRH that clarifies roles and aligns with wider partnerships, global initiatives, and other continental governance structures.

At the Third African Society of Pharmacovigilance (ASOP) Conference held in Mombasa, Kenya, in December 2016, SIAPS delivered two plenary presentations, one on the future of pharmaceutical systems resilience and the second on capacity building for PV at the national and regional levels. SIAPS also participated in a WHO-led PV training at a preconference meeting that focused on work-sharing for progress, data quality, causality assessment, and signal detection. A key highlight from the training was the planned transition of Vigiflow from using WHO-adverse reaction terminology to that of the Medical Dictionary for Regulatory Activities and the proposed roll-out plan.

To support the AMRH Initiative and building capacity of regional centers of regulatory excellence (RCOREs) in PV, SIAPS delivered a presentation on PV system strengthening from an implementing partner’s perspective at the regulatory conference organized by the Kenya Pharmacy and Poisons Board, which is a PV RCORE. SIAPS also participated in the panel discussion on post-marketing surveillance and PV held during the same conference.

**Technical Products to Support National Health Systems**

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


- Pharmaceutical management considerations for financial protection programs. The current discourse on increasing financial protection for individuals focuses heavily on financing and revenue generation with minimal attention to investments in the broader health and PSS approaches. This paper, developed with policymakers and other decision makers in mind, models the complex interactions that
occur from the moment funds are allocated to the pharmaceutical system to the time it reaches a beneficiary. This paper highlights the key functional areas of the pharmaceutical system and pharmaceutical management considerations needed to facilitate the attainment of UHC targets. Through select case studies, it illustrates some of the challenges that LMICs have faced and how they have successfully addressed those challenges. It also provides a practical guide describing how to ensure that pharmaceutical management is strengthened in a way that will enable countries to meet UHC objectives.

- Technical brief entitled Developing Better Terms of Reference to Improve the Performance of Pharmaceutical Sector Committees: Case Studies from South Africa provides guidance and a template for developing or updating TOR for councils, committees, and boards that make decisions or provide oversight in the pharmaceutical sector. The brief provides three case examples of the use of the TOR guidance and template in South Africa and summarizes the lessons learned. Available at http://siapsprogram.org/publication/developing-better-terms-of-reference-to-improve-the-performance-of-pharmaceutical-sector-committees-case-studies-from-south-africa/

- Systems-Based Approaches to Improving Medication Adherence. SIAPS’ new thought leadership document published during the reporting period provides a rationale for looking at adherence through a systems strengthening lens and describes multiple strategies and tools to support better adherence, particularly in resource-limited settings. The document puts forth a framework that recognizes that multidisciplinary and multilevel approaches and interventions are necessary to strengthen systems for better adherence. Each chapter focuses on a different level of the health system and suggests key respective interventions. This document is relevant for a wide variety of health care actors involved in improving medication adherence. The document can be downloaded at http://siapsprogram.org/publication/systems-based-approaches-to-improving-medication-adherence/

- Building Coalitions to Combat Antimicrobial Resistance: A How-to Guide. Coalitions, particularly those that bring relevant stakeholders together across sectors, professions, and disciplines, are important mechanisms for achieving participatory and multisectoral action against the multi-faceted, common problem of AMR. However, LMICs often lack widespread advocacy and coalitions against the threat of AMR. To support this process, SIAPS extensively updated and published in August 2017 this new version of its guidance document. The key components of the guide include identifying and engaging AMR-related stakeholders; advocacy and coalition-building guidelines; practical implementation examples from country- and regional-level initiatives; and user-friendly implementation tools and templates. The field-tested approach and lessons learned will help countries forge multi-disciplinary and multi-sectoral coalitions to fight AMR. This guide is included as a resource in the national action plan toolkit references of WHO’s Manual for Developing National Action Plans. The guide can be downloaded at http://siapsprogram.org/publication/altview/building-coalitions-for-containing-antimicrobial-resistance-a-guide/english/


Global Engagement

In PY6, SIAPS convened meetings with WHO’s Essential Medicines and Health Products (EMP) Department to discuss the sustainability of the EMP portal after the end of SIAPS. WHO/EMP has demonstrated continued interest and commitment to maintaining the portal and its incorporation into their newly proposed communication strategy. As such, WHO informed SIAPS that concrete steps for sustaining and continuously improving the portal are well underway.
SIAPS has also continued to collaborate with WHO on the Coalition of Interested Parties (CIP) for RSS in PY6. In December 2016, SIAPS participated in a panel discussion at the International Conference of Drug Regulatory Authorities in Cape Town, South Africa, to present the CIP approach to participants at the preconference meeting, including international organizations and regulators from all over the world. The CIP was launched as a network of international RSS partners in June 2017 following a two-day WHO meeting attended by SIAPS in Geneva. Although the partners acknowledged the need for a variety of tool options to support their work in RSS, they again agreed to use the GBT indicators as the standardized metrics for measuring and monitoring the status of regulatory systems and to incorporate them into their work.

Regional Engagement

While all countries of the world are impacted by AMR, LMICs generally face big challenges in fighting the threat due to various reasons, including lack of funding and expertise. To address this gap, in PY6, SIAPS collaborated with its regional partner the Ecumenical Pharmaceutical Network (EPN) to strengthen its capacity to provide regional and country-level AMR-related technical assistance and foster south-south collaboration. This is in line with SIAPS’ practical goal and technical approach of building capacity of and fostering collaboration between local organizations.

SIAPS provided the necessary funding to enable three EPN member organizations—the Zimbabwe Association of Church-related Hospitals (ZACH), Gertrude’s Children’s Hospital (GCH) in Kenya, and the Christian Health Association of Malawi (CHAM)—to design, implement, and report on antimicrobial stewardship and containment-related interventions. SIAPS also supported EPN headquarters in providing technical assistance and oversight to those members.

Activities led by ZACH aimed to increase engagement with the media and improve accuracy of reporting on AMR. ZACH held a training workshop for 23 journalists from a variety of media networks and newspapers; 23 publications and/or broadcasts were produced (10 print/electronic articles, 8 radio broadcasts, and 5 television segments) in the 5 months following the workshop, compared to approximately 20 articles published in the year prior to the workshop.

In Kenya, GCH focused its efforts on improving adherence to STGs. Following a baseline assessment and implementation of educational interventions targeted to 70 prescribers and 15 pharmacy staff, GCH conducted a post-intervention audit that showed an improvement in STG adherence: an adherence rate of 31.2% compared to the baseline rate of 26.2%.

In Malawi, CHAM conducted a baseline assessment on hand washing and hygiene, which showed that lack of supplies, negative staff attitudes, and inactive IPC committees contributed to the low levels of hand washing. CHAM trained 109 health care workers on proper hand washing, restocked the two participating facilities with hand-washing supplies, and supported recruitment of new members into the IPC committees. The results of the post-intervention assessments demonstrated the following improvements—availability of soaps in sinks (improved from 67% to 96%), presence of hand-washing posters (improved from 7.5% to 57.5%), health care workers carrying hand rubs (improved from 0% to 13%), and health care workers using hand rubs (improved from 0% to 20%). Hand-washing committees were also established in both hospitals.

One of the strategic objectives of the NEPAD Agency’s AMRH Program is to increase capacity of the regulatory work force in Africa. To this end, several regulatory agencies were selected (11 to date) to become RCOREs in different areas of pharmaceutical regulatory functions.

In support of this RCORE initiative, SIAPS provided support to NEPAD through a local consultant to develop key performance indicators (KPIs) for the RCOREs. Following the development of the first draft, the NEPAD technical team was expected to conduct an internal review and provide
feedback. Subsequently, these KPIs for RCOREs were expected to be piloted in selected RCOREs. However, due to the delay in getting the necessary feedback, SIAPS’ continued support for this activity was put on hold pending NEPAD’s feedback.

East African Community Medicines Regulation and Harmonization Program Portfolio

The EAC is a regional, intergovernmental economic organization of six partner states in East Africa with headquarters in Arusha, Tanzania. The EAC Medicines Regulatory Harmonization (MRH) Program is part of the AMRH initiative. In the last quarter of PY 5, in collaboration with the EAC secretariat, SIAPS developed a concept note about the methodology and approach to carry out a pilot PV system baseline assessment for the national regulatory authorities in the EAC. The note included application of harmonized PV indicators and assessment tools elaborated by the PV Expert Working Group in the previous quarter during the SIAPS-led capacity-building workshop of June 2016 in Kigali, Rwanda. The harmonized indicators and assessment tools were adapted from SIAPS’ and SPS’ PV Indicator (IPAT) tool and WHO indicators manual.

Based on preparatory work mentioned above, SIAPS continued to support and work with the EAC and PV Expert Working Group in PY 6 of the SIAPS Program to harmonize and strengthen PV systems in the region and continued supporting the organization of meetings to raise awareness about safety of medicines, including the Zanzibar meeting of October which was organized to develop harmonized PV guidelines and baseline assessment timelines; the meeting included other stakeholders supporting the EAC PV strategy, such as WHO, World Bank, and NEPAD.

During the International Conference of Multi-Stakeholders for Promoting Pharmaceutical Investments that was held in November 2016, NEPAD fully endorsed SIAPS’ support and approach to PV system strengthening. In December 2016, SIAPS participated in the organization and execution of the third ASOP meeting in Mombasa, Kenya. SIAPS took this opportunity to present to PV experts and conference attendees on SIAPS’ HSS approach, systemic capacity-building for strengthening PV systems, and use of PV data for strategic decision-making. In February 2017, the baseline survey of the PV systems in all member states (except South Sudan) was launched. SIAPS supported the PV national experts and data collector teams from all partner states to analyze data and write reports of their findings. SIAPS also provided technical assistance to the national regulatory teams with a data entry and management tool.

In March 2017, in collaboration with WHO, SIAPS facilitated the PV sessions during the EAC stakeholders meeting in Nairobi, Kenya, which was held to discuss the findings of the assessment, and to kick start the development of a business plan aimed at strengthening PV in the EAC. The EAC member states agreed to cost the activities on the basis of the findings of the survey which will be later incorporated into the business plan that will be developed under NEPAD’s leadership.

Between April and June, SIAPS used feedback and comments from the March stakeholders meeting to review the harmonized PV indicators, assessment tools, and data management tool. During the same period, SIAPS attended several meetings of the EAC PV core team to provide input to the development of the draft EAC PV business plan. The PV core group is now comprised of NEPAD (lead), the EAC secretariat, WHO, Gates Foundation, SIAPS, World Bank, and Kenya PPB RCORE in PV. In July 2017, SIAPS participated in a workshop, comprising the PV core team and EAC PV experts, which was organized to review the draft EAC PV business plan and proposed recommendations prepared by the consultants. The draft EAC business plan was further presented to the EAC Steering Committee in October. The committee, which comprises chief pharmacists and heads of NMRAs, approved the plan and recommended that it be presented as two documents: the detailed version and a summarized, easy-to-read version. The revised documents will be presented to an extraordinary meeting of the steering committee likely to take place in December 2017.
INTERMEDIATE RESULTS
The Challenge

Good governance helps protect pharmaceutical systems from corruption and mismanagement, which can diminish access to medicines and lead to the distribution and use of unsafe, ineffective, or poor-quality products that may harm patients. These problems can also lead to wastage and misuse of scarce resources as well as inflated prices for medicines, which can be costly for governments, institutions, and individuals. Governance in pharmaceutical systems is particularly relevant in light of the current push for universal health coverage (UHC), for which medicines are indispensable. Promoting transparency and accountability is a prerequisite for improving access to essential medicines and strengthening health systems to achieve UHC.3

In PY6, SIAPS continued to help countries address governance issues that impact key pharmaceutical management functions and the supporting management systems (human resources, information, and financial) and to improve the adoption of and adherence to good governance principles, such as transparency, accountability, and participation. SIAPS’ technical leadership activities and collaboration with global and regional initiatives and partners working in governance, including regulatory systems strengthening (RSS), have been especially pertinent, given the increasing attention at the global level to health system governance, corruption, and regulatory constraints. The following is a summary of our work and achievements in governance and RSS in PY6.

SIAPS Approach for Strengthening Pharmaceutical Sector Governance

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

Key Achievements during Program Year 6

Technical Leadership

In the pharmaceutical sector, numerous governance structures, such as councils, committees, and boards, make crucial decisions about selection, procurement, distribution, and use of medicines, diagnostics, and other pharmaceutical products. One of the underlying causes of poor functioning of such bodies is the absence of robust or weak terms of reference (TOR) that define their roles and responsibilities and provide the framework within which they must function. In this year, SIAPS developed a technical brief entitled, *Developing Better Terms of Reference to Improve the Performance of Pharmaceutical Sector Committees: Case Studies from South Africa*, which provides guidance and a template for developing or updating TOR for those bodies that make decisions or provide oversight in the pharmaceutical sector. The brief provides three case examples of the use of the TOR guidance and template in South Africa and summarizes the lessons learned. This brief is intended for those charged with developing TOR for all types of pharmaceutical sector committees and for committee members who want to review and bolster existing TOR.

With the increasing focus on strengthening governance in health systems comes greater attention to learning how governance, as well as leadership and management interventions, impact health and pharmaceutical systems. However, data on the impact of these interventions is often difficult to collect and measure, and the evidence base for guiding the selection of interventions is lacking. In PY6, SIAPS collaborated with USAID’s Leadership, Management, and Governance (LMG) Project to prepare a compendium that examines and documents the evidence that exists regarding the role of governance, leadership, and management in strengthening health system performance—specifically, pharmaceutical systems—in low- and middle-income countries (LMICs). The chapter on pharmaceutical systems is one of five that constitutes the compendium that documents the evidence of how leadership, management, and governance influence and impact health-service delivery and performance. To prepare the chapter, SIAPS worked with LMG staff to scan peer-reviewed and gray literature by using a rapid assessment methodology. The resulting compendium is not intended to be a systematic or exhaustive review of the literature, but rather a formative evaluation of the current evidence to stimulate discussion and inform further research and study. The compendium will be published early in PY7.

On December 2, 2015, the eLearning course “Good Governance in the Management of Medicines,” developed by SIAPS with assistance from the Knowledge for Health (K4Health) Project, was launched on USAID’s Global Health eLearning (GHeL) Center. As of September 30, 2017, the course has been successfully completed by 363 learners (112 females and 251 males) from 67 countries, including 65 from Nigeria, 60 from Sudan, and 21 from Kenya; 113 (31%) of learners who have earned a certificate report working for a national government.

SIAPS’ technical leadership in RSS during PY6 contributed to regional medicines regulatory harmonization programs in Africa and the coordination of international development partners.
To help advance the “coalition of interested partners” approach that WHO and SIAPS piloted in Bangladesh and introduced to key international partners in PY5, SIAPS participated in a panel discussion at the International Conference of Drug Regulatory Authorities in Cape Town, South Africa, to present the concept to participants at the preconference meeting, including international organizations and national regulators. The Coalition of Interested Partners was launched as a network of international RSS partners, with broad support, in June 2017 following a two-day WHO meeting attended by SIAPS in Geneva. SIAPS was asked to serve on the network’s task force, which is expected to convene next year. SIAPS also continued to collaborate with the New Partnership for African Development (NEPAD) agency and other technical partners to advance the African Medicines Regulatory Harmonization Program (AMRH). This year, the focus was on revising AMRH’s governance structure to facilitate the participation of a more diverse group of partners and clarify roles and responsibilities. SIAPS participated in a critical NEPAD-led meeting in Midrand, South Africa, at which the major players contributed to the reforms and reached consensus on key elements of the new governance framework, which is designed to bring in more resources while still maintaining strong coordination under NEPAD leadership.

Policies, Legislation, and Contractual Agreements

Pharmaceutical products and the entities that manage them must be carefully regulated because products that are unsafe, of poor quality, or used incorrectly are potentially harmful. Policies and legislation provide the framework for the regulation of pharmaceutical products, personnel, and establishments in a country and must be supported by guidelines, SOPs, effective contractual agreements, and monitoring systems. Effective medicines registration, licensing of pharmaceutical establishments, and control of promotion, availability, prescribing, and dispensing of products rely on appropriate and enforceable legislation and policies. The following are examples of our work in PY6 to help countries develop or revise, adopt, and monitor adherence to pharmaceutical policies and legislation that support health sector priorities and promote good governance in pharmaceutical systems.

In Swaziland, the Medicines and Related Substances Control Bill was enacted into law on November 11, 2016. The new law, which replaces legislation dating back to 1929, provides for the establishment of the country’s first national medicines regulatory authority. The principal secretary of Swaziland’s MOH recognized SIAPS’ contribution and support toward this landmark achievement. SIAPS continued to support the Chief Pharmacist’s Office in advocating for the enactment of the Pharmacy Bill, which provides for establishment of a Pharmacy Council to regulate the pharmacy profession. SIAPS helped the office prepare for the debate on the bill at a joint sitting of the Houses of Parliament.

In PY6, SIAPS concluded its long-term collaboration with international and local partners to assist the national medicines regulatory authority (DNPL) in Guinea with revising the existing 1994 national pharmaceutical law. The draft pharmacy bill was finalized at a SIAPS-supported workshop and has been sent to the minister of health for review and endorsement. Once approved, the bill will be presented to the National Assembly for adoption.

Also in Guinea, the ministerial decree that provides for the establishment of the Logistics Management Unit was approved by the minister of health. In Sierra Leone, the Parliament enacted the National Medical Supplies Agency Act, which transforms the National Pharmaceutical Procurement Unit into a parastatal body: the National Medical Supplies Agency. These regulations were drafted with assistance from SIAPS as part of efforts to bolster the governance infrastructure, and thereby improve public sector supply chain management (SCM) in the two countries.
In March 2017, the Harari regional health bureau in Ethiopia enacted a directive to support implementation of the Auditable Pharmaceuticals Transactions and Services (APTS) initiative, which was introduced to achieve greater transparency and accountability in the management of pharmaceuticals and related finances. All nine of the country’s regional states and both administrative states have now approved APTS regulations, which support expansion and ultimately the sustainability of the initiative. As of March 2017, 77 health facilities throughout the country were implementing APTS, including 2 hospitals in the Harari region.

In Ukraine, SIAPS concluded its long-term technical assistance to help the government streamline the selection of medicines procured with public funds. In March 2017, the national essential medicines list (NEML), which will be used nationwide as the sole list for public procurement, was approved by the Cabinet of Ministers. This is a landmark achievement in a country that, until now, has had multiple, nonharmonized lists of medicines available. SIAPS also helped to finalize the standard operating procedures (SOPs) for the NEML expert committee and develop amendments to adjust the timelines included in the regulations, which will provide for and foster good governance in the selection of the NEML expert committee members and regulate the medicine selection process in the future. The NEML, the decree, and the SOPs are expected to help to make procurements less vulnerable to duplication, inefficiencies, and conflicts of interest.

The Government of Ukraine is interested in setting up a reimbursement system that utilizes the NEML, and, in support of that effort, SIAPS assisted the Ministries of Health, Finance, and Economics in reviewing key considerations for the system’s design and implementation. Amendments to the decrees on reimbursement and price regulation, including those suggested by SIAPS, passed the Cabinet of Ministers and were published on March 25, 2017. In addition, regulations that address the use of NEML medicines and the methodology for quantifying NEML product needs were prepared with assistance from SIAPS and submitted to the MOH for public comment.

Standards, Guidelines, and Procedures

A challenge that many LMICs confront is a lack of robust guidelines and SOPs that define norms and standards for performing pharmaceutical functions. Over the course of the program, SIAPS supported 23 countries in developing, revising, or updating a variety of guidelines (pharmaceutical and disease-specific), product lists (essential and specialty medicines, devices, equipment, product catalogues) and SOPs, on the basis of international guidance and best practices that provide the foundation for good governance and sound practices in pharmaceutical systems. Some examples of our work in PY6 are set out below.

In Swaziland, the MOH public procurement manual and the accompanying standard bidding documents were finalized and submitted to the Swaziland Public Procurement Regulatory Agency for final review and approval. As a result of this SIAPS-supported activity, the country now has a set of robust procurement documents that are consistent with existing public procurement legislation. The completion of these documents represents an important milestone toward promoting standardized practices in public pharmaceutical procurement. Also in Swaziland, guidelines and policy documents for the import and export of pharmaceutical products, which were developed by the pharmaceutical importation and exportation committee with support from SIAPS, were finalized, gazetted, and uploaded onto the MOH website. SIAPS also helped get the guidelines endorsed by the Swaziland Revenue Authority as part of efforts to facilitate collaboration across agencies in strengthening importation procedures in the country.

3 countries have developed or updated their national medicines policy with assistance from SIAPS
8 SIAPS-supported countries have developed or updated pharmaceutical laws and regulations
SIAPS technical assistance to a working group in **Ukraine** established by the MOH’s State Expert Center to develop national pharmacovigilance (PV) guidelines successfully concluded with the finalization of the last 10 of 16 modules that together constitute the guidelines. All 16 modules of the national PV guidelines, which are based on updated modules issued by the European Union to set out best practices for member countries, have now been submitted to the MOH for approval.

In **Benin**, SIAPS provided technical assistance to establish a standard list of medicines and medical supplies for response to Ebola and other viral hemorrhagic fevers (VHFs) and used this list to quantify Ebola and Lassa fever supplies needed to respond to a one-month outbreak. The SOP manual, which sets out procedures for managing Ebola and VHF commodities, was also prepared this year and is now ready for printing and dissemination.

SIAPS supported the development of the fifth edition of the **Namibia** national guidelines for antiretroviral therapy (ART), which were launched in November 2016. SIAPS contributed to the sections that address community dispensing of antiretroviral (ARV) medicines, appropriate dosing for adults and children, and safety of ARVs and other related medicines. Additionally, SIAPS worked with partners to develop and orient staff on SOPs that set-out the processes for dispensing ARVs to community-based ART groups and support implementation of differentiated models of care at high-volume ART sites.

The MOH in **Guinea** endorsed the 17th edition of the country’s NEML, and the newly revised NEML in **Mozambique** has been submitted to the MOH for final approval. Both NEMLs were developed and validated with assistance from SIAPS. Additionally, SIAPS worked with the secretariat of the NEML committee in **Mozambique** to finalize guidelines for revising and updating the NEML in the future and to update the TOR for the NEML committee. These documents will enable country counterparts to perform these activities independently of SIAPS after the program closes.

**22 countries have developed or updated pharmaceutical and disease-specific guidelines and SOPs with assistance from SIAPS**

**12 SIAPS-supported countries have updated national medicines, device, and equipment lists**

### Transparency and Accountability

Good governance requires effective organizational structures and transparent procedures that support appropriate decision making, authority, and oversight; holds entities and individuals accountable for their performance; and, enables greater participation of stakeholders, including civil society. The following are examples of SIAPS’ activities in PY6 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 **Sierra Leone**, SIAPS helped the Directorate of Drugs and Medical Supplies (DDMS), which is the directorate within the Ministry of Health and Sanitation (MOHS) responsible for oversight and support in the pharmaceutical sector, review its organogram and define the roles and responsibilities of the constituent units. The organogram, which defines the structural framework for implementing DDMS’ mandate and the TOR for the four newly established key functional units—Governance, Human Resources Management, Products and Technologies, and Administrative and Finance—are now approved. SIAPS’ support to the process included helping the DDMS convene meetings that enabled department heads and district pharmacists to review their proposed roles and responsibilities under the reorganization and propose improvements. The organogram and TOR will help clarify roles and responsibilities and enhance accountability within the directorate. In addition, SIAPS facilitated a two-week Leadership Development Program
training of trainers course that built the capacity of pharmacists from DDMS to train others in the principles of leadership, management, and governance practices, among other topics. The new trainers then co-facilitated their first training for 35 participants from across the country.

As a result of SIAPS advocacy, **Sierra Leone**’s 2017 MOHS mid-year health sector performance review included a dedicated session on the pharmaceutical sector for the first time. A panel of stakeholders, which included representatives from civil society organizations (CSOs), participated in a facilitated discussion on key issues affecting the sector. PY6 also marked the launch of Sierra Leone’s web-based pharmaceutical dashboard. Initially developed for data management and display of real-time patient and product information for ARVs and related products, the electronic early warning system has been expanded to include products for malaria, TB, leprosy, and reproductive health programs. This brings the number of countries and regions that designed, launched, and implemented dashboards for monitoring and oversight with assistance from SIAPS to eight.

In the **Philippines**, the Department of Health (DOH) took important steps toward establishing the Supply Chain Management Unit (SCMU) and improving transparency and accountability for SCM in the country. SIAPS worked with representatives from three DOH bureaus—Pharmaceutical Division, Logistics Management Division, and Knowledge Management Information Technology Services—as well as national health programs to identify roles and responsibilities of the proposed SCMU and other DOH offices involved in SCM and propose an organizational structure for the SCMU. At a second SIAPS-supported consultation workshop, the draft TOR for the SCM governance framework was reviewed and finalized.

**Bangladesh** has introduced the e-Government Procurement (e-GP) system as part of efforts to enhance transparency and promote good governance in public procurement and, at the end of PY5, SIAPS helped the Directorate General of Health Systems (DGHS) complete its registration in the e-GP system. In this program year, SIAPS provided technical assistance in building capacity and supporting implementation, which included assisting the Central Medical Stores (CMS) Depot to process procurement packages through the e-GP system.

In 5 SIAPS-supported countries, CSOs now play a greater role in monitoring and oversight in pharmaceutical systems
8 SIAPS-supported countries and regions are using dashboards for monitoring and oversight

**Coordination, Partnership, and Advocacy**

Throughout the project, SIAPS has supported partnership and coordination efforts that promote more informed and collaborative decision making, foster transparency and accountability, streamline SCM and service delivery, and improve the efficiency of planning, allocation, and mobilization of government and donor resources. In PY6, SIAPS country offices directed their attention to planning for the transition of these activities to country counterparts and partners before the program close-out. Some examples are set out below.

- In the **Philippines**, SIAPS has been supporting the Quezon City Health Department in establishing Barangay Health Management Councils (BHMCs), which bring together community-based groups, officials, and health providers to improve TB program management and service delivery in urban-poor settlements (barangays). SIAPS began providing technical assistance to design and pilot the BHMC initiative in 2012, and the model has now been rolled out to all six city districts. In PY6, SIAPS finalized the guide that the country team developed to support further expansion of the BHMC initiative. The guide provides step-by-step information to assist local government units prepare for establishing
BHMCs (conducting a situational analysis and bringing together the BHMC core team and secretariat); initiating BHMC functions (developing and implementing a work plan, tracking implementation and results of planned activities); systematically monitoring and evaluating BHMC performance; and employing strategies to institutionalize and sustain the BHMCs. The guide will enable other Quezon City local government units and health officers to establish a BHMC in their own barangay.

- Throughout PY6, SIAPS assisted the procurement and supply management thematic group of Guinea’s national malaria control program to convene regular meetings to review stock levels of antimalarial products. The group, which SIAPS helped establish, updated supply plans and identified critical actions for MOH and partners to take to avert shortages and stock-outs. Additionally, SIAPS collaborated with United Nations Population Fund (UNFPA) to help the Directorate of Pharmaceuticals and Medicines conduct quarterly performance reviews of Guinea’s reproductive health program. SIAPS and UNFPA supported the collection, aggregation, and analysis of data and the generation of key performance indicators in preparation for the meetings. Also in PY6, at the request of the USAID/Guinea Mission, SIAPS supported the 19th assembly of the Association Africaine des Centrales d’Achat des Medicaments Essentiels, March 1-4, 2017. The assembly brought together representatives from 21 CMS to share best practices and discuss interventions to address common challenges.

- In Swaziland, Burundi, and Angola, SIAPS concluded its support to groups that provide platforms for fostering coordination among pharmaceutical sector supply chain stakeholders in the countries. In preparation for project close-out, secretariat responsibilities for Swaziland’s supply chain technical working group were transitioned to the Clinton Health Access Initiative. Similarly, other development partners were identified to support the thematic group on medicines in Burundi and the logistics, operations, and procurement subcommittee in Angola after close-out.

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

Strategic Planning

Long-term strategic plans guide the implementation of approaches, methods, and mechanisms to help achieve priorities and goals set out in national policies and promote good governance in the pharmaceutical sector. In PY6, SIAPS primarily focused its efforts on assisting national governments to finalize the products of strategic planning exercises and analyze priorities to inform the development of future strategic plans.

To prepare for the review and revision of Swaziland’s national pharmaceutical strategic plan, SIAPS is supporting the government in conducting an end-term evaluation of the existing plan for 2012-2016. SIAPS’ technical assistance in this program year included preparing TOR for the task team that was subsequently appointed to lead the end-term evaluation and review of the existing plan, serving as the secretariat and supporting meetings, working with the team to develop an action plan to guide the process, and facilitating the data collection from various key respondents and health facilities.

Two countries finalized national supply chain strategies, which had been developed with assistance from SIAPS. In Angola, the National Directorate of Medicines and Medical Equipment (DNME) and the Central Procurement Agency for Medicines and Medical Supplies finalized and submitted the national supply chain strategy to the MOH for approval. In Benin, SIAPS helped the MOH’s Department of Pharmacy, Medicines, and Laboratory to cost the newly developed five-year strategic plan for SCM (2016-2021).
After a fire destroyed Guinea’s CMS (PCG) and wiped out millions of dollars’ worth of medicines and supplies, SIAPS provided lead support to the steering committee established by the MOH to develop a contingency plan that identified immediate actions needed as well as a mid-term strengthening plan for addressing PCG’s warehouse capacity and safety constraints. Immediate actions identified in the contingency plan included determining the extent of losses, checking stock status and identifying emergency procurements needed, and supporting PCG to resume warehousing and distribution activities.

In Namibia, SIAPS facilitated a focus group session at the 2017 National Pharmacist’s Forum to solicit inputs into the strategy for improving the performance of the CMS, which will form the basis for developing a three-year strategic plan to reposition the CMS and improve the national public sector supply chain.

Regulatory Systems Strengthening

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

In Angola, as part of its handover of regulatory activities to the MOH, SIAPS developed and submitted to the DNME a technical report “Situation Analysis: Introducing Pharmaceutical Product Registration Policy in Angola,” which included a road map for establishing a product registration system. DNME will disseminate and use the road map after SIAPS closes to enlist support from stakeholders for implementation of the recommended actions.

In September 2016, the regulatory authority in Ethiopia began implementing the web-based Medicines Registration Information System, a country-specific version of Pharmadex, which was developed and launched with SIAPS assistance. All applications are now being submitted online and processed electronically, including applications for new products, variations, renewals, and product purchase orders. Applicants can also use the system to track the progress of their applications through the review process.
In PY6, the Directorate General of Drug Administration (DGDA) of Bangladesh officially launched the Common Technical Document (CTD) guidelines for registration applications as well as the online medicine registration system, Pharmadex, both of which were major, multi-year efforts supported by SIAPS to strengthen product registration. In the lead up to the launch of these two initiatives, SIAPS finalized the user manual and provided extensive hands-on training for DGDA officials and applicants from the pharmaceutical industry. To initiate use, the DGDA enlisted the country’s top 10 pharmaceutical manufacturers, requiring them to submit new registration applications for cardiovascular products by using Pharmadex and to submit the dossiers in the CTD format. The first dossier in CTD format was successfully submitted, screened, and reviewed online in the final quarter of the year. An action plan for implementation of CTD and Pharmadex, which was developed with assistance from SIAPS, will guide further roll-out of the new requirements next year.

SIAPS also continued its collaboration with WHO and other international development partners to create a coalition that will enhance coordination of regulatory systems strengthening efforts at the country level. This coordinated “coalition approach” was piloted in Bangladesh with the DGDA, where SIAPS assisted the agency in developing a five-year strategic plan (2017-2021) and a one-year implementation plan for the regulatory system, which in turn guided the identification of technical and financial support for DGDA’s activities and goals. The plan aligns with the MOHFW’s fourth sector-wide development program (2017-2022) and will assist Bangladesh in achieving the maturity level required for WHO prequalification. SIAPS helped the DGDA organize workshops with the relevant stakeholders to gather input, reach consensus on key elements of the plan, disseminate it, and assign capacity-building needs to technical partners.

This year, SIAPS support contributed to the registration of tenofovir/emtricitabine (TDF/FTC)-based ARV formulations (Truvada®) for pre-exposure prophylaxis (PrEP) by the Namibia Medicines Regulatory Council (NMRC). TDF/FTC for PrEP, which is included in the recommendations of the fifth edition of the Namibian HIV Treatment Guidelines, has the potential to significantly reduce new HIV infections among high-risk groups. SIAPS also continued working with NMRC to improve the overall efficiency of the registration system and reduce the time to approve pharmaceutical products through the use of a web-based version of Pharmadex. In addition to customizing, testing, and updating the software according to NMRC’s requirements and specifications, SIAPS oriented and trained NMRC staff and began work on a users’ guide that will facilitate implementation after SIAPS ends. The tool is expected to be finalized and deployed at the beginning of next year. SIAPS’ efforts to improve product registration in Namibia have contributed to a 24% reduction in the average number of days to evaluate and approve a medicine registration application since 2013, falling from 34 days to 26 days, and an increase in the percentage of NEML items that have at least one registered product available, from 61% in 2011 to 78% in 2017.

SIAPS continued to work with the Pharmacy Department (PD) in Mozambique to roll-out Pharmadex by updating and expanding the software and training applicants to use the new system. During PY6, the registration unit at the PD started using Pharmadex for all new registration applications and, with assistance from SIAPS, introduced measures to monitor use of the system so that barriers to use can be identified and addressed. In addition, SIAPS assisted the PD to transfer the records of 4,232 products already registered in the country from the physical archive to the electronic archive to facilitate renewals and variation applications for those products. The templates for registration renewals and variations were finalized at the end of the year and are expected to be deployed at the beginning of next year. Collectively, SIAPS’ assistance to Mozambique in product registration
has helped the PD reduce the average number of
days to register a product from 281 in June 2016
to 150 in June 2017. During the year, SIAPS also
provided substantial support to the PD to further
strengthen the monitoring and evaluation (M&E)
system, which it helped the department develop
and implement last year as part of a broader effort
to improve transparency, accountability, and use
of strategic information within the regulatory
system. Specifically, SIAPS assisted the PD’s
M&E staff to collect data, prepare and submit
the department’s quarterly reports, coordinate
data review meetings with the relevant PD units,
conduct internal data quality assurance tests
in select areas, and further institutionalize the
indicators within the department and streamline
them with the MOH’s M&E system.

SIAPS continued to support the Office of the
Chief Pharmacist in Swaziland this year with the
operationalization of the Medicines Regulatory
Authority established under the new Medicines
and Related Substances Control Act of 2016.
To improve importation, SIAPS helped the
office finalize and issue the import and export
policy and guidelines for pharmaceuticals;
designate ports of entry for pharmaceuticals
in collaboration with the Swaziland Revenue
Authority; and enforce minimum requirements
established by the MOH for importers. As
a preliminary step toward monitoring and
ensuring the quality standards of pharmacy
personnel and retail pharmacies, SIAPS assisted
the pharmaceutical recruitment and training
committee to assess training institutions for
pharmacy training standards under the direction
of the Swaziland Higher Education Council and
helped the Chief Pharmacist’s Office develop and
disseminate a notice calling for the registration
of retail pharmacies and begin compiling the list.

Based on a request from the USAID Mission
in Benin, SIAPS conducted an assessment of
the medicine registration system, including
information management, at the Department
of Pharmacy (Direction de la Pharmacie, du
Médicament et des Explorations Diagnostiques
[DPMED]) of the MOH, provided
recommendations for strengthening the
system, and proposed an action plan. Notably,
SIAPS agreed to help DPMED optimize use of
the existing electronic registration tool, rather
than introduce a new tool.
Ensuring Sustainable Access to TB Medicines through Inclusion in the Philippine National Formulary

March 2017

Using a systems strengthening approach, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is building the capacity of the pharmaceutical system at all levels to reduce the country’s tuberculosis (TB) burden through increased access to pharmaceutical and laboratory services. Specifically, program objectives are to:

- Ensure the availability of effective, quality, and safe pediatric fixed-dose medicine combinations (FDC) for TB
- Ensure the availability of effective, quality, and safe anti-TB medicines for multi-drug resistant (MDR) TB
- Build the capacity of the National Tuberculosis Program in registering existing and new TB medicines in the Philippine National Formulary.

Background

TB caused an estimated 14,000 deaths in the country in 2015, according to the World Health Organization’s (WHO) Global Tuberculosis Report for that year, which classifies the Philippines as a high TB-burden country. The National TB Control Program (NTP) of the Department of Health (DOH) leads the effort to ensure access to anti-TB medicines. The DOH’s Pharmaceutical Division (PD) and Food and Drug Administration (FDA) also help ensure access through regulating in-country registration, quality, safety, and affordability.

Seeking Sustainable Access to New Drugs

The DOH requires medicines to be included in the Philippine National Formulary (PNF), the country’s essential medicines list, before government funds can be used to acquire them.

Pediatric anti-TB medicines, which are commonly kept in bottles, present storage and distribution problems for the NTP and health facilities because of their bulky size. Further, administering them is time consuming and imprecise. New pediatric fixed-dose combination TB medicines recommended by the WHO have several advantages. However, they were not included in the PNF, so therefore could not be purchased with government funds.

Further, the program wanted the PNF to include the anti-TB for MDR-TB medicines it currently uses. These are acquired through the Global Drug Facility (GDF) under a grant from the Global Fund, and are exempted from PNF inclusion. However, depending solely on the inclusion exemption as well as external funding for these medicines is not sustainable.

Therefore, the NTP plans to transition to government funding for these medicines, and including them in the PNF was a prerequisite step. The NTP also sought to build its capacity to acquire needed drugs in the future and to help ensure sustainable access to them.

Approach

SIAPS helps countries adopt new medicines and regimens by using a systems strengthening approach that engages stakeholders, builds on
existing systems or establishes new ones where appropriate, strengthens human resources via trainings, improves the distribution chain for new TB medicines, and records and reports information for decision making in relevant areas.

SIAPS promotes stewardship and pharmaceutical governance by working with NTPs to coordinate all in-country partners and to define roles and responsibilities for implementation of these new medicines and regimens. The overall goal is to promote sustainability among all parts of a health system.

**Intervention**

To begin the project, SIAPS helped coordinate regular planning meetings and discussions with the NTP’s Drugs and Supplies Management (DSM) sub-technical working group. SIAPS then facilitated collaboration among the NTP, the PD, WHO, and the GDF.

The NTP then finalized the list of anti-TB for MDR-TB medicines to be acquired through the GDF. Assisted by SIAPS, the DSM prepared the required rationale, references, and guidelines used as basis for presentation to the Formulary Executive Committee (FEC) of the PD. The DSM then circulated the prepared documents and presentation for review by the NTP manager and DSM sub-technical working group members and revised the materials accordingly. Finally, the DSM coordinated with the PD to finalize the NTP manager’s presentation to the FEC.

**Results**

In October 2015, three new pediatric fixed-dose formulations were approved for inclusion in the PNF, two of which are dispersible flavored tablets. This ensures that the program will be able to acquire these medicines by using government funds. In addition to being easier to administer to children, the tablets are easier to store, take up less storage space in warehouses and health facilities, and are easier to distribute, thereby drastically reducing the logistics management burden and costs.

Further, five anti-TB medicines for MDR-TB were included in the PNF in September 2016. This will ensure that these medicines are consistently available to patients whether procured using government or external funds.

<table>
<thead>
<tr>
<th>MDR drugs</th>
<th>Capreomycin 1 g powder for injection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Para-aminosalicylic acid 4 g sachet</td>
</tr>
<tr>
<td></td>
<td>Moxifloxacin 400 mg film-coated tablet</td>
</tr>
<tr>
<td></td>
<td>Prothionamide 250 mg film-coated tablet</td>
</tr>
<tr>
<td></td>
<td>Cycloserine 250 mg capsule</td>
</tr>
<tr>
<td>Pediatric drugs (new formulations)</td>
<td>Rifampicin 75 mg + isoniazid 50 mg + pyrazinamide 150 mg dispersible fixed-dose combination tablets</td>
</tr>
<tr>
<td></td>
<td>Rifampicin 75 mg + isoniazid 50 mg dispersible fixed-dose combination tablets</td>
</tr>
<tr>
<td></td>
<td>Ethambutol 100 mg tablet</td>
</tr>
</tbody>
</table>

With this experience, the DSM can take the lead on completing the approval documents and process to acquire new drugs the program needs. The DSM now regularly meets with its sub-technical working group to compile a list of needed medicines and coordinate completing requirements for inclusion approval.

**Way Forward**

The DSM needs close coordination to agree upon and finalize medicines that should be included in the formulary. Further, the program should be able to clearly justify inclusion of these products, together with reference guidelines and recommendations. Lastly, the FEC should set up a meeting schedule that is coordinated and finalized with the appropriate NTP manager.

The NTP is already planning to include other medicines in the formulary such as bedaquiline, a powerful new drug for the management of MDR-TB, and rifapentine to manage latent TB. Faced with evolving global recommendations and guidelines, the NTP is now in a better position to adapt and keep up with progress in managing TB and ensure that the Philippines has access to the best possible medicines and treatment.
The Challenge

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

SIAPS Approach for Increasing and Enhancing Capacity

SIAPS approach for increasing and enhancing capacity focuses on working with stakeholders to assess the country’s capacity to manage pharmaceuticals at all levels. Then, with consensus, SIAPS identifies areas for improvement and develops interventions to strengthen the system and build capacity.
Key Achievements during Program Year 6

Strengthening Capacity of Individuals, Institutions, and Organizations

A key area where SIAPS focuses its efforts is on pre- and in-service trainings for health care professionals through local institutions. Designing and implementing training curricula, courses, and programs for pharmacists, physicians, nurses, and other health care workers helps strengthen the cadre of professionals ready to effectively manage, prescribe, and monitor the use of medicines.

Pre-Service Trainings

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

In Dominican Republic, SIAPS supported the second certified course (diploma) on RMU. The final module and closing ceremony was held in February 2017. The students presented seven medicine use studies as the final product of the course. SIAPS provided technical peer-reviews for the pharmaceutical supply management certified (diploma) course and provided materials to the Universidad Central del Este for future use. A course on RMU was held in July 2017 and SIAPS consultants facilitated the first and second modules of the course. USAID sponsored tuition for 21 students.

In Namibia, SIAPS supported the National Health Training Center (NHTC) in training students on the Electronic Dispensing Tool (EDT) and facility electronic stock card (FESC) prior to their deployment at a rural ART site. The EDT and the FESC have been implemented in public health facilities to manage patients at ART sites and the inventory of ARVs and antimicrobial TB medicines. The University of Namibia’s School of Pharmacy (UNAM-SoP) was supported in revising the pharmacy curriculum to include lecture sessions on using the FESC for pharmaceutical inventory management. In summary, 38 pharmacist assistants, 22 pharmacy technicians, and 33 pharmacists graduated from the NHTC and UNAM-SoP. The 93 graduates brought the cumulative number of pharmacy professionals trained in SIAPS’s program lifetime to 252, which is 53% above the life-of-project target of 164 graduates. USAID’s support to the NHTC and UNAM-SoP through SIAPS significantly increased the availability of local, qualified, certified pharmacy staff to decentralize and expand access to ART services and improve the quality of dispensing services.

In-Service Training

To date, 10 countries have developed or revised 40 in-service health professional training curricula with SIAPS assistance (figure 1).

![Figure 1. In-service health professional training curricula developed or reform](image-url)
In **Bangladesh**, a two-day basic logistics management orientation was conducted for 412 health officials from the Directorate General Health Services (DGHS) representing 11 districts. DGHS officials attended the training to motivate local-level health managers. SIAPS technical advisors in the field provided assistance to ensure completion of post-training action plans. SIAPS and Save the Children jointly held a day-long training of trainers (TOT) on supply chain management systems in July 2017. The training was targeted to health managers, statisticians from the three districts, and divisional coordinators from the DGHS Management Information System Unit and the MaMoni Health Systems Strengthening Project. More than 700 participants received trainings in 22 groups of 30 to 35 participants. A pharmacovigilance workshop for maternal, newborn, and child health medicines was organized in collaboration with the Bangabandhu Sheikh Mujib Medical University (BSMMU) in August 2017.

In **Burundi**, SIAPS, in collaboration with FHI360, organized a training of 118 community health workers (CHWs) in Giteranyi health district in Muyinga province to scale-up the integrated community case management of child diseases (iCCM). Following the training session, a one-week practical internship took place in the health facilities during October 17-20, 2016. On October 20, the official launching ceremony of the iCCM in Giteranyi and distribution of the basic kit of necessary equipment and supplies to CHWs was held.

In **Ethiopia**, in collaboration with Pharmaceutical Fund Supply Agency and Clinton Health Access Initiative (CHAI), SIAPS organized a TOT course on antiretroviral treatment (ART) and comprehensive HIV care for pharmacists based on the revised training curriculum; 42 pharmacists participated. The training was conducted by trainers with long experience in ART training and who were involved in revising the curriculum. The course was expected to equip pharmacists with sufficient and practical knowledge of comprehensive HIV care/ART service and antiretroviral (ARV) medications available in Ethiopia to enable them to train other pharmacy professionals on dispensing appropriate treatment regimens, successful management of treatment side effects and drug interactions, and counseling patients effectively to increase treatment adherence.

In **Sierra Leone**, SIAPS trained pharmacists from the Directorate of Drugs and Medical Supplies (DDMS), hospitals, and districts on leadership, management, and governance using the Leadership Development Program (LDP) approach. SIAPS taught pharmacists basic practices of good leadership, management, and governance to help them identify challenges, solve problems, and lead their teams. It was the first such training in the country, which is still rebuilding and strengthening its health system after the Ebola epidemic. To create a pool of LDP facilitators who could then cascade the program as trainers throughout the 13 districts of Sierra Leone, 17 pharmacists from DDMS, districts, and hospitals participated in a two week TOT. The new trainers facilitated the first cascade training for 35 participants drawn from the pharmaceutical sector.

To increase capacity for pharmaceutical supply management and services, SIAPS/Swaziland has trained 104 health professionals (72 female, 32 male) involved in HIV/TB pharmaceutical management at 88 health facilities in the four regions. Participants included pharmacists, pharmacy technicians, and nurses responsible for medicine management. The trainings included topics such as inventory management, adverse drug event reporting, and LMIS for ARVs and TB medicines. The training materials were co-developed with MOH pharmacists, who also facilitated the training. After the training, participants were expected to improve management of stock in the facilities, ordering, and reporting to the central level.
Building Institutional Capacity to Strengthen Pharmaceutical Systems

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

SIAPS/Bangladesh facilitated a subnational procurement workshop for the district-level procuring entities in seven regions. During the workshop, it was identified that most of the local-level procurement is done without following the government’s procurement rules for using public funds. SIAPS customized the subnational procurement guidelines and facilitated the training for subnational procurement entities so that governments’ rules and regulations are followed. A procurement training was conducted for 500 district-level managers to accelerate the procurement system at the subnational level using Public Procurement Rules and the Public Procurement Act. The countrywide training took place through 18 orientation workshops.

SIAPS/Philippines provided technical assistance to the Laboratory Conference for Regional National TB Program Coordinators to identify the capacity building needs of regional laboratory managers. During the three-day conference, meetings and workshops were aimed at developing leadership and management of the TB laboratory network. Staff from each region represented at the conference performed an analysis of their current NTP regional laboratory network status, identified problems and root causes, and utilized the information to create a regional plan to address capacity gaps. The main regional technical assistance needs identified included building: leadership and management capacity of the coordinators to manage the laboratory network; capacity to decentralize laboratory trainings; and capacity to lead and manage laboratory network expansion. These plans will now become the basis for future technical assistance for the regions.

SIAPS/Philippines collaborated with the National Tuberculosis Reference Laboratory Training and Development Unit and the Regional National TB Program (NTP) coordinators of Central Luzon, Calabarzon, and the National Capital Region to develop the GeneXpert TOT course and the Understudy Training Program. These are part of the initiative to decentralize laboratory training to build the capacity of laboratory managers up to the peripheral level. These trainings contributed to the country’s efforts to expand rapid TB diagnostic laboratories using GeneXpert nationwide. This collaboration supports the Philippine Health Agenda through the Philippine Strategic TB Elimination Plan: Phase 1 2017–2022.

SIAPS/Philippines finalized the Barangay Health Management Council (BHMC) Guide to help local government units (LGUs) establish BHMCs in their areas to improve delivery of TB control services. The guide includes the steps to be taken during the preparatory phase, including guidance to conduct the barangay situational analysis and the organization of the BHMC core team and secretariat. It also covers the development of the BHMC work plan, implementation of the plan, and monitoring and evaluation (M&E) of the implementation process and BHMC performance.

SIAPS/Sierra Leone conducted TOT for DDMS and all district pharmacists and district information and M&E officers on the use of the registers and reporting so they can conduct cascade training for peripheral health units (PHUs) and hospital staff. Cascade training on the treatment registers for approximately 1,500 PHU staff from all 13 districts was completed. After the cascade training, registers was distributed to every health facility, and the obsolete versions were retrieved.
Other Approaches for Capacity Building

Supportive Supervision and Mentoring

SIAPS/Benin participated in a joint field visit to conduct supportive supervision of Ebola commodity management in three hospitals in Cozo, Bassila, and Saba, and one Ebola treatment center in the departmental hospital of Zou-Collines. The purpose of the visit was to assess Ebola products that would be needed to respond to outbreaks and follow-up on the implementation of recommended actions from previous supportive supervision. Based on the field visit and on-site observations, recommendations were made, including preparing reports to document any donated Ebola products and using stock cards to document all transactions made on Ebola products to ensure traceability.

SIAPS/Namibia supported the annual service quality assessments for 12 clinics, 16 health centers, and 35 district and referral hospitals. During the on-site technical assistance, the teams mentored and trained more than 70 health care workers on SIAPS implemented tools (EDT, FESC, and PMIS). The teams also provided technical assistance on report development and submission, validated pharmaceutical service information, and guided facility staff on data quality improvements. The findings from service-quality assessments enabled SIAPS to target technical assistance to the Ministry of Health and Social services (MOHSS) based on evidence from the data and allowed managers at MOHSS to make evidence-based decisions in managing pharmaceutical services.

SIAPS/Swaziland provided support to ART sites to improve pharmaceutical service through supportive supervision on pharmaceutical inventory management, good dispensing practices, counseling of patients on ARV/TB treatment, and monitoring ADRs to improve adherence of patients to treatment. SIAPS provided supportive supervision to 14 out of the 16 target health facilities. SIAPS also conducted annual supportive supervision visits to 40 facilities in the Manzini and Lubombo regions. The purpose of these visits was to monitor the availability of quality pharmaceutical products and the provision of effective pharmaceutical services for HIV, TB, family planning, and laboratory. Results from the visits showed that in the Manzini region, 34% of facilities were overstocked and 40% were understocked, indicating weak inventory management. Only 40% of facilities had adequate storage space for essential medicines.

In the West African Region, SIAPS supported the National AIDS Control Program (PNLS) of Togo in conducting supportive supervision at the five pilot sites where EDT software is already installed. The purpose of this supervision was to build the capacity of EDT users; identify issues affecting the use of EDT in the five sites before the roll-out nationwide of EDT; and also assess the quality of data through two indicators reported on the SIAPS M&E plan. The supervision team assessed the quality of data by using two indicators—the concordance between the EDT record and physician prescription with regard to patient number, regimen, type of treatment, drugs, and the concordance between physical stock and theoretical stock. Significant progress has been made in regard to the second indicator where, in the past, some ART sites did not meet the 100% of concordance; each of the five sites demonstrated 100% of concordance between physical stock and theoretical stock. The PNLS team was able to visit each ARV site once a week for four consecutive weeks. As a result, EDT is actively used at the five pilot sites to record patients and medicines used to treat HIV-positive patients. Four pilot sites have already abandoned the paper-based dispensing register; however, the Teaching Hospital of Tokoin was still using both EDT and the paper-based log book because of a bug blocking generation of the monthly LMIS report to send to PNLS for resupply.
Tools for Capacity Building

SIAPS/Bangladesh provided an orientation session for the Directorate General Family Planning (DGFP) field-level staff in 27 selected subdistricts on the impact of the service delivery point (SDP) dashboard module in DGFP LMIS; 1,662 field staff (1,230 female and 432 male) attended the orientation. The SDP module focuses on the effective management of commodities to ensure availability of all the major contraceptives and prevent stock-out at the last mile.

SIAPS/Mali supported the MOH’s Department of Pharmacy and Medicines and the National Center for Disease Control in organizing training sessions on the effective management of health program commodities. The objective of the trainings was to strengthen the skills of the working groups of the different programs on the newly developed modules included in the electronic portal OSPSANTE. Central-level staff, members of the civil society, and staff from USAID and NGO partners participated in the trainings: 9 members (5 female and 4 male) of the Nutrition Technical Group, 11 members (3 female and 8 male) of the HIV Technical Group, and 10 members (1 female and 9 male) of the Ebola Technical Group.

The Namibia Medicines Regulatory Council (NMRC) under MOHSS aimed to improve its medicine registration system to ensure the safety and efficacy of medicines and to improve the potential to export medicines. SIAPS/Namibia trained six NMRC staff on the in-house implementation of the web-based registration system (Pharmadex) before it is opened up for use to external pharmaceutical companies.

SIAPS/Guinea supported the Directorate of Family Planning (DNPM) in training 511 health personnel from prefectures, hospitals, and health facilities to equip them with adequate knowledge and skills to fulfill their responsibilities and correctly operate the logistics system. Using adult learning theories, participants were trained on using the SOPs manual to integrate the LMIS and corresponding forms to order, monitor, and manage health commodities. Trained health personnel were provided with copies of blank LMIS reports sufficient to support reporting of logistics data for six months. In addition, the Logistics Management Unit (LMU) launched routine monitoring of the logistics system to determine if health facilities were reporting logistics data. The project initiated deployment of the eLMIS in Guinea by installing the server and providing administrator training for super users. Health facilities with trained staff started submitting their monthly LMIS reports by using the integrated reporting forms in February 2017.

SIAPS/Mali strengthened the capacity of local partners, including the Department of Pharmacy and Medicines and the National Agency of Telehealth and Medical Informatics, to take over the management of OSPSANTE. A two-day training was conducted by SIAPS on the back- and front-ends of OSPSANTE. To ensure a seamless transition, SIAPS also provided all system requirements to host OSPSANTE in a server owned by national entities. In addition, SIAPS has provided technical support to the Regional Health Directorate of Bamako to train six health districts on the nutrition and HIV portals in OSPSANTE. The objective of these trainings was to strengthen the skills of the working groups of the different health programs; 15 people (7 female and 8 male) were trained. After the acceptance test, the participants entered reports from January through May 2017 for these programs.

SIAPS/Mozambique assisted the Pharmacy Department in training three applicants in dossier submissions using Pharmadex. During the trainings, applicants provided feedback on the system and made suggestions for improvement. During this quarter, the number of dossiers submitted on Pharmadex increased from 57 submissions (last quarter) to 144 submissions.

SIAPS/Swaziland provided refresher trainings for users of the eLMIS. This activity was prompted by concerns about the quality of reporting by facilities to the central level. One issue that was flagged at these facilities was inadequate infrastructure to connect to the Internet. Because of such problems, sites reverted back to using the manual LMIS form, and as a way of intervention, SIAPS worked with the MOH Health Management Information Systems to rectify issues with the Internet infrastructure.
TECHNICAL HIGHLIGHT

Leadership Development Training to Strengthen Pharmaceutical Management in Sierra Leone

August 2017

Background

The catastrophic Ebola epidemic that began in 2014 aggravated Sierra Leone’s already weak pharmaceutical supply system. The country’s public-sector storage, handling, distribution, and waste disposal practices were in dire need of improvement. Peripheral health units (PHUs) lacked reliable medicine consumption data, which compromised inventory control and accurate forecasting, leading to frequent stock-outs or overstocks.

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program received two years’ of funding from the US Agency for International Development (USAID) in September 2015 to provide technical assistance to rebuild and strengthen the post-Ebola pharmaceutical management system and improve the supply chain and rational medicines use in Sierra Leone.

As part of that, SIAPS is helping Sierra Leone strengthen pharmaceutical sector leadership and governance at all levels and to improve management and accountability, including institutionalizing and operationalizing quality assessment/improvement protocols and processes. The project’s technical assistance targets include district health management teams, hospitals, and PHUs in all 13 districts. Among the key stakeholders is the country’s Directorate of Drugs and Medical Supplies (DDMS), which is responsible for coordinating and providing pharmaceutical services.

Intervention

In May 2017, SIAPS held a Leadership Development Program (LDP) training, developed by Management Sciences for Health, to build the capacity of the DDMS, district and hospital pharmacists, and SIAPS field staff. It was the first such training in the country.

The program aims to train pharmacists on basic principles and practices of good leadership, management, and governance to help them identify challenges like system and budget constraints—and to lead their teams in handling them with maximum efficiency, collaboration, and transparency. Another training goal is to help pharmaceutical managers optimize the SIAPS-supported Continuous Results Monitoring and Support System (CRMS), which has been implemented nationwide. The training created a pool of local LDP facilitators who can extend their knowledge to other DDMS staff and to pharmacists throughout all 13 districts in Sierra Leone.

Step One: TOT

First, SIAPS supported training of trainers (TOT) for 17 future local LDP facilitators to cascade the program to other DDMS staff and district/hospital pharmacists throughout Sierra Leone. (Senior DDMS managers selected all participants, including the TOTs.) They were coached on key sections of the LDP content and taught how to facilitate them. The trainees practiced in front of their colleagues and LDP leaders, who provided further feedback and coaching. Upon completion
of their course, 13 of these 17 new trainers served as LDP facilitators for a senior management alignment meeting (SAM), a larger audience immediately comprising district medical officers, hospital superintendents, and external partners.

**Step Two: Cascade Training**

Then, a larger group of 35 participants trained in modules 1 through 4 of the LDP out of 10 modules (the remaining modules not covered due to project-related challenges). Topics covered included understanding leading and managing practices; introducing a “Challenge Model” and creating a shared vision; measuring results; and identifying obstacles to results and their root causes.

The purpose of the LDP cascade training is to help participants:

- Mobilize others in their workplace to envision and realize a better future for all
- Apply a systematic approach to define and address challenges and produce intended results
- Produce results that support the mission and shared vision of the team
- Build a work climate that supports commitment to continuous improvement

**Methodology**

The LDP follows an empowerment model of development practices, which involves participants in designing solutions to challenges they face. It is a participatory, adult learning process, as opposed to information delivered via a lecture. In line with this model, the two LDP facilitators, one an MSH LDP specialist and the other a consultant engaged by SIAPS, facilitated group learning for the first four modules of the program.

The facilitators organized participants in teams of up to seven people to ensure full participation by each individual. The teamwork is designed to also create camaraderie among participants and strengthen work relationships. The facilitators used potential day-to-day scenarios, challenges, and examples to generate discussion. The advantage of this learning method is that it is not prescriptive. Participants identify common, real-life issues and generate their own ideas and solutions.

During these discussions, trainees brainstormed solutions to the many challenges that the pharmaceutical system is facing in Sierra Leone, such as drug stock-outs. With facilitators’ guidance, the participants proposed possible solutions, such as proactively communicating needs to the central storage unit as well as working to ensure availability of transport. The participants also discussed another key management challenge, poor data quality, realizing that individual action was needed to resolve this issue.

**Objectives**

Learning objectives for TOT participants included the ability to:

- List and explain eight leading and managing practices
- Demonstrate application of the Challenge Model
- Deliver LDP modules 1 through 4
- Coach district and PHU teams in implementing CRMS
- Plan implementation of LDP output
- Plan for cascading the LDP to peripheral teams
Results

The “before and after” measurement of the objectives for TOT shows (on average) an increase in confidence, skills, and knowledge on a 10-point scale from 0 (low) to 10 (high).

The SIAPS facilitators observed that five TOT participants were well prepared to internalize the content and were able to follow the script/guide when they facilitated the modules during the cascade training. The remaining dozen, however, had not fully mastered the content and keeping to the script. It may be that the adult learning process was new to them and they had a hard time making the shift to facilitation.

Challenges

- Work-related responsibilities conflicted with the training schedule, resulting in some of the participants missing some sessions in order to attend to office duties.
- The time used for the TOT was shortened to allow for enough time to do practicums for the subsequent SAM session. Only three days were allotted for the training, instead of the five days TOT normally requires.

Lessons Learned

- It takes time to shift mindsets to new procedures. The TOT participants who were more accustomed to a traditional didactic training approach had a harder time shifting to a facilitated adult and participatory learning model. To deal with this, a full five days should be allocated to TOT training. Trainees must also ensure that they engage with the material and prepare thoroughly.
- The prescriptive manner of the LDP Facilitators Guide contradicts the way it’s implemented, which is based on creative group facilitation. The guide spells out what a facilitator should say and ask to the letter. Some trainees took this to mean memorizing content, even though lecturing is discouraged. Others felt that, having mastered the content, they should be permitted to deliver it in their own words.
- Participation by senior management made a big difference in trainee enthusiasm. The director of DDMS was present throughout the training, which showed government support of the process. It also gave the participants a chance to bring forth the challenges they face at work.
Going Forward

SIAPS recommends that DDMS management appoint a local facilitator to coordinate further LDP training in all 13 districts. The facilitator would coordinate cascading of the program to other departments and hospitals apart from pharmacy, improving the program’s sustainability.

The TOTs from the DDMS, selected districts, and hospitals showed that they mastered the first four LDP modules. They displayed a shift in their thinking towards greater responsibility and empowerment that will help them serve as coaches in their workplaces. At the end of the TOT, they reflected on how they can act more like “managers who lead.” As a group, they committed to:

- Proactively engaging stakeholders rather than waiting for orders from above
- Taking ownership of and responsibility for one’s actions in the workplace
- Taking action on challenges and adopting a persevering, can-do attitude
- Engaging and inspiring other stakeholders

At the conclusion of the training, Dorothy Peprah, the global health security agenda advisor who represented USAID in Sierra Leone, gave certificates of attendance to the participants and described the training as “an important milestone and an engine for pharmacists to improve on the health of the people of Sierra Leone.”
The Challenge

The collection, analysis, and use of health and pharmaceutical management information drive better decision making at all levels of a health system. This information, when used through efficient systems for decision making, ensures an uninterrupted supply of medicines; provides insights into the factors that enable patients to adhere to treatment regimens; provides evidence for development and revision of national treatment protocols; facilitates better quantification, procurement, and costing for medicines and other health supplies; and ultimately contributes to stronger health systems and better health outcomes.

While the importance of reliable management information systems for decision making is universally acknowledged as a key element of resilient health systems, many countries still face challenges in identifying their management information needs and systemic gaps in collecting, validating, and processing data into usable information that links patients and medicines for policy and decision makers.

SIAPS has supported the integration of pharmaceutical data collection, analysis, and presentation of information to help staff at all levels of a country’s health system make evidence-based decisions to improve the management of health commodities and pharmaceutical services. Through the introduction of its tools, SIAPS has helped countries ensure that quality pharmaceutical information is available 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 relying on cross-cutting
interactions with governance, capacity building, financing, supply chain, and pharmaceutical services in order to make longer term, sustainable improvements. SIAPS emphasizes stakeholder buy-in and ownership and advocates for effective information systems and long-term sustainability of interventions.

**SIAPS Approach for Addressing Information for Decision-Making Challenges**

SIAPS approach for addressing information for decision-making challenges focuses on supporting the integration of pharmaceutical data collection, processing, and presentation of information to help staff at all levels of a country’s health system make evidence-based decisions to manage health and laboratory commodities and pharmaceutical services.

The SIAPS Program’s three main concepts relating to information and information systems were identified as the key to improving decision making. These were 1) data availability and use; 2) data quality; and 3) system design and use of tools. To address these areas, SIAPS applied several strategies, including assessing local information needs, leveraging mobile and Internet technologies, integrating multiple PMIS platforms, and strengthening the capacity of local organizations to customize, maintain, and take ownership of PMIS tools and data. SIAPS also worked with countries to improve data quality, ensure that information systems capture data on both product and patient-focused parameters, and disseminate data in a timely manner to relevant stakeholders through appropriate reporting channels. Data generated from SIAPS-supported systems now allow in-country decision makers to access critical information, including for example, treatment regimens, consumption rates, and stock data.

During PY6, SIAPS had two priority directions for IR3: 1) finalizing country-specific versions of SIAPS electronic tools and transferring ownership to in-country counterparts to ensure their sustainability and 2) preparing relevant documentation and cleaning source codes for the transfer of the tools to the GitHub open source repository which will effectively make them available to countries and partners who may wish to further evolve and expand the tools.

**Key Achievements during Program Year 6**

**Information Systems support both Patients and Pharmaceutical Management**

SIAPS has finalized and supported the scale-up and continued transfer of its electronic pharmaceutical management tools to stakeholders in countries through direct and virtual technical assistance, training super users, and bolstering the skills of program managers to successfully own, evolve, and manage SIAPS PMIS tools.
<table>
<thead>
<tr>
<th>Tool</th>
<th>Where it’s used</th>
<th>Achievements in PY6</th>
</tr>
</thead>
<tbody>
<tr>
<td>RxSolution</td>
<td>South Africa, Lesotho, Namibia, Swaziland, and Uganda</td>
<td>• Rolled out to 613 sites&lt;br&gt;• In South Africa, the source code was handed over to government officials and RxSolution is now supported by implementing partners, with Management Sciences for Health providing technical assistance</td>
</tr>
<tr>
<td>Pharmadex</td>
<td>Ethiopia, Bangladesh, Mozambique, Namibia</td>
<td>• Pharmadex source codes and ownership handed over to Bangladesh government officials</td>
</tr>
<tr>
<td>QuanTB</td>
<td>Bangladesh, Zimbabwe, Zambia, Nigeria, DRC, Mozambique, Philippines, South Sudan, Myanmar, Ethiopia, Uzbekistan, Sierra Leone, Guatemala, Honduras, Venezuela, Colombia, Brazil, Uruguay, Mexico, Dominican Republic, and Nicaragua, and more</td>
<td>• Version 4.1 was made available for download from SIAPS website&lt;br&gt;• 1,702 unique downloads; since 2014, there have been 2,269 downloads of in 136 countries&lt;br&gt;• QuanTB has become the official tool of StopTB Global Drug Facility (GDF) for procurement and as an early warning system; all 28 GDF priority client countries are reportedly using QuanTB</td>
</tr>
<tr>
<td>e-TB Manager</td>
<td>Armenia, Azerbaijan, Bangladesh, Brazil, Cambodia, Indonesia, Namibia, Nigeria, Ukraine, Vietnam</td>
<td>• Globally, managing over 650,000 TB and MDR-TB cases&lt;br&gt;• Version 3.0 with enhanced functionalities and able to run on portable devices has been launched&lt;br&gt;• Final handover of the tool in Bangladesh</td>
</tr>
<tr>
<td>Quantimed</td>
<td>Bangladesh, Cameroon, South Sudan, Ethiopia, Swaziland, Mali, Afghanistan, Angola, Sierra Leone</td>
<td>• Deployed in Angola and Sierra Leone for quantifying HIV and malaria commodities at the national levels&lt;br&gt;• Being used to quantify RMNCH commodities and essential medicines</td>
</tr>
<tr>
<td>Electronic Dispensing Tool (EDT)</td>
<td>Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Morocco, Namibia, Nepal, Rwanda, Tanzania, and Togo</td>
<td>• More than 700 sites in 12 countries, supporting approximately 800,000 ART patients each year&lt;br&gt;• Successfully piloted at five ARV sites in Togo</td>
</tr>
<tr>
<td>Pharmacovigilance Monitoring System (PVIMS)</td>
<td>Georgia, Philippines, and Swaziland</td>
<td>• Provides case management for patients using bedaquiline or delamanid to treat multidrug-resistant TB&lt;br&gt;• Is the active TB drug safety monitoring and management system in Georgia, Philippines, and Swaziland&lt;br&gt;• Adopted as the national pharmacovigilance tool in the Philippines</td>
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</table>

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

Working to expand the knowledge base of pharmaceutical best practices and improve utilization of information for TB control decision-making, SIAPS published two peer-reviewed journal articles this year. The first article was published in the *European Respiratory Journal Open Research*. The article presented results of an in-depth analysis of Ukraine's experience implementing e-TB Manager, a digital health tool, as their nationwide TB registry. Key takeaways from this study included, Ukraine's significantly expanded use of its TB registry for patient care and decision making down to the rayon (district) level, despite what once seemed to be insurmountable obstacles to using the tool. Figures in the article illustrate the use of the registry against the total TB burden in the country. Furthermore, the quantitative analysis showed that registry users can find the information they need to care for patients and improve their workplace productivity. The authors concluded that "our end-of-program findings are significant, given that Ukraine’s global ranking on overall government usage of information communication technologies (ICTs) declined from 56 in 2009 to 124 in 2015. Ukraine’s global ranking for political and regulatory environment for ICTs also declined from 95 in 2009 to 122 in 2015 (the same years..."
as the nationwide scale-up of the registry).” The open access article can be freely shared and distributed from: [http://openres.ersjournals.com/content/3/2/00002-2017](http://openres.ersjournals.com/content/3/2/00002-2017)

The second peer-reviewed article was published by the *International Journal of Medical Informatics*. This article covers a study that SIAPS led on e-TB Manager, an institutionalized digital health tool used to manage patients with TB. The e-TB Manager user-experience analysis was conducted in eight languages, among more than 1,500 respondents in nine diverse country health systems that cumulatively bear nearly one-third of the world’s TB burden. A key takeaway is that users find e-TB Manager reliable for case management and confirm that it helps improve patient care and workplace productivity. This open access article can be freely shared and distributed from: [http://www.sciencedirect.com/science/article/pii/S1386505617300783](http://www.sciencedirect.com/science/article/pii/S1386505617300783)

**The Way Forward**

SIAPS is committed to making the source code for its pharmaceutical management software tools available in an open source repository. To do this, SIAPS created a GitHub account with repositories for each program, along with a list of supporting documentation for each program that will be included in the repository. SIAPS added the source code for EDT, Quantimed, e-TB Manager, QuanTB, and Pharmadex to each program’s repository. SIAPS is still in the process of adding the code for RxSolution and PViMS. In addition to the source code, SIAPS is posting supporting documentation (e.g., administrative and user guidelines, technical specifications, etc.) in the repositories. As the information for each tool is completed, the repository for the tool will be made public. This posting process will begin in November 2017.
TECHNICAL HIGHLIGHT

Strengthening Capacity for Monitoring and Evaluating Mozambique’s Regulatory System

May 2017

The US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health, helps countries build stronger and more resilient pharmaceutical systems.

In Mozambique, SIAPS has been working with the Ministry of Health’s (MOH) pharmaceutical department (PD), which functions as the country’s regulatory authority, to strengthen its capacity at the national level. The PD’s main function is to ensure access to safe, effective, and quality pharmaceuticals through the public and private sectors that contribute to the best possible health outcomes.

Background

Prior to 2013, the PD did not have a formal, comprehensive system to measure its performance in essential medicine regulatory functions, including marketing authorization; medicine quality control; pharmacovigilance; licensing of health professionals and establishments (pharmacies, wholesalers, and manufacturers); inspection of pharmaceutical establishments; and clinical trials. One of the PD’s priorities has been to develop a monitoring and evaluation (M&E) system to assess department performance; improve transparency and ensure accountability; help guide the planning, coordination, and implementation of regulatory activities; and foster a culture of evidence-based decision making (figure 1).

Figure 1. Theory of change
Intervention

Between 2013 and 2016, SIAPS worked with the PD to help the department create, implement, and institutionalize a comprehensive M&E system (figure 2).

Assess Existing Regulatory System

In 2012, SIAPS began working with the PD to establish an M&E system. A series of assessments took place to evaluate the regulatory system in Mozambique and facilitate the selection of a core set of regulatory system performance metrics for the PD. Required actions were defined to further build the PD’s capacity to collect, analyze, report, and use data for decision making.

Establish M&E Sub-unit and Build its Capacity

From October 2015 to May 2016, an M&E technical working group, comprising a team of SIAPS technical advisors and two PD staff selected as M&E focal points, assisted in the development of new M&E tools, including a performance indicator reference sheet, worksheets for data collection, a performance monitoring plan, and a data quality assessment tool. SIAPS then trained the two PD M&E staff in the use of the tools.

The M&E staff were also trained in how to perform a data quality assessment (DQA) to:

- Verify the quality of reported data for key indicators
- Assess the capacity of data management systems to collect, manage, and report quality data
- Implement corrective measures through action plans to strengthen the PD’s data management and reporting system and improve data quality

In May 2016, SIAPS supported the PD in organizing a stakeholder workshop for about 30 participants to reach consensus, build capacity, and chart a clear path on how to foster evidence-based decision making at all levels in the department. Attendees included two PD staff selected as M&E focal points and six representatives from the PD’s main units, including registration, inspection, pharmacovigilance, administration, judiciary, and the quality control laboratory. In collaboration with the head of the PD, roles and responsibilities for the two PD M&E focal points and six PD unit representatives were defined.

Conduct Pilot Test and Validate Tools

In January 2016, equipped with knowledge of basic concepts and tools, the M&E staff performed the first baseline data collection for 13 pilot indicators. These indicators were selected for their relevance, methodological reliability, source reliability, comparability, and alignment with other National Medicines Regulatory Authorities that SIAPS supports and that had more mature regulatory systems. The staff reported the results to PD unit representatives for review and analysis. After consensus on information quality and accuracy, the final version of the report was submitted to the head of the PD and discussed at an April 2016 PD board meeting. Based on the results, the heads of each sector and related areas defined strategies to improve the performance of their respective units and future data collection.
Develop Results Framework and Define Additional Performance Indicators

Based on its assessments and reviews of quarterly reports, the M&E team identified the need for a results framework with clear strategies to achieve PD goals. The team developed a framework based on the six strategic objectives of the PD4 as stated in the Strategic Plan of the Health Sector 2013–2017 (Levantamento Estratégico para o Plano Estratégico do Sector da Saúde (PESS) 2013-2017):

- Pharmaceutical governance strengthened
- Compliance with good manufacturing and marketing practices
- Financial and asset management capacity strengthened
- Assurance that medicines circulating in the country are efficient, safe, and of good quality
- Enhanced institutional capacity
- Use of information for decision making

Based on these objectives, the PD identified 49 additional indicators for a total of 62. These included the 13 pilot indicators and other indicators per WHO guidelines.5

Institutionalize Indicators within MOH Results Framework

The final step was to decide which indicators would be part of the MOH’s overall results framework and how often results should be reported to the MOH. This action promotes transparency and accountability between the PD and the MOH Directorate of Planning and Cooperation (DPC). The two departments are working to incorporate nine PD indicators into the MOH results framework.

Adopting and using appropriate indicators helps health organizations obtain data for decision making and operate more efficiently. These measures in turn help ensure the efficiency of pharmaceutical services; increase people’s access to quality, safe, and cost-effective medicines; and promote rational medicine use.

<table>
<thead>
<tr>
<th>Indicators to be Incorporated into the MOH Results Framework</th>
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<tbody>
<tr>
<td>• Number of regulatory actions taken in the previous year as a result of national pharmacovigilance activities</td>
</tr>
<tr>
<td>• Average number of days for granting registration</td>
</tr>
<tr>
<td>• Percent of medicine samples analyzed out of the total number of existing medicines</td>
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<tr>
<td>• Percent of quality medicines in the total number of samples analyzed</td>
</tr>
<tr>
<td>• Percent of imported pharmaceutical products that are registered</td>
</tr>
<tr>
<td>• Percent of essential medicines list products that are registered</td>
</tr>
<tr>
<td>• Number of notifications of suspected adverse drug events (ADRs) reported by provinces</td>
</tr>
<tr>
<td>• Percent of ADRs reviewed</td>
</tr>
<tr>
<td>• Number of health professionals trained in pharmacovigilance</td>
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</tbody>
</table>


The development team used UNAIDS criteria, which describe the 12 main components of a functional M&E system, to assess the progress of Mozambique's M&E system.

<table>
<thead>
<tr>
<th>Component of a functional M&amp;E system</th>
<th>Progress</th>
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</thead>
<tbody>
<tr>
<td>Organizational structure</td>
<td>M&amp;E functions incorporated into PD administrative unit (October 2015)</td>
</tr>
<tr>
<td>Human capacity</td>
<td>With SIAPS support, two PD staff designated to the M&amp;E sub-unit and trained to collect, analyze, and report data</td>
</tr>
<tr>
<td>Communication, advocacy, and culture</td>
<td>SIAPS Mozambique held the first M&amp;E workshop with M&amp;E specialists from SIAPS headquarters to consolidate and review results and reports (May 2016). The workshop raised awareness of the importance of an M&amp;E system. Other activities that contributed to a transparent, accountable M&amp;E culture included routine data collection and analysis, reports to PD sectors, and reporting and discussion of drafted reports and results at monthly and quarterly data review meetings.</td>
</tr>
<tr>
<td>Results framework</td>
<td>Framework developed based on PD strategic objectives</td>
</tr>
<tr>
<td>Performance monitoring plan (PMP), including performance indicators reference sheet</td>
<td>PMP with related indicators developed. A performance indicator reference sheet and a DQA tool were developed to guide the M&amp;E staff on frequency of data collection and reporting.</td>
</tr>
<tr>
<td>M&amp;E database</td>
<td>Indicators table tracker developed in addition to PMP. The table tracker helps to monitor the progress of each indicator in a quarterly basis.</td>
</tr>
<tr>
<td>Planning and budgeting</td>
<td>Conducted by SIAPS; transitioned to PD activities in April 2017</td>
</tr>
<tr>
<td>Data dissemination and use</td>
<td>Four quarterly reports produced since January 2016</td>
</tr>
<tr>
<td>Routine program monitoring</td>
<td>13 baseline indicators established during the pilot phase</td>
</tr>
<tr>
<td>Evaluation and research</td>
<td>Quarterly data review meetings set for PD board; first meeting held in April 2016.</td>
</tr>
<tr>
<td>Supportive supervision and data auditing</td>
<td>Provincial supportive supervision in Gaza province in November 2016 identified opportunities for improving data quality and collection. Two PD internal data quality assessments were conducted in May and December 2016.</td>
</tr>
</tbody>
</table>

Once the PD’s M&E system was established in December 2015, the PD began monitoring activities toward project objectives. The department now reviews performance data in monthly staff meetings and board meetings.

Soon after adopting the M&E system, managers became more attuned to evidence-based decision making and adjusted strategies and activities accordingly. For example, the PD’s registration sector developed measures to monitor the use of Pharmadex, the department’s computerized medicine registration system, on a weekly basis. The measurements included the number of dossiers submitted to the system and the evaluations conducted. These methods drew managers’ attention to the time required to complete applications and alerted users if an intervention was needed to complete a request. This has helped improve the efficiency of the registration process, including a 36% decrease in the average time taken to evaluate and approve a registration application from March 2012 (429 days) to March 2016 (275 days).

Routine monitoring by PD M&E staff has also helped PD managers track the progress of their own activities and solidify future goals. Overall, the M&E system is contributing to improving the PD’s transparency, accountability, and efficiency.

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7 A performance indicator reference sheet is used by USAID to define performance indicators. It helps ensure indicator data quality and consistency.
Challenges and Lessons Learned

Improving information flow was critical to making the M&E system more efficient. For example, the M&E technical working group analyzed provincial data to investigate and revise the information flow for adverse drug reaction reports and found gaps in the coding and data processing that hampered proper tracking of notifications. In response, the PD designed an improved data capture process and is introducing standardized ADR report identification codes in all health facilities.

Early adopters of the M&E system saw its benefits. However, other units felt challenged in adopting it, seeing monitoring as a control rather than a quality measure. Avoiding a blaming culture and focusing on finding the root causes of problems and solving them quickly improved system acceptance.

Defining performance indicators as part of a logical framework with causal relationships among goals, objectives, actions, and intended outcomes and impacts also improved the commitment of PD stakeholders. Advocating with the DPC to institutionalize the indicators helped speed up the process, ensured alignment with MOH objectives, and further promoted country ownership and sustainability.

Going Forward

Ongoing Reviews

SIAPS recommends that:

- The new M&E system undergo internal reviews at least every five years according to the PD strategic review timeframe.
- The PD maintain active communication, participation, and coordination with the South African Development Community on indicators and results to promote a unified approach for the region
- The DPC conduct annual external DQAs to audit the quality of reported data
- The M&E focal points continue to provide monthly progress updates following data review meetings within each PD unit, and the PD issue quarterly progress reports to compare performance against its annual work plan

Scaling Up

Data collection practices have improved existing tools and prompted the adoption of better methods for capturing and recording data. Additional efforts must be made to establish these principles and to standardize archival techniques for all processes in the PD to improve overall data collection efficiency.

Data for Decision Making

Only nine of the 62 PD indicators will be included in the MOH results framework. However, the PD will monitor all indicators as part of its own decision making process. Data from each PD unit should be integrated to allow triangulation and analysis from a system-wide perspective.

Capacity Building

The M&E function should be a separate unit reporting directly to the head of the PD for better time and resource allocation. New staff involved with developing and adopting the M&E system should learn about its purpose and process, as well as how to conduct reviews, to help ensure its sustainability.
The Challenge

Pharmaceutical systems cannot function well without an adequate level of funding. Financial resources are finite and, in many cases, may be insufficient to meet all public health needs. Hence, the onus is on governments and country stakeholders with donor support to accurately estimate financial need, develop creative mechanisms to generate funds, and ensure prudent and economical use of these finite resources to avoid stock-outs of much-needed pharmaceuticals. Even countries that have adequate resources to procure medicines must always manage the allocation and flow of funds efficiently to ensure equitable access. Financing pharmaceuticals, therefore, broadly covers resource mobilization, resource pooling, and efficient allocation of funds to provide equitable access for all to needed medicines.

SIAPS Approach for Strengthening Financing to Improve Access to Medicines

The SIAPS approach for strengthening financing strategies and mechanisms for improved access to medicines encourages proper use of existing financial resources, advocating for greater resource mobilization, and reducing financial barriers that prohibit access to medicines by those most in need.
Key Achievements during Program Year 6

During this last year, SIAPS supported countries by working to identify pharmaceutical funding gaps and advocating for the redistribution of resources and stocks to address these gaps. By fostering collaborative relationships among partners, SIAPS continued to strengthen countries’ quantification plans for medicine procurements from the Global Fund, the President’s Malaria Initiative (PMI), and other funders. Furthermore, SIAPS promoted transparent financial transactions at hospitals and health facilities, highlighting the need to develop alternative procedures for resource allocation after analyzing medicine utilization and spending.

Mobilizing Additional Financial Resources

During the year, SIAPS/Bangladesh assisted the National Tuberculosis Program (NTP) in conducting a quantification exercise for five key second-line TB drugs used for patients with extensive drug-resistant tuberculosis (XDR-TB) and submitted an emergency procurement order to the Global Fund. Because the NTP’s Global Fund grant to procure first-line TB drugs ended in December 2016, SIAPS provided an analysis to the NTP and relevant stakeholders on alternative procurement options to assist the Government of Bangladesh in their efforts to identify mechanisms for procuring first- and second-line TB drugs. SIAPS participated in the seventh Global Fund Joint Monitoring Mission of the NTP, where SIAPS demonstrated the medicine utilization capabilities of an electronic TB-patient management system to the mission.

As fiscal constraints threatened commodity security in Swaziland, outputs of the SIAPS-supported commodity quantification and forecasting exercises were used to inform government rebudgeting processes. The total requirement for antiretrovirals (ARVs), including medicines for Kaposi sarcoma and opportunistic infections in the last year, was SZL 367 million (USD 26.5 million). The preliminary budget allocation was confirmed at SZL 274 million (USD 19.5 million). The resulting gap of about USD 7 million was closed by earmarked funding from a Global Fund HIV/TB grant and PEPFAR COP16, thereby averting stock-outs. SIAPS coordinated USAID’s donation of pediatric and second- and third-line ARVs, which covered patients enrolled in treatment from December 2016 through March 2017. SIAPS also supported the Swaziland Health Laboratory Services (SHLS) and the Central Medical Stores with their three-year budget and financial planning meetings.

In the Dominican Republic, SIAPS convened a meeting of all stakeholders involved in ensuring the continuous supply of ARVs and communicated the need to adjust current financial projections for product need. The meetings and presentations also highlighted potential funding gaps if the budget allocation from the Ministry of Finance (MOF) remained the same as in previous years. During these meetings, participants highlighted the successful strategies for attracting increased budgetary allocation for FY17. Using these experiences, the Ministry of Health (MOH) successfully advocated for expanding the budget allotments for ARVs in their advocacy meetings with the MOF.

Similarly, in Sierra Leone, SIAPS, along with other stakeholders, contributed to the approval of the 2017 quantification of free health care supplies. Data from SIAPS’ Continuous Results Monitoring and Support System (CRMS) was used as one of the sources to inform the mobilization of resources meeting with partners, including DFID and UNICEF.

Analyzing and Tracking Costs

Pharmaceuticals usually account for a large proportion of a health systems budget, and a relatively small number of pharmaceuticals

Using the automated APTS system in Ethiopia, medicines worth approximately USD 8,955 were redistributed to nine health facilities to avoid expiry.
may account for most of the annual consumption within a pharmaceutical system. Hence, tracking and analyzing cost centers and high expenditures within the pharmaceutical sector is key to good resource allocation and redistribution. In the last year, SIAPS/Ethiopia introduced the Auditable Pharmaceutical Transactions and Services (APTS) at six hospitals and four health centers in Addis Ababa and the Oromia region. In the Oromia region, two pharmacists and one accountant completed an APTS training of trainers, enabling them to provide on-site training to 17 staff members at their facility. Including the most recent introductions of APTS in year six, APTS is now operational in 77 facilities throughout Ethiopia. Using APTS, health facilities are currently tracking their medicine sales and regularly reporting to the health departments in their regions and to the Federal Ministry of Health. An innovative action taken this year was the automation of the APTS system in a number of hospitals in East Amhara. The hospitals with the automated APTS conducted a one-year analysis of their APTS reporting system, highlighting a number of medicines acquired by the facility and provided to patients. Upon completion of the analysis and its dissemination to stakeholders, medicines worth approximately 233,482.85 birr (USD 8,595) were redistributed to nine health facilities to avoid expiry. Dilchora and Adama Hospitals in the Oromia region completed ABC/VEN analyses. The results, which were shared with the drug therapeutics committees, led to inventory valued at 131,798.54 birr (USD 4,852) being redistributed to other local health facilities to avoid expiry and waste of financial resources.

Reducing Financial Barriers to Access

In Ukraine, SIAPS continued its support to the reimbursement program named Affordable Medicines. The program covers 21 essential medicines for cardiovascular diseases, type 2 diabetes, and asthma and has 157 different pharmaceutical product forms, 23 of which are provided free to patients. A number of medicines are dispensed with a small copayment. The MOH indicates that 4,715 pharmacies are currently accredited to participate in the program, and this number is growing as new contracts are concluded between pharmacies and regional budget holders.

The health technology assessment (HTA) activities under SIAPS were successfully completed this year, and the HTA road map developed in the current year is awaiting approval by the Cabinet of Ministers.
Swaziland Develops Key Performance Indicators to Improve Warehouse Management

March 2017

Background

In Swaziland, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program has the core mandate of ensuring uninterrupted availability of life-saving medicines. One of the interventions that SIAPS has designed to achieve this is to build capacity and skills of health care workers involved in the pharmaceutical management of TB, ARV, sexual reproductive health (SRH), and laboratory commodities. SIAPS works to ensure access to quality pharmaceutical products and effective pharmaceutical services through systems strengthening approaches to achieve positive and lasting health outcomes.

SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health (MSH).

In 2014, SIAPS supported the Ministry of Health (MOH), Central Medical Stores (CMS), and Swaziland Health Laboratory Services (SHLS) by conducting a workshop to build capacity and improve performance of staff that works in warehouse operations. The Imperial Health Services warehouse was used as a model to showcase warehousing best practices.

SIAPS is confident that the study tour gave participants insight into the latest approaches to improve warehouse management and to work toward ensuring uninterrupted availability of health products. It is expected that the participants will contribute to MOH’s efforts to improve warehousing, especially with the newly acquired warehouse under refurbishment, funded by a Global Fund HIV/TB grant.

Using key performance indicators (KPIs) is a popular method for organizations to set objectives. In the same line, CMS and SHLS developed KPIs during the study tour as a roadmap to improving identified weaknesses in their warehouse management practices. These KPIs will be implemented and monitored by CMS and SHLS staff with technical assistance from the SIAPS team.

Strategic Response

The CMS warehouse and SHLS warehouse have been experiencing challenges with managing minimum and maximum stock levels. Additionally, even though there is a clear process flow structure within these warehouses, it is not properly implemented. Such issues may lead to expensive pharmaceutical wastage through expires or stock-outs. SIAPS sought to improve its technical support to CMS and SHLS counterparts.

Summary of Interventions

CMS and SHLS staff, with technical assistance from the SIAPS team, developed the following KPIs, which they will track periodically to evaluate progress toward achieving the desired outcomes.
The KPIs will be tracked according to the schedule, and reports will be presented to both CMS and SHLS management. The SIAPS technical team will be responsible for providing oversight and ensuring that the activities leading to the achievement of the stated objectives are undertaken.

Way Forward
The Challenge

The SIAPS Program started in the face of several challenges linked to the availability of medicines and other health products. For example, there was the threat of multidrug-resistant (MDR-) and extensively drug-resistant tuberculosis (XDR-TB) and TB/HIV co-infection linked to the limited access to quality assured first- and second-line TB medicines. Similar access issues existed for medicines and other health products needed for HIV/AIDS, malaria, and maternal, newborn, and child health programs (MNCH). Common at that time was the need for emergency distributions of medicines for HIV/AIDS, malaria, and TB. Underlying operational challenges included inaccessibility to last-mile supply chain data; a heavy data-burden on supply chain workforce; inefficiencies in management of procurement, warehousing, inventory, and transportation; and inadequate workforce numbers and capabilities. Therefore, it was crucial to explore ways to maximize efficiency and long-term sustainability of vertical programs, which were created in the rush to get life-saving medicines and other health commodities to as many people as quickly as possible.

During implementation of SIAPS, the global health supply chain landscape changed in many ways. Vertical program supply networks started in the early 2000s in many countries became more mature, necessitating their integration into mainstream essential medicine supply systems. New initiatives emerged, such as UN Commission on Life-Saving Commodities for MNCH, the Global Financing Facility in Support of “Every Woman Every Child,” and the UN campaign that called for action on non-communicable diseases, such as cardiovascular disease, cancer, chronic lung diseases, and diabetes. Coordination among major players in global health improved, for example, the launch of the Health Data Collaborative, a joint effort by multiple
global health partners to work alongside countries to improve the availability, quality, and use of data for local decision-making and tracking progress toward the health-related Sustainable Development Goals. These initiatives have led to increased attention to health supply chains by major donors like the Global Fund and USAID. Presently, Global Fund is financing supply chain diagnostics in its high-impact countries, and in 2015 USAID awarded the eight-year Global Health Supply Chain Program Multiple Award Indefinite Delivery and Indefinite Quantity contract, which is one of the mechanisms through which it offers global health commodity-related technical assistance.

Nevertheless, major supply chain challenges and problems abound in SIAPS program year six (PY6). They include the existence of limited human-resource capacity for conducting supply chain management (SCM) functions, such as forecasting and quantification, ineffective processes pertaining to forecasting and quantification, procurement, warehousing, inventory management and transportation. Other common issues across several countries are poor supply chain strategic planning and weak warning systems to monitor actual and planned consumption of medicines. In addition, there is a dearth of reliable information for SCM decision making across several countries.

SIAPS Approach for Improving Supply Management
SIAPS approach for improving supply management focuses on strengthening the supply sub-system building blocks of governance, financing, human resource capacity, information for supply decision making, and medicine availability with the broad objective of reducing stock-outs, minimizing wastage, and ensuring continuous availability of quality medicines and other health products.

Key Achievements during Program Year 6
Effective quantification and procurement and good warehousing and transportation operations are crucial functions for guaranteeing access to medicines, which leads to positive disease prevention and treatment outcomes. Therefore, a core component of SIAPS’ technical assistance was to enhance these supply chain functions. During PY6, SIAPS worked with partners in supported countries to make additional progress improving these functions. Illustrative achievements during this year are described in the following summary.

Supply chain planning
In quarter 1 of PY6, SIAPS facilitated the development of Angola’s national pharmaceutical supply chain strategic plan, which was submitted to the Ministry of Health (MOH) for approval. In addition, SIAPS supported procurement planning and monitoring in Angola for malaria and HIV/AIDS commodities.

In Burundi, SIAPS supported a meeting of the National Malaria Control Program’s Department of Pharmacy, Medicines, and Laboratories (DPML) Thematic Group of Medicines forum in October 2016, which brought together public and private stakeholders from the pharmaceutical sector to discuss the national strategic plan for supply chain and the 2017 DPML work plan. In addition, in quarter 1, the national commodity security committee was formed, which was endorsed by the minister of health under the leadership of DPML.

In Mali, SIAPS and other implementing partners were involved in validating the MNCH commodities quantification results and updating the family planning contraceptive supply plan and the malaria commodity supply plan through the Comite National de Coordination and various technical working groups. Using data collected from OSPSANTE, SIAPS provided guidance to the MOH as procurement planning and monitoring reports for malaria products and contraceptives were submitted to stakeholders for review.

In the Ukraine, SIAPS conducted a national supply chain assessment in quarter 1 of PY6, which the MOH used as a basis for action planning.
Quantification and procurement

In Benin, SIAPS completed a quantification exercise for Ebola products and began working with the Directorate of Pharmacy, Medicines, and Laboratory to validate the quantification. A tool was developed to quantify products needed on the basis of morbidity and service utilization during a one-month outbreak of disease. To support future quantifications, SIAPS assisted the MOH in developing guidelines for the quantification of Ebola products. Thirty-four members of Benin’s National Procurement and Supply Management Committee were trained on Ebola commodity quantification and use of the standard medicines and medical supplies list for Ebola response.

Bangladesh’s subnational procurement practices had been irregular and not in line with the government’s procurement rules and regulations. Therefore, SIAPS capacitated district-level procurement entities in seven regions by customizing subnational procurement guidelines. Transparency is expected to improve, as well as effective and efficient use of limited resources.

In the Dominican Republic, SIAPS developed guidelines for quantifying and programming medicines and supplies after conducting a procurement needs assessment exercise for FY17. Standard operating procedures (SOPs) for PROMESE/CAL (Programming, Procurement, and Distribution) were drafted in the fourth quarter of PY5. In quarter 1 of PY6, SIAPS advocated to the director of PROMESE/CAL for immediate implementation of these SOPs. Additionally, SIAPS contributed to planning discussions for distribution of family planning commodities to regional warehouses by using the SUGEMI distribution cycle. SIAPS began supporting the distribution of ARVs from a rented warehouse to six regional health-service centers, which was completed in quarter 2 of this year.

In Mali, SIAPS assisted the Pharmacie Populaire du Mali in quantification of essential medicines, including data validation at the regional levels.

In quarter 3, SIAPS in Sierra Leone focused on quantification of HIV/AIDS commodities, implementation of the CRMS throughout the country, and improving warehousing systems and capacities at the health-facility level. SIAPS provided critical support and guidance to the National HIV/AIDS Secretariat and the HIV quantification working group in the development and timely submission of a three-year (2018-2020) proposal for a Global Fund grant.

In Swaziland, SIAPS assisted the Central Medical Store (CMS) in conducting their national quantification for ARVs, TB medicines, sexual and reproductive health commodities, medicines to treat opportunistic infections, and antimalarial commodities. CMS lead the quantification activity and completed the process within three months, demonstrating the capacity SIAPS had built within CMS.

In Uzbekistan, SIAPS used QuanTB for quantification and as an early warning system to monitor actual and planned consumption of TB medicines. The objective was to avoid TB medicine stock-outs and expiries at the regional and facility levels.

Warehousing operations

SIAPS provided technical assistance to conduct a Warehouse Management System (WMS) needs assessment for Philippines’ Department of Health (DOH). The technical assistance included visits to multiple DOH warehouses at the central and regional levels to identify crucial steps for implementing enhanced WMS technology. Findings from the assessment were presented to DOH officials, who used them to develop a five-year improvement plan. The plan delineates WMS improvement actions into immediate-, short-, and long-term interventions. One expected deliverable in the plan is the deployment of a WMS technology solution with multi-location capability.

Another significant warehouse operations strengthening initiative took place in Mali with assistance from SIAPS. Construction of a
Warehouse in a Box (WiB) was launched this quarter, marking the end of a long planning, design, resource mobilization, and commissioning process. The official groundbreaking ceremony took place on August 15, 2017, in the presence of Malian health, political, and administrative authorities, and the WiB construction process was launched in the regions of Kayes, Koulikoro, Mopti, and Bamako.

Inventory management

In partnership with Guinea’s National Malaria Control Program, SIAPS provided technical assistance last year that enabled stakeholders to analyze the country’s stock level of malaria commodities, highlight bottlenecks, and develop approaches to mitigate stock-outs and expiry of medicines. Consequently, in quarter 1 of PY6, the Central Pharmacy of Guinea (PCG) worked to complete a physical count of pharmaceutical products in preparation for implementation of a new computer-based inventory system. SIAPS technical advisors assisted PCG in carrying out the activity, organizing storerooms, and updating inventory records. Physical inventory count revealed, for example, that of all the artesunate-lumefantrine (AL) formulations, only the AL child stock-level was below the recommended minimum of eight months of stock at the central level.

As part of this effort to improve inventory management in Guinea, SIAPS, in collaboration with UNFPA, supported DNPM’s central, regional, prefectural, and health-facility levels in quarter 3 of PY6 to review performance on FP/RH supply chain indicators and commodity availability at the end-users’ level. Key findings included stock card availability (65%), average stock-out rate (21.7%), and stock accuracy (71.9%). These findings revealed that inventory management tools were not rigorously used and that stock-outs were recurrent in health facilities.

SIAPS/Bangladesh worked alongside government agencies to introduce inventory management solution in 11 additional districts in collaboration with the Directorate General of Health Services (DGHS).

Swaziland Health Laboratory Services (SHLS) and the MOH’s Central Medical Stores (CMS) have been working toward better utilization of available infrastructure for storage and distribution of laboratory commodities. Therefore, SIAPS assisted them with the annual stock take, relocation to a refurbished CMS warehouse, deployment of an electronic inventory management system (RxSolution) at the site, and order picking. Also, in quarter three, a quantification exercise was completed and the results were used to inform government budgeting for the fiscal year. The total requirement for ARVs including medicines for opportunistic infections was SZL 367 million (USD $26.5 million). The exercise helped identify a gap of about USD $7 million, which was filled by a Global Fund HIV/TB grant and PEPFAR COP16 funding.

Logistics management information system

SIAPS launched the Supply Chain Management Portal (SCMP) Service Delivery Point dashboard module in Bangladesh in quarter 1 of this year. The new portal strengthened procurement and logistics management in Bangladesh and contributed to reduced workloads, enhanced efficiency, and product availability. In addition to launching SCMP, in the same quarter, SIAPS demonstrated its TB Warehouse Inventory Management System to 21 officials from the National Tuberculosis Program after the system was updated with user feedback.
TECHNICAL HIGHLIGHT
Improving Accountability and Transparency in Pharmaceutical Supply Chains

Background
Pharmaceutical expenditures account for approximately 25% of total health expenditures, range from 7% to 68% across countries, and are typically one of the top health care expenditures for governments globally. However, ineffective pharmaceutical supply chains negatively impact the full value of positive health outcomes that should be derived from these expenditures. A key contributor to ineffective pharmaceutical supply chains is poor compliance with processes, including a lack of accountability and transparency coupled with corruption. These issues may occur in any functional area of supply chain management, including selection of pharmaceuticals, demand forecasting, manufacturing, procurement, warehousing, and distribution.

This summary provides examples of best practices for improving accountability and transparency in supply chain management that have been implemented in developing countries with technical assistance from the US Agency for International Development (USAID)-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. These best practices (table 1) have improved governance in supply chains and helped eliminate opportunities for corruption and undetected mismanagement, thereby helping to reduce the loss of pharmaceutical products.

Table 1. Best Practices for Improving Accountability and Transparency in Pharmaceutical Supply Chains

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<th>Best practices</th>
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<td>1. Adoption and use of standard treatment guidelines (STGs) and essential medicines lists (EMLs) to guide procurement</td>
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<td>2. Procurement price benchmarking</td>
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<td>B. Forecasting and supply planning (quantification)</td>
<td>1. Multistakeholder collaboration</td>
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<td></td>
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<td>4. Auditable Pharmaceutical Transactions and Services (APTS)</td>
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<tr>
<td>E. Warehousing and distribution</td>
<td>1. Warehousing location labeling and racking systems</td>
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<tr>
<td></td>
<td>2. Guidelines, standard operating procedures, and performance measurement</td>
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A. Best Practices: Pharmaceutical Selection and Procurement

1. Participatory Selection Process, Including Adoption of STGs and EMLs

An effective selection process will determine which medicines the public sector will purchase and might also determine patient eligibility for reimbursement. STGs are a good management tool to facilitate objectivity and utilization of standards in promoting regimen and treatment selection for rational prescribing. EMLs can then be developed based on the STGs. These tools can guide procurement and promote adherence to prescribing of recommended medicines and related diagnostics.

In Namibia, SIAPS supported the Ministry of Health and Social Services to update and publish the country’s fifth editions of STGs and EML. First, a committee was re-established and new terms of reference of the stakeholder group were adopted to ensure a rigorous, transparent, and consistent medicine selection process. This participatory process allowed the committee to approve new HIV, AIDS, and tuberculosis medicines and palliative care products for inclusion in the EML and STGs. In addition, forms were included in the STGs and EMLs to submit requests and supporting documents for changes and updates, ensuring a systematic and transparent process.

Similarly, SIAPS is assisting the Government of Ukraine to establish a national EML that will be used to make decisions about procurement. The intervention involves reviewing and analyzing existing medicines lists and legislative and regulatory frameworks and identifying how they are currently being used by procurement entities. The findings of the analysis will be presented and discussed at a stakeholder review and consensus workshop, and the results of the workshop will be used to develop a plan and recommendations for a unified national EML to replace the existing multiple medicine lists.

2. Procurement Price Benchmarking

The transparent procurement of medicines ensures the best value for both the country and the patient. Many countries have used the International Price Indicator Guide, which is an information resource produced by Management Sciences for Health (MSH) and widely disseminated. It contains recent pharmaceutical supplier and buyer prices that can be used as a guide to assess procurements. For example, SIAPS recently supported an assessment of HIV commodity procurement prices in Swaziland using this guide. The results of the assessment may be used to inform decisions about more competitive procurement methods.

Another price benchmarking initiative being implemented in Ukraine with support from SIAPS is a web-based price observatory. SIAPS assisted civil society organizations (CSOs) to develop an observatory that will periodically capture price data. It will enable procurement price monitoring and benchmarking against domestic and international reference prices. The information will be publically accessible and easy to benchmark against other watchdog centers and guides, such as the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies and MSH’s International Price Indicator Guide. The information can be used by decision makers and CSOs to advocate for transparent and accountable procurement practices by public-sector national and regional authorities.

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3. Procurement Framework Contracts
SIAPS is assisting the provincial (oblast)-level procurement authorities in Ukraine to establish framework contracts for public procurement of health products using US government anticorruption funding. Framework contracts are long-term arrangements used to decrease purchase prices by establishing a safer and more stable commercial relationship for the supplier without committing to concrete quantities, thereby giving flexibility to the procurement agent. These long-term contracts are widely used by governments in industrialized countries because they foster a competitive and transparent market environment. An important success factor is the implementation of a procurement performance system, which includes the process for supplier performance evaluation and selection for long-term contract and capability-building activities. Once price data become available, they will be used to conduct a comparative procurement performance analysis to assess the effect of long-term contracts on procurement.

4. Procurement Information
Sharing procurement information with stakeholders in a timely manner helps to quickly inform all parties about real or potential problems and enables them to respond appropriately to minimize the impact. Procurement information sharing platforms include collaborative workshops, electronic platforms, and trainings. Access to information enables better policy formulation and process improvements, better transparency and visibility into procurement decisions, and informed decision making. E-Procurement platforms are effective in reducing corrupt practices, such as kickbacks in pharmaceutical management operations. For example, in Bangladesh, SIAPS assisted the Ministry of Health and Family Welfare (MOHFW) with the development of a supply chain management portal. This e-tool helps the MOHFW integrate 32 annual procurement plans from the Ministry’s line directors as well as track the procurement process and pipelines. This has streamlined the process and improved data visibility and the availability of pharmaceuticals. Additional benefits of this streamlined, web-based system include better procurement coordination among MOHFW directorates, logistics teams, and other stakeholders; strategic procurement decision making; reduced lead time of the procurement process from 78 weeks to 58 weeks; regularly published procurement opportunities and tender results; and increased governance effectiveness, transparency, and competition throughout the procurement process. Enhanced transparency and accountability of the procurement process led to the World Bank approving the MOHFW’s USD 63 million procurement plan within the stipulated timeframe in 2012.

Another example is South Africa’s National Department of Health, which recently implemented electronic submission of bids to improve the management of the bid information database, enhance transparency, and reduce errors and improve efficiency in the data entry process.

B. Best Practices: Forecasting and Supply Planning (Quantification)
1. Multistakeholder Collaboration
Quantification involves properly forecasting quantities of products that are required to meet the system needs over a defined period and supply planning (i.e., detailing the quantities required to fill the supply pipeline, costs, and arrival dates of shipments). Establishing multistakeholder collaborations for the quantification process rationalizes and strengthens public-sector procurement.

2. Technical Working Group
Swaziland has consistently conducted evidence-based forecasting and developed quarterly supply plans that are overseen by a functional Technical Working Group (TWG). The quarterly supply planning activities have helped the Ministry of Health (MOH) to better track and plan shipments from different funding sources (e.g.,
United Nations Population Fund (UNFPA), PSI, the Global Fund to Fight AIDS, Tuberculosis and Malaria. One supply plan allowed UNFPA to cancel the unnecessary procurement of 12,000 sets of the Jadelle Implant for a savings of USD 102,000. This exercise has increased transparency, avoided wastage, allowed analysis of funding gaps, and provided an early stock-out warning system. The cost reduction has been continuous and beneficial. During one quarter, the procurement budgets for antiretroviral therapy and reproductive health commodities decreased by 6.4% and 69.2%, respectively.

Other countries currently establishing their own coordination and quantification TWGs include Angola, Cameroon, and Ethiopia.

C. Best Practices: Logistics Management Information

1. Monitoring and Use of Supply Chain Data

Monitoring and using supply chain data is essential for effective supply chain governance. Near- or real-time supply chain data allow management to identify problems and design anticorruption processes that may be implemented and regularly monitored. For example, in Mali, SIAPS is supporting the Directorate of Pharmacy and Medicines to redesign the existing logistics management information system to address the problem of poor data transmission from lower to higher levels. The intervention includes building staff capability and establishing controls that ensure accountability at each tier as information travels up the supply chain.

D. Best Practices: Supply Chain Oversight

1. Supportive Supervision

Supportive supervision allows for continual monitoring and improvement of processes, which contributes to enhanced supply chain accountability. This practice enables better coordination across the supply chain and provides more clarity on personnel performance, product status and location, and more accurate supply and distribution planning.

2. Logistics Management Unit

An LMU with responsibility for coordinating functions and decisions across the supply chain has been implemented with significant success in several developing countries. For example, South Sudan recently established an LMU, which enabled the MOH to monitor and report on health facility availability of prioritized tracer pharmaceuticals. Generally, an LMU should establish clear roles and responsibilities for supply chain actors as well as an official organogram, including job descriptions. The LMU may also maintain a national supply chain dashboard, which allows for more effective stock management and better visibility regarding wastage, pilferage, and expiries.

3. Strategic Planning

Collaboratively developed supply chain improvement plans are important accountability tools that oversight entities may rely on. SIAPS recently helped Angola’s central medical warehouse (CECOMA) and Mali’s central medical warehouse (PPM) develop three- to five-year warehousing improvement plans, including resource requirements and performance targets.

4. Auditable Pharmaceutical Transactions and Services

In Ethiopia, SIAPS designed a package of data-driven interventions that ultimately resulted in a continuous supply of essential medicines, optimal budget utilization, and improved pharmacy services. Piloted in a hospital in the rugged highlands of northern Ethiopia, APTS underwent rigorous testing in a number of health facilities, with groundbreaking results.13

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13 More information about APTS is available on the SIAPS website.
APTS effectively curtails wastage of medicines due to expiry, pilferage, and misappropriations, thereby improving efficiency and effectiveness in the overall management of pharmaceuticals and services.

**E. Best Practices: Warehousing And Distribution**

1. **Warehousing Location Labeling and Racking Systems**

The risk of pilferage or product diversion is present throughout the supply chain, including during storage and distribution. In Cameroon, SIAPS worked with the Central Medical Store (Centrale Nationale d’Approvisionnement en Médicaments et Consommables Médicaux Essentiels – CENAMÈ) and Regional Pharmaceutical Supply Centers (Centres d’Approvisionnement Régionaux – CAPR) to improve storage practices by reducing congestion, clearing out expired or obsolete goods, and developing a racking system. SIAPS has been working with the MOH to develop an early warning system and storage staging plan based on distribution plans and schedules that will redistribute and track products to avoid overstocking. A comprehensive labeling system allows for better identification of products in the warehouse, increasing the visibility of inventory.

2. **Guidelines, Standard Operating Procedures, and Performance Measurements**

Efficient warehousing and distribution systems and procedures will ensure accountability and transparency in the supply chain. Examples include splitting key responsibilities and segregating the workforce, regular stock takes, formal systems for requisitioning and receiving stock for lower levels, and formal systems for disposal of expired stock.

In Angola, SIAPS supported CECOMA to revise its organizational structure and develop clear roles, responsibilities, and job descriptions based on the improved organogram and to develop and implement clear warehouse standard operating procedures and a transportation management guide. SIAPS also assisted CECOMA to develop and implement a customized human resource capability and performance improvement training program and warehouse management performance monitoring metrics. A detailed capacity-strengthening plan, including capacitating staff on logistics management tasks related to warehousing and distribution and selecting key warehouse performance indicators, dashboards, and performance benchmarks, was established.

**Pharmaceutical Manufacturing and Registration**

As with the supply chain functions mentioned above, pharmaceutical manufacturing and registration functions often lack adequate transparency and accountability and are also susceptible to corrupt practices that can allow falsified and substandard pharmaceuticals to enter the supply chain. SIAPS has supported Angola, Bangladesh, South Africa, and other countries in implementing best practices that strengthen national pharmaceutical regulatory systems, including establishing and updating legal and regulatory frameworks and building capacity for inspections, sample testing, and regulatory enforcement actions.

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<td>Using Power and Influence Analysis to Address Corruption Risks: The Case of the Ugandan Drug Supply Chain</td>
<td>U4 (2013)</td>
<td>Brief describing the need to identify powerful stakeholders that should be engaged in anti-corruption strategies using the example of Uganda’s supply chain</td>
<td><a href="http://www.u4.no/publications/using-power-and-influence-analysis-to-address-corruption-risks-the-case-of-the-ugandan-drug-supply-chain/">http://www.u4.no/publications/using-power-and-influence-analysis-to-address-corruption-risks-the-case-of-the-ugandan-drug-supply-chain/</a></td>
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</table>
The Challenge

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

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 through which medicines are provided, SIAPS helps ensure that availability is accompanied by responsible use.

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

SIAPS Approach for Improving Pharmaceutical Services

Ensuring good pharmaceutical services ensures efficacious, safe, and cost-effective use of quality-assured pharmaceuticals for those people who need them and when and where they are needed. SIAPS uses a pharmaceutical system strengthening approach that is rooted in the WHO health systems framework and the key principles of the Global Health Initiative to help countries build their capacity to improve pharmaceutical services, focusing on improving medicine use and containing antimicrobial resistance (AMR).

Key Achievements during Program Year 6

Patient Safety and Therapeutic Effectiveness Ensured

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

With SIAPS technical assistance, the Adverse Drug Reaction Monitoring (ADRM) Cell in Bangladesh has made significant progress in strengthening its adverse drug event (ADE) reporting system. During the July to September 2017 period, the ADRM Cell received more than 100 adverse drug reaction (ADR) reports sent from hospitals and pharmaceutical companies. The cell has also now decided to make an agreement with national health programs, such as the National Tuberculosis, National Malaria, EPI/Adverse Event Monitoring Following Immunization (AEFI), and HIV/AIDS Programs so that ADR reports from those programs are included in the overall PV program. The final draft of the National PV Guideline and standard operating procedures (SOPs) of the ADRM Cell were shared with the Adverse Drug Reaction Advisory Committee (ADRAC) for their review.

In Swaziland, SIAPS supported the Pharmacovigilance Unit (PVU) in analyzing ADR reports collected from health facilities in the country and identify the suspect drugs. The program also facilitated inclusion of ADR monitoring and reporting in the National AIDS Program reporting mechanisms to improve reporting rates. SIAPS engaged a data clerk to assist in capturing the ADR reports in health facilities. SIAPS continued to support the National TB Control Program (NTCP) in implementing bedaquiline (BDQ) for managing MDR- and XDR-TB patients by contributing to the revision of SOPs and monitoring patient safety. SIAPS participates in the BDQ clinical access program expert committee meetings for the selection and monitoring of patients on BDQ. Additionally, SIAPS supported the NTCP by contributing to the development of the short-course MDR-TB regimen guidelines and training health professionals on those guidelines. SIAPS also helped publish the latest edition of the Medicines Safety Watch Newsletter to disseminate information regarding ADRs and other medicine safety alerts. The medicine safety work in Swaziland was also externally disseminated through a presentation at the Union World Conference on Lung Health in October 2016.
In the Philippines, SIAPS continued its support to NTP and FDA to strengthen the PV system to ensure the safety of patients enrolled in operational research studies and the roll-out of the standard shorter-treatment regimen (SSTR) for drug-resistant TB. SIAPS has successfully deployed the Pharmacovigilance Monitoring System (PVIMS) in the Department of Health (DOH) IT infrastructure. PVIMS is also being implemented as the national active drug safety monitoring and management (aDSM) database for the Philippines. SIAPS has oriented 195 participants in four regions (6, 10, 4A, and 5) on PVIMS.

SIAPS also provided technical guidance to the Lung Center of the Philippines–National Center for Pulmonary Research (LCP-NCPR) in reporting serious BDQ ADEs to the Global Drug Facility. SIAPS collaborated with DOH-PD, LCP, FDA, and DOH-NTP on developing and finalizing the Pharmacovigilance Monitoring System (PVIMS) User Guide: Active Reporting of Adverse Events. The user guide outlines the key data needed and serves as a reference in reporting ADEs through PVIMS, from making the initial valid report to providing supplementary data required for analysis. The guide features SOPs that will support PVIMS implementation. The DOH secretary also contributed to the development of the user guide, and DOH released a department memo on issuing PVIMS user accounts and institutionalized the document in DOH.

Utilizing the PVIMS user guide, SIAPS organized and conducted a PVIMS training and planning workshop in partnership with the DOH-PD to support aDSM implementation. Attended by 63 first-implementers of the SSTR from the nine regions, this was the first forum where participants discussed ways to strengthen the coordination, recording, and reporting of PV information. Each region drafted regional plans to implement a key aDSM activity—the standardized way of collecting aDSM data for suspected ADEs. SIAPS also provided on-site mentoring on aDSM data collection and PVIMS use at 7 of 10 facilities that are the first implementers of SSTR. This on-site mentoring helped strengthen the process of reporting suspected ADEs experienced by patients under SSTR and BDQ through PVIMS. All the sites visited have successfully encoded PV data in PVIMS. PVIMS is now used by these facilities in reporting suspected ADEs, the core requirement of aDSM implementation. SIAPS also organized a MedDRA (Medical Dictionary for Regulatory Activities) coding basics webinar attended by select staff from the LCP research and training team. The MedDRA webinar was expected to help the research team code ADEs from the BDQ and nine-month treatment regimen (9MTR) studies and to help the training team during the roll-out of SSTR training implementation. In addition, SIAPS continued to support NTP operational research and migrated the 9MTR study data of 56 patients to PVIMS. A total of 836 ADEs were coded into MedDRA prior to migration to PVIMS. SIAPS also mentored the LCP-NCPR team on encoding BDQ data in PVIMS. LCP-NCPR is using PVIMS as their PV tool/database.

In Namibia, SIAPS supported the MOHSS/Namibia Medicines Regulatory Council (NMRC) and partners in conducting a multistakeholder meeting on PV and medicine safety. The meeting was also attended by USAID-supported partners, such as KNCV, who have a special interest in tracking ADEs related to TB/HIV medicines. Participants at the meeting developed a plan of action that included training and increasing the number of ADE reports submitted to the Therapeutics Information and Pharmacovigilance Center (TIPC). Additionally, SIAPS supported TIPC in analyzing 415 ADR reports for 2016/2017 that were received from all 14 regions of Namibia and a pharmaceutical company. The top 20 suspected products were mainly ARVs, anti-TB medicines, and vaccines. SIAPS is supporting TIPC on further analysis to find causality. SIAPS also supported TIPC in capturing the backlog of yellow safety forms into the WHO Vigibase database for reporting.
To improve and make easier the registration, collection, and analysis of ADE data, the Pharmaceutical Department in Mozambique approved the ADR codification system. The next step is to ensure that the focal points are able to create codes and ensure adequate use of codes at all levels. To support this, SIAPS assisted the PV Center in preparing a codification presentation that should be shared with all the provincial PV units and used as training material in supervision activities.

In Ukraine, modules 7-16 of the national PV guidelines were submitted to MOH for approval in April 2017. The first four modules were approved in May 2015, and the rest of the modules (5-16) are now pending approval.

In Ethiopia, SIAPS carried out face-to-face discussions on ADE monitoring with 116 health providers at 3 health facilities in Addis Ababa. SIAPS also assisted in distributing ADE report forms, newsletters, and allergy cards to health facilities and helped prepare the 17th PV newsletter. SIAPS worked with the Food, Medicines, and Health Care Administration and Control Authority (FMHACA) branch office experts and regional regulatory and EPI coordinators to carry out two rounds of assessments on the AEFI Surveillance System in Amhara and Oromia Regions by using a semistructured questionnaire. A consultative meeting on the AEFI Surveillance System was also held, attended by 38 participants from 11 regional health bureaus (RHBs) and regulatory authorities.

**Medication Use Improved**

SIAPS is building local capacity for rational medicine use (RMU) by strengthening drug and therapeutics committees (DTCs), medication adherence, and other activities at hospitals and health facilities.

Key DTC-related activities this year include:

- In Sierra Leone, SIAPS supported the Ministry of Health and Sanitation (MOHS) in establishing DTCs in four hospitals (Connaught, Ola During, PCMH, and Makeni Government), followed by a national launch of DTCs by the MOHS.

The electronic treatment register (eTR) for managing patient and product information was revised, and a DTC operational manual was drafted. A hospital DTC profile and checklist for regular monitoring of DTC performance have been drafted and will be used as tools to monitor the current status of DTCs nationwide. In addition to providing mentorship in the use of eTRs, SIAPS conducted a DTC progress workshop that was attended by representatives from 19 hospitals, the Directorate of Drugs and Medical Supplies (DDMS), UNICEF, and WHO; during the workshop, the draft documents were validated. The eTR is being implemented in the four hospitals with DTCs. A prescription review was conducted in the four hospitals as part of the mentorship of DDMS DTC focal staff and hospital pharmacists to capture baseline data on key RMU indicators. At Connaught Hospital, the Pharmacy Department now routinely participates in ward rounds, with the objective of improving pharmaceutical care. At Makeni Hospital, the DTC has succeeded in garnering management support for establishing a cost-recovery pharmacy. Following the successful launch of DTCs at the four hospitals in Freetown and Makeni, five more hospitals were also oriented on establishing DTCs.

- SIAPS/Mozambique supported the Hospital Pharmacy Department (HPD) in holding a DTC workshop in Maputo Province from October 28 to November 2, 2016; 32 pharmacists, physicians, and nurses attended the workshop, which focused on how to collect, analyze, and report prescription indicators, medication errors, and consumption data. The training also supported efforts to establish continuous quality improvement actions to promote RMU in hospitals.

- During the previous reporting period, SIAPS had supported the HPD to design, test, and scale medicine use studies (prescription, medication errors, and consumption) through hospital DTCs. To complement these studies, DTCs need to perform other activities, such as evaluating medicine use, improving ADR reporting and analysis, managing medicine
formularies, and improving treatment adherence. During this reporting period, SIAPS assisted HPD in validating the methodology for patient waiting time as part of the ambulatory pharmacy study in Lichinga Provincial and Pemba Provincial Hospitals. Also, in the pharmacies visited, it was seen that the majority of medications are not prepackaged, and most of the time, the person who repacks the medicines is the same person who dispenses them. This contributes to increased patient waiting time, besides increasing the chances for error in dispensing. Therefore, in Pemba Provincial Hospital, SIAPS helped perform the consumption analysis to identify the medicines that are most consumed to ensure that those medications are prepacked. Additionally, the findings of the study on adherence to ART conducted in Polana Canico General Hospital were presented and discussed with the Hospital Directorate; the directorate committed to improve the indicators that were below target.

- **SIAPS/Ethiopia** provided technical support and onsite orientation to DTCs in Dire Dawa city administration. The support was provided to the existing DTCs (Sabian Hospital, Legehare and Genda Gerada Health Centers), and to reestablish others (Genda Kore, Number One, and Melka Jebdu Health Centers). The technical support included the development of action plans, revision of the terms of reference, development of medicine lists, prescription reviews, ADR reporting, and improving pharmacy service at their health facilities.

- **In Ukraine**, a training workshop was conducted for DTC members from five regional AIDS centers on October 10-13, 2016. All five regions developed action plans for implementation of drug use reviews at their respective centers.

- **In Namibia**, during the annual pharmaceutical supportive supervision visits and service quality assessments, SIAPS supported the MOHSS in mentoring more than 70 pharmacy staff on their role in monitoring and promoting RMU through therapeutic committees (TCs). SIAPS also supported the Karas regional management team in conducting a training of three TCs in their role in promoting RMU and preventing the development of AMR, including HIV-DR. The SIAPS-supported capacity enhancement in Namibia yielded results as reported by MOHSS managers during the annual pharmacists’ forum held during the reporting year. The Karas regional pharmacist reported improvements in pharmaceutical services, inventory management, and medicine use. The results were partly attributed to SIAPS-supported training of three TCs; TC activities increased by 13.9% following the training in PY6Q1.

During the reporting year, SIAPS also supported several medication adherence-related activities.

SIAPS/Namibia collaborated with the MOHSS’ Directorate Special Programs (DSP) in developing an implementation plan for a short-text adherence reminder system at ART sites. A progress report on the lessons learned from implementation was presented to MOHSS’ technical advisory committee (TAC) for HIV/AIDS. SIAPS also supported MOHSS in presenting findings and recommendations as a poster entitled Pediatric Antiretroviral Treatment Uptake, Adherence, Regimen Switches, and Retention in Care in Namibia at the 12th International Workshop on HIV Treatment and Prevention Adherence held in Miami in June 2017, and as an oral presentation at the third Medicine Utilization Research in Africa (MURIA) Symposium held in Windhoek in June 2017. In addition, SIAPS Namibia supported the MOHSS in disseminating findings and recommendations through an oral presentation entitled Short Message Service (SMS) Reminders Improve Patient On-Time Pill Pick-Up of Their Antiretroviral Medicines in Namibia. It was presented at MOHSS TAC in May 2017 and at the 12th International Workshop. The abstract was rated as one of the top three and slated for oral presentation at the opening of the conference. In addition, SIAPS Namibia finalized the 2016 annual early warning indicator (EWI) report for adult and pediatric patients from all ART sites (50 main sites, 163 outreach/integrated management
of adolescent and adult illness sites) across the country. Data was abstracted on the following five indicators: on-time pill pick-up, retention in care, pharmacy stock-outs, dispensing practices, and viral load suppression. Also in the reporting period, the 2014 EWI report was published in the PLoSOne journal (http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0166649).

With SIAPS’ technical assistance, Namibia started implementing group ARV refills through community adherence support groups (CASGs) as part of a community-based ART (CBART) program, a decentralization model adopted by Namibia in the 2016 national ART guidelines. During this reporting year, SIAPS supported the MOHSS and partners in configuring the Electronic Dispensing Tool (EDT) for dispensing ARVs to CASGs and in developing and orienting health workers on pharmacy dispensing SOPs, process flow for group ARV dispensing, and monitoring tools that are used by pharmacy staff and CASG leaders. The EDT is used to capture ART patient information including adherence to treatment in public health facilities. CASG leaders of CBART were also oriented on using paper-based tools to support dispensing to CBART group members at community-based ARV pick-up points. Nurse and clinical mentors were also oriented on the tools to enhance their capacity to support CASG leaders in dispensing ARVs and monitoring patients’ adherence to treatment. As of May 31, 2017, 55 groups had been created with about 660 ART patients who were ready for implementation of CBART. SIAPS also met with Project HOPE, Tonata PLHIV, and IntraHealth to review the progress in implementing CBART activities, challenges, and actions for improvement. Eleven pharmacy staff were trained on CBART SOPs for dispensing ARVs to CBART groups.

SIAPS/Namibia also oriented the new PEPFAR regional director based in South Africa on USAID-supported CBART activities in the Onandjokwe District. SIAPS collaborated with the Onandjokwe District management team, USAID, and other development partners to demonstrate how USAID-implemented activities have improved the management of ART patients at health facilities and community-based points in the district. SIAPS supported pharmacy staff at the Onandjokwe ART pharmacy in demonstrating the use of EDT and mEDT for patient and stock management at health facilities. The facility staff demonstrated how the EDT has been adapted to implement CBART through bulk dispensing to CASG leaders. CBART beneficiaries testified on benefits of CBART, including improved adherence to ART, good viral load suppression among group members, and no waiting in long queues to obtain ARV medicines after travelling long distances. They also shared challenges faced, including infrastructural challenges with the meeting place in the community, which make it hard to hold meetings in adverse weather.

SIAPS supported the HPD of Mozambique’s MOH to carry out a study of ARV treatment adherence by using indicators developed by the International Network for Rational Use of Drugs in the Polana Caniço General Hospital in Maputo City. The main findings of the study are presented in the table below:

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Result</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of patients with total adherence</td>
<td>95.8</td>
<td>95</td>
</tr>
<tr>
<td>% of days covered by ARVs dispensed for a defined sample of patients in the period under review (180 days)</td>
<td>58</td>
<td>100</td>
</tr>
<tr>
<td>% of patients who experienced a gap in ARV availability for more than 30 days in a row during 30 days</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>% of patients who attended the clinic on or before their scheduled day</td>
<td>96</td>
<td>96</td>
</tr>
<tr>
<td>% of patients who attended the clinic within three days of their appointment</td>
<td>96</td>
<td>72-96</td>
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</tbody>
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During this reporting period, SIAPS also published and disseminated the thought leadership document entitled Improving Medication Adherence through Systems Strengthening Approaches. The document was published on the SIAPS website: (http://siapsprogram.org/publication/systems-based-
IR5B PHARMACEUTICAL SERVICES IMPROVED TO ACHIEVE DESIRED HEALTH OUTCOMES

approaches-to-improving-medication-adherence/) and disseminated through key listservs and social media channels along with an accompanying blog post (http://siapsprogram.org/2016/11/09/improving-medication-adherence-it-takes-a-system/). This publication provides a rationale for looking at adherence through a systems-strengthening lens and describes multiple strategies and tools to support better adherence, particularly in resource-limited settings. It puts forth a framework that recognizes that multidisciplinary and multilevel approaches and interventions are necessary to strengthen systems for better adherence. Each chapter focuses on a different level of the health system (macro, meso, and micro) and suggests key interventions that relate to the core functions of the health system. This publication is relevant for a wide variety of health care actors, particularly policy makers, program managers, government stakeholders, implementing partners, donors, and health managers involved in improving medication adherence.

During the reporting year, SIAPS also supported Namibia, Uzbekistan, and Mali in strengthening medicine use research, review, and survey. In Namibia, SIAPS provided technical assistance to the University of Namibia’s School of Pharmacy (UNAM-SoP) as a member of the organizing committee for the third MURIA Symposium which UNAM-SoP hosted in Windhoek in June 2017 with the theme influencing patient care and policy. SIAPS also collaborated with MOHSS, the National Tuberculosis and Leprosy Programme (NTLP) technical working group (TWG), and partners (CDC, UNAM-SoP, and the Namibia University of Science and Technology) to train 26 participants from the DSP and selected regions on basic principles of conducting operational research, how to structure and conduct scientific operational research, and identifying research areas at health facilities, which the TWG would support to further develop into scientific operational research topics. In Uzbekistan, with SIAPS support, an anti-TB drug use review was conducted in 10 oblasts to promote optimal medication therapy according to the national treatment guidelines and to prevent errors and minimize ADEs in patients associated with the second-line treatment; 914 MDR-TB patient cards were reviewed. In Mali, SIAPS provided support through PNLP to MOH for organizing the end-user verification survey. The field phase took place August 9-29, 2017, in five regions and the District of Bamako. The preliminary results of this phase, among others, are:

- 96.20% (76/79) of the visited health facilities have the STGs for malaria
- 91% (1,147/1,260) of the staff involved in the management of malaria cases received formal training
- 93% (2,029/2,179) of malaria patients under age 5 seen at the visited sites with uncomplicated malaria were treated with ACT in accordance with the malaria STGs

During the reporting period, SIAPS supported the following additional activities that contribute to RMU:

- SIAPS collaborated with University Research Co. and the Lubombo region’s pharmacy personnel to establish a Lubombo Pharmacy Representative Committee in Swaziland. The committee primarily focuses on identifying problems and sharing best practices in the delivery of quality pharmaceutical services. The plan is to establish such a committee in another region after piloting in Lubombo is over. SIAPS also assisted several health facilities (Raleigh Fitkin Memorial Hospital, Dvokolwako Health Center, Mkhuzweni Health Center, Pigs Peak Government Hospital and Baylor Clinical Center of Excellence Clinic) to initiate quality improvement projects to monitor RMU in the health facilities.

- The SIAPS-supported course on RMU in the Dominican Republic started in July 2017. USAID sponsored 21 tuition fees. SIAPS consultants facilitated the first and second modules of the course. This certified course is being implemented in partnership with Universidad Central del Este. SIAPS also organized a two-day national workshop in August 2017 for the promotion of RMU.
National professionals presented on progress in this area; national authorities shared the strategic vision of the institutions they represented; and clinicians analyzed current prescription practices and developed plans to address irrational use of medicines.

- **SIAPS/Ethiopia**, in collaboration with the Ethiopian Pharmaceutical Association (EPA), and RHBs provided three training events (at Dessie, Mekele, and Hawassa) on reproductive, maternal, neonatal, and child health (RMNCH) to pharmacists in community pharmacies on rational dispensing and use of RMNCH medicines and appropriate referral to enable them to manage and/or refer mild illnesses, such as diarrhea and pneumonia, and to provide appropriate counseling on family planning methods. During this reporting period, SIAPS Ethiopia also supported six health facilities in Oromia, Dire Dawa, Harari, and Amhara regional states in organizing different medicine use education sessions, where 1,059 patients and the public were reached (54% females). Topics covered through the sessions included ARV medicines, opportunistic infections, RMNCH, medicine storage, risks of self-medication, AMR, and proper use of medicines. Additionally, SIAPS Ethiopia continued to provide technical support to advance clinical pharmacy services, focusing on the identification and management of treatment errors, adherence counseling, and pharmaceutical care activities for patients on ART. SIAPS distributed reporting tools to health facilities and trained stakeholders on how to use them. From October to December 2016, six health facilities (three in Dire Dawa, two in Amhara, and one in Harari regions) identified and managed 79 treatment errors. All of the medication errors were corrected immediately at the point of service.

**Pharmaceutical Service Standards are Defined, Adopted, and Implemented**

During this project year, SIAPS rendered technical assistance in several countries in revising and implementing STGs, EMLs, and formularies. SIAPS supported the following achievements during the reporting period:

- **In Ukraine**, with support from SIAPS, the methodology for selecting medicines for inclusion on the EML was approved by the Ministry of Justice and the SOPs for the EML Expert Committee were finalized. The committee developed a final draft of the EML in December 2016. Public discussion of the EML was subsequently completed, and the comments and suggestions were incorporated. The final EML was approved by the Cabinet of Ministers on March 16 and published on March 25. A public relations campaign is also being developed to support the roll-out of the EML.

- **In Mozambique**, SIAPS collaborated with the Pharmacy Department to finalize the updated terms of reference and the monitoring plan for the national EML (NEML) committee, and assisted in finalizing the NEML and submitted it to the MOH for review and approval. The National Medicines Formulary was also updated by incorporating input from the Pharmacy Department, and is now pending submission to the MOH.

- **In Swaziland**, SIAPS continued to support the introduction of BDQ for the management of MDR- and XDR-TB by printing and disseminating the BDQ clinician’s pocket guide. SIAPS also participates in the Expert Committee on Clinical Access to ensure the continued safety monitoring of more than 70 patients currently on BDQ. SIAPS is also currently working with other local partners on review of HIV treatment and care guidelines. The MOH has assigned SIAPS the responsibility of updating the drug interactions and ADR section of the guidelines. The team will also look at rationalizing and simplifying treatment regimens to improve quantification for ARVs. The data from the current ADR system will be used to guide decisions on changes in the treatment guidelines, including addition and deletion of medicines. During the reporting period, SIAPS also facilitated a
meeting of the National Essential Medicines Committee. In that meeting, participants from the MOH raised important issues on the need to regularly update the EML and STGs.

- In the **Dominican Republic**, SIAPS organized a one-day workshop during the quarter on methods of analyzing requisitions for the inclusion of new molecules in the NEML. The participants, mostly from MOH’s regulatory departments, applied the methods and procedures shared during the workshop to analyze the requisitions recently received from health facilities.

- In **Ethiopia**, the final editorial work for the formulary was completed, and SIAPS supported the printing of 4,000 copies. FMHACA has taken responsibility for distribution of the printed formulary to health facilities as part of the cost sharing scheme.

- In **Guinea**, SIAPS and WHO supported the Direction Nationale de la Pharmacie et du Medicament (DNPM) in organizing consultation meetings and a subsequent workshop to validate the NEML. The workshop included representatives from the MOH, referral hospitals, the School of Medicine and Pharmacy, and the Guinea Pharmacy Council. SIAPS worked further with DNPM to finalize the NEML and secure the health minister’s endorsement. Printing of the NEML is ongoing and will be followed by dissemination and training of prescribers and dispensers in all health facilities on its use.

- In **Philippines**, in partnership with the NTP, expansion plans and waste management job aids were developed for the roll-out of SSTR for the programmatic management of DR-TB.

- In **Namibia**, the National ART Guidelines were finalized and officially launched by the Minister of Health and Social Services, Dr. Bernard Haufiku, at the inaugural National AIDS Conference held in Swakopmund in November 2016. SIAPS supported the development of the guidelines in the areas of RMU, medicine safety, and community models of dispensing ARVs.

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**Emergence of AMR Slowed**

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

SIAPS provided mini-grants to three Ecumenical Pharmaceutical Network (EPN) member organizations and supported EPN headquarters in providing technical assistance and oversight to them to design, implement, and report on antimicrobial stewardship- and containment-related interventions. The Zimbabwe Association of Church-Related Hospitals (ZACH), Gertrude’s Children’s Hospital (GCH) in Kenya, and the Christian Health Association of Malawi (CHAM) were the three organizations that implemented the AMR-related interventions. Below is a summary of the three projects, which have been completed with final reports submitted to SIAPS:

- ZACH’s activities aimed to increase awareness of AMR by increasing engagement with the media and improving accuracy of reporting on AMR. ZACH held a training workshop for 23 journalists from a variety of media networks and newspapers; 23 publications and/or broadcasts were produced (10 print/electronic articles, 8 radio broadcasts, and 5 television segments) in the 5 months following the workshop, compared to approximately 20 total articles published in the year prior to the workshop.

- In Kenya, GCH focused its efforts on improving adherence to STGs. Following a baseline assessment and educational interventions with 70 prescribers and 15 pharmacy staff, GCH conducted a post-intervention audit that showed an improvement in STG adherence: an adherence rate of 31.2% compared to the baseline rate of 26.2%.

- In Malawi, CHAM conducted a baseline assessment on hand washing and hygiene that showed that a lack of supplies, poor staff-attitudes, and inactive infection prevention and control (IPC) committees contributed to
low levels of hand washing. CHAM trained 109 health care workers on proper hand washing, restocked the two participating facilities with hand-washing supplies, and supported recruitment of new members for the IPC committees. Results of post-intervention assessments demonstrated the following improvements: availability of soaps in sinks (from 67% to 96%), the presence of handwashing posters (from 7.5% to 57.5%), HCWs carrying hand rubs (from 0% to 13%), and HCWs using hand rubs (from 0% to 20%). Hand-washing committees were established in both hospitals.

SIAPS supported publication of AMR courses (parts 1 and 2) through the Global Health eLearning portal. Part 1 provides a primer on the basic principles of AMR, its impact on individuals and societies, and why it warrants major, concerted global action. Part 2 explores in further detail the factors that drive AMR and interventions that can combat it. From its publication on September 16, 2016, until September 30, 2017, 1,454 individuals (782 female, 669 male, 3 unknown gender) from 83 countries earned certificates after taking the revised AMR part 1 course. Similarly, from its publication on November 11, 2015, until September 30, 2017, 1,168 individuals (584 female, 582 male, 2 unknown gender) from 80 countries have earned certificates after taking part 2.

In Swaziland, SIAPS continued to support the development of the National AMR Containment Strategic Plan 2017–2022. During the reporting period, a stakeholder consultative meeting was held for all stakeholders to make inputs on the draft. This activity was implemented jointly with the WHO Swaziland country office. Subsequently, a consensus-building meeting of senior managers from the MOH, Ministry of Agriculture, and Ministry of Natural Resources was held to gain approval of the draft strategic plan. The committee worked on the final comments and will submit the document for editorial work and final formatting. The document is expected to be printed and launched during the next quarter.

During the reporting year, SIAPS/Namibia provided technical assistance to the MOHSS AMR TWG in reviewing drafts of the situational analysis regarding strategies to combat AMR and the multisector action plan for containing it in Namibia. The situational analysis and the AMR action plan have now been finalized and are awaiting approval by senior MOHSS managers. SIAPS also provided technical assistance to the steering committee for reducing hospital-acquired infections (HAIs), promoting RMU, and IPC. The assistance included developing training materials and planning for RMU, IPC, and HAI workshops for health facilities in the Oshikoto Region.

In Bangladesh, a workshop on AMR was organized by WHO in August 2017 where MOHFW; DGHIS; CDC; Bangabandhu Sheikh Mujib Medical University; the International Centre for Diarrhoeal Disease Research, Bangladesh; SIAPS; USAID; US Pharmacopeia-Promoting the Quality of Medicines Program; the Food and Agriculture Organization; and other partners were present. SIAPS mentioned that they would be happy to be a part of this huge movement against AMR.

Supporting drug and therapeutics committees in Sierra Leone to promote safe, appropriate medicine use

October 2017

Irrational medicine use and poor pharmaceutical management at all levels are widespread problems in many developing countries, including Sierra Leone. Misuse, underuse, and overuse of medicines; weak systems that compromise medicine safety; the waste of scarce resources due to expiry; and the rise of antimicrobial resistance (AMR) are particularly worrying because they directly affect health outcomes. Because of a lack of sound data for decision making, health workers may need to select products for medicines lists, supply, and prescribing based on observation and preferences.

As part of its technical assistance in post-Ebola recovery work to help Sierra Leone strengthen its pharmaceutical system, SIAPS is facilitating the selection of appropriate, safe products to be procured and used at different levels of the public health system. Promoting rational medicine use cuts down on waste, improves health outcomes, and helps prevent the spread of AMR.

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Collaborating with hospital departments
- Infection control
- Microbiology
- Pharmacy
- Hospital management

Establishing medicine use interventions
- Treatment guidelines
- Medicine use evaluations
- Support for pharmacovigilance

Identifying medicine and technology use problems
- Prescription indicator studies
- ABC analyses

DTCs

Managing formulary or essential medicine lists
- Develop and implement
- Monitor compliance

Training and educating
- Pre-and in-service with clinicians
- Directly to patients

Graphics adapted from Drug and Therapeutics Committees: A Practical Guide

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Drugs and therapeutics committees (DTCs) are a proven way to strengthen health systems and reduce practices that lead to morbidity and antimicrobial resistance.

Strategic Approach

Drugs and therapeutics committees (DTCs) are a proven way to strengthen health systems and reduce practices that lead to morbidity and AMR by stemming inappropriate medicine use and promoting sound management among health care professionals. A DTC provides a forum for improving health care delivery through participation and evidence-based practice reviews. This group manages medicine selection and procurement, promotes good prescribing and dispensing practices, and implements strategies to improve medicine use throughout a health care facility. DTCs also make necessary decisions on a health facility’s reported adverse drug reactions and provide an environment conducive to continuing education. SIAPS and the Directorate of Drugs and Medical Supplies (DDMS) supported the creation of hospital DTCs in Sierra Leone.

Implementation

Although there were attempts to establish DTCs in selected hospitals in Sierra Leone before SIAPS, they were short lived due to a lack of strategic planning. To help establish a framework for implementation, SIAPS supported a series of stakeholder engagement, foundational, training, and rapid review activities.

Building capacity

In November 2016, SIAPS provided short-term technical assistance from its technical expert in Ethiopia, who spent two weeks with the SIAPS/Sierra Leone and DDMS teams to share experiences from the successful establishment and implementation of DTCs in Ethiopia. In November 2016, SIAPS, in collaboration with the DDMS, conducted a rapid baseline assessment on tracer medicines in four hospitals, used the findings of the assessment to conduct a DTC familiarization and establishment workshop, and drafted terms of reference for establishing and operationalizing DTCs.

This fast track approach enabled four hospitals—Connaught Tertiary, Ola During Children’s, Makeni Government, and Princes Christian Maternity—to begin establishing DTCs. These hospitals held orientation meetings, selected DTC members, and launched the DTCs in March 2017. SIAPS provided the four hospitals with computers, printers, projectors, stationery, and office furniture. Subsequent workshops were held with other district hospitals, and six (Magburuka/Tonkolili, Kabala/Koinadugu, Kono, Kenema, Kailahun, and Bo) are on track to establish DTCs in the last quarter of 2017.

To promote sustainability and institutionalization, a new organogram for the DDMS includes a rational medicine use unit responsible for DTC matters. This new DTC subunit received technical assistance from SIAPS in Sierra Leone to work with hospital pharmacists who attended a Leadership Development Program (LDP) training in May 2017.19 The LDP, developed more than a decade ago by Management Sciences for Health, is a structured program that fosters personal development in handling real-life challenges using a team-based, action-oriented learning approach.

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The training was customized to support the role of DTCs in improving patient care through rational medicine use and improved access to medicines. SIAPS also conducted a DTC brainstorming and harmonization session for all represented hospitals and DDMs during the LDP training to discuss expectations, progress, challenges, and next steps.

Guiding and monitoring progress

In July 2017, a DTC Progress Workshop was conducted in Freetown for hospital pharmacists; hospital medical superintendents; district pharmacists; and representatives from the DDMS, the Pharmacy Board of Sierra Leone (PBSL), and the SIAPS team in Sierra Leone. SIAPS co-facilitated the workshop with the DDMS’s Department of Rational Medicine Use. The agenda included a discussion on the role that DTCs play in pharmacovigilance and the introduction of a DTC operational manual, individual DTC work updates, and action plans.

The Deputy Director of the DDMS opened the workshop by highlighting the importance of DTCs in promoting rational medicine use and medicine safety and in improving pharmaceutical supply management.

The head of the Department of Rational Medicine Use also briefly introduced the concept of pharmacovigilance and explained the process by which DTCs should identify, assess, and report adverse drug events to the PBSL. The PBSL will perform causality studies as needed and report results to the Uppsala Monitoring Center, which collects worldwide adverse drug event data for further studies on adverse reactions.

During the session, DTCs provided updates on project results. Each group reported on meetings conducted, number of members, status of establishing terms of references, ongoing or completed activities, and challenges that the hospitals face and DTC efforts to address them.

Ola During Children’s Hospital launched its DTC in August 2017 in the presence of representatives from key hospital departments, the DDMS, and SIAPS.

Results

New prescriptions format enhances data gathering and security

The lack of standardized, preprinted prescription templates is a major challenge to many health facilities in Sierra Leone, hampering efficiency and effective data gathering. Prescriptions are critical official documents of the health system and require secure storage. They provide data that can be analyzed to yield key patient and product-related information, as well as prescribing and dispensing data for rational medicine use initiatives. In consultation with the DDMS, the DTCs have taken the initiative to revise and use the standardized prescription template. Six hospitals have introduced new prescription forms to guide drug-use information gathering, including rational use.

Connaught Tertiary Hospital in Freetown has succeeded in revising and implementing the hospital treatment chart as part of its DTC functions. The adoption of the improved treatment chart will harmonize patient recording and will be used as a data source for the pharmacy/treatment register.
Electronic treatment register helps supply data for decision making

A significant addition to DTC operations was the development of and orientation to an electronic treatment register (eTR). The eTR was developed to capture prescription information on patients (age, gender, pregnancy, lactation status, and total number); diagnosis (condition, number of diagnoses per prescription, malaria test status); and treatment (number of medicines per prescription, number of antibiotics and injectable medicines per prescription, and dispensing fulfillment). Its capabilities include aggregating, summarizing, and printing relevant data.

A SIAPS staff member was embedded in the DDMS in June and early July to provide technical assistance to the newly established DTCs and to orient and train participants from nine hospitals on the revised eTR and on adverse drug event reporting. The four DTC pioneer hospitals have used the SIAPS-donated computers to pilot eTRs. They captured data from either in-patient treatment charts or out-patient prescriptions for January and February 2017. SIAPS analyzed the pilot data and worked with the DDMS to further refine the eTR and to introduce data analysis formulas into the tool. The four pilot hospitals have fully implemented the system; ideally, each hospital instituting a DTC will use it.

Initial rapid reviews provide baseline for measuring rational medicine use

In November 2016 and again in August 2017, SIAPS supported the first four DTCs in conducting a rapid review of prescriptions for informing the status of selected rational medicine use indicators. Regular DTC reviews help identify areas of needed improvement in rational medicine use, which the committees can address through prescriber, dispenser, and patient partnerships. The first two reviews measured antibiotic prescribing, injectable medicine use, brand versus generic medicines, number of medicines prescribed per encounter, and average rate of prescription forms that include all required information.

Table 1. Rapid Review Results from Connaught, Makeni, Ola During Children’s, and Princes Christian Maternity Hospitals

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of prescription form completion</td>
<td>49%</td>
</tr>
<tr>
<td>Average number of medicines prescribed per encounter</td>
<td>3.7</td>
</tr>
<tr>
<td>% of prescriptions for antibiotics</td>
<td>66%</td>
</tr>
<tr>
<td>% of prescriptions for injectable medicines</td>
<td>25%</td>
</tr>
<tr>
<td>% of prescriptions for brand name products</td>
<td>47%</td>
</tr>
</tbody>
</table>

An in-hospital pharmacy improves access to affordable, quality products

Hospital DTCs can become a focal point for planning for other areas of hospital improvement. Makeni Government Hospital financed and established a cost recovery unit within its pharmacy department. Patients who fall outside the mandate of the government’s free health care initiative, which offers medicines and related supplies to pregnant women and children under the age of five, did not have access to medicines at the hospital’s pharmacy. Instead, they filled their prescriptions at private pharmacies, where they faced a greater risk of problems with availability, quality, and affordability. Having a cost recovery pharmacy within the hospital not only helps ensure patient access to essential medicines, but also helps guarantee that the medicines are safe.
effective, and dispensed accurately, completing the cycle of quality services, treatment, and case management. The income generated from the sale of medicines can also help the hospital to further improve patient services.

Next Steps

The newly established DTCs created action plans during the May 2017 LDP training. Depending on each hospital’s progress to date, plans included finalizing terms of reference, implementing revised prescription forms, or developing a hospital medicines list. Each plan included a time line for completion. The SIAPS country project director encouraged participants to continue mobilizing hospital budgets for DTC work.

The DDMS and SIAPS also introduced a draft DTC operational manual, which will be used for day-to-day DTC management. The manual outlines steps for establishing or revitalizing a hospital DTC; managing DTC meetings, including preparation, agenda, conducting, and writing meeting minutes; and establishing action points. The manual also explains the technical functions of a hospital DTC and provides operational templates and examples. Meeting leaders discussed the manual’s key content and objectives and asked participants to review it and provide questions or comments. SIAPS also assisted the DDMS in developing a template for its own DTC update and action plan and a follow-up checklist for monitoring the DTCs’ progress.

SIAPS has been working through the newly established DTCs to advocate for progress with the government’s AMR plan, which is in progress, and is supporting the DDMS and PBSL in the review and revision of a national medicines list. This includes creating the selection committee that will work with the DDMS and PBSL in the medicines selection process.

Following the first baseline rapid review of prescriptions in November 2016, a second progress review was conducted in August 2017, and a comparative report will be prepared to inform progress and identify gaps that need to be addressed.

Further Reading


HEALTH AREAS
MATERNAL, NEWBORN, AND CHILD HEALTH

Background

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

To address these and other issues, in 2012, the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) was launched with a focus on 13 essential reproductive, maternal, newborn, and child health (RMNCH) commodities, and it identified a set of recommendations aimed at increasing access to and availability of these commodities. Two years later, recognizing the need for heightened attention for maternal, newborn, and child health (MNCH), USAID and the global MNCH community renewed their commitment to ending preventable child and maternal deaths (EPCMD) by setting new targets (fewer than 50 maternal deaths per 100,000 live births and fewer than 20 child deaths per 1,000 live births) to be achieved by 2035.

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

As the UNCoLSC came to an end and the sustainable development goals were launched with ambitious commitments to reduce maternal, newborn, and child mortality rates, which requires more intensified efforts and holistic, systems strengthening approaches, the UN and the World Bank launched the Global Financing Facility (GFF) to support Every Woman Every Child—a platform to better leverage financing to support country-led investment plans aimed at improving RMNCH.
The Challenge

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

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

A remaining challenge in the global MNCH community is how to maintain momentum in the wake of UNCoLSC’s closure in 2016. It is crucial that RMNCH commodities remain high on countries’ agendas and that they prioritize access to and availability of commodities for women and children. This is a focus that should permeate the GFF approach to ensure prioritization of access to and appropriate management of quality RMNCH commodities.

SIAPS Strategy

Achieving the targets of EPICMD will require a focused systems strengthening approach.

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

SIAPS strategies implemented at the global and country levels include improving governance of pharmaceutical systems, strengthening supply chain management capacity, increasing the availability of pharmaceutical information for decision making, developing appropriate pharmaceutical financing strategies, and promoting rational use of medicines and supplies.
Key Achievements during Program Year 6

Global-level Contributions

UN Commission on Life-Saving Commodities for Women and Children

Most of the UNCoLSC’s technical reference teams (TRTs) ended or merged with other groups this year. The Maternal Health (MH) TRT merged with the Maternal Health Supplies Caucus (MHSC), and as the Supply Chain TRT came to an end, SIAPS finalized its legacy document.

SIAPS continued to participate in the Chlorhexidine TRT monthly calls and quarterly meetings and contributed when needed, particularly by presenting updates on the status of chlorhexidine implementation in Afghanistan and Democratic Republic of Congo (DRC) and providing technical input on global advocacy documents.

The Pneumonia and Diarrhea TRT has become a virtual group for information sharing. SIAPS attended the amoxicillin product presentation meeting hosted by UNICEF, presented the study in DRC using dispensing envelopes and job aids, and contributed to the discussions on next steps. It was agreed to publish the studies of Management Sciences for Health, UNICEF, and PATH and to post the finalized generic files of the envelopes and job aids on the Every Breath Counts and Lifesaving Commodities websites.

Other Global Partnerships and Initiatives

SIAPS works closely with global partners and actively participates in standing technical communities of practice in both child and maternal health. The SIAPS MNCH portfolio continued to be engaged at the global level by participating in regular meetings of the MHSC of the Reproductive Health Supplies Coalition and the Supply Chain Management (SCM) subgroup of the Community Case Management (CCM) taskforce. In addition to participating in various working groups, SIAPS participated in the Every Breath Counts call on how to advance the pneumonia agenda, was requested to provide input on the UNICEF Supply Division strategic plan, and provided the USAID team with talking points about SIAPS MNCH work and the GFF for the GFF Investors Group meeting in Tanzania. USAID will provide technical assistance on access to and management of commodities to the GFF through SIAPS in the upcoming year. At the end of this year, discussions were held with USAID on the content of the technical assistance, the budget, and the timeframe. The obligation for the activity was received at the end of September 2017 and work will start in October with the development of a work plan.

Other work of the MNCH Core portfolio in global technical leadership is presented in table 1.

Table 1. Key Contributions in Global Technical Leadership for MNCH, PY6 2016–2017

<table>
<thead>
<tr>
<th>Technical Resource Team (TRT)/Partner/Taskforce</th>
<th>Key Contributions and Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive Health Supplies Coalition</td>
<td>• Facilitated the merger of the MH TRT into the MHSC</td>
</tr>
<tr>
<td>• MHSC</td>
<td>• Contributed to the finalization of the MHSC work plan</td>
</tr>
<tr>
<td>• Systems Strengthening Working Group (SSWG)</td>
<td>• Presented a webinar on the RMNCH quantification supplement for the MHSC</td>
</tr>
<tr>
<td></td>
<td>• Attended the RHSC annual meeting in Seattle, WA, and represented SIAPS at the SSWG and MHSC meetings and the quarterly meeting of the MHS Caucus in Washington, DC.</td>
</tr>
<tr>
<td></td>
<td>• Submitted an abstract for the RHSC annual meeting in October 2017, which was accepted for presentation in the MHSC meeting on the mapping of financial flows for MNCH medicines conducted in four countries.</td>
</tr>
<tr>
<td>Supply Chain TRT/UNCoLSC</td>
<td>• Finalized the Supply Chain TRT’s legacy document</td>
</tr>
<tr>
<td>Chlorhexidine TRT/UNCoLSC</td>
<td>• Supported the introduction of chlorhexidine in Afghanistan and DRC</td>
</tr>
<tr>
<td>Diarrhea and Pneumonia TRT/UNCoLSC</td>
<td>• Presented the DRC study on amoxicillin product presentation using the dispensing envelopes and job aids that will be made available on the Every Breath Counts and Lifesaving Commodities websites</td>
</tr>
</tbody>
</table>
### Technical Resource Team (TRT)/ Partner/ Taskforce

<table>
<thead>
<tr>
<th>CCM Taskforce/ SCM Subgroup</th>
<th>Key Contributions and Products</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Continued to chair the SCM subgroup meetings and has been engaged in the discussion of the CCM Taskforce on its transition to a child health taskforce. After discussion in several meetings, it was agreed by the SCM subgroup that a commodities subgroup would be of value in the new Child Health Taskforce. The group will wait for next steps from the steering committee once the future of the taskforce is determined.</td>
</tr>
<tr>
<td></td>
<td>• Conducted a mapping exercise of other technical working groups in child health and commodities so the group can define its niche in the child health taskforce</td>
</tr>
<tr>
<td></td>
<td>• Coordinated a presentation in a subgroup meeting on the lessons learned from JSI’s SC4CCM project</td>
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<tr>
<td></td>
<td>• Coordinated the participation of the SCM subgroup in satellite sessions on district systems strengthening at the Vancouver Health Systems Research conference. During the conference:</td>
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<tr>
<td></td>
<td>– VillageReach presented on the integration of HMIS and LMIS work conducted for the UNCoLSC SC TRT under SIAPS</td>
</tr>
<tr>
<td></td>
<td>– Staff from the Maternal and Child Survival Program presented on behalf of the SCM subgroup</td>
</tr>
<tr>
<td></td>
<td>• Organized a session on strong systems to ensure commodity availability and use at the community level for the Institutionalizing Community Health Conference in South Africa in March 2017</td>
</tr>
<tr>
<td></td>
<td>– Presented a general overview to define a pharmaceutical system and why strengthening it is important for community health services, with some country examples</td>
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<tr>
<td></td>
<td>– Coordinated presentations on USAID-funded activities in Ethiopia to strengthen the pharmaceutical system and on Malawi’s experience in scaling up C-stock, an mHealth community-level information system</td>
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</table>

| iCCM FTT                    | • Contributed to the review of the documentation of the work of the FTT |
|                            | • Finalized the French version of the documentation protocol for use in francophone countries to document iCCM implementation under the Global Fund’s New Funding Model |
|                            | • Participated in the final meeting of the FTT in November 2016 |

| CORE Group                 | • Attended a plenary session on Child Health Policy and Programming Transitions |

| Pharmaceutical Systems Strengthening | A case study on pharmaceutical systems strengthening for CCM was submitted to the SIAPS global call for case studies in pharmaceutical systems strengthening to highlight successful strategies to improve access to and use of pharmaceutical products and services |

### Tools and Innovations

SIAPS works to develop tools to assist countries in ramping up efforts to decrease maternal and child mortality, thereby contributing to EPCMD. This year, SIAPS finalized and disseminated three tools aimed at improving access to and availability of essential MNCH commodities.

- **How to assure access of essential RMNCH medicines in Countdown to 2015 countries: Looking at policy and systems factors**, an article submitted to BMC Health Services Research journal and currently under peer review. This paper was commissioned by the Countdown to 2015’s Working Group on Health Systems and Policies under the Countdown to 2015 for Maternal, Newborn and Child Survival and has stimulated discussion on indicators and measurement in the formation of the Countdown to 2030 initiative.

- **Subnational procurement assessment in Kenya**. The purpose of the Kenya subnational procurement assessment is to provide a snapshot of the practices employed at the subnational level to ensure the availability of MNCH commodities and identify options for the government to increase access to these commodities through improved procurement practices and more efficient use of existing funds.

- **Mapping financial flows in four countries**. SIAPS collected data to map financial flows in Bangladesh, Kenya, Nepal, and Uganda. The results were presented to the USAID/Washington MCH team and the individual country reports and a summary document of the key bottlenecks for financing MNCH commodities were finalized. SIAPS has presented the results at a brownbag organized by World Bank. SIAPS will also be presenting the results at the MHSC meeting at the RHSC annual meeting.
Country-level Contributions

SIAPS/MNCH has worked with the Bangladesh country team to include MNCH commodities in the pharmacovigilance (PV) system in Bangladesh. A concept note was developed and shared with the Directorate General of Drug Administration and Bangabandhu Sheikh Mujib Medical University’s (BSMMU) Gynecology and Obstetrics Unit and the Pediatric Department. In addition, training materials were developed. The SIAPS core MNCH team, in collaboration with the SIAPS/Bangladesh team, facilitated a half-day workshop on MNCH PV organized by the Directorate General of Drug Administration at BSMMU Hospital. Seventy participants from BSMMU, including chairs, professors, associate professors, and assistant professors of gynecology and obstetrics, neonatology, pharmacology, and pediatrics department were oriented on PV and PV reporting mechanisms for MNCH medicines. SIAPS/Bangladesh staff have followed up to ensure that PV focal persons were nominated for each department, and a training of additional doctors in each department will be conducted during the last quarter of 2017.

The Way Forward

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

SIAPS, through its support to the GFF, will continue to provide global technical leadership on pharmaceutical systems issues related to RMNCH, finalize and disseminate guidance and essential tools in pharmaceutical management that will help ensure access to quality RMNCH commodities, and work to enhance the evidence base for effective strategies to increase access to medicines and services for RMNCH.
Background

Despite the availability of highly effective diagnostic and treatment tools, tuberculosis (TB) remains a critical global health problem. In 2015, approximately 1.4 million people died of TB, including 400,000 who were HIV positive. Of the 10.4 million cases of TB estimated to have occurred in 2015, national TB programs (NTPs) were notified of only 6.1 million, leaving a gap of approximately 4.3 million people who were either not diagnosed or not reported (WHO, 2016).

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

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

- Supporting countries with the highest TB, drug-resistant TB (DR-TB), and/or TB-HIV burdens
- Leveraging interagency strengths and innovative approaches
- Supporting multilateral and international global programs, policies, and research for TB prevention, care, and treatment

The Challenge

A number of systemic pharmaceutical management issues hinder TB control. First, there is a notable gap between evidence-based pharmaceutical management improvement best practices and their translation into global and country policies and practices. This discrepancy results in inefficient TB medicine supply mechanisms and slow uptake of new medicines, regimens, and diagnostic products and highlights the need to strengthen governance, leadership, and coordination among global initiatives and countries. Another challenge is human resource capacity and leadership for pharmaceutical supply management and services within TB programs, specifically with regard to forecasting and quantification, inventory management,
supply planning, early warning, and rapid decision making. Without institutional improvements in capacity, short-term gains in pharmaceutical management will not be sustained.

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

The first new TB medicines in more than 40 years—bedaquiline and delamanid—were endorsed by WHO for the treatment of MDR-TB and released onto the market in 2011 and 2012. In April 2015, USAID and Janssen Pharmaceuticals announced a donation of 30,000 treatments of bedaquiline to treat DR-TB patients. WHO also issued guidance to help countries quickly introduce these medicines. However, uptake has been slow by countries for myriad reasons, including a lack of expertise, infrastructure, and appropriate systems to monitor the efficacy, safety, and potential adverse effects of these medicines. As of September 2017, 15,891 bedaquiline treatments had been ordered by 62 countries, a lower number than expected at the beginning of the donation program.20 Countries have also experienced delays with the introduction of other new TB tools, such as shorter DR-TB regimens (STR); one of the main reasons for the delays is the lack of skills and tools for rational transitional supply planning. Consequently, there is an increased demand from countries for knowledge on how to manage programmatic implementation of and access to new TB tools.

In addition, access to quality TB diagnosis, treatment, and pharmaceutical services in the private sector remains limited and is often substandard. With regard to improper use of TB and DR-TB medicines, a lack of monitoring of medicine utilization and management of adverse events can result in poor treatment outcomes and foster the development of drug resistance. Patient-centered TB diagnosis and treatment relies on the capacity of health staff to track and assess patient data and ensure the implementation of evidence-based care. Concurrent treatment of co-morbidities, such as TB/HIV and TB/diabetes, results in a greater risk of

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**SIAPS Strategy**

The primary goal of the SIAPS TB Core portfolio is to ensure the availability of quality pharmaceutical products and support the implementation of effective pharmaceutical services for achieving global and USG TB program targets also represented in the USG health goals, namely protecting communities against infectious diseases, fostering an AIDS-free generation, and strengthening health systems. SIAPS builds on many years of experience, methodologies, and tools developed and tested by Management Sciences for Health, and its USAID-funded programs. As a result, SIAPS has at its disposal an array of instruments to address TB pharmaceutical management gaps within the health system. The four key strategies employed by the TB portfolio are pharmaceutical governance for TB strengthened at global and country levels; capacity for TB pharmaceutical supply management and services increased and enhanced; improved utilization of information for TB control decision making; and improved pharmaceutical services and access to TB products to achieve goals.

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20 USAID Updates on the Bedaquiline Donation Programme: Our Approach to Technical Assistance for Shortened Treatment Regimen, BDQ, DLM Introduction and Scale up. Dr. Ya Diul Mukadi, USAID. UNION, Guadalajara, Mexico, October 11, 2017
adverse events, which may contribute to treatment interruptions and poor patient outcomes. With the introduction of new tools in the fight against TB, including bedaquiline and delamanid, pediatric formulations, short-course treatment regimens, and new diagnostic tools, SIAPS builds country capacity to improve access to lifesaving medicines and technologies for TB patients.

Key Achievements during Program Year 6

Pharmaceutical Governance for TB Strengthened at the Global and Country Levels

SIAPS shares its tools, best practices, and knowledge with partners and countries through global forums and information sharing platforms. SIAPS participated in the 47th Union World Conference on Lung Health, which is organized annually by the International Union against Tuberculosis and Lung Disease. The conference took place in Liverpool, UK, October 26–29, 2016, with the theme Confronting Resistance: Fundamentals to Innovations. SIAPS' highlights at the conference included the launch of QuanTB version 4.0—a free tool for forecasting, quantification, supply planning, and early warning, and e-TB Manager version 3.0—a comprehensive online platform for managing all data collection, information, and reporting needs of TB programs. SIAPS conducted two half-day workshops with partners: Lessons Learned from Increasing Access to Bedaquiline and Delamanid for Management of Drug-Resistant TB and Digital Health Technology for the End TB Strategy: Developing Priority Products and Making Them Work. SIAPS participated in and coordinated two symposia: Active TB Drug Safety Monitoring and Management: A Transformative Approach to Limit Treatment Related Patient Harm and Early Warning System to Improve Patient Access to TB Medicines: From Quantification to Decision Making. In addition, SIAPS presented eight abstracts from SIAPS-supported countries during the conference, expanding the knowledge base on drug use reviews, implementation of digital health tools such as e-TB Manager and QuanTB, and implementation results of an early warning system in several countries and regions.

SIAPS prepared several abstract submissions and proposed a workshop and several symposia for the 2017 Union Conference in Guadalajara, Mexico, that highlighted best practices and the SIAPS experience in providing technical assistance to countries in improving access and scale up of new TB medicines, regimens, and diagnostics; the submissions were accepted and included in the 2017 Union Conference agenda.

Capacity for TB Pharmaceutical Supply Management and Services Increased and Enhanced

To enable access to SIAPS-developed tools and best practices, SIAPS launched two eCourses to the public that are hosted on the MSH LeaderNet platform (LeaderNet.org). Following the release of QuanTB v4 at the 47th Union Conference, SIAPS updated the training modules and videos and released a free, self-paced course for health professionals on LeaderNet. The goal of this course is to strengthen learners' skills for appropriate quantification of first- and second-line medicines and other TB commodities to ensure an uninterrupted supply in NTPs. The course includes two modules on quantification methods and assumptions and on the use of the tool and has interactive video demonstrations and knowledge checks. The full course takes approximately five hours to complete. A certificate will be provided for those who complete the full course. As of September 2017, more than 150 professionals had registered for the course.

The second eCourse SIAPS launched in PY6 is “Using New TB Medicines and Regimens.” This year, SIAPS launched two eCourses: “QuanTB version 4.0” is an interactive course to strengthen skills in quantification of first- and second-line medicines for TB.

“Using New TB Medicines and Regimens” is a free, self-paced course for health professionals on new TB medicines - bedaquiline and delamanid - and the use of new regimens.
nurses, pharmacists, and all health care workers currently engaged in the management of MDR-TB patients. Workers in NTPs, ministries of health, and nongovernmental organizations who are looking to introduce new TB medicines and regimens in their countries will also greatly benefit from this course.

The information in this course was developed from publicly available resources from the World Health Organization (WHO) and elsewhere. It has been taught at in-person workshops to hundreds of health care workers in five countries. The course includes eight modules with interactive case studies. Learners can choose to review all modules or select those most relevant to their practice setting. A certificate will be provided for those who complete the full course. As of September 2017, 184 professionals had registered for the course.

Improved Utilization of Information for Better Decision Making

SIAPS’ e-TB Manager is a key TB program management platform in 10 countries. In PY6, SIAPS released e-TB Manager 3.0. This version fully implements the new case management module, mobile support, and indicator generators and has an offline mode that allows users with poor internet connectivity to synchronize work done offline with the online version. Because of funding constraints, additional modifications to e-TB Manager 3.0 were halted.

To expand the knowledge base of pharmaceutical best practices and improve utilization of information for TB control decision making, SIAPS published two peer-reviewed journal articles in PY6. An article published in the *European Respiratory Journal Open Research* presented results of an in-depth analysis of Ukraine’s experience in implementing e-TB Manager and strengthening TB recording and reporting. The open access article, which has had more than 1,400 downloads to date, is under a CC BY-NC license and can be freely shared and distributed from http://openres.ersjournals.com/content/3/2/00002-2017.

The second article was published by the International Journal of Medical Informatics. This article covers a user experience analysis that was conducted in eight languages among more than 1,500 respondents in nine diverse country health systems that cumulatively bear nearly one-third of the world’s TB burden. A key takeaway is that users find e-TB Manager to be reliable for case management and that it improves patient care and workplace productivity. The study is listed among the journal’s most downloaded articles, with more than 1,500 downloads. This open access article is under a CC BY-NC-ND 4.0 license and can be freely shared and redistributed from http://www.sciencedirect.com/science/article/pii/S1386505617300783.

SIAPS recorded an audio narrative on key findings of the user experience analysis on e-TB Manager, which is available at http://audioslides.elsevier.com/ ViewerLarge.aspx?source=1&doi=10.1016/j.ijmedinf.2017.03.017.


In PY6, SIAPS continued to clean and finalize QuanTB based on feedback from users in the field. QuanTB version 4.1 was put on the SIAPS website for download. Demand for QuanTB is increasing exponentially, with 1,702 unique downloads between October 2016 and September 2017. Since November 2014, there were 2,269 unique downloads of QuanTB by users in 136 countries.

SIAPS continued to work with the developer to finalize PViMS, an online reporting and analytical tool for active pharmacovigilance (PV), based on feedback from the implementation in Georgia, Swaziland, and Philippines, and revise the user manual.
In PY6, SIAPS decided to make its electronic tools readily available to professionals and partners for further development via GitHub, a repository of open source code software and electronic tools. This includes, among others, all SIAPS tools developed with USAID TB funding, such as QuanTB, eTB Manager, and PViMS.

**Improved Pharmaceutical Services and Access to TB Products**

Accurate forecasting of TB medicine needs for different scenarios is a challenge in many countries due to a lack of reliable tools to align TB case data and medicine stock, expiry, and consumption data. Two SIAPS analytical reports on the economic impact of stock-outs in Philippines and Kenya, which were developed and disseminated in PY6, illustrate the challenge. To address this, SIAPS implemented a regional systems strengthening technical assistance approach that involved supporting NTPs in USAID-focus countries to establish, institutionalize, and implement an early warning system (EWS) to ensure availability and reduce stock-outs and expiries of TB commodities. This was done by developing and building country capacity to implement QuanTB, an electronic forecasting, quantification, supply planning, and EWS tool.

In PY6, SIAPS conducted a global evaluation of the QuanTB EWS implementation and related SIAPS technical assistance, which was summarized in Implementing an Early Warning System for TB Medicines: Global Report. Twelve individual country reports were also produced that highlight key achievements and the impact of the intervention on country TB commodity and overall supply chain management as well as experiences, challenges, lessons learned, and sustainability of QuanTB. The reports can be found at [http://siapsprogram.org/quantb-implementing-an-early-warning-system-for-tb-medicines/](http://siapsprogram.org/quantb-implementing-an-early-warning-system-for-tb-medicines/).

With the completion of project funding, SIAPS’ direct technical assistance with TB core support focused on the transfer of tools and knowledge to NTPs to ensure the sustainability of system strengthening gains from the project.

In DRC, SIAPS continued to provide support to the NTP to overcome challenges in pharmaceutical management. SIAPS staff provided direct, hands-on technical support in quantification, forecasting, and supply planning and in generating EWS reports.

In Ethiopia, SIAPS provided technical support to build capacity of key staff of the national quantification team, the NTP, and Challenge TB to implement QuanTB and its EWS. SIAPS helped to monitor stock status for TB medicines at the Pharmaceutical Funds and Supply Agency. SIAPS provided technical assistance in the development of a standard operating procedure for the distribution of small amounts of TB medicines (pediatric TB medicines, leprosy medicines, second-line medicines, and medicines for retreatment TB cases) to health facilities and guidance for the integration of diagnostic supplies into the Integrated Pharmaceutical Logistics System for faster acquisition of diagnostic supplies. SIAPS assisted in the development of a supply plan for new TB pediatric formulations and shorter MDR-TB treatment regimens.

In Kenya, SIAPS technical support increasingly focused on skills transfer for sustainability of interventions. During PY6, several EWS reports were generated, and action points were reviewed by the SIAPS consultant and discussed during monthly commodity security meetings. A key outcome of the technical assistance provided by SIAPS was the aversion of a potential stock-out due to fast tracking a pending delivery of capreomycin. In addition, SIAPS provided technical input during the review of NTP integrated curriculum and training materials to strengthen the modules on medicine safety and pharmacovigilance (PV) for MDR-TB and TB medicine inventory management. SIAPS also contributed to planning and implementing a midterm program review in February/March 2017.

In Nigeria, SIAPS staff provided technical support in quantification, forecasting, supply planning (using QuanTB), active TB drug safety
monitoring and management (aDSM), and PV for the introduction of a new STR. With SIAPS support, Nigeria was able to avoid the risk of expiry of TB pediatric formulations through pipeline monitoring using QuanTB. SIAPS staff participated in procurement and supply management (PSM) meetings and a DR-TB program review meeting in Lagos state; facilitated a training on pharmaceutical care and logistics management information system of MDR-TB commodities; and built the capacity of providers and laboratory staff from North East (Bornu, Yobe) on commodity and patient management for drug-susceptible TB. The SIAPS regional advisor led the process of pipeline monitoring using QuanTB and made a presentation from the dashboard and graphs produced with the tool to mitigate stock-outs or wastage. Quarter 2 of PY6 was the final quarter of technical assistance in Nigeria for TB Core.

In South Sudan, SIAPS conducted a quantification review for pediatric TB medicines and generated an EWS report. The report was shared with the Global Drug Facility and the Global Fund and was used to help plan a grant for new pediatric formulations. SIAPS also followed up on action points that arose from the EWS report, resulting in fast-tracking first-line adult formulations and ethambutol 100 mg for children to avoid potential stock-outs flagged by the EWS QuanTB report.

In Zambia, SIAPS assisted the NTP in collecting and validating data and generating several QuanTB EWS reports. A meeting with GDF staff highlighted various supply chain issues that needed to be addressed. With SIAPS support, the NTP requantified the initial order of new pediatric formulations and drafted a transition plan for phasing out the old formulations. Similar support was provided to develop a quantification and transitional supply plan for the introduction of WHO-supported new MDR-TB regimens. SIAPS provided technical assistance and support on PSM strengthening as part of the WHO program review team. Recommendations on improving management of the TB medicine supply chain were made and shared with the NTP. Key interventions will form part of the national strategic plan 2017–2022, which is currently being drafted.

Rapid Introduction and Adoption of New TB Medicines and Regimens

To expedite the scale-up of new TB medicines and regimens, such as bedaquiline, delamanid, and STR, in PY6, SIAPS continued to work with five countries (Georgia, Kenya, Philippines, Swaziland, and Uganda) by providing technical assistance tailored to country-specific challenges and transferring the ownership of tools and approaches to local stakeholders. The five countries were the first subscribers to the SIAPS eCourse on Using New TB Medicines and Regimens.

SIAPS technical assistance focused on two areas—improving access to medicines through better quantification, supply planning, and early warning using QuanTB and improving patient safety through the introduction of active PV monitoring using PViMS.

During PY6, most success was achieved in Georgia, Philippines, and Swaziland. All three countries have been using QuanTB for order quantification and supply planning since 2014 and have tested and implemented PViMS as the WHO-required aDSM. Georgia has enrolled 415 patients on bedaquiline or delamanid, with 240 still on treatment as of September 2017, and is reporting serious adverse events (SAEs) via PViMS. SIAPS contributed to aDSM cascade training in Georgia in August–October 2017, which resulted in 79 SAEs reported after the training, compared to 37 SAEs reported since the new medicines were released in 2014. Doctors have become much more aware of adverse events that would have been missed before training and underreported.

To increase access to new MDR-TB medicines, bedaquiline and delamanid, SIAPS worked with Georgia, Kenya, Philippines, Swaziland, and Uganda to improve capacity in quantification, supply planning, and pharmacovigilance.
In Philippines, SIAPS partnered with the Department of Health’s Pharmaceutical Division, Food and Drug Administration, and the NTP to adopt and implement PViMS as a national PV tool. SIAPS supported the development of guidelines and standard operating procedures; established a national database; and conducted a training workshop in September 2017 for 63 health professionals from nine regions and from government partners, including all 10 health facilities that are piloting STR, bedaquiline, and delamanid. SIAPS consultants also provided on-site hands-on mentoring for the staff at seven health facilities in seven regions that are implementing STR, bedaquiline, and delamanid.

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 course of bedaquiline and is steadily enrolling eligible patients.

In Uganda, SIAPS provided technical assistance on revising the supply plan for bedaquiline and companion medicines for 20 patients undergoing treatment with bedaquiline and helped the NTP review recording and reporting forms and processes for SAEs. In Kenya, the uptake of new medicines was slow because of the country’s weak capacity to diagnose and select patients for treatment with new medicines. SIAPS helped Kenya adjust the country’s procurement and supply plan to reflect the realities of slow uptake.

Lessons Learned and Way Forward

The USAID approach, which allowed SIAPS to use core funding for direct technical assistance to priority high-burden countries via regional and full-time in-country technical advisors, proved efficient in achieving project results; however, identifying and training such advisors is a challenge that slowed down the implementation of this strategy in some countries.

Early engagement of country stakeholders and the rapid transfer of SIAPS tools, best practices, and knowledge to NTPs are key for their successful adoption and implementation as national tools and practices.

With SIAPS ending in 2018, buy-in from all stakeholders, including global donors, countries, and implementing agencies, is required to ensure the sustainability of project gains in countries. For example, the adoption of QuanTB by the Global Drug Facility as its forecasting, quantification, supply planning, and early warning tool significantly improved the supply of TB medicines by reducing stock-outs and waste of medicines, and the implementation of e-TB Manager by ChallengeTB as a programmatic management of drug-resistant TB (PMDT) strengthening platform improved planning and decision making in countries such as Indonesia, Vietnam, and Nigeria.

Ongoing capacity strengthening in good PSM practices and the use of modern electronic tools, especially for the introduction and scale up of new TB medicines and regimens, remains a challenge because of high staff attrition and turnover rates in countries and will require continuous investments from donors and countries.

The rapid introduction and scale-up of new TB medicines and regimens requires local champions for good coordination of all players. Ordering medicines based on approved cohorts and funding without factoring in the diagnostic, treatment, and patient holding capacity and other PMDT challenges of a country often leads to overstock and waste or stock-outs of TB medicines.

SIAPS developed PViMS to consolidate and analyze PV data for more evidence-based decisions to promote patient safety. Managing adverse events without an electronic system can be challenging in settings with low statistical capacity.

All SIAPS electronic tools developed with TB core funding, including QuanTB, e-TB Manager, and PViMS, help countries address the need for information for decision making and are in great demand, particularly in countries introducing new TB medicines and regimens. As the project is ending, SIAPS made a decision to make these tools publically available through an open source repository for further development and evolvement by any interested partner or country.
REGIONS
SIAPS Strategy for LAC/AMI

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

Highlights from Program Year 6

Pharmaceutical services improved to achieve desired health outcomes

The National Directorate of Medicines (DIGEMID) in Peru requested technical assistance for a nationwide implementation of the SOPs for pharmaceutical management that DIGEMID developed last year with SIAPS’s help. These SOPs will improve the supply of antimalarials, essential medicines, and supplies used by disease control programs. During the year, SIAPS supported the final revision of the SOPs, creating a nationwide roll-out plan in public sector health facilities, and the methodology for regional training workshops. The first workshops are to be held in October 2017. As SIAPS AMI is ending in September 2017, SIAPS has coordinated with local counterparts for them to conduct workshops that occur after SIAPS closes.

Managing for results in malaria control and treatment

SIAPS visited Bogota, Colombia, in October 2016 to present the evaluation of malaria control strategies that use an adequacy approach to national and local authorities and technicians. The participants agreed on the implementation of low-cost local interventions to close the performance gap and on the inclusion of this type of evaluation in the regular malaria program activities. A final report was developed and distributed to all interested parties.

Designing interventions for a difficult to reach location in Brazil

During SIAPS supported the systematization of interventions to improve access to malaria diagnosis and treatment in the gold mining areas of Para, Brazil. This year, SIAPS monitored the progress of the implementation of these interventions and the results. A report was developed and distributed to national counterparts and AMI partners.
SIAPS/West Africa Regional Project (WARP) facilitates the availability of quality pharmaceutical products, especially those related to HIV/AIDS, to achieve high level, desirable health outcomes in targeted West Africa countries.

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

Highlights from Program Year 6

Supporting the nationwide rollout of EDT

During the fifth program year, SIAPS assisted the National AIDS Control Program of (PNLS) Togo in piloting EDT at five sites. EDT is actively used at the sites to record patient data and medicines used to treat HIV-positive patients; four sites have completely stopped using a paper-based dispensing register. This year, SIAPS continued supporting EDT users through supportive supervision visits, trainings, and addressing software issues affecting the use of EDT at the pilot sites. The supervision team assessed the quality of data using two indicators: 1) the concordance between the EDT record and physician prescriptions with regard to patient number, regimen, type of treatment, and medicines; and 2) the concordance between physical stock (physical inventory conducted the day of the site visit) and theoretical stock (stock on hand in the EDT on the day of the site visit). Impressively, all five pilot sites showed 100% concordance for both indicators.

SIAPS then led an evaluation of the pilot phase to inform technical and management functions prior to the nationwide rollout. The evaluation is expected to be finalized at the beginning of the next fiscal year.

Preventing stock-outs by analyzing commodity management with OSPSIDA

With support from SIAPS, Togo’s PNLS entered shipment data into OSPSIDA, a SIAPS-developed HIV/AIDS commodity management tool, to allow for a thorough analysis of the pipeline. When reviewing OSPSIDA reports, SIAPS and the PNLS noted that there would be stock-outs of two key products—tenefovir-lamivudine-efavirenz and abacavir-lamivudine—if orders were delivered as initially scheduled. Teneovir-lamivudine-efavirenz alone is used by 70% of patients on ARV treatment in Togo. Based on OSPSIDA data, the PNLS requested urgent delivery from the supplier, and products were delivered and distributed to care and treatment sites as quickly as possible to prevent treatment interruption to the majority of patients.

Transferring full ownership of OSPSIDA to the Government of Cameroon

Following a capacity-building exercise conducted on hosting and performing routine maintenance of OSPSIDA at the end of the fifth program year, SIAPS supported the National AIDS Control Commission of Cameroon (CNLS) in copying and transferring data from the regional dashboard (www.ospsida.org) to Cameroon’s dashboard (www.ospsida-cameroun.cm), which is hosted on a server in Cameroon. Cameroon’s dashboard went live in December 2016.

SIAPS provided remote capacity-building exercises to CNLS staff to assist them in managing and monitoring the effective use of OSPSIDA Cameroon to avoid any interruption of data entry. This transition has been completed successfully and was documented as a key achievement to ensure country ownership and the sustainability of OSPSIDA in Cameroon.
COUNTRIES
SIAPS Strategy in Bangladesh

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

Highlights from Program Year 6

Contributions to the MOHFW Sector Program

Objectives of the SIAPS program in Bangladesh were approved and included in the Ministry of Health and Family Welfare’s (MOHFW) fourth sector program—the Health, Population and Nutrition Sector Program (2017–2022). SIAPS contributed to the following key strategic objectives:

1: Strengthen governance and stewardship of the public and private health sectors

4: Strengthen the capacity of the MOHFW’s core health systems—financial management, procurement, and infrastructure development

6: Strengthen the evidence base for health sector decision making

7: Improve equitable access to and utilization of quality health, nutrition, and family planning services

Successful pilot of the Asset Management System

To promote transparency and efficiency in health facilities, SIAPS collaborated with key stakeholders, such as the MOHFW and the World Bank and other donors, to develop the electronic asset management system (AMS) to track information pertaining to medical and nonmedical equipment. The AMS was piloted in December 2016 at Moulvibazar District Hospital; this intervention was a disbursement-linked indicator tied to the results-based financing program with the World Bank and valued at USD 5 million. Following the success of the pilot, SIAPS conducted a feasibility study for scaling up the AMS in three districts. At the end of the program year, the AMS Technical Working Committee had gained approval from the minister of the MOHFW to continue implementation and requested SIAPS’s assistance in the roll out.

Ensuring the availability of MNCH commodities through an information management system

During this program year, SIAPS assisted the Directorate General of Health Services in establishing an electronic logistics management information system (eLMIS) for 25 life-saving priority maternal, newborn, and child health (MNCH) medicines using the DHIS2 platform. The eLMIS is currently used in 3,070 health facilities in 14 districts. As of July 2017, the average reporting rate had increased to 95%, up from 80% the previous year. Implementation partners, including UNICEF, UNFPA, and MaMoniHSS (Save the Children), have sought SIAPS’s technical assistance to roll out the system in their working districts, and an effective partnership has been established among these organizations.

Developing a five-year strategic plan to strengthen the regulatory system

SIAPS has provided technical assistance to develop the five-year strategic plan (2017–2021) to strengthen pharmaceutical regulation in the Directorate General of Drug Administration (DGDA). The plan was drafted in collaboration with a diverse group of partners, including the MOHFW, DGDA, USAID, WHO, Promoting the
Quality of Medicines program, the Bangladesh association of pharmaceutical industries, and pharmaceutical companies. The strategic plan sets out seven goals to address specific weaknesses and ultimately strengthen the medicine regulatory system. The plan also aligns with the MOHFW’s fourth sectorwide program to improve health services.

SIAPS also provided technical assistance to develop the 2017–2018 training plan as a component of the strategic plan. This training plan has been handed over to the DGDA and other development partners so that all partners will have a role in increasing the capacity of DGDA staff.

Introducing online medicine registration using common technical documents

SIAPS developed Pharmadex, a country-specific online drug registration system that was successfully launched in May 2017. Pharmadex is now being used as a platform for the effective implementation of drug registration applications, called common technical documents (CTDs), by tracking the process of drug registration, licensing, and overall regulatory management. During this program year, SIAPS developed the CTDs and provided training to the DGDA and pharmaceutical manufacturing officials on medicine registration and reviewing CTD-based medicine dossiers through Pharmadex. SIAPS continues to provide support to companies and DGDA officials on the registration and evaluation process of CTDs in Pharmadex.

In collaboration with the DGDA, SIAPS introduced the retail prices of 28,212 registered allopathic products in various pack sizes on the DGDA web portal (http://www.dgda.gov.bd/), where users can search for and compare prices of allopathic products easily.

Improving procurement and supply management functions in the National TB Program

Throughout the life of the program, SIAPS has been working with the National TB Program’s (NTP) procurement and supply management working group. With SIAPS support, the group now meets regularly and conducts quantification and forecasting using QuanTB. This program year, SIAPS contributed to the NTP’s Global Fund grant application by assisting in quantification, forecasting, and budgeting for the three-year grant.

This year, SIAPS also introduced the Warehouse Inventory Management Systems (WIMS) in the central TB warehouse at Shyamoli, with data entry beginning in June 2017. At the end of the sixth program year, TB medicines and products were being added to the electronic system, enabling the NTP to compare system generated and manual data for verification, accuracy, and triangulation. The WIMS is part of the NTP’s overall upgrade to the inventory system at the Shyamoli central warehouse.
SIAPS Strategy for Benin

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

Highlights from Program Year 6

Strengthening the medicine registration process

This year, SIAPS supported the DPMED to strengthen the medicine registration process and related information management system. In October 2016, SIAPS conducted an assessment of the country’s medicine registration system and recommended actions to strengthen it through the implementation and use of Pharmadex, a SIAPS-developed online medicine registration platform. Ultimately, DPMED officials and SIAPS agreed to update the country’s existing registration system and SIAPS conducted a situational analysis. New recommendations were made, and a high-capacity server was procured to optimize the full implementation of the existing electronic registration tool. SIAPS further assisted by supporting the DPMED in processing the backlog of registration applications.

Finalizing the cost of implementing the five-year supply chain strategic plan

SIAPS supported the DPMED in drafting and finalizing the five-year (2016–2020) strategic plan for supply chain management. Following approval of the plan, SIAPS worked closely with various government entities at the central and regional levels to estimate the plan’s cost. Together, they reviewed activity targets, accompanying strategies, and required resources. SIAPS then developed a budget template and collected information on unit cost, and the DPMED approved of a final cost of USD 62,633,541 for the strategic plan.

Capacity building to improve pharmaceutical system resiliency

SIAPS completed the quantification exercise and supported the MOH to hold a stakeholder meeting to establish guidelines for the quantification of Ebola products. Using historical procurement data and online sources, SIAPS completed the development of an Excel model that was used to estimate the needed quantity of each product based on combined morbidity and service utilization statistics during a one-month outbreak.

SIAPS also supported the DPMED and the National Directorate for Public Health to finalize the Ebola standard operating procedures manual, including logistics system management, which was developed for commodities used for the prevention and treatment of Ebola and other viral hemorrhagic fevers. The manual was ready for printing and dissemination in August 2017.

Analyzing stock availability of malaria commodities

USAID requested SIAPS to conduct an end user verification survey in Benin. The survey is a mechanism to track and report the availability of malaria health commodities, medicines, and rapid diagnostic tests (RDTs) and on the adequacy of malaria case management. The first round of the survey was conducted in July 2017 in the Borgou and Alibori regions.
The survey showed that all health facilities had at least one presentation of artemether-lumefantrine (AL) on the day of the visit, but none had all four presentations despite the fact that all AL presentations are available at the central level. The main reason is that facilities were requested to use AL3x6 and AL6 that were about to expire. Survey findings showed that 15% of visited health facilities had stock-outs of RDTs on the day of the visit, and 18% experienced three days or more of stock-outs for this product during the previous three months. The stock-outs were solely due to the close expiration date of the available RDTs at the regional warehouse and not to a shortage. The procurement unit was reluctant to buy more of those items as long as the remaining balance was above the alert threshold.
DOMINICAN REPUBLIC

SIAPS Strategy in the Dominican Republic

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

Highlights from Program Year 6

Enhancing service by improving staff’s knowledge of pharmaceutical management and rational use

Last year, SIAPS finalized the educational modules for the certified course on rational medicine use, which was implemented in partnership with the Universidad Central del Este (UCE). This year, SIAPS continued its participation and supported a second certified course (diploma) on rational medicine use, which ended in February 2017. USAID sponsored tuition for 21 students who began the third course in July 2017 at UCE.

Before closing the SIAPS/Dominican Republic program at the end of September 2017, SIAPS revised the content for the fourth Pharmaceutical Supply Management Diploma course. The revised course content and materials are now fully owned by UCE for future use.

Supporting information availability to implement the HIV/AIDS Test and Start Strategy

This year, SIAPS supported pharmaceutical management components in the nine health facilities implementing the HIV/AIDS Test and Start Strategy. This support included monitoring visits and collecting data on ARV consumption and stock availability. With this information, SIAPS developed a “traffic light” visual aid to facilitate the identification of overstock and stock-outs in facilities and spur immediate implementation of corrective measures. Through these efforts, health facilities demonstrated improvements in pharmaceutical practices and increased availability of ARVs.

Enabling decentralized procurement management with simplified tools for data analysis

SIAPS finalized the guidelines for the quantification and programming of medicines and supplies. These guidelines include links to all electronic applications for data entry and analysis and will expedite future programming exercises without the need for external technical assistance. Prior to conducting the needs estimation exercise for 2018, SIAPS tested and trained personnel on the using the electronic applications. Consumption and stock data from SUGEMI were used by 131 hospitals and seven regional health services (RHSs) to conduct their estimates. After the exercise, SIAPS supported the consolidation of the regional estimates and presented the final results to Ministry of Health and Finance authorities.

Improving commodity data availability at different levels

To make SUGEMI more comprehensive, SIAPS participated in discussions to integrate family planning commodities and second-line TB medicines into the system. The MOH staff of these disease programs, in coordination with national and regional pharmaceutical units, managed the transfer process.

In PY6, SIAPS also supported the National Medicines Directorate and RHSs in the development of one national and nine regional SUGEMI bulletins. These bulletins include information on the consumption and availability of essential medicines, including ARVs and TB medicines. By the close of SIAPS, RHSs were able to produce these bulletins with minimal support from SIAPS.
SIAPS Strategy in Ethiopia

Building on a decade of related work in Ethiopia, SIAPS is active in a broad range of program areas, including strengthening pharmaceutical governance, management, and policy. Work this year focused on supporting new regulatory measures to help ensure quality pharmaceutical services, strengthening information management for antiretroviral therapy, and increasing access to quality medicines through the implementation of an online quality assurance system.

Highlights from Project Year 6

Streamlining the medicines registration process to increase efficiency and transparency

In support of the medicine registration system at the Food, Medicines, and Ethiopian Healthcare Administration and Control Authority (FMHACA), SIAPS developed the Medicines Registration Information System (MRIS), a web-based software program, to reflect optimized product registration processes. Between the system’s launch in September 2016 and the end of SIAPS in Ethiopia in December 2016, 222 registration applications were processed, of which 158 (71%) were new applications, 43 (19%) were variations, and 21 (10%) were renewals. In addition, 321 purchase order applications were received through the MRIS, 219 (68%) were of which approved. The remaining 32% of the applications were being processed as SIAPS closed in Ethiopia. Prior to ending the program, SIAPS led a successful transition of MRIS ownership to the FMHACA. Through the MRIS, Ethiopia has institutionalized efficiencies, transparency, and accountability in the market approval process.

Furthering the national AMR agenda and promoting AMR containment in facilities

SIAPS/Ethiopia supported the development of a national antimicrobial resistance (AMR) strategy and a plan of action to guide efforts in the prevention and containment of AMR. During this program year, SIAPS helped the National AMR Advisory Committee develop its plan for carrying out the 2015–2020 Strategy for the Prevention and Containment of Antimicrobial Resistance. By the end of SIAPS, the multi-institutional committee was meeting regularly to continue its role as advisor, advocate, and catalyzer in the prevention and containment of AMR.

To complement national-level interventions, SIAPS built the capacity of members of health facility drug and therapeutics committees (DTCs) to establish audit and feedback mechanisms on the use of antibiotics in hospitals and supported DTCs to conduct regular antimicrobial use evaluations. By March 2017, approximately 54% of DTCs had implemented AMR advocacy or containment-related activities, and prescriptions containing antimicrobials decreased from 62% in 2013 to 58% in 2016 among SIAPS-supported DTCs. Notably, six hospitals demonstrated an average reduction in antimicrobial prescriptions from 53% to 37%.

Pharmaceutical services

Recognizing the benefits of patient-centered care on health outcomes, the Federal Ministry of Health (FMOH) adopted clinical pharmacy as one of the key services in the pharmacy chapter of the 2010 Ethiopian Hospital Reform Implementation Guidelines. SIAPS assisted with the introduction and provided continued support to institutionalizing clinical pharmacy services by
supporting the development and implementation of a well-structured in-service training program to build the clinical knowledge and skills of practicing hospital pharmacists in 65 hospitals.

This year, SIAPS provided technical support to hospitals on documenting clinical pharmacy services, identifying and addressing treatment errors, adherence counseling, and pharmaceutical care. During this program year, SIAPS and its partners at 43 hospitals took part in the in-service training program to review the overall status of the implementation of clinical pharmacy services.

Highlights of results include:

- 95% of hospitals started providing ward-based clinical pharmacy services
- Clinical pharmacy interventions were documented in 88% of hospitals
- 8,257 drug therapy problems have been identified since clinical pharmacy services were initiated, 87% of which led to a pharmacist intervention
- The multidisciplinary teams in patient wards accepted 88% of the pharmacists’ recommendations.
- Hospital management and team members were highly favorable of the contributions of clinical pharmacy services to improving treatment outcomes, including 97% of CEOs, 94% of chief clinical officers, 95% of ward physicians, 100% of nurses, and 97% of pharmacists

Overall, this initiative helped spur a paradigm shift in pharmacy practice in Ethiopia. Clinical pharmacy has now become an integral part of hospital services, although continued support from the FMOH will be required to scale up and consolidate the service at all hospitals.

Reinforcing parts of the Auditable Pharmaceutical Transaction and Services initiative

The Auditable Pharmaceutical Transaction and Services (APTS) initiative is a package of interventions designed to address issues of accountability, transparency, and quality of service at the health facility level. In PY6, all 11 regions had enacted APTS regulations, with the final region approving them after the close of SIAPS. APTS regulations are now being implemented in 77 health facilities, 70 hospitals, and seven health centers throughout the country. The introduction of new cadres, such as pharmacy accountants and cashiers, has transformed access to financial information related to medicine sales, reduced wastage, and contributed to a substantial reduction in patient waiting time, while increasing patient satisfaction.

This year, SIAPS continued supporting health facilities in their APTS initiatives, including the reorganization of dispensing processes and patient waiting areas to improve patient satisfaction. Many of the hospitals SIAPS assisted this year have achieved cost savings by implementing this initiative and are now able to fully finance the changes made with SIAPS’ recommendations. This, among other achievements, demonstrates a major impact of implementing APTS—hospitals are improving patient care while achieving efficiency in a sustainable manner.
SIAPS Strategy in Guinea

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

Highlights from Program Year 6

Revised pharmaceutical law

A national committee was set up by the National Directorate of Family Planning (DNPM) to revise existing pharmaceutical legislation. The law did not reflect the current pharmaceutical sector, nor did it recognize international best practices, standards, or the globalization of the pharmaceutical industry. During this program year, SIAPS assisted in facilitating the coordination and validation process by working with internal and external stakeholders to gather their input. SIAPS also helped recruit legal and pharmaceutical experts to ensure that the proposed law conforms to Guinean Law and Penal Code and international standards. By the end of SIAPS, the DNPM had finalized a draft of the revised pharmacy law and sent it to the Minister of Health for signature and validation, after which the law is expected to be discussed and adopted by the national assembly.

Finalization of the updated National Essential Medicines List

SIAPS/Guinea has been assisting the DNPM in revising and updating the 2013 National Essential Medicines List (NEML) by facilitating meetings and workshops with internal stakeholders throughout the MOH. During the second quarter of this year, the Minister of Health endorsed the revised NEML, which enables patients to benefit from the inclusion of safe and effective treatments of priority diseases, increased rational use, and optimization of available health resources.

Enhance the capacity of Guinea’s National Malaria Control Program

During PY6, SIAPS/Guinea aimed to enhance the capacity of its National Malaria Control Program (PNLP) to sustain quantification activities. SIAPS assisted the PNLP to conduct monthly meetings of the Procurement and Supply Management Technical Working Group, which analyzes malaria commodity supply levels, identifies bottlenecks, and develops solutions to mitigate stock-outs and expiries. These meetings help stakeholders identify and agree on interventions to address supply chain challenges affecting commodity availability at the facility level.

To further improve the PNLP’s ability to conduct quantification activities, SIAPS supported integrating the PNLP’s management information systems (MIS) with the MOH MIS (i.e., DHIS2 and the integrated logistics management information system (LMIS)), by reviewing and adapting the PNLP reporting tools to the DHIS2 and LMIS report formats.

Establishing a Logistics Management Unit for better supply management

As part of its work in creating a resilient pharmaceutical system following the Ebola outbreak in 2014, SIAPS assisted the DNPM in establishing a Logistics Management Unit (LMU). The LMU was created through Ministerial decree to institutionalize good supply chain management practices by linking logistics activities throughout the supply chain system through the use of an
LMIS. This assistance included developing terms of reference for a steering committee charged with overseeing the LMIS, finding office space, and recruiting LMU staff.

Once the LMU was staffed at the central level, SIAPS supported LMU staff in coordinating and reviewing LMIS reports from the district and facility levels. Throughout the year, SIAPS trained 511 health personnel from all regions on the standard operating procedures for the paper-based LMIS and assisted the LMU with following up to ensure consistent reporting. As a result, the average LMIS data reporting rate for the first quarter of 2017 was 70.51%.

To further streamline data management, SIAPS helped deploy the electronic LMIS (eLMIS) v2.0. During the third quarter, SIAPS completed the installation of the eLMIS server and conducted system administrator training for 25 super users at the central level to ensure deep understanding of the server and how to maintain and troubleshoot the system. Building capacity and transferring skills to a selected pool of national experts helps safeguard the eLMIS platform going forward.

Institutionalizing an operational system in regional warehouses

Guinea's central medical store (PCG) has been undergoing a process to automate its operations by installing SAGE L100, which can manage human resource functions, such as payroll, operations, and financial management, as well as supply management. SIAPS assisted with project management to meet the go-live date, trained PCG staff on SAGE L100 modules, and recruited a database specialist as a super user to train PCG staff and monitor the system’s operational efficiency.

Activities included working with Catholic Relief Services (CRS), the European Union/Projet d’Appui a la Santé, and other partners to procure and install computer hardware and network equipment to deploy SAGE L100 in six PCG regional depots. SIAPS also supported the PCG during a stock count of all pharmaceutical products stored at the PCG main warehouse in Conakry and all six regional depots. In addition, SIAPS assisted the PCG in analyzing and validating master data (e.g., item base data, finance data, employee base data) prior to uploading the master file to the live system.

After the tool became functional, PCG staff used it independently and SIAPS provided occasional onsite assistance. Prior to closing the program in Guinea, SIAPS worked with the PCG leadership team to assess SAGE’s progress, address process and system issues in a timely manner, answer questions, and provide guidance and support. Future technical assistance will be provided by partners, such as CRS, to ensure the institutionalization of the SAGE software.
SIAPS Strategy for Mali

In Mali, the SIAPS strategy emphasizes Ebola; malaria; family planning; and maternal, newborn, and child health commodities. To meet Ministry of Health (MOH) and stakeholder priorities and expectations, SIAPS focuses on strengthening pharmaceutical sector governance, improving human and institutional capacity, and establishing a functional logistics management information system.

Highlights from Program Year 6

Supporting innovative storage warehouses

To overcome storage management infrastructure obstacles, SIAPS and other partners have supported the central medical store (PPM) in designing and building Warehouses-in-a-Box (WiBs), which are prefabricated warehouses that can be rapidly deployed and expanded to meet the country’s commodity storage needs. During this program year, SIAPS supported the PPM in the planning, design, and selection of a local vendor to construct WiBs. At the end of the year, the chosen contractor, Resolve, had begun building WiBs in the regions of Kayes, Koulikoro, and Mopti and the district of Bamako.

Including Ebola commodity management in OSPSANTE

Mali health officials at the central and regional levels have been using OSPSANTE, which is a SIAPS-developed health commodity and patient care dashboard. The MOH, warehouses, and health facilities input information into OSPSANTE and it tracks and aggregates data on malaria, HIV, family planning, essential medicines, maternal and child health, and nutrition, allowing for improved analyses. This year, SIAPS and the MOH established an Ebola portal to further enhance the country’s ability to make evidence-based decisions about Ebola and other hemorrhagic fever-related commodities. SIAPS worked closely with the Department of Public Health Emergency Operations to plan and train peripheral-level officials to enter Ebola commodity data into OSPSANTE and monitor the availability of commodities. A total of 35 providers were trained, and as of May 2017, the reporting rate at the district level was 83.3%.

Continued capacity building for the sustained use of OSPSANTE

As part of the ongoing effort to build sustainable capacity in pharmaceutical management, SIAPS has strengthened the skillset of local partners, such as the DPM and the National Agency of Telehealth and Medical Informatics, who are now equipped with the knowledge to assume management of OSPSANTE. SIAPS conducted training on OSPSANTE’s front- and back-end systems and provided the system requirements for hosting OSPSANTE on a server owned by national entities.

To further achieve sustainability in using OSPSANTE, SIAPS has been working with the National Technical Committee and development partners to establish interoperability between OSPSANTE and DHIS2. This activity is expected to be completed early in the next fiscal year.
SIAPS Strategy in Mozambique

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

Highlights from Program Year 6

Updated the National Essential Medicines List

During the sixth program year, SIAPS led the efforts and worked with the Pharmaceutical Department (PD) to update the National Essential Medicines List (NEML). SIAPS sought input from the PD and relevant entities to produce a guide for future revisions of the NEML, the updated terms of reference for the NEML Committee, the monitoring and evaluation (M&E) plan, the distribution plan, and a concept note to review the National Formulary Manual. The NEML is expected to be finalized and sent to the Minister of Health for approval early in the next fiscal year.

Institutionalizing efficient processes in pharmaceutical governance

Throughout the life of the program, SIAPS has assisted the PD in strengthening the regulatory system. SIAPS has worked to institutionalize Pharmadex, an electronic medicine registration system; assisted in pharmacovigilance functions; and improved the organizational management of the PD. One activity is the creation of an M&E framework. M&E data from the fourth quarter showed a decrease in the average number of days needed to register a product, from 428 days in 2011 to 274 days in 2017. At the close of this fiscal year, 47% of NEML products were registered.

This year, SIAPS has focused on increasing efficiency in the importation process. The aim is to eliminate unnecessary activities and standardize procedures, thereby simplifying the work flow and reducing the amount of time needed for the authorization of imported pharmaceutical products. After gathering input from inspection staff and identifying obstacles, SIAPS produced flow charts and process maps for the main functions, including requesting a certificate of importation, requesting a narcotics certification, and clearing customs. The PD and importation officials are tracking changes through indicators that measure the number of days for each processing step.

Analyzing pharmaceutical services to improve health outcomes

Over the last three years, SIAPS has been assisting the Hospital Pharmacy Department (HPD) of the Ministry of Health in improving the performance of hospital drug and therapeutics committees (DTCs). The HPD, SIAPS, and DTCs have collaborated to improve medicine use evaluations, adverse drug reaction reporting and analysis, management of the medicine formulary system, and HIV treatment adherence; they have also mapped processes to improve efficiency. This year, SIAPS supported the HPD in designing, testing, and scaling medicine use studies in hospital DTCs. SIAPS and the HPD conducted a pilot study to evaluate patient waiting times in the ambulatory pharmacies of two provincial hospitals. Another sponsored pilot focused on assessing ART adherence, with the following results:

- 95.8% of patients demonstrated total adherence (target is 95%)
- 58% of patients were covered by antiretrovirals (ARVs) dispensed for a defined sample of patients for an average of 180 days in the period under review (target is 100%)
- 8% of patients experienced a gap in ARV availability of more than 30 days (target is 0%)
- 96% of patients went to appointments on or before their scheduled visit (target 96%), and of those, 96% went within three days of their scheduled appointment day

SIAPS and the HPD analyzed the methodologies and will develop a plan to scale-up these studies to other health facilities.
**NAMIBIA**

### SIAPS Strategy for Namibia

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

### Highlights during Program Year 6

**Facilitating the registration and case management of newly available ARVs**

Pre-exposure prophylaxis (PrEP) is the WHO-recommended preventative measure of using ARVs to treat those who are not infected with HIV and are at high risk of infection. The fifth edition of the Namibian HIV Treatment Guidelines recommends the early adoption and uptake of the TDF/FTC-based ARV formulation (Truvada) for PrEP of HIV. However, the formulation was not registered for this indication by the Namibia Medicines Regulatory Council (NMRC). As a result of SIAPS advocacy within the NMRC, a pharmaceutical company submitted an application for the licensure of a generic TDF/FTC formulation. The NMRC approved this license in May 2017, after which SIAPS facilitated the expedited registration of TDF/FTC through Pharmadex.

PrEP treatment is further enabled by using ARV dispensing tools, including the SIAPS-developed Electronic Dispensing Tool (EDT), to streamline management and reporting to the National AIDS Coordination Program. SIAPS enhanced the EDT to cater to specific reporting on PrEP uptake and as of September 2017, at least 66 PrEP patients were being monitored through the EDT.

The availability and use of TDF/FTC for PrEP could significantly reduce the emergence of new HIV infections among high-risk groups. The NMRC’s approval of TDF/FTC brings Namibia one step closer to achieving an AIDS-free generation.

**Enhancing transparency and improving hospitals’ ability to monitor and order commodities**

Last year, SIAPS and the MoHSS developed and began installing the facility electronic stock card (FESC), which monitors commodity consumption and automatically reports facility-level data to the MoHSS pharmaceutical information dashboard to track commodities at the facility, regional, and national levels. The FESC is expected to improve efficiency in pharmacy management by automating inventory control, extending accountability through increased transparency, and enabling better informed decision making at the facility level.

This year, SIAPS contributed to the scale up of the FESC by training facility and clinic staff throughout the country. In July 2017, SIAPS, the MoHSS, and USAID celebrated equipping the 50th health facility with the FESC. The efficient use of the FESC helped the Intermediate Hospital Oshakati reduce the amount of time staff spend reordering medicines from about two weeks to two days. Staff are now able to devote additional time to providing pharmaceutical care. This also contributed to a reduction in average
waiting time at the pharmacy from one to two
days to approximately 30 minutes, while expired
medicines and products decreased from 12% in
2016 to less than 2% in August 2017.

To ensure the FESC’s sustainability, SIAPS supported
the University of Namibia’s School of Pharmacy in
updating the curriculum for pharmacy students
to include lecture sessions on using the FESC for
pharmaceutical inventory management.

*Increasing access to ARVs through decentralized dispensing*

With SIAPS technical assistance, Namibia
began implementing group ARV refills through
community adherence support groups (CASN) as
part of community-based ART (CBART), an ART
differentiated care model adopted by Namibia
in the 2016 national ART guidelines. SIAPS
supported the MoHSS and partners in configuring
the EDT for dispensing ARVs to CASGs, a
change from dispensing to individuals. SIAPS
also developed and oriented health workers on
pharmacy dispensing SOPs, which include process
flow for group ARV dispensing and monitoring
tools that will be used by pharmacy staff and
CASG leaders. The EDT is used for dispensing
ARVs and capturing ART patient information,
including adherence to treatment in public health
facilities. As of May 2017, 55 groups had been
created with approximately 665 ART patients who
were ready for implementation of CBART.
SIAPS Strategy in Philippines

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

Highlights from Program Year 6
Promoting community-level TB program management and service delivery

During the sixth year of the program, SIAPS continued to support the Quezon City Health Department in implementing the Barangay Health Management Council (BHMC) Initiative throughout the city. The initiative brings together community groups, officials, and health providers to improve TB program management and service delivery in poor urban settlements (barangays). This year SIAPS finalized the BHMC guide to help local government units establish BHMCs in their areas. It includes guidance for the preparatory phase, which includes the barangay situational analysis and the organization of the BHMC core team and secretariat; operationalizing the BHMC, including developing, implementing, and monitoring the BHMC work plan and evaluating the results; and monitoring and evaluating BHMC establishment and performance. It also includes strategies to institutionalize and sustain BHMCs.

To promote cross-national learning, SIAPS conducted a meeting and field visit to a BHMC in Quezon City in response to a request from Japan’s Nagasaki University School of Tropical Medicine and Global Health for its graduate students. The participants in this activity included students from Japan, Myanmar, Uganda, Ghana, the Democratic Republic of Congo, and other countries and supervising staff of Nagasaki University. The discussions and field visit gave students and faculty real-time exposure to BHMCs as they exist and operate in the community.

Institutionalizing the active PV surveillance system to increase patient safety

Last year, SIAPS worked closely with the Philippine Food and Drug Administration (FDA) to launch the Pharmacovigilance Monitoring System (PViMS), a web-based application that streamlines and simplifies data collection and analysis of PV information. This year, SIAPS successfully deployed PViMS in the Department of Health (DOH) infrastructure, where it initially will be operationalized in the Lung Center of the Philippines-National Center for Pulmonary Research. Importantly, PViMS serves as the country’s national active TB drug-safety monitoring and management (aDSM) database and is the active PV tool for the shorter standard-treatment regimen (SSTR) for MDR-TB and operational research for bedaquiline, the first TB medicine to be approved by the US Food and Drug Administration in more than 40 years. In addition, data encoded in PViMS can be generated into an e2B format, which is the preferred FDA format for ADR reports.

SIAPS developed and finalized the PViMS User Guide: Active Reporting of Adverse Events together with the Lung Center of the Philippines, the FDA, the National TB Program, and the DOH divisions Knowledge Management Information Technology Services and Pharmaceutical Division (PD). The user guide outlines the key data needed and serves as a reference in reporting adverse events through PViMS. Information will be used throughout the analytical process, from making the initial report to providing supplementary data.
required for analysis. The guide features SOPs that will support the PViMS implementation. The DOH has disseminated the document throughout the department.

Utilizing the PViMS user guide, SIAPS organized and conducted the PViMS training and a planning workshop in partnership with the DOH-PD on aDSM implementation. Attended by 63 participants from 9 regions, this was the first forum for staff from different DOH central and regional offices of the NTP, PD, FDA, and 10 sites implementing STTR to discuss ways to strengthen the coordination, recording, reporting, and health workers’ capacity building of PV in their respective systems. Each region drafted plans to implement one of the key activities of aDSM.

SIAPS Philippines also provided on-site mentoring on aDSM data collection and the use of the PViMS in 7 of 10 facilities that are the first implementers of SSTR. Staff were capacitated to report serious adverse events experienced by patients under SSTR and bedaquiline in PViMS, a core requirement of aDSM implementation. All visited sites have successfully encoded PV data in PViMS.

Building capacity in laboratory diagnostics at the regional levels

SIAPS collaborated with the National TB Reference Laboratory Training and Development Unit, and NTP coordinators from three regions to develop the GeneXpert training of trainers course and the GeneXpert Understudy Training Program. GeneXpert is a TB diagnostic test that uses TB bacteria for diagnosis. These are part of the initiative to decentralize laboratory training to build capacity of laboratory managers up to the peripheral level. These trainings will hasten the expansion of rapid TB diagnostic laboratories using GeneXpert nationwide, thereby increasing access to quality TB diagnosis. This collaboration supports the Philippine Health Agenda through the Philippine Strategic TB Elimination Plan: Phase 1 2017–2022.
SIERRA LEONE

SIAPS Strategy for Sierra Leone

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

Highlights from Program Year 6

Supporting reforms to the national entity for pharmaceutical procurement

When SIAPS began operating in Sierra Leone, the National Pharmaceutical Procurement Unit (NPPU) was the government entity responsible for procuring the country’s medicines and products. However, the NPPU’s weaknesses became apparent during the Ebola outbreak, resulting in a lack of coordination among the Ministry of Health and Sanitation (MOHS) and development partners. Consequently, the MOHS proposed replacing the NPPU with the National Medical Supplies Agency (NMSA) as the unit responsible for the procurement, warehousing, and distribution of drugs and other medical supplies to operate in a transparent, accountable, and cost-effective manner.

This year, SIAPS worked with the MOHS to reform the NPPU, provided comments on the draft bill, and participated in the subsequent parliamentary committee discussions, after which it was presented to Parliament for approval. SIAPS also advocated for professional warehousing of pharmaceuticals, including safe incineration.

Parliament approved the act in August 2017, and it is now awaiting presidential assent.

Institutionalizing comprehensive oversight of the pharmaceutical sector

The Directorate of Drugs and Medical Supplies (DDMS) is the MOHS directorate responsible for oversight and support in the pharmaceutical sector. SIAPS has strived to build the capacity of DDMS officials since the program began in 2015, and last year, SIAPS provided technical assistance in the development of a DDMS organogram. The organogram was approved this year and is currently used as the structural framework to implement DDMS’ mandate. Importantly, it incorporates the functions of a pharmaceutical system—governance, capacity, information, finance, and services—and creates units to manage these thematic areas. Office IT equipment and technical reference books have already been procured to bolster the directorate’s capabilities.

Leadership Development Program

To support good governance in the pharmaceutical sector, SIAPS conducted a ten-module Leadership Development Program (LDP) to teach pharmacists the basic practices of good leadership, management, and governance to help them identify challenges, solve problems, and lead their teams. It was the first such training in the country and 17 pharmacists from the DDMS, districts, and hospitals participated in the two-week training of trainers (TOT). The purpose was to create a pool of LDP facilitators who could then cascade the program as trainers throughout the country’s 13 districts.

At the end of the TOT and future cascade trainings, participants receive a 4-GB flash drive containing an extensive library of workshop materials.
materials and other technical materials that the trainers can use for future training in their respective districts and participants can use to further their skills and knowledge. The pre- and post-evaluation of the LDP training showed an increase in confidence, skills, and knowledge of the participants, who were awarded certificates in recognition of their training. By the end of the program year, the trainers had facilitated the first cascade training for 35 participants from the pharmaceutical sector.

**Ensuring patient safety within health facilities**

SIAPS works with Drug and Therapeutics Committees (DTCs) because they are a key mechanism for strengthening pharmaceutical management systems and ensuring rational medicine use at health facilities. This year SIAPS Sierra Leone helped draft a series of guides to support DTC functions—an operational manual, profile and performance tracking checklist, and an action plan form. To facilitate communication and coordination between hospital DTCs and the DDMS, a focal person was identified and introduced to hospital DTC members.

SIAPS Sierra Leone continued assisting hospitals in establishing DTCs and as of the third quarter, 9 hospitals had DTCs and 19 hospitals were in the process of forming DTCs. SIAPS also mentored the DDMS DTC focal staff and hospital pharmacists in a four-hospital prescription review to capture baseline data on rational medicine use indicators.
SIAPS Strategy for Swaziland

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

Highlights from Program Year 6
Assisting in the formation of a functional regulatory authority

This year, SIAPS’ efforts in improving Swaziland’s regulatory system reached a milestone with the enactment of the Medicines and Related Substances Control Bill into law in November 2016. This law created a path for the establishment of the Medicines Regulatory Authority (MRA), which will become operational early next year. The MRA’s mission is to improve medicine availability, pharmaceutical service delivery, patient safety, and treatment adherence for patients on antiretrovirals, tuberculosis and malaria medicines, and reproductive health commodities.

To support the MRA’s formation, SIAPS provided assistance to the Office of the Chief Pharmacist in launching subcommittees focused on the MRA’s key functions. In particular, SIAPS supported the pharmaceutical recruitment and training committee to conduct an annual assessment of higher training institutions to ensure pharmacy training quality standards under the direction of the Swaziland Higher Education Council and to develop a list of all retail pharmacies to enable the MOH to maintain minimum quality standards for retail pharmacies, pharmacy personnel, and pharmacy training programs.

Further, SIAPS is assisting in the designation of ports of entry for pharmaceuticals in collaboration with the Swaziland Revenue Authority and setting terms to limit importers of pharmaceuticals to those who meet the MOH’s minimum requirements. The aim is to ensure that medicines marketed in Swaziland are compliant with acceptable international quality standards.

Enabling continuous improvement in the eLMIS

SIAPS continued supporting the collection and analysis of quality data by scaling up the use of the electronic logistics management information system (eLMIS). Data verification and mentorship support visits were conducted at 43 health facilities across the four regions of the country this year. The results indicated that 42% of health facilities were proficient in data compilation, while the remaining 58% faced challenges in using the system, including problems with data backlogs, numerous data sources to extract from, and a lack of capacity to compile LMIS reports. Most visited hospitals (75%) and clinics (60%) calculated average monthly consumption appropriately, but others struggled with this and as a result had issues determining the correct quantities to order. A general problem across facilities is intermittent access to the internet, which affects the quality of reporting by health facilities to the central level, particularly because some sites have reverted to using the manual LMIS form.

To improve data quality, SIAPS provided refresher
trainings for eLMIS users. SIAPS also contracted with a developer to update the eLMIS and include more functionality, such as offline data entry and new report templates. The offline functionality for upload/download of Excel templates on the eLMIS has been developed and is undergoing user testing by the MOH. A task team has been established that is responsible for creating in-house test cases and testing the developer’s test cases. The eLMIS will also include a reporting function for narcotic medicines that are controlled under the Office of the Chief Pharmacist. By increasing user capabilities and improving the software, the MOH will have better quality data for program management.

**AMR containment**

Last year, SIAPS began supporting the MOH’s development of the National Antimicrobial Resistance (AMR) Containment Plan 2017–2022 to guide the government and private sector in decreasing the use of antimicrobials in human and animal health. This year, SIAPS assisted in consensus building efforts so that the plan was fully endorsed by the MOH, Ministry of Agriculture, and Ministry of Natural Resources. By the end of the program year, the plan was being finalized; next steps include developing an implementation plan to be in place before the beginning of the next government financial year in April 2018.

**Improving capacity in Swaziland’s procuring entity**

SIAPS continued consulting with the Swaziland Public Procurement Regulatory Agency and the MOH to produce a final version of the Procurement Procedures Manual. By the end of the program year, the manual was close to final and is expected to be adopted as the procurement guideline for the MOH early next year. SIAPS has also been providing support to the MOH Procurement Unit on procurement tasks, including contract management and filing. Undertakings in this regard included actively participating in bid openings and evaluations and assisting with defining and clarifying specifications of various tenders.

Pursuant to supporting the MOH Procurement Unit, two senior members were trained on public-private partnership (PPP) projects. This was seen as crucial due to the MOH’s increasing propensity to enter into PPP agreements. The comprehensive training addressed the financial, legal, project management, and commercial aspects of PPPs. An additional benefit of this training is that it provided the Procurement Unit with the necessary knowledge and skills to enable it to champion the procurement of PPPs and to advocate for development of governance policies for PPP procurement.
SIAPS Strategy in Ukraine

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

Highlights from Program Year 6

Harmonizing Ukraine’s pharmacovigilance policies to align with international standards

SIAPS was tasked with developing national pharmacovigilance (PV) guidelines and aligning them with European Union (EU) regulations, particularly in terms of approaches to data collection, reporting, and analysis and decision making regarding safety of medicines. The national guidelines comprise 16 modules and represent the adapted version of the Guidelines on Good Pharmacovigilance Practices (GVP) by the European Medicines Agency, which evaluates pharmaceutical products in the EU. PV activities are organized by distinct but connected processes, and each GVP module presents a major component of PV.

SIAPS began supporting this activity in 2013, and concluded adapting the remaining modules to the Ukrainian context this implementation year. Four modules had been approved by the MOH as of June 2017, with the remaining ones under review. Once finalized, the national PV guidelines will apply to all medicines authorized in Ukraine and will facilitate the performance of PV activities nationwide by promoting RMU and patient safety by reducing adverse events.

Revising the national essential medicines list

SIAPS has been assisting the Government of Ukraine in establishing a NEML to be used as the country’s sole list for public procurement and potentially for reimbursement. Though this activity stalled for a period of time, the NEML Expert Committee continued working to finalize the NEML and took comments and suggestions from the public discussion before seeking final approval. As a result of the delay, there was time to develop two additional documents: regulations on the use of NEML medicines and a methodology for quantifying medicines included in the NEML. The MOH, Ministry of Economics, and Ministry of Finance all approved the NEML, which the Cabinet of Ministers approved in March; the NEML has been in effect since July 2017.

Setting up a program to reimburse and contain the cost of pharmaceuticals

In PY6, SIAPS supported the development of legislation to amend the price regulations framework and introduce reimbursement of medicines for ambulatory care. Price referencing was introduced as a cost-containment policy measure in January 2017. The maximum wholesaler price is determined from the lowest prices for the same medicine by international nonproprietary name in five neighboring EU countries. This pricing mechanism is applied to those pharmaceuticals included in the national reimbursement list, which is a subset of the NEML. The program is centrally financed from the state
budget through the mechanism of special targeted subvention. Financial support for the program is included in the budgetary resolution for 2018–2020, from which the state budget will be drafted.

To implement the state reimbursement program entitled Affordable Medicines, SIAPS worked closely with key stakeholders, including the MOH, State Expert Center, the nonprofit Patients of Ukraine, distributors (wholesalers), and pharmacies (retailers). SIAPS’ role was to assist in developing a comprehensive set of procedures and rules to facilitate the selection of products, price registration, and prescription rules to support implementation of the program.

The reimbursement program began in April 2017; there are 157 pharmaceutical products available in the program, with 23 of them free and others having a small co-pay. The program also covers 21 essential medicines for cardiovascular diseases, type 2 diabetes, and asthma. By the close of SIAPS in June 2017, 4,715 pharmacies were participating in the program, with the number expected to grow as new contracts between pharmacies and regional budget holders are signed.
SIAPS Strategy in Uzbekistan

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

Highlights from Program Year 6

*Strengthening the supply system of anti-TB medicines*

This program year, all 14 regions of the Republic of Uzbekistan have been using QuanTB, the quantification and early warning system, to monitor actual versus planned consumption of anti-TB medicines and to avoid stock-outs and expiries at the oblast and district levels of TB facilities.

SIAPS supported drug use reviews (DURs) in 10 oblasts, which promote optimal medication therapy according to the national treatment guidelines, prevent medical errors, and minimize adverse effects associated with second-line treatment. A total of 914 MDR-TB patient cards were reviewed.

Finally, the National Tuberculosis Program of the Republic of Uzbekistan, with support from SIAPS, conducted a knowledge exchange workshop on how to tackle the MDR-TB burden using QuanTB and DURs.