Systems for Improved Access to Pharmaceuticals and Services


Annual Report: Program Year 4
October 2014–September 2015
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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

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<td>ACPE</td>
<td>Accreditation Council for Pharmacy Education</td>
</tr>
<tr>
<td>ACT</td>
<td>artemisinin-based combination therapy</td>
</tr>
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<td>ADE</td>
<td>adverse drug event</td>
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<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
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<td>APTS</td>
<td>Auditable Pharmacy Transactions and Services</td>
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<tr>
<td>ART</td>
<td>antiretroviral treatment</td>
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<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>CCM</td>
<td>community case management</td>
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<tr>
<td>CHW</td>
<td>community health worker</td>
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<tr>
<td>CPD</td>
<td>country project director</td>
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<tr>
<td>DGFP</td>
<td>Directorate General Family Planning</td>
</tr>
<tr>
<td>DGHS</td>
<td>Directorate General Health Services</td>
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<tr>
<td>DOT</td>
<td>directly observed treatment</td>
</tr>
<tr>
<td>DTC</td>
<td>Drug and Therapeutic Committee</td>
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<tr>
<td>EML</td>
<td>Essential Medicine List</td>
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<tr>
<td>ECSA</td>
<td>East, Central, and Southern Africa [region]</td>
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<tr>
<td>EUV</td>
<td>end use verification</td>
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<tr>
<td>EWS</td>
<td>early warning system</td>
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<td>FDA</td>
<td>US Food and Drug Administration</td>
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<td>FMHACA</td>
<td>Food, Medicine and Health Care Administration and Control Authority</td>
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<tr>
<td>FP</td>
<td>family planning</td>
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<tr>
<td>GDF</td>
<td>Global Drug Facility</td>
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<tr>
<td>Global Fund</td>
<td>Global Fund for AIDS, Tuberculosis and Malaria</td>
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<td>GHI</td>
<td>Global Health Initiative</td>
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<tr>
<td>HMIS</td>
<td>Health Management Information System</td>
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<td>IPTp</td>
<td>Intermittent Prevention Treatment during Pregnancy</td>
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<tr>
<td>LCP</td>
<td>Lung Center of the Philippines</td>
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<tr>
<td>LFA</td>
<td>local fund agent</td>
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<tr>
<td>LLITN</td>
<td>long-lasting insecticide treated net</td>
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<tr>
<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>Acronym</td>
<td>Full Form</td>
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<td>--------------</td>
<td>-------------------------------------------------------</td>
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<tr>
<td>MCNH</td>
<td>maternal, child, and neonatal health</td>
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<tr>
<td>MDR-TB</td>
<td>multidrug-resistant tuberculosis</td>
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<tr>
<td>MOF</td>
<td>Ministry of Finance</td>
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<tr>
<td>MoH</td>
<td>Ministry of Health</td>
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<td>MOHFW</td>
<td>Ministry of Health and Family Welfare</td>
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<tr>
<td>MOHSS</td>
<td>Ministry of Health and Social Service</td>
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<tr>
<td>MRA</td>
<td>Medicines Regulatory Authority</td>
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<tr>
<td>NDP</td>
<td>National Drug Policy</td>
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<tr>
<td>NDRA</td>
<td>National Drug Regulatory Authority</td>
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<tr>
<td>NHTC</td>
<td>National Health Training Center</td>
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<tr>
<td>NMCP</td>
<td>National Malaria Control Program</td>
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<td>NMRC</td>
<td>Namibia Medicines Regulatory Council</td>
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<tr>
<td>NTDs</td>
<td>Neglected Tropical Diseases</td>
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<tr>
<td>NTP</td>
<td>National Tuberculosis Program</td>
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<tr>
<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
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<tr>
<td>PMDT</td>
<td>programmatic management of drug-resistant TB</td>
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<tr>
<td>PMI</td>
<td>President’s Malaria Initiative</td>
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<tr>
<td>PMTCT</td>
<td>prevention of mother to child transmission</td>
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<tr>
<td>PR</td>
<td>primary recipient</td>
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<tr>
<td>PTC</td>
<td>Pharmaceutical and Therapeutics Committee</td>
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<tr>
<td>RDT</td>
<td>rapid diagnostic test</td>
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<tr>
<td>RH</td>
<td>reproductive health</td>
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<tr>
<td>RMU</td>
<td>rational medicine use</td>
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<tr>
<td>SACU</td>
<td>South African Customs Union</td>
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<td>SADC</td>
<td>South African Development Community</td>
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<tr>
<td>SANU</td>
<td>Southern Africa Nazarene University</td>
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<tr>
<td>SCM</td>
<td>supply chain management</td>
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<tr>
<td>SCMP</td>
<td>Supply Chain Management Portal</td>
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<tr>
<td>SIAPS</td>
<td>Systems for Improving Access to Pharmaceuticals and Services [Program]</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<td>SPS</td>
<td>Strengthening Pharmaceutical Systems [Program]</td>
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<tr>
<td>TB</td>
<td>tuberculosis</td>
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<td>TDF</td>
<td>Tropical Disease Foundation</td>
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<tr>
<td>TOR</td>
<td>terms of reference</td>
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<tr>
<td>TOT</td>
<td>training of trainers</td>
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<tr>
<td>UNITAID</td>
<td>global health organization for increased funding for HIV and AIDS, TB, and malaria drugs</td>
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<tr>
<td>VPP</td>
<td>Voluntary Pooled Procurement</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>XDR</td>
<td>Extensively drug-resistant tuberculosis</td>
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Systems thinking is now a widely accepted concept in global health\textsuperscript{1,2}. Over recent years, governments and donors have acknowledged that it is simply not enough to guarantee the availability of medicines with a view to improving health outcomes, when there is no assurance of the availability of quality medicines, which are prescribed and dispensed appropriately by health care workers and used properly by the patient. In order to achieve improvements in health for their populations and address health inequities, governments and donors must invest in strengthening health systems. Health systems depend on the continuous availability of safe, effective, and affordable essential medicines and other health technologies of assured quality to deliver effective health interventions that improve health outcomes. This is in alignment with USAID’s Vision for Health Systems Strengthening (2015-2019). To that end, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program focuses on achieving positive health outcomes by assuring the availability of quality pharmaceutical products and effective pharmaceutical services.


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

**A pharmaceutical system** consists of all structures, people, resources, processes, and their interactions within the broader health system that aims to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services and promotes 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. The critical components of a pharmaceutical system are its core functions, structures, the supporting health system resources, and an enabling policy, legal, and governance framework.

SIAPS Program objectives are to help countries to—

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

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

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

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

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

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

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

All interventions are designed to focus on sustainable systemic improvements of pharmaceutical management and pharmaceutical service provision through capacity building of institutions and individuals. Furthermore, the SIAPS Program recognizes that sustainable improvements in all pharmaceutical system components are critical for responsive, resilient system performance that can meet the test of epidemics, such as the recent Ebola outbreaks in West Africa, and ensure uninterrupted access of life-saving commodities.

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The SIAPS Approach to Pharmaceutical System Strengthening

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

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

\textsuperscript{7} Julio Frenk. 2010. The Global Health System: Strengthening National Health Systems as the Next Step for Global Progress. PLOS Medicine, 7(1); e1000089.
comprehensive solution including medicines availability, therapeutic substitution based on product availability, strengthened quality assurance in the supply chain to assure product quality, rational use to avoid overuse as it relates to stock-outs and supply imbalances. Therefore, SIAPS strives to build capacity for comprehensive, patient-centered pharmaceutical care practices, anchored by effective informational systems, tools, and capacity to help promote rational medicines use, improve medication adherence, and slow the development of drug resistance.

Working to Strengthening Pharmaceutical Systems

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

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

Our core and resource partners bring a mix of skills and expertise in pharmacy education and training, pharmaceutical health insurance, cost-effectiveness evaluations and research, logistics management, pharmacovigilance, pharmacoeconomics and epidemiology, laboratory strengthening, mission sector coordination, research and evaluation, operations research, and management information systems. Core partners include the Accreditation Council for Pharmacy Education (ACPE), Harvard University, the Logistics Management Institute (LMI), and the University of Washington. Specialized resource partners include the African Medical Research Foundation (AMREF), Ecumenical Pharmaceutical Network (EPN), Results for Development (R4D), Imperial Health Sciences (IHS), VillageReach, and the William Davidson Institute.
The SIAPS program's ultimate objective is to institutionalize its PSS interventions to ensure the sustainability of activities beyond the life of the program. Consequently, central to the execution of the SIAPS PSS framework is involving key local stakeholders: local governments, service providers, and the community. Lessons learned from the first four years of operationalizing the SIAPS PSS framework, as guided by the SIAPS core operating principles, are described below.

Build on and Strengthen Existing Systems

Country ownership challenges USG and recipient nations alike to work to create sustainable health systems that are eventually owned, managed, and operated by host governments and their citizens. SIAPS technical assistance will continue to be designed to simultaneously address countries’ most pressing needs in the short term, while building on existing systems and local capacity to increase country ownership, and therefore sustainability of USAID investments, in the long term. As such, SIAPS activities are developed in alignment with in-country health goals, and designed, implemented, and monitored in close collaboration with in-country stakeholders. Advocacy has been critical to SIAPS’ success in securing necessary commitment and facilitating effective and sustainable improvements in pharmaceutical system in Angola, Bangladesh, the DRC, Dominican Republic, Ethiopia, Namibia, and Swaziland. SIAPS will therefore continue to match advocacy strategies to host governments’ needs.

Integrate Public Health Programs and Supply Systems

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

Build the Capacity of Local Organizations and People

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

Engage in In-Country Coordination of Support from Various Stakeholders

SIAPS helps to capacitate governing bodies to create and use mechanisms for in-country stakeholder collaboration to optimize donor resources, coordinate pharmaceutical management planning, and harmonize tools and approaches. In this regard, SIAPS endeavors to enlist the various stakeholders, including civil society, that have an interest in or are affected by SIAPS-supported activities and to build the capacity of partners who will take over leadership and oversight of these efforts. SIAPS will build on collaboration strategies applied in Angola, Bangladesh, Burundi, DRC, East Africa, Ethiopia, Guinea, Latin America and the Caribbean (Amazon Malaria Initiative), Lesotho, Mali, Philippines, South Sudan, South Tajikistan, Uzbekistan, and the West Africa Regional Project. This approach is tripartite: strong working relationships with government counterparts; active engagement and coordination with other donors, implementing agencies, and development partners; and involvement of the private sector.

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

Continuously monitoring and evaluating program progress using defined metrics is critical to informing course correction in order to attain program success. SIAPS has a defined Performance Monitoring Plan (PMP) to track program progress. In Cameroon, the review of SIAPS indicators during program implementation of a capacity-building intervention revealed a risk of decreased performance on some post-training indicators. This prompted SIAPS/Cameroon to reshape the supervision activities and feedback methodology in a bottom-up approach. Stock-outs at facility level declined from 100% in PY2 and PY3 to less than 40% in quarters 2 and 3 of PY4 as a result.

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

SIAPS convened a consultative meeting of its partners to identify definitions of a pharmaceutical system and PSS, and components to be included in a measurement framework for systems strengthening. The meeting brought together SIAPS core and resource partners, experts from USAID, the Pan American Health Organization (representing WHO), and Boston University School of Public Health. We are using these activity results to help develop a measurement framework with associated indicators for PSS.

Harmonize Information Systems to Improve Patient Care

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

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

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

Share Lessons Learned and Best Practices Widely

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

In fiscal year 2015 (FY15), SIAPS continued to advance its goal of assuring the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes by working with local counterparts and partners in 47 countries, with field support in 16 countries. This fiscal year SIAPS provided technical assistance to regional programs in West Africa, Central Asia, Latin American and the Caribbean, as well as Asia (Regional Development Mission for Asia). The only close-out activity during FY15 was in Lesotho.

The SIAPS Program Award was initially $197,926,458 over 5 years. In the tail end of FY15, the program was granted an extension of twelve months, until September 22, 2017 and the Program Award increased to $225,926,458.

Due to the cumulative nature of pharmaceutical systems strengthening efforts, this report presents highlights of SIAPS’s accomplishments over the course of the entire Program; Program Years 1-4 (PY1 - PY4): October 2011 to September 2015. Country and regional portfolios have demonstrated their contextual application of the SIAPS PSS approach by showcasing key interventions, and the results that have culminated in PY4. Results are also presented here by our core portfolios - health program areas that demonstrate SIAPS’s contributions to the health goals of the USG and Cross Bureau that demonstrates contributions to USAID/W Office of Health Systems (OHS) priority objectives. Lastly, the report presents results by SIAPS intermediate result areas, representing the multiple countries and regions where we work.
SIAPS is a strategic program committed to contributing to USG health initiatives, including the President’s Emergency Plan for AIDS Relief (PEPFAR) goal of achieving an “AIDS-Free Generation” through HIV and AIDS prevention, care, and treatment. PEPFAR recently released the roadmap for its third phase since inception, “PEPFAR 3.0,” which emphasizes “sustainable control of the epidemic” to reach the Joint United Nations Program on HIV and AIDS’ (UNAIDS) ambitious 90-90-90 global goals—90 percent of people with HIV diagnosed, 90 percent of them on antiretroviral therapy (ART), and 90 percent of them virally suppressed by 2020. The 2014–2018 road map seeks to deliver on the promise of an AIDS-free generation by focusing on five action agendas—impact, efficiency, sustainability, partnership, and human rights.

2 http://www.pepfar.gov/documents/organization/234744.pdf
BACKGROUND AND CHALLENGES

At the end of 2013, 11.7 million people were receiving ART in low- and middle-income countries. However, in Sub-Saharan Africa where there is high numbers of people with HIV, coverage is still low—only 24% of children and 37% of adults in need of ART were receiving ART.

In the second decade of ART, increased focus is on further scale up of access and the quality of care for the People Living with HIV and AIDS (PLWHA) on ART. There are critical components of HIV programs that are expected to enhance the attainment of reduced morbidity and mortality, that are either missing or inadequately focused on that reduce the possibility of achieving the goals of a successful ART program and 90-90-90, where by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy, and 90% of all people receiving antiretroviral therapy will have viral suppression. These include the monitoring of prescribing practices (the percentage of initial ART prescriptions congruent with national/WHO guidelines), adherence as measured by pill count (the percentage patient adherence to antiretroviral therapy by pill count or other standardized measure), patient retention on first-line ART (the percentage of patients retained on first-line ART at 12 months) and loss to follow-up (the percentage of patients lost to follow-up at 12 months). These aspects of HIV programs need intensified attention and strategies if programs are to achieve the goals of reduced risk of transmission of HIV to uninfected populations in addition to reduced mortality and morbidity.

Despite a decade of system improvements, the lack of easily retrievable and reliable patient and commodity data collection tools, there is a lack of use of data for decision making in the quantification, forecasting, supply planning, and procurement of ARVs. There have been notable improvements in the countries that SIAPS has supported including Ethiopia, Namibia and South Africa though use of electronic dispensing tools. These countries have generated a wealth of data that needs to be collated and analyzed to guide decision making. SIAPS has developed and implemented the “Pharmaceutical Management Information dashboard Concept” in The West African Regional Program and Namibia and has found this intervention handy in providing usable information for decision makers to make decisions that are backed with evidence.

There is a persistent shortage of trained personnel to deliver pharmaceutical services and poor integration of ART into routine service delivery at health facilities. HIV services continue to be delivered as vertical services, limiting the sustainability of these programs.

There is limited focus on pediatric HIV treatment.

There is gap in implementing routine monitoring of early warning indicators of HIV drug resistance. The global trends of multidrug-resistant tuberculosis

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4 PEPFAR 2014, UNAIDS 2014
and extensively drug-resistant TB strains reinforce the need for all national HIV and AIDS program managers to develop strategies to monitor early warning indicators of HIV drug resistance and to develop strategies to minimize the risk of HIV drug resistance.

» In the current era of dwindling funding for HIV and AIDS programs, strategies to increase local funding for HIV programs continue to be vital in ensuring sustainability of ART programs. Weak coordination and lack of information on the comprehensive perspective of national HIV program has contributed to in-effective mobilization of stakeholders for resources and program implementation. There is a gap in coordinating stakeholders and ensuring that programs accessing Global Fund grants are adequately supported to meet the pharmaceutical and compliance expectations of the Global Fund to minimize the risk of delays or cancellation of grants.

» ART guidelines are frequently being updated based on WHO recommendations and new regimens entering the market. There is a need to strengthen guideline committees to plan and implement transitions between regimens to minimize wastage and the risk of interrupted access to treatment. There is also an urgent need to support countries to optimize ART regimes to ensure that the majority of patients are on as few regimens as possible.

» There is also a need to strengthen medicine regulatory systems to improve registration, pharmacovigilance, inspection, and support supervision of health facilities to ensure the quality of ARVs. There is also a need to enhance

**SIAPS Strategy for Improving HIV and AIDS Health Outcomes**

SIAPS supports national HIV programs, departments of pharmacy, and USAID implementing partners, and builds country capacity to sustain and increase access and coverage of quality ARVs to the population in need of ART. Through SIAPS support, program managers and department heads are supported to identify opportunities to increase the effectiveness, efficiency, and sustainability of HIV and AIDS programs. Further, SIAPS promotes data transparency and accountability as stipulated in PEPFAR’s efficiency agenda. This is also aligned with PEPFAR’s strategy to increase country ownership of HIV and AIDS efforts and ensure that countries are at the center of decision-making, leadership, and management of their HIV and AIDS programs.

SIAPS support to ART programs is framed around the key components of the pharmaceutical systems strengthening approach.

- **Pharmaceutical Systems** — laws and regulations, medicines policy, regulatory affairs, quality assurance pharmacovigilance
- **Supply Chain Management** — quantification, supply planning, procurement, distribution; warehousing, inventory management
- **Pharmaceutical Services** — case management, pharmaceutical care; rational use; adherence; antimicrobial resistance; standard treatment guidelines /essential medicines list, diagnostics
- **Pharmaceutical Management Information System (PMIS) and Logistics Management Information System (LMIS)** — service data, patient information, product information, electronic tools
transparency when procuring ARVs to ensure that the public is guarded from counterfeit or substandard ARVs.

Knowledge sharing is a key component to SIAPS. Centers of excellence for the care of patients on ART serve as platforms for sharing best practices, as well as platforms for referral centers. There is a need to develop models of pharmaceutical service delivery at ART sites that serve as a benchmark for care for other centers in the countries we work in.

NOTABLE ACHIEVEMENTS

SIAPS portfolios that receive PEPFAR funding include Angola, Cameroon, Dominican Republic, Democratic Republic of Congo (DRC), Ethiopia, Lesotho, Mozambique, Namibia, South Africa, Swaziland, Ukraine, and West Africa Regional (Benin, Burkina Faso, Cameroon, Guinea, Niger, and Togo) (Table 1). In accordance with USAID requirements, SIAPS HIV and AIDS portfolios have monitored and reported data using PEPFAR’s common set of “Next Generation” indicators to demonstrate contribution to the collective/global goal of achieving an AIDS-free Generation within the context of the national HIV and AIDS M&E plan of each country. In PY4, the number of sites supported by SIAPS increased by 11% from 2,141 to 2,381 in eight countries.

Table 1. Number of ART Sites at SIAPS Supported Countries

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Cameroon</td>
<td>34</td>
<td>104</td>
<td>104</td>
<td>98</td>
<td>104</td>
</tr>
<tr>
<td>Swaziland</td>
<td>133</td>
<td>133</td>
<td>133</td>
<td>133</td>
<td>133</td>
</tr>
<tr>
<td>DRC</td>
<td>625</td>
<td>625</td>
<td>625</td>
<td>625</td>
<td>625</td>
</tr>
<tr>
<td>Lesotho</td>
<td>104</td>
<td>103</td>
<td>149</td>
<td>178</td>
<td>178</td>
</tr>
<tr>
<td>Namibia</td>
<td>52</td>
<td>52</td>
<td>62</td>
<td>62</td>
<td>62</td>
</tr>
<tr>
<td>Angola</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>West Africa Regional</td>
<td>533</td>
<td>533</td>
<td>533</td>
<td>599</td>
<td>599</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>660</td>
<td>675</td>
<td>680</td>
<td>680</td>
<td>680</td>
</tr>
<tr>
<td>Total number of sites supported</td>
<td>2,141</td>
<td>2,225</td>
<td>2,286</td>
<td>2,375</td>
<td>2,381</td>
</tr>
</tbody>
</table>

The number of patients at SIAPS-supported sites is 864,884 patients in nine countries (Table 2) (excluding sites supported in Namibia, South Africa, and South Sudan).

Table 2. Increase of Patients at SIAPS-Supported Sites Over Nine Months

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dominican Republic</td>
<td>26,518</td>
<td>26,518</td>
<td>26,518</td>
<td>29,768</td>
</tr>
<tr>
<td>DRC</td>
<td>29,896</td>
<td>29,896</td>
<td>29,896</td>
<td>29,896</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>329,627</td>
<td>332,226</td>
<td>339,471</td>
<td>342,926</td>
</tr>
<tr>
<td>Swaziland</td>
<td>122,221</td>
<td>125,421</td>
<td>128,356</td>
<td>128,356</td>
</tr>
<tr>
<td>West Africa Regional</td>
<td>-</td>
<td>280,822</td>
<td>315,161</td>
<td>333,938</td>
</tr>
<tr>
<td>Total</td>
<td>508,262</td>
<td>794,883</td>
<td>839,402</td>
<td>864,884</td>
</tr>
</tbody>
</table>

SIAPS continues to support the development and implementation of the electronic dispensing tool and other tools that ensure timely ART service delivery and enhanced use of local data in planning, implementation, and evaluation of HIV/AIDS programs. The analysis and review of facility level patterns of regimens in use, ART uptake, active patients, and consumption of commodities not only enhance the use of evidence in decision making but also ensures that prescribing and dispensing practices are compliant with treatment guidelines. Regular review of regimens is pivotal to optimizing the number of regimens in use and ensures that ART patients are put on limited number of regimens, minimize pill burden to ensure optimal adherence to treatment and reduce the supply chain burden of managing multiple regimens.

SIAPS support has focused on long-term improvements by incorporating pharmaceutical and HIV management in pre- and in-service training curricula of all health workers to increase the number and capacity of health workers that manage HIV and AIDS. SIAPS strategies focus on enhancing integration of ART services into existing service delivery mechanisms (outpatient and inpatient).

SIAPS portfolios develop strategies for enhancing access of ART for children, and monitor the impact of these strategies on reduction in morbidity and mortality.

SIAPS support enhances coordination between the national bodies responsible for controlling HIV and AIDS, the technical departments of the Ministries of Health, and the supply chain teams in the quantification and procurement planning for ARVs.

Innovation in Pharmaceutical Information Systems

SIAPS/PEPFAR builds on a number of USAID-funded programs that have garnered a wealth of experience using electronic tools at the point of care in several countries, including the electronic dispensing tool (EDT) and the RxSolution pharmacy management system. EDT is used to ensure that the medicines for HIV and AIDS, malaria, tuberculosis, and opportunistic infections have been appropriately dispensed. It helps the dispenser to carefully monitor patient adherence, response, and possible side effects; and allows a clinic to compile service statistics needed to support management decisions. RxSolution is an integrated computerized pharmaceutical management system that allows health facilities to manage pharmaceuticals and medical supplies, from procurement to patient dispensing.

Routine patient data collected through EDT at the point of care and the system data collected through RxSolution represent great potential resources for conducting clinical, epidemiological, high level data analysis and operational research to inform decision making. SIAPS continues to work with key stakeholders including the Harvard Pilgrim Health Care Institute to determine opportunities for analyzing data to enhance evidence-informed decision making.

Support to Increase Availability of Quality ARVs

Unreliable data and information on patients and stock at all levels, and weak information systems result in unreliable quantification and ineffective supply
planning. For example, Cameroon has committed to increase the coverage of treatment of PLWHA to 80% by 2015. The efficient functioning of the public pharmaceutical management system is critical to the success of the Ministry of Public Health (MOPH) plans for scale-up of HIV and AIDS activities. SIAPS/PEPFAR supported initiatives reduce the risk of stock-outs and enhance availability of ARVs, including implementation of the Option B+ initiative. SIAPS/PEPFAR helped identify gaps, analyzed options, and developed and implemented strategies to enhance coordination of local stakeholders and efficiency of the supply chain. SIAPS/PEPFAR supported MOPH to streamline procurement and distribution and meet performance and reporting requirements to access Global Fund grant for HIV. SIAPS/PEPFAR continues to provide technical assistance for quarterly review of the quantification and supply plan for ARVs. Furthermore, in Cameroon, through support supervision, SIAPS/PEPFAR has supported quarterly monitoring of patient and commodity data to ensure stock availability at ART treatment sites.

Support to Pharmacovigilance
In South Africa and Namibia, SIAPS has supported development of antiretroviral cohort adverse event monitoring in Kwazulu-Natal and Windhoek Central Hospital (http://siapsprogram.org/publication/antiretroviral-cohort-adverse-event-monitoring-in-kwazulu-natal/).

Strengthening Rational Use of ARVs

The SIAPS West Africa regional project conducted a situation analysis of the information management gaps in five countries in the region that served as platform for developing effective interventions for the program (http://siapsprogram.org/publication/situational-analysis-of-information-systems-and-coordination-for-managing-hiv-and-aids-related-commodities-in-five-west-and-central-african-countries/).

Global Technical Leadership
SIAPS/PEPFAR has contributed to the global agenda of developing and continuing the focus on pediatric treatment as a major intervention that will reduce morbidity and mortality and contribute to the AIDS-free generation goal through participation in the Global Child Survival Working Group (CSWG) of Inter-Agency Task Team on prevention and treatment of HIV infection in pregnant women, mothers, and their children (IATT). This committee has reviewed the selection of pediatric ARV formulations; published peer reviewed papers on pediatric HIV treatment, and worked with CDC, UNICEF, WHO, CHAI and
other key players in the management of pediatric HIV and AIDS. The IATT has updated the pediatric ARV formulary list, provided guidance on new HIV and AIDS treatment regimens, and developed tools including drug information pages and the “Double Dividend initiative.” The Double Dividend is an initiative that is meant to accelerate action towards achievement of the dual goals of ending pediatric HIV and AIDS and improving child survival. SIAPS works with WHO AIDS Medicines and Diagnostic Services and other partners to support countries in scaling-up access to prevention, treatment, and care. SIAPS’ support in this area is on strengthening the pharmaceutical management system for a wider range of essential medicines and supplies and integration of services, where appropriate.

**LESSONS LEARNED**

Despite the fact that PEPFAR is the single largest funder of the SIAPS program, lack of Cross Bureau funding for HIV and AIDS has limited the capacity of the program to comprehensively incorporate key global strategies into national programs. The lack of cross bureau funds has also limited SIAPS ability to position pharmaceutical related interventions that will provide a platform for discussion and implementation of effective interventions across developing countries.

Portfolio work plans are driven by the goals and recommendations of local missions, which interpret PEPFAR global strategies differently. There is a need to examine how global strategies are incorporated into technical activities in the field to ensure optimal and cohesive efforts towards achieving PEPFAR goals through national programs.
THE CHALLENGE

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

SIAPS Strategy for Improving Malaria Commodities Management

SIAPS endeavors to improve pharmaceutical governance and build national level capacity to manage malaria products, improve the quality of information systems, strengthen financing strategies, and improve the quality of pharmaceutical services provided to malaria patients. At the country level, SIAPS collaborates with National Malaria Control Programs (NMCP) and Central Medical Stores to develop and implement strategies to strengthen pharmaceutical management to prevent malaria and improve case management.
KEY ACHIEVEMENTS

Policies, Guidelines, Regulations, and Partners Coordination

In close collaboration with malaria partners, SIAPS produced key policy documents. In collaboration with the Burundi MOH, SIAPS developed the Department of Pharmacy, Medicines, and Laboratory strategic plan for 2015–2017. Support was provided to the National Essential Medicine Supply Program of DRC to develop the first strategic plan for the National Medicine Supply Chain System. In South Sudan, SIAPS collaborated with the NMCP and partners to finalize the development of the 2014/15–2020/21 National Malaria Strategic plan.

SIAPS continued its efforts to support good governance and coordination in pharmaceutical supply chain by facilitating Pharmaceutical Supply Management (PSM) working group meetings in Angola, DRC, Mali, Guinea, Burundi, Niger, and South Sudan. In addition, to strengthen country level coordination, SIAPS collaborated with in country malaria partners to hold regular malaria coordination meetings, and to develop joint work plans, operational plans, and strategic plans.

Supply Chain Management

SIAPS supports the MOHs and NMCPs in strengthening their capacity to appropriately manage malaria and the malaria commodity supply chain by training health care workers in quantification, pharmaceutical management, and malaria case management. SIAPS also advocates for and supports country-led supportive supervision which includes coaching and on-the-job training.

SIAPS has conducted quantification of artemisinin-based combination therapies (ACTs), rapid diagnostic tests (RDTs), and severe malaria medicines in Angola, Burundi, and Mali.

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

SIAPS played a key role in the fight against Ebola in Guinea. SIAPS collaborated with the central medical store, NMCP, WHO, and other partners to ensure availability of appropriate Ebola commodities and their use. SIAPS activities include the following:

Provided the technical specifications for Ebola commodities to be procured

- Supported the quantification and distribution plans of Ebola commodities
- Trained pharmacists and storekeepers on the management of Ebola health commodities and supplies
- Reviewed malaria case management protocols in accordance to WHO recommendations
Information for Decision Making

SIAPS implements PMI tools, such as the End Use Verification (EUV) and the Procurement Planning and Monitoring Report for malaria (PPMRm), to avert stock-outs of lifesaving commodities, monitor their appropriate use, and facilitate procurement decisions. The EUV process has given country MOH partners the opportunity to assess and take steps to correct and improve the availability and use of malaria commodities.

» In Burundi, delivery of malaria commodities was expedited to avert stock-outs.

» In DRC, ACTs were redistributed from facilities with excess stock to those without stock to avoid expiries and to prevent stock-outs.

In May 2015, SIAPS provided support to Mali’s MOH in the design and implementation of the Outil de Suivi des Produits de la Santé (OSPSANTE), a web-based dashboard that captures, aggregates, tracks, and makes information available and accessible for malaria and family planning commodities. The tool facilitates timely data aggregation and helps the MOH and its stakeholders gain information for better and faster decision making. Warehouse managers from regional, national, and hospital pharmacies have been oriented on data entry and other transactions using the dashboard. SIAPS continues to capacitate and mentor the trained managers at the district level OPSSANTE data entry. This new tool made a significant improvement on the reporting rate. The number of health facilities that completed and submitted an LMIS report for the most recent months increased from 67% to 87%.

CAPACITY BUILDING AND SUSTAINABILITY

The Continuous Result Monitoring System (CRMS) is a comprehensive indicator-based performance management system used by SIAPS and the PMI program in Oromia Regional State, Ethiopia, to track progress in malaria products management, strengthen systems, and improve health outcomes. SIAPS has empowered decision makers in the Oromia Region by making information derived from CRMS reports readily available for making decisions. This is achieved by holding review meetings, where stakeholders critically examine challenges, address issues that negatively affect the diagnosis and treatment of malaria, and set priorities for future interventions that strengthen access to antimalarial drugs and contribute to improved malaria case management. Also, Drug and Therapeutics Committees at the health facility level have used CRMS report information to design interventions for improving rationale use of antimalarial medicines. SIAPS aims to stop its routine support to facilities that show improvements in managing the CRMS process and managing malaria.
patients and malaria commodities. In this regard, SIAPS officially graduated nine health facilities—Adama HC, Olenchite HC, Wonji Hospital, Batu No1 HC, Wolliso HC, Nekemte Hospital, Dembidolo Hospital, Nejo Hospital, and Delomena Hospital. These facilities are ready to handle antimalarial medicine management activities in collaboration with the district and zonal health offices. They are also able to generate CRMS reports to monitor their progress and identify challenges for future improvement.

**LESSONS LEARNED**

In many countries, challenges remain in planning, the coordination of forecasting and supply planning, and the use of data to make decisions and avoid delays, shortages, and frequent emergency orders of malaria commodities.

The implementation of PMI tools (EUV and PPMRm) have proven to be useful in alerting countries of impending stock-outs and expiries.

Continuous capacity building and mentoring are essential in ensuring country ownership and sustainability.
BACKGROUND

This year the Millennium Development Goals came to an end and while some countries remained on track to achieve the goals for reducing maternal and child deaths, many were not. Despite progress made in reducing both maternal and child mortality rates over the recent decades, both rates still remain high. Alarmingly, a large proportion of these deaths could be avoided if women and children had access to adequate health services, where the necessary quality medicines and supplies were available and skilled health providers were present. The preventative and curative measures for the major causes of maternal and child deaths are well known, but access to them remains elusive for many.

CHALLENGE

Many essential maternal, neonatal, and child health (MNCH) medicines and supplies are generic products that are currently widely available in both the public and private sectors. However, ensuring access and availability of these medicines and supplies in-country requires improving pharmaceutical policy, enforcing compliance with policies and procedures, especially in procurement, and addressing regulatory components of the health system. Additionally, 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 of commodities, 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.

Scarce 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. In addition, several key medicines

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**SIAPS Strategy for Improving MNCH Health Outcomes**

In 2014, recognizing the need for heightened attention for 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) invest in empowering women and supporting an
enabling environment, and (5) create transparency and mutual accountability at all levels,
with strengthened commitment to common metrics for tracking progress.¹ Achieving these
targets will require a focused systems strengthening approach.

The SIAPS program works with global and in-country partners to improve access to and
use of life-saving medicines for women and children. Promoting a 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.

A key component of this systems approach is to implement strategies to increase access to
esential MNCH medicines and supplies, thereby contributing to EPCMD. These strategies
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. All strategies will need to be addressed
at both the global and country levels.

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¹ USAID. Acting on the Call: Ending Preventable Child and Maternal Deaths Report, June 2014, Available from:
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 may be required to ensure that they are available when needed and hopefully make it easier to identify the gaps in demand specific to MNCH requirements.

**SIAPS ACHIEVEMENTS**

**Global Level Contributions**

SIAPS has been actively engaged in supporting the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) since its creation in 2012. SIAPS participated in the planning meetings during which the 13 commodities prioritized by the UNCoLSC were defined. SIAPS then worked to elaborate the background materials that informed the final recommendations of the commission. Following the publication of these recommendations, SIAPS continued to provide support through its participation in many of the Commission’s Technical Resource Teams (TRT). Table 1 provides a brief summary of SIAPS’ contributions to the TRTs.

**Table 1. SIAPS support to UNCoLSC, FY 2014–2015**

<table>
<thead>
<tr>
<th>Technical Resource Team</th>
<th>Key Contributions and Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maternal Health</strong></td>
<td>• Conducted an options analysis with national stakeholders in Mali that resulted in the decision to integrate oxytocin into the Expanded Program on Immunization (EPI) cold chain at the district and community levels</td>
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<tr>
<td></td>
<td>• Collaborated with Concept Foundation and WHO to conduct a workshop in Uganda on optimal procurement of maternal health commodities</td>
</tr>
<tr>
<td></td>
<td>• Supported the revision of the DRC treatment guidelines to include misoprostol for prevention and treatment of postpartum hemorrhage</td>
</tr>
<tr>
<td><strong>Supply Chain</strong></td>
<td>• Revised guidance on quantification of 13 priority commodities in English and French</td>
</tr>
<tr>
<td></td>
<td>• Co-facilitated the francophone South-to-South workshop on quantification of RMNCH commodities that followed the Reproductive Health Supplies Coalition Sécurité Contraceptive en Afrique Francophone meeting in Dakar in September 2015</td>
</tr>
<tr>
<td></td>
<td>• Worked with two Ecumenical Pharmaceutical Network members in DRC—the Baptist Church in Central Africa (CBCA) and Sois de Sante Primaire En Milieu Rural (SANRU)—to provide training on quantification of the 13 priority products</td>
</tr>
</tbody>
</table>

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### Key Contributions and Products

**Chlorhexidine**
- Produced the chlorhexidine introduction strategy in Afghanistan and DRC
- Supported the revision of the DRC treatment guidelines to include chlorhexidine for umbilical cord care as well as the adoption of these guidelines and the introduction strategy by the MOH Secretariat General

**Diarrhea and Pneumonia**
- Developed the protocol to pilot the use of amoxicillin job aids and product presentation in DRC
- Provided information on case studies and inputs for the zinc/oral rehydration solutions (ORS) lessons learned—a paper is being developed by the zinc and ORS subgroup

**Injectable Antibiotics**
- Received an award from Save the Children under the Injectable Antibiotics TRT as a cost-sharing initiative to conduct the landscape analysis of antibiotics for newborn sepsis in DRC
- Finalized and submitted the study protocol for the newborn sepsis landscape analysis in DRC

SIAPS also works closely with global partners and actively participates in standing technical communities of practice such as the Community Case Management (CCM) Task Force. As part of the CCM Taskforce, SIAPS is fully engaged with the Integrated Community Case Management (iCCM) Financing Task Team. As part of its efforts with the Procurement and Supply Management (PSM) sub-group, SIAPS finalized the iCCM PSM checklist and PSM guidance document that was disseminated to countries going through the Global Fund New Funding Model (NFM) process. SIAPS developed a document aimed at convincing malaria program managers of the benefits of iCCM to malaria. As a reflection of the appreciation of the global technical leadership that SIAPS is recognized for, SIAPS now chairs the Supply Chain Management sub-group of the iCCM Taskforce.

In addition to ongoing participation in global partnerships like the UNCoLSC and CCM Taskforce, SIAPS, was requested by USAID to gather information on Reproductive, Maternal, Neonatal, and Child Health (RMNCH) programs in five MNCH priority countries—Ghana, Kenya, Mozambique, Nepal, and Rwanda, using a tool developed by the UNCoLSC. SIAPS worked with USAID and the RMNCH Strategy and Coordination Team SC to communicate the results to USAID missions and country ministries of health and to obtain approval to display the results from the data collection.

SIAPS finalized the data analysis for the review of current pharmaceutical management policies and systems that affect access to essential RMNCH medicines and supplies across countries. This activity is being done in collaboration and as a cost-share with WHO.

### 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, the *Intervention Guide for the Management of Childhood Illnesses* was
finalized. There are three versions—an electronic version with links to URLs or references, a web-based version with links to URLs and the actual references that can be disseminated via web distribution, and a CD version with links to URLs and the actual references that can be disseminated via CD. The guide was successfully validated in three districts in Zambia and SIAPS is currently working with UNICEF and the School of Public Health of the University of Zambia to incorporate the guide in their planned activities as well as to see if it is useful to integrate into UNICEF’s DIVA approach.

Country-Level Contributions

To assist countries in their efforts to end preventable child and maternal deaths, SIAPS supports the development of innovative approaches to addressing barriers to access using a systems strengthening approach. Specifically, in child health, SIAPS assisted the Ministry of Health in Guinea to improve access to treatment for diarrhea and pneumonia through CCM. SIAPS has brought supply chain management for CCM prominently into the planning cycle. In Guinea, SIAPS supported the development of a community logistics management information system (LMIS) has been developed to generate data on consumption and stock-outs among community health workers on a regular basis.

These and other examples of country support illustrate SIAPS’ efforts to end preventable child and maternal deaths and are summarized in the table below.

<table>
<thead>
<tr>
<th>Country</th>
<th>Key Accomplishments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angola</td>
<td>• Supported national commodity security working group</td>
</tr>
<tr>
<td></td>
<td>• Conducted national quantification exercise</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>• Finalized assessment of pharmaceutical management practices at the district level</td>
</tr>
<tr>
<td></td>
<td>• Developed five-year forecast for essential RMNCH commodities</td>
</tr>
<tr>
<td></td>
<td>• Created technical working group to support development and pilot of an LMIS for the</td>
</tr>
<tr>
<td></td>
<td>Directorate General of Health Services</td>
</tr>
<tr>
<td>DRC</td>
<td>• Revised national MNCH guidelines revised in alignment with revised EML that includes</td>
</tr>
<tr>
<td></td>
<td>chlorhexidine and misoprostol</td>
</tr>
<tr>
<td></td>
<td>• Developed national plan for introduction of chlorhexidine</td>
</tr>
<tr>
<td></td>
<td>• Supported all UNCoLSC efforts in-country</td>
</tr>
<tr>
<td>Guinea</td>
<td>• Supported MOH in planning scale up of CCM</td>
</tr>
<tr>
<td></td>
<td>• Conducted quantification exercise for CCM medicines and supplies</td>
</tr>
<tr>
<td></td>
<td>• Developed a community LMIS</td>
</tr>
<tr>
<td>Mali</td>
<td>• Developed new LMIS that now includes community level</td>
</tr>
<tr>
<td></td>
<td>• Developed training materials, tools and job aides for the new LMIS</td>
</tr>
<tr>
<td>South Sudan</td>
<td>• Provided pharmaceutical management support for introduction of misoprostol</td>
</tr>
<tr>
<td></td>
<td>• Supported development of LMIS to increase visibility of data on availability of MNCH</td>
</tr>
<tr>
<td></td>
<td>medicines</td>
</tr>
</tbody>
</table>
As the Millennium Development Goals came to an end, new, more ambitious commitments were made to reduce maternal, newborn, and child mortality rates requiring more intensified efforts and holistic, systems strengthening approaches. To achieve the global targets set for ending preventable child and maternal deaths, the appropriate medicines and supplies must be available when and where women and children need them, and acquiring these products and the services in which they are provided must not represent a financial hardship for women and their families. This requires a strong pharmaceutical system in which the quality of medicines in circulation is assured, appropriate medicines and supplies are provided, strong supply chains ensure availability of quality products at service delivery points, and service providers are able to administer the products and counsel patients on their appropriate use.

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

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

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

Through its NTD program, SIAPS will continue to enhance NTD program managers’ capacity for supply chain management (SCM) for improved storage and transportation, rational medicines use, improved medicine forecasting and adverse event (AE) reporting to ensure NTD commodity security and safety. Collaboration with partners ensures that capacity building and improved medicines forecasting will be carried out effectively and efficiently, gaining a maximum of results with a minimum of cost-effective input.
In discussions with the Task Force for Global Health (TFGH) as well as RTI International (RTI) and FHI 360, several issues present as a gap or void in the current supply chain guidelines. The proper disposal of waste is often overlooked during trainings of community health workers and drug distributors. Also, the proper disposal of expired or damaged (questionable quality) drugs was described as a problem by many donation programs. This is an aspect of the supply chain that would benefit from a comprehensive guideline that program managers can refer to following mass drug administrations (MDAs).

**CHALLENGE**

A 2011-2012 assessment conducted by Management Sciences for Health’s USAID-funded Strengthening Pharmaceutical Systems Program (the predecessor of SIAPS) in Cameroon, Mali, Tanzania, and Uganda showed marked weaknesses in the capture, transmission, aggregation, and analysis of data related to NTD products, especially during MDAs carried out by community health workers.

**SIAPS Strategy for Improving NTD Health Outcomes**

The main objective of SIAPS’s NTD Core portfolio is to strengthen pharmaceutical management systems to achieve global NTD goals. SIAPS will provide technical input to USAID, WHO, the TFGH, global NTD networks, national NTD programs, and other relevant bodies to address technical leadership issues related to NTD medicine policy, including donations, medicine regulation, SCM, serious adverse event reporting, and patient safety.

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

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

- Strengthen NTD management at all levels throughout the supply chain system by providing technical expertise on SCM at working group meetings and scientific conferences that focus on forecasting, quantification, and ordering; customs clearance, logistics, and inventory management; storage; management of AEs; reporting; and waste disposal
- Collaborate with national drug regulatory authorities in USAID-supported countries to build their capacity for SCM and improving AE management and reporting
- Develop, test, and disseminate training and operational manuals including information management tools at the global and country levels to collate and provide timely information on stock status, pipelines, and deliveries of NTDs at all levels
- Provide technical assessment of NTD SCM and capacity and provide technical assistance to improve systems
Even when available, aggregate NTD reports do not reach program managers at the national level in time to allow them to develop accurate forecasts and prepare timely and comprehensive donation applications and procurement from manufacturers. In addition, there is no system at the global level that collates supply pipelines and tracks the stock status of these commodities in priority countries. Improvements are required to address identified weaknesses, including poor in-country coordination between the various NTD programs in forecasting, quantification and ordering, customs clearance, logistics and inventory management, management of AEs, and waste disposal.

**SIAPS ACHIEVEMENTS**

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

Since October 2013, SIAPS has participated and presented abstracts in selected meetings, groups, and conferences contributing to the work of different NTD advisory and technical working groups, especially supply chain, serious adverse events (SAEs)/adverse drug reaction (ADR) reporting, and M&E working groups. Participation at these meetings has promoted proper supply chain and pharmacovigilance coordination with the USAID NTD program and the TFGH, which houses the major donation programs (Mectizan Donation, International Trachoma Initiative, and Children without Worms). Such meetings included American Society for Tropical Medicine and Hygiene Annual Meeting, WHO Global NTDD Efficacy Working Group, WHO Global NTD M&E Working Group, NTD Nongovernmental Development Organization Meeting, WHO South East Asian Regional Office Program Managers Review Group, and the African Program to Eliminate Onchocerciasis Program meeting.

Building on the previous SPS work, SIAPS developed a three-day SCM workshop directed at national level supply chain and NTD program managers, piloted the workshop in Addis Ababa that included the MOHs, WHO, and implementing NGO representatives (RTI International) from Ethiopia, Tanzania, and Uganda. SIAPS also drafted a training manual separate from the workshop which includes standard operating procedures for NTD information data collection, processing, and reporting across programs to help reduce staff burden at the different levels of the supply chain system. This manual and training workshop toolkit addresses receipt, issue, return of unused products, tracking expiries, consumption, stock levels, shipment status, and reporting adverse drug effects of NTD products. SIAPS will work with the TFGH, WHO, and several countries to develop the toolkit for the different levels of the supply chain.

SIAPS worked with country program managers for RTI ENVISION and the Senegal Ministry of Health (MOH) NTD and drug supply operational MOH staff to assess their supply chain and pharmaceutical management systems and made recommendations on how to streamline their programs.
SIAPS worked with partners to develop clear guidelines on rational use of NTDDs and how to dispose (or recycle, if appropriate) of waste following MDAs. SIAPS drafted guidelines to include standard operating procedures for NTD waste management. This guide addresses returning expired or questionable quality NTDDs to the Central Medical Stores for appropriate documentation and disposal; disposal or proper cleaning of used NTDD bottles; and disposal of other supplies and diagnostics used during MDAs, M&E, and surveillance activities.

LESSONS LEARNED AND WAY FORWARD

The primary challenges in improving pharmaceutical management for NTD are developing strategies for countries with new NTD programs and extremely weak supply chain structures to get the best return as quickly as possible. SIAPS is developing several tools and providing technical assistance in priority countries to address these issues.
Despite availability of highly effective treatments, tuberculosis (TB) remains a critical global health problem. In 2014, approximately 1.5 million people died of TB, including 0.4 million people who were HIV-positive (WHO, 2015). Of the 9.6 million cases of TB estimated to have occurred in 2014, national TB programs (NTP) were notified of only 6 million, leaving a gap of one-third or approximately 3.6 million people who were either not diagnosed or not reported (WHO, 2015).

Adding to the challenge is the rapid emergence of drug-resistant forms of TB. In 2014, approximately 480,000 people worldwide developed multidrug-resistant (MDR)-TB—only a quarter of these were detected and reported in 2014 (WHO, 2015). In the new US government (USG) TB Strategy (2015–2019), there are three cardinal strategies in line with the WHO End TB Strategy for reducing the burden of TB on individuals and communities:

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

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

In addition to human resources, other health systems building blocks in many high-burden TB countries require individual strengthening and improved synergy, particularly in areas such as 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 essential components, 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- or middle-income settings with the greatest burden of TB. This gap may result in part from limited pharmaceutical research expertise at the country level, lack of supportive infrastructure, or limited funding for research in the face of competing priorities. However, such research promotes inclusivity in the design and implementation of interventions and is necessary to generate data for strategic decision making.

These challenges are compounded by limited access to, and improper use of, quality assured TB medicines in many high-burden countries. Limited access to medicines stems in part from a lack of valid quantification information and supply chain bottlenecks at the country level. In addition, access to quality TB diagnosis, treatment, and pharmaceutical services in the private sector remains limited and is often substandard. With regards to improper use of TB and DR-TB medicines, a lack of monitoring of drug utilization and management of adverse reactions can result in poor treatment outcomes and foster the development of drug resistance. Patient-centered TB diagnosis and treatment relies on the capacity of health staff to provide quality services.

### SIAPS Strategy for Improving TB Health Outcomes

The primary goal of the SIAPS TB Core portfolio is to assure 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 USG health goals, namely, Protecting Communities against Infectious Diseases (PCID), fostering an AIDS Free Generation (AFG), and strengthening health systems. SIAPS builds on many years of experience, methodologies, and tools developed and tested by Management Sciences for Health, and its different USAID programs. As a result, SIAPS has at its disposal an array of instruments to address TB pharmaceutical management gaps within the health system. The four key strategies employed by the TB portfolio are: (1) pharmaceutical governance for TB strengthened at global and country levels, (2) capacity for TB pharmaceutical supply management and services increased and enhanced, (3) improved utilization of information for TB control decision making, and (4) improved pharmaceutical services and access to TB products to achieve goals.
to track and assess patient data and ensure the implementation of evidence-based care. Concurrent treatment of comorbidities such as TB/HIV and TB/diabetes results in greater risk of adverse events, which may contribute to treatment interruptions and poor patient outcomes.

SIAPS ACHIEVEMENTS

Pharmaceutical governance for TB strengthened at global and country levels

SIAPS has targeted improved pharmaceutical governance for TB by collaborating with primary global partners, in particular, the Stop TB Partnership and the Global Drug Facility (GDF). The GDF is an international mechanism that provides access to quality-assured first- and second-line TB medicines and consumables for rapid diagnostic tests. SIAPS has supported this global mechanism by seconding a full-time Interim Manager to oversee GDF operations. Since December 2012, the GDF lead times for procurement have decreased from an average of 85 days to 57 days over a one-year period. Additionally, since its involvement in mid-2012, SIAPS helped increase the number of suppliers and successful tender in the end of 2012, helping reduce the prices of second-line drugs by approximately 14.5% to 26%. SIAPS also participates in GDF monitoring missions and provides technical assistance in NTP review missions, providing technical assistance on monitoring the performance of the pharmaceutical management system for TB, including quantification, inventory management, and procurement of TB medicines. Working with the GDF, SIAPS provided technical leadership to produce the GDF position paper on the New Pricing Model; an approach that outlines how lead times associated with price negotiations and quotation approvals can be reduced.

In March 2015, after extensive preparatory work and consultations with global TB partners, USAID, in conjunction with Janssen Pharmaceuticals, announced a donation of 30,000 treatments of bedaquiline, the first new TB medicine in the past 50 years to be delivered to drug-resistant TB patients via Global Drug Facility (GDF). As one of the technical assistance providers to countries for the rapid introduction of new TB medicines through the bedaquiline donation program, SIAPS promoted stewardship by bringing all in-country partners together to define roles and responsibilities for programmatic implementation of new medicines and novel regimens. Georgia, a SIAPS technical assistance recipient country, is the first beneficiary country to put patients on treatment through the bedaquiline donation program.

In addition, SIAPS contributes to the Task Force for the Development of New Policies for the Treatment of TB, a collaboration of the Stop TB Partnership and WHO that is comprised of representatives from leading technical organizations. Upon request, SIAPS contributed a section to the taskforce’s Policy Implementation Package (PIP), a reference document designed to guide NTPs through the process of rational introduction of new TB medicines and regimens into their programs. SIAPS conceptualized, analyzed, developed, and wrote “Systems approach for ensuring uninterrupted supply of new and existing quality-assured medicines.” This section will support policy and decision makers to recognize the three stages for ensuring access to new medicines in their countries. The PIP was released at the 45th Union World Conference on Lung Health in November 2014.
Building on our past success in providing technical leadership at the global level, SIAPS participated in a WHO three-day workshop composed of working groups that provided a chapter-by-chapter review of the draft Essentials of Implementing the End TB Strategy, a comprehensive document guiding the implementation of the strategy for the next decade.

### Capacity for TB pharmaceutical supply management and services increased and enhanced

SIAPS works on a number of levels to improve pharmaceutical management capacity. On a global level, SIAPS facilitates sessions at the WHO Collaborating Centre for Tuberculosis and Lung Diseases focusing on improving skills for pharmaceutical management for TB, MDR-TB, and TB/HIV; forecasting, supply planning, quantification, and early warnings for stock-outs; and pharmaceutical management and early warning indicators. At the regional level, SIAPS aims to increase the pool of international consultants trained to conduct GDF monitoring missions, WHO NTP reviews, and short-term technical assistance by conducting regional trainings for GDF and Stop TB Partnership consultants, NTP managers, and international partners. In addition, every project year SIAPS collaborates with the GDF to host a full-day workshop on pharmaceutical management for TB at the Union World Conference on Lung Health. Lastly, SIAPS collaborated with the GDF to hold two regional conferences on pressing issues in pharmaceutical management. The conference in March 2015 focused on improving global access to TB medicines and pharmaceutical services to support the WHO-End TB Strategy.

### Improved utilization of information for better decision making

SIAPS works to improve information for decision making through the availability and interoperability of electronic tools combined with systems strengthening. SIAPS has improved e-TB Manager, a web-based tool for managing primary information needed by NTP, through regular updates and new features for enhanced and expanded use. e-TB Manager integrates data across a variety of aspects of TB control, including information on people who are suspected of having TB, patients, medicines, laboratory testing, diagnosis, treatment, and outcome. e-TB Manager is currently used in 2,737 sites in 11 countries. Globally, more than 3,698 active e-TB Manager users are managing 420,794 TB cases, DR-TB cases, and presumptive TB individuals.

Additionally, SIAPS developed QuanTB, an electronic forecasting, quantification, and early warning tool designed to improve procurement processes, ordering, and planning for TB treatment. QuanTB has been adopted by the GDF as its standard tool for quantifying orders and monitoring medicines availability in client countries. The tool is continually updated and the current version 2.0 was used regularly as the national tool for quantification and monitoring of TB medicines in 14 countries. To date there have been almost 1,000 downloads of the QuanTB tool. SIAPS also collaborated on the United Way worldwide grant, on behalf of Eli Lilly and Company Foundation (managed by KNCV), on an electronic health
(eHealth) and mobile health (mHealth) interoperability project. The grant was to develop a data dictionary based on QuanTB for forecasting and quantification standardization and interoperability that allows users of different electronic systems to exchange and share TB data easily.

Improved pharmaceutical services and access to TB products

To improve access to TB diagnosis and treatment, SIAPS has worked in three primary areas. The first is to provide technical assistance to the USAID priority high-burden countries to strengthen access to TB medicines by implementing early warning systems for stock-outs/waste of TB medicines. SIAPS has done this through a regional technical assistance mechanism combined with QuanTB; together, these allow staff sufficient time to address supply problems by providing alerts when the risk is high for medicines expiries and stock-outs, and flagging the need for emergency medicine orders. It also allows the rapid identification of gaps in pharmaceutical systems and the ability to monitor improvement interventions.

SIAPS has trained NTP drug management staff and partners from 16 countries (Bangladesh, DRC, Ethiopia, Kenya, Malawi, Mozambique, Myanmar, Nigeria, Philippines, South Sudan, Tajikistan, Tanzania, Uganda, Uzbekistan, Zambia, and Zimbabwe) to use QuanTB for quantification and tracking of TB medicines. Of these countries, 14 have adopted QuanTB tool for a quantifying and monitoring TB medicines at the national level. Within the first six months of implementing QuanTB, six countries reported to SIAPS on their use of QuanTB for medicines tracking and the decisions made based on data generated with QuanTB. The following table highlights the results:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Baseline</th>
<th>At 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of countries that reported a stock-out of at least one first-line anti-TB medicine</td>
<td>80% (4/5)</td>
<td>0%</td>
</tr>
<tr>
<td>Percentage of countries that reported a stock-out of at least one second-line anti-TB medicine</td>
<td>50% (3/6)</td>
<td>17% (1/6)</td>
</tr>
</tbody>
</table>

The second arm of SIAPS’ efforts to improve the quality and accessibility of TB diagnosis and treatment is to strengthen linkages between the public and private sectors. SIAPS has worked with the NTPs in Kenya, Pakistan, and Tanzania to improve oversight of the private sector and increase its potential to contribute to NTP efforts and goals. The focus is on developing the capacity of the private sector to identify and refer clients with presumptive TB to diagnostic and treatment centers, and the development of a legal and operational basis for collaboration between private medicines sellers and TB programs.

In the private sector, SIAPS developed training materials, conducted training of trainers, and trained pharmacists and dispensers in TB recognition and referral in Tanzania and Pakistan. As a result, in Tanzania, 81 TB patients were identified and diagnosed by NTLT treatment and diagnostic centers. In Pakistan, pharmacists have been trained and two memorandums of understanding were signed by 115 pharmacies in Rawalpindi and 70 pharmacies in Lahore to expand the linkages between the public sector and private pharmaceutical sector.

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

To improve patient safety, SIAPS created guidelines, tools, and standard operating procedures for active surveillance of TB/HIV co-medication. In six sentinel sites in Swaziland, health care workers were trained in data collection, while data clerks and physicians were trained to improve data quality. From July to September 2013 to April 2015, 2,080 patients were enrolled for adverse event monitoring; 939 occurrence of different adverse events were reported with peripheral neuropathy reported the most (14%). It is expected that active surveillance will become a routine practice in Swaziland’s health program and will greatly improve safety of TB/HIV co-medication and health outcomes. SIAPS also finalized and published Drug Use Reviews: A Practical Strategy to Ensure the Rational Use of Anti-Tuberculosis Medicines and provided training to the NTP staff in Kenya to pilot the program. The medical records of 103 drug-resistant TB patients were reviewed, with SIAPS providing technical assistance to the Kenya Division of Leprosy, TB and Lung Disease for data analysis and interpretation of results. The publication was presented at the 45th UNION World Conference.

LESSONS LEARNED AND WAY FORWARD

Two primary challenges in improving pharmaceutical management for TB are shifting donor priorities, which results in reallocation of resources, and staff and retention in certain areas (such as capacity building and information technology). In addition, the new USAID approach that allows 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; however, identifying and training such advisors is a challenge that slowed down the implementation of this strategy in some countries.

Through the implementation of TB-related activities, SIAPS recognized that when properly implemented and with follow-up, the early warning system using QuanTB provided immediate results and was able to prevent treatment interruptions, improve procurement and ordering practices, and prevent waste due to stock-outs. Secondly, an important emerging technical area for SIAPS is active pharmacovigilance for new medicines and regimens. SIAPS has developed several tools for monitoring medicines use and managing risks of medication, and is supporting global capacity in this area through its involvement in global policies development for new TB medicines in addition to providing technical assistance in priority countries.
The Office of Health Systems (OHS) serves as USAID’s center of excellence and focal point to provide 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

Using OHS Cross Bureau funds, SIAPS cross-cutting activities at global and regional levels contribute to the USAID’s priority functional area related 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. Our priorities are to:

• Strengthen pharmaceutical sector governance to promote transparency and accountability through appropriate laws, regulations, policies, and standard operating procedures (SOPs)

• Increase and enhance human and institutional capacity to regulate and manage pharmaceutical systems and services

• Develop and support use of pharmaceutical management information systems embracing both products and patients, including information systems for procurement, logistics, services, and regulatory systems

• Reduce financial barriers to access through more efficient and effective use of financial resources and support for innovative financing strategies and approaches

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

These priority objectives in turn contribute to USG goals—Ending Preventable Child and Maternal Deaths (EPCMD), AFG, Protecting Communities against Infectious Diseases (PCID), and UHC. SIAPS’s key activities and achievements using OHS Cross Bureau funds are described below.

GLOBAL TECHNICAL LEADERSHIP

A seminal SIAPS activity entails developing a framework and metrics to measure and evaluate pharmaceutical system strengthening interventions. The framework and corresponding metrics (or indicators) would monitor and measure whether investments in pharmaceutical systems strengthening are helping to develop stronger, more sustainable systems.

Various conceptual frameworks and indicators are available to assess pharmaceutical systems, and governments are encouraged to collect data to monitor system performance. While there is a need to effectively capture and communicate the impact of investments in strengthening pharmaceutical systems, as yet there is no global agreement on a standardized approach, including a framework, metrics, and tools for measuring the effects of pharmaceutical system strengthening interventions.

The SIAPS Program is committed to improving access to accurate and timely pharmaceutical management information, enabling countries to measure the performance of their pharmaceutical systems, and use this information for resource allocation, intervention design, and evaluation to enhance the delivery of pharmaceutical services.² Country health system planners and donors can use this pharmaceutical systems measurement framework and indicators to identify weaknesses and vulnerabilities in pharmaceutical systems and to strategically plan targeted interventions and investments as part of an overall sector development

plan. It will support the planning of pharmaceutical systems strengthening in terms of policy/governance, human resource requirements, information needs, financing, and service delivery to be able to respond to priorities, such as EPCMD and AFG, while building more resilient and adaptable systems that can sustain access and safe, appropriate use of medicines and other pharmaceuticals in the long term.

To this end, SIAPS outlined the steps for developing a framework and metrics for measuring pharmaceutical systems strengthening. As a first step, SIAPS conducted a review of the literature on pharmaceutical systems and strengthening them to identify pertinent definitions, frameworks, and tools or metrics for assessing or evaluating a pharmaceutical system or some important component thereof. The search yielded three definitions for a pharmaceutical system and no explicit or implicit definitions of pharmaceutical systems strengthening, and confirmed the lack of agreement on a standardized approach, metrics, and tools for measuring pharmaceutical systems strengthening. Although none of the reviewed frameworks explicitly depict a pharmaceutical system, they provided a useful starting point for identifying the key components of a pharmaceutical system.

The results of the literature search were used to draft a background discussion paper which served as the basis for a consultative meeting that SIAPS convened with its partners to agree on the definitions of a pharmaceutical system and its strengthening and to identify the key pharmaceutical system components that are deemed necessary to measure pharmaceutical systems strengthening. The more than 30 meeting participants represented more than 13 organizations, including SIAPS core and resource partners and experts from USAID, PAHO (representing WHO), Boston University School of Public Health, and MSH staff.

The agreed upon definitions are:

**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. The critical components of a pharmaceutical system are its core functions, structures, the supporting health system resources, and an enabling policy, legal, and governance framework.

The meeting participants agreed on seven components that must be included in a measurement framework for pharmaceutical systems strengthening. They also proposed an initial set of elements for each system component that will form the basis for identifying indicators for the measurement framework.

Figure 1 depicts the components and the system outcomes and attributes, based on the agreed on definitions.
The publication, *Defining and Measuring Pharmaceutical Systems Strengthening: Report of the SIAPS Partners’ Consultative Meeting. September 11-12, 2014*, includes the background discussion paper and provides more details of the meeting deliberations. An article is also in development for submission to a peer-review journal to document the process and outputs, and form a basis for global dialogue in this important topic.

Following the consultation, SIAPS validated the selected components and the proposed elements with seminal publications and frameworks in the literature to identify anomalies or important omissions. We also solicited input from staff attending the SIAPS Global Technical Summit (June 2015) on the elements necessary for measuring progress in pharmaceutical systems strengthening and the feasibility of obtaining data.

SIAPS has selected the key elements that form the basis for identifying corresponding indicators. The literature on health systems resilience was also reviewed to identify relevant definitions, characteristics of resilient health systems, and approaches to measurement to further inform the selection of indicators. We will partner with an academic institution to use the database of compiled indicators and evaluation tools to select indicators that relate to performance and resilience/sustainability. SIAPS will also develop data collection tools and a how-to manual. This is expected to be completed by the end of 2015. Once completed, the framework and indicators will be shared with key stakeholders for review and comment. SIAPS will then pilot it in two to three EPCMD priority countries. Results will be used to refine the draft pharmaceutical systems strengthening framework, indicators, and data collection tools.

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In a final step, SIAPS will actively disseminate these products with international partners and USAID-funded programs working to strengthen pharmaceutical systems or some component thereof, and the wider HSS community, with recommendations for adopting the framework and replicating it elsewhere.

The intended outcome of the activity are definitions for a pharmaceutical system and its strengthening and a framework and corresponding metrics that are generally accepted and used by policy makers, planners, and donors to monitor the performance and resilience of pharmaceutical systems, and use this information for intervention design and evaluation to enhance the delivery of pharmaceutical services.

This activity not only contributes to the goals of OHS, but also provides quantifiable data on strengthening pharmaceutical systems, which dependent upon the intervention, may be shown to contribute to USG health goals—EPCMD, AFG, and UHC.

Also, throughout the program years, SIAPS maintained close coordination with other donors, global initiatives, and international and regional organizations in the area of pharmaceutical systems strengthening. This has been done to better coordinate efforts, efforts, improve allocation of resources, develop consensus on global/regional strategies to be pursued and replicated, harmonize tools and approaches, document technical approaches, and increase introduction and expansion (mainstreaming) of best practices. Such efforts are intended to strengthen pharmaceutical systems, especially for US priority public health initiatives such as EPCMD, UHC, PCID, and AFG.

During these forums, SIAPS also supports USAID’s leadership role by ensuring that USAID interests in pharmaceutical management are adequately represented and that USAID-funded activities are well coordinated with those of other donors and implementing partners.

For example, SIAPS continued to collaborate with DELIVER and SCMS on information sharing and the development of needed tools and approaches for improved pharmaceutical management. SIAPS participated in several technical meetings and conferences organized by donors and multilateral organizations including Essential Medicines and Health Products Division of WHO program; the AIDS Medicines and Diagnostics Service; and the Coordinated Procurement Planning program for HIV and AIDS to share information and identify solutions.

SIAPS continued to be solicited to participate and to contribute to global technical leadership activities and events such as Global Supply Chain Summits; Global Fund High Impact Africa II regional meetings; WHO technical briefing seminars; and to present at annual USAID Mini-University sessions. SIAPS also continued to respond to invitations for global action planning and for sharing best practices. For example, SIAPS continued to be actively represented in forums such as the International Pharmaceutical Federation (FIP), the International AIDS Society (IAS), the American Public Health Association (APHA), and the African Society of Pharmacovigilance. Deliverables from these activities, including trip and technical reports describing those collaborations and their impact, as well as posters and PowerPoint presentations, were all shared with USAID.
Also this year, SIAPS has collaborated with the Essential Medicines and Health Products Division of WHO (to revitalize the WHO Essential Medicines and Health Products Information Portal, an open-access, searchable, online library of curated essential medicines publications. Although there is vast experience and knowledge on pharmaceutical management, much of it is relatively inaccessible, hidden in the grey literature or reported only at project levels. This activity has facilitated access to quality pharmaceutical management information including the documentation of evidence-based interventions for policy makers, program managers, academics, and implementing partners. Such access is achieved not only by improving the functionalities of the portal to suit the needs of the users but also by expanding the information content of the portal, thus enabling stakeholders to have better access to information and an increased opportunity to replicate and to scale-up best practices directed to improving access to quality-assured medicines and effective pharmaceutical services.

The portal is now a comprehensive online library of curated essential medicines-related publications of both grey and peer-reviewed literature. As of the end of FY15, the portal contained more than 5,000 pharmaceutical publications in English, French, and Spanish, and has an extensive indexing system, catalogued by region and country and with links to other topical libraries. The upgraded portal now has several features to support users’ access. The portal has also been expanded to include additional non-WHO documentation including USAID-funded documentation, country-based practices, country and global policy and guidance, as well as new subject areas related to pharmaceutical systems strengthening.

Technical Products to Support National Health Systems

The SIAPS Program has worked to contribute to new knowledge, and develop tools and approaches to support implementing pharmaceutical system strengthening interventions at the global, regional, and country level to benefit low- and middle-income countries. The following represents some of the key technical publications that were produced by SIAPS:

- Continuing Pharmaceutical Education: Guide to Establishing Quality Assured and Accredited Programs – in final draft


• How to Investigate Antimicrobial Use in Hospitals: Selected Indicators (available in English, French, and Spanish) http://bit.ly/VlsTZR

• Infection Control Self-Assessment Tool for Primary Health Care Facilities (ICAT-PHC) http://bit.ly/1yLha5M


• USAID e-learning module on good governance in pharmaceutical systems – awaiting publication

Global Engagement

In recognition that the program cannot work in isolation to strengthen national pharmaceutical systems, SIAPS collaborates with thought leaders (donors and international organizations) at the global level to support the achievement of its mandate. Some examples include:

» SIAPS contributes to USG and global efforts to contain the emergence and spread of antimicrobial drug resistance (AMR). SIAPS provided support to USAID in AMR global action planning; supported countries in design/implementation of AMR interventions; attended Uppsala Health Summit/ReAct meeting to discuss AMR Global Action Plan; prepared papers for FIP and APHA conferences on AMR advocacy; initiated the inventory for AMR materials; and initiated update materials on infection control and rational use. Coinciding with WHO’s Assembly resolution on AMR, SIAPS also dedicated the month of May 2015 as an AMR month resulting in the posting of several technical updates, technical briefs, publications, blog, and presentations on its website[^4] and social media.[^5]

» SIAPS supported WHO’s Good Governance for Medicines (GGM) technical working group in the revision of the GGM transparency assessment tool and attended the Geneva meeting to discuss the review. SIAPS also provided support in identifying other WHO/SIAPS short-term collaborative activities which now include review of guidance documents on codes of conduct and conflict of interests, and the support to training materials.

[^4]: http://siapsprogram.org/antimicrobial-resistance/
SIAPS shared experiences from the West Africa Regional Project (WARP) with AIDS Medicines and Diagnostics Service, a network of technical partners providing support and guidance to countries in procurement and supply management of HIV and AIDS commodities. The program also participated in the Coordinated Procurement Planning meeting aimed at planning activities for monitoring and preventing stock-outs of ARVs and diagnostics in high risk countries.

SIAPS is a conduit for global dialogue on medicines management within the context of UHC. Hot on the heels of the MSH-led conference, “UHC and Medicines: Initiating a Dialogue,” in June 2013, SIAPS hosted a second conference “A Practical Approach to Designing Medicines Benefit Management,” for select countries in the southern Africa region in Cape Town, South Africa, in September 2014. This provided the opportunity for participants to discuss how medicines are managed in their programs and learn more about the MSH Medicines Benefit Management tool and about some of the experiences piloting this tool.

SIAPS continues to align with WHO priorities through supporting their European Union/African, Caribbean, and Pacific Island countries (ACP)/ WHO Renewed Partnership program to strengthen pharmaceutical systems and improve access to quality medicines in 15 ACP countries (2012–2016).

Regional Engagement

Cross Bureau funding also allowed SIAPS to participate in regional pharmaceutical systems initiatives. Examples include:

SIAPS supported the West Africa Health Organization (WAHO) for the regional consultation on the draft of the African Model Law and the launch of the sub-regional regulatory harmonization initiative.

SIAPS participated in NEPAD’s African Regulatory Harmonisation (AMRH) initiative technical working group on Regulatory Capacity Development (RCD) to support the selection process for Regional Centers of Regulatory Excellence (RCOREs). SIAPS also facilitated a meeting of AMRH Pharmacovigilance (PV) RCOREs in Accra to define PV priority areas of focus and the coordination and governance of PV RCOREs.

SIAPS continues to strengthen the capacity of the Ecumenical Pharmaceutical Network (EPN), a global network of faith-based organizations working in 31 countries, to build its capacity in strengthening pharmaceutical services in church health systems. As a result of this partnership, the EPN developed and conducted a training-of-trainers program on antimicrobial resistance (AMR) for member participants from Tanzania, Zambia, and Zimbabwe. As a result, action plans to contain AMR at participants’ respective institutions were developed and enacted upon. In an effort to build its institutional capacity for monitoring and evaluation (M&E), SIAPS supported EPN to develop a methodology to evaluate the impact of its technical assistance. SIAPS is currently assisting EPN to assess the feasibility of conducting a pilot in Cameroon for the establishment of pooled procurement systems for
its member organizations. If feasible, lessons learned from the pilot will be applied in other EPN supported countries.

» Lastly, Cross Bureau funds have recently allowed SIAPS to share its West Africa experiences in establishing and managing dashboards for monitoring HIV and AIDS product availability through the West Africa Region.
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.

SIAPS works in several ways to strengthen governance and improve the adoption of and adherence to good governance principles such as transparency, accountability, participation, and responsiveness. SIAPS assists countries to establish and implement policies and legislation supported by the rule of law; strengthens organizational structures enabling them to exercise appropriate decision making, authority, and oversight; improves systems and processes in accordance with best practice norms and guidelines; and bolsters human resource management to 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. While this approach takes time, it ultimately enables more successful handover of interventions to country counterparts and helps to promote sustainability of results.

Because governance issues can affect all pharmaceutical management activities as well as the supporting human resources, information, and financial management systems, SIAPS interventions to strengthen governance are intrinsically linked with interventions that contribute to achievements in the other SIAPS intermediate results (IRs).
SIAPS Approach for Strengthening Governance in Pharmaceutical Systems

The SIAPS approach for strengthening governance in pharmaceutical systems focuses on assisting countries to establish policies and legislation supported by rule of law; organizational structures that are able to exercise appropriate decision making, authority, and oversight; transparent, ethical, accountable systems and processes that are based on best practice norms and guidelines; and human resource management systems that promote effective performance and ethical practices.

KEY ACCOMPLISHMENTS

SIAPS country programs have continued to make advancements in strengthening pharmaceutical sector governance, thereby contributing to the improved access and use of pharmaceutical products and the achievement of USG goals. Progress made towards this IR from the start of the program to the end of program year 4, including some notable activities and achievements, are highlighted below.

Policies, Legislation, and Contractual Agreements

Pharmaceutical products 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 pharmaceuticals in a country and must be supported by guidelines, standard operating procedures (SOPs), effective contractual agreements, and monitoring systems. Effective medicines registration, licensing of pharmaceutical establishments, and control of promotion, availability, prescribing, and dispensing of products rely on appropriate and enforceable legislation and policies. Successful management of contractual agreements for delivery of pharmaceutical services depends on the development of robust contracts and the establishment of systems and indicators to monitor their implementation. SIAPS helps countries to use participatory and transparent processes to develop or revise, adopt, and monitor adherence to pharmaceutical policies, legislation, and contractual agreements that support health sector priorities and promote good governance in pharmaceutical systems.

In Haiti, SIAPS provided technical assistance to the Ministry of Public Health and Population to develop the country’s first ever national medicines policy and helped Guinea and Namibia to update their national pharmaceutical policies. Six SIAPS-supported countries have developed or updated pharmaceutical laws and regulations to date. In Swaziland, SIAPS helped formulate two pieces of legislation that will establish the first-ever medicines regulatory authority in the country. SIAPS advanced legislation in South Sudan that provided for the establishment of the Food and Drug Control Authority and an autonomous central medical store. SIAPS provided technical assistance in Ethiopia to develop federal and regional regulations to support implementation and institutionalization of the innovative Auditable Pharmaceuticals Transactions and Services (APTS) package of interventions. SIAPS helped formulate a ministerial decree in the Dominican Republic that makes use of the recently revised essential medicines list compulsory for medicines procurement and a decree in Burundi that improves the control of malaria commodities provided free of charge to deter their resale and misuse. Most recently, SIAPS assisted the Guinean national medicines regulatory authority in convening preparatory stakeholder meetings to identify needed
revisions to the national pharmaceutical legislation and drafting the new bill which is now ready for review by the law council, ministry of health directorates, and other stakeholders.

SIAPS also helped to strengthen contractual agreements between the central medical stores in Guinea and provincial depots in South Africa and their respective clients and, in Bangladesh, supported the development of a standard framework agreement tender document. Additionally, in Ukraine, SIAPS helped two provincial-level procurement authorities establish framework contracts to foster competitive and transparent public procurement of health products. This technical assistance recently culminated in the award of the first successful tenders—antibiotics for a children’s hospital valued at over USD 21,000 in Poltava oblast, and infusions at a contracted value of up to USD 116,200 in Dnipropetrovsk oblast.

Standards, Guidelines, and Procedures

A challenge that many low- and middle-income countries confront is a lack of robust guidelines and SOPs that define norms and standards for performing pharmaceutical functions, based on international guidance and best practices. Since the start of the project, SIAPS has assisted 17 countries and one regional initiative to prepare or revise pharmaceutical and disease-specific guidelines and SOPs that reflect international guidance and best practices and provide the foundation for good governance and sound practices in pharmaceutical systems. For example, as South Africa moves forward with the implementation of a national health insurance system, SIAPS has partnered with in-country stakeholders to develop and implement a range of new policies, guidelines, and procedures to support licensing of pharmacies, procurement of health products, and appropriate medicines selection and rational use. Most recently in South Africa, SIAPS helped formulate a guidance document that can be used to develop or review terms of reference for any pharmaceutical sector committee and used it to review them for the NEML committee and the committee responsible for evaluating bids for pharmaceutical product tenders. In Bangladesh, SIAPS helped the Directorate of Family Planning establish a central procurement coordination mechanism and revise procurement policies and procedure manuals which together helped reduce the ordering lead time for family planning commodities from 78 weeks at the beginning of the project to 33 weeks in 2015.

SIAPS has assisted eight countries—Angola, Bangladesh, the Democratic Republic of Congo (DRC), the Dominican Republic, Guinea, Lesotho, Mozambique, and Namibia—to update their national essential medicines, device, and equipment lists using approaches that facilitate skills transfer to counterparts for implementing future revisions.

Transparency and Accountability

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

SIAPS is assisting the Ethiopian government to achieve greater transparency and accountability in the management of pharmaceuticals, related finances, and delivery of services at public health facilities through implementation of the APTS package of data-driven interventions. After a successful pilot in 2011, SIAPS has helped to scale up APTS to 45 health facilities in four regions and two city administrations to date. Implementing hospitals are now reporting significant reductions in medicines wastage, increased revenue, and improvements in the availability of essential medicines.

In Guinea, SIAPS assisted the central medical stores to launch an international tender for essential medicines, prequalify suppliers, and review bids, which culminated in a more transparent, equitable, and competitive process. In South Africa, SIAPS helped the National Department of Health to implement electronic submission of bids to improve efficiency and transparency. Five SIAPS-supported countries and one region are using dashboards that enable them to access timely information and easily monitor processes and provide oversight. For example, as a result of SIAPS technical assistance, South Africa’s National Department of Health now has a dashboard and metrics to monitor the provision of pharmaceutical services and compliance to standards relating to rational medicines use, access, availability, financing, and human resource management.

Most recently, in South Africa, SIAPS helped the Free State Province develop and launch the Pharmaceutical Leadership and Governance Initiative in response to a request for assistance from the Pharmaceutical Services Directorate in addressing issues identified in the Auditor General’s report that impact medicines availability in the public sector. SIAPS adapted the Pharmaceutical Leadership Development Program (PLDP) to meet the capacity-building needs identified for pharmacists particularly with respect to fostering good governance to improve medicine availability.

As a result of SIAPS support, civil society organizations (CSOs) now play a greater role in monitoring and oversight of pharmaceutical management operations in Ethiopia, Mali, and Swaziland. For example, five CSOs in Mali recently participated in two national quantification workshops and contributed to identifying assumptions and reaching consensus on their use to calculate needed quantities of family planning commodities, especially when data are missing. It is anticipated that this inclusive and transparent process will improve forecasting accuracy and also donor confidence in the quantification process.

Additionally, in Ukraine, SIAPS assisted CSOs in reviewing draft regulations on reference pricing, after which the organizations issued a public statement on the policy and its potential impact on access to essential medicines in the country. To build their capacity and expertise, SIAPS trained representatives from five Ukrainian CSOs on medicines pricing and approaches to price referencing, and is working with the All Ukrainian Network of People Living with HIV to test a price monitoring tool developed by SIAPS to support their advocacy efforts. In Cameroon, SIAPS partnered with Positive-Generation, a local CSO, to launch the organization’s annual report and present data on ARV availability to improve patient access to information on HIV-related medicines and products.
Coordination, Partnership, and Advocacy

At the global and national levels, SIAPS works to facilitate conversations among partners and stakeholders to achieve a mutual understanding of governance issues, agree on next steps to address them, and advocate for required support. Through participation in the technical working group for WHO’s Good Governance for Medicines (GGM) program, SIAPS has been providing technical inputs to support WHO in revising the GGM transparency assessment tool. At the country level, SIAPS is increasingly engaged in advocacy efforts targeting key decision makers to help expedite otherwise lengthy legislative procedures. For example, in Swaziland, SIAPS is collaborating with the Ministry of Health to explain to parliamentarians the content and importance of draft bills that replace existing pharmaceutical legislation dating back to 1929 and expedite implementation of the bills once they are passed.

Many SIAPS countries are supporting the implementation of coordination efforts that promote more informed decision making, foster transparency and accountability, supply chain management and service delivery, and improve the efficiency of planning, allocation, and mobilization of government and donor resources. SIAPS has implemented activities in ten countries to improve coordination across ministries, implementing partners, country donors, and health initiatives. For example, SIAPS helped establish and support ongoing meetings of coordination mechanisms for logistics in Angola, Bangladesh, Burundi, Guinea, Lesotho, Mali, Philippines, and Swaziland, and for quantification in Cameroon and Ethiopia. SIAPS also worked in Mali, during a period of severe civil unrest, to establish a national committee for the coordination and monitoring of health commodities to maintain uninterrupted access to essential medicines and services. In Guinea, SIAPS partnered with WHO and UNICEF to assess the impact of the Ebola epidemic on Guinea’s central medical store and identify urgent actions needed to support its role in coordinating national logistics for Ebola supplies among the increased number of partners working in the country.

In the Philippines, SIAPS helped Quezon City to establish three grassroots health management councils—comprised of community-based groups, officials, and health providers—to improve TB services in urban poor settlements (barangays). SIAPS’s support has helped improve council members’ skills in TB program management, oversight, advocacy, and coordination. Inspired by the councils’ contribution to a 27 percent increase in the numbers of suspected TB cases tested and 23 percent increase in smear-positive cases receiving treatment in remote areas, and the reduction of TB medicines stock-outs through better stakeholder collaboration, the Quezon City Council recently passed an ordinance to establish the health councils in each of the city’s urban poor settlements. SIAPS is now working with Quezon City to draft implementing rules and regulations and assisting district health officers who supervise the councils to develop monitoring plans. Most recently, SIAPS helped three existing and four new councils develop community action plans for 2015–16 that focus on ensuring community stakeholder participation, aligning stakeholder objectives, mobilizing funds, enhancing referral, and improving information management at the barangay level.

Strategic Planning

Long-term strategic plans guide the implementation of approaches, methods, and mechanisms to help achieve priorities and goals set out in nationals policies and
promote good governance in the pharmaceutical sector. Working in partnership with national governments, SIAPS helps countries to analyze local contexts, formulate well-informed strategic plans that address identified priorities, engage stakeholders, build consensus, plan for adequate resources, and develop results-based implementation monitoring systems. In Guinea, Namibia, South Sudan, and Swaziland, SIAPS helped the ministries of health to develop national pharmaceutical strategic plans, all of which have been approved and provide a roadmap for pharmaceutical services development in the health sector. In Angola, SIAPS provided technical assistance to map progress against the national pharmaceutical strategic plan and helped outline priorities to be addressed in the remaining years of the plan. This allowed the ministry to define and realign work plans and fiscal priorities with the national health development plan.

Additionally, SIAPS has helped develop or revise a range of strategic plans in 10 countries, including for the central medical stores in Mali and Guinea, procurement of reproductive health commodities in Bangladesh, supply chain management in Lesotho and DRC, the Faculty of Pharmaceutical Sciences in DRC, the national TB reference laboratory in the Philippines, and for disease programs in Burundi, Philippines, South Sudan, Ukraine, and Uzbekistan.

**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—such as medicines registration, inspection, and pharmacovigilance—may not be executed effectively, efficiently or ethically, thereby putting people at greater risk of using unsafe and poor quality medicines and limiting their access to the essential medicines they need. SIAPS provides support to national medicines regulatory authorities to assess their systems, build their technical capacity, reform processes to align them with international standards and make them more efficient and transparent, and upgrade information management systems for improved transparency, oversight, and accountability—all with the aim of enabling timely access to quality medicines and other health supplies.

Using the regulatory system assessment tool (RSAT) developed under the SPS program, SIAPS has collaborated with national medicines regulatory authorities in Angola, Bangladesh, and Mozambique to conduct comprehensive assessments of their systems. The assessments results were used to develop recommendations and options for improvement, which were then shared with stakeholders for validation and prioritization. The agreed upon priorities served as a basis for selecting, planning, and implementing appropriate interventions for each country with support from SIAPS as well as other partners.

SIAPS has worked to strengthen capacity and improve processes for product registration in Angola, Bangladesh, DRC, Ethiopia, Mozambique, and Namibia. With support from SIAPS, three of these countries have adopted the internationally-endorsed Common Technical Document format and specifications to standardize the medicines registration application process and five are implementing the registration module of SIAPS’s web-based regulatory information system (Pharmadex), or a comparable electronic system, to make their processes more efficient and transparent. In DRC, SIAPS’ efforts to strengthen the medicines registration process through the establishment and
continued support of a national registration committee have resulted in an increase in the number of registered medicines, from 200 in 2010 prior to SIAPS intervention to more than 4,000 in 2015. Seventy-two percent of the medicines included on DRC’s essential medicines list currently have at least one product registered, up from 44% in 2011. Additionally, the list of registered medicines is now publicly available, regularly disseminated throughout the health system, and used by government inspectors to control medicines at ports of entry.

SIAPS also works to improve inspection processes, in addition to overall quality assurance systems for medicines as implemented through regulatory bodies. In Bangladesh, SIAPS assisted the Directorate General of Drug Administration (DGDA) to develop and update its guidelines and tools for conducting inspections for Good Manufacturing Practice inspections of pharmaceutical manufacturing sites and also regular inspections of pharmaceutical suppliers. Additionally, the functionality of the DGDA’s website was expanded allowing for more efficient submission and processing of pharmaceutical establishment inspection reports, including sample collection forms for testing. SIAPS provided technical support to the Namibia Medicines Regulatory Council (NMRC) to operationalize the medicines quality monitoring guidelines and to conduct medicine quality surveillance at 24 public health facilities as part of the Ministry of Health and Social Services’ post-marketing surveillance initiative for assuring quality of ARVs and medicines used to treat opportunistic infections. SIAPS supported the Council in collecting a total of 172 medicine samples, of which 25% were ARVs, for quality testing. Most recently, SIAPS’ on-going support for quality surveillance at both central and site levels in Namibia resulted in the NMRC issuing three circulars to recall poor quality products from the market, including two batches of co-trimoxazole tablets used in the prophylaxis of opportunistic infections in AIDS and four batches of other essential medicines. In addition, assistance from SIAPS contributed to the inclusion of Ebola commodities into the regular quality control system in Guinea.

In recognition of the interdependence of key regulatory functions and the need to address a country’s regulatory system as a whole to achieve greater effectiveness and sustainability, SIAPS often provides technical support across multiple, interrelated regulatory functions. In Bangladesh, for example, after conducting a comprehensive assessment in 2012, SIAPS provided technical assistance to strengthen product registration, inspection, pharmacovigilance, and the supporting information systems.

In addition to country-specific efforts to strengthen regulatory systems, SIAPS has provided technical support to two regional regulatory harmonization initiatives, the African Medicines Regulatory Harmonization (AMRH) and the East African Community (EAC) programs. These initiatives are intended to promote the standardization of good pharmaceutical regulatory practices and information sharing across countries, in addition to improving the efficiency, effectiveness, and rigor of regulatory processes. SIAPS reviewed AMRH’s model law for the continent and participated in the technical working group for regulatory capacity development in the region, providing targeted support for the two regional centers of regulatory excellence for pharmacovigilance.
STRENGTHENING REGULATORY SYSTEMS TO IMPROVE ACCESS TO SAFE, EFFECTIVE, AND QUALITY MEDICINES

CHALLENGE

Inadequate regulatory processes allow medicines of uncertain safety and quality to enter the supply system

After decades of civil unrest and chronic under-funding of the health sector, the Democratic Republic of the Congo (DRC) lacked the regulatory capacity to effectively manage the complexity of registering and approving new medicines. There were also notable weaknesses in the governance of the registration process: authority to register medicines was assigned to just one person rather than a committee, no mechanism existed for tracking decision making, and there was no official register of approved medicines that could be used in the control of importation and sale of medicines. These weaknesses in the product registration system contributed to the influx and distribution of unregistered and poor-quality medicines. A 2007 study reported that samples of antimalarials purchased in the informal market in Goma, DRC, did not meet quality standards in terms of packaging and, more disturbingly, bioavailability and bioequivalence standards, which affect therapeutic efficacy. These are issues that can be better evaluated and regulated through a robust medicine registration process.

SIAPS ACTIVITIES

Improving the transparency and efficiency of the medicines registration system

As a first step toward strengthening the regulatory system, the Strengthening Pharmaceutical Systems (SPS) Program assisted the Directorate of Pharmacy and Medicines (DPM) (part of the Ministry of Health [MOH]) to develop guidelines and standard operating procedures (SOPs) for product registration, and then to train the staff. These efforts led to the establishment of the first national medicine registration committee in 2010. SPS also helped the DPM create a registered medicines database, which contained information on the 200 products registered at that time.

Building on this work, SIAPS has provided further training for national registration committee members to build their competencies and promote best practices. The DPM, with SIAPS assistance, has further improved the SOPs to better align them with international guidance and good governance recommendations. SIAPS also helped the committee establish a schedule for quarterly meetings and set up systems for biannual publishing and posting of the registered medicines list.

In August 2012, SIAPS supported the publication and dissemination of the first list of registered medicines in DRC. The list was quickly and widely used to improve the regulation of medicines—customs officers used it to check for unregistered
medicines at border posts and provincial pharmacists used it to track and confiscate unregistered products during inspections of pharmaceutical premises. When these improved regulatory actions triggered a rapid influx of applications for product registration that created a backlog, SIAPS helped the registration committee adjust their procedures, particularly task distribution, to improve efficiency and reduce the backlog, which was successfully eliminated in 2013.

RESULTS Streamlined, transparent, country-owned processes for registration of medicines

SIAPS technical support has helped strengthen the capacity of the national registration committee and streamline medicines registration. As a result, the number of registered medicines has increased from 200 in 2010 to over 3,000 in 2014; 72% of the medicines included on DRC’s essential medicines list currently have at least one product registered, up from 44% in 2011. The backlog of applications has been completely eliminated and the time taken to process a new application has been reduced from a peak of 85 days in 2013 to 70 days at the end of 2015.

Now independently funded and managed by the MOH for over a year, the national registration committee has continued to meet regularly every quarter. Attendance of the SIAPS team at the meetings is no longer needed to drive the process and the team only participates on request. The lists of registered and newly approved medicines have been posted on MOH and provincial pharmacist inspectors notice boards and made publicly available biannually. The lists continue to be used by customs officers and inspectors to control importation and conduct inspections nationwide.

The MOH now has the capacity to systematically evaluate and approve medicines for registration in a timely manner using processes that are more transparent and less vulnerable to corruption. Customs officers and inspectors are also better equipped to identify and confiscate unregistered medicines at the border and in circulation in DRC. A stronger product registration system is helping the government ensure that medicines in the country are safe, effective, and of acceptable quality.

Figure 1. Percentage of EML Items that Have Registered Products in DRC
To further enhance the transparency and credibility of the national registration committee, the DPM recently accepted a SIAPS recommendation to extend committee membership to external stakeholders, including active health practitioners, experts working in academia, and members of professional associations. SIAPS will now focus its efforts on assisting the DPM recruit and train new members. Also, to increase efficiency and transparency, SIAPS is supporting the DPM to introduce software to help streamline and track medicines registration as well as publish the list of registered medicines on its website.

The World Health Organization (WHO) recently helped the DPM conduct an evaluation of the registration process. On the basis of the gaps identified, WHO developed a set of recommendations, many of which align with planned SIAPS technical assistance activities. Furthermore, SIAPS is planning to revise and enhance the existing SOPs which can be used to train new members of the committee and serve as an oversight tool for checking that decision making and tasks are executed appropriately.

THE CHALLENGE

Developing stronger pharmaceutical systems that allow for greater and more equitable access to medicine hinges on the availability of skilled health care workers, program managers, and leaders: people with the appropriate and upgraded knowledge, skills, and competency based training to effectively implement activities related to 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 country governments and universities to health facilities and health care workers—to address pressing human resource capacity challenges such as health care worker shortages, resource constraints, and policy-level issues. Using a participatory approach, we identify areas and opportunities for capacity improvement and develop strategies to strengthen the system in the long-term while also working to develop solutions to immediate or short-term threats to medicines availability and access.

The SIAPS approach to capacity building is guided by MSH’s capacity building framework which emphasizes nine interrelated components. These components, which are categorized into individual (performance and personal capacity) and institutional (workload, facility, supervisory, support service, structural, 

**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.

Data as of 9/12/15

- **11 pre-service and 33 in-service pharmaceutical curricula developed or revised across 11 countries**
- **35,902 People Trained in pharmaceutical management**
- **SIAPS supporting 10 countries in using post-training action plans for knowledge transfer and learning**
systems and role capacity), are vital considerations in SIAPS’ efforts to strengthen national pharmaceutical systems capacity (see figure below). This approach emphasizes strengthening the pharmaceutical management capacity of individuals, institutions, and networks through participatory methodologies and innovative approaches. Finally, recognizing the value and importance of partnership, SIAPS leverages its effective working relationships with local and global institutions to develop and implement collaborative interventions that are both locally relevant and sustainable.

KEY ACCOMPLISHMENTS

Strengthening Capacity of Individuals, Institutions, Organizations, and Networks

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 to strengthen the cadre of professionals ready to effectively manage, prescribe, and monitor the use of medicines.

Pre-Service Curriculum Reform

SIAPS works with local universities and other training institutions to strengthen the pharmaceutical training that future pharmacists and health care workers receive by developing more robust training curricula, courses, and programs. To date, SIAPS has helped develop or reform eight health professional pre-service training curricula in the areas of medicines supply management, pharmacy law ethics, rational use of medicines, and pharmacovigilance. Four of these programs have been accredited by relevant in-country governing bodies. SIAPS has also supported the placement of pharmacy personnel in underserved and rural areas of the DRC, Lesotho, Namibia, South Africa, Swaziland, and Vietnam.

Moreover, SIAPS works with a number of university training programs to build the capacity of the pharmaceutical training institutions to enhance the pharmaceutical education capacity and produce pharmaceutical professionals locally as a key mechanism to sustain the system.

» In Dominican Republic, SIAPS assisted the Universidad Central del Este (UCE) in the organization of the certified course (diploma) on pharmaceutical supply management, which has been developed to builds the capacity of health care providers so they can effectively manage the country’s national pharmaceutical management system. In addition, SIAPS assisted UCE in drafting educational modules for a certified course on rational medicines use (RMU). The course is expected to be implemented in November 2015.

» In Namibia, SIAPS helped initiate training programs for pharmacists and pharmacy assistants at the National Health Training Centre. Additionally,
Namibia’s antimicrobial resistance (AMR) coalition-based strategy (developed in 2013 with technical assistance from SIAPS) identified the University of Namibia (UNAM) as an organization to play an integral role in the pre- and in-service training of health care professionals to enhance RMU and to combat AMR.

» South Africa worked with the University of Western Cape (UWC) to develop the online RMU course, which is offered as a stand-alone course or as part of a Master’s in Public Health. The course was launched on July 2015, and 12 participants from South Africa, Botswana, and Nigeria enrolled. Through this initiative, SIAPS provided technical assistance to deliver the first distance learning course aimed at strengthening RMU in Africa.

In-Service Trainings

In addition to pre-service training, SIAPS also works to improve in-service training opportunities for practicing pharmaceutical and health professionals. SIAPS aims to build technical skills among practitioners and their capacity for leadership, management, and mentoring. Since SIAPS’ inception, 34 in-service training curricula have been developed or revised in 10 countries, exceeding the program target of 30 training curricula. To date, more than 35,000 pharmaceutical staff of over 20 countries have been trained in various aspects of pharmaceutical management including financing, leadership, regulatory, quality assurance, pharmaceutical care, medicine safety, antimicrobial resistance, and supply chain management (procurement, quantification, inventory management, and information management, among others).

In South Africa and Lesotho, SIAPS leveraged work from previous programs to develop and implement a customized pharmaceutical leadership development program (PLDP) which combines pharmaceutical management knowledge and sound leadership practices to better equip pharmacy managers to respond to challenges in their workplace. In Lesotho, the Supply Chain Management Leadership Development Program (SCMLDP) has been fully institutionalized. As proof of country ownership, SCMLDP has transitioned to the Ministry of Health (MOH) Supply Chain Coordinating Unit (SCCU) that fully funds the trainings.

Building Local Capacity to Strengthen Pharmaceutical Systems

In full support of USAID’s efforts to empower and enable country governments and local institutions to develop, implement, and own the technical assistance and capacity building activities occurring in country, SIAPS strives to ensure its capacity-building efforts address immediate country needs but also take into account long-term goals which 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—

» To build capacity in the pharmaceutical management areas, during the third quarter, Mali supported 18 local institutions to provide training on pharmaceutical management. In particular, SIAPS assisted the Department of Pharmacy and Medicines (DPM) to design and organize four comprehensive
three-day workshops to train MOH staff and others stakeholders on the use of OSPSANTE (Outil de Suivi des Produits de la Santé), a dashboard designed for management and tracking of antimalarial and family planning commodities. During the fourth quarter, Mali supported a total of 15 local institutions and organizations (DPM, PPM, PNLP, DRS, and health districts) to providing training or technical assistance in pharmaceutical management. The trainings focused on pharmaceutical management tools, such as stocks cards and logistic reporting tools, including requisition forms and how to calculate commodities needs as included in the LMIS SOPs developed in 2012 and adopted in 2013.

» South Sudan provided technical assistance to World Vision through facilitation of pharmaceutical management training for their health care providers. During the third quarter, ten health workers were trained (eight male and two female), including clinical officers, midwives, and nurses from the refugees’ camps and health facilities which include Mapudu PHCC and Napere PHCU. This forms part of SIAPS support in rolling out the pharmaceutical management interventions to the health-facility level to improve medicines availability and use.

» SIAPS collaborated with the Korea International Cooperation Agency (KOICA) and the World Health Organization (WHO) to provide a long-term training program on regulatory functions for the Directorate General of Drug Administration (DGDA) in Bangladesh. Moreover, SIAPS assisted the DGDA to find an appropriate training center and design a training program to strengthen their overall regulatory functions.

Using Innovative Approaches to Capacity Building

The SIAPS approach to building human resource capacity recognizes the importance of face-to-face trainings, but goes beyond traditional trainings by complementing these efforts with additional proven and innovative capacity-building methodologies. These include establishing supportive supervision and task shifting structures, implementing continuous quality improvement measures, engaging the private sector, exploring online learning platforms, and placing an emphasis on effective knowledge sharing and exchange.

Supportive supervision promotes effective and equitable health care through measured improvements in the procedures, personal interactions, and management of primary health care facilities and pharmacies while focusing on meeting staff needs for management support, logistics, training, and continuing education. SIAPS assists governments and in-country counterparts to design and implement a supportive supervision plan and helps conduct supportive supervision visits. For example, in Lesotho, SIAPS mentored 24 health care workers in management of laboratory commodities, and conducted 135 supportive supervision visits to health facilities for LMIS and nutrition assessment counseling (NACS) in three implementing districts. These activities have contributed to an increase in the NACS reporting rate from 4% to 95%. During this past year, in Swaziland, facility supportive supervisions have been largely transitioned to the MOH while SIAPS continued to provide technical assistance and logistical support. This year, 100% of SIAPS-supported regions have documented supportive supervision visits to ART sites. In general, all facilities were found to be using standardized ordering, reporting, and inventory management tools.
Our multifaceted approach to capacity building also recognizes the growing importance of electronic tools and new media to support its work of strengthening pharmaceutical systems. For example, during this year, Ethiopia, Namibia, South Sudan, and the National AIDS Control Program of Togo conducted trainings on the use of the Electronic Dispensing Tool (EDT) to ensure better dispensing practices and treatment decisions for patients. The EDT is used in ART clinics to manage ART patients and ARV medicines.

TB Program officials from Bangladesh, Philippines, Uzbekistan, Tanzania, and Malawi received training on the use of QuanTB, an electronic forecasting, quantification and early warning tool designed to mitigate risk of stock-outs, improve procurement processes, and ordering and planning for TB treatment. In Uzbekistan, the countrywide rollout of the system was completed in September 2015.

In an effort to make pharmaceutical management topics as widely accessible as possible, SIAPS has developed online courses on good governance and antimicrobial resistance, which will be freely available on USAID’s Global Health e-Learning Center website.

Global Technical Leadership and Guidance

Harnessing our expertise in pharmaceutical systems strengthening, SIAPS provides thought leadership, technical guidance, and input into many global initiatives, programs, and strategies.

SIAPS has helped build the technical capacity and leadership of several international initiatives, such as the Stop TB Global Drug Facility (GDF) by participating in the GDF Advisory Group, supporting two members of the GDF Technical Review Committee, and regularly providing a pharmaceutical specialist in GDF monitoring missions and WHO TB program reviews. With SIAPS technical leadership and input, the GDF has developed and is successfully implementing a strategy aimed at increasing procurement efficiency and market safety. As a result, the GDF is able to expedite the supply of TB commodities to countries by securing additional suppliers of quality-assured TB medicines, establishing rotating stockpiles of medicines and making procurement funding flexible, and shortening procurement lead times. Currently, SIAPS is assisting the GDF in formulating its strategy and operational plan to establish itself as a prime supplier of TB medicines to the countries procuring via the New Funding Mechanism of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Importantly, SIAPS has also served as an advocate and technical resource to strengthen the capacity of countries that are striving to adopt and achieve universal health coverage (UHC) as well as those countries seeking information about the management pharmacy benefit programs. SIAPS, in collaboration with Harvard University and WHO, has organized two major conferences to raise awareness and the general capacity of program managers and policy makers on the importance of medicine benefit programs as part of UHC.
CASE STUDY

SUPPORTING PRE- AND IN-SERVICE TRAINING PROGRAMS TO EXPAND AND STRENGTHEN THE PHARMACEUTICAL WORKFORCE

CHALLENGE

Effective pharmaceutical services hampered by human resource shortages and medication errors

A number of low resource countries are facing a severe and prolonged shortage of health workers, particularly in the pharmaceutical sector where pharmacists, pharmacy assistants, and technicians are becoming especially scarce. With treatment programs, such as those for HIV/AIDS and TB, expanding in many countries, more pharmacists and pharmacy assistants are required to provide effective services. Additionally, overstretched pharmacists and other healthcare workers are often unable to provide effective patient-centered pharmaceutical care which is recognized as a critical opportunity to prevent drug resistance, reduce irrational medicines use, eliminate wasteful spending, and most importantly, improve patient health outcomes.

In 2010, Swaziland’s 287 government facilities shared a total of 16 pharmacists.\(^1\)

In Ethiopia, a shortage of qualified pharmacy personnel contributed to an environment where pharmacists are rarely included as members of the clinical team and are unable to provide patient-centered pharmaceutical care. As a result, some studies show that nearly 75% of patients experience drug-related problems during treatment.\(^2\)

Until recently, Swaziland, like many developing countries, did not have an established training program for pharmaceutical health workers, instead relying on programs in South Africa, Ukraine, or Russia to train their students. However, these students frequently find other work and decide not to practice in their home country which further exacerbates existing shortages in the pharmaceutical workforce. In 2010, Swaziland’s 287 government facilities shared a total of 16 pharmacists.\(^3\)

Students practice interpreting laboratory results as part of the pharmacy training program at SANU.
Since the inception of SANU’s pharmacy program, nearly 74 students have enrolled.

**Swaziland: Increased local capacity to train pharmacy personnel**

Since the inception of SANU’s pharmacy program, nearly 74 students have entered the training program, the first of whom graduated with a Certificate of Pharmacy in July 2014. With this new cadre of pharmacy workers entering workforce, Swaziland has taken an important step forward in meeting its human resources needs to deliver high-quality pharmaceutical care and services. The Diploma in Pharmacy program (three-year program) was also launched in 2014 and additional academic institutions have expressed interest in offering the program and adapting it for part-time or distance learning.

**Ethiopia: Clinical pharmacy services improve quality of care and patient outcomes**

More than 200 pharmacists across 44 hospitals have been trained through in-service training programs supported by SIAPS, PFSA, EPA, and local universities; and clinical pharmacy services are now being provided at over 40 facilities nationwide. The pharmacist is increasingly viewed as an integral member of the clinical team and the practice of patient-centered clinical pharmacy services is becoming the standard at many facilities across Ethiopia. This shift in pharmacy services has also triggered improvements in the recognition and resolution of drug-therapy problems (Figure 1), documentation of patient medication profiles (Figure 3), medication adherence, and reporting of adverse drug reactions. Pharmacists also now have greater and more meaningful interaction with patients which

**SIAPS ACTIVITIES**

**Swaziland: Developing a first-ever in-country pharmacy training program**

Given the dearth of pharmacy workers, coupled with new federal regulations which specify the specialized training required for pharmaceutical personnel, the Ministry of Health (MOH) set out to establish the first-ever pharmacy training program in Swaziland with support from SIAPS.

After SIAPS conducted a feasibility study, the MOH decided that the training program would support three types of pharmacy personnel (pharmacy assistants, pharmacy technicians, and pharmacists). In a widely consultative process, the training curricula were developed with inputs from tertiary educational institutions, private sector pharmacists, MOH stakeholders, the Pharmacy Association, local pharmaceutical companies, and non-governmental institutions. SIAPS worked with local stakeholders to identify training needs, create the curriculum content, and outline job descriptions for the new functions. After receiving government funding for the program, the Southern Africa Nazarene University (SANU) established the Department of Pharmacy at its Faculty of Health Sciences in 2012 and with technical support and guidance from SIAPS began offering a two-year certificate and a three-year diploma in pharmacy services.

**Ethiopia: Improving care through patient-centered clinical pharmacy services**

Staff shortages combined with high-levels of drug-related problems among patients spurred SIAPS to partner with local organizations (including the Pharmaceutical Fund and Supply Agency (PFSA), the Ethiopian Pharmaceutical Association (EPA), and schools of pharmacy from four Ethiopian universities) to create consensus and advocate for a more patient-centered approach for the provision of pharmaceutical services, one that integrates pharmaceutical personnel into an interdisciplinary team of care providers.

Continuing and building upon previous efforts from SIAPS’ predecessor program (Strengthening Pharmaceutical Systems [SPS]), SIAPS worked with its local partners to hold forums, trainings, and workshops to introduce the concepts of clinical pharmacy services to active health practitioners, university staff, and policymakers. SIAPS also supported the incorporation of patient-oriented pharmacy services into national guidelines and standards, and developed a range of short-term intensive in-service trainings, as well as training of trainers sessions, and routine in-service sessions to rapidly expand the implementation and practice of clinical pharmacy services.

**RESULTS**

**Building a cadre of skilled pharmaceutical professionals**

**Swaziland: Developing a first-ever in-country pharmacy training program**

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has served as a critical opportunity for better patient education, counseling, and follow up.

Figure 1. Drug-therapy problems identified and percent addressed between August 2012 and May 2014

<table>
<thead>
<tr>
<th>Type of DTPs</th>
<th># DTPs</th>
<th>% addressed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unnecessary drug therapy</td>
<td>514</td>
<td>82</td>
</tr>
<tr>
<td>Needs additional drug therapy</td>
<td>906</td>
<td>83</td>
</tr>
<tr>
<td>Ineffective drug</td>
<td>346</td>
<td>73</td>
</tr>
<tr>
<td>Dosage too low</td>
<td>316</td>
<td>89</td>
</tr>
<tr>
<td>Adverse drug reaction</td>
<td>162</td>
<td>73</td>
</tr>
<tr>
<td>Dosage too high</td>
<td>311</td>
<td>85</td>
</tr>
<tr>
<td>Noncompliance</td>
<td>349</td>
<td>92</td>
</tr>
<tr>
<td>Total</td>
<td>2904</td>
<td>83</td>
</tr>
</tbody>
</table>

In Swaziland, based on the experiences and key lessons learned from the implementation of the initial pharmacy program, SIAPS continues to support SANU to implement the Diploma in Pharmacy program to expand the program and provide students with a choice of training facilities across Swaziland.

In Ethiopia, new pharmacy students are now acting as ambassadors for the continued scale up of clinical pharmacy services and help to complement previously held in-service trainings. While persistent attrition and staff shortages continue to challenge the health system, SIAPS continues to work with its local partners and universities to institutionalize and ensure sustainability of clinical pharmacy services. SIAPS is also planning to support partners in evaluating the impact of clinical pharmacy services and disseminate results to all relevant stakeholders.

SIAPS’ approach with regards to management information system is to harmonize and integrate the collection and presentation of accurate quality pharmaceutical and other commodities data and ensure that it is processed in a timely and consistent manner. This data assists decision makers and health workers at all levels of a country’s health system to make evidence-based decisions, to manage health and laboratory commodities, pharmaceutical services, and measure, monitor and evaluate progress. SIAPS’ approach includes careful assessment of interventions related to information systems to determine the feasibility and long-term effect of their implementation and, when required, strives to find the best solution to address health-related data collection, processing, reporting and decision-making challenges that support country ownership and sustainability. SIAPS pharmaceutical management information tools such as RxSolution, Pharmadex, e-TB Manager, QuanTB, OPSSANTE, OSPSIDA, EDT, and Data Collection and Analysis Tool (DCAT) support both product and patient information. The demand for these tools in SIAPS and non-SIAPS countries keeps on growing and SIAPS works with various partners to expand the use of these tools.
KEY ACCOMPLISHMENTS

Data Utilization

SIAPS tools, technical assistance, and systems strengthening approach allow for effective use of data for analysis and evidence-based decision making.

In South Africa, the analysis of RxSolution inventory and usage data from 13 sites in the Free State province showed gaps in inventory management that were discussed with departmental officials in an effort to improve management and availability of pharmaceuticals.

In September 2015, SIAPS helped the Uzbek Ministry of Health successfully complete a nationwide roll-out of QuanTB, a tool that serves as an electronic forecasting, quantification and early warning tool to support TB programs. It is designed to improve procurement processes, ordering, and planning for TB treatment. By completing this roll-out, Uzbekistan distinguishes itself in the former Soviet space by implementing QuanTB at the regional level.

Also with the use of QuanTB, SIAPS continues providing support in maintaining an early warning TB medicines supply system in Tajikistan. The system allows addressing challenges in supply planning that result in stock-outs and overstocks of TB medicines.

In Mali, the logistic data reporting rate improved after the intervention of the web-based system/dashboard OSPSANTE. The percentage of surveyed health facilities that completed and submitted an LMIS report for the most recent reporting period increased from 67% to 87%.

During this quarter, SIAPS/Mali supported the national malaria control program (PNLP) to conduct the second EUV survey of this current program year. This EUV was conducted during the rainy season (August 21–September 17, 2015) in 79 health facilities in five of Mali’s eight regions. The data collected during this exercise showed significant progress on logistic data reporting rate as well as on the availability of malaria commodities at the lowest level. In fact, 74.36% of facilities surveyed during the EUV submitted stock reports and orders on time.

Data Quality

In Bangladesh, SIAPS continues assessing the quality of reports and contributes to designing supervision plans for poor performing sites monitored using the SDP dashboard module. A follow-up analysis in August 2015 shows that around 98% of total sites maintain high data quality standards.

In Ethiopia, EDT helps health facilities to prevent medication errors, improve medicines dispensing counseling and adherence to treatment to ART patients. During the fourth quarter, 143 medication errors were identified by hospitals and health centers, which were communicated to the prescribers and corrected.

In Lesotho, SIAPS continues to provide technical assistance to the MOH to improve availability of ARVs, HIV rapid test kits, and other HIV related commodities through the implementation of the district-based supportive supervision and mentoring of all health facilities. IR3 indicators show that 100%
of health facilities keep complete patient information as per national standards (target: 90%), and 97% use country-appropriate tools for reporting logistic and patient data by district (target: 90%).

In Swaziland, SIAPS conducted logistic data validation and verification to improve the quality of ART LMIS reports submitted by facilities to the Data Management Unit (DMU). This is a continuation from the previous quarter where SIAPS supported the DMU in carrying out a data quality assessment for 45 health facilities.

Information System Design and Collaboration

SIAPS home office and field teams work together with various national and international partners to continuously develop new solutions to ensure effective implementation of information systems.

In Bangladesh, the health information system mapping exercise report was finalized in consultation with stakeholders and submitted to HQ. With the technical assistance of the William Davidson Institute, SIAPS HIS team analyzed the extent to which evidence-based information can be used in selecting supply chain interventions and recommended a framework to determine which supply chain technical assistance activities will yield a higher impact on supply chain performance.

In response to the current demand of expanding the Equipment Tracking Module to a comprehensive asset management system, SIAPS/Bangladesh facilitated a field visit by a World Bank team to pilot sites to assess the current status, demonstrate the system’s functionality, and seek inputs for further improvement.

In DRC, SIAPS, in collaboration with MEASURE Evaluation, conducted a baseline study regarding malaria case management in selected health facilities from 44 PMI-supported health zones. The baseline will be used in the future to quantify improvement and estimate the level of support needed for those zones.

SIAPS team in the Philippines met with the National Tuberculosis Program and key TB partners to introduce and demonstrate the PV DCAT that will be used in two operations research studies: nine month TB regimen and bedaquiline use.

In South Africa, SIAPS met with Aurum Institute to discuss opportunities for rolling out RxSolution in correctional services facilities. It was agreed that SIAPS will train Aurum to conduct RxSolution pre-implementation assessments, to install the tool, and to support these facilities.
E-TB MANAGER PROMOTES TREATMENT QUALITY AND EVIDENCE-BASED FORECASTING OF TB MEDICINES IN UKRAINE

CHALLENGE
Lack of accurate data hinders TB control efforts

Each year, tuberculosis (TB) claims more lives in Ukraine than any other infectious disease. Achieving TB control is hampered, in part, by weak information, tracking, and reporting systems in-country. Effective TB control requires harnessing, integrating, and analyzing complex data from across all levels of the health system, including data on TB and MDR-TB cases, medicines consumption patterns, and commodity forecasting projections.

Assessments conducted in 2013 on the management of TB drugs in Ukraine highlighted specific pharmaceutical management challenges, particularly in terms of data collection, capacity constraints, data quality, and frequency of reporting. Of note, cases of TB within the penitentiary system—roughly 15% of all TB cases in Ukraine—were poorly tracked; even when available, data from the penitentiary system were not integrated with the information system at the Ministry of Health (MOH), which skewed TB surveillance data. Furthermore, ongoing political unrest and personnel changes at the MOH continue to hinder efforts to address these challenges.

SIAPS ACTIVITIES
Using integrated data management systems to stop the spread of TB

Recognizing that managing pharmaceutical information is essential to curbing the spread of TB in Ukraine, the MOH adopted a SIAPS tool, e-TB Manager, to help manage TB-related data. e-TB Manager is a web-based platform that integrates data across major aspects of TB control, including tracking TB and MDR-TB cases, monitoring the quantities of medicines available for treatment, reporting laboratory test results and treatment regimens prescribed, and following treatment outcomes. The e-TB Manager tool can be used for regular and ad-hoc reporting, routine monitoring and evaluation, and epidemiological surveillance at regional and national levels. It can also help program managers identify gaps in TB control efforts, monitor medicine use, and forecast future pharmaceutical needs.

The tool has been successfully rolled out in every region of Ukraine with 597 active users at over 1,000 facilities, tracking nearly 130,000 cases of TB. SIAPS supported the implementation and maintenance of the system by training 21 local users who then provided trainings at all health facilities using e-TB Manager. Additionally, SIAPS established a help desk in collaboration with the Ukrainian Center for Disease Control (UCDC).
which provides online and phone support for e-TB Manager users. The tool has been successfully rolled out in every region of Ukraine with 507 active users at over 1,000 facilities, tracking nearly 130,000 cases of TB. There were more than 1,000,000 electronic transactions reported in the system during 2013, signaling widespread use of the system. To improve monitoring and transparency, the UCDC has started regularly publishing the number of TB and MDR-TB cases managed in e-TB Manager on their website.

RESULTS Controlling TB with better data for decision making

With the national rollout of e-TB Manager complete, the amount of time needed to prepare facility-, regional-, and national-level TB reports has decreased from several days to 1-2 hours, and compliance with national quarterly reporting increased from 77% to 98%. Additionally, because e-TB Manager monitors which treatment regimens are being prescribed, the tool has helped increase adherence to national TB treatment protocols. Notably, SIAPS has also helped integrate TB data from the State Penitentiary System into the national system through e-TB Manager which has, in turn, enabled UCDC to more accurately assess and monitor epidemiological trends, identify potential issues, and plan regional interventions. For example, e-TB Manager has enabled better follow-up of patients who transfer between treatment facilities or move from the penitentiary system to public facilities. As a result, the UCDC was able to track approximately 800 transferred patients in 2013 to ensure that they received appropriate care and treatment.

NEXT STEPS Building on government commitments to increase use of the tool

On October 19, 2012, the ministry issued Order No. 818, “Order on Electronic TB Registry (e-TB Manager) Operations” and following the order’s enactment, e-TB Manager received official certification for data security compliance to manage TB patients’ personal data according to national legislation. Ukraine’s experience in e-TB Manager to date, along with new legal backing, will facilitate continued implementation in all 27 regions of Ukraine as part of the ministry’s information system for TB management.
A pharmaceutical system can only function effectively when there are adequate financial resources, efficient allocation of funding, and effective benefit programs, which promote equitable access to medicines. Being able to generate and manage financial resources for the provision of health commodities is a critical step toward making essential medicines accessible for mothers, children, families and communities. In addition, building country-level capacity to use available resources efficiently through the adoption of cost-effective mechanisms for the selection of medicines and pharmaceutical services can enable countries to stretch limited resources to cover additional populations with important services and products.

The SIAPS approach to pharmaceutical financing includes analyzing the sources of financing and revenue within the context of the country architecture, and assessing policies, laws and regulations, human resources, and information systems. Appropriate evidence-based financing interventions are designed to improve both technical capacity and resource allocation in the pharmaceutical services and supply chain systems, bridging financial gaps to achieving equitable access to life-saving commodities.
Since its inception, SIAPS has helped countries conduct analyses to improve decisions regarding cost containment and efficiency, and generate options for improved resource allocation and mobilization. These include the evaluation of alternate supply chain models; analysis of financial flow; identification of options to remove roadblocks; development and implementation of systems for tracking, monitoring, and controlling pharmaceutical spending; and analysis and evaluation of pricing policy options.

Reducing Financial Barriers to Patients in Accessing Medicines

Medicines comprise of up to 30% of health spending in low and middle-income countries. However, as many countries work to roll out universal health coverage (UHC) initiatives, SIAPS recognized that many of these initiatives did not account for medicines benefit programs. To create greater awareness on the importance of integrating pharmaceutical considerations into UHC programs, SIAPS, Management Sciences for Health (MSH), and key partners co-sponsored two seminal meetings to address key considerations for designing medicines benefits programs in low- and middle-income countries.

In anticipation of increased support needed by countries working toward UHC, SIAPS and MSH developed a guide on establishing medicines benefits management programs and an accompanying assessment tool that will support policy makers and program managers in making programmatic decisions, enhancing equity, reducing financial barriers to patients, and ultimately improving access to medicines. SIAPS has pre-tested the tools in three countries and will launch the products more widely in the next year of implementation. In addition, a technical overview brief on UHC and medicines benefit programs was developed this year, which examines the different pharmaceutical functions within UHC programs and addresses the policies, approaches, and regulatory requirements needed to develop equitable and transparent systems. The brief incorporates a number of recent medicines benefit management case studies drawn from low-, middle- and high-income countries, including one based on an evaluation of the Ghanaian insurance program, one describing the system in New Zealand, and one based on an assessment of South Africa’s medicines benefit management system.

Additionally, in Mozambique, SIAPS contributed to the development of a new strategic plan to create more transparent and sustainable medicine pricing and supported the revision of the price control system for pharmaceuticals. SIAPS has also supported the development of equity enhancing national medicine pricing policies in Angola and Ukraine. In the DRC, SIAPS collaborated with the Kasai Occidental Provincial Medicines Committee to scale-up a medicines costing exercise and standardize the cost of health care across all 44 health zones, enabling future reductions in fees charged to patients residing in the health zones.

Increased Efficiency in the Use of Existing Resources

SIAPS has provided technical support in conducting costing exercises to help
countries identify and understand cost drivers when providing pharmaceutical services. For example, based on cost data collected in Benin and Kenya, SIAPS developed a tool to estimate costs of distributing malaria medicines and rapid diagnosis tests, which enables stakeholders to effectively budget and allocate resources.

Through SIAPS support, five countries worked to improve use of public funds through the development and rollout of standardized treatment protocols, essential medicines lists, and formularies, as well as the establishment of drug and therapeutics committees. In Gauteng Province in South Africa, SIAPS supported the drug and therapeutics committee in making a series of recommendations, which are expected to save over 1.5 million US dollars (USD) in the treatment of hypertensive patients.

In Ethiopia, the Auditable Pharmacy Services and Transactions Systems (APTS) was developed and piloted by SIAPS in 2012, introducing principles of good governance into the way pharmaceuticals are managed at health facilities. APTS was designed to address issues of accountability, transparency, and traceability of pharmaceutical transactions and services at health facilities, improving the availability of medicines and health products at facilities and optimizing budgetary allocations. By the end of September 2015, APTS was operational at 45 health facilities in seven regions of Ethiopia. SIAPS provides on-site trainings on APTS to health professionals at all levels. In a recent report, the average availability for a selected package of 15 key medicines in health facilities implementing APTS was 96%. Through APTS implementation, hospitals in Ethiopia have saved a total of approximately USD 173,231.75 by reducing medicines expiry. Overall, APTS sites continue to increase revenue from the sale of medicines and display expiry rates below the 2% target set by the Federal Ministry of Health (FMOH). A major milestone in the implementation of APTS in Ethiopia was achieved when the FMOH received a directive for the indemnity of APTS implementation for action by policy makers. This milestone demonstrates the long-lasting impact this SIAPS intervention will achieve as efforts are made towards sustainability.

Mobilizing Additional Financial Resources

SIAPS continues to provide technical assistance to countries in conducting funding gap analyses. As of September 2015, eight funding gap analyses were conducted in three countries—Cameroon, Dominican Republic, and South Sudan. In the Dominican Republic, SIAPS conducted an analysis of the MOH’s financial gap related to the procurement of medicines and supplies. A technical report on the key findings from the analysis of the country’s medicines usage and figures from the MOH’s proposed budget was presented to national authorities and other key stakeholders in hopes that additional resources will be set aside in the MOH’s budget for the procurement of pharmaceutical products and supplies.

SIAPS has shown its commitment to mobilizing resources from donors and partners by supporting countries in their submission of Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) concept notes and grant applications. Since 2012, SIAPS has supported six countries (Burundi,
Cameroon, Dominican Republic, Guinea, Namibia, and Swaziland) to raise an estimated USD $408 million by assisting in the generation of quantification and forecasting data for the corresponding sections of Global Fund applications. A total of 18 Global Fund proposals and grants have been developed and submitted with technical assistances from SIAPS.

In the fourth year of project implementation, SIAPS assisted countries in accessing additional financial resources to support the provision of health services and pharmaceutical products. In Burundi, SIAPS provided technical guidance to the National Malaria Control Program (NMCP), a Global Fund Principal Recipient for Malaria, to develop a GFTAM concept note and grant documents under the New Funding Mechanism (NFM), while coordinating the overall process through four in-country workshops. Financial resources from the Global Fund grant will enable NMCP to implement malaria activities from 2015 to 2017.

In partnership with the National AIDS Control Committee in Cameroon, SIAPS provided technical assistance to ensure compliance with Global Fund requirements concerning the forecasting and management of HIV and AIDS commodities. In Cameroon, SIAPS is also a member of the Country Coordinating Mechanism (CCM). This year, SIAPS has contributed to the approval of an HIV/TB concept note and drafting of grant-making documents, following the concept note’s approval. SIAPS advocated for funding for the distribution of Ebola-related commodities in Guinea. Funds were successfully secured from the CDC Foundation through the eHealth Africa Project. SIAPS Swaziland collaborated with the Swaziland Health Laboratory Services to ensure that the MOH released the department’s budget allocation on time, allowing for essential procurements and services to continue.

An estimated $408,000,000 has been raised in six SIAPS-supported countries in the generation of quantification and forecasting data for the corresponding sections of Global Fund applications.
CASE STUDY

CLOSING THE FINANCIAL GAP TO ENSURE AVAILABILITY OF HIV AND AIDS COMMODITIES IN THE DOMINICAN REPUBLIC

CHALLENGE

Obtaining accurate data to mitigate stock outs

Stock-outs of antiretrovirals (ARVs) have been a persistent problem in the Dominican Republic, precipitated by insufficient funding and a lack of an efficient management information system to provide the necessary data for adequate forecasting and supply planning. SIAPS provided the government with technical assistance for the establishment of an Integrated Management System for Pharmaceuticals and Medical Supplies (Sistema Único de Gestión de Medicamentos e Insumos; SUGEMI) and supported the use of data generated from this system to analyze needs and to identify the root causes for existing stock-outs. Initially, the system identified a financial gap of more than $2.5 million to cover adult HIV medicines needs, despite contributions from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

SIAPS ACTIVITIES

Information systems support informed financial decision making

SIAPS’ predecessor project, Strengthening Pharmaceutical Systems, worked with the government to establish the SUGEMI system to provide more accurate information on consumption, forecasting, pricing, and distribution. SUGEMI is an information system that is fully aligned with the country’s health sector reform process, compatible with the decentralized health sector, and designed to coordinate information across different vertical disease programs. These features were essential to promote the long-term sustainability and local ownership of the system.

Data from all requisition and dispatch forms are consolidated and sent to the central warehouses on a quarterly basis for the development of a bulletin that is used by the National Pharmaceutical Management Unit (UNGM) for decision making. The bulletin provides information on stock on hand, including the number of units in stock as well as available months of stock for ARVs, TB medicines, and other tracer medicines. The UNGM then uses this data to redistribute medicines, make purchasing adjustments, and analyze national medicine consumption.

SUGEMI is an information system that is fully aligned with the country’s health sector reform process, compatible with the decentralized health sector, and designed to coordinate information across different vertical disease programs.
In 2012, using data from SUGEMI, SIAPS collaborated with key partners (the Global Fund Principal Recipient, the National Medicines Management Team, the General Directorate for Control of Sexually Transmitted Infections and AIDS and the National Council on HIV and AIDS) to carry out the first national quantification and costing exercise for the purchase of adult ARVs for 2013.

This exercise revealed that the number of adult patients on ARV treatment had increased at a rate of 33.4% or 2,958 cases per year between 2009 and 2012, while funding for ARVs during the same period decreased by an average of 21.7% (USD 965,382). The exercise also estimated that the country would require $6.1 million for the procurement of ARVs in 2013. While just over half (59%) of this funding could be provided by the Global Fund, a funding gap of $2.5 million was identified which could leave patients without the necessary ARVs to continue or start treatment.

After additional analysis indicated that ARV varied in price depending on the source, SIAPS recognized the potential for cost reduction if ARVs were procured through the Voluntary Pooled Procurement/Partnership for Supply Chain Management (VPP/PFSCM) mechanism. Using this more competitive pricing, SIAPS determined that the overall cost for ARVs could be reduced from $6.1 million to $5.2 million. Additionally, SIAPS helped the MOH identify and recover a deposit from a former supplier which, combined with additional cost-saving measures, was enough to not only close the funding gap but resulted in a funding surplus in the amount of $775,000.

**RESULTS**

Supply chain analytics, based on the SUGEMI information system, helped create new solutions and allowed the Ministry of Health (MOH) to mobilize enough resources to cover the procurement funding gap for adult ARVs. Specifically, SIAPS was able to help MOH:

- Bridge the funding gap by identifying a new international provider for ARVs (i.e., VPP), saving more than $910,000
- Recover a $500,000 deposit held by the previous provider
- Foster political will and support by developing and disseminating informational policy briefs
- Successfully develop and allocate $1.9 million for the procurement of ARVs in 2013
- Generate a financial surplus of more than $775,000

The availability of adult ARVs in the Dominican Republic has significantly improved. Figure 1 further demonstrates the increased availability of ARVs at the central and health-facility levels.

Figure 1. Percentage of Availability of ARVs for Adults, October 2012 and June 2014*

* measured as a percentage of adult ARV formulations available at the central warehouse and health facilities compared to ARV formulations that should be available, according to Standard Treatment Guidelines
SUGEMI has enabled consistent reporting and data quality checks, improved medicine availability at health facilities, and addressed health financing issues in procurement. With the money saved, procurement of diagnostic supplies and other materials to cope with the increased number of patients is now more feasible. Since March 2013, the consumption and stock on hand indicators in SUGEMI have been complemented by other performance monitoring indicators (such as degree of consistency between requisition and dispatches, percentage of units reporting on a timely basis, etc.). SUGEMI has proved to be a feasible and sustainable solution to improve the availability and quality of patient and supply chain data which has allowed the MOH to make strides toward improving health outcomes in the Dominican Republic.
THE CHALLENGE

Providing effective pharmaceutical services extends beyond medicines availability to include strategies to ensure that patients receive quality, safe, and efficacious medications appropriate to their clinical needs, are provided with accurate medicine information, and are able to adhere to treatment regimens. Recognizing that health outcomes are optimized only when essential medicines and other health commodities are both available and provided through effective pharmaceutical care and services, SIAPS works to strengthen the components of the pharmaceutical system that allow for effective pharmaceutical supply chains and services.

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.

Improving the Availability of Pharmaceuticals through Stronger Supply Chain Systems

Achievement of global health goals, such as an AIDS-free generation, ending preventable child and maternal deaths, and protecting communities from infectious diseases depend on effective supply chains for essential medicines and other health commodities. However, in countries most affected by major
public health diseases, their pharmaceutical system supply chains are confronted by many constraints. These include weak human resource capacity and high turnover; weak leadership; poorly defined supply chain operating systems and procedures; inadequate infrastructure; poor coordination among stakeholders, insufficient funding; unavailability of reliable supply chain data; inadequate use of available data and tools; and poor medicine storage conditions and practices.

SIAPS has been providing technical assistance to country MOHs and other partners with the objective of resolving the above constraints. SIAPS’s technical assistance focuses on strengthening the health system functional components of governance, financing, human resource capacity building, service delivery, and information for decision making. Progress made in these areas, as reflected across SIAPS’ other result areas, creates synergy that contributes to reducing stock-outs, minimizing wastage, and ensuring continuous availability of quality medicines and other health technologies. The SIAPS approach builds on existing systems and local capacity, and leverages work with other in-country partners. To increase supply chain efficiency and product availability, SIAPS often assesses a country’s or program’s capacity to manage pharmaceuticals and health technologies at the different levels of the health system, taking into consideration capacities of both public and private sectors. Then, using a stakeholder consensus approach, SIAPS helps countries develop and implement interventions aimed at strengthening the system for the long term. One example of such intervention is building the capacity of facility level staff to track medicine consumption and manage inventory to maximize availability and reduce waste. In Swaziland, increased routine supportive supervision visits to PEPFAR-supported ART sites achieved 0% stock-out of medicines at the health facility level at the end of the program.

Assessing Supply Chain Capacity

SIAPS uses a structured and consultative assessment process to examine supply chains. The examination allows identification of bottlenecks and development of two or more intervention options for consideration. Analysis of these intervention options informs recommendations for implementation, which must be endorsed by stakeholders.

Along with its partner organizations, Logistics Management Institute and Imperial Health Sciences, SIAPS has conducted such assessments, examining the supply chain systems strengths and weaknesses in Angola, Bangladesh, Mali, and Swaziland.

Angola’s central medical store was assessed in 2012 and major warehousing weaknesses including ineffective organization structure, a lack of consistent product identification and location systems, and necessary infrastructure improvements were identified. Based on recommendations made by SIAPS, and in collaboration with its partners, the central medical store started to implement the suggested recommendations in 2014. However, the outcome of this intervention has not been assessed.

In Bangladesh, two supply chain organizations that support the Government of Bangladesh’s Ministry of Health and Family Welfare (MOHFW), the Central Medical Store Depot (CMSD) and Central Warehouse, were assessed in 2013. Though previous projects had contributed to improvements in business processes
in these organizations, significant issues, including lack of temperature controlled storage, insufficient back-up power, insufficient storage capacity, gaps in internal security, too few occupational safety and health measures, and limited product identification and location systems were identified. Based on findings from the assessment, recommendations were made for changing business practices at CMSD and health facilities, which are currently being implemented. At the end of September 2015, Bangladesh had shown a significant improvement from a baseline of 14% of health facilities using a standardized checklist to monitor storage conditions, to 88% of health facilities doing so.

**Supporting Accurate Quantification of Health Commodities**

Accurate and evidence-based quantification exercises involving all stakeholders contribute to better coordination of medicines procurement and supply management, improved access to medicines, and cost savings.

SIAPS provides technical assistance and works to build capacity to develop effective quantification systems which make it easier to accurately estimate short term procurement requirements and assist in-country stakeholders in planning and solicitation of medium- to long-term financial requirements for medicines and other health technologies. In Cameroon, Mali, Swaziland, Burundi, Namibia, Uganda, Kenya, and Ethiopia, SIAPS has helped establish forecasting and supply planning coordination committees, with specific terms of reference, across health programs to create more streamlined, horizontal, and reliable quantification systems. Also, quantification interventions implemented by SIAPS have contributed to the increase in availability in commodities at the central warehouse and health facility levels in many SIAPS-supported countries. For example, in Mali, Ethiopia, and DRC, the decrease in stock-outs from baseline was equal to 22%, 22%, and 62%, respectively (Figure 1).

![Figure 1. Percentage of warehouses with stock-outs of a pre-selected group of medicines for 3 days or more in the last 3 months in Mali, Ethiopia, and DRC.](image)

SIAPS has also conducted quantification exercises and trainings on quantification principles, methodologies, processes and tools such as Quantimed to further develop country staff capacity to forecast and plan their supply of essential medicines and other health technologies. In fiscal year 2014, quantification trainings and exercises for a range of medicine and health technology groups, including HIV and AIDS, TB, malaria, and reproductive health, were conducted in Angola, Bangladesh, Burundi, DRC, Ethiopia, Lesotho, Mali, Namibia, and South Sudan with SIAPS support. These exercises have enabled countries to carry...
out their short-term procurements and develop medium- and long-term financial requirements estimates for solicitation of funds from donors.

In Lesotho, SIAPS has helped develop and facilitate the Supply Chain Management Leadership Development Program (SCMLDP), which is an in-service program that capacitates leadership teams in supply chain functions, including quantification. The program is designed to have teams develop action plans during workshops and health facility visits that allow peer-to-peer mentorship to review progress against supply chain performance indicators. This monitoring-training-planning system is an ongoing and continuous improvement approach to self-learning and skills building designed for optimal sustainability.

**Moving Effective Supply Chain Management Forward**

SIAPS has also worked with local stakeholders, including government ministries, donors, and supply chain partners, to evaluate existing practices and improve procurement methods and procedures while emphasizing transparency and best-value procurement. The program helps countries develop and adopt procurement policies and procedures while also establishing appropriate organizational and institutional structures for supply chain management. For example, SIAPS developed a methodology and set of tools to assess the effect of local procurement on the availability of maternal and child health medicines and validated these tools in Bangladesh. The purpose of the assessment was to understand how local procurement practices affect access to quality maternal health medicines at the district level and inform a broader discussion on potential strategies to improve access to maternal health medicines.

As part of the project’s core operating principles, SIAPS has worked to strengthen existing systems and support integration to drive increased system efficiency. Vertical supply chains for different public health programs are often set up in parallel to facilitate the delivery of commodities which help to manage different diseases. As these programs mature, SIAPS works with the countries to integrate their vertical programs. In Lesotho, the Ministry of Health is working closely with SIAPS to build their new Supply Chain Coordination Unit (SCCU), developing a strategic plan to increase communication across multiple health programs and health system levels.

**Improving the Use of Supply Chain Information for Decision Making**

Overall, SIAPS has shown a cumulative decrease in stock-out rates from 33% at baseline to 29% across all countries at health facilities. Complementing SIAPS’ work to streamline procurement processes is the establishment of Logistics Management Units in Bangladesh, South Sudan, Ethiopia, and South Africa to systematize information flow, strengthen data driven decision making, and increase coordination and strategic planning for procurement. By integrating supply services through logistics management units, SIAPS also helps to leverage resources across programs and partners, maximize financial resources for health commodities, and minimize expiries and waste.
THE CHALLENGE

WHO estimates that nearly 50% of all medicine use is inappropriate.\(^1\) The health system, health care providers, patients, and the community all contribute to this problem in a variety of ways. In addition to increasing morbidity, mortality, cost, and adverse events, irrational medicine use also contributes to the global problem of antimicrobial resistance (AMR).

SIAPS has contributed to the various sub-IR areas related to pharmaceutical services such as assuring patient safety and therapeutic effectiveness, improving medicine use, developing/implementing pharmaceutical standards, and slowing of the emergence of AMR. The following is a summary of our work and achievements in these areas in program year 4.

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).

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KEY ACCOMPLISHMENTS

Patient Safety and Therapeutic Effectiveness Assured

During this reporting year, SIAPS helped countries adopt both active and passive approaches to identify medicine-related problems, including adverse drug reactions (ADRs). SIAPS also helped countries establish or strengthen systems to support sustainability in pharmacovigilance (PV) activities.

In Bangladesh, SIAPS continued to support the Directorate General of Drug Administration (DGDA) and the Adverse Drug Reaction Monitoring (ADRM) Cell to strengthen the medicine safety system. Bangladesh has now secured full membership as the 120th member of the WHO Uppsala Monitoring Center in Sweden. SIAPS worked with DGDA to orient more than 60 doctors and nurses, visited six hospitals to discuss the progress and implementation status of adverse event reporting activities in the hospitals, and trained 86 DGDA and pharmaceutical industry officials on Good Manufacturing Practices (GMP) and adverse drug event (ADE) data analysis. SIAPS facilitated a technical session to the ADR advisory committee on reviewing adverse drug events (ADE) reports, which established a subcommittee for reviewing all ADE reports before further validation by the entire committee.

SIAPS Burundi assisted the Department of Pharmacy, Medicines, and Laboratory (DPML) to establish a PV system in eight sentinel sites. SIAPS worked to help validate guidelines and training materials, as well as training 24 sentinel sites’ health care providers, and conducted a sensitization meeting to raise awareness for 48 health workers and managers on the importance of and their roles in implementing pharmacovigilance (PV) activities. SIAPS also assisted the DPML and Programme National Intégré de Lutte contre le Paludisme (National Malaria Control Program [PNILP]) to set up a PV database for ADR reports. The database will serve to capture ADEs submitted to DPML. Currently, staff members of six selected sentinel sites have been trained and are able to report the ADEs encountered. The sentinel sites have already started to report, with 10 ADE reports having been sent to DPML and captured in the PV database.

In Ethiopia, SIAPS supported efforts to raise PV awareness among health care providers at 35 health facilities. SIAPS distributed ADE reporting forms, national PV framework, allergy cards, newsletters, and preventable adverse-event bulletins to health facilities, regional health boards, and the southern branch of the Food, Medicines and Health Care Administration and Control Authority. The health facilities that reported ADRs increased from 62 at the end of PY3 to 152 at the end of PY4. In total, 270 ADEs have been entered into the national database, and acknowledgment/feedback provided to 215 health care providers who reported them. In the last three years, based on the ADR reports, two regulatory decisions have been made, an investigation was carried out on a fixed-dose ARV medicine, and two product-quality defect reports were prepared and shared with the Facility Inspection Directorate.

SIAPS Mozambique supported the Pharmacy Department to provide on-the-job training to the new PV focal person at the Nampula Pharmacovigilance Unit to
strengthen ADR reporting. In addition, approximately 30 final-year pharmacy students at Unilurio University were trained in PV. It is expected that these students will be able to collect ADRs from hospitals when they are assigned as interns, and continue to practice ADR reporting activities after graduation.

SIAPS Namibia and the University of Washington (UW), Seattle, have completed the active surveillance study at Windhoek Central and Katutura Intermediate Hospitals. The study found that 16% (66/413) of patients experienced at least one adverse event. SIAPS and UW provided technical guidance to the Therapeutics Information and Pharmacovigilance Centre (TIPC) to conduct a pharmacoeconomics analysis of potential costs and cost-effectiveness of a national active surveillance program compared to the existing spontaneous ADR reporting system. The results will inform Namibia’s PV strategies going forward. SIAPS also assisted the TIPC to conduct a preliminary analysis of ADR reports for TB medicines from four PEPFAR-priority regions. Major ADRs reported were joint pain, dizziness, and headache.

SIAPS Philippines provided technical assistance to the nine month MDR-TB treatment regimen (bedaquiline) operations research study. SIAPS contributed to training on good PV practices to the national counterparts and international partners by jointly developing PV standard operating procedures (SOPs) for cohort event monitoring with partners, developing safety monitoring and ethical considerations guidelines, and making joint monitoring visits to TB services sites. SIAPS helped the National Tuberculosis Program (NTP) finalize the “SOPs for Active Pharmacovigilance Surveillance.” Hence, the Philippines became one of the first countries to develop SOPs for active cohort event monitoring. In the fourth quarter of PY4, four Programmatic Management of Drug Resistant TB (PMDT) treatment centers started implementing the nine-month MDR-TB treatment regimen operations research study, guided by the SOPs. By end of the PY4, one serious adverse event occurring in the nine month regimen study has been identified and reported to the FDA. The Philippines FDA will release feedback on the causality analysis to NTP and the research team after its review. In the Philippines, the SIAPS indicator “percentage of SIAPS-assisted sites that have implemented PV or medicines safety activities” has reached 80% (4/5) by the end of PY4 from 0% in September 2013.

SIAPS South Africa worked with the National Pharmacovigilance Center (NPC) to implement the decentralized PV system in Mpumalanga (MP) and North West (NW) provinces. SIAPS helped the NPC roll out the decentralized PV system in 24 clusters (comprising 266 feeder clinics) in MP, and in 20 clusters (comprising 294 facilities) in NW. SIAPS also assisted the NPC to form a PV district support team made up of nurses, doctors, and pharmacists to monitor and support the PV clusters. In addition, SIAPS provided ongoing technical assistance for the interpretation of data collected from the rolled out sites. SIAPS also assisted in trainings to prepare for the Northern Cape rollout, and PV training to 22 final-year BPharm elective students in the Nelson Mandela Metropolitan University. In South Africa, the SIAPS indicator “percentage of SIAPS-assisted sites that have implemented PV or medicines safety activities” has risen to 100% (560/560) by the end of PY4 from 0% in October 2012.

SIAPS Swaziland continued to work with the MOH’s Pharmacovigilance Unit to strengthen monitoring and reporting of adverse events through active and passive surveillance activities. During this reporting year, SIAPS supported
seven HIV/TB active surveillance sentinel sites through mentorship and data collection visits. The PV data analysis showed that, by end of June 2015, a total of 2,080 patients had been enrolled in the active surveillance system and 939 adverse events reported. According to the reports, the most common ADRs among patients on ARVs were rash (21%), peripheral neuropathy (16%), and vomiting (11%). Patients on TB treatment mostly complained of peripheral neuropathy (14%), ototoxicity (12%), and rash (8%). SIAPS facilitated stakeholder feedback forums to disseminate the findings from the causality assessment of ADE reports. SIAPS also assisted in capturing adverse events from passive surveillance and disseminating the results through the Medicines Safety Watch Newsletter. Additionally, SIAPS facilitated preliminary steps toward the use of bedaquiline for the management of MDR-TB patients, and supported the development of communication by the MOH mandating the reporting on bedaquiline through the SIAPS-supported active surveillance system. SIAPS facilitated the formation of a PV core team to develop the national Patient Safety Monitoring Committee. The improvement in reporting ADRs has propelled Swaziland from being a provisional member to a full member of the WHO Uppsala Monitoring Center.

In Ukraine, SIAPS continued to provide support in developing and implementing the Pharmacovigilance Automated Information System (PAIS). SIAPS worked with the State Expert Center (SEC) to improve the automated system and piloted it in the AIDS centers. Since the start of the pilot till the end of the reporting year (three reporting quarters), 210 cases have been entered into the system. SIAPS also worked with SEC to develop PV guidelines, of which four modules have been approved and four more modules developed.

**Medication Use Improved**

Patient-centered pharmaceutical care is defined as the responsible provision of medication-related care designed to achieve health outcomes that improve or maintain a patient’s quality of life. In Ethiopia, SIAPS introduced pharmaceutical care activities in hospitals that allow pharmacy staff to work with a multidisciplinary team to provide better medication services to patients. SIAPS has trained 200 pharmacy staff to provide clinical pharmacy services and 53 hospitals have initiated such a service by end of PY4. During this project year, SIAPS worked with the national counterparts to conduct the first national assessment and supportive supervision on the implementation of clinical pharmacy services at 43 public hospitals in 5 regions and 2 city administrations. The report from eight hospitals in the Amhara Region showed that these hospitals were able to serve 1,151 patients; of these, 871 (75.7%) have a documented patient medication profile, and 275 drug therapy problems were identified and interventions were planned and implemented for 257 (93.5%) of those problems. Of the interventions recommended, 252 (98.1%) were fully accepted.

In South Africa, SIAPS assisted in the development of a master set of SOPs for pharmaceutical services for the NDOH. SIAPS also worked with stakeholders to build a hospital pharmacy model at Dr. George Mukhari Academic Hospital that can serve as a center of excellence for pharmaceutical services.

Proper case management of a disease or health condition helps assure effective treatment and medication safety, promotes high-quality care and cost-effective outcomes, and helps contain drug resistance. Between project years one and
three, SIAPS supported community case management (CCM) for malaria in Burundi, CCM for tuberculosis (TB) in Tanzania, and integrated CCM (iCCM) for pneumonia, diarrhea, and malaria in Mali, DRC, and Guinea. During this project year, SIAPS Burundi, after successfully helping implement CCM for malaria treatment in two health districts in the previous project year, supported transfer of the CCM activity to USAID’s Integrated Health Project Burundi at the end of the first quarter of this project year. SIAPS has trained more than 500 community health workers, and reached the targets for the overall implementation period—caregivers of 88% of children under five sought care from community health workers within 24 hours of the onset of fever in the child. Of those children who tested positive for malaria with a rapid diagnostic test, 91% were treated with ACTs within 24 hours of the onset of fever.

Support for medication adherence is essential for empowering patients to better manage their therapies. In Ethiopia, SIAPS provided support to selected ART sites to have access to phones to call patients who are lost to follow-up or miss appointments. During the second reporting quarter, 12 health facilities in 4 regions called 237 patients out of 259 (92%) who missed their appointments or were lost to follow-up. Of those, 155 patients out of 237 (65%) were brought back to treatment, 12 were transferred to other health facilities, and 17 were reported deceased. In Namibia, SIAPS is continuing to assist in-country stakeholders to use the Electronic Dispensing Tool to monitor early-warning indicators for HIV-drug resistance. During this reporting year, SIAPS helped MOHSS assess service quality in selected regions to address gaps in ART patients’ adherence to treatment, and pilot a SMS-based adherence reminder system. The SMS service includes sending automated short messages to ART patients to remind them about their pharmacy appointments and to encourage adherence to ART. The SMS reminder system will be rolled out to 10 more ART sites after the pilot.

Drug information services provide information to health workers and patients to improve medicine use and promote treatment adherence. In Ethiopia, SIAPS supported seven health facilities (HFs) to establish drug information services (DIS) by providing reference materials, patient education guidelines, and on-site training. Two of the HFs’ DIS Units also received computers and related hardware, and furniture. SIAPS also technically and financially supported Oromia RHB to strengthen DIS units at 36 hospitals. During a supportive supervision visit in Q4, it was found that 75% of the hospitals have functional DIS, and half of them provided education to patients in the waiting areas. Through SIAPS support, 185 patient education sessions were carried out in 25 HFs, and more than 4,000 patients of whom more than 60% were female, attended the sessions.

SIAPS promotes rational medicines use through various interventions. In Burundi, clindamycin is used with quinine as a second-line treatment for uncomplicated malaria cases as per the malaria standard treatment guideline (STG). In this reporting year, SIAPS helped the PNILP to train or refresh knowledge of 187 health care workers on malaria STG with pre- and post-training tests. The training resulted in a 26% knowledge gain; and 145 laboratory technicians trained to malaria diagnosis resulting in at least a 24% knowledge gain and 19% skill gain. The PNILP also received SIAPS assistance since August 2014 to prepare a rapid introduction and scale-up of clindamycin in three provinces. In the Dominican Republic, SIAPS supported the Universidad Central del Este to finalize the administrative proposal for the certified course (diploma)
on rational medicine use (RMU) and complete the first draft of the training modules. SIAPS will continue to support the revision and validation of the training modules in the coming project year. SIAPS Namibia participated in the National Annual Pharmacists Forum. The participants suggested that the Division of Pharmaceutical Services should assess private practitioners’ compliance with ART guidelines and estimate the number of patients referred to the public sector who have failed first-line therapy as a result of irrational prescribing and dispensing of ART. SIAPS, therefore, assisted the Div:PhSs to develop a tool for this rapid assessment. In South Africa, SIAPS assisted Western Cape Pharmacy Services to train 46 health care professionals on RMU. A notable achievement during this reporting period was the launching of an online RMU course that SIAPS developed with the University of Western Cape (UWC). It is offered as a stand-alone course, or as part of the master of public health curriculum. The online course includes 11 sessions aimed at transferring skills and expertise to promote RMU, and so far, 12 participants from South Africa, Botswana, and Nigeria have enrolled in the course. To ensure sustainability, support for the course is being transitioned to UWC.

Drug and Therapeutics Committees (DTCs) are used to manage the selection of medicines, evaluate medicine use, and implement strategies to improve their use throughout the health care system. In the Democratic Republic of Congo (DRC), SIAPS supported the Health Provincial Division to conduct medicine use studies in four provinces, and made comparisons between hospitals with and without Drug and Therapeutics Committees (DTCs). By the end of the quarter, the studies were completed in three provinces. Of the seven hospitals participating in the studies, four have DTCs and three do not. The results will be reported after all provinces complete the study. In Ethiopia, The indicators “SIAPS-assisted DTCs that have implemented AMR advocacy or containment-related activities” have increased from 29.2% to 54.2%, and “facilities implementing good practices for medicine dispensing” have increased from 54.2% to 91.7%, over the period of two years. Ethiopia’s Woldia General Hospital conducted a study on the use of the combination antimalarial artemether-lumefantrine. The results showed that blood tests were ordered for 87.5% (196/224) of fever cases; 36.7% (72/196) of those were deemed appropriate indications for artemether-lumefantrine. However, the remaining 124 cases, which tested negative for malaria, were also given the antimalarial. Woldia’s DTC then developed a plan to improve prescribing practices, including orientation of all physicians to follow the country’s malaria STG.

In Mozambique, SIAPS provided technical assistance to the Hospital Pharmacy Department (HPD) of MOH to prepare training for the Hospital DTCs staff. The training objectives were to improve the identification and monitoring of medication errors and to develop interventions to monitor compliance with best practices for the acquisition, storage, distribution, and dispensing of medicines. SIAPS provided technical assistance to the HPD to develop SOPs for conducting medicine use review by DTCs. SIAPS helped train the staff of HPD and four hospital DTCs to pilot test the SOPs, and to implement the pharmacy management guidelines developed by the HPD, including establishment and management of DTCs and pharmaceutical care for outpatients. After the training and pilot test, SIAPS supported the HPD to revise the SOPs based on the experiences of the pilot test. In Namibia, SIAPS assisted the Khomasdal Health Center by presenting on the role of therapeutics committees (TCs) in combating AMR including HIV drug resistance and the TC’s role in managing medicine use in health facilities. Twenty-five health
care workers and administrators attended the TC meeting that raised awareness among health care workers of their role in monitoring HIV-drug resistance early warning indicators and promoting rational use of ARVs and other medicines.

SIAPS South Africa also provided technical assistance in strengthening pharmacy and therapeutic committees (PTC) and introduced tools for use by the PTCs to enhance RMU. SIAPS trained members of two district PTCs in KwaZulu-Natal. The eThekwini District PTC was established as a result of the Pharmaceutical Leadership Development Program offered by SIAPS. SIAPS also provided training to new and existing PTC members in Eastern Cape and Limpopo to orient them on the issues of governance and the roles and functions of PTCs.

In Swaziland, eight facilities which received SIAPS training had at least one DTC meeting in the third reporting quarter. Issues discussed included the use of STGs, triplicate prescriptions for the pharmacy, refilling of chronic medications, development of an antibiotic policy, and implementation of the new integrated HIV guidelines. To advocate and act for AMR containment, Swaziland’s Raleigh Fitkin Memorial Hospital DTC implemented a quality improvement program that included performing culture and sensitivity tests on inpatients prescribed antibiotics. The results showed high levels of pathogen resistance to several antibiotics, including ceftriaxone and vancomycin. In response, the DTC led the development and implementation of hospital guidelines on prescribing antibiotics and switching from intravenous to oral antibiotic therapy. The Laboratory Department provides culture and sensitivity test reports monthly to the DTC to monitor drug sensitivity patterns for appropriate antibiotic prescribing.

Cumulatively, from the start of the SIAPS Program till the end of April 2015, SIAPS had collaborated with in-country stakeholders in DRC, Ethiopia, Jordan, Mozambique, South Africa, and Swaziland to provide 51 DTC-related trainings to 1,411 participants along with ongoing support, such as on-site technical assistance and supportive supervision. Following the trainings and technical assistance, 447 DTCs had been created and 49 revitalized by the end of April 2015. The committees helped conduct 36 medicine use studies or evaluations and 68 ABC/VEN analyses; developed or implemented 5 treatment/prophylaxis guidelines and 2 formularies; developed 5 DTC or rational medicine use-related policies; conducted 15 in-service trainings on RMU or DTC topics; and revised 2 pre-service curricula to include DTC-related topics. These results along with selected country examples of DTC-related work were packaged as an abstract and submitted for presentation at the 2015 International Pharmaceutical Federation (FIP) World Congress. The abstract got accepted and was presented as a poster at the Congress held in Dusseldorf, Germany from September 29 to October 3, 2015. http://siapsprogram.org/publication/strengthening-local-capacity-to-establish-or-improve-performance-of-drug-and-therapeutics-committees-in-low-and-middle-income-countries/.

Medicine use evaluations (MUEs) and reviews are critical methods for health facilities to review and improve how medicines are prescribed, dispensed, administered, and used. In Ethiopia, SIAPS supported DTCs to conduct prescription review in 24 health facilities. The review identified gaps in prescribing and dispensing practices such as incomplete drug- and patient-related information, inappropriate use of antibiotics and injections by health care providers, unavailability of standard labeling materials and poor labeling practices, and inadequate patient knowledge of the dose, frequency, indication,
and duration of treatment. The DTCs are now working on strategies to address these gaps and improve medicine use. An ABC/VEN analysis at Ethiopia’s Dessie Referral Hospital showed that 18.3% of the hospital’s total cost of medicines was for antibiotics, with ceftriaxone second on the list of top 10 antibiotics. The resulting medicine use review showed that ceftriaxone was prescribed appropriately in only 55% (56/102) of the patients and that general practitioners were the most frequent prescribers (67% of the cases). Taking action, the hospital DTC developed a ceftriaxone use policy that specified proper indications, dosing, and duration, and required complete documentation of medical records, including clinical outcomes, following its use. In Namibia, SIAPS supported the Kunene Region therapeutic committee to conduct an MUE in Opuwo District. SIAPS is providing technical assistance in ensuring high-data quality and aggregating the data to compile an informative report.

In South Africa, SIAPS helped the West Rand District PTC conduct a medicine use review, which found that 62.5% of the HIV and AIDS treatments complied with the STGs. SIAPS also assisted the Western Cape Provincial PTC to conduct their first province-wide MUE, which identified a potential medicine use problem for aspirin. This led to a training in which participants developed criteria for aspirin use in the Province. In addition, SIAPS assisted the Essential Drug Program in doing a medicine review through basic costing exercise and motivational review on the use of labetolol in eclampsia. It was found that there was no evidence of superiority to the standard medicines available on the essential drugs list. In Ukraine, SIAPS has been supporting a drug use review pilot project at the Kyiv Oblast TB dispensary. During this project year, the pilot was completed and an advanced draft report developed. The report will be presented to the State Expert Center of the MOH, and the Ukrainian Center for Disease Control in the first quarter of PY5. Following this success, drug use reviews are now being piloted in two AIDS facilities. In Uzbekistan, SIAPS assisted the NTP to pilot a drug use review in three TB facilities in Tashkent City. A report of this review has been drafted and is currently being finalized. SIAPS organized a workshop to discuss the findings with the representatives of all the three TB facilities that participated in the pilot. As a result of the discussions, an improvement plan was elaborated. It includes both educational and operational interventions.

Pharmaceutical Service Standards are Defined, Adopted, and Implemented

The establishment of minimum standards and guidelines of pharmaceutical services for public and private sectors provides guidance for service delivery and for evaluation of performance. These minimum standards include STGs, essential medicine lists, formularies, procedures, or regulations. SIAPS Angola, Dominican Republic, Mozambique, Namibia, South Africa, and Ukraine have supported corresponding Ministries of Health to develop national essential medicine lists (NEMLs). SIAPS Dominican Republic, Guinea, and South Africa supported country counterparts to develop various treatment guidelines. SIAPS Angola, Bangladesh, and South Africa helped in developing formularies.

The Angola EML was finalized. SIAPS Angola is supporting the drafting of National Formulary manual which is complementary to the EML. SIAPS
Bangladesh helped revise the sections on ADR monitoring and include all the anti-TB medicines and regimens in the updated Bangladesh National Drug Formulary. It was finalized and published during this project year. DGDA printed 10,000 copies of the formulary with SIAPS support and will distribute them widely to physicians and other relevant stakeholders. Dominican Republic’s 2014 revision of the NEML was finalized. SIAPS also supported the revision of the therapeutic guidelines for primary health facilities to make it compatible with the NEML. In Guinea, SIAPS collaborated with partners to revise the malaria treatment guidelines in light of the Ebola outbreak. New case management protocols and tools were adopted. In Mozambique, the final NEML and the draft of policies and procedures for use of the NEML were pending final review and approval. SIAPS Namibia supported the Div:PhSs and the EML Committee in the final review and formatting of the sixth edition of the Nemlist. SIAPS South Africa assisted the Essential Drugs Program (EDP) on the completion, publication, and implementation of primary health care (PHC) STGs and EML. The input from SIAPS helps improve transparency and governance in the process of selecting essential medicines. SIAPS South Africa also helped finalize the Gauteng and Limpopo provincial formularies. In addition, SIAPS assisted the EDP to review four chapters in the PHC STG and EML mobile application, and to test the application. The EDP intends to launch the application in November 2015.

SIAPS supported the MOH in Swaziland to convene the National Essential Medicines Committee meeting to discuss amendments to the list of medicines availed to clinics, with particular focus on Maternal, Neonatal, and Child Health (MNCH) medicines to help achieve the Prevention of Mother to Child Transmission (PMTCT) goals and Ending Preventable Child and Maternal Deaths (EPCMD) Initiative. A list of MNCH priority medicines was approved for inclusion in the tracer commodities list and categorized as vital medicines. SIAPS also worked with the non-communicable diseases technical working group on listing medicines for the Diabetes Mellitus Algorithm Rapid Assessment Tool to be implemented in health facilities. In Ukraine, establishing a NEML was recommended in a situation analysis for public procurement and reimbursement. SIAPS has started to help develop the NEML with local experts. The final versions of the regulations for EML and EML expert committee were approved by the MOH and were submitted to the Ministry of Justice for approval. Methodology of selection of medicines for the NEML is still under development. The expected date of posting of the methodology for public discussion is expected at the end of October 2015.

During this project year, the Pharmaceuticals Fund and Supply Agency of Ethiopia collaborated with SIAPS country office to develop a SOPs manual for clinical pharmacy services; 2,000 copies were distributed to 181 hospitals and health-related institutions to enable them to standardize the provision of service. The manual contains step-by-step procedures for the provision of clinical pharmacy services for inpatients along with the necessary documentation and reporting forms.

Also, as already noted above, SIAPS worked with partners to support the Philippines NTP to finalize their SOP for active pharmacovigilance surveillance. Implementation of the SOP started July 1, 2015, with the initiation of the nine-month MDR-TB treatment regimen operations research.
Emergence of AMR Slowed

SIAPS endeavors to establish global, regional, and country-level AMR coalitions, and to contribute to AMR containment through collaborated efforts.

SIAPS participated in a regional meeting in Suriname organized by the Pan American Health Organization to discuss strategies to prevent the emergence of ACT resistance in the Americas. SIAPS collaborated with Knowledge 4 Health to address reviewers’ comments on the AMR part 2 Course. The course is currently being finalized and will be published globally through the Global Health eLearning platform in the first quarter of PY5. SIAPS also presented a session on Fight Antimicrobial Resistance or Go Back to the Pre-Antimicrobial Era at the USAID Global Health Mini-University held on March 2, 2015. The presentation is available on the Mini-University website at http://www.mini-university.com/wp-content/uploads/2015/08/Fight-Antimicrobial-Resistance-OR-Go-Back-to-the-Pre-Antimicrobial-Era.pdf.

To coincide with this year’s World Health Assembly decision to pass a resolution on the WHO Global Action Plan on AMR, SIAPS dedicated May and June 2015 to AMR. In line with this theme, SIAPS posted several AMR-related blogs and presentations to the SIAPS website (http://siapsprogram.org/antimicrobial-resistance/) and linked them to SIAPS Facebook and Twitter pages. In addition, five SIAPS representatives attended the Uppsala Health Summit 2015 on “A World without Antibiotics” held in Uppsala, Sweden, on June 2–3, 2015. SIAPS participated in the discussions on strategies to contain AMR, including implementation of the newly endorsed WHO Global Action Plan on AMR. SIAPS submitted two abstracts, one on advocacy and coalition-building on AMR and the other on community case management, for presentation at the 2015 American Public Health Association (APHA) annual conference. Both were accepted for oral presentation.

In **Ethiopia**, SIAPS trained 34 media personnel and pharmacy professionals in Tigray region on AMR, and supported Oromia RHB to advocate for the prevention and containment of AMR through 156 health facilities in the region. SIAPS assisted the government to draft the second edition of the *Strategy for the Prevention and Containment of Antimicrobial Resistance* (2015–2020) and share it among a wide range of stakeholders in a workshop to get feedback on the draft and to get key institutions to commit to implementation of the strategy. In **Namibia**, SIAPS continued to support the HIV drug resistance (HIV-DR) early warning indicators activity. SIAPS provided assistance for data analysis and validation of the 2015 study on indicators and preliminary results have been compiled. In addition, SIAPS is a technical resource to the University of Namibia (UNAM) School of Medicine’s project on infection control and hospital hygiene. SIAPS is also a member of the steering committee that coordinates the partnership between UNAM-School of Medicine and the University of Bonn, Germany, for activities relating to infection prevention and control (IPC) and combating hospital-acquired infections. SIAPS also actively participated in the fifth annual medical doctors’ and dentists’ forum to advocate AMR containment strategies, and to raise awareness on AMR.

In **South Africa**, the SIAPS-assisted *National Strategic Framework for Antimicrobial Resistance 2014-2024* and the AMR background document...
were signed by the Minister of Health and the Director General of the NDOH. In addition, SIAPS worked with local stakeholders to help develop an implementation plan for antimicrobial stewardship in the country. SIAPS conducted a one-day Infection Control Assessment Tool refresher course in the Nkangala health district in the Mpumalanga Province; 38 participants attended the training. A three-country (South Africa, Namibia, and Swaziland) survey of using early warning indicators as a potential predictor of HIV drug-resistance risk was initiated. The South African protocol was developed based on the South African country-context, and the use of RxSolution as an information source for various indicators. SIAPS also worked with EDP to analyze the FY 2012–2013 consumption of specific antibiotics prone to generating resistance. The information generated will serve as a baseline for the surveillance of antibiotic consumption as recommended in the National Antimicrobial Strategy.

In the previous reporting years, SIAPS supported the Ecumenical Pharmaceutical Network (EPN), a faith-based regional organization, in advancing AMR-related activities such as conducting training of trainers for its selected constituent members. The EPN Board has now adopted AMR as a key strategic priority action area in their recently developed 2016–2020 strategic plan, with expectations of helping to contain AMR and hence improving health outcomes among populations served by EPN. This institutionalization of AMR-related actions by EPN demonstrates the feasibility of sustainable capacity transfer and the development of local ownership for scaling up effective interventions and contributing to overall health systems strengthening.

IPC is a key intervention to contain AMR. It is one of the five key objectives of the WHO Global Action Plan on AMR that was endorsed by the 68th World Health Assembly in May 2015. By minimizing or eliminating the risk of spread of nosocomial infections, IPC interventions decrease the volume of antimicrobials used and thus reduce selection pressure and the risk of resistance development. Building on the work of its predecessor programs, SIAPS has supported IPC activities in several countries, including Namibia and South Africa. In March 2015, a poster summarizing our infection control work was presented at the 15th International Congress of the International Federation of Infection Control and XIII National Conference of the Hospital Infection Society, New Delhi, India. Entitled “Strengthening infection prevention and control systems in resource-limited settings using a self-assessment and continuous quality improvement approach”, the presentation is accessible at http://siapsprogram.org/publication/strengthening-infection-prevention-and-control-ipc-systems-in-resource-limited-settings-using-a-self-assessment-and-continuous-quality-improvement-cqi-approach/.
Along with passive surveillance, sentinel site-based active surveillance is a key approach to strengthening a country’s pharmacovigilance (PV) and medicine safety system. As new essential medicines for HIV/AIDS and drug-resistant tuberculosis (TB) are being introduced and scaled up in resource-limited countries, monitoring adverse drug reactions (ADRs) and therapeutic effectiveness associated with these medicines is increasingly important. A well-integrated, comprehensive pharmacovigilance system is necessary for improving patient management, making evidence-based treatment decisions, and promoting rational medicine use.

Swaziland has a high burden of both HIV/AIDS and TB, and the nation’s pharmacovigilance system has traditionally relied on passive surveillance mechanisms based on spontaneous reporting. In a passive surveillance system, health professionals and others are encouraged to report adverse events, but no other active measures are used. Thus, relying on passive surveillance alone can lead to under-detection and underreporting of adverse drug events. In Swaziland, the Ministry of Health (MOH) had only been receiving about 30 adverse reaction reports per year since the passive surveillance system was implemented in 2010. This low level of reporting spurred the introduction of an active surveillance system to complement the passive system.

Pharmacovigilance is necessary for improving patient management, making evidence-based treatment decisions, and promoting rational medicine use.

SIAPS ACTIVITIES

SIAPS mobilized stakeholders from the Swaziland National AIDS Program (SNAP) and the National Tuberculosis Control Program (NTCP) to introduce and implement the Sentinel Site-based Active Surveillance System for Antiretroviral and Anti-TB (SSASSA) treatment programs. SIAPS partnered with the Pharmacovigilance Unit of the MOH to create the protocol and tools for the electronic SSASSA system, and developed a patient recruitment system at HIV and TB sites.

The new system documents and quantifies incidence rates of adverse events associated with antiretrovirals (ARVs) and anti-TB medicines and determines risk factors at selected sentinel sites. In addition to collecting and compiling the type
and rate of adverse events, the SSASSA system tracks and reports data on adherence, severity of adverse events, patient demographics, and reasons for switching regimens.

The SSASSA was officially launched in 2013, and subsequently installed at five hospitals and one clinic.

SIAPS continues to support the implementation of the active surveillance system through supervisory visits to ensure data collation, causality assessments, and other patient analyses are occurring correctly. SIAPS also supports the dissemination of pharmacovigilance data from the SSASSA system at both the national and regional levels.

RESULTS

Based on the most recent data from June 2013 to May 2014, a total of 956 patients have been enrolled, and 58 adverse events have been recorded. Figure 1 depicts the types of adverse events reported, the most common of which is peripheral neuropathy (26% of all events). Figure 2 illustrates adherence levels among 428 patients, as measured by timing of follow-up and medicine use. As indicated in the graph, nearly 90% of patients had a follow-up visit that was on time or early, and remembered to use their medicine.

Figure 1: Adverse events reported across six sites, June 2013-May 2014 (n=58)

Figure 2: Patients seen for follow up and reported adherence levels across six sites, June 2013-May 2014 (n=428)

The Ministry and other relevant stakeholders are working to collect additional data and utilize this information for ongoing patient management and national-level decision making around guideline reviews, changes to treatment regimens, and adherence interventions. SIAPS continues to support the MOH in developing Medicine Safety Watch, a quarterly newsletter designed to disseminate information on medicines safety. Copies are printed and distributed to all health facilities, and electronic copies are mailed to stakeholders.

One of the main challenges of this activity is that only four of the six sites have enrolled patients and captured data using the active surveillance system. The MOH, with support from SIAPS, is exploring the underlying constraints to using the system at these sites. In addition, data collection has not been optimal at all facilities. Recommendations have been made to modify SSASSA data fields to improve the collection of reliable data, and to update the SSASSA and the Data Collection and Analysis Tool to address compatibility issues.

The use of SSASSA in Swaziland demonstrates that active surveillance programs, which have mostly been implemented almost exclusively in industrialized countries, can be initiated successfully in resource-limited settings if system-based support and local collaboration are in place. Such an active surveillance system creates an enabling environment for regulatory decision-making and risk management planning. National bodies have provided overall leadership and governance for the implementation of these activities, and have identified and engaged other key stakeholders to contribute. Human resource capacity has also been strengthened, as evidenced by the extensive training that health care workers have received on capturing data and reporting ADRs.
NEXT STEPS  Scaling up active surveillance to monitor other medicines in additional settings

The SSASSA active surveillance system will be scaled up to monitor the safety of ARV and TB regimens throughout the country. It will also be applied to future active surveillance of other medicines, settings, and populations to prevent harmful health outcomes.

SIAPS is also currently providing support in Namibia to implement active surveillance pharmacovigilance at two sentinel HIV/AIDS sites. Drawing on lessons learned from these two countries, SIAPS plans to help implement active surveillance programs in other countries.

Development of Sustainable HIV/TB Active Surveillance System in Swaziland – Protocol and Operational Plan

COUNTRIES
The Government of Angola (GOA) Health Sector Development Plan 2012-2025 (Programa Nacional de Desenvolvimento Sanitario, PNDS 2012-2025) aims at promoting universal access to health care, ensuring equity in care, and improving the mechanisms of management and financing of the National Health System, with a view to combat poverty and improve the well-being of the population. Challenges and priorities in strengthening the Angolan pharmaceutical system have been highlighted throughout PNDS projects. SIAPS is collaborating and providing technical assistance to support the Angola Ministry of Health (MOH, Ministério da Saúde) in strengthening the public health pharmaceutical supply chain management (SCM) system.

Key gaps in the pharmaceutical SCM system include a shortage of qualified, skilled, and competent human resources at different levels of the supply chain; poor forecasting and supply planning at the national and peripheral levels, resulting in an imbalance between demand and supply and frequent stock-outs; poor coordination of medicine SCM activities due to the lack of a national SCM strategy; lack of, or inadequate, health information, including logistics management information, mainly due to improper use of available tools; inadequate use of data in decision making; and long, suboptimal, and inefficient administrative procedures in public procurement of medicines.

The current Angolan regulatory system lacks a medicines registration system, there is no national quality control laboratory or local production units for easy quality inspection, and the country has long and porous borders with neighboring countries that have similar or even worse challenges. Hence, there is a high risk of illicit importation of products from questionable sources, including poor-quality and counterfeit medicines, with minimal chances of their being tracked and removed from the market once detected.

These weaknesses adversely impact the availability of safe, quality, and cost-effective essential medicines and other related health commodities in Angola, thereby hindering current national efforts to achieve the long-term goal of ending preventable child and maternal deaths, eliminating endemic diseases of public health importance, such as malaria, and achieving an AIDS-free generation.
KEY INTERVENTIONS

Over the past four years, the Angola SIAPS Program has provided technical assistance to the MOH and responded to USAID/PMI and USAID/PEPFAR country plans to ensure sustainable systemic improvements of the SCM system through capacity building of institutions and individuals across all key health system functional components, including governance, institutional and individual capacity development, and logistics management information systems (LMIS), and by improving availability and use of selected public health commodities.

The program has selected and designed its interventions on the basis of findings of baseline assessments that were previously conducted. To ensure local ownership and sustainability, planning and implementation of the interventions was done through a locally led, integrated, participatory process involving MOH counterparts, namely MOH’s Direcção Nacional de Medicamentos e Equipamentos (DNME, National Directorate of Medicines and Medical Equipment), Central de Compras de Medicamentos e Meios Medicos de Angola (CECOMA, Central Procurement Agency for Medicines and Medical Supplies), the National Malaria Control Program (NMCP), the Instituto Nacional de Luta Contra o Sida (INLS, National HIV and AIDS Control Institute), the National Reproductive Health Program, the provincial directorates of health, schools of pharmacy, the Ordém dos Farmacêuticos de Angola (OFA, Pharmacy Council of Angola), and various other key local stakeholders, donor agencies, and development partners.

Activities were implemented in close collaboration with all counterparts, focusing on strengthening the pharmaceutical system and with the vision of country ownership and transition of technical skills to the MOH through capacity building, mentorship and training activities, intervention selection and design, and collaborative efforts with other implementing partners. These activities can be categorized into two main interventions: strengthening national medicine regulatory functions and improving public health SCM systems, with more emphasis on the latter per USAID/Angola priorities for SIAPS to build the supply chain systems in Angola.

KEY ACHIEVEMENTS

Strengthening National Medicine Regulation

Findings and recommendations of the SIAPS medicines regulatory systems assessment informed the MOH to embrace regional initiatives to strengthen its national medicine regulatory functions, currently implemented by both DNME and the General Inspectorate of Health (IGS, Inspecção Geral de Saúde). A high-level regional meeting of all ministers of health of African Union member countries and WHO country representatives was held in Luanda, Angola, in 2014 to discuss strategies and define guiding principles to set up an African medicines regulatory agency.

SIAPS was involved in the current efforts to establish a semi-autonomous institution that will play the role of national medicines regulatory authority. A policy brief document, the draft statute governing the proposed National
Medicines Regulatory Institute (INARFA, Instituto Nacional de Regulação Farmacêutica) with its structure and functions, was prepared by DNME, with technical input from SIAPS. This document was used as advocacy for the establishment of this new entity to ensure that only quality, cost-effective, and safe pharmaceutical products, including commodities for prevention, diagnosis, and treatment of malaria, HIV, and AIDS, are allowed to enter the country, and are safely used by communities.

**Improving Public Health SCM Systems**

**Governance: Coordination and Transparency**

To address the issue of coordination, SIAPS provided technical and logistical support to the interagency coordination committee/subcommittee for Logistics, Operations and Procurement (Sub-Comissão para a Logística, Aprovisionamento e Operações, CCI/SCLAO) under the coordination of the DNME to jointly coordinate all the key stakeholders in public SCM, including the INLS, NMCP, DNME, CECOMA, implementing partners, and UN agencies, to identify specific bottlenecks that affect the public health services and make recommendations for appropriate solutions. It also serves as a high-level advocacy platform for the entire pharmaceutical supply chain. Because of this support, 15 meetings of this subcommittee have been held, with 60% of its recommendations fully implemented or in the process of being implemented by the MOH and relevant local stakeholders. In addition, information sharing among different public health programs enabled improved utilization of resources, leading to higher efficiencies through a more participatory and timely decision-making process.

To sustain an inclusive mechanism of forecasting and supply planning, SIAPS advocated for the establishment and implementation of new, structured, phased, consensus-based national quantification mechanisms for HIV and AIDS and antimalarial commodities, involving participation of key government, nonprofit, and donor stakeholders. At the core of the new mechanisms is the Quantification Technical Working Group (TWG) comprised of representatives of the MOH and various stakeholder organizations. MOH’s specific institutions lead the quantification process and followed logical phases, including forecasting needs by using appropriate methods, data, and assumptions; validation of assumptions and forecasts; supply planning; and a funding gap analysis. The Malaria and HIV and AIDS Quantification TWGs were first trained by SIAPS to capacitate and equip them with appropriate skills. These groups meet regularly to forecast national needs, revise procurement plans, and monitor the stock levels. SIAPS is a member of these TWGs.

With SIAPS support, a first edition of the national essential medicines list (NEML) has been drafted, validated, and submitted to the MOH for approval. As a complement to the NEML, SIAPS is participating in the development of the national formulary manual to be submitted to the national medicine committee for endorsement and validation. Once approved and disseminated, the NEML will serve as a primary reference tool for the rational purchasing, distribution, and prescription of medicines, thereby reducing costs to the health system.
Direct Outcomes of the TWGs

- Increased availability of condoms at the health-facility level, especially in pharmacies
- Progressive introduction of new products that enhance patient adherence to treatment
  - 11-fold increase in the distribution of the new recommended combination of tenofovir, emtricitabine, and efavirenz (TDF/FTV/EFV) for new treatment patients (from 840 treatments per month to 9,577 treatments per month)
  - 3.75-fold reduction in the distribution of zidovudine/lamivudine/EFV (5,644 treatments per month to 1,505 per month)
  - 11-fold reduction in the distribution of TDF/lamivudine/EFV (16,154 treatments per month to 1,378 treatments per month)
- Estimations of the current financial gap in artemisinin-based combination therapies, rapid diagnostic test kits, and long-lasting insecticide-treated nets, all of which were submitted to government and development counterparts, such as PMI and Global Fund, for funding mobilization, as a result of the malaria TWG exercises

SIAPS assisted DNME in reviewing its 2010-2015 National Pharmaceutical Strategic Plan and to develop its 2015 annual work plan. In addition, CECOMA was also assisted in developing its annual work plan and revising its restructuring organogram on the basis of functions and not products. The new organogram has been approved in the new law governing the organic statute of CECOMA.

Human resources/capacity building

To enhance institutional and individual capacity in pharmaceutical SCM and medicine regulatory systems, the program has conducted hands-on, skills-based training of 249 staff, drawn from the central, peripheral, and pre-service levels to equip them within various aspects of pharmaceutical management and medicine regulatory systems. In total, 62 final year students from 2 schools of pharmacy received a pre-service training in pharmaceutical SCM and in collaboration with the DNME and the National Pharmacy Council. In six selected provinces (Luanda, Cunene, Bie, Huambo, Huila, and Uige), 145 staff from all the municipalities participated in a training of trainers in pharmaceutical management, with a focus on antimalarial products. After the training, post-training action plans were developed and monitored. Moreover, 20 staff have been trained in quantification of malaria and HIV and AIDS commodities at the national level, and 8 senior staff from DNME received on-the-job training in medicines registration systems. At the CECOMA level, 14 technicians received warehouse management systems training and 2 leaders from the same institution conducted a study visit to a state-of-the-art warehouse in South Africa, run by SIAPS’ warehousing resource partner Imperial Health Sciences (IHS) to complement the theoretical training.

As a direct result of these trainings and other capacity-building activities, including follow-up supervisory visits, health facilities and municipal and provincial warehouses have been upgrading their storage conditions for medicines, resulting in improved inventory management, storage, and distribution.
of public health products, including USAID-funded commodities. In addition, wastage of public health products, including USAID-funded commodities, has been reduced at the national and provincial levels as a result of improved warehouse management and/or inventory management at health facilities.

**Information for decision making**

To improve the availability of HIV and AIDS, malaria, and FP commodities, the program has worked with all 18 provinces and the national public health programs to collect and analyze data on the status of stock levels at provincial and national levels in a timely manner. This activity resulted in the redistribution of excessive stock in some provinces to other provinces in need, the revision of distribution plans, and closer monitoring of supply plans. The program also assisted the NMCP and DNME to conduct regular end-use verifications (EUVs) and procurement plans and monitoring reports for malaria (PPMRms) surveys to monitor the availability and use of selected essential medicines, especially antimalarial products. In total, 16 PPMRms have been submitted to PMI and to NMCP, covering all 18 provinces and CECOMA. In addition, seven EUVs have been conducted in 332 health facilities, including all 18 provincial warehouses. Their findings were used to improve malaria case management.

When necessary, the program assisted INLS to prepare HIV and AIDS commodities orders to avoid stock-outs and educate prescribers to change their prescription habits to the recommended pharmaceutical solid forms for pediatric patients and the recommended fixed-dose combinations, instead of singular products that are difficult to manage and are linked to low adherence rates.

**Service Delivery/Supply chain**

SIAPS worked closely with the National Reproductive Health Program, CECOMA, UNFPA, and Pathfinder to conduct regular physical inventories at the national level and to prepare annual forecasting and semi-annual distribution plans. In particular, Huambo Province was supported to improve their LMIS of FP commodities.

SIAPS continued to provide direct support to CECOMA to improve warehouse management processes and procedures in collaboration with IHS. This assistance was designed by using a participatory, on-the-job, hands-on, capacity-building approach that included improving the warehouse operations management system (WMS) and tools and LMIS; setting up product identification and location systems and developing a WMS roadmap, i.e., foundational systems and procedures for future development and implementing an automated WMS; strengthening the quality of warehouse standard operating procedures (SOPs) and other guiding documents for warehouse management; establishing and implementing key performance indicators, dashboards, and benchmarks to monitor staff and overall warehouse performance; and optimizing warehouse layout to improve processes and efficiently utilize storage space. In addition, security for sensitive products in the CECOMA warehouse has been enhanced following rigorous stock monitoring and storage organization in a controlled area. These changes in CECOMA are being led and monitored by CECOMA leadership for ownership and sustainability through regular technical meetings.
CONTRIBUTION TO USG GOALS

SIAPS Angola interventions are closely aligned with the PEPFAR 3.0 agenda on impact, sustainability, partnership, and efficiency, and also contribute to the USG goals of achieving an AIDS-free generation, protecting communities from infectious diseases, ending preventable child and maternal deaths, and increasing universal health coverage. SIAPS has developed and strengthened participative forecasting and stock monitoring mechanisms to improve availability and management of medicines, including ARVs and antimalarial commodities. Using available tools such as EUVs and PPMRms, the program has successfully collaborated with other key partners in SCM of malaria, FP, and HIV and AIDS commodities to improve data visibility of stock levels at the national and provincial levels and to guide informed decisions aimed at improving their management. By strengthening the capacity of health care workers, pharmaceutical service delivery is improved.

LESSONS LEARNED

SIAPS recognizes the importance of the full engagement of the country counterparts during the planning and the implementation of the project. Full support from the leadership of MOH is paramount for ownership and sustainability. However, the measurement of some outcomes and impact indicators in a weak reporting system has been difficult, as it requires additional resources including funds, time, and staff.

Implementing a third-generation health systems strengthening project such as SIAPS should take into consideration the level of preparedness of the implementing countries, as some post-conflict countries, such as Angola, are still struggling to build their health systems in general, including pharmaceutical systems in particular.

SUSTAINABILITY

For long-term sustainability and to enhance country ownership of the FP and antimalarial supply chain systems, the implementation of the suggested improvements to CECOMA warehouse and distribution management processes and procedures will be facilitated by significant investments by the GOA in infrastructure and equipment, as new CECOMA warehouses are being finalized in the four regional warehouses (namely Luanda, Huila, Malange, and Benguela).

During capacity-building sessions, trainings, and supportive supervisions, SIAPS has been using a strong team of motivated local facilitators at both the national and provincial levels. The program has also developed and used locally customized, hands-on, skills-based training materials adapted to local context and needs. Trainings are complemented with ongoing follow up, on-the-job capacity building, mentoring, and supportive supervision. The available tools will facilitate the local teams to continuously enhance human resource capacity in pharmaceutical management.
As the project is entering its final year of implementation, many challenges remain: the weak human resource capacity in a post-conflict country, the current “pull” supply systems with little involvement of the health facilities in requisitioning; the gratuity of products in the public sector, which results in little incentive to properly manage them; a weak medicines regulatory system, with all the consequences associated with uncontrolled sources and low-quality products; and high costs of implementing a program in a very expensive environment, have negatively impacted implementation of the program.

However, SIAPS Angola will prepare a transition plan for activities that need to be transferred to government institutions or to other similar technical assistance mechanisms. All guiding documents developed by SIAPS have been gradually handed over to the key stakeholders that have the responsibility for their implementation. Given the current local context, additional technical support to the GOA, in the area of pharmaceutical systems strengthening, is still needed.
Bangladesh has made many achievements in supply management for health commodities over the past few decades, yet, remaining issues in pharmaceuticals system strengthening pose challenges for the Ministry of Health and Family Welfare (MOHFW) and its key directorates, namely, the Directorate General of Family Planning (DGFP), Directorate General of Health Services (DGHS), National Tuberculosis Program (NTP), and the Directorate General of Drug Administration (DGDA) to effectively support health and population program implementation. Although stock-outs of key commodities have decreased at the national level, much work needs to be done to strengthen the system to ensure uninterrupted supplies of high quality and safe commodities at service delivery points. Documented challenges in procurement process management, storage and distribution of health commodities, and consumption monitoring remain, all of which are the primary source of information for forecasting and quantification. Registration of imported health commodities, management of TB commodities, and overall quality assurance in the health supply chain have continued to be areas of concern.

SIAPS Bangladesh began in September 2011, after the successful completion of SPS. The main aim is to improve the availability of quality pharmaceuticals and effective pharmaceutical services to achieve desired health outcomes. SIAPS began working with the DGFP, and based on much success, the MOHFW requested that SIAPS widen the effective technical assistance to the MOHFW and other key directorates, namely DGHS, NTP, and DGDA. SIAPS focuses on good governance, procurement, logistics, institutional capacity-building, and improving the regulatory system, with the aim of ensuring continuous availability of quality commodities to support quality health care delivery and patient safety, and the timely availability of reliable data to support evidence-based decision making.

**Background**

Bangladesh has made many achievements in supply management for health commodities over the past few decades, yet, remaining issues in pharmaceuticals system strengthening pose challenges for the Ministry of Health and Family Welfare (MOHFW) and its key directorates, namely, the Directorate General of Family Planning (DGFP), Directorate General of Health Services (DGHS), National Tuberculosis Program (NTP), and the Directorate General of Drug Administration (DGDA) to effectively support health and population program implementation. Although stock-outs of key commodities have decreased at the national level, much work needs to be done to strengthen the system to ensure uninterrupted supplies of high quality and safe commodities at service delivery points. Documented challenges in procurement process management, storage and distribution of health commodities, and consumption monitoring remain, all of which are the primary source of information for forecasting and quantification. Registration of imported health commodities, management of TB commodities, and overall quality assurance in the health supply chain have continued to be areas of concern.

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**Key Interventions**

SIAPS works closely with the MOHFW and its key directorates at the national, regional, district, sub-district, and service delivery point levels to address the challenges through the following key interventions.
Governance

To promote good governance, transparency, and accountability, SIAPS has been providing technical assistance in the development of pharmaceutical management guidelines and policy/procedures documents. The purpose of these key policy/procedures guidelines is to support government and health care managers on the importance of efficient procurement and supply management within the MOHFW and its different wings. SIAPS facilitates the process of adequate quantification and procurement of national health commodities to ensure appropriate value for money. SIAPS has also formed different coordination and decision-making bodies among high-level government officials to strengthen the pharmaceutical systems of Bangladesh.

Capacity Building

To support pharmaceutical management capacity building, SIAPS developed five in-service health professional training curricula and has trained more than 14,000 people in various aspects of pharmaceutical management across the country. SIAPS has worked with local institutions to reform their training curricula and modules and has supported the capacity building of key officials from the different directorates. SIAPS conducts on-the-job training for practicing managers, which has led to the creation of a pool of master trainers within the DGFP.

Supply Chain Management

SIAPS has been supporting the quantification and forecasting exercises for the MOHFW, particularly for the DGFP, DGHS, and NTP, to provide effective information for procuring the optimal amount of drugs. Strategic information provided through this intervention is used by the government to ensure value for money.

SIAPS introduced and facilitated the functioning of different online systems, aimed at improving the use of information for decision making. These systems include the Supply Chain Management Portal (SCMP), an online central repository for all procurement and supply chain activities under the MOHFW; the Upazila Inventory Management System (UIMS), which maintains inventory at upazila
family planning stores; the Warehouse Inventory Management System (WIMS), which maintains inventory at the family planning warehouses at the district level; e-TB Manager, a web-based tool for managing information needed by the NTP; QuanTB, an electronic forecasting, quantification, and early warning tool designed to improve procurement processes, ordering, and planning for TB treatment; and the DGDA web portal, all to inform evidence-based decision making.

**Medicine Regulation and Rational Use**

SIAPS has been working with the DGDA in the areas of medicine registration and pharmacovigilance to ensure the quality of medicines and patient safety. SIAPS developed the country-specific PharmaDex for the online drug registration system and supported 30 hospitals and pharmaceutical companies to report adverse drug events to the Adverse Drug Reaction Advisory Committee (ADRAC). The national pharmacovigilance program in Bangladesh, established with SIAPS assistance, has been accredited as the 120th member of the WHO International Monitoring Center (IMC).

**KEY ACHIEVEMENTS**

**Governance**

To date, the following manuals, guidelines, and standard operating procedures (SOPs) have been developed: DGFP Procurement Procedures Manual; DGFP Supply Manual; Procurement Operations Manual for MOHFW; Framework Agreement; Table of Equipment for 10-, 20-, 50- and 250-Bed Hospitals; SOP for TB Drugs and Supplies; and the Bangladesh National Formulary. At the same time, several national-level coordination bodies were formed and are functioning within the MOHFW and its key directorates to strengthen the pharmaceutical procurement and supply system: the Logistic Coordination Forum for DGFP, Supply Chain Coordination Forum in DGHS, Forecasting Working Group for DGFP, Procurement and Logistics Management Cell (PLMC) in the MOHFW, and the ADRAC in the DGDA.

**Supply Chain Management**

The PLMC, the central procurement coordinating body in the MOHFW, has made significant progress in supply chain areas. The procurement efficiency of the MOHFW and its directorates has improved considerably since the inception of the PLMC. As of September 2013, SCMP data shows that procurement lead-time has been reduced from 78 weeks to 33 weeks in the DGFP, and 52 weeks in the DGHS, ensuring that pharmaceuticals are available throughout the Bangladesh supply chain system.

The introduction of the service delivery point dashboard module, part of the SCMP, has widened the scope of the electronic logistics reporting system for DGFP, thereby ensuring availability of commodities at the service-delivery level. Through capacity building and creating a pool of master trainers, stock-outs at the sub-district level and service delivery points have been reduced to 2% and 1%, respectively. This has resulted in no stock-outs of FP commodities countrywide.
since 2011. In addition, over the last four years, SIAPS quantification support has saved the Government of Bangladesh (GOB) approximately USD $6.48 million.

SIAPS has supported the development and integration of the Procurement and Supply Management Working Group (PSMWG) within the NTP and has promoted and supported the use of QuanTB and the creation of an early warning system, which has provided the NTP with the necessary data to maintain TB medicine stock at an optimal level.

**Medicine Regulation and Rational Use**

SIAPS assisted the DGDA in incorporating the international standard adverse drug event reporting system into the WHO-IMC website after launching the National Pharmacovigilance Program in the country.

**CONTRIBUTION TO US GOVERNMENT GOALS**

SIAPS Bangladesh objectives contribute both to the USAID Mission goals as well as global US Government goals, particularly to universal health coverage (UHC) and medicine availability. Because of improvement in the procurement and supply chain systems, the availability of essential medicines has increased. SIAPS-supported TB interventions have enabled the increase in TB treatment, through building capacity for TB pharmaceutical supply management and electronic recording and reporting of comprehensive TB patients’ information into e-TB Manager. Improvements in the drug regulatory system have contributed to UHC by improving medicine regulation, adverse event reporting, and patient safety.

Moreover, SIAPS objectives contribute to the GOB’s sector wide Health, Population, and Nutrition Sector Development Program (HPNSDP). The HPNSDP goal is “to ensure quality and equitable health care for all citizens by improving access to and utilization of health, population, and nutrition services.” In particular, the key components of HPNSDP are improving health services and strengthening health systems.

**LESSONS LEARNED**

Promoting passionate leadership and interest within the MOHFW will make a big difference in the support for program implementation (for example, PLMC establishment, piloting Pharmadex, both of which had strong MOHFW support). Promoting the engagement of GOB officials throughout all stages of implementation is important. Country context and the need and readiness of the stakeholders are some of the key determinants for the success of an intervention. It is also important to recognize that different interest groups outside the GOB can play a vital role in implementing innovative tools. It is also important to recognize, and plan for any delays in country adoption and adaptation of new tools, as technology may require longer time to develop than initially anticipated.
SUSTAINABILITY

SIAPS has been addressing and promoting sustainability by institutionalizing the following key interventions:

- A pool of master trainers has been created to manage the SIAPS-supported health information system tools (DGFP: 74 master trainers; DGDA: content management team) and generate routine monthly reports for evidence-based decision making.

- SIAPS-supported Forecasting Working Group, PSMWG, and PLMC coordination mechanisms have been positively received by the GOB and donors, as they have seen evidence that the interactive in-depth discussions and strategic decisions have value for money.

- SIAPS-initiated activities are considered “game changers” in the Bangladesh health sector (i.e., procurement reform, PV program to promote patient safety), and the MOHFW has already incorporated many SIAPS agendas into the next health sector program strategy (2016-2021).

- SIAPS is involved in the next sector-program development core committee, which provides the opportunity to continue SIAPS key interventions in the next sector wide program.

Sustainable Handover of the SCMP to MOHFW’s PLMC

SIAPS is in the process of officially handing over the SCMP to the PLMC by 2016, with the support and collaboration of the MOHFW. The following items are part of that process:

- MOHFW/PLMC will issue a circular so that concerned authorities can officially use the portal.

- SoftWorks, SIAPS Bangladesh’s IT partner, will submit an inventory of technologies used to develop the SCMP (UIMS, WIMS, eLMIS, Equipment Tracker, DGDA drug database). In addition, SoftWorks will prepare and submit the data dictionary, source code, and technical documentation in both hard and soft copy formats to MOHFW/PLMC.

- The Development Wing of MOHFW will highlight the issue of management and maintenance of the SCMP and request that the Financial Management and Audit Wing and the Finance Division create a new code in the revenue budget for meeting SCMP expenditures in the future.

- Like DGHS and DGFP, CMSD and DGDA will start the process for creating an IT setup in their organizations.

- SIAPS will assist the PLMC in preparing a bid document for outsourcing the maintenance of SCMP.

- The data center of DGHS will be the home for SCMP; SoftWorks and SIAPS will work closely with the DGHS IT team to facilitate the transition to the DGHS.
Malaria is a major health problem in Burundi. Of confirmed malaria cases reported in children, 54% are in children younger than 5 years and 30% of deaths in this group are caused by malaria. To address the challenge of malaria, the National Malaria Control Program (Programme National Intégré de Lutte contre le Paludisme (PNILP) updated the 2013–2017 strategic plan that focuses on the use of long-lasting insecticidal nets and indoor residual spraying, improving accessibility to effective antimalarial medicines, and early detection and control of epidemics. The health system has faced medicine stock-outs, poor access to quality health services, and lack of accurate laboratory diagnostic capabilities. Thus, ensuring prompt, effective, safe, and rapid diagnostic tests and artemisinin-based combination therapy (ACT) for patients with diagnosed and confirmed malaria was a great challenge for the PNILP.

The PNILP and the Department of Pharmacy, Medicines, and Laboratories (DPML) play major roles in reaching the goal of reducing malaria-related morbidity and mortality by 75% by 2017. Based on thorough assessments of the management and organizational capacity of PNILP (under the Strengthening Pharmaceutical Systems project, 2012) and Department of Pharmacy, Medicines, and Laboratories (DPML) in 2013, improving governance, leadership, transparency, accountability, and coordinating among stakeholders were recommended as strategic next steps for both institutions. SIAPS supports the Government of Burundi in combatting malaria morbidity and mortality by improving the security of malaria commodities in the country and strengthening best practices in case management.

**SIAPS INTERVENTIONS AND ACHIEVEMENTS**

**Governance**

SIAPS assisted the PNILP to update the national malaria strategy, as well as develop internal administrative, finance, human resource, and procurement procedures. The DPML also developed its strategic plan for 2015–2017 and administrative procedures with SIAPS’ technical assistance. PNILP and DPML are now familiar with planning activities and monitoring achievements, having
developed annual work plans and monitored progress since 2013 through workshops supported by SIAPS. SIAPS financially assisted the PNILP and DPML in providing successful capacity building opportunities to 49 persons on the Management and Organizational Sustainability Tool; program development, planning, and management; strategic planning; principles and procedures of the Global Fund’s new funding mechanism; TOMPRO/financial management software; and administrative, finance, human resources, and procurement procedures.

SIAPS assisted the PNILP in revising the national strategic plan as required to apply for a Global Fund grant. The revised plan outlines sound strategies to reduce malaria morbidity and mortality with evidence-based data collected through the M&E plan. During PY4, SIAPS supported the PNILP in developing and securing three malaria grants for a total of USD $58,574,074, including a successful concept note to the Global Fund for 2015–2017.

SIAPS assistance to develop procedures and norms, as well as staff training, has resulted in improved governance within PNILP and DPML. PNILP now has documented planning and management structures and has instituted an internal control system to prevent and detect abuse and fraud; an effective and accurate financial management system; and capacity and data collection tools to track program results. As part of the selection process for a Global Fund principal recipient, PNILP has met the initial benchmark of 73% of evaluation criteria including governance and financial management criteria. The PNILP concept note has been approved by the Global Fund for funding malaria activities in 2015–2017, as a result of PNILP’s improved capacity to plan and develop solid proposals.

Improving Accountability, Transparency, and Coordination

To address the challenges faced by PNILP in M&E and reporting malaria activities, SIAPS assisted in developing the M&E section of the national malaria strategy by supporting PNILP to train M&E staff and providing basic equipment to facilitate operations. In addition, SIAPS assisted the PNILP in conducting regular quarterly coordination meetings of Roll Back Malaria (RBM) in-country partners for an open and participatory planning and monitoring process. With SIAPS’ support, PNILP has embraced best practices to conduct coordinated RBM partners’ quarterly planning and evaluation meetings to discuss results, weaknesses, and strengths and to elaborate corrective actions accordingly. This contributed to confirming PNILP as principal recipient of Global Fund funds under the new funding mechanism.

UNINTERRUPTED SUPPLY CHAIN MECHANISM FOR MALARIA COMMODITIES IS IN PLACE

Quantification and Forecasting

SIAPS’ quantification and forecasting assistance addresses recurring stock-outs of essential products used in treatment of principal diseases, including malaria. SIAPS assisted PNILP to develop terms of reference and regulations for the malaria quantification committee and a quantification manual that set governance
and accountability standards for malaria quantification exercises. SIAPS trained 26 persons (12 women and 14 men) on quantification and supply planning using Quantimed in November 2012 and PipeLine in February 2014.

To assist the PNILP to ensure financial resources were in place for malaria commodities, SIAPS assisted in three quantification exercises and quarterly supply planning analysis which identified gaps in commodity funding. These gaps formed the basis for mobilizing funds for purchasing sufficient malaria commodities. SIAPS assisted the PNILP in updating quantification for the Global Fund malaria concept note.

To supplement Global Fund-funded malaria commodities, SIAPS assisted in delivering 7,081,225 rapid diagnostic tests (RDTs) and 8,394,295 ACT treatments purchased with USG funds. The Global Fund malaria concept note approved in March 2015 includes 13,153,340 ACT treatments for a value of USD $8,763,684 and 18,898,425 RDTs for a value of USD $10,687,181 to be funded by the Burundi Government and donors (President’s Malaria Initiative [PMI], Global Fund, UNICEF, World Vision, etc.).

Improving Capacity for Supply Chain Management

Limited staff capacity at all levels contributes to suboptimal stock levels and stock-outs of essential malaria commodities. To strengthen governance, SIAPS collaborated with the Supply Chain Management System (SCMS) to develop a harmonized Logistic Management Information System (LMIS) manual that includes commodity management and reporting tools, and plans for introducing clindamycin as a second-line treatment for uncomplicated malaria and scaling up the use of injectable artesunate to treat severe malaria. The manual, tools, and plans set measures for governance and accountability in the supply chain.

SIAPS assisted the DPML in training 630 logistic personnel from the central, district, and peripheral levels in inventory management. SIAPS also worked with the PNILP to strengthen the capacity of 45 health district managers to manage inventory and estimate monthly needs for stock replenishment through a feedback mechanism established in November 2014. The PNILP used the mechanism to conduct analyses of district monthly commodity reports and orders. PNILP provides formal feedback to district managers on accuracy, completeness, time, precision, and estimation of needed commodities. The analyses of district reports, requisitions, and stock status at Burundi’s Central Medical Store (CAMEBU) improved the use of information to determine order quantities. As result, stock accuracy at district and health-center levels increased from 71% in March 2014 to 88% in September 2015; and the value of expired malaria commodities remained at zero at CAMEBU October 2014 to September 2015.

Improving Availability and Use of Pharmaceutical Management Information for Decision Making

The harmonized LMIS manual, feedback mechanisms, and data analysis process mentioned above increased the percentage of health facilities that completed and submitted LMIS reports from zero (September 2014) to 96% (September 2015).
Likewise, the percentage of district pharmacies receiving regular formal feedback on submitted reports and requisitions increased from zero (November 2014) to 63% (September 2015).

SIAPS supported the PNILP in conducting four EUV surveys and assisted CAMEBU in analyses of monthly stock status, which enabled SIAPS to develop 15 procurement planning and monitoring reports for malaria (PPMRm). SIAPS assisted the PNILP, CAMEBU, and DPML in training 49 persons (16 women and 33 men) in data collection and demand and use. In addition, SIAPS assisted the MOH in conducting the Malaria Indicator Survey (MIS) in 2012 and the evaluation of community case management of malaria in the pilot health districts in 2013.

EUV results feed decision making and concrete implementation measures to ensure better case management of malaria and uninterrupted availability of malaria products. In addition to helping develop and update the 2013–2017 malaria strategic plan, EUV results informed the development and update of the malaria concept note submitted by the PNILP to the Global Fund in January 2015. The evaluation of community case management of malaria has been of great help to improve community level services and plan for national roll out. The evaluation provided important information for the integrated community case management (iCCM) section of the concept note and the iCCM of the childhood illness policy document. Stock status and PPMRm reports informed procurement decisions, including advocating for accelerated deliveries of malaria commodities to anticipate stock-outs.

**Community Case Management of Malaria (PECADOM)**

Community case management (PECADOM) has been introduced in Burundi to bridge geographical barriers by bringing the management of malaria cases in children under age 5 into the community where children live. With SIAPS’ assistance, PECADOM abides by the guidelines for scaling up community case management, which provide for effectiveness and accountability. SIAPS assisted in developing diagnosis, case management, and consultation job aids. SIAPS also supported the PNILP in training 529 community health workers (CHWs) who treated children under 5 in two health districts and 27 health center workers who coordinate CHWs. SIAPS provided technical assistance in developing a reporting form and user guide, data analysis guide, and caseload database and user guide that help communities with timely reporting of standardized data to the central level via health districts. To improve community level services, SIAPS helped develop a consultation book, referral form, requisition forms, and stock cards for ACT and RDTs; in addition, CHWs were trained in stock management, identification of danger signs, and referral, diagnosis, consultation, and dispensing.

PECADOM helped reduce the number of deaths related to malaria among children under 5 by early treatment. Stock-outs experienced by CHWs decreased from 20% in 2013 to 9% in 2014. From 2012 to 2014, the percentage of cases treated with ACTs within 24 hours of the onset of fever increased from 81% to 91%. In two health districts that implemented PECADOM with SIAPS assistance, CHWs diagnosed and treated 48,450 cases since 2014, representing 24% of all malaria cases recorded in these two districts.
Improving Malaria Services for Pregnant Women

The intermittent preventive treatment in pregnancy (IPTp) policy has been introduced in Burundi to reduce the prevalence of severe maternal anemia and cases of low childbirth weight due to placental malaria, and thus decrease maternal and neonatal deaths. In 2014, SIAPS collaborated with WHO and UNICEF to assist MOH in developing the IPTp policy and implementation plan that provides health managers and care providers with governance and accountability standards. The IPTp policy was launched in February 2015. SIAPS worked with partners to develop training materials on IPTp, such as training and reference manuals for trainers and health care providers. To ensure that the country mobilizes sufficient resources for the service to be free of charge, SIAPS aided the MOH in quantifying sulfadoxine-pyrimethamine (SP) needed for 2015–2017. To enable pregnant women to access IPTp, SIAPS assisted the PNILP in delivering 1,860,000 SP tablets procured by PMI and in distributing SP procured by PMI, UNICEF, and the Global Fund from CAMEBU to health districts in accordance with the policy implementation plan.

Improving Malaria Case Management in Health Centers and Hospitals

To improve malaria case management at health facilities, SIAPS focused on updating malaria standard treatment guidelines (STGs). SIAPS assisted the PNILP in updating the 2012 malaria STGs and developing the 2014 guidelines for the national pharmacovigilance system. The two guidelines provide the basis for governance and accountability in management of malaria, patient safety, and rational use of malaria commodities. SIAPS assisted the MOH in developing training modules on STGs, pharmacovigilance, and malaria diagnosis; guidelines and checklists for integrated supervision; and guidelines for supervision of malaria activities. SIAPS assisted the MOH in training public sector health care providers, managers, and private sector pharmacists as the table below illustrates. SIAPS assisted in disseminating algorithms, and job aids in health centers, and over 1,200 copies of the malaria STGs have been distributed countrywide.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Women</th>
<th>Men</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaria diagnosis (2012 and 2015)</td>
<td>91</td>
<td>374</td>
<td>465</td>
</tr>
<tr>
<td>Malaria case management/STGs (2012, 2013, and 2014)</td>
<td>228</td>
<td>537</td>
<td>765</td>
</tr>
<tr>
<td>Pharmacovigilance (2015)</td>
<td>2</td>
<td>25</td>
<td>27</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>321</strong></td>
<td><strong>936</strong></td>
<td><strong>1,257</strong></td>
</tr>
</tbody>
</table>

SIAPS assisted in updating the form used by health centers to report malaria. The form enables aggregation of information on malaria cases and commodities at the health center level to feed into the national health information system. The information allows integrated analysis of malaria epidemiological and commodity trend countrywide and enables making decisions accordingly. In addition, SIAPS assisted in developing adverse drug reaction (ADR) reporting forms and a caseload database that allows information flow from health centers to DPML for adverse drug events analysis and decision making. Through trainings and supervision visits, SIAPS assisted the PNILP in improving health care providers’ competencies to deliver quality malaria services. Disseminated algorithms and job aids also enabled standardized and quality services. SIAPS worked with the PNILP to distribute malaria commodities from CAMEBU to health districts to ensure that products are available for patients.
As a result, from March 2014 to September 2014, the percentage of facilities with an available copy of malaria STGs increased from 40% to 62%; the percentage of prescriptions in compliance with malaria STGs increased from 76% to 93%; and the percentage of patients surveyed that knew correct information about their medications increased from 51% to 92%.

**CONTRIBUTION TO USG GOALS**

SIAPS’ pharmaceutical systems strengthening approach in Burundi contributes to USG PMI, ending preventable child and mother deaths (EPCMD), and universal health coverage (UHC) goals. With a focus on mortality among children less than five years of age, PMI’s strategy of reducing malaria-related mortality aligns closely with the USG’s vision of EPCMD.

SIAPS efforts to assist PNILP and DPML to strengthen supply chain systems for malaria commodities and strengthen roll-out PECADOM and IPTp contribute to reducing the 30% of deaths among children less than 5 years of age caused by malaria in Burundi.

PECADOM and IPTp strategies contribute to UHC by increasing access for children and pregnant women in poor rural areas. These groups now receive quality free preventive and curative malaria services in their local communities. SIAPS’ assistance in delivering malaria medicines and mobilizing funds for malaria activities also contributes to UHC. Transparency, governance, supply chain strengthening, facility case management and information systems contribute to UHC and EPCMD, as they all influence the availability of products and services for PECADOM, IPTp, and pharmaceutical services in the country.

**LESSONS LEARNED**

Effective communication and coordination with health districts and key institutions allowed implementation of trainings and supervision of health workers. Because there was a lack of capacity building for health district managers and major institutions, SIAPS suggested soliciting the support of existing institutions in the implementation of project activities.

Community level supply chain management and quality of care can be improved through enabling district-level managers to train and coach CHWs on essential malaria community case management functions during regular monthly meetings. SIAPS assisted PNILP to institute the monthly meetings with priority training topics coupled with mandatory submission of reports and requisitions malaria commodities. As a result, the reporting rate rose from 79% in quarter 1 to 100% in quarter 4; likewise, stock-outs of ACTs experienced by CHWs dropped from 20% to 9%.

Regular and effective coordination with RBM partners allowed PNILP to identify delays in implementation of malaria activities by other stakeholders. For example, when Global Fund support was not able to train designated districts on malaria STGs, SIAPS supported PNILP to ensure all health districts were trained.
Because of stock-outs of RDT for three months in 2014, SIAPS assisted PNILP in conducting coordinated supply plan reviews and pipeline analysis, coupled with stock-level analysis at CAMEBU. Increased availability of information on stock levels and order tracking for the many stakeholders involved in supplying commodities helped them to avoid potential stock-outs, by such means as accelerating specific deliveries. The end result was decreased stock-outs and improved stock security of malaria commodities at CAMEBU.

Implementation of several SIAPS activities was delayed as a result of shifts in government priorities. IPTp and pharmacovigilance activities were planned in PY1 and implemented in PY3 and PY4. Close follow-up allowed the project to advocate for activities and implement quickly. Now, IPTp is being scaled up nationally and the adverse drug reaction system is in place.

Because of leadership changes in major institutions, PNILP delayed implementation of governance, organizational structure, and coordination activities. Continuous negotiations and collaboration allowed SIAPS to advance the agenda and achieve set objectives.

**SUSTAINABILITY**

**Governance**

With SIAPS’ assistance, the PNILP and DPML have developed capacities in strategic planning, M&E, processes creation, utilization of management tools, policy development, and staff technical and managerial training. Nevertheless, the MOH and PNILP still depend on external funds and partners’ technical assistance. In the last six years, the health sector represented between 8% and 12% of the national budget. Within the MOH budget, the PNILP represents (without salaries) less than 1%. High turnover, particularly of PNILP’s management team, is a setback to sustainability of achieved results.

**Supply Chain**

SIAPS contributed to developing job aids, LMIS manual and tools, quantification committee TORs and regulations, and quantification manuals that have been institutionalized within the MOH. Despite these accomplishments, MOH is not ready to independently conduct these functions, such as quantification and forecasting. The MOH nomination of the malaria quantification committee is pending and next steps include shepherding this committee in training on tools and appropriate methods to build skills once members are nominated.

**Malaria Case Management**

SIAPS contributed to building capacity through trainings, modules and job aids, guidelines, and policies to improve the management of malaria at health centers, hospitals, and the community level. This capacity will remain and continue to be utilized after the SIAPS Program ends. However, given staff mobility within and out of the health sector in the absence of a national human resources strategy for the health sector, achieved results may be unstable in the long term.
USAID and the US Centers for Disease Control (CDC) are implementing the US President’s Emergency Plan for AIDS Relief (PEPFAR) program in Cameroon’s Center, Littoral, North West, and South West regions. Interventions are predominantly focused on prevention to mother-to-child transmission of HIV (PMTCT). In 2012, USAID invited SIAPS to Cameroon to assist the National AIDS Control Committee (NACC) in managing and preventing the frequent and severe stock-outs of ARVs that the country was facing. In Cameroon, stock-outs are a symptom of numerous systemic dysfunctions from the central level to the periphery. The dysfunctions stem relates to governance, and a lack of coordination among institutions, inefficient procurement processes, unpredictability of budget availability, inefficiencies of the storage and distribution systems, lack of qualified staff, and inadequate information system.

Since Program Year (PY) 3, SIAPS Cameroon has worked at all levels of the pharmaceutical supply system, including the national, regional, and health facility levels. At the peripheral level, SIAPS has focused interventions in the four PEPFAR-supported regions (four regional medical stores and 98 ART PMTCT sites). In addition, USAID requested SIAPS to extend interventions to Adamawa and Est regions (two regional medical stores and six ART sites).

In September 2015, SIAPS was requested to close out the activities in Adamawa and Est to align technical assistance strategy to the new PEPFAR 3.0 strategy, and to increase the coverage of PMTCT health facilities in PY5. SIAPS has deployed staff in Yaoundé (MSH office and regional medical stores), as well as in Bamenda, Buea, and Douala.

**Table 1. Number of ART and PMTCT facilities covered by SIAPS in Cameroon**

<table>
<thead>
<tr>
<th></th>
<th>US-involved support</th>
<th>PY3</th>
<th>PY4</th>
<th>PY5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adamawa</td>
<td>USAID</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>East</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Centre</td>
<td>7</td>
<td>39</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Littoral</td>
<td>USAID and CDC(PEPFAR)</td>
<td>7</td>
<td>26</td>
<td>39</td>
</tr>
<tr>
<td>North West</td>
<td>7</td>
<td>18</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>South West</td>
<td>5</td>
<td>15</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Total number of SIAPS-supported sites by PY</td>
<td>34</td>
<td>104</td>
<td>132</td>
<td></td>
</tr>
<tr>
<td>% of national patients on treatment</td>
<td>55%</td>
<td>76%</td>
<td>TBD</td>
<td></td>
</tr>
</tbody>
</table>
In Cameroon, SIAPS’ strategy has been to design interventions to avoid nation-wide stock-outs of ARVs and has transitioned to designing decentralized interventions to ensure the availability of medicines at the point of care in 104 ART and PMTCT sites.

**KEY INTERVENTIONS**

The SIAPS project in Cameroon has been implemented through a comprehensive approach which started with a thoughtful analysis of the context conducted through technical assessments of the pharmaceutical supply system. As a result, SIAPS’ strategy for Cameroon was designing systems strengthening interventions under which supporting actions were prioritized to respond to urgent needs. As such, during PY2 and PY3, SIAPS focused on establishing the necessary foundations to avoid nation-wide stock-outs of ARVs. Gradually during PY3 and PY4, SIAPS decentralized interventions at the periphery in the four PEPFAR regions to ensure the availability of medicines at the point of care in 104 ART and PMTCT sites. The main interventions can be summarized in four major blocks including institutional governance, data availability, management of information, logistics capacity, and human capacity building.

**Institutional governance and compliance with the Global Fund and other donors’ requirements**

In 2012, stock-outs of ARVs at the national level were closely linked with governance issues, including fragmented roles and responsibilities across institutions, lack of coordination to solve short- and long-term questions on access to HIV commodities, and lack of capacity to respond to Global Fund and other donor’s requirements. The NACC, the principal recipient of the Global Fund, had difficulties in fulfilling grant conditions, which caused significant delays in the disbursement of funds and affected the capacity to procure HIV health commodities.

SIAPS intervened by responding to urgent issues related to quantification and fulfillment of Global Fund conditions, ensuring adequate involvement of key government staff and other partners, such as ESTHER and the Clinton Foundation. SIAPS also assisted the NACC in the preparation of Global Fund documents related to the Round 10 extension, submission of the HIV concept note, and grant making documents. In PY3, SIAPS also facilitated the establishment of a quantification and stock monitoring committee, and capacitated its members to conduct quantification. In addition, during PY4 SIAPS joined other technical and financial partners, as well as the civil society organization, Positive Generation, to jointly advocate for pharmaceutical reforms.

**Data availability and use of pharmaceutical information at national level**

In 2012, the HIV program in Cameroon had not yet put in place a recording and reporting system to capture patient and pharmaceutical data and information. Tools had been developed but not yet printed and disseminated. As such, although the general perception was that stock-outs were widespread and critical, there was no data to analyze the magnitude of the problems at the different levels and geographic areas. During PY2 and PY3, SIAPS and other partners assisted with printing and implementing the approved tools, and implemented a training and supervision strategy to ensure adequate use of registers and reports in 34 health facilities in PY3, and 104 in PY4. These include the ART patient registers, ART dispensing registers, stock cards, and seven different types of reports. In PY4, as the reporting system was working well, SIAPS started to introduce the use of...
pharmaceutical data captured at regional and health facility to improve national stock monitoring exercises conducted by the HIV Quantification Committee. However, progress in introducing new information in national monitoring is slow, and will require further assistance during PY5.

**Storage and distribution of HIV health products**

Limited storage capacity, inadequate storage conditions, and improper use of available spaces at all levels of the supply systems were identified in the SIAPS assessment report as key factors that affect the capacity of Cameroon to rapidly scale up ART. SIAPS’ intervention focused on the procurement of some essential equipment with training to improve storage conditions, and optimize storage spaces. During PY2 and PY3, SIAPS contributed with providing necessary equipment to the National Essential Medicines Stores (CENAME), as well as to six regional medical stores to address immediate needs. SIAPS also worked closely with the French Development Agency (ADF) to develop standard operating procedures (SOPs) for pharmaceutical supplies management. These activities were conducted and aligned with intensive trainings targeting key staff at national, regional and facility levels. SIAPS also assisted the NACC to define the most adequate supply chain to ensure implementation of PMTCT Option B+. In PY4, SIAPS deployed a regional technical advisor to each of the four regional medical stores of the PEPFAR regions, with the purpose of decentralizing the SIAPS project in the regions, and shorten distances to quickly respond to needs. This deployment of technical assistance was accompanied by a vehicle (pick-up) to the four regional medical stores, along with a SIAPS driver, to support technical and distribution activities in each of the regions.

**Capacity building at the peripheral level**

The assessment of the pharmaceutical management systems in Cameroon analyzed the scarcity of skilled human resources in the health care system, and urged to increase the pharmaceutical staff. Until recently Cameroon did not have a training institution for pharmacists and mid-level pharmacy staff. In the ART clinics, the situation was even worse, as HIV commodities were stored generally outside the hospital pharmacy, and often in the dispensing area itself. The HIV program had not implemented any intervention to build the capacity of HIV pharmacies and stock keepers. During PY2 and PY3, SIAPS conducted intensive trainings with the objective of introducing the most basic notions on pharmaceutical management to the ARV dispensers and stock keepers, including the developed SOPs and reporting requirements. Trainings were followed by quarterly supervisions to ensure application of knowledge to routine activities. However, at the beginning of PY4 SIAPS Cameroon evaluated the outcomes of the interventions that aimed to improve access to HIV commodities, and observed that the number of stock-outs at facility level had not been significantly reduced despite the availability of products at the national and regional levels, and also despite the capacity building interventions conducted. The SIAPS team identified that ART site coordinators had very limited involvement in supervising and supporting in pharmaceutical activities and pharmacy staff creating bottlenecks at the health facility level. Since February 2015, SIAPS boosted training and supervision with quarterly regional feedback meetings addressed to ART site coordinators to discuss indicator results and supervision observations, and agree on options for improvement.
KEY ACHIEVEMENTS

The main achievements of the project are shown in the five sections below.

Significant stock-outs reduction

The reduction of stock-outs at the 104 health facilities supported by SIAPS has been notable since the beginning of the project. There has been a reduction from 100% health facilities having experienced at least one stock-out every quarter in PY2, to only 34% of the health facilities having experienced stock-outs in PY4. The major improvement was achieved during PY4, where in Q1 more than 90% of health facilities still registered stock-outs but decreased to 34% by the end of the fiscal year. Also, the response from health facilities to solve a stock-out situation has been improved, from an average of more than six days per stock-out in PY4Q1 to around 1.2 days in Q4. This progress has been achieved as a result of all four interventions previously described.

Improved storage conditions

Improvement in storage conditions is directly linked with the availability of SOPs (governance), procurement of equipment, training, supervision, and use of information. Storage conditions of HIV commodities improved in Cameroon National Essential Drugs Procurement Centre (CENAME) during PY2 and PY3 with the provision of equipment and assistance to ensure space optimization. However, due to the need to decentralize SIAPS activities to the periphery, in addition to the resistance of CENAME to work on management procedures, storage conditions at CENAME in PY4 were not monitored. At the regional and facility levels, improvements were achieved, such as in PY2 none of the central and regional medical stores supported by SIAPS complied with minimum storage requirements. As of September 2015, the six regional medical stores supported by SIAPS complied with basic good storage requirements. At the facility level, in January 2015, only 15% of the 104 health facilities supported by SIAPS complied with basic storage requirement, while in September 2015 this percentage increased to 78.8%. This notable improvement was achieved by the health facilities, which mobilized internal resources to improve storage conditions, after discussions during supervision and feedback meetings. No equipment or funding was provided by SIAPS or other partners to improve the storage spaces. For example, some health facilities made wooden pallets through local carpenters, others rearranged office and storage spaces and existing furniture to improve the store rooms and dispensing areas, and, on some cases, some health facilities managed to install air conditioning in pharmacy spaces.

Improved availability and quality of data in 104 ART and PMTCT sites

Progress in data availability is directly linked to the intervention to increase data availability and training on pharmaceutical data management. In 2012, health facilities were not recording and reporting any information on pharmaceutical information, such as patients per regimen or stock on hand. As of September 2015, more than 80% of the 104 SIAPS-supported health facilities were updating the ART registers, dispensing registers, and stock cards daily. In addition, more than 85% of the 104 health facilities were reporting monthly logistics information, and more than 50% complied monthly with deadlines requirement.
Increased human capacity

Building human capacity in Cameroon has largely centered on training and supervision, although all interventions have integrated training and other capacity building activities. Between PY2 and PY4, SIAPS conducted a total of 33 trainings addressing nine different topics on pharmaceutical management, and targeting specific needs at central, regional, and health facility level. The total number of participants in all training as of September 2015 was 741, out of which 56% were female. As per level of training, 81% of the participants worked at health facilities, 4% at the regional level, and 15% at the central level. Trainings in combination with supervision and regional feedback meetings have obtained significant results. For example, NACC national staff members are now able to conduct quantification exercises, using Quantimed and Forlab. The health facilities are supervised at least once every quarter by teams composed by regional and health facility managers and SIAPS advisors. And ART site coordinators can now conduct internal supervision of the pharmaceutical services, and interpret whether a stock on hand situation at any given moment is adequate to fulfill patients’ needs.

Progress towards better governance

Some of the root causes affecting governance of the pharmaceutical system are still present, and fall beyond the scope of SIAPS’ technical assistance mandate. However, SIAPS has made contributed towards improvements in this sector. During PY2 and PY3, SIAPS assisted in developing some normative documents, including the SOPs for pharmaceutical supply management at the health facility level, the terms of reference of the Quantification and Stock Monitoring Committee, and SOPs for quantification at national level. Although only the terms of reference of the committee have officially been adopted, the other documents serve as reference documents in routine activities. The Quantification and Stock Monitoring Committee is still experiencing some challenges in its routine functioning, but the technical quality of the quantification exercises and stock monitoring reports are increasing. In PY4, SIAPS started working with the Positive Generation, a civil society organization, to explore areas of common work in patients’ access to treatment and analyze whether observations and indicators from both institutions lead to similar conclusions. Last fiscal year, SIAPS also began a partners’ committee, the Medicines Cluster, which aims to increase collaboration among technical and financial partners working in the pharmaceutical system, and jointly advocate for pharmaceutical reform.

CONTRIBUTIONS TO USG GOALS

SIAPS interventions during PY2 to PY4 in Cameroon contributed to the overall USG goal towards an AIDS-free generation. As showed in the results section,
SIAPS is significantly contributing to improving the availability and access to HIV commodities, mainly ARVs and rapid test kits, which allows more patients to have access to care, and prevent new infections. As part of PEPFAR strategy in Cameroon, SIAPS gradually focused on interventions in PMTCT and that commodities will be available for the implementation of Option B+. This support is essential to contribute to Ending Preventable Mother and Child Deaths (EPMCD) caused by the transmission of HIV.

In addition, SIAPS is actively contributing in Cameroon to four strategic objectives indicated in the Regional USAID HIV and AIDS Prevention and Care Strategy 2011-2016, which aims to mitigate the impact of HIV and AIDS in the West and Central Africa region. The four out of the five main objects were (1) addressing country needs to advance regional priorities, (2) supporting innovative approaches to scalable HIV response, (3) fostering sustainability through systems strengthening, and (5) improving strategic collaboration among stakeholders (objective 4 did not apply).

LESSONS LEARNED

After three years of implementation of the SIAPS project in Cameroon, SIAPS has gained a good understanding of the pharmaceutical supply system and the context in which it operates.

Overall, SIAPS has been very successful in ensuring a close collaboration and partnership at the regional level, with the Regional Delegations of Public Health, the Regional NACC, and the regional medical stores, as well as the health facility level. The decentralization of the health care system and the pharmaceutical system through the regions offer a very good opportunity to plan and conduct activities customized to specific regional needs, prioritizing different aspects, and also tailoring expectations according to the real context. The decentralization of the technical staff to the regions has also proved to be an effective strategy to improve results as well as acceptability of SIAPS interventions by the regional authorities.

However, at the national level, technical assistance alone is not as effective as could be expected. As such, governance-related issues as well as issues related to collaboration among national institutions affect the effectiveness of SIAPS technical assistance in systems strengthening. These limitations are somehow mitigated by the good partnership among technical and financial partners working in the health and pharmaceutical system, and, overall, the partners work to seek synergic collaboration.

However, it is strongly recommended that the design of central-level interventions in Cameroon, aiming to improve technical capacity to manage pharmaceuticals, be integrated to strategies aiming at strengthening governance, management, and leadership. MSH who has large experience in implementing other USAID projects related to leadership, management and governance in the health sector, could offer a good opportunity to creating this integration of pharmaceutical supply management and leadership, management and governance.
SUSTAINABILITY AND COUNTRY OWNERSHIP

SIAPS has successfully built the capacity of national staff across different organizations, as well as key managers and technical staff in the peripheral levels, to ensure quality quantifications and stock monitoring at all levels of the supply system. There is also capacity and tools to maintain other system strengthening activities, such as supervision. In 2016 and 2017, the Global Fund will make additional financial resources available to implement pharmaceutical supply system strengthening activities at national and peripheral levels, especially in regions not supported by PEPFAR. However, there is no clear technical leadership within the government to effectively manage pharmaceutical supply questions, and as such, the sustainability of SIAPS interventions is fragile until the hand over to the adequate government institutions and staff is ensured.

In relation to the logistics capacity of the HIV program, the situation is also worrisome. The HIV program at the end of 2014 has approximately 145,000 patients on treatment representing around 27% of ART coverage. The Acceleration Plan aims to reach 36% by the end of 2016, 50% by end of 2017, and 62% by 2018. However, the current supply system is already close to saturation at central and regional levels. Health facilities are sometimes obliged to store ARVs and RTKs at the waiting rooms, because of the lack of space to accommodate the volumes of commodities. The Minister of Health is willing to allow the private sector to procure and dispense ARVs through private wholesalers and retail pharmacies to decrease the burden on the public sector. However, there are still not concrete plans to increase the capacity to manage increased volumes of medicines in the public sector, and the operational channels of complementarity of public and private sectors have not been discussed.

In this context, technical assistance to strengthen the HIV supply system will require additional funding in following years. Furthermore, this assistance will be needed to cover both PEPFAR and non-PEPFAR supported regions in both public and private sectors, as an uneven support in PEPFAR regions in relation to non-PEPFAR regions can also have an overall negative impact in PEPFAR-supported regions. For example, if data availability is only ensured in PEPFAR regions, national quantifications may be affected, thus affecting again the overall availability of HIV products.

Finally sustainability and country ownership questions need to be considered within the risk of a further deterioration of the security in the country as a consequence of the Boko Haram terrorist group, and the refugee camps on the borders of Chad and Central Africa Republic.
Tuberculosis (TB) continues to be a critical public health threat in Central Asia. Uzbekistan, Tajikistan, and Turkmenistan are included in the World Health Organization (WHO) European Region’s 18 high-priority countries that require TB interventions. In addition to high TB incidence, Uzbekistan, Tajikistan, and Turkmenistan also experience alarmingly high rates of multidrug-resistant TB (MDR-TB). Uzbekistan and Tajikistan are among the 27 high MDR-TB burden countries in the world.

<table>
<thead>
<tr>
<th>Country</th>
<th>MDR-TB Rate in New Cases</th>
<th>MDR-TB Rate in Retreatment Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uzbekistan</td>
<td>23%</td>
<td>62%</td>
</tr>
<tr>
<td>Tajikistan</td>
<td>8.1%</td>
<td>52%</td>
</tr>
<tr>
<td>Turkmenistan</td>
<td>14%</td>
<td>38%</td>
</tr>
</tbody>
</table>

Data from Global Tuberculosis Control, WHO, WHO/HTM/TB/2015.22

The high rates of MDR-TB in these countries likely result from a number of underlying causes, including improper prescribing practices, misuse of medicines, and inadequate quantification and supply planning resulting in stock-outs of anti-TB medicines. Decision-making and managerial interventions aimed at overcoming these challenges are limited by a lack of reliable data, often due to weak information systems.

The four key SIAPS strategies employed by the TB Central Asia Portfolio are strengthening pharmaceutical governance for TB on global and country levels, increased capacity for TB pharmaceutical supply management and services, improved use of information for decision making in TB control, and improved pharmaceutical services and access to TB products to achieve goals.

**KEY INTERVENTIONS**

**Strengthening Pharmaceutical Sector Governance**

SIAPS provided technical assistance to Uzbekistan’s Ministry of Health (MOH) to conduct a comprehensive indicator-based assessment of the TB pharmaceutical management system. SIAPS facilitated the creation of the MOH TB Pharmaceutical...
Management Working Group, with representatives from the MOH, National TB Program (NTP), Drug Regulatory Authority, and the Republican DOTS Center. The working group was involved in designing the assessment methodology, developing the assessment protocol, training data collectors, and collecting and analyzing the data. The assessment was performed to help gather evidence to support developing strategic approaches for strengthening the country’s TB pharmaceutical management system. In addition, the performing the assessment helped enhance the MOH’s capacity for conducting the similar assessments in the future.

Strengthening TB Medicines Supply Chain Systems

The indicator-based assessment revealed a number of problems including stock-outs of medicines at all levels of the health system. Interviews with medical personnel indicated that the stock-outs were caused by mistakes in quantification and delays in the delivery of medicines. Similar problems were detected in Tajikistan by other organizations. To address this, SIAPS facilitated a process of selecting priority interventions to strengthen the supply chain system for TB medicines.

- **Improving supply planning by establishing a system for early warning and quantification.** QuanTB, an electronic forecasting, quantification, and early warning tool, was implemented in Uzbekistan and Tajikistan. Implementing QuanTB has helped stakeholders make decisions on quantification, ordering, and responding to potential problems in relation to the supply of anti-TB medicines. Medical product availability has increased and service delivery has improved.

- **Build capacity for the consistent and efficient use of logistics management information systems (LMIS).** Uzbekistan and Tajikistan have well designed paper-based LMISs. But assessments have shown that LMIS requirements are not always followed and use of the system’s data output varies from facility to facility. The main problem for poor implementation is the lack of training of TB pharmaceutical management staff. To increase the capacity of TB staff, SIAPS provided technical assistance by developing training curricula and materials, training local trainers, and conducting countrywide trainings for staff involved in TB pharmaceutical management.

- **Develop capacity to use strategic information for decision making.** SIAPS provided technical assistance to the Tajikistan NTP to address the gaps in using data effectively to make decisions for supply planning purposes. SIAPS developed an automated tool which aggregates the reports on medicines consumption and stock levels from TB facilities. This allows the NTP to monitor metrics (reporting rates, average monthly consumption) and manage stock levels, which will minimize expiries and stock-outs of TB medicines. The system currently is being piloted in six regions of Tajikistan.

Strengthening Uzbekistan’s NTP Pharmaceutical Services

The assessment also revealed problems in the rational use of anti-TB medicines. In 16% of cases, first-line treatment did not conform to standard treatment guidelines;
in 46% of cases, second-line regimens used for treatment of MDR-TB patients were different from what was prescribed by MDR-TB physicians’ committees (consiliums). This contributes to poor treatment outcomes and the ongoing development and transmission of MDR-TB. SIAPS supported the NTP in piloting a Drug Use Review (DUR) system for improving prescribing practices. The DUR is a quality assurance intervention that, in a step-by-step manner, identifies and remedies problems related to drug use by collecting, analyzing, and interpreting data through systematic criteria-based reviews. The results of the DUR were discussed with the staff of TB facilities and an improvement plan was developed.

**Capacity Development for the Pharmaceutical Management of TB**

To ensure that Tajikistan’s TB medical personal are adequately and continuously trained on TB pharmaceutical management, SIAPS provided technical assistance to develop a training curriculum as part of the general post-diploma education of TB doctors and nurses. The curriculum was reviewed by the NTP and has been submitted for approval to the Tajikistan’s MOH. SIAPS also provided on-the-job training and remote support to the NTP’s pharmaceutical manager for addressing different pharmaceutical management tasks. In addition, SIAPS trained staff from TB facilities in two regions of Turkmenistan on the use of eTB Manager, an electronic TB information system.

**KEY ACHIEVEMENTS**

**Strengthening Pharmaceutical Sector Governance**

The comprehensive indicator-based assessment of the TB pharmaceutical management system in Uzbekistan contributed to the development of Uzbekistan’s National TB Control Strategy (2016-2020), and national capacity for conducting a similar assessment in the future was developed.

**Strengthening TB Medicines Supply Chain Systems**

Early warning and quantification systems have been piloted successfully and rolled out nationwide in Uzbekistan and Tajikistan. In Tajikistan, the system is fully functional and NTPs are now able to anticipate supply problems for anti-TB medicines and take remedial actions to avoid stock-outs or expiries.

All Uzbekistan’s TB facility staff members responsible for medicines management were trained on the use of the LMIS. The comparison of results of the pre- and post-tests of the trainees showed significant improvement in their knowledge and skills. Feedback from the NTP’s supportive supervisory teams has also been very positive, with health professionals detailing how the knowledge acquired during the training is used daily in the TB facilities. Trainings on the use of the LMIS are currently underway in Tajikistan.

SIAPS developed an automated tool designed to receive and automatically aggregate the quarterly LMIS reports on consumption and stock levels of medicines. The system will be piloted in six districts of Tajikistan. Using the system will ensure that reports are submitted on time, their accuracy will improve,
and the time needed for aggregation of the data received from the different facilities will be greatly reduced. This is important for improving the supply planning of anti-TB medicines within the country and minimizing stock-outs or overstocks of medicines.

**Strengthening Pharmaceutical Services of the NTP**

The DUR program was piloted in three facilities in Tashkent, Uzbekistan. Data from the DUR revealed existing gaps in the rational use of anti-TB medicines in these facilities. Working with the staff at the facilities, an improvement plan, including educational and operational interventions, was developed. The staff of the TB facilities expressed the desire to implement the DUR program on a regular basis as it helped them assess the current status of the rational use of anti-TB medicines within their facility, plan their interventions, and assess the impact.

**Capacity Development for the Pharmaceutical Management of TB**

The in-service curriculum on TB pharmaceutical management for TB doctors and nurses has been developed in Tajikistan in PY4, reviewed by the NTP, and was submitted for approval to the MOH. After its approval pharmaceutical management will become a routine part of the continuous education for TB doctors and nurses.

**CONTRIBUTION TO USG GOALS**

SIAPS interventions are in line with the US Government Global Tuberculosis Strategy (2015-2019). Specifically, SIAPS Central Asia contributes to Objective 3, part C aimed at developing “reliable procurement and distribution systems for all essential TB medicines and supplies, and ensure that systems provide TB medicines and supplies reliably to all relevant health facilities”. Also, strengthening the systems to ensure availability and accessibility to anti-TB medicines contributes to achieving the UHC goals. It also responds to the EPMCD’s call for action’s strategic shift to “reach the most underserved populations.”

**LESSONS LEARNED**

Involvement of the local colleagues in all stages of the program implementation was critical for the success: they worked with SIAPS on planning, preparation, implementation and monitoring of the activities. This insured development of the sense of ownership among the National Partners and also helped in development of their capacity. During this work the head of the TB pharmaceutical management working group in Uzbekistan and NTP pharmaceutical manager in Tajikistan became champions leading the activities and advocating for strengthening of TB pharmaceutical management systems in their countries.

Introducing good web based electronic tool, such as eTB Manager does not guarantee that it will be implemented successfully: in Turkmenistan’s case, although, the NTP expressed its commitment to piloting and implementation of eTB Manager, very little was done for that, although the system has been
customized for the country, the users were trained and WHO developed an infrastructure for that. In the future, a more thorough assessment of readiness and real commitment of the national partners to implement the web-based electronic tools is needed.

**SUSTAINABILITY AND COUNTRY OWNERSHIP**

In order to ensure sustainability, the SIAPS Central Asia approach includes the involvement of national stakeholders in all stages of the interventions: planning, implementation, monitoring, and evaluation. This has helped the successful implementation of interventions and has also helped develop the capacity at the National and facility levels. National staff, as well as health service providers, have been provided with appropriate processes and tools. National level staff members are able to perform complex TB pharmaceutical management tasks including: forecasting and quantification of medicines, implementing DUR programs, conducting indicator based assessments, and utilizing data for decision making. As a result of SIAPS interventions, the TB Pharmaceutical Management Working Group will continue working in Uzbekistan and is ready to address different ongoing and strategic challenges. The Tajikistan NTP Pharmaceutical Manager is capable of managing and coordinating the pharmaceutical management activities of the different stakeholders in the country.

The Uzbekistan and Tajikistan NTPs are the owners of the early warning system and are managing it on a daily basis. The TB pharmaceutical management curriculum will formally become in-service training for all TB doctors and nurses in Tajikistan. SIAPS continues to work with other international partners (Project Hope, KNCV, WHO) working on TB control in the countries to ensure that all work is coordinated and supports the National stakeholders to ensure the sustainability of the achievements.
The Democratic Republic of the Congo (DRC) National Health Strategic Plan (PNDS) 2011–15 describes medicines as an essential link in the development of the health system. Pharmaceutical services play a critical role in any health system; the 2009 World Health Organization (WHO) Essential Medicines report asserts that all the strategies governments and development partners put in place to fight diseases depend on essential medicines. Unfortunately, the DRC health system lacked a fully functional pharmaceutical regulatory systems and a comprehensive national pharmaceutical policy framework to guide regulation of the pharmaceutical system and coordination of pharmaceutical sector activities to achieve system objectives based on priority health problems. This has resulted in: (1) the mushrooming of illegal and uncontrolled pharmaceutical businesses; (2) non-adherence to good distribution practices and good manufacturing practices by suppliers, wholesalers, and local manufacturers; (3) loopholes that facilitated the circulation of counterfeited and substandard medicines in the country, which directly leads to the high number of unregistered and unauthorized medicines in circulation.

Furthermore, the lack of infrastructure, reliable information systems, the shortage of trained and qualified pharmaceutical personnel, the overwhelming reliance on international funding, and the poor coordination among those partners, have resulted in bottlenecks that hampered the smooth delivery of pharmaceutical services in the country. This led to poor quantification and management of pharmaceutical commodities, and ill-informed decision-making. To address this issue, SIAPS provided a comprehensive institutional capacity building support to Drug Regulatory Authority (DRA) to streamline and better coordinate the registration processes.

### Key Interventions

#### Supporting the Drug Regulatory Authority to Improve the Governance and Leadership

From 2012 to 2015, SIAPS continued supporting the DRA to develop the annual operational plans to improve governance, support the implementation of a fully functional pharmaceutical regulatory system and develop a comprehensive...
SIAPS has been supporting the Drug Regulatory Authority in DRC to develop a registered medicines directory for pharmacist inspectors and customs officers at the main entry points for medicines to track unregistered and unauthorized medicines.

national pharmaceutical policy framework. SIAPS assisted the DRA to establish a Medicine Registration Committee that meets on a quarterly basis to better coordinate and streamline registration processes. To ensure efficiency, accountability, and control, members of the registration committee were trained on standard operating procedures (SOPs), a registered medicines directory was developed and updated each quarter and disseminated for use by pharmacist inspectors and customs officers at the border posts, the main entry points for medicines, to track unregistered and unauthorized medicines. In addition, SIAPS assisted the DRA to update the national essential medicine list (NEML) and to include 13 lifesaving products for maternal, newborn, and child health (MNCH).

SIAPS supported the DRA and health provincial division to better coordinate the supply mechanism of essential medicines, and to play a stewardship role to ensure equitable distribution, redistribution, and reallocation of pharmaceutical resources throughout the country. SIAPS also assisted the DRA to train pharmacist inspectors to promote good distribution and dispensing practices.

Support the Warehouses/CDRs to Improve the Storage Condition

During the past four years, SIAPS supported ongoing supply chain management activities, including the improvement of storage conditions (e.g., procurement of thermos-hygrometer, dehumidifier, equipment for the cold chain, extinguishers, solar power kits), and provides technical assistance to the central regional medical stores (CDRs), in USAID supported provinces, to address the gaps identified during the various assessments conducted by the MOH and implementation partners (e.g., SCMS), and through other surveys, such as the end user verification (EUV) surveys. SIAPS also supported the CDRs to update their SOPs to ensure good distribution practices where HIV, malaria, tuberculosis (TB), and family planning/maternal, newborn, and child health (FP/MNCH) commodities are managed. Furthermore, SIAPS assisted the Regional Procurement Association for Essential Medicines, the largest warehouse in the eastern part of DRC, to meet the USAID/European Union pre-qualification standards in order to be used as a local supplier, and thus address the long lead-time faced when importing pharmaceutical products from international suppliers.

Support Quantification of Pharmaceuticals

To ensure appropriate quantification of medicines and related supplies, SIAPS began by supporting the MOH to update the NEML as a tool for medicine selection at health facility level. With other USAID implementing partners, SIAPS supported the assessment of the LMIS and developed the LMIS roadmap, including data collection tools to ensure that relevant supply chain data and information are available and submitted in time to inform the quantification process. SIAPS assisted the MOH to implement quantification tools, such as QuanTB and Quantimed, and conducted training of relevant health workers on the quantification of critical pharmaceutical commodities such as antimalarials, antiretroviral (ARVs), TB drugs, and the 13 life-saving MNCH products. In addition, SIAPS assisted the MOH to establish quantification committees at both the national and provincial levels to ensure that stakeholders from all levels are involved in the quantification process for the above mentioned products.
Support to Warehouses and Health Zones to Improve Medicines Management and Distribution

Through this intervention, SIAPS helped to improve pharmaceutical management and distribution of pharmaceuticals from CDRs to health zones and to health facilities in USAID supported provinces. The intervention design consisted of the following: (1) training health care workers on SOPs for good distribution practices and pharmaceutical management, (2) in-service training of CDR and health zone store staff on stock management and elaboration of quarterly distribution plans, (3) supporting the MOH to coordinate the medicine distribution at both national and provincial levels through technical assistance to the national medicine committee (CNM) and provincial medicine committees (CPMs), (4) implementing the use of an electronic tool (DISMED) to better monitor medicines distributed in USAID-supported health zones, (5) updating SOPs for managers at the warehouse and health facility levels, and (6) a roadmap was developed for implementing activities related to LMIS.

Support the Capacity Building

SIAPS provided technical and financial assistance to the University of Kinshasa Faculty of Pharmaceutical Sciences (FOPS) to develop a strategic plan to better coordinate and monitor and evaluate faculty operations. In addition, SIAPS assisted FOPS to develop a competency framework which defines required cognitive, procedural, and compartmental/behavioral competencies that a graduated pharmacist should have at the time of graduation. The developed competency framework is the basis for the overhaul of the current training curriculum which, according to the Accreditation Council for Pharmacy Education (ACPE) evaluation conducted in July 2014, does not respond to the public health concerns of the country and does not address the supply chain issues faced in the pharmaceutical sector. FOPS is the first training institution in DRC to have a strategic plan, and during the official presentation ceremony of the strategic plan in June 2015 before the country stakeholders, the Minister of High Education recommended that all other DRC training institutions adopt this model and use FOPS strategic plan as a reference for the development of their own plans. FOPS is so far the only training institution in DRC that meets the World Bank requirement as it requires that training institutions should submit their strategic plan as a prerequisite for any funding.

Another major SIAPS intervention consisted of supporting the National Malaria Control Program (NMCP) to train health care workers on malaria medicines and case management according to the revised guidelines of the NMCP, and to conduct biannual EUV surveys to evaluate the availability and access to malaria commodities. SIAPS has also supported the MOH to implement multidrug-resistant tuberculosis (MDR-TB) and TB/HIV co-infection active pharmacovigilance (PV) system and training health care workers on the PV system (including the appointment of TB focal persons for PV activities).

To ensure better coordination and implementation of PV activities, SIAPS provided institutional capacity building to the pharmacovigilance center (CNPV). A collaborative system between key stakeholders, namely CNPV, DRA, and drug and therapeutic committees (DTCs), was established following recommendations from the Minister of Health. Training on PV was conducted for health care
workers, especially members of the newly established DTCs, to ensure smooth implementation of PV activities at provincial and health facility levels. As a result, key stakeholders participate in regular meetings for effective planning and good coordination of PV activities. On an average, CNPV receives 1,500 individual case safety reports (ICSRs) per year with a completeness score (> 75%) well beyond the average score for other countries (50%).

**KEY ACHIEVEMENTS**

**Support the DRA to improve governance and leadership**

- The percentage of EML products that have been registered has increased from 44% at baseline in December 2011 to 72% in September 2015.

- The average number of days taken to evaluate applications of medicine registration has decreased from 82 days at the baseline in December 2011 down to 67 days (September 2015).

- The number of registered medicines circulating into the country has increased, from 455 at the baseline to 4,009 as of September 2014.

- A medicine registration database has been developed, and the registered medicines directory is available, updated on a quarterly basis, and disseminated for the use by pharmacist inspectors and custom officers to tract unauthorized medicines within the pharmaceutical market and at the border posts that are main point of entry for pharmaceuticals.

- The number of pharmaceutical management guidelines, lists, and SOPs developed (or updated) and submitted for adoption has increased from zero (December 2011) to 9 in September 2015. The following documents (norms, lists, guidelines) were produced:
  
  - The National Essential Medicine List version 2014 updated
  - Registered medicines directory August 2012
  - Registered medicines directory update December 2014
  - Standards treatment guidelines May 2015
  - Standards for the usage of oxytocin, misoprostol, and chlorhexidine digluconate 7.1%
  - Implementation strategy for chlorhexidine digluconate 7,1% December 2014
  - Fact sheets for MNCH
  - Fact sheets for the management of essential medicines for Health Zone Central Offices
  - Fact sheet for the management of essential medicines for Health Centers
  - Fact sheet for the management of essential medicines for Referral Hospitals
Support the Warehouses/CDRs and Health Facilities to Improve the Storage Conditions

• The percentage of health facilities using a standardized checklist to monitor storage conditions has increased from zero in December 2011 to 61% in September 2015.

Support to Warehouses and Health Zones to Improve Medicines Management and Distribution

• The percentage of health facilities with stock-outs of a pre-selected group of medicines for three days or more in the last three months has decreased from 100% in December 2011 to 52% in September 2015.

• The percentage of warehouses with stock-outs on a pre-selected group of medicines for three days or more in the last three months has decreased from 100% in December 2011 to 38% in September 2015.

Support Capacity Building

• The number of persons trained with SIAPS support in pharmaceutical management has increased from none in December 2011 to 892 in September 2015.

CONTRIBUTION TO USG GOALS

SIAPS’ interventions in improving the governance of pharmaceutical systems, strengthening supply chain management capacity, and promoting rational medicines use ensures that HIV, malaria, TB, FP/MCH commodities, as well as essential medicines are increasingly accessible and available in DRC. The work done by SIAPS to bolster the pharmaceutical system in DRC undoubtedly contributes to USG goals toward an AIDS-free generation, universal health coverage, and preventing deaths from infectious diseases and among mothers and children.

SIAPS works with in-country partners to improve access to malaria, TB, and HIV medicines, and the life-saving medicines for women and children, including contraception. Promoting a systems strengthening approach, SIAPS activities go beyond addressing supply chain issues 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. To contribute to the universal coverage strategies, SIAPS provided support and assistance to MOH and other partners in forecasting, quantification, warehousing, and distribution to reach for an uninterrupted supply of quality and affordable essentials medicines.

LESSONS LEARNED

• To ensure medicines supply continuity, medicine should be procured from both local and international suppliers, as the long lead time of procuring
from international suppliers compromises the timely availability of medicines.

- Government involvement is prerequisite to any successful implementation.
- Partner’s coordination is central to avoid mismanagement and wastage of resources due to overlapping interventions.
- Performance and incentive are linked.
- Shortage and high turn-over of health care workers at health facilities challenge good implementation.

**SUSTAINABILITY AND COUNTRY OWNERSHIP**

- All the norms, lists, guidelines, and SOPs developed with SIAPS assistance are now owned by the MOH.
- The medicine registration sessions are now routinely held by the DRA.
- National and provincial medicine committees meetings are now regularly conducted without SIAPS support.
- The NMCP has adopted EUV as one of its monitoring and evaluation mechanism and majors findings of EUV are part of the NMCP annual report.
- Pharmacovigilance activities are routinely conducted.
- The MOH contacted SIAPS staff to assist with DTC implementation in non-USAID-supported health zones.
- SIAPS has been the very first MOH partner to advocate for and provide support to DRA, by emphasizing the key role the DRA plays in strengthening health systems. Following SIAPS support to the DRA, many MOH partners, such as WHO, European Union, and Belgian Cooperation, are now providing significant support to the DRA with and without SIAPS collaboration.
BACKGROUND

A study conducted by the Strengthening Pharmaceutical Systems (SPS) Program in 2009, determined that the primary cause of inefficiencies and stock-outs at all levels was the fragmentation of the supply process into multiple vertical systems organized around Disease Control Programs (DCPs), such as tuberculosis (TB) and HIV/AIDS\(^1\). Based on this evidence, the Ministry of Public Health (MoH) asked the US Agency for International Development (USAID) for technical assistance from its pharmaceutical supply management partners for implementing what would subsequently be known as the Integrated System for Medicine and Supply Management (Sistema Único de Gestión de Medicamentos e Insumos; SUGEMI). In 2010, a ministerial decree to establish SUGEMI as the institutional mechanism for organizing the pharmaceutical supply system in the public network of health care facilities was issued.

In 2012, after the institutionalization of SUGEMI, the availability of adult ARVs in health facilities was 77\(^%\)\(^2\). This resulted in the government frequently requesting financial assistance from USAID to cover the unanticipated shortfalls. To address this issue, the MoH requested technical assistance for the integration of HIV/AIDS pharmaceutical supply management into SUGEMI as an efficient and sustainable strategy to confront the problem\(^3\).

KEY INTERVENTIONS

Since 2012, the pharmaceutical supply system has been substantially reorganized. This was accomplished with a systemic approach that took into consideration all health system functions contributing to access to medicines (governance, human resources, information, financing and service delivery)\(^4\), as well as local determinants, such as the ongoing health sector reform and decentralization.

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2 http://siapsprogram.org/2015/09/14/financing-of-arvs-in-the-dominican-republic/


Organization of a Unified Pharmaceutical System Within Health Sector Reform:

Before 2012, the pharmaceutical system was fragmented, with the MoH holding regulatory and service provision roles in pharmaceutical management. After 2012 the system was integrated, with the MoH keeping a regulatory role, and service provision transferred to the newly created National Health Service (NHS) and Regional Health Services (RHS). To support this, the following technical assistance strategies were used by SIAPS:

- **Governance**: Drafting and implementation of a Ministry Decree which reinforced the separation of functions between regulatory and health provision units (2010 – 2015).


**Quantification and Procurement**: Before 2012, the estimation of needs for procurement was conducted independently by health facilities and DCPs. This resulted in fragmented procurement with no financial analysis. Since 2012, a coordinated national exercise for the estimation of needs, using standardized methodology, has been implemented. National pooled procurement is currently implemented by the national logistics operator (PROMESE/CAL) and planning for procurement exercises are followed by financial analysis. To support this, the following technical assistance strategies were used by SIAPS:

- **Governance**: Development of a Presidential decree supporting the pooled procurement of medicines and supplies (2013).


**Information System**: Prior to 2012 there was no information for decision making on pharmaceutical management. Currently, decisions are based on the SUGEMI pharmaceutical management information system, evaluations, and operative research. To support this, the following technical assistance strategies were used by SIAPS:


**KEY ACHIEVEMENTS**

Simultaneous interventions in different health system functions contributed to an
increase in ARV availability in health facilities, from 77% in 2012, to 92% in 2015\(^5\).

This systemic approach demonstrated impact not only on ARV availability, but also in other areas:

- National and international resources were mobilized for the renewal or construction of six regional medicine stores\(^6\)
- The pooled procurement of medicines, facilitated by SIAPS, saved USD 53 million in 2014\(^7\)
- The revision of the high cost medicines list in 2014, saved USD 62 million in 2015, which was then invested in the procurement of ARVs and other essential medicines\(^8\)

A systemic approach, considering all health system functions and national driving forces, has shown to be very successful and sustainable in strengthening the pharmaceutical system. The implementation of a national pharmaceutical system in Dominican Republic has shown not only positive impacts on the immediate pharmaceutical management problem (ARV stock-outs), but also on the overall public pharmaceutical supply and health system.

**CONTRIBUTION TO USG GOALS**

SIAPS is supporting the USAID goal of reforming the country’s health sector. This includes expanding access to quality health care, improving HIV/AIDS treatment and prevention services, detecting and treating TB, and implementing a health component under the social security system\(^9\). The SIAPS systemic approach is embedded in the USAID 2015–2019 vision for health systems strengthening\(^10\). Program achievements have contributed towards achieving an AIDS-free generation and to universal health coverage, particularly access to medicines.

**LESSONS LEARNED**

The organization of a unified pharmaceutical system is a long-term endeavor, one that SIAPS has been supporting since the start of the program. The

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implementation of SUGEMI would not have been possible without the commitment of the USAID mission to an intervention that would not provide immediate results. The results are now evident and sustainable as documented in the following section.

**SUSTAINABILITY**

A combination of political, legal, institutional, technical, and financial factors have been taken to ensure the sustainability of SUGEMI and, therefore, its impact on the availability of the HIV program medicines and supplies:

- **Political and Legal**: SUGEMI is supported by Ministry and Presidential decrees, and is a key strategy in MOH’s extension of the health sector reform and decentralization.

- **Institutional**: The MoH has appointed personnel at nine regional Pharmaceutical Directorates, and has created a National Coordinating Unit. All SUGEMI routine procedures are currently implemented through these units without the need of any technical assistance.

- **Technical**: All procedures for the routine operation of SUGEMI have been developed and are currently implemented by all MoH staff, without the need of technical assistance. All technological resources (such as the electronic application for the information system) were locally developed and are being maintained by the MoH.

- **Financial**: The financial sustainability of SUGEMI, at its present stage of development, depends on the budgeting of key recurrent activities and the appointment of a few key staff at the central level, currently financed by USAID. The estimated USD 400,000 the MoH should program for these budget lines is a small fraction of the savings produced by SUGEMI11.

**REMAINING INTERVENTIONS**

For FY17 SIAPS plans to provide technical assistance in the revision of the national catalogues, and essential medicine and commodities lists, which are the foundation for a sound procurement plan. SIAPS will also provide support towards the estimation of needs for ARVs, if the HIV/AIDS Program decides to adopt the new WHO guidelines for universal treatment and new pharmaceutical therapies.

In the following year there will be a critical mass of professionals available to replicate training courses and activities. SIAPS will encourage the MoH to consider financial resources in budget proposals for the logistic costs of training new personnel in the implementation of SUGEMI procedures, and specialized training on pharmaceutical supply management and rational use. Technical assistance may still be needed to train national counterparts in the analysis of the information generated by the PROMESE/Clients logistic information system,

and for an assessment of the implementation of the alternative procurement mechanisms by PROMESE.

SIAPS will be available to provide technical assistance if national health authorities request support on specialized analyses such as: health and economic implications of underfunding ARVs and other medicines; prioritization of product procurement, if resources are insufficient; and exploration of alternative financial sources.

**TRANSITION PLAN**

SIAPS does not have an office or vehicles in the Dominican Republic. Computers, printers and projectors will be transferred to the MoH. Technically, most current operations have been decentralized and are already implemented by national counterparts. An official act for the symbolic hand over of technical documents and other materials is scheduled for August 2016.
In Ethiopia, pharmacy practice at public health facilities (HFs) and community pharmacies has largely been commodity-centered, rather than being patient-centered, which has prevented the pharmacist from becoming an active member of the health care team and contributing to better health outcomes. The absence of auditing practices and lack of transparent and accountable systems for managing medicines transactions and services at HFs has resulted in wastage of resources, especially those obtained through donations, including drugs for opportunistic infections (OIs) and antimalarial medicines.

During the early years of SIAPS, irrational use of medicines was widespread and was manifested by irrational prescribing by physicians and nurses, poor pharmacy dispensing practices, and inappropriate use of medicines by clients. The fourth National Health Sector Development Program (2010/11–2014/15; HSDP) states that the percentage of antibiotic prescribing was 58% and antibiotic use in the treatment of non-pneumonia acute respiratory tract infection was 61%, both of which indicate a major deviation from recommended norms.1 Moreover, the document also indicates that only 68% of patients were given adequate information on dispensed medicines; that 35% of HFs encountered stock-outs of essential medicines; and that 8.24% of stock was wasted due to expiry. The overprescribing of antibiotics has contributed to many of these agents becoming ineffective, necessitating the use of newer, more potent, toxic, and more expensive medicines.

In the past few years, Ethiopia has made remarkable achievements with regard to increasing access to antiretroviral therapy (ART), reducing malaria-related deaths, and improving maternal, neonatal, and child health (MNCH). In addition, a number of interventions were implemented to improve the quality of services at HFs. However, the capacity of the executive organs at different levels of the health system to coordinate multiple stakeholders and lead those initiatives in an effective and sustainable manner was limited. Although the provision of ART to adults has been successful, there have been substantial challenges in increasing patient enrolment (especially children), quality of care, retention-in-treatment, monitoring adherence, and detection of treatment failure.

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1 FMOH. Health Sector Development Program IV 2010/11–2014/15.
SIAPS seeks to contribute to PEPFAR, PMI, USAID, and the Government of Ethiopia’s (GOE) common goal of reducing HIV, AIDS, malaria-related morbidity and mortality, and MNCH deaths. To realize this in the past four years, SIAPS Ethiopia worked in partnership with key GOE stakeholders including the Federal Ministry of Health (FMOH), the Food, Medicines, and Health Care Administration and Control Authority (FMHACA), the Pharmaceutical Fund and Supply Agency (PFSA), regional health bureaus (RHBs), HFs, universities, and professional associations with the overall goal of strengthening the pharmaceutical system to ensure access to medicines and quality pharmacy services that will lead to improved health outcomes.

**KEY INTERVENTIONS AND ACHIEVEMENTS**

SIAPS Ethiopia provides “next generation” technical assistance and leadership to the Ethiopian health sector in pharmaceutical systems strengthening with a deliberate focus on patient-centered services and health outcomes for all health elements. More importantly, SIAPS Ethiopia supports USAID and the GOE to reconcile the long-term goals of country ownership and sustainability with the immediate needs for continuing scale-up and expansion of prevention and treatment programs without adversely affecting health outcomes. The focus of SIAPS Ethiopia is to enhance pharmaceutical services through patient-centered solutions while continuing to support essential supply chain functions at the interface between medicines and patients. This has been attained through implementing interventions targeted at different health system building blocks with a focus on medicines and technologies/pharmaceuticals.

**Strengthening Pharmaceutical Sector Governance**

**Key Interventions**

SIAPS has supported key government stakeholders in the development, updating, and implementation of regulations and directives, standards, policies, guidelines, and SOPs that govern operations in the pharmaceutical sector including the selection, acquisition, prescribing, dispensing, and use of medicines. The development of national minimum standards for health care settings; the expanded review and updating of standard treatment guidelines (STGs); development and enactment of legislation for APTS (Auditable Pharmaceutical Transactions and Services); development of national strategic frameworks for pharmacovigilance (PV) and the prevention and containment of antimicrobial resistance (AMR); automation of the medicine registration system; development of facility-specific medicines lists; and development of SOPs for the effective implementation of clinical pharmacy services are some of the key areas to which technical assistance was provided successfully to the GOE to create better mechanisms of governance for ensuring transparency and accountability in the management of medicines and pharmaceutical services. The development and implementation of all these governance interventions were designed to address priority gaps in the sector.

**Achievements**

As part of ensuring the safety and quality of health care services in both the private and public sectors, 39 HF standards were developed and are being
implemented by the regulatory authority. Health care settings are being relicensed per the new requirements, which is a significant step forward in terms of improving health services and ownership by the government. The STGs for the three levels of care (health centers, primary hospitals, general hospital) were revised to include updates and expanded coverage of diseases. In addition, the Ethiopian medicines formulary was updated in 2013 and manuals on good prescribing and good dispensing practices were developed and implemented in 2012. The formulary, manuals, and STGs are distributed to hospitals and health centers to help standardize prescribing practices, improve access to evidence-based information, and optimize treatments, thereby contributing to improved health outcomes. A health regulatory information centre has been established at FMHACA and is providing services, thereby improving transparency and access to information by clients and the public. During June 2014 to June 2015, the center received and responded to 1,290 calls from 9 regions. Some of the key categories of questions asked included food quality and safety issues (19%), rational medicines use (RMU; 17%), unethical professional practices (16%), maternal health (14%), and quality of service (10%). The majority of these questions (60%) came from the public.

As part of our support to medicine registration, SIAPS helped in the systematic review and optimization of product registration processes and tools to improve efficiency of the system in preparation for automation. Eight types of applications were identified, for which the processes and associated tools were reviewed. Out of the 46 tools, including guidelines, SOPs, checklists, and forms, 28 (74%) were modified/optimized; 8 new tools were developed and introduced, based on international best practices. Web-based software has been developed to reflect the optimized processes and requirements. An organizational change management plan was developed and is being implemented to guide the transition from a manual to an electronic system.

Transparency and accountability of practices related to pharmaceutical management and services is institutionalized through APTS legislation enacted by five RHBs and FMOH. A manual on APTS has also been developed and was used during the past four years to guide implementation at HFs; 23 hospitals developed and implemented facility-specific medicines lists and the Drug and Therapeutics Committee (DTC) at a primary hospital developed a policy on RMU. SOPs for clinical pharmacy services was developed and implemented in hospitals as part of standardizing processes and maintain uniformity of practice across hospitals. SOPs for managing information on ARVs dispensing and patient medication records have been updated, enabling health managers to access important information to guide decision making.

Improving Pharmaceutical Services to Achieve Better Health Outcomes

Key Interventions

Recognizing the importance of effective pharmaceutical care and services in optimizing health outcomes, SIAPS has provided technical assistance on strengthening different components of the pharmaceutical systems that contributed towards improved availability of medicines and quality services. SIAPS provided technical assistance to public hospitals to implement
systems (APTS) for monitoring medicine transactions and services to create transparency and accountability in the management of medicines and pharmacy services. SIAPS collaborates with stakeholders and partners to promote RMU by strengthening DTCs and drug information services (DISs); enhancing adherence to treatment (with a focus on ART); preventing and containing AMR; strengthening the national PV/adverse drug reaction (ADR) monitoring system; and institutionalizing patient-centered pharmacy practice (clinical pharmacy/pharmaceutical care) to improve treatment outcomes and promote public health.

As part of supporting the fight against malaria, SIAPS supports Ethiopian stakeholders in improving the management and use of antimalarial medicines.

**Achievements**

**Auditable Pharmaceutical Transactions and Services**

APTS is a package of interventions designed to address issues of accountability, transparency, and quality of services at the HF level. As of September 2015, 45 hospitals have implemented APTS and have shown remarkable improvement in patient satisfaction, waiting time at pharmacies, and patients’ knowledge of medicines dispensed to them. In most hospitals, availability of key medicines increased from 65% to more than 95%. The change in layout of the pharmacy, introduced with APTS, dramatically improved patient convenience at service delivery points, especially for mothers and the elderly. Wastage of medicines due to expiry has been reduced from 8.24% to less than 2%. APTS enables determination of human resource needs, which facilitated hiring of the pharmacy workforce, leading to an optimized pharmacist-to-patient ratio. The introduction of new cadres, such as pharmacy accountants and cashiers, has transformed access to financial information related to medicine sales, reduced leakage, and contributed to a substantial reduction in waiting time and patient convenience.

**Rational Medicine Use**

To promote RMU, SIAPS Ethiopia has supported the establishment and strengthening of DTCs at 218 HFs. These DTCs have been used to scale up interventions on promoting RMU at the HF level. To date, 75% of DTCs have documented evidence-based improvements in medicine use (up from 54%); 54% of DTCs have implemented AMR advocacy or containment-related activities (up from 29%); 78 HFs have provided evidence-based information on medicines on a regular basis (up from 20); 39 DTCs conducted prescription reviews to identify drug use problems (up from 12); 37 DTCs conducted ABC value analysis (up from 3); 136 HFs used standardized prescription papers (up from 0). Among 24 target facilities, 21 (88%) of them implemented good dispensing standards for medicines (up from 13 [54%]); 59 HFs provided patient education on use of medicines on a regular basis (up from 0); and the diagnosis was written in 45.8% of prescriptions (up from 0). In terms of prescribing indicators, prescriptions containing injections decreased from 28.2% in 2013 to 21.1% in 2015 and
prescriptions containing antibiotics showed only a slight decrease from 62.2% in 2013 to 59.6% 2015.

**Antimicrobial Resistance**

SIAPS Ethiopia supported a coordinated national effort through the National Advisory Committee (AMR Advisory Committee) to advance the prevention and containment of AMR by development of a national strategic framework and a plan of action to guide interventions. The multidisciplinary National Advisory Committee on AMR meets regularly and is being used as a national platform. SIAPS, in coordination with FMOH, WHO, professional associations, and other partners, has supported the celebration of AMR day on a yearly basis to facilitate awareness in policy makers and the wider public.

One of the other important interventions identified was the use of mass media to empower the public by creating awareness and educating them on AMR prevention and containment. To achieve this, SIAPS Ethiopia employed an innovative strategy, i.e., building the capacity of journalists to disseminate AMR-related information to the public via print and electronic media; 151 journalists drawn from different mass media agencies were trained on AMR prevention and containment. This has resulted in unprecedented access to the media. From 2012 to 2014, the different mass media outlets broadcast 218 stories on AMR and RMU. The highest number of media broadcasts were made in 2014 (41.1%), followed by 2012 (32.4%), and 2013 (26.5%). The most broadcasts were made on radio (83.5%), followed by newspapers (8.7%), and television (7.8%). The messages were broadcast in 10 languages throughout the country. Among the broadcast topics were antimicrobial use and resistance prevention and containment (26.1%), RMU (17.9%), medicine use in tuberculosis cases (10.1%), ARV use and adherence (9.6%), medicine use in treating malaria (4.6%), and the remaining 31.7% were on self-medication and sharing of medicines, infection prevention, and counterfeit medicines.

**Pharmacovigilance**

The various approaches used by SIAPS Ethiopia to strengthen the national PV/adverse drug event (ADE) monitoring center have resulted in remarkable successes in terms of increased ADE reporting, data management, and decision making. The automated Pharmacovigilance Data Management System designed and introduced by SIAPS has transformed the recording, aggregation, and reporting of PV data at FMHACA. The ADE reporting guideline and form were revised to incorporate medication errors and product defects, in addition to ADRs, which has enabled the tracking of counterfeit and substandard medicines. The facility-level in-service training and face-to-face discussions in conjunction with providing regular feedback on ADE reports, have contributed to the progressive increase in the ADE reporting rate since 2011. The yearly number of ADE reports has increased from 79 in 2012 to 411 in 2015, an increase of more than 400%. Reports on suspected product quality problems are reviewed by the PV forum and based on recommendations of this forum, regulatory decisions are taken by the authority. Of the 840 reports received in 4 years, 138 were related to suspected product-quality issues. Among the products reported with quality problems, 52.9% had visual/physical changes, 24.6% had negative effects, and 17.4% had packaging problems. Further follow-up and investigation on these products
resulted in recall of 14 products, the temporary closure of one manufacturing facility, suspension of a market authorization license, and permanent cessation of production for one product. To ensure sustainability of these interventions, SIAPS Ethiopia supported health colleges and universities in incorporating PV into the pre-service curriculum for the new generation of health cadres.

**Clinical Pharmacy Services/Pharmaceutical Care**

Recognizing the potential benefits of client-centered care on patients’ health outcomes, SIAPS Ethiopia supported the introduction of clinical pharmacy services. A well-structured in-service training program to build the clinical knowledge and skills of practicing hospital pharmacists was developed and implemented. Between May 2012 and September 2014, 200 pharmacists from 65 hospitals all over the country were trained and deployed. The training program and subsequent advocacy and consultative meetings contributed to raising awareness of the policy makers and managers at FMOH, the RHBs, and the hospitals on the importance of clinical pharmacy services to improving the quality of patient care. That awareness has encouraged them to emphasize and support implementation of clinical pharmacy initiatives. As a result, out of the 65 hospitals involved in the training, 60 (92.3%) started providing clinical pharmacy services; 47 (72.3%) included the service in their annual plans. Pharmacists monitored patients from admission to discharge and participated in multidisciplinary rounds (89.2%) and morning sessions (72.3%). In 24 hospitals (37%), pharmacists provide pharmaceutical care to patients with chronic diseases, a new addition to existing services. A retrospective survey conducted at 38 hospitals indicates that 38,184 patients benefitted from the services and 43% of these were documented. A drug therapy problem (DTP) was identified and documented for 4,800 patients (29.2%). The major DTPs included a need for additional drug therapy (29%), unnecessary drug therapy (18.8%), and noncompliance (14%). Interventions were recommended for 91% of the DTPs. Prescribing doctors fully accepted 83% of pharmacists’ corrective recommendations. This initiative has created a paradigm shift in pharmacy practice in Ethiopia. Clinical pharmacy has now become an integral part of hospital services, but continuing support is required to consolidate the service.

**Antimalarial Drug Management**

With funding from PMI, SIAPS Ethiopia works in unison with RHBs and different agencies of FMOH to address the challenges in managing and dispensing antimalarial drugs (AMDs). SIAPS assisted in improving the storage and dispensing practices at 53 sites by refurbishing premises and supplying equipment and furniture. SIAPS supported the Oromia RHB in the development and implementation of AMD stock transfer guidelines to help reduce the frequency of stock-outs and unnecessary expiry due to overstock at regional stores and service delivery points. At the target sites, the percentage of warehouses with stock-outs of AMDs for 3 days or more in the last 3 months decreased from 76% (baseline) to 54% and the percentage of HFs where AMD stock records correspond with physical count increased from 32% to 100%. In addition, a new drug management
handbook was developed in the local language and distributed to health extension workers to provide guidance on management of antimalarial and other essential medicines. In collaboration with the Oromia RHB, SIAPS designed and implemented the Continuous Results Monitoring System (CRMS), which is a comprehensive, indicator-based performance management system used to track the availability, storage, and proper use of AMDs. The system was implemented at 64 HFs in the Oromia Region. Data from CRMS shows significant changes to diagnostic and prescribing practices. For example, the number of malaria cases treated without laboratory diagnosis decreased from 54% in 2011 to 20% in 2015 in the targeted HFs. As a result, the amount of medication consumed through inappropriate prescription has decreased by more than half in the same period. The discrepancy between doses of AMDs dispensed and the number of patients treated reduced from 58% to 21%. CRMS has also directly improved the availability of artemether-lumefantrine, a medicine used to treat *Plasmodium falciparum* malaria, from 79% in 2012 to 93% in 2015. As CRMS continues to make improvements at these HFs, SIAPS has found that graduating them from routine support is an essential strategy to ensure sustainability. With this objective, nine HFs in the Oromia Region were graduated in 2015 after taking steps to fully own CRMS and demonstrating the capacity to monitor availability, handling, and appropriate use of AMDs on their own.

**Enhancing Capacity for Pharmaceutical Management and Services**

**Key Interventions**

SIAPS Ethiopia’s intervention in capacity building focuses on filling gaps in government priorities related to human capital and institutional preparedness to provide quality pharmaceutical services in a sustainable manner. A series of in-service trainings were conducted to effectively implement tools and systems. As part of building systems capacity, SIAPS introduced new tools and procedures into the pharmaceutical sector to streamline the delivery of patient-centered pharmacy services and management of pharmaceutical transactions in hospitals. Regulations that govern the proper management of pharmacy operations in HFs have been introduced at both the federal and regional levels, which ultimately advance institutional capacity through the allocation of adequate human and financial resources and pharmaceutical management. Our interventions in capacity building directly affect gaps related to governance, service delivery, information, and finance which collectively impacts access to medicines and services.

**Achievements**

A total of 5,820 pharmacy personnel, medical doctors, hospital CEOs, financial personnel, journalists, and managers were trained during the last four years, of which 30% were females. Major areas of in-service training included prevention and containment of AMR, clinical pharmacy services, DISs, DTCs, RMU, ART, AMD management, electronic dispensing, APTS, and leadership and management. The various SOPs introduced to the health system have helped in standardizing pharmacy practices across HFs. The enactment of new regulations has given legitimate authority to health managers to recruit more pharmacists and new cadres, such as accountants. The number of pharmacists has almost doubled in APTS-implementing hospitals. The tools introduced in connection
to APTS have enabled hospitals to track information on product movements, finance (revenue), losses, services, and performance of the pharmacy work force, which not only helped to ensure transparency but also facilitated evidence-based decision making. The hospital pharmacy layout designs provided to hospitals have contributed to dramatic improvements in dispensing premises at 45 APTS sites. Instituting user-friendly systems and tools has enabled HFs to deliver services that meet patients’ expectations. The training in clinical pharmacy has brought a paradigm shift to the provision of pharmaceutical care by introducing a new patient-centered service delivery model to pharmacy services for the first time in the country.

Strengthening Capacity to Use Information for Decision Making

Key Interventions

Our approach to improve information systems is to strengthen pharmaceutical data collection, processing, and presentation of information to help staff at all levels of the health system make evidence-based decisions that improve health outcomes. To achieve that, SIAPS Ethiopia has designed and implemented information systems to address both disease-specific and overall health system strengthening needs. SIAPS has continued supporting HFs providing ART services to properly implement the Electronic Dispensing Tool (EDT) and its paper-based versions. Similarly, SIAPS helped introduce the CRMS and End Use Verification Survey tools at PMI sites to effectively respond to information needs related to AMD management and use. In addition, SIAPS has designed and introduced data capturing and reporting paper-based tools at HFs implementing APTS and clinical pharmacy services. Recently, SIAPS was engaged in optimizing and automating the country’s medicines registration system to ensure efficiency, transparency, and accountability. These interventions have synergistic effects with other interventions designed to strengthen pharmaceutical systems by empowering health system managers and practitioners to make effective decisions.

Achievements

In the HIV and AIDS program, 100% of SIAPS-supported pharmacies at ART sites keep complete patient information on ART. Bimonthly national ART patient-uptake and regimen breakdown reports are produced from 677 and 370 ART sites, respectively, and disseminated regularly to inform decision makers. This strategic information is also used as a key resource for national quantification of ARVs. Recently, it helped the country’s ART program to successfully transition stavudine-based treatment to a tenofovir-based regimen. Close monitoring of regimen prescribing patterns and trends generated by ART pharmacies on a bimonthly basis provided timely data for plan adjustments. This not only helped achieve a smooth transition, but also saved resources by preventing wastage and expiry of the phased-out D4T. For front-
Close monitoring of regimen prescribing patterns and trends generated by ART pharmacies on a bimonthly basis provided timely data for plan adjustments. This not only helped achieve a smooth transition, but also saved resources by preventing wastage and expiry of the phased-out D4T.

Pharmacies, the information on patient-medication history is being routinely used to detect and prevent medication errors, drug interactions, and adverse events. In 2015, 19 ART sites identified and resolved 466 medication/prescribing errors, which could have endangered patient safety. Most of the errors were related to an inadvertent change in regimen, all of which were communicated to prescribers and corrected. They also used the system to track patient adherence to appointment dates and worked with patients to improve adherence.

In support of the malaria program, 44 PMI sentinel sites have implemented CRMS to report logistic and patient data on malaria treatment, and 180 PMI sites are using a malaria treatment register to document and report data on AMD dispensing and use. These information systems have helped managers make informed decisions to ensure availability and proper use of AMDs by minimizing overstock and wastage and adhering to national malaria treatment guidelines. Our data capturing and information generation at APTS and clinical pharmacy implementing sites has a wider impact on essential health services, including HIV and AIDS, malaria, and MNCH. Hospital CEOs and pharmacy heads are applying information generated from these two initiatives to improve medicines’ availability, optimize budget utilization, minimize stock-outs and wastage, prevent medication errors, and enhance treatment outcomes by promoting multidisciplinary team work for better access to effective medicines and quality pharmaceutical care.

Strengthening Financing Mechanisms to Improve Access to Medicines

Key Interventions

Our interventions on finance have specifically been geared toward optimizing the use of existing financial resources allocated to medicines. SIAPS Ethiopia worked on building the capacity of HFs to achieve cost-savings and value for money during selection and prioritization of medicines for procurement, to maximize revenue from medicine sales, and to minimize wastage of medicines due to expiry and pilferage. SIAPS Ethiopia also provided technical assistance to RHBs and HFs to improve their systems of financial management (cash and credit sales, dispensing to exempted/free patients, etc.), implement ABC analyses and subsequent reconciliation with VEN in their medicines list to identify stock that is at risk of expiry, and take appropriate measures (such as redistribution to other HFs) to avoid unnecessary losses. In addition, new product and finance management tools were introduced to help ensure transparency and accountability, which significantly reduced stock-outs, wastage, and loss of cash collected from medicines sales.

Achievements

In the past four years, the number of HFs that regularly track sales of medicines by using APTS tools has increased from 0 to 45. The annual revenue (in Birr) collected from medicine sales at selected sites that implemented APTS increased by 23%. Wastage of medicines at target hospitals implementing APTS was reduced by 46%. The number of HFs that conducted ABC/VEN analyses has increased from 0 to 28. As a consequence, availability of medicines has increased from 65% (HSDP baseline) to more than 95%. Overall, HFs capacity to monitor
revenue and wastage of medicines has improved substantially, which has contributed to improved availability of essential and lifesaving medicines on a continuous basis.

CONTRIBUTIONS TO US GOVERNMENT GOALS

In the past four years, SIAPS Ethiopia’s interventions have been aligned to contribute to PEPFAR, PMI, USAID, and the GOE’s common goal of reducing morbidity and mortality from (or related to or as a result of) HIV, AIDS, malaria, and MNCH deaths.

SIAPS Ethiopia has employed a multipronged approach to strengthening pharmaceutical systems by providing technical assistance in key areas that have been identified as having a significant impact on the performance of the pharmaceutical sector. These interventions are designed deliberately to contribute toward achieving PEPFAR and PMI prevention and treatment goals and ending MNCH deaths by improving access to lifesaving medicines and quality pharmaceutical services in support of ART and malaria programs. As SIAPS continued to support the achievement of these goals, the comprehensive nature of capacity-building interventions and systems strengthening have had a system-wide effect and positively affected broader US Government goals, including MNCH. SIAPS supported the establishment of a transparent and accountable system (APTS) to institute good governance in the management of medicines transactions, reduction of wastage, and optimizing utilization of budget allocated for medicines at HFs; institutionalize patient-focused pharmacy services to improve pharmaceutical care and adherence to treatment; and improve economic and health outcome benefits from the rational use of ARVs, medicines for OIs, AMDs, and lifesaving medicines for MNCH.

LESSONS LEARNED

While implementing the interventions stated above, SIAPS Ethiopia has learned notable lessons that should be taken into account in the design and implementation of future interventions. These lessons are as follows:

- Building the capacity of individuals and institutions is essential to establishing local capacity to advance pharmaceutical system strengthening interventions.

- Aligning the work plan with government counterparts is imperative to securing the commitment and political will of the host institutions for optimal involvement and participation.

- Creating strong partnership with and leveraging engagement and participation of key stakeholders, donors, and implementing partners unifies understanding and messaging on the government’s role in promoting country ownership.

- Engaging relevant actors outside of the health sector can have a powerful impact on improving pharmaceutical sector performance, some of which should be addressed with specific interventions. (Performance of the
pharmaceutical sector is influenced by multiple factors, some of which are situated beyond the health sector.

- Generating evidence using data-driven information and showcasing or demonstrating how it can be used to support organizational goals can have a tremendous impact on influencing managers and policy makers’ behavior and use of information for decision making.

- Institutionalizing key interventions through incorporation into the government’s guidelines and legislation is a powerful tool to ensuring ownership and sustainability.

SUSTAINABILITY

SIAPS Ethiopia has consistently encouraged country ownership and invested in country-led plans, building sustainability through systems strengthening, and leveraging key multilateral organizations, global partnerships, and the local private sector, where possible. SIAPS has promoted learning and accountability through effective monitoring and evaluation of results and using research, innovation, documentation, and dissemination to accelerate results. Central to USAID/SIAPS Ethiopia’s system-strengthening efforts is alignment of its work plan with that of GOE stakeholders (especially FMOH, PFSA, FMHACA, and RHBs).

All of our interventions have been planned with the ultimate goal of increasing access to quality medicines and services, improving treatment outcomes, and ensuring that these achievements are fully owned by stakeholders in a sustainable way. To achieve this, SIAPS Ethiopia has emphasized building the capacity of FMHACA, PFSA, RHBs, and schools of pharmacy so that they can provide technical assistance and better support implementation of plans at the HF level. DTCs are strengthened to own and lead the implementation of facility-level interventions, including RMU and AMR. Providing intensive support for implementation of the Pharmacy Chapter of the Ethiopian Hospital Reform Implementation Guidelines (EHRIG) and CRMS at selected HFs was a key intervention to creating model facilities that others could learn from. Recently, seven EHRIG sites and nine CRMS sites were graduated, taking on additional responsibility to support and mentor other HFs within their vicinity. RHBs and zonal and district health offices have taken responsibility to provide close follow-up and support as needed. By employing a training of trainers approach, SIAPS has created a pool of trainers in different regions on various thematic areas, including DTCs, APTS, and ART to build local training capacity. Training manuals in support of these areas have been developed and approved by FMOH. The enactment of APTS regulations has institutionalized many of the critical interventions, thereby creating accountability on the part of implementers and ensuring sustainability. The inclusion of PV and AMR courses into the university curriculum has integrated these interventions into preservice education. SIAPS’ efforts to create a strong pharmacy structure within the health sector and ensure engagement of FMOH, RHBs, and PFSA experts in supportive supervision and mentoring activities has paved the way for ownership and sustainability by building their capacity to takeover this role in the long term.
**Guinea**

### Funding for FY15

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<td>PMI</td>
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### Total Funding FY12-FY15

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<td>PMI</td>
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**BACKGROUND**

Guinea is a coastal West African country with a population of approximately 10.63 million, the entirety of which is at risk for malaria, which is still a major public health issue, with an incidence of 101/1,000 as of 2010; 92% of infections are caused by *Plasmodium falciparum*, and according to national health statistics, the morbidity rate for malaria is 148/1,000. Among children under the age of five, malaria accounts for 31% of consultations, 25% of hospitalizations, and 14% of hospital deaths.

The goal of the SIAPS Program in Guinea is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes at all levels. To this end, SIAPS is working closely with its MOH partners to improve pharmaceutical sector governance, transparency, policy, legislation, and capacity building, as well as strengthening supply chain management, data management, and reporting.

While the main focus of activities remains malaria, SIAPS has visibly broadened its scope of work to aid in managing the Ebola outbreak in Guinea and to expand the logistics management information system (LMIS) to other key disease programs.

**KEY INTERVENTIONS**

SIAPS works jointly with the central medical store (PCG), the National Medicines Regulatory Authority (DNPL), the National Malaria Control program (PNLP), and the regional and district directorates to overcome the country’s challenges in implementing key interventions that are mainly focused on the USAID/Presidential Malaria Initiative (PMI) targeted zones.

**Governance in Pharmaceutical Management**

During the four last years in Guinea, SIAPS helped improve governance and transparency of pharmaceutical management through its collaboration with the PCG and the DNPL. SIAPS conducted a systemic assessment of the

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1. Guinea National Health Statistics
2. ibid.
pharmaceutical sector jointly with the DNLP. SIAPS then supported the DNPL in the development, validation, and adoption of national reference documents for governance and transparency in pharmaceutical management, including the revised National Pharmaceutical Policy in 2014, with the associated implementation plan for 2014-2018; the National Essential Medicines List; and the revised therapeutic flow charts to promote rational medicine use. SIAPS also provided sound leadership in the development of the first draft of the pharmaceutical law in Guinea.

In addition, SIAPS collaborated with the PCG to strengthen compliance with the good pharmaceutical practices recommended by WHO, through trainings and updating standard operating procedures (SOPs) in light of WHO guidelines. SIAPS also strengthened the quality assurance system in the PCG and promoted transparency by supporting the first competitive tender successfully completed by the PCG.

Pharmaceutical Management Capacity Building

Since the inception of the program, SIAPS has collaborated with institutions and stakeholders at all levels of the health system to strengthen their capacities in pharmaceutical management. SIAPS trained PCG staff on quality assurance and initiated the “medicines for all” training for practitioners in the field. Moreover, SIAPS supported training on medicines data collection with the LMIS for malaria, management of Ebola commodities, good distribution practices (WHO), end user verification (EUV) surveys, and supportive supervision.

Pharmaceutical Information System

High-quality data are critical to the decision-making process. SIAPS works with its MOH partners to provide decision makers with accurate and useful information for planning and managing both malaria and Ebola commodities.

In 2012, SIAPS efforts led to the development of a new monthly reporting template and process, with all health districts and facilities in the 19 PMI-supported zones trained in this new process. SIAPS distributed Internet keys to districts with a recurrent monthly Internet credit, and an Excel template is being emailed monthly to the Health Management Information System (HMIS) and the NMCP who analyze the data.

Furthermore, SIAPS initiated and organized quarterly malaria review meetings of regional and district health staff (in coordination with PNLP, PMI/USAID, and Global Fund implementing partners) and supported the establishment of the NMCP working group on malaria commodities, including all donors and partners, to review consumption data and lead quantifications.

Financing Strategies and Mechanisms to Improve Access

Under this strategy, SIAPS envisioned providing support to MOH to disseminate the findings from the health cost recovery study and distribution costs for malaria commodities. In this respect, SIAPS started the study preparatory phase by writing the terms of reference with MOH counterparts in May 2015.
Supply Chain Management to Improve Availability

Since the launch of the program in 2012, SIAPS reinforced the capacities of staff at different levels to better manage medicines and prevent stock-outs. In addition, SIAPS conducted five distributions of malaria commodities. SIAPS also supported inventory exercises for all health units within the PMI-supported regions. SIAPS worked jointly with partners to address the issue of payment for storage of malaria commodities at the PCG, since a common funding basket has been established for both Global Funds and PMI-funded commodities.

SIAPS relevantly contributed to the startup of the new ACCESS project and the withdrawal of artesunate-amodiaquine (ASAQ) and its replacement by artemether-lumefantrine (AL) in the six districts of Guinea where the project is implemented.

Ebola Outbreak Activities

To tackle the Ebola outbreak, SIAPS participated in the response by strengthening Ebola logistics, which consisted of:

- Participating in the national Ebola Logistics Committee
- Supporting the distribution of protective kits for health workers
- Providing assistance to the PCG in the acquisition of Ebola commodities (technical specifications)
- Integrating these commodities into the national supply chain
- Training key staff
- Developing new malaria guidelines based on the Ebola context

KEY ACHIEVEMENTS

Governance in Pharmaceutical Management

On the basis of the results of the systemic assessment of the pharmaceutical sector and the in-depth analysis of the gaps within the pharmaceutical laws in Guinea, SIAPS played an important role in development of the first draft of Guinea’s new pharmaceutical law. Once validated by the Guinea National Assembly, this law will be a key regulatory tool that will strengthen the governance in the country. SIAPS also facilitated revision of the National Pharmaceutical Policy and the development of the implementation plan for 2014-2018, which provided the country with a clear vision of activities.

In addition, SIAPS helped revise the national essential medicines list and therapeutic flow charts to promote rational medicine use. These flow charts were last reviewed in 1993 and were no longer applicable to current realities. The new version of these documents is helping to upgrade health care workers’ knowledge in priority disease case management. To date, the team has reviewed all therapeutic flow charts together with documentation from the key health
programs including child health, malaria, HIV, community health, tuberculosis, and maternal and child health, in line with current national treatment guidelines and WHO recommendations.

SIAPS also collaborated in updating 13 SOPs in light of WHO guidelines and supported PCG’s first competitive tender for procurement of essential medicines and prequalification of products and suppliers. Following on this success, PCG launched its first international tender in October 2014. In December 2014, SIAPS helped review the bids with the National Commission for Public Procurement of Guinea and supported the commission during the prequalification process.

In addition, SIAPS supported the PCG in the adaptation of its five-year strategic plan to the Ebola context and to develop a budget for it. This activity was carried out in collaboration with WHO, UNICEF, UNFPA, and others partners.

**Pharmaceutical Management Capacity Building**

To date, SIAPS has built the capacity of approximately 750 health workers and has supported the following achievements:

- Job descriptions for regional pharmacists (DNPL) have been developed
- The Medicines Registration Department at DPNL has been reorganized, making it more efficient and effective
- PCG staff have been capacitated and have produced annual work plans
- Quality assurance teams at PCG have been restructured and trained on the new SOPs and are now implementing self-inspections; weather and moisture monitoring forms for PCG warehouses were revised to meet WHO good practices of medicine distribution recommendations
- Storage capacity at PCG’s central and regional warehouses has been improved to meet good distribution practice norms
- Terms of reference for a new working group (composed of the main PNLP partners) focused on supply management of malaria medicines have been finalized
- SIAPS, in collaboration with WHO, established a committee to revise Medicine for All training modules and develop a new module specific to Ebola commodities
- Six pharmacists from the regional depots of the PCG were trained in the decentralization of stock and the distribution of antimalarial medicines, which is in line with future decentralization plans to the regions in a bid to improve routine drug distribution

**Pharmaceutical Information**

SIAPS has positively impacted the management of pharmaceutical data by working jointly with the Health Management Information System (HMIS), the NMCP, and other MOH partners to set up clear and approved procedures for
data collection, data quality assurance, data analysis, and providing feedback. A quarterly competition was initiated to motivate districts to improve reporting rates, timeliness of reports, and quality of data. As a result, facility reporting rates exceeded 95% in PMI zones in 2014 (from an estimated baseline of 30% in 2012), reaching 99% in the first three months of 2015; timeliness of reporting exceeded 85% in 2014. Refresher trainings on specific reporting errors are provided routinely at regional malaria review meetings.

SIAPS supported the establishment of the PNLP working group on malaria commodities, including all donors/partners. The working group reviews consumption data and leads quantifications. Additionally, it provides support for PNLP’s M&E working group and helps coordinate PNLP activities by all partners (SIAPS, DELIVER, Stop Palu, and CRS) following an integrated action plan.

In addition, SIAPS helped develop integrated supervision guidelines on malaria and supported the PNCP in the first national supervision of health facilities in 2015.

**Supply Chain Management to Improve Availability**

SIAPS carried out two supervised emergency distributions in 2011-2012, following long periods of ACT stock-outs countrywide; SIAPS was the only partner helping both NMCP and PCG distribute malaria commodities in Guinea at the time. Three additional distributions, based primarily on consumption data, were also conducted, in an attempt to establish a pull system for malaria commodities.

SIAPS is now responsible for working with the PCG and the NMCP for the storage and distribution of antimalarial commodities. In view of the unreliable monthly report data from the different health units (epidemiological data, monthly consumption, and stock status), and inconsistencies observed between the reported data and overstocks, SIAPS supported an inventory exercise for all health units within the PMI-supported regions of Boke, Conakry, Kindia, Labe, and the Prefectoral Health Directorate of Dinguiraye. The exercise also captured information on the monthly consumption of the supported health units. These interventions resulted in the following achievements:

- Consumption data is being cross-checked, which allows for the identification of discrepancies between data reported by health facilities and their real consumption
- Commodity distribution plans are now made with more accurate data
- Additional funds for these activities allocated by PMI for 2016 and 2017

SIAPS worked jointly with CRS (Global Fund principal recipient) to address the issue of payment for storage of malaria commodities at the PCG since the institution of a common funding basket. Of note, the storage costs are paid at a rate of 1% of the total value of the commodities received by each partner (SIAPS/PMI, CRS/Global Fund), but the distribution costs are paid at a rate of 4% of the value of distributed products, irrespective of the originator of the order. To this effect, an official document specifying the terms of payment was jointly drawn up by PNLP, SIAPS, and CRS.
All of these efforts led the achievement of relevant results in supply chain management in the country:

- Health facilities with stock-outs of a preselected group of medicines for three days or more in the last three months\(^3\) decreased from 76% (2012) to 46% (2014).

- The percentage of health facilities with all varieties of ACTs available on the day surveyed increased from 24% in 2012 to 72% in 2014.

**Ebola Outbreak Activities**

In mid-2014, SIAPS helped PCG quantify Ebola commodity needs and develop distribution plans. In November 2014, SIAPS conducted a joint mission with the essential medicines program of WHO/Geneva and the UNICEF regional office in Dakar to assess the impact of Ebola on the operations of the PCG and determine urgent actions required to support the PCG, with particular emphasis on PCG’s role in coordinating logistics for Ebola at the national level.

In addition, SIAPS trained 63 pharmacists and Ebola logisticians on Ebola commodity logistics. SIAPS also assisted the NMCP in drafting a malaria case management plan in the context of the Ebola outbreak and terms of reference for a survey measuring the impact of Ebola on malaria treatment.

Finally, in August 2015, SIAPS, in collaboration with WHO, supported the establishment of an ad-hoc committee for the integration of Ebola-related commodities into the current quality control system at the PCG. Going forward, all commodities, including those specific for emergency response, are now quality assured, alongside other inputs at the PCG to streamline and enhance central supply management procedures.

All of these efforts contributed to overcoming the Ebola outbreak in the country.

**CONTRIBUTION TO USG GOALS**

SIAPS Guinea’s strategies are closely in line with PMI’s in terms of efficiency and sustainability and contributed to reducing malaria-related mortality by 50% across the 15 PMI high-burden countries in Africa. Improving availability of essential medicines has contributed to Universal Health Coverage in the country. SIAPS Guinea’s interventions are also aligned with the US Government’s vision of ending preventable child and maternal deaths, as malaria is the principle cause of death in children under five in Guinea. To this end, SIAPS contributes to reinforcement of governance and transparency in the pharmaceutical sector, the constant availability of pharmaceutical commodities, rational medicine use, and using good-quality data for decision making.
LESSONS LEARNED

- Pharmaceutical data-quality remains poor and onsite supervision findings show that malaria commodities are still mismanaged within health facilities nationwide.

- A lack of leadership and coordination between the vertical disease programs and the PCG at the central level limits the implementation of a reliable and integrated logistics management system.

- There remains weak technical and human resource capacity for ensuring good-quality logistics data and data analysis needed to inform decision makers at all levels of the supply chain. This results in stock-outs or overstocks of pharmaceutical products for the different disease programs.

- A lack of congruence between the different information tools to the needs of their users.

CONSTRAINTS

The Ebola outbreak was the main constraint faced by SIAPS during this year. The outbreak focused the attention of all health system stakeholders, especially the MOH, and prevented implementation of SIAPS activities on a regular basis as previously planned. Because of the Ebola outbreak, one of the EUV surveys and one of the regional malaria review meetings planned during this year had to be postponed. Consequently, the outbreak reduced the attendance rate of patients in health facilities across the country and impeded the correct use of malaria commodities. Lastly, the countrywide election activities were disruptive to transportation and planned activities, further slowing down implementation.

SUSTAINABILITY

One of the major challenges identified has been the need for Government of Guinea partners to take more ownership of the EUV survey, in particular, the analysis of the data and follow-up of recommendations. SIAPS has started working to gradually transfer competencies to the NMCP.

SIAPS Guinea worked with the MOH to ensure the sustainability of compliance with the good practices in pharmaceutical governance and commodities effective management by supporting the redaction and adoption of the pharmaceutical sector reference document and quality assurance procedures. Other activities included the update of pharmaceutical laws and SOPs, the adoption of good practices for PCG regarding international tender for procurement of essential medicines, and the finalization of a pre-qualification of products and suppliers.

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4 Impact of the Ebola epidemic on Malaria prevention and treatment in Guinea, Summary findings from a field study conducted by the National Malaria Control Program (PNLP) and CDC with funding from the Global Fund in November 2014
BACKGROUND

For over ten years, the Ministry of Public Health and Population, known as the Ministère de la Santé Publique et de la Population (MSPP), in partnership with donors, foundations, and other nongovernmental organizations (NGOs) has implemented a number of projects in Haiti to ensure the availability and accessibility of essential medicines to the Haitian population. However, efforts have not always yielded all the expected results.

This has been attributed to many factors. The pharmaceutical sector in Haiti suffers from deregulation and as a consequence, poor quality and counterfeit medicines are being sold throughout the country. This situation creates serious concerns about patient safety. Medicines are perceived as an easy source of profit and treated like any other commodity.

As part of the strategy to reform the health system, the MSPP decided to review the obsolete national pharmaceutical policy (NMP). The revised NMP will serve as the commitment from the Haitian Government to provide quality pharmaceutical services and essential medicines to the Haitian population on the basis of equity and justice.

USAID/Haiti, along with other development partners, has been supporting the MSPP for many years to improve availability and access to quality pharmaceutical products. Currently, and with the President’s Emergency Plan for AIDS Relief (PEPFAR) funding, the local USAID Mission is providing assistance to the Government of Haiti (GOH) to ensure availability of HIV, AIDS, and family planning commodities through the Supply Chain Management System (SCMS) Program. USAID/Haiti has also recently requested technical assistance of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program to support the Direction de la Pharmacie, du Médicament et de la Médecine Traditionnelle (DPM/MT) of the MSPP in identifying priority pharmaceutical sector policy gaps to which USAID may provide assistance.

KEY INTERVENTIONS

To assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes, SIAPS worked
closely with the MSPP, through its DPM/MT at the national and provincial levels, as well as with other implementing partners and private sector representatives, to address pharmaceutical management challenges through the following four interventions:

**Situation Analysis to Identify Gaps Related to the Pharmaceutical Sector**

From February 12 to 17, 2012, a SIAPS team conducted a scoping mission to Haiti to better understand the key pharmaceutical sector gaps to be addressed by revising the NMP. A series of interviews were organized with MSPP key stakeholders and decision makers, implementing partners, donors, international health agencies, and private sector and academic/training institutions. These interviews provided important information on key priority gaps in the pharmaceutical sector, which were considered in the revision of the NMP.

The team was also able to review key documents related to the pharmaceutical sector including DPM/MT assessment reports, the previous NMPs (1997 and 2009), Pharmacy Law Act 1997, the National Health Strategic Plan for 2005-2010, DPM/MT standards and procedures, Assessment of Pharmaceutical Sector Report (2002). A technical report was developed, summarizing the key findings and recommendations from this situation analysis.

**Revision of Haiti’s National Medicine Policy**

From May 27 to June 1, 2012, the SIAPS team facilitated a series of five one-day stakeholders’ engagement workshops for the revision of the NMP. Each workshop gathered, on average, 20 participants to address specific sections of the proposed policy revisions.

Following the stakeholders’ engagement workshops, the SIAPS team worked with the DPM/MT team to elaborate the revised NMP document, based on the recommendations of stakeholders, taking into consideration recent global trends and WHO recommendations. The first draft of the NMP document was shared with the head of DPM/MT during the debriefing meeting on June 8, 2012. Comments were further solicited from in-country stakeholders and incorporated into a revised draft of the NMP. The second draft of NMP, including all the initial comments received from stakeholders, was sent to the DPM/MT on July 10, 2012.

The NMP was eventually finalized taking into account all comments from stakeholders; 5,000 copies were printed in May 2015.

**Launch and Dissemination of the National Medicine Policy**

The first ever approved Haitian NMP was officially launched in June 2015 by the Minister of Health during a ceremony endorsed by the president of Haiti and attended by the prime minister and many other members of the GOH, heads of technical agencies, partners of the MSPP, and other stakeholder representatives.

As a follow-up to this launch, in July and August 2015, SIAPS supported and participated in a series of workshops in all 13 health departments across all regions (North, West, and South) covering the whole country. The main purpose
of these workshops was to promote the NMP and identify opportunities for securing its successful implementation. This was also an opportunity to identify the various challenges that might hinder implementation. Scarce human resources and inadequate budget allocation were the main challenges identified at all levels, including the DPM/MT and facilities that render pharmaceutical services.

SIAPS also assisted the DPM/MT to draft Haiti’s strategies regarding research and development and access to essential medicines as important areas to be included in the NMP.

Options Analysis for Haiti’s Integrated Health Supply Chain

To date, the MSPP has solely relied on donor assistance and NGOs to provide essential medicines and other health technologies to public health sector facilities. This assistance includes procurement, storage, and distribution and has led to the creation of multiple parallel supply chain networks. To address the multiplicity of supply networks and improve coordination, the GOH, as part of its health sector strategy, decided to establish an integrated health supply chain network, the *Système National d’Approvisionnement et de Distribution des Intrants* (SNADI). The purpose of this initiative is to integrate all these networks into one national supply network overseen by a central entity, the *Centrale Nationale d’Approvisionnement et de Distribution des Intrants* (CENADI), a central warehouse that will be the main hub of the Haitian public sector health supply chain.

SIAPS has been supporting the DPM/MT to analyse several supply network options to generate information that GOH/MSPP may use to make decisions for implementation of this strategy. The analysis process included literature review, stakeholder meetings, and data collection. All relevant documents, reports, statistics, and presentations were reviewed. This was followed by the development of data collection tools to address identified data/information gaps. The data was collected and a set of recommendations was included in a first comprehensive report. This led to the development of an options analysis framework, which was widely shared and discussed with the DPM/MT and other key stakeholders.

Several supply network options, their costs, and comparative advantages and limitations were formulated. Additional option implications considered included relevant national policies, strategies, legal and regulatory framework requirements, capacity of existing structures and human resources, organizational statutes and funding opportunities, mapping of current and potential players, and their respective roles. Results of this analysis were shared with all relevant parties and, based on the feedback received, a revised draft report was completed and resubmitted to DPM/MT.

In October 2015, a meeting of the Technical Committee (CT) mandated by MSPP to support planning for the implementation of the integrated supply chain was held to discuss analysis findings. The CT is made up of representatives from all key donors and partners active in Haiti’s public health supply system. Considering that private sector distribution cost data (3PL) was not available at the time data was collected for the analysis, the CT requested that SIAPS update the analysis results, including recently generated private sector distribution cost data, available through SCMS project. This update will provide additional information for
better evaluation of the analyzed options. Once this data is incorporated, the final analysis report will be submitted to DPM/MT by the end of December 2015.

**KEY ACHIEVEMENTS**

With SIAPS support, the first approved Haiti NMP was developed and disseminated throughout the country. The NMP received widespread endorsement from the GOH and other stakeholders, which was undoubtedly affected by the inclusive engagement with government officials, donors, and other stakeholders from the beginning of the intervention. The dissemination of the NMP was widespread and ultimately 10 workshops were held countrywide, reaching 490 participants, including departmental pharmacists, hospital pharmacists, and other health workers.

**CONTRIBUTION TO USG GOALS**

The availability of quality data contributed to better decision making to avoid stock-outs at the health facility level for essential medicines, but also for medicines and commodities for HIV, FP, MNCH, and malaria. SIAPS’ work in Haiti focuses on indirectly supporting all these programs by optimizing the supply chain and improving the governance of pharmaceutical services. This is expected to directly contribute to an AIDS-free generation, universal health coverage, and reducing MNCH deaths.

**LESSONS LEARNED AND SUSTAINABILITY**

The main challenge faced in Haiti is the lack of capacity (manpower and skills) of the counterparts to take over the various activities supported by SIAPS. This has considerably slowed down progress and raised issues about buy-in and sustainability. The creation of the TWGs should partially mitigate this problem.

Once an option for the SNADI has been selected, its implementation will require a major shift in the commitment of the GOH to ensure that all required resources are available.

The USAID Mission in Haiti is fully supporting the integration of the supply chain and, as a result, all USAID partners involved in providing health products have been asked to use the storage facilities and the distribution network managed by SCMS. So far, there is no clear indication that other partners, such as PAHO, that have been providing essential medicines through their essential medicines program “PROMESS” will support the SNADI strategy.
Since 2002, as a partner of the USAID-sponsored Amazon Malaria Initiative (AMI), MSH programs in pharmaceutical management have supported the introduction of artemisinin-based combinations in South America to confront the resistance of *P. falciparum* to previous therapies. Due to this and other contributing factors, malaria has significantly decreased in the Americas during past 10 years. In 2015, some countries have explicitly included elimination strategies in their operational plans.

Paradoxically, the current epidemiological situation has imposed new challenges on pharmaceutical supply management, for example:1

- The decrease in incidence has not been homogeneous. Higher incidence now occurs in remote and/or difficult to access locations, or in populations not covered by conventional health services.

- Pharmaceutical suppliers have little or no interest in marketing the reduced volumes of medicines that are now required, which has left some countries’ national solicitations for the purchase of first-line medicines with no bidders, and national markets without suppliers of medicines for treatment of severe cases.

- Procurement of antimalarial supplies, which is now frequently outside the control of national malaria control programs (NMCPs), rely on historical morbidity records. This results in difficulties for the NMCPs in ensuring sufficient quantities are purchased to maintain adequate inventories in facilities located in areas of very low or null malaria incidence. Similarly, the distribution of supplies fails to consider the risk of outbreaks or reintroduction of malaria, meaning that areas of low or no incidence no longer receive medicines.

- In areas of low incidence, personnel lose the skills required to diagnose and treat malaria, while institutions lose the capacities to monitor, prevent, and control malaria. This situation has contributed to delays in the response to outbreaks that occur in areas where cases had disappeared.

Since 2012, SIAPS has been implementing system strengthening approaches to address these challenges.

KEY INTERVENTIONS

This systemic approach, based on the public health functions (governance, human resources, information, financing and service delivery)\textsuperscript{2,3} was implemented at three levels—

- **Regional**: Through the Pan American Health Organization (PAHO), and the Amazon Network for the Surveillance of Antimalarial Drug Resistance (Red Amazónica de Vigilancia de la Resistencia a los Antimalarials)
- **National**: In 12 countries: Guatemala, Belize, Honduras, Nicaragua, Panama, Colombia, Ecuador, Peru, Bolivia\textsuperscript{4}, Brazil, Guyana, Suriname.
- **Subnational**: In approximately 202 subnational jurisdictions (counting only first-level subdivisions, whether department, state, province, or district)

Introduction of Artemisinin Fixed-Dose Combinations: Before 2012, Bolivia and Peru were still using artemisinin as monotherapy in combination with other antimalarials. In 2012, fixed-dose combinations (FDCs) were introduced in Bolivia and Peru, through pilot programs. To support this, the following technical assistance strategies were used by SIAPS:

- **Governance**: Collection of evidence, preparation of policy briefs, and advocacy to change treatment policies.
- **Service Delivery**: Development of a plan for the introduction of FDCs in Peru.

Supply of Antimalarials to Low/Null Incidence Areas: Prior to 2012, the supply of antimalarials to low/null incidence areas (but still at high risk of reintroduction) was not considered. Currently, estimations and operative plans have been developed for the supply of antimalarials to these areas. To support this, the following technical assistance strategy was used by SIAPS:

- **Service Delivery**: Production of national guidelines for the estimation of needs and distribution of antimalarials to low incidence areas.

Regional Stock Information System: Before 2012, national information of stock availability was not shared with between countries in the region. Currently, national malaria programs share this information, facilitating timely procurement and donations among countries. To support this, the following technical assistance strategies were used by SIAPS:

- **Information**: Development and implementation of regional antimalarial stock monitoring system and quarterly information bulletin.

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\textsuperscript{4} Not supported by USAID since 2013.
• **Governance:** Coordination of regional antimalarial stock monitoring system and product of a quarterly bulletin, transferred to PAHO.

**Regional Procurement Scheme for Antimalarials:** Before 2012, procurement of antimalarials relied on national providers. Many countries had local bids with few competitors, such as Honduras, Peru, and Ecuador. Currently, a pooled procurement has been implemented though the PAHO strategic fund with limited USAID resources being used only for the treatment of severe cases. To support this, the following technical assistance strategy was used by SIAPS:

• **Governance:** Regional workshops and coordination meetings with the PAHO strategic fund to implement a pooled procurement of antimalarials, and a regional scheme for the donation of medicines for severe cases.

**Improvement in Storage Conditions:** Prior to 2012, previous MSH projects had documented poor conditions for the storage of low rotation antimalarials in low incidence areas. To address this, SIAPS developed “**Guidelines to Improve Storage Conditions of Antimalarials in Low Incidence Areas.**” To support this, the following technical assistance strategy was used by SIAPS:

• **Service Delivery:** Implementation of operational research, development of guidelines for good storage practices in primary health facilities, and implementation of a pilot test in Peru.

**Training of Primary Health Workers:** Before 2012, local providers had limited information on diagnosis and treatment in low incidence areas. SIAPS developed educational materials and trainings on diagnosis and treatment in low incidence areas for these local providers.

• **Human Resources:** Development of primary health level guidelines for antimalarial management in low incidence countries and training of personnel in Peru, Colombia, Bolivia, and Guatemala.

**KEY ACHIEVEMENTS**

The systemic approach applied by SIAPS allows the simultaneous implementation of different interventions, depending on the weaknesses of a particular country or the region as a whole.

Simultaneous interventions in different health system functions contributed to a continuous supply of antimalarials despite the challenges associated with low transmission. Data recorded quarterly by the regional stock monitoring system shows that in 2015, the availability of antimalarials in central and regional warehouses was 86%, a significant improvement from the 79% reported in 2012.  

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CONTRIBUTION TO US GOVERNMENT GOALS

The USAID-funded AMI seeks to prevent and control malaria in the Amazon Basin and Central America, while bringing lessons learned and networking to other countries, both in the region and around the globe. Main lines of assistance are antimalarial efficacy monitoring, resistance surveillance, prevention of emergence of resistance to antimalarials, access to quality diagnosis and treatment, quality assurance and control of pharmaceuticals and other supplies for malaria, vector surveillance and integrated vector management, epidemiological surveillance, and networking and systems strengthening. The SIAPS systemic approach to providing this assistance is embedded in the USAID 2015–2019 vision for health system strengthening. It has simultaneously contributed to prevent child and maternal deaths, and to protect communities from infectious diseases.

LESSONS LEARNED

AMI is simultaneously supporting high burden countries and countries that are moving towards an elimination phase. The pharmaceutical management of antimalarials in low incidence areas requires a different approach. SIAPS has developed methodologies and tools that are successfully used in Latin America, and could be adopted in other countries moving toward malaria elimination.

SUSTAINABILITY

The sustainability of these practices and its impact on the availability of antimalarials and diagnostic supplies is assured through a combination of political, legal, institutional, technical, and financial factors:

- **Political and Legal**: Some AMI countries have developed plans for the elimination of malaria. These initiatives are supported by a Regional Action Plan to be launched by PAHO and USAID in 2016. The implementation of these plans will utilize the tools and methods developed by SIAPS and previous USAID-supported pharmaceutical management programs.

- **Institutional**: Innovative pharmaceutical management practices, such as the distribution of antimalarials to facilities in low incidence areas, have been incorporated into national norms and operational procedures, and are routinely implemented by health workers without technical assistance. The collection and reporting of stock information was handed over to PAHO, an AMI partner, which holds a leadership position for the continuation of regional coordination and the distribution of regional information bulletins.

- **Technical**: All pharmaceutical management practices developed with SIAPS technical assistance are currently implemented by Ministry of Health staff, without the need of technical assistance. Technological resources (such as the electronic application for the regional information system) were locally developed and are maintained by PAHO and the malaria programs.

- **Financial**: AMI/SIAPS has not financed any personnel responsible for recurrent malaria program activities, nor introduced any technological
innovations demanding maintenance expenses. Some practices, such as the donation of medicines among countries, have contributed to a continuous supply of antimalarials, while preventing losses due to expiration, which has resulted in financial savings.

REMAINING INTERVENTIONS

In the following year, Brazil and Colombia will have the competency to conduct their own performance evaluations of their malaria control strategies. Technical assistance may still be needed if other AMI countries decide to implement performance evaluations, particularly for the National Malaria Control Programs that are transitioning to pre-elimination phases.

The production and dissemination of the Regional Bulletin for the Availability of the Malaria Medicines will be fully sustainable due to the follow up by PAHO, and the commitment of the majority of AMI countries. Technical assistance may still be needed to replicate this regional practice at national scale (using the same information): production and dissemination of national bulletins, dissemination to interested parties in regions/municipalities, and interventions to correct eventual overstocks and stock-outs.

SIAPS will continue to provide technical assistance to those countries that, at the current epidemiological trends, will need to revise their criteria to make sure that areas with no cases, but still at risk of reintroduction, receive a stock of antimalarials. SIAPS will support the design and implementation of innovative interventions to improve access to diagnosis and treatment in remote communities and populations living under special circumstances.

TRANSITION PLAN

Administratively, SIAPS does not have an office or vehicles in any of the Latin American countries supported by AMI. Technically, most current operations are already implemented by national counterparts. The last AMI steering committee meeting is scheduled for September 2016. SIAPS will take the opportunity to present a summary of the pharmaceutical management achievements and technical assistance interventions provided by SIAPS, and provide guidance for those that may still require AMI support.
The 2009 Lesotho Demographic and Health Survey confirmed that Lesotho had a severe, generalized HIV epidemic with a prevalence of 23%.

The prevalence has remained the same ever since, and Lesotho currently has the second-highest HIV prevalence in the world, following Swaziland. The 2011–2016 National Strategic Plan (NSP) aims to reduce the rate of new infections by 50% by 2016. As per the NSP, the Government of Lesotho (GoL) intends to have 80% of adults and children living with HIV receive antiretroviral therapy (ART) by that time. The GoL has maintained its commitment providing universal access to high quality preventative, treatment, care and support services to its citizens. Since the national scale-up of a comprehensive care and treatment program began in 2004, remarkable progress has been made in turning the tide of the HIV/AIDS epidemic in Lesotho.

The sustainability of progress made in the HIV/AIDS also requires the inclusion of tuberculosis (TB) services. Around 80% of people living with HIV in Lesotho are also co-infected with TB. The rate of new infections in Lesotho has been rising steadily, making identifying, diagnosing, and treating TB patients an urgent health priority that must be addressed alongside HIV/AIDS.

Since FY12, SIAPS-Lesotho has provided support to the Ministry of Health (MoH) to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. SIAPS Program’s work is guided by the Partnership Framework to Support Implementation of the Lesotho National HIV and AIDS Response and the Partnership Framework Implementation Plan (PFIP), developed by both the GoL and the USG in 2009. This work addresses the following challenges: 1) the insufficient and outdated medicines laws which do not include medicines registration, safety, and quality systems; 2) the lack of human resources; 3) a weak logistics information system, leading to inadequate use of information for decision making; 4) the unreliable supply of pharmaceutical and laboratory commodities which contribute to stock outs, including those of essential commodities used to diagnose and treat HIV/AIDS and TB.

1 MOHSW, 2009. Demographic Health Survey, p202-203
2 http://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/lesotho
3 National HIV & AIDS Strategic Plan 2011/12 – 2015/16
4 Ibid.
6 http://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/lesotho
FY15 is the final year of SIAPS activities in Lesotho. SIAPS has assisted in the success of achieving the health outcomes in Lesotho by working closely with the MoH and key PEPFAR implementing partners. During FY15, SIAPS mainly focused on providing technical assistance to close gaps and bottlenecks in the key supply chain functional areas and transition the remaining activities to the MoH and other partners. The activities SIAPS has supported over the last four years have been pivotal to strengthening the pharmaceutical system in Lesotho, and will ensure continuous availability of quality pharmaceutical commodities to the public.

**KEY INTERVENTIONS**

**Strengthening the Availability of Health Commodities through Supervision and Mentorship**

With the MoH, SIAPS conducted a capacity needs assessment to identify the causes of frequent stock-outs and expirations of tracer commodities at health facilities. The analysis found that senior health care workers required capacity building in management, including coaching, supervision, and team building, as well as requisite knowledge in monitoring and evaluation. After engaging with the district health management teams (DHMTs) to prioritize areas for improvement and developing strategies to address gaps identified, SIAPS, with the DHMTs, designed and delivered a supportive supervision and mentorship (SSM) program and the Supply Chain Management Leadership Program Development (SCMLPD). The SCMLPD builds leadership and management capacity, as well as supply chain knowledge and skills among the supply chain coordinating unit (SCCU), DHMTs, and health facilities.

To address the shortage of staff capacity in supply chain and logistics management, SIAPS supported embedding a supply chain manager in the MoH’s Disease Control Directorate (DCD) to coordinate pharmaceutical and laboratory management at the central level; support quantification, procurement and warehousing; standardize tools; and process orders for ARVs and ART-related commodities. SIAPS also had two supportive supervision coordinators supporting all hospitals to supervise the district logistics officers (DLOs) and a laboratory logistics advisor to improve the laboratory logistic information management system (LMIS). Additionally, SIAPS placed five DLOs in the DHMTs (Berea, Botha Bothe, Mafeteng, Maseru, and Mohale’s Hoek) to improve the LMIS through supportive supervision and mentoring of health care workers.

**Increasing Pharmaceutical Human Capacity through Pre-Service and In-Service Trainings**

Health care workers in Lesotho had consistently demonstrated underdeveloped skills in administering supply chain management tools, thus preventing completion, accuracy, and timely submission of reports, which then resulted in stock-outs and overstock of medicines and commodities. The MoH requested SIAPS’ assistance to improve the human capacity of health care workers at all levels.

SIAPS conducted a needs assessment to identify constraints and worked with partners (the National University of Lesotho [NUL], the National Health Training College [NHTC], Nationals Drug Services Organisation [NDSO], among others)
to review the curriculum for the NHTC pharmacy program and conduct pre- and in-service workshops. The NHTC pharmacy program was revised from to be a competency-based program, replacing a content only curriculum, to ensure graduates have the skillset to manage a supply chain system. SIAPS worked with partners to install RxSolution in a simulation laboratory at the National University of Lesotho (NUL), and also delivered the Supply Chain Management Leadership Development Program (SCMLDP) to improve the competencies in using supply chain tools and inventory management.

**Using Data for Decision Making in Supply Chain Management System**

In 2012, using data for decision making in supply chain management was poor due to untimely and often inaccurate data, low submission rates, and a lack of standardized, user-friendly data collections tools, causing stock outs of HIV-related commodities and other medicines and commodities (e.g. nutrition, family planning, and TB). SIAPS worked with the MoH to establish and improve governance structures, such as the Supply Chain Management Technical Working Group (SCMTWG) and the SCCU, which, as of March 2015, oversees and coordinates national level forecasting, quantification, and procurement of all medicines and health commodities. In FY14, SIAPS assisted the MoH to revise the standard treatment guidelines (STGs) and essential medicines list (EML), and to develop the Procurement and Supply Chain Strategic Plan (FY15). These documents were used to improve the availability of health commodities at health facilities in the quantification and forecasting of medicines and commodities.

To improve the quality of data and increasing using data for decision making, SIAPS supported the National Drug Service Organization (NDSO) to compile monthly stock status reports on antiretrovirals (ARVs) and other HIV-related commodities to ensure that all commodities were stocked to set maximum and minimum stock levels, in adherence to the Procurement and Supply Chain Strategic Plan. Pharmaceutical and laboratory logistics management information systems (PMIS and laboratory LMIS) were set up in health facilities and in all 18 laboratories in the country. SIAPS supported the dissemination and training of both manual and e-tools for PMIS (daily dispensing tally sheets [DDTS] and RxSolution, respectively) and the design and implementation of laboratory LMIS in all laboratories. The MoH and SIAPS additionally standardized requisition forms for TB, family planning, and nutrition for data collection and reporting of commodities.

**KEY ACHIEVEMENTS**

**Strengthening the Availability of Health Commodities through Supervision and Mentorship**

This intervention has effectively addressed capacity gaps of health care professionals at all levels to empower leaders in the pharmaceutical sector to efficiently manage information for decision making and perform logistic tasks to prevent stock-outs and overstocks.

As a result of the work by the DLOs, the 171 of 182 facilities use country-appropriate ART requisition forms to report logistics and patient data. The percentage of health facilities that received feedback from the DHMTs and the
To date, there have been 664 SSM health facility visits, and SSM has successfully improved the skills of 1714 workers in pharmaceutical management and 134 workers in laboratory LMIS. By September 2015, 255 workers had been trained in SCMLDP. The SCMLPD is fully institutionalized, with the SCCU now fully owning the program and is supported financially by the Global Fund Coordinating Unit (GFCU).

DLOs on the previously submitted report or data steadily increased from 73.9% in December 2014 to 88.4% by September 2015.

**Increasing Pharmaceutical Human Capacity through Pre-Service and In-Service Trainings**

The inclusive approach to increasing capacity in supply chain guarantees that the current health care workforce and future generations have the skills to maintain an uninterrupted supply chain of health commodities. This intervention will ultimately save costs that arise due to poor management and through improved management of health commodities, save lives. The NHTC pharmacy curriculum was revised, reviewed, and is undergoing accreditation at the NHTC. As of September 2015, the number of health care workers trained in drug supply management, laboratory LMIS, and monitoring and evaluation of ART programs was 116. As previously mentioned, SIAPS has also been successful in enhancing skills through mentoring and supportive supervision in pharmaceutical management, PMIS, laboratory LMIS, and the SCMLDP.

**Using Data for Decision Making in Supply Chain Management System**

This intervention has successfully impacted supply chain management across the building blocks of pharmaceutical systems strengthening, to improve inventory control, evidence-based forecasting, and supply planning using data. SIAPS has trained 17 health care workers in using RxSolution, and this tool is currently installed in 17 hospitals across Lesotho. The improvements in capacity building in the laboratory LMIS can be seen in reporting, where currently 100% of laboratories are completing submission reports on time, an increase from 61% in December 2013. Additionally, all SIAPS-supported health facilities are using ART DDTS. Accurate reporting on inventory has contributed to a decrease in the percentage of health facilities with stock outs of a pre-selected group of medicines for three days or more in the last three months from 8.65% in June 2014 to 2.65% in September 2015.

**CONTRIBUTIONS TO THE USG GOALS**

These interventions have been guided by the Partnership Framework to Support Implementation of the Lesotho National HIV and AIDS Response, developed by the GoL and USG. The activities use partnerships to build capacity, supply management systems, and standardize information collection and data utilization to contribute to universal health coverage, ending preventable maternal and child deaths, and reducing the spread of HIV. Establishing good governance structures and strengthening the supply chain management system ensures a continuous supply of medicines and commodities. Institutionalizing pre- and in-service trainings leads to improved pharmaceutical services and better health outcomes.
LESSONS LEARNED

• The use of competency-based in-service training programs, such as the SCMLDP—

• which is centered on a team-based approach to capacity building can promote a shared vision—reinforce leadership values and practices, and foster sustainable pharmaceutical system strengthening interventions.

• Involving the MoH personnel as the leaders and champions of intervention implementation improved data ownership from facilities, DHMTs, and the MoH.

• Embedding SIAPS staff in the MoH and the DHMTs is a comprehensive mechanism for institutionalizing targeted capacity improvements. The embedded staff were able to recognize challenges early on and resolve them before they can turn into problems.

• The availability of relevant tools and job aids is critical for helping newly trained workers apply their skills in the workplace and facilitate transformation from individual skills to systems-level practices.

• Standardizing data collection and reporting tools improves data accuracy and provides confidence in using the information for effective decision making. In addition, regular participatory data quality audits are critical for assuring long-term data quality improvements and the institutionalization of a “culture of data.” Once validated, the use of electronic tools can be effective in ensuring data quality. In addition, electronic tools reduce paperwork and address human resource constraints by increasing efficiency and broadening access to information by using mobile and/or web-based communication approaches. However, electronic tools are not appropriate for all contexts and must be implemented with due consideration to contextual determinants.

SUSTAINABILITY

SIAPS has effectively worked with the GoL, partners, and stakeholders to ensure the pharmaceutical system in the country will continue to improve after the program ends. As this is the last year of SIAPS presence in Lesotho, all the achievements made by SIAPS will be sustained through the SCCU. The SCCU is a management structure based at the MoH, responsible for organizing, monitoring, and supporting all supply chain activities for medicines and all health products. Through a continuous improvement approach, the SCCU will continue identifying supply chain challenges, developing and implementing interventions to address the challenges, and coordinating procurement of health commodities. The SCCU is a vehicle to institutionalize good supply chain management practices, both upstream and downstream logistics activities. Thus far, the SCCU is fully capacitated in the coordination of the SCMTWG, logistics and data management, quantification, supervision of DHMTs, and medicines distribution.
BACKGROUND

With an under-five mortality rate of approximately 95 per 1,000 between 2006 and 2012; over 2.3 million cases of malaria per year; a high fertility rate of 6.1 children born per woman; and a maternal mortality ratio of 368 deaths per 100,000 live births, Mali is a low-income country with a heavy burden of disease and poor levels of development indicators.

Since 1998, the Government of Mali (GOM) has developed 10-year plans for social and health development named Plan Décennal de Development Social and Sanitaire (PDDSS) to respond to the demands on its health system posed by these health burdens. Each PDDSS is implemented through a 5-year program for social and health development named Programme de Développement Socio-Sanitaire (PRODESS).

An assessment of PRODESS II conducted by the Ministry of Health (MOH) in 2011 identified some of the weaknesses in the pharmaceutical sector, such as frequent stock-outs of essential medicines in health facilities, low storage capacity, and suboptimal conditions for medicines at all levels of the health system.

PRODESS III (written in 2012/2013 to cover 2014/2018) identified that the unreliable procurement system was at the center of many of the issues in supply chain management (SCM) for essential medicines and health commodities, with the main causes being:

- Lack of a functional logistics management information system (LMIS)
- Insufficient number of skilled and well-trained staff for pharmaceutical management
- Incomplete implementation of pharmaceutical guidelines (Schema Directeur d’Approvisionnement et de Distribution des Medicaments essentiels [SDADME]) and/or lack of compliance to SDADME principles
- Absence of a coordination mechanism among GOM partners and donors for medicines SCM
To better understand the situation, in 2012, SIAPS supported the Directorate of Pharmacy and Medicines (DPM), which is responsible for managing health commodities under the MOH, to conduct a situational analysis of the existing LMIS. The situational analysis identified strengths and weaknesses of the existing system, which included lack of adherence/compliance to the implementation of SDADME directives leading to poor management and inconsistent availability of essential medicines at the health-facility levels, poor data collection, and a poor reporting system for commodities information.

The overall goal of the SIAPS Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. In Mali, the specific emphasis is on malaria, family planning (FP), and maternal, newborn, and child health (MNCH) commodities. To meet USAID Mission expectations and address the priorities identified on assessments done by SIAPS and other stakeholders, SIAPS Mali focused its interventions on 1) strengthening pharmaceutical sector governance, 2) improving human and institutional capacities, and 3) establishing a functional LMIS.

**KEY INTERVENTIONS**

To assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes, SIAPS works closely with the DPM, the Central Medical Store (the Pharmacie Populaire du Mali [PPM]), and government counterparts at the national, regional, district, and facility levels, as well as other partners to address challenges through the following key interventions.

**Establishing and Implementing a Functional LMIS**

Following the situational analysis, SIAPS outlined priority areas for improvement and provided a baseline against which interventions could be measured. Addressing the findings and building on the work conducted by SIAPS’ predecessor program, Strengthening Pharmaceutical Systems, SIAPS worked in collaboration with the DPM to redesign the LMIS to improve availability, accuracy, and quality of data. New LMIS standard operating procedures (SOPs) were developed as well as training materials for all levels of the health system. A pool of trainers was set up, and SIAPS supported the DPM and the regional directorate of health (Direction Régionale de la Santé [DRS]) to provide training, mentorship, and on-site supportive supervision to build the capacity of pharmaceutical stock managers. Trainings on the new LMIS, including the dissemination of specific SOPs and LMIS-related tools, were expanded beyond the regional level and involved stock managers at district and the community health centers (CSCOMs). This support helped the DPM put a methodology and tools in place to improve stock management and data collection and to significantly increase the logistic data reporting rate. A web-based portal called OSPSANTE was developed to track, aggregate, and disseminate reported logistic data.
Strengthen Coordination among Stakeholders Involved in the Supply Chain

To address the lack of coordination among key stakeholders involved in Mali’s pharmaceutical supply chain, SIAPS Mali supported the MOH to set up a coordination platform and mechanism, Comite National de Coordination et de suivi de la gestion des medicaments (CNC). The terms of reference for this mechanism were developed as were the list of members and a calendar of activities. In December 2013, the Minister of Health signed the decision that officially established this national committee that aims to contribute to accountability and sustainability of the CNC. The subcommittee for quantification and the technical working groups (TWGs) for each disease were also officially established by the same MOH decision. Representatives from the MOH, donors, and private sector and civil society organizations participated in committee activities and form a quantification subcommittee and TWGs that are in charge of medicines forecasting and commodity supply plans for malaria, MNCH, HIV, and FP. Information on medicines procurement and distribution and all specific supply chain-related data and concerns are shared during quarterly and ad-hoc meetings of this national technical committee to identify and implement corrective actions.

Since the CNC’s establishment, SIAPS has supported the quantification subcommittee to conduct annual comprehensive quantification exercises for FP, malaria, and HIV commodities. To do so, SIAPS worked with the CNC TWG committee to use innovative tools, such as Quantimed for forecasting HIV and malaria commodities and Reality Check for forecasting FP commodities. By the end of these quantification exercises, the stakeholders developed a consensus national supply plans by using PiPeline, which are updated quarterly.

Similar coordination mechanisms were set up at the regional level in Sikasso, Mopti, Segou, Kayes, Koulikoro, and Bamako. SIAPS regional representatives who are located within the DRS provide support to organize similar quarterly coordination meetings to identify and overcome bottlenecks in the health system. Participants in the coordination meetings include the regional directors of health, district health officials, hospital CEOs, physicians, and pharmacists.

Build Capacity to Manage the PPM

In Mali, the PPM is the strategic entity that handles procurement, storage, and distribution of pharmaceuticals to the regional and district levels. The PPM is also responsible for handling the pharmaceuticals that are procured by donors and other development partners, such as the Global Fund, USAID, and UN agencies. SIAPS Mali conducted a situational analysis of the operating procedures, practices, business/financial situation, and the overall supply chain environment (suppliers, clients, and governance). This subsequently led to the PPM’s first five-year strategic plan to (2015-2019), which aims to define a clear vision and strategic orientation for the PPM to ultimately improve business processes, infrastructure, and storage capacity.
KEY ACHIEVEMENTS

Establish and Implement a Functional LMIS

SIAPS supported the DPM and the DRS to train 24 trainers on newly developed LMIS SOPs and the subsequent roll-out. As of September 2015, 1,260 persons were trained on pharmaceutical management and LMIS with SIAPS support, including pharmacists, district warehouse and health information managers, and health-facilities stock managers. The trainings focused on pharmaceutical management tools, such as stock cards, and logistic reporting tools, such as requisition forms. Stock managers were also trained on how to calculate commodity needs as included in the LMIS SOPs developed in 2012. To ensure that trainees can effectively implement acquired skills and knowledge on a daily basis, SIAPS provided technical assistance to the DRS to conduct supervision and coaching visits.

To date, because of SIAPS’ support, the percentage of health facilities that completed and submitted an LMIS report for the most recent reporting period increased from 8% in 2012 to 87% in September 2015. In addition, 79% of health facilities are using consumption data to inform ordering compared to 50% in 2012. As a result, the establishment of this comprehensive LMIS has enabled evidence-based decisions and has contributed to the improvement in the availability of medicines at all levels of the pharmaceutical system. The stock-out rate of medicines has decreased from 50% in October 2012 to 28% in September 2015 at the district level and from 84% in December 2014 to 39% in September 2015 in health facilities. Lastly, the availability of essential medicines improved from 35% in 2012 to 62% in 2015.

Strengthen Coordination among Stakeholders Involved in the Supply Chain

SIAPS supported the organization of quarterly meetings of the national technical committee to validate key commodities quantification and also address medicine supply chain issues, particularly those related to commodities stock status, medicines distribution, and other bottlenecks. To date, 29 meetings of the technical coordination committee for pharmaceutical management and its subgroups have bee held, and 24 civil society organizations have regularly participated in and/or monitored pharmaceutical management operations.

The coordination of stakeholders at the national level contributes to obtaining consensus around a national supply plan for key commodities, as well as donor cohesion and confidence in financing the purchase of key commodities. This contributes to making products at all levels available for case management.

At the regional level, SIAPS supported the DRS to organize quarterly coordination meetings in USAID-supported regions to validate medicines’ stock status and address any pharmaceutical management issues identified during joint supportive supervision visits at health facilities and CSCOM. These meetings allow stakeholders to discuss pharmaceutical management issues, including the data quality assurance process, reporting rates, key findings, and other concerns identified during supervision and coaching visits.
Build Capacity to Manage the PPM

Through a participatory and consensus-driven process, a five-year vision was adopted and programmatic objectives were set to improve the performance of the supply plan. SIAPS advised PPM on the best ways to improve PPM performance in terms of increasing the service levels by improving product availability, efficiency (by minimizing wastage of resources and unnecessary overhead), and customer satisfaction. All these activities contributed to make the pharmaceutical systems more transparent and accountable.

Support was also provided to the PPM to finalize the development of five SOPS. It is anticipated that once developed or reviewed, these SOPs will be followed and implemented by PPM staff at both national and regional levels to improve transparency and accountability for medicine storage and distribution.

CONTRIBUTION TO USG GOALS

The availability of quality data contributed to better decision making to avoid stock-out at the health-facility level for essential medicines, but also for medicines and commodities for HIV, FP, MNCH, and malaria. SIAPS’ work includes a focus on HIV, FP, MNCH, and malaria and as such, TWGs were established in the CNC to analyze the supply of those commodities. This contributes directly to reducing MNCH deaths, an AIDS-free generation, and universal health coverage.

LESSONS LEARNED

The main challenge that the program faces is the need of a task force responsible for the main technical activities, particularly the LMIS and quantification process. Although a TWG exists, the country still needs to establish a logistics management unit (LMU) to manage all medicine logistics concerns with less technical support.

There remains limited ownership of actors at all levels to analyze data and make relevant decisions.

When strengthening the pharmaceutical system, the leadership of the highest national pharmaceutical sector authorities and stakeholders is key; it allows for decision making to remove bottlenecks in the implementation of activities and allows intervention to be sustainable.

SUSTAINABILITY

By the end of SIAPS in September 2016, the sustainability of the interventions in the pharmaceutical sector is mostly guaranteed due to a combination of political, legal, institutional, technical, and financial factors.

- It is planned to hand over the tool OSPSANTE to the DPM and the Agence Nationale de Télésanté et d’Information Médicale. The code sources will be given to them to continue improving the tool as needed.
and also to continue using the tool to render available data for decision making. The LMIS interventions were led and implemented by the DPM, and the technical skills have been transferred to local actors; there is a continuous transfer of competencies from SIAPS staff to MOH staff.

- During the last year of SIAPS, a task force (the LMU) will be put in place to fully transfer all technical competencies for quantification, LMIS, warehouse management, etc. Difficulties remain as to the financing of interventions, however, all these interventions are included in the MOH’s annual work plan and budget and the new USAID bilateral projects are also planning to support the MOH. All implemented activities are included in the PPM 5-year strategic plan; SIAPS supported the PPM to present their strategic plan to all partners, and some of them, such as the Global Fund and the Dutch Embassy, have committed to support implementation of the 5-year plan. It is planned to hand over this activity to PPM and its partners.
Background

Inefficient and irrational use of medicines is a well-documented problem in developed and developing countries, leading to an increase in costs and adverse clinical effects on patients. This inappropriate use of medicine could be reduced if various health care professionals involved in different aspects of drug use are involved to promote principles of drug management.\(^1\) In Mozambique, the Department of Hospital Pharmacy (DFH) at National Direction for Medical Care (DNAM) has identified the establishment of Drug Therapeutic Committees (DTCs) within hospitals as a priority intervention to improve the appropriate use of medicines at the hospital level. In this activity, SIAPS collaborated with DFH to review and define the terms of reference (TORs) and membership profile for the committees, and to identify which hospitals have already established a DTC.

In 2012, SIAPS conducted a comprehensive assessment of the regulatory system in Mozambique to analyze the challenges of the outdated system. Following the regulatory assessment, SIAPS and the pharmaceutical department (PD) agreed to update the national essential medicines list (NEML) to streamline procurement activities, minimize institutional costs, and optimize patient care.

SIAPS is working with partners in the pharmaceutical sector and in priority health programs to improve pharmaceutical services so that pharmaceutical products are not only available at service delivery points, but are also prescribed and dispensed appropriately, used correctly by patients, and monitored for safety and efficacy, with the aim of achieving desired health outcomes. SIAPS is providing technical support for the implementation of the national pharmacovigilance system to improve medicine safety; the creation of DTCs at hospitals to improve medicine use; the collection and analysis of medicine use information for decision-making; and, implementation of integrated supportive supervision and other supportive materials (e.g. guidelines, SOPs, training materials, job aids) to improve the quality of pharmaceutical management and services according to established standards as well as to strength the regulatory system in Mozambique.

KEY INTERVENTIONS

Drug and Therapeutic committees

Since 2013, SIAPS Mozambique has been strengthening the capacity of the HPD to improve the functions of hospital DTCs at the central and provincial levels using a systemic approach. This takes into consideration health system functions contributing to access to medicines and use of services (governance, human resources, information, and service delivery), as well as local pharmaceutical sector reforms. One of the main objectives for SIAPS Mozambique is to increase the number of appropriate drug policies in health facilities.

The DTC legal framework was approved in 2013, after which the MoH officially established 13 DTCs in hospitals across the country. At this time the DTCs lacked the necessary training and tools to implement appropriate DTC activities. As a result, SIAPS supported the development of the terms of reference (TOR) for the hospital DTCs, incorporating DTC participant input, and provided the TOR to MOH for review and adaption for the country. In addition, an initial plan of action was developed for the pilot hospitals. SIAPS also supported the HPD in overseeing activities of all DTCs and the design and piloting of standard operating procedures (SOPs) for medicine use studies.

Human Resources

In 2013, SIAPS-Mozambique developed and implemented a DTC orientation program, which provided an overview of the DTC role, main functions, and responsibilities to 70 physicians, pharmacists, and other health professionals from hospital DTCs, MOH, and NGOs. This activity was followed up with on the job trainings for DTC members, which focused on interpreting results of studies, identifying medicine use problems, how to improve medicine use, and the DTC TOR.

SIAPS supported the DTCs in addressing medicine use problems, by designing policies for prescriptions and use of medicines at provincial health facilities. Additionally, SIAPS improved the capacity of provincial hospitals by streamlining the DTC’s formulary system and policies and ensuring their implementation by the procurement department.

Essential Medicines List Mechanism

The NEML was published and approved in 2010, but never updated as there was no established mechanism to review it. In 2014 SIAPS collaborated with national stakeholders to develop a detailed concept note that included the rationale for the EML and the criteria for selecting an EML committee, including the TOR and proposed membership qualifications; recommended key steps to revise the Mozambique EML; and proposed a mechanism for monitoring the use of the EML once it was finalized. SIAPS also assisted the PD in setting up an appropriate committee and defining standardized and evidence-based criteria for selecting the EML medicines.

SIAPS worked with the MoH to develop an Essential Medicines List, as well as build the capacity of MoH staff to ensure a common understanding of the concepts of an EML and best practices in selecting medicines for the EML.

SIAPS supported the MoH in developing a preliminary list of medicines for the EML with the participation of specialists, hospital and clinic practitioners, DTCs, and MOH public health departments. This list was comprised of approximately 925 medicines.
and was based on the current EML, national formulary, and current practices. SIAPS support was extended to the development of other sections of the EML document, such as drafting policies and procedures, revising guidelines, advising on the purchase of non-EML medicine. The recommendations of the workshop were revised and the committee has submitted the EML for Minister of Health approval.

Alongside with revision, SIAPS also focused on building the capacity of MoH staff to ensure a common understanding of: 1) the concept of essential drugs program and the process of developing an EML; 2) the concepts and evidence-based practices used in selecting medications for an EML; 3) the evidence-based medicine selection, in accordance with WHO principles; 4) working with local and international specialists to build MoH staff’s knowledge to review the EML. Using evidence-based practices avoided ineffective, unnecessary or dangerous medicines as well as duplicative and non-essential drugs. This will allow the limited MoH budget to be used efficiently so that more drugs can be purchased with less or the same amount of financing.

Ultimately, the finalized list will be the basis of selection to procure medicines for the public sector, thereby helping to ensure availability of medicines in primary health care facilities for the most prevalent diseases, including malaria, tuberculosis, HIV/AIDS, and diarrhea, as well as those affecting maternal and child health (MCH). It is expected that this list will improve supply of medicines, lead to more rational prescribing, and improve the quality of care.

**Strengthening the Medicines Regulatory System in Mozambique**

SIAPS-Mozambique worked in close collaboration with the PD to assess and revise regulatory tools, including data requirement list for different types of medicine registration, SOPs of medicine registration review process and guidance documents. SIAPS also worked closely with the PD to review the current laws and regulations which can allow the PD to revise the regulatory tools and implement the new medicine registration data management system.

In 2013, SIAPS developed a customizable web-based medicine registration system, Pharmadex, based on the registration process and regulatory tools being used in the country. Pharmadex is designed to improve data management by electronically streamlining the medicines registration process. The PD revised the guidelines on data requirements for medicines marketing authorizations to strengthen data requirements and ensure the quality of imported medicines. SIAPS worked closely with the technical working group of registration unit of the PD to streamline the medicine registration review process through multiple workshops.

SIAPS created a platform to test and provide training for Pharmadex in the PD’s registration unit. A master trainer was identified who could teach their colleagues, provide feedback, and detect technical errors. SIAPS also provided technical capacity building training for reviewers so that the reviewers can improve their regulatory tools, such as guidance on data requirements for medicines registration and the SOP of the registration review process for essential medicines. SIAPS provided support to build technical capacity of the PD on the concept of common technical document (CTD) to improve the understanding on data requirements for medicine registration and to improve the understanding on the international standards practices for global medicine regulatory harmonization efforts.
SIAPS installed the local server at the PD so that Pharmadex can be accessed by users regardless of the connection to internet. SIAPS also procured computers and printers for the unit, as well as created an internal shared folder for centralized access to medicine registration data in a confidential manner.

**KEY ACHIEVEMENTS**

**Following technical assistance, the institutionalization of a transparent, participatory, evidence-based and consensus-oriented mechanism to develop and update the essential medicines list was developed for the first time in the country.**

Pharmadex is slated to go live at the beginning of PY5 using the local server of the PD. With SIAPS technical assistance, 13 DTCs were revitalized and helped conduct interventions to improve medicine use and manage medication errors; identify problems in medicine; develop standard treatment guidelines (STGs); manage adverse drug reactions; evaluate and select medicines for the formulary list; and ensure that the formulary system and other drug policies developed by the DTCs are implemented by the procurement department.

The process to update and revise the NEML has been productive. SIAPS has contributed in the establishment of a governance structure, engaging with essential stakeholders in the MoH to create an institutionalized EML committee.

**DTC Interventions Improving Rational Medicine Use**

Pemba Provincial Hospital conducted a study on the rational use of the antimalarial, Artemether-Lumefantrine (A/L). The results showed that of 30,366 malaria cases tested with rapid diagnostic tests (RDTs), only 20% were positive, but 97% were treated with A/L: 76% of individuals tested were treated even though they had a negative test result. Based on this information, Pemba Provincial Hospital DTC developed a policy stating that A/L can only be dispensed upon presentation of a positive blood test.

An ABC/VEN analysis at Maputo Provincial Hospital showed that 43% of the hospital’s total consumption of medicines was for antibiotics, with cotrimoxazole and amoxicillin with clavulanic acid suspension being the third- and fourth-highest prescribed medications. In addition, the hospital also verified that 49 of 270 pediatric clinical chart reviews presented unnecessary medicines administered. Taking action, the Maputo Provincial Hospital DTC developed and implemented policies for the appropriate use of antibiotics for bronchopneumonia treatment in pediatrics.

The TOR for the EML committee will guide their work, which is focused on using consensus and evidence to update the EML. To date, SIAPS has trained 75 MoH staff on the EML process.

The SIAPS-Mozambique health system strengthening approach has demonstrated impact not only on hospital settings but also in the National Hospital Pharmacy Department. The role of this department has been recognized as a key component of medical care direction in the MoH, and as a result staff has been increased from four to eight people.
CONTRIBUTION TO USG GOALS

SIAPS Mozambique addresses the USAID priority objectives for health systems strengthening, and the support to DTCs and the EML system has contributed to building capacity and sustainability. Capacity building has improved both individual and institutional performance in the EML committee and at provincial hospitals: Increasing the effective and efficient management of pharmaceutical systems and services, including promoting the evidence-based use of medications, assuring therapeutic efficacy, protecting patient safety, and slowing the emergence and spread of antimicrobial resistance.

Interventions aimed at building the capacity of provincial hospitals to ensure that the formulary system and other drug policies developed by the DTCs are implemented by the procurement department. Stronger supply chain components now help to ensure an uninterrupted supply of quality health commodities, including creating a supportive environment for commodities security and sustainable supply chains in the medical products, vaccines, and technologies function of USAID’s Health System Strengthening vision. Combined, these interventions are aligned with the USG goal for universal health coverage, particularly access to medicines.

LESSONS LEARNED

Through the combination of DTCs from different hospitals for trainings, the DTC teams have been able to share their experiences, challenges, and best practices, bringing lessons and ideas from other areas back to their facilities.

Since DTCs and the EML system are a new reality in the country, they still need additional support. The interventions implemented by SIAPS to date have addressed the roles, structure, supervision, and legal authority of DTCs and EML committees, yet capacity building remains a necessity. There remains a need to address the systems, support services, and personal capacity of the stakeholders involved. Building an inter-sectorial decision making forum, promoting accountability, putting in place reporting systems, and making available tools and resources are still needed to strengthen the DTCs and EML committee.

SUSTAINABILITY

The sustainability of the DTCs and, therefore, its impact on the availability of the HIV, TB, MNCH, and FP medicines and supplies is supported by a combination of political, legal, institutional, technical and financial factors:

DTCs

- Political and Legal: DTCs are supported by the Ministry Diploma.
- Institutional: Following the DTC Diploma, the MoH appointed personnel for 13 provincial hospitals and three central hospitals. DTC results create positive impacts in health facilities, members are more eager to contribute with their time and ideas, and DTC credibility has increased as their actions have brought transparency and credibility to the health system,
which has resulted in stakeholders being more eager to finance systems gaps.

- **Technical**: The DTC orientation program was developed and presented to MoH, NGOs, and hospital staff to provide an overview of the DTC role, main functions, and responsibilities. In addition, on the job trainings for DTC members have been provided, focusing on interpretation of results, monitoring and identification of medicine use problems, medicine use improvement, and the DTC TOR.

- **Financial**: It is within the DTCs capacity to ensure that the formulary system and other drug policies developed are implemented by the procurement department; this will allow cost effective planning and procurement resulting in cost savings that can be used for other public health resources.

**EML System**

- **Political and legal**: The EML and its policies are supported by Ministry Diploma.

- **Institutional**: The EML committee is a multidisciplinary team appointed by the Ministry of Health with approved TORs.

- **Technical**: The EML mechanism was supported by SIAPS local and international consultants, which also trained EML committee members on how to develop, update and monitor the EML.

- **Financial**: The EML mechanism’s deliverables will improve cost control and transparency in the use of resources, improving credibility in the system therefore more funding.

**Medicines Regulatory System**

- **Technical**: Local IT supports has been identified as a key success factor to deploy the system and to solve IT related issues. Since the PD does not have its own IT support, the sustainability issue was brought up. The PD was advised to work on their budget and human resources for IT support to secure the sustainability of the system.

It is highly recommended to establish the in-house training program to share/transfer the knowledge and to create a certificate program to improve the qualification of reviewers and to improve the quality of their review work.

**TRANSITION PLANNING**

**DTCs**

To effectively transfer these activities to facilities, the HPD, stakeholders, and associated partners and institutions, SIAPS will work with the HPD to revisit the broadly defined scope of work of the DTCs, select a package of interventions they should focus on, and create the system to monitor these interventions. HPD will
then analyze data and make evidence-based decisions at the national level, based on the DTC reports. The selection process of the model intervention package and the way forward will be done in collaboration with major stakeholders. It is expected that a detailed transition plan will result from the findings of this workshop.

**EML System**

To effectively transfer these activities to the MoH, stakeholders, and associated partners and institutions, SIAPS will work with the MoH to redefine the EML committee TOR and build capacity for EML dissemination and monitory. Taking in account that SIAPS has one more year, a detailed plan for the next EML revision should be performed to include the budget, as well as proposed funding sources or strategies.

**Medicines Regulatory System**

Pharmadex is a free of charge and an open source tool, and to assure smooth transition of the system, SIAPS plans to provide additional IT training for the users so they can update the system in the future. Once the PD has its own IT staff, SIAPS will train them to ensure the sustainability of Pharmadex after SIAPS.
NAMIBIA

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**BACKGROUND**

Namibia is among the countries with the highest prevalence of HIV; in 2013, an estimated 13.1% of the adult population was living with HIV. Namibia also faces a high TB burden, with the TB/HIV co-infection rate at 47% in 2012. The country’s antiretroviral therapy (ART) and TB programs are well supported and have achieved universal access at the previous WHO recommendation of 350 CD4 cells/mL. With the updated WHO recommendation of universal access for those with 500 CD4 cells/mL, the country is facing new challenges such as ensuring patients’ long-term adherence to ART, retention in care, minimization of lost-to-follow-up (LTFU), and the growing threat of HIV-drug resistance (DR) and multi-drug resistant (MDR)-TB.

There continues to be a shortage of skilled pharmaceutical human resources, with an enormous dependency on non-Namibian personnel to provide ART and other essential pharmaceutical services. The scale-up of ART services has overstretched the public sector capacity. Partnerships between the Namibian Government and the private sector to dispense ARVs to public sector patients are practically nonexistent, and private sector pharmacists do not always have updated skills in pharmaceutical care for HIV, AIDS, and maternal, neonatal, and child health (MNCH) programs.

The pharmaceutical supportive supervision that was conducted by the Ministry of Health and Social Services (MoHSS) in the fiscal year 2013/14 revealed uneven quality of ART and other pharmaceutical services across all levels of the public sector health system. Furthermore, there is inefficient regulation of pharmaceutical products and personnel and a dearth of local evidence on antimicrobial resistance (AMR) and HIV-DR to inform medicine selection and treatment guideline decisions. Due to the shortage of medical and pharmaceutical personnel, MoHSS recently began the roll-out of the Nurse Initiated and Managed ART (NIMART) strategy to make ART services available at primary health care (PHC) facilities operated by nurses.

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Improving Pharmaceutical Sector Governance

SIAPS provides technical assistance to the MoHSS Division of Pharmaceutical Services for updating the National Medicines Policy and National Pharmaceutical Master Plan, Namibia Essential Medicines List (Nemlist), and treatment guidelines and strengthening pharmaceutical regulatory systems to ensure the availability of safe, efficacious, high-quality medicines for HIV and related co-infections, MNCH, and other priority public health diseases and conditions.

Ensuring Access and Availability of Quality-Assured Medicines for HIV and AIDS

To ensure access and availability of safe, effective, and quality medicines in the country, SIAPS collaborated with the Namibia Medicines Regulatory Council (NMRC) to train and increase the pool of medicines dossier reviewers. SIAPS Namibia also strengthened the Quality Surveillance Laboratory to improve medicine quality control and conduct routine tests for post-market surveillance. A strong and effective medicines regulatory function is necessary to ensure timely registration of pharmaceuticals and to constantly monitor the quality and safety of HIV and AIDS medicines, including those for opportunistic infections. A web-based Pharmadex tool was designed, customized, and implemented for the MoHSS. The tool will improve efficiency of the NMRC, facilitate review of applications for medicine registration, and improve dissemination of information on essential medicines.

Increasing the Pharmaceutical Work Force

Since 2012, SIAPS has supported the MoHSS in the long-term planning of strengthening pharmaceutical human resources and concurrently building the capacity of local institutions (University of Namibia [UNAM] and the National Health Training Centre [NHTC]) to provide pre-service and in-service pharmaceutical management training, accredited by the Health Professions Council of Namibia and the Namibia Qualifications Authority. Interventions have led to increased workforce numbers, reduced vacancy rates, better regional and rural distribution of pharmacy staff (especially where the HIV prevalence is still high), and improved capacity of trained health care workers to deliver quality ART services.
Enhancing the Use of Pharmaceutical Information for Decision Making

The major source of data on ART services continues to be the SIAPS-supported Electronic Dispensing Tool (EDT). The data generated from this tool is used to determine gaps in the coverage and provision of ART services by region, district, and health facility. This informs Namibia’s strategies for achieving the UNAIDS 90-90-90 target for ending the HIV and AIDS epidemic and for efficiently scaling-up ART services. The information also contributes to PEPFAR’s Data for Accountability, Transparency, and Impact (DATIM). The visibility and timely availability of quality data on ART provision continues to be a priority for SIAPS support to the MoHSS.

Improved Pharmaceutical Services and Treatment Outcomes

Poor patient adherence to ARVs and anti-TB medicines leads to ineffective viral and mycobacterial control and poses a high risk for the development of HIV- and TB-DR. The limited monitoring of medication safety, the high burden of MDR-TB, and the limited availability of pharmaceutical information essential for decision making negatively impacts on the success of treatment outcomes in HIV and TB management. The initiation of patients on ART at a higher CD4 threshold according to the new ART guidelines, coupled with the decentralization of ART services from district hospitals to health centers, has resulted in increased patient loads at service delivery points and at ART/TB dispensing points. This potentially increases the risk of compromised quality of ART pharmaceutical care, particularly in the slackened adherence monitoring and counseling by health care workers, a condition that favors the development of HIV-DR. SIAPS is assisting the MoHSS Division of Pharmaceutical Services and the National AIDS Control Program to implement a multipronged approach for strengthening pharmaceutical services delivery by monitoring and improving patient safety (pharmacovigilance); rational use of HIV and AIDS medicines; prescriber and dispenser compliance with ART and opportunistic infection guidelines; support to therapeutics committees; support to the decentralization of ART services; and the implementation of an HIV-DR early warning system.

Using the SIAPS approach to pharmaceutical systems strengthening, the interventions have focused on pharmaceutical service delivery, human resource development, governance, and information systems at the national and health-facility levels, primarily in the regions and districts with a high HIV burden.

KEY ACHIEVEMENTS

Strengthened Pharmaceutical Governance: Efficiency in registering essential medicines has improved

- SIAPS supported the reduction of the medicine registration dossier backlog from 711 applications to 100 applications over a one-year period (FY15), reflecting an 86% improvement in process efficiency. The NMRC website has been redesigned and is now available to all health care workers and the general public for more transparency of regulatory information and better access to information on the medicines licensed for
use in Namibia.

• The average number of days taken to evaluate and approve regulatory applications has been reduced from 53 days in 2012 to 48 days in 2014.

• Registered products on the Nemlist have increased from 61% in 2013 to 66% in 2014.

• Medicine quality monitoring has been operationalized through routine in-country post-market surveillance activities.

### Strengthened Capacity of Institutions in Pre-Service Training of Pharmaceutical Human Resources

• Since 2012, 114 new pharmaceutical personnel have graduated from two pre-service training institutions (14 pharmacists from UNAM-School of Pharmacy [UNAM-SoP], 100 pharmacist assistants [PAs] from the NHTC).

• The number of PAs graduating from NHTC annually quadrupled from 6 graduates in 2006 to an average of 25 in the last 3 years.

### PAs Trained through USAID/SIAPS Support are Playing a Critical Role in the Delivery of HIV and AIDS Treatment Services in Namibia

Mr. Martin Mandumbwa, a PA who graduated from the NHTC in 2014 and currently works at a public sector ART facility in Namibia, expresses happiness at his ability to serve the Namibian people, especially those on the public sector ART program. Martin manages the pharmaceutical services of the clinic’s two pharmacies, one of which is dedicated to ART services. He provides counseling and ARVs to the patients and advises them on correctly taking their medicines for maximal benefit.

Increasing the number of PAs and pharmacists is critical to the Government of Namibia’s efforts to control the country’s HIV epidemic and to provide decentralized, more accessible, and quality HIV and AIDS treatment and prevention services to the nation.

Mr. Martin Mandumbwa, PA, dispensing medicines to a patient at Robert Mugabe Clinic in Windhoek, Namibia.

“I am very happy with the training I received at NHT because I can dispense ARVs. I can initiate patients on ARVs, that includes counseling them, making sure that they understand what they are about to undergo.”

Photo Credit: SIAPS Namibia, September 2015
Improved Availability and Use of Pharmaceutical and Patient HIV Treatment Information for Decision Making

- Through SIAPS’ support, public sector ART facilities have continued to use country-appropriate tools for ARV dispensing and the reporting of medicines logistic and ART patient data.

- Over 90% of health facilities complete logistic management information system (LMIS) reports monthly.

- With SIAPS technical assistance, Pharmaceutical Management Information System (PMIS) and EDT data are continuously analyzed by MoHSS and partners for ARV quantification, monitoring early warning indicators (EWIs) of HIV-DR, and implementation of ART adherence interventions. Recommendations from the 2012 HIV-DR EWI report led to an ongoing collaborative study on intensified ART defaulter tracing, an intervention aimed at retaining more patients on ART in HIV clinical care.

- Health facilities are increasingly receiving prompt feedback on the reports/data they submit to the national level: 59% in 2014 to 68% in 2015.

- The proportion of health facilities that used medicines consumption data to inform ordering of ARVs improved from 17% in March 2012 to 20% in March 2015.

- The eTB Manager (DR-TB case and pharmaceutical management) has been rolled out to 14 hospitals.

Pharmaceutical Service Delivery Strengthened

- The proportion of patients achieving a 75% or greater ART adherence increased from 78% in 2012 to 80% in 2015.

- Three standardized scored checklists were updated and used for monitoring pharmaceutical service delivery at public sector health facilities. A manual for conducting structured supportive supervision visits (SSVs) was developed for the MoHSS, and annual national pharmaceutical SSVs were conducted from 2012 to 2015.

- The overall average score by health facilities on pharmaceutical service indicators during SSVs improved from 55% in 2011 to 61% in 2015. The better overall scores reflect improvements in pharmaceutical service delivery as measured by selected indicators such as pharmaceutical storage practices, use of stock cards, cold chain management, therapeutics committees, PMIS implementation, use of EDT for stock and patient management, and quantification of the amount of pharmaceuticals to order from the medical stores.
Improving Rational Use of Medicines

- The Nemlist was updated.
- A multidisciplinary national taskforce/working group for AMR containment was established at the national level comprising private and public health practitioners (doctors, pharmacists, and nurses) from Windhoek Central and Katurura Intermediate Hospitals.

Improvement in ART Adherence

- Adult and pediatric ART retention rates improved from 76% and 82% in March 2013 to 95% and 94% in June 2015, respectively.
- Regular monitoring and analysis of HIV-DR EWIs has led to a reduction in ART patients LTFU from 21% in 2013 to 4% in 2015.
- On the basis of recommendations from the EWI data, the MoHSS has implemented adherence promotion interventions, such as the short messaging services reminder for patients on ART.

Pharmacovigilance

The MoHSS initiated active surveillance of first-line ARVs at two hospitals for the early detection of medication-related adverse events (ADRs) and the spontaneous reporting of ADRs to the Therapeutics Information and Pharmacovigilance Center by health facilities.

CONTRIBUTION TO US GOVERNMENT GOALS

The United States Government, through the President’s Emergency Fund for AIDS Relief (PEPFAR), has supported the scale-up of the ART, TB, and home-based care and treatment services/programs throughout Namibia. To ensure an integrated approach, SIAPS focuses on interventions to improve ARV selection, use, and the governance of pharmaceutical products and services. Building on previous assessments and data from the program-supported ART PMIS and the EDT, SIAPS contributes to the development of evidence-based strategies for the effective and efficient delivery of ART patient services. SIAPS uses a multipronged approach to address the challenges facing pharmaceutical service delivery to ensure that the achievements of the MoHSS HIV and AIDS and TB program objectives as well as the USAID objectives are sustained, including expanding ART access to people living with HIV and AIDS. SIAPS, as a member of the Universal Health Coverage Advisory Committee of Namibia (UHCAN), advises the MoHSS on pharmaceutical service aspects of Namibia’s universal health coverage strategy.

Patients, especially those living in the rural areas of Namibia, may not have ready and easy access to essential medicines for the treatment of HIV and AIDS. Therefore, strengthening access to quality essential pharmaceuticals and services is SIAPS’ key objective for supporting the universal coverage of ART services. This will ensure that 90% of eligible persons receive ART services and that 90% of those on ART are retained on treatment for sustained viral suppression per the Namibian ART guidelines of 2014. This will help Namibia attain an AIDS-Free Generation and end preventable maternal and child deaths.
LESSONS LEARNED

SIAPS’ continued technical assistance to stakeholders and trained health care workers enhances the implementation of post-training actions. The post-training action plans developed during training and the post-training on-the-job support and mentoring of pharmaceutical personnel by SIAPS’ technical advisers are critical to enabling health care workers to operationalize the knowledge and skills gained from traditional classroom training sessions. By design, SIAPS is largely a system strengthening project with limited financial and human resources for site-level technical support at specific health facilities. Subsequent projects should build-in more on-site mentoring of staff to utilize knowledge and skills gained and have a system of measuring post-training impact, which was not adequately done in the current SIAPS interventions.

The dissemination of monitoring and evaluation (M&E) information creates opportunities for sharing SIAPS’ experiences across regions and generates action for improving services. For example, the planned structured dissemination at the MoHSS national annual pharmacists’ forum of routinely generated M&E information and the information derived from SSVs enables pharmacists from all regions to exchange ideas on how to budget for and implement activities to improve pharmaceutical inventory management and the functionality of therapeutics committees that provide oversight on pharmaceutical services in public health facilities. Without such a structured and focused dissemination, use of data for decision making is limited.

The shortage and high turnover of pharmaceutical human resources in Namibia has stifled the timely implementation of some planned project activities because the appropriate MoHSS staff were sometimes not available or could only commit a limited amount of time to the activities agreed upon during SSVs, on-the-job mentoring, and training. The MoHSS needs to finalize restructuring and recruitment of sufficient numbers of staff and develop measures for ensuring the proper handover and transfer of knowledge and skills when staff contracts at health facilities come to an end.

Limited stewardship of activities by the MoHSS Division Pharmaceutical Services affects follow-up of recommendations and impairs full transitioning of supported activities.

The NMRC’s procedures for recalling unsafe medicines needs strengthening as does the routine surveillance and testing of the quality of medicines at health facilities. Such surveillance activities are critical for identifying important medicine-quality problems that may have otherwise gone unreported by health care workers during regular service delivery. Prompt implementation of recalls will prevent patients from accessing and using unsafe medicines.

Medicine quality assurance systems at the health-facility level need improvement, especially for prepackaged medicines. This aspect may be added to inventory management training in subsequent activities.

Site visits for activities such as SSVs can be used to follow up on other activities to utilize resources effectively. For example, SSVs for pharmaceutical services can be used to follow up on implementation of EDT mobile at PHC facilities offering ART, an activity that was piloted by SIAPS in the Kavango and Zambezi regions.
The Namibia Training Authority (NTA) could support local institutions like the NHTC, but the NHTC needs support to access and conform to NTA’s requirements. The NTA support would enable the NHTC to enhance some of the work, such as curriculum reviews, quality assurance systems, and tracer studies that SIAPS has been supporting.

Advances in cell phone technology and the availability of mobile devices in the general population can be leveraged to spread adherence messages and help patients remember their ART appointment dates.

**SUSTAINABILITY AND COUNTRY OWNERSHIP**

SIAPS collaborates with key local government stakeholders and other relevant partners to ensure that supported interventions are implemented in partnership. In FY15, SIAPS developed guidance documents such as manuals for conducting structured pharmaceutical SSVs, medicines use evaluations, EDT installation and user guides, and the eTB Manager user guide, all of which will guide MoHSS stakeholders toward a continuity of processes. SIAPS has enhanced the capacity of two local training institutions (NHTC and UNAM-SoP) through joint activity implementation and the development of materials on pharmaceutical management, which these two institutions can continue using for pre- and in-service training of pharmaceutical personnel. In addition, SIAPS Namibia will develop and implement a detailed transition plan, reflecting how each applicable program activity will be effectively transferred to local government stakeholders and associated partners and institutions.

**SIAPS NAMIBIA GEOGRAPHIC COVERAGE**

- SIAPS implements in all 14 regions with a focus on the 7 high-HIV-burden regions
- 50 main ART sites use the SIAPS-supported EDT for ARV dispensing and ART patient data capture
- More than 50 integrated management of adult and adolescent illnesses PHC facilities are using mobile EDT for NIMART services
- 13 designated regional DR-TB centers are using eTB Manager
- All 348 public and faith-based supported health facilities benefit from health system strengthening technical assistance
  - NHTC and UNAM-SoP
  - MoHSS units at the national and central levels

**TRANSITION PLANS**

SIAPS Namibia will develop and implement a detailed transition plan reflecting how each applicable program activity will be effectively transferred to local government stakeholders and associated partners and institutions.
Enhanced registration of medicines and post-market surveillance of quality of ARVs and other essential medicines has been transitioned to the NMRC, using the guidelines that SIAPS supported the NMRC to develop.

Structured supportive supervision for improved and sustained pharmaceutical service delivery: SIAPS in FY16 will continue supporting the MoHSS to operationalize the SSV manual developed in FY15 to provide structured supportive supervision and sustain pharmaceutical service delivery. The guide is easy for MoHSS staff to follow, even those newly recruited (given the high staff turnover).

SIAPS is working with the MoHSS to identify and enhance the capacity of IT staff to support, maintain, and use electronic tools such as EDT and RxSolution. Also, SIAPS is a member of the MoHSS working group on health information systems, which intends to ensure that existing systems are interoperable and data can be exchanged among them, such as the electronic patient management system and EDT.

**PLANS FOR REMAINING INTERVENTIONS**

In FY16, SIAPS in Namibia will continue technical support for robust systems for timely registration and regulation of pharmaceuticals, including ARVs; for MoHSS initiatives for patients’ adherence to ARV and anti-TB medicines to prevent DR; for working with health information system partners at MoHSS to ensure interoperability and data validation between IT systems (for example, using unique codes applicable to multiple systems); and for NHTC and UNAM-SoP to incorporate SIAPS-supported in-service training modules into pre-service curricula. SIAPS has supported development of manuals such as one for structured supportive supervision and medicines use evaluations in public facilities and a guide for post-market surveillance of quality of medicines, which was operationalized in FY15. SIAPS will support MoHSS to operationalize the manuals as key guides to structured service-quality improvements.

After September 2016, SIAPS in Namibia has three options for current planned and other relevant activities. The three possible options for activities in September 2016 when the SIAPS contract ends are (1) finalized, (2) transition to the MoHSS, and (3) transition to a new contractor. Each of the FY16 activities and those that may be emerging MoHSS/client needs in 2016 will be classified accordingly. SIAPS has been and will continue discussing with MoHSS the activities that will still need support after the SIAPS contract ends.
BACKGROUND

Malaria remains a major public health problem in Niger. Over the past four years, an average of 3,800,000 presumed cases of malaria were recorded per year (equivalent to an incidence rate of 24,910 cases per 100,000 inhabitants) and there were an annual average of 2,862 deaths (or a mortality rate of 0.25%). Malaria represents 31% of all the morbidity incidents recorded in 2013 and constitutes the primary cause of death in all regions in the country, being responsible for 57% of deaths overall and 76% of deaths among children under 5. Malaria affected 106,012 pregnant women in 2013 and caused 25 deaths (or a mortality rate of 0.02%).1 However, these figures do not reflect the real situation of the country given the low coverage rate of the population (48% in 2013) and the number of malaria cases that escape notification at the community level.

The entire Nigerien population is exposed to malaria. However, pregnant women and children under five years of age are the most vulnerable groups and frequently develop severe malaria. The epidemiology of malaria in Niger is characterized by stable endemicity with a seasonal increase during and after the rainy season (June to December).

The National Malaria Strategic Plan 2011–2015, developed by the National Malaria Control Program (NMCP), highlighted the importance of maintaining constant availability of stocks and improving the current supply chain management system for malaria commodities. Support was requested and obtained from US Agency for International Development (USAID) in the form of technical assistance to be provided to NMCP by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, which began its activities with the NMCP in 2015.

In Niger, the objective is to strengthen pharmaceutical management of health products to treat malaria. Specifically, SIAPS intervention in Niger is long-term technical assistance to build NMCP supply chain staff capacity by embedding a Supply Chain Technical Advisor within the NMCP for 18 months.

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1 Health statistical directory in Niger, SNIS 2013, p.59.
KEY INTERVENTIONS AND ACHIEVEMENTS

SIAPS works closely with the NMCP and government counterparts at the national level to address challenges through the following key interventions.

Launch of a Supply Chain Technical Committee for Malaria Products

To strengthen the management of malaria products and coordination among the various stakeholders, SIAPS assisted the NMCP and Medicines Regulatory Authority (Direction de la Pharmacie et de Médicine Traditionnelle) in finalizing the arrêté (decree) and scope of work for a new technical committee which will focus on supply chain issues related to malaria commodities management. The work of this new technical committee was endorsed by all stakeholders, including NMCP, the Medicines Regulatory Authority, and the Central Medical Store (CMS). The arrêté establishing this technical committee has been approved and signed by the Ministry of Health on May 19, 2015. Partners such as UNICEF and Médecins Sans Frontières (MSF) support this new committee as it is enables all partners involved on malaria supply chain sitting at the same table and discussing issues, recommendations to improve availability of commodities, and the performance of this program.

Global Fund Concept Note Development

SIAPS supported the writing of the Global Fund concept note for the 2016 to 2018 malaria grants funding. The Global Fund is the principal funding of malaria activities in Niger and on July 17, 2015, the Global Fund notified Niger that the technical review panel approved the concept note for an amount of USD $36,735,493 and an additional USD $2,449,465. Having this concept note approved and awaiting the signature of the grant is a great achievement for the NMCP.

Seasonal Malaria Chemoprevention

The NMCP is implementing seasonal malaria chemoprevention (SMC) in 11 districts in Niger with funding from the Achieving Catalytic Expansion of Seasonal Malaria Chemoprevention in the Sahel (ACCESS-SMC) project. Project implementation is led by the Malaria Consortium in partnership with Catholic Relief Services (CRS). SIAPS worked closely with SMC implementing partners CRS and MSF to centralize all micro-planning and the coordination of SP + AQ commodities management to ensure availability of commodities during the four cycles of the campaign. This year, around 620,000 children under five years of age received malaria prevention treatment, which results in the reduction of malaria morbidity in these regions.

Improve Mechanism of the Distribution of Malaria Commodities to Health Districts

During this year, SIAPS, in collaboration with the NMCP and the Central Medical Store (CMS), supported the development of tools to establish a distribution plan for rapid diagnostic tests (RDTs) and artemisinin-based combination therapy (ACTs). It specifies that the Global Fund and UNICEF procure the commodities...
for the government, which will be distributed to the districts’ health facilities according the NMCP’s plan. This is the first time that a distribution plan is developed based on estimated needs of health districts using 2014 data provided by partners (MSF and UNICEF). Previously, the distribution plan was developed using unknown formulae on an Excel sheet (paper-based) without evaluating the districts’ needs. This achievement allows now the NMCP to assess the level of stock of products distributed at the district level and also to monitor the use of commodities in the context where there is no logistics information system and no stock management report.

SIAPS collaborates with the NMCP and CMS to use data from the health districts to inform the distribution plan for rapid diagnostic tests and ACTs.
According to the World Health Organization (WHO), the Philippines is one of the nine high tuberculosis (TB) burden countries that has reached its 2015 Millenium Development Goal targets of reducing TB incidence, prevalence, and mortality. However, TB still remains a major public health concern in the country: being the sixth leading cause of mortality with estimated 10,000 deaths in 2014. Moreover, 21% of the drug-resistant TB (DR-TB) patients in 2014 were re-treatment cases, and the burden of DR-TB appears to be escalating at an alarming rate.\(^1\)

Despite the significant decline in TB burden, TB control in the Philippines still faces multiple constraints such as low patient detection, treatment enrollment, and treatment drop outs; inadequate access to quality assured TB diagnostic and treatment services; weak information systems; and limited technical and management capacity of national, regional, provincial, and peripheral TB program managers and health care provider staff.\(^3\)

### Key Interventions

Using a systems strengthening approach, SIAPS 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.

SIAPS is working with the Department of Health (DOH) and its agencies: the National TB Control Program (NTP), Food and Drug Administration (FDA), Pharmaceutical Division (PD), Logistics Management Division (LMD), Central Office Bids and Awards Committee (COBAC), National TB Reference Laboratory (NTRL), and local government units in Region 4A and Quezon City.

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3. Department of Health- National Tuberculosis Control Program (2013) Updated 2010-2016 Philippine Plan of Action to Control Tuberculosis
Laboratory Systems Strengthening

SIAPS is working with NTRL in strengthening the capacity to lead and manage the NTP laboratory network. Technical assistance is focused on developing national laboratory strategic plans, developing and updating policies and guidelines for the new diagnostic technologies, strengthening NTRL’s current organization structure, improving NTRL information management processes, and capacity building in laboratory information management and monitoring. Looking ahead, SIAPS will continue supporting NTRL on national laboratory systems strengthening initiatives and extend its technical assistance to the regional level where the focus will be on organizational strengthening, staff capacity building, and improving information management processes.

Improving Community Grassroots Health Leadership, Management, and Governance

To build the capacity of local government in community grassroots health leadership, management, and governance, the Quezon City Health Department (QCHD) and SIAPS introduced the Barangay Health Management Council (BHMC) in 2011 in selected barangays in the city. SIAPS provides technical assistance to QCHD and organized workshops for 12 BHMCs on the use of innovative practices and tools to improve their leadership management and governance capacity and effectively perform their functions including planning, implementation, monitoring and evaluation (M&E) of health programs, coordination of stakeholder activities, aligning stakeholders, and mobilizing resources. In its last year, SIAPS and QCHD will work together to increase the numbers of councils in the city.

Supply Chain Management Capacity Building

Under the Systems for Pharmaceutical Services (SPS) Program and in the initial years of SIAPS implementation, SIAPS focused on assisting the NTP on the management and use of second-line drugs (SLDs). In FY13, SIAPS was requested by NTP and USAID to extend its assistance to the management of first-line drugs (FLDs). Since then, SIAPS has been collaborating with the NTP on the overall management of TB medicines and laboratory supplies, particularly on strengthening the governance capacity of the organized drug supply management working groups, supporting the quantification of annual medicine requirements of FLDs and SLDs, assisting NTP in procurement through the Global Drug Facility framework, and building the capacity of the peripheral supply staff using the Practical Guide for the Management of Pharmaceuticals and other Health-Related Commodities (PGMP), which SIAPS helped produce.

SIAPS will continue focusing on institutionalizing the drugs and supplies management (DSM) governance structures at central and regional levels and use of technical guidelines and SOPs in its last year.

Strengthening Information Management Systems

In 2013, SIAPS was commissioned by NTP and USAID to do an assessment to understand the processes of information in the TB program. The SIAPS staff observed that a significant problem of the NTP information system was the
availability and utilization of quality data for decision making. Starting FY14, SIAPS worked with NTRL on developing SOPs for information management, and helping improve the skills of NTRL and BHMC technical staff improve skills on information management and utilization for decision making and planning.

**Pharmacovigilance System Strengthening**

To ensure patient safety for new multidrug-resistant TB (MDR-TB) medicines and novel regimens, SIAPS is collaborating with the FDA and working with other agencies in setting up a functional pharmacovigilance surveillance system, including developing and implementing SOPs and building the capacity of NTP and FDA staff on good pharmacovigilance practices, particularly on cohort event monitoring and reporting.

**KEY ACHIEVEMENTS**

**Laboratory Systems Strengthening**

- In 2011, SIAPS assisted NTRL in the establishment of an NTP laboratory working group, which resulted in improved national level coordination, cooperation, and collaboration among NTRL, NTP, and other TB lab stakeholders (Global Fund, other USAID-funded projects, WHO). It also harmonized donor and technical partner interventions in support of NTP laboratory services at the national level, and enhanced NTP capacity to manage TB diagnostic services themselves.

- Through the NTP laboratory working group, the NTP Laboratory Network Strategic Plan, a sub-plan of the Philippine Plan of Action to Control Tuberculosis (PhilPACT), was developed and approved for implementation in 2013.

- The policy for the use and scale-up of Xpert MTB/Rif implementation was developed by NTRL, with the technical assistance by SIAPS and other partners. NTRL used the policy to direct the expansion of Xpert MTB/Rif laboratories in the country. As of December 2014, there were 84 functional Xpert MTB/Rif laboratories (vs. 16 laboratories in 2011).

- The NTRL organizational structure was revised and enhanced in 2014 to include the redefined roles and functions of NTRL technical units, which aid NTRL in minimizing overlaps and improving work efficiency.

- The NTRL planning process was improved by incorporating the analysis of the TB burden in the country along with the review of NTP performance and TB diagnostic services, problem prioritization, and the formulation of effective and sustainable strategies.

- An improved laboratory network M&E system with indicators, plan, and tools has been developed in 2014. A training course on laboratory network monitoring to improve laboratory processes in monitoring and analysis of laboratory network performance was developed, and implemented by SIAPS in 2014 for selected NTRL national staff.
Improving Community Grassroots Health Leadership, Management, and Governance

In 2011, SIAPS, with the support of the QCHD, developed and implemented the BHMC), an initiative aimed at improving health program leadership, management, and governance at the (barangay) grassroots level. Through the BHMC, barangay officials, health workers, and community stakeholders are able to organize and coordinate their efforts to strengthen local health systems and improve TB control services. Using a team approach to health leadership, management, and good governance, BHMCs ensure broad stakeholder participation to develop focused plans that address their priority health problems.

The BHMC initiative was piloted in Barangay Payatas, an urban-poor community of 120,000 people, in 2011. As of September 2015, 12 BHMCs have been established in Quezon City covering 40 barangays and over 1 million population, many of whom are poor. The Quezon City government has also institutionalized BHMC by passing City Ordinance No. 2419 series of 2015 entitled “Establishing Guidelines for the Creation of a Barangay Health Management Council.”

The BHMCs have resulted in:

- Increased participation of the barangay leaders and collaboration with health personnel and program managers that has led to increased political and financial support for health programs.
- Increased barangay funding for diagnostic services, medical supplies, human resources, infrastructure improvements, and health promotion activities.
- Better coordination of program activities, and increased collaboration among partners and stakeholders. This increased collaboration has led to increased availability and sharing of resources, such as medical specialists (through the TB Diagnostic Committee), anti-TB medicines during shortages, infrastructure for remote smear testing stations, and other technical resources to support the programs requirements.
- Strengthened partnerships with groups working in the community, such as the schools, church, private practitioners, business groups, special interest organizations (e.g., groups for elderly, people with disabilities), and other NGOs.
- Improved management of other health programs, such as the maternal health, and child nutrition programs using the BHMC model.

Table 1. Case Finding Results in Payatas Public Health Centers, 2011–2014

<table>
<thead>
<tr>
<th>Number of Cases</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>% Change (2014 vs. 2011)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presumptive TB cases</td>
<td>925</td>
<td>1,179</td>
<td>1,283</td>
<td>1,389</td>
<td>50</td>
</tr>
<tr>
<td>Smear positive detected</td>
<td>103</td>
<td>127</td>
<td>146</td>
<td>121</td>
<td>17</td>
</tr>
<tr>
<td>Smear positive put on treatment</td>
<td>101</td>
<td>124</td>
<td>124</td>
<td>108</td>
<td>17</td>
</tr>
</tbody>
</table>
Supply Chain Management Capacity Building

Increased coordination for TB DSM at national, regional, and local government unit levels (through DSM working groups), which promotes discussion and information sharing among stakeholders. As of September 2015, there were no stock-outs of FLDs or SLDs at the national level. This was achieved through the regular collaboration of NTP with the Global Fund Principal Recipient on forecast, quantification, and deliveries.

Improved NTP capacity for supply chain management on forecasting and quantification using the QuanTB tool. In January 2014, QuanTB was adopted by the NTP to forecast SLDs for the Programmatic Management of Drug-Resistant TB (PMDT) and used its outputs for the procurement plans of 2014 to 2015. NTP has reported that the process of forecasting in QuanTB is more simplified and easy to use compared to the former tool. The early warning mechanism of the QuanTB tool also prompted actions to retrieve and redistribute near expiring medicines to prevent expiration and waste.

Improved capacity of national, regional, provincial, and health facility staff on supply chain management using the PGMP and job aids, a reference guide on standards in supply chain management. A total of 412 health staff in Region 4A, Region 8, Districts 2 and 3 in Quezon City, and NTP PMDT received training on PGMP.

From April to June 2015, 111 out of 164, or 68% of DOTS facilities in Region 4A have completed requisition for the next quarter based on current stock levels (vs. 0%) in March 2014. Moreover, in the one-year post-training monitoring done in Region 4A, there was marked improvement stock management in the DOTS facilities.

Table 2. DOTS Facility Stock Management Improvement

<table>
<thead>
<tr>
<th>Indicator (n = 14 DOTS facilities)</th>
<th>March 2014</th>
<th>September 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of DOTS facilities that keep and maintain stock cards</td>
<td>36%</td>
<td>100%</td>
</tr>
<tr>
<td>% of DOTS facilities with stock cards that correspond to actual physical count</td>
<td>14%</td>
<td>29%</td>
</tr>
<tr>
<td>% of DOTS facilities with system for monitoring expiration</td>
<td>34%</td>
<td>79%</td>
</tr>
<tr>
<td>% of DOTS facilities with pallets or shelves that keep stock off the floor</td>
<td>58%</td>
<td>79%</td>
</tr>
</tbody>
</table>

Strengthening Information Management Systems

SIAPS achievements in assisting the NTP to strengthening its information management systems, thus far include:

- Assessed the NTP information system and provided recommendations to improve information management and its use for decision making and planning.

- Developed SOPs for laboratory information management at the NTRL; this was approved and implemented by NTRL in 2014. SIAPS also developed the Laboratory Information Utilization course to improve the skills in the management and use of information for decision making. In
November 2014, 10 National NTRL staff (8 male, 2 female) were had taken the laboratory course.

- In June 2014, SIAPS developed and implemented the TB tracking tool in 10 facilities in District 3, Quezon City.

**Pharmacovigilance System Strengthening**

SIAPS is working with the NTP and FDA to establish a functional pharmacovigilance system in the country. Work on pharmacovigilance affairs only begun in 2013, but significant results have already been accomplished, including:

SOPs for active pharmacovigilance surveillance for the new MDR-TB and novel TB regimen studies were developed. The Philippines is one of the first countries to develop guidelines and SOPs.

SIAPS contributed to the development of nine-month MDR-TB and bedaquiline implementation guidelines. Twenty staff members from NTP, FDA, and national TB partners (10 male, 10 female) were trained on good pharmacovigilance practices and causality analysis.

**CONTRIBUTION TO USG GOALS**

SIAPS contributes to USAID Philippines’ goal of reducing the TB prevalence by improving the supply and demand of integrated family health services, and improving health policies and systems as well as the overall global health goal of universal health coverage, particularly ensuring medicines are available and accessible.

At the national level, SIAPS supported the delivery of quality TB services through the strengthening of NTP and NTRL leadership, management, and governance capacity focused on laboratory, supply chain, and information management systems; and through assistance in the scale-up of new rapid diagnostic technologies and introduction of novel TB medicines and regimens. The implementation of the BHMC model at the grassroots level fostered the increased accessibility of TB services and mobilization of communities for the demand of these services. By developing and enhancing policies and guidelines for TB control, in collaboration with NTP and other key TB stakeholders, SIAPS contributed to the strengthening of health systems critical for the delivery of quality services.

**LESSONS LEARNED**

When implementing new initiatives (i.e., BHMC), it is important to get the commitment and support of the key decision makers in the health services, field health workers, and community (e.g., LGU health authorities, barangay leaders) prior to the implementation of any activity. Advocacy for the decision makers and planners is critical. In national institutions such as the NTRL, the strong political will and cooperation of the organization’s leaders is needed to ensure that interventions are implemented as planned. In addition, by showing the results of the intervention, including the limitations, risks, and potential, we will be able to get the program managers’ cooperation and support.
We also need to strengthen our capacity to monitor and supervise the implementation, and be able to show the results of our interventions, including the development of customized indicators. This should be shared with the implementing partners.

SUSTAINABILITY

SIAPS health systems strengthening approach supports the US Global Health Initiative of ensuring stakeholder ownership and sustainability. Sustainability of the technical interventions are assured by these factors:

- Political: SIAPS technical strategies are implemented in response to key partners (NTP, NTRL, FDA) and USAID requests and priorities.

- Technical and institutional: Technical laboratory and pharmaceutical inputs are incorporated in NTP strategic plans, manual of procedures, and policies (e.g., Xpert/ MTB Rif scale-up, BHMC implementation).

- Financial: With the increased political and financial support of the local governments, BHMC scale-up in other districts in Quezon City is ensured.
BACKGROUND

Poor quality and counterfeit medicines are immediate threats to public health worldwide. Published studies indicate widespread availability of substandard medicines in the Greater Mekong Subregion (GMS) with the amounts increasing in recent years. The presence of illegal or banned malaria treatment medicines (oral artemisinin-based monotherapies [oAMT]) on the market leads to artemisinin resistance. To combat counterfeit and substandard medicines and the emergence of artemisinin resistance in the GMS, the President’s Malaria Initiative (PMI) has been supporting the activities of the USAID’s Promoting the Quality of Medicines (PQM) program, implemented by the US Pharmacopeial Convention, in the Mekong Subregion. The activities are geared toward strengthening medicine quality monitoring and technical capacity in national medicine quality control laboratories, information sharing, and other related activities.

The President’s Malaria Initiative (PMI), with funding provided by the USAID Regional Development Mission for Asia (RDMA) and the USAID Missions in Burma (Myanmar) and Cambodia, requested the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program to conduct a study of donor, country, regional, and other efforts to combat the availability of substandard and counterfeit medicines in the GMS, focusing specifically on Cambodia, Myanmar, Lao People’s Democratic Republic (Lao PDR), and Thailand. The study aimed to inform stakeholders, including PMI, other donors, host-country governments, and regional institutions, of what has been accomplished to date to address medicine quality, gaps, and possible opportunities for further programming.

ANALYSIS OF THE REGULATORY CAPACITY TO ASSURE THE QUALITY OF ANTIMALARIAL MEDICINES

Beginning in 2013, SIAPS conducted a review of regulatory and quality assurance efforts in the GMS with the following objectives: (1) to inform PMI of past and current initiatives to improve the region’s capacity to combat counterfeit, substandard, and banned antimalarial medicines; (2) to understand the current barriers to effective medicine quality control for malaria; and (3) to recommend specific areas of focus or interventions to further improve regional and country capacity to combat counterfeit, substandard, and banned or illegal antimalarial medicines.
Key stakeholders for this analysis include: Ministries of Health, Justice, and Industry; National Medicines Regulatory Authority; National Medicines Quality Control Laboratory; law enforcement, customs, and border control agencies; health professional, country trade, and regional associations; regional economic forums; WHO and other donor agency representatives; academic and research institutions; and key USAID implementing partners.

From November 2013 to June 2014, SIAPS and in-country consultants conducted an analysis through a desktop review of over 350 published and unpublished official documents, studies, and reports; key informant (telephone or face-to-face) interviews with 11 regional and 32 country experts, including pre-in-person questionnaire surveys of stakeholders, as appropriate; and local site visits. Findings and recommendations result from information gathered through both the desk review and the key informant interviews.

FINDINGS AND RECOMMENDATIONS

Key Findings

The assessment identified several factors contributing to antimalarial resistance in GMS, including weak medicine regulatory systems, unknown product quality and characteristics, market factors, lack of patient adherence, and insufficient health provider knowledge and inadequate practice. Based on these factors, this study reports findings, including identified obstacles, related to the current status of: policy and regulatory frameworks; regulatory action on oAMT; institutional regulatory and quality assurance capacity; enforcement of GMP and supply chain standards; product quality testing and post-market surveillance; and counterfeit medicine control actions.

Major findings were initially presented for validation by key local government staff in March 2014, and thereafter presented to USAID. SIAPS developed the final report, which was reviewed by USAID and finalized in March 2015.

Key Recommendations

The recommended interventions to USAID, stakeholders (including PMI), other donors, host-country governments, and regional institutions target the key contributing factors of artemisinin resistance. Notably, they collectively require the development of comprehensive approaches to ensure that regulatory and access interventions are mutually supportive, while the pharmaceutical regulatory system is strengthened to establish resilience.

Continue to strengthen medicine regulatory and quality assurance systems and enforcement capacities. Sub-recommendations include:

- Support technical capacity building
- Encourage and support country participation in the WHO Good Governance for Medicines program
- Assist in updating or revising appropriate policies, laws, and regulations
• Strengthen governance structures

• Assist in identifying, planning, advocating for, and establishing sustainable sources of revenue that will contribute to growing country and institutional ownership of financing the regulatory and quality assurance system

• Support country capacity to engage in regional police enforcement initiatives to combat fake or counterfeit medicines

• Support intercountry collaboration and information exchange in the GMS

Support to develop individual country strategy and implementation plans for Asia Pacific Leaders Malaria Alliance (APLMA) recommendations. Sub-recommendations include:

• Undertake comprehensive stakeholder mapping and developing an engagement plan

• Determine priority actions and realistic target outputs and outcomes

• Assess short- and medium-term feasibility (legal framework, expected political commitment/support, operational requirements, budgetary needs)

• Mobilize financial and potential technical assistance resources

• Ensure that APLMA-endorsed recommendations are aligned with other options for the way forward

Continue to coordinate PMI (and other USAID) GMS regulatory and quality assurance technical support with other development partners and initiatives, particularly WHO and APLMA.

• PMI and USAID, which have been supporting those involved with country antimalarial resistance containment capacity building activities in the GMS, will continue to play this important role and should have a coordinating role as with the APLMA initiative.

Complement regulatory strengthening with improved access to quality antimalarial medicines. Sub-recommendations include:

• An integrated approach linking regulation with a market or distribution channel should be explored. Such an approach should target (1) areas where resistance has been documented (geographically remote and border areas) and (2) vulnerable population subgroups (the poor and migrant populations)

• A complementary regulatory-market access approach would have the following components:
  • Regulations that support (minimum) standard quality infrastructure and services in target geographic areas and their appropriate enforcement by local authorities
  • An uninterrupted supply of quality ACT products to outlets or
services acceptable and accessible to the community (high-risk group)

- Subsidized prices to facilitate product affordability
- Training of appropriate (diagnostic and) treatment management to public and private providers
- Incentives to private providers and retailers
- Behavior change communications to providers and consumers

**CONTRIBUTION TO USG GOALS**

This assessment outlines a strategy to strengthen the regulatory and quality assurance systems in the GMS region. Strengthening the regulatory system through the legal system, regulatory, and quality control agencies, as well as good drug policy enforcement are critical steps in eliminating counterfeit and substandard antimalarials and halting the production and use of oAMT in the region. Doing so will directly improve regional efforts to treat malaria among vulnerable populations, particularly pregnant women and children. Reducing illness and deaths in mothers and women by increasing the availability and quality of ACTs contributes towards ending preventable maternal and child deaths, as well as protecting communities from infectious diseases.
South Africa, which is implementing the largest antiretroviral therapy (ART) program in the world, has more than two million patients on ART. In 2013, nearly 1% of the country’s 50 million residents, (roughly 450,000 people\(^1\)) had developed active tuberculosis (TB). Communicable diseases are the leading cause of death for children under five.\(^2\) In addition, more than 70% of the population receives their care from public health care facilities,\(^3\) all of which puts extreme pressure on the government to ensure uninterrupted availability of essential medicines, including antiretrovirals and vaccines. In this context, suboptimal stock management and irrational use of medicine has serious public health implications with the potential to undermine all progress made against HIV and AIDS, TB, and in reducing mother and child mortality. Furthermore, limited leadership and management at the provincial, district, and facility levels have compounded the challenges surrounding access to essential medicines.

The overall goal of South Africa’s SIAPS Program is to strengthen the capacity of pharmaceutical systems at all levels to support the government’s priority health programs and initiatives to improve health outcomes. The program aims to include strengthening pharmaceutical sector governance, enhancing capacity for pharmaceutical supply management and services, improving use of information for decision making for pharmaceutical services, improved access to medicine, improved availability of medical products, and improved rational use of medicine and patient safety.

**KEY INTERVENTIONS**

SIAPS works closely with the National Department of Health (NDOH) and government counterparts at the national, provincial, district, and facility level to address challenges through the following key interventions.

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Governance

Since the inception of the program in South Africa, SIAPS has collaborated with the National Department of Health (NDOH) to strengthen pharmaceutical systems governance through the development of key policies, guidelines, norms, and contractual documents. These documents include a national policy on pharmaceutical and therapeutic committees, contractual documents for the Central Chronic Medicine Dispensing and Distribution (CCMDD) program, and revised criteria for the awarding of licenses to pharmacies. SIAPS South Africa interventions to strengthen governance are an essential component of all interventions.

Pharmaceutical Leadership and Development Program

SIAPS interventions under the Pharmaceutical Leadership and Development Program not only improves individual’s technical pharmaceutical knowledge, but also provides sound leading and managing practices to better equip pharmacy managers to respond to challenges in their work environment and improve service delivery.

SIAPS’ Pharmaceutical Leadership and Development Program (PLDP) presents a novel approach by combining technical pharmaceutical knowledge with sound leading and managing practices to better equip pharmacy managers to respond to challenges in their work environment and improve service delivery. At the request of the Provincial Heads of Pharmaceutical Services, the PLDP was first introduced in South Africa in 2011 and since then, has been implemented in seven of South Africa’s nine provinces. The SIAPS Program expanded the PLDP to the North West, KwaZulu-Natal (KZN), and Limpopo provinces, and provided the Leadership Development Program (LDP) in the Western Cape. Workplace-based teams use information gained during the workshops to address real workplace challenges and produce measurable results. Inspired by a shared vision of what they can accomplish, participants gain confidence in their ability to lead, manage, and produce results. Through the PLDP/LDP, leadership and management capacity has been strengthened, and pharmaceutical service delivery in the provinces has improved.

RxSolution

The South African government identified the need to optimise pharmaceutical management at the facility level by implementing an electronic system which would support informed decision making at all levels. Strengthening structures and systems that ensure the availability of pharmaceutical information for decision making is central to SIAPS’ goal. To that effect, SIAPS South Africa has continued supporting the implementation of RxSolution®, an electronic pharmaceutical management system used to manage inventory, down referral, and medication dispensing. The system was introduced in South Africa under RPM Plus Program. The system facilitates electronic management of pharmaceutical inventory while enabling users’ easy access to trends on consumption and other information.

Rational Medicine Use
Pharmacy and therapeutics committees (PTCs) are designed to ensure the safe and effective use of medicines in health facilities. Since 2012, SIAPS South Africa has supported the development and standardization of PTCs. It has used guidelines, standards, and policies to harmonise the structure, functions, functionality, and communication strategy across the provinces, districts, and facilities. SIAPS strengthens the role of PTCs in monitoring and analysing pharmaceutical expenditures and making evidence-based decisions to identify cost saving interventions. In addition, SIAPS builds capacity on rational medicines use at the pre- and in-service levels, through mentoring, training, and reforming university curricula.

**KEY ACHIEVEMENTS**

**Governance**

To date, SIAPS has facilitated or contributed to the development, review, revision, and finalization of 17 policy documents promoting good governance, including revised criteria for issuing of pharmacy licenses, the National Policy for the Establishment and the Functioning of Pharmaceutical and Therapeutics Committees, and the National Contraception Clinical Guidelines. In addition, SIAPS helped strengthen the contractual agreements between the provincial warehouses (depots) in South Africa and their respective clients. SIAPS has supported the implementation of the Central Chronic Medicines Dispensing and Distribution (CCMDD) Program, for which it developed the M&E framework that will help routine tracking of the program, as well as serve as a mechanism to monitor the performance of service providers.

SIAPS, in coordination with the NDOH, has been an integral part of the implementation of a new method of electronic tender bid submission. The new format reduces manual data capture and improves management of bid information.

SIAPS helped formulate a guidance document that can be used to develop or review terms of reference (TOR) for any pharmaceutical sector committee. The guidance document is being used to review the TORs of various national committees including the National Essential Medicines List (NEML) Committee and the committee responsible for evaluating bids for pharmaceutical product tenders.

With assistance from SIAPS, the NDOH has developed and implemented a national dashboard to monitor the provision of pharmaceutical services and compliance to standards relating to rational medicines use, access, availability, financing, and human resource management. Four domains, cutting across the WHO health system building blocks, with a key role in supporting service delivery were identified: rational medicines use and patient safety; financial management; medicine supply management and human resource management. In addition, 42 norms and standards were developed at input, process, output, and outcome levels. The dashboard has provided the NDOH with a mechanism to assess the provision of pharmaceutical services across the provinces, thus promoting transparency and accountability. Governance, financial management and supply chain management are being strengthened and accountability improved.
The Pharmaceutical Leadership and Development Program (PLDP) has not only built individual capacity of health care providers, but strengthened institutional capacity at the health service delivery level. The interventions implemented under SIAPS have resulted in a wide range of individual, organizational, and health service delivery outcomes, including improved quality of service provision, medicine availability and accessibility, patient safety and compliance, and patient experience; increased rational use of medicine; and enhanced organizational capacity. By the end of September 2015, 261 pharmacists, clinical managers, and facility managers had completed the LDP/PLDP.

### Table 1. Examples of District Level LDP/PLDP Achievements

<table>
<thead>
<tr>
<th>District /Province</th>
<th>Measurable Result</th>
<th>Baseline</th>
<th>Endline</th>
</tr>
</thead>
<tbody>
<tr>
<td>eThekwini South District, Kwa-Zulu Natal (KZN) Province</td>
<td>100% reporting on stock-out and expired medicine data elements by 15 PHC clinics</td>
<td>67% of Primary Health Care (PHC) clinics reporting on PHC stock-outs (2013)</td>
<td>100% reporting on medicine stock-outs (TB, tracer, and ART medicines) (2014)</td>
</tr>
<tr>
<td></td>
<td>33% reporting on expired medicines (2013)</td>
<td>100% reporting on expired medicines (2014)</td>
<td></td>
</tr>
<tr>
<td>uMgungundlovu District, KZN Province</td>
<td>Reduce the % of chronic repeat prescription cards containing inappropriately prescribed items to less than 40%</td>
<td>76% of chronic repeat prescriptions cards had inappropriately prescribed medication (2012)</td>
<td>26% of chronic repeat prescriptions cards had inappropriately prescribed medication (2013)</td>
</tr>
<tr>
<td>Gugulethu CHC, Western Cape Province</td>
<td>Turnaround time is &lt; 3 hours for 75% of the chronic diseases of lifestyle (CDL) patients on appointment date</td>
<td>54% of the CDL patients spend &gt; 3 hours in the facility on their appointment date (2014)</td>
<td>90% of the CDL patients were leaving the facility within 3 hours (2014)</td>
</tr>
<tr>
<td>Dr. Ruth Segomotsi Mompati, North West Province</td>
<td>Increase the number of patients initiated on isoniazid preventive therapy per month</td>
<td>Average of 3 patients per month (Apr–Aug 2012)</td>
<td>Average of 8 patients per month (Sep 2012– Jan 2013)</td>
</tr>
<tr>
<td>Ngaka Midiri Molema District, North West Province</td>
<td>Improve compliance with NCS measures in 10 PHCs from 33% to 60%</td>
<td>33% average compliance with NCS in 10 PHCs (2012)</td>
<td>77% average compliance with NCS in 10 PHCs (2013)</td>
</tr>
</tbody>
</table>

A striking example of a health service delivery achievement is found in the eThekwini South Service Area in KZN. The 2012 annual review of the District Health Information System (DHIS) highlighted poor reporting by PHC facilities on data relating to medicine stock-outs and expired medicine. This information is necessary for planning and decision making at district, provincial, and national levels. The PLDP team from eThekwini South implemented a quality improvement initiative to improve reporting of these data elements at the 15 PHC clinics. Interventions were introduced including strengthening the system for monitoring and reporting of data; strengthening the data validation process; and the training of PHC and pharmacy personnel on data elements, their collection, and interpretation of information generated. Following these interventions, reporting on medicine stock-outs (TB, tracer, and ART medicines) improved from 67% to 100% during the period August to December 2013. Reporting on expired medicines also improved from 33% to 100% during the same period. In addition, the reporting on ART and TB medicines improved from 53% to 100%, and 27% to 100% respectively.
Based on the success of the PLDP, an expanded team was created in eThekwini to implement another quality improvement intervention. This was part of the PLDP sustainability initiative, conducted in KZN over the period of a year starting in August 2014. Using the PLDP tools and approach, the team scanned their environment and identified the establishment of a district PTC as a key enabler for organizing and focusing the use of limited resources for medicine to improve health outcomes. Following the mobilizing and alignment of key stakeholders, the eThekwini South PTC was formed and its members trained on the terms of reference (TOR). An operational plan and communication protocol to streamline communication on out-of-stock medicines were developed, implemented, and monitored using a cooperative approach.

**Rx Solution**

RxSolution is a flagship project of SIAPS South Africa. By the end of September 2015, RxSolution had been implemented in 395 health facilities in 8 of the 9 provinces across the country. RxSolution is currently able to interface with the following systems:

- **Remote Demander Module (RDM):** software used by facilities (mostly hospitals and large clinics) to place orders with the depot system, MEDSAS. This interface allows demanders to create orders from RxSolution and to import them into RDM before sending them to MEDSAS.

- **RxPMPU:** a system developed by SIAPS that supports the processing of electronic orders from facilities using the direct delivery procurement model currently being implemented by the NDOH.

In 2014, the NDOH endorsed RxSolution as a tool for the management of pharmaceutical inventory. Training on RxSolution has been integrated into the pre-service curricula for pharmacists and mid-level pharmacy personnel at the Nelson Mandela Metropolitan University (NMMU) since February 2014.

**Rational Medicine Use**

SIAPS South Africa has supported the establishment and strengthening of governance structures to promote rational medicines use. In May 2013, the Gauteng Provincial PTC, with technical assistance from SIAPS, developed the *Guidelines for Implementation of PTCs* in an attempt to harmonise the role of district and facility PTCs and promote rational medicine use as a key function. Within Gauteng, the West Rand District PTC used the tool provided by the guidelines to implement a medicine use evaluation. The use of cefixime, an antibiotic, was assessed at primary health care level. The findings from the evaluation were presented to the district PTC. Actions implemented resulted in a decrease in expenditure on this antibiotic.

SIAPS has supported the institutionalisation of rational medicine use in undergraduate and post-graduate curricula. Under the Strengthening Pharmaceutical Systems Program, an elective module on PTC was developed for fourth year pharmacy students at the NMMU Pharmacy School. SIAPS collaborated with NMMU to update the course material and increase the focus
on rational medicines use. In 2015, the PTC module was integrated in the core curriculum of the Bachelor of Pharmacy for third-year students. SIAPS worked with the University of Western Cape (UWC) School of Public Health and School of Pharmacy on the development and implementation of the first Rational Medicines Use online course. The course is an elective module in the Master of Public Health program at UWC but can also be taken as a stand-alone course. The course was successfully launched in July 2015, and has been entirely handed over to the UWC.

To date, SIAPS South Africa has provided technical assistance with the development or updating of the Adult Hospital Standard Treatment Guidelines and Essential Medicines List; Guidelines for Implementing PTCs; and a National Strategy Framework for Antimicrobial Resistance (AMR) 2014-2024.

**CONTRIBUTION TO US GOVERNMENT GOALS**

SIAPS South Africa interventions are closely aligned with the PEPFAR 3.0 agenda on impact, sustainability, partnership, and efficiency, and also contribute to the US Government goals of achieving an AIDS-free generation, protecting communities from infectious diseases, ending preventable child and maternal deaths, and increasing universal health coverage. SIAPS has developed and strengthened systems using tools, such as RxSolution, to improve access to and management of medicines, including ARVs. By strengthening the leadership and management capacity of health care workers, pharmaceutical service delivery is improved. SIAPS has worked with universities to institutionalize pharmaceutical management in both under and post graduate curricula.

Promoting rational medicines use and the systematic use of pharmaceutical management information for decision making has also helped improve medicines availability and strengthen pharmaceutical services, both of which are essential to achieving desired health outcomes. A common thread through all SIAPS South Africa work is the fostering of partnerships by actively engaging with stakeholders at the national, provincial, district, and facility levels.

**LESSONS LEARNED**

Lessons learned from the implementation of various interventions, including the PLDP and LDP, have illustrated the importance of the stakeholders assuming ownership for the introduction and rollout of any system strengthening intervention. In addition, it is imperative that there is a clear understanding of the current situation, as well as the desired end point before any work commences. Quality time must be spent on the design of the approach to be used, whether it is the rollout of a tool such as RxSolution or conducting of a medicine use evaluation in a province. The identification, mobilization, and alignment of stakeholders are also essential to the success of any intervention. SIAPS South Africa has learned that involvement of counterparts in the design of interventions and co-creation of any tool or product are also essential contributors to success.

Challenges experienced in the rollout of RxSolution have included a lack of buy-in for the implementing and use of systems, as well as a lack of support from Information Technology divisions in facilities, districts, and provinces.
Furthermore, failure to define roles and responsibilities clearly, although a critical success factor for all projects, is of paramount importance in the implementation of a new electronic system. Experience has shown that technical capacity building was not sufficient in the implementation of RxSolution and needed to be supported by strong leadership and careful change management. SIAPS South Africa will be using lessons learned, as well as principles and practices learned, in the PLDP/LDP to strengthen interventions aimed at using electronic systems to provide information to support decision making.

**SUSTAINABILITY**

SIAPS South Africa has ensured efforts for sustainability are embedded in all project activities. This is done largely through facilitating ownership by the national and provincial governments.

- The intervention to promote rational medicine use has institutionalised the governance structures: the NDOH has taken full ownership of PTCs and rational medicines use activities; the reformed curricula are being transitioned to the respective universities.

- The implementation of RxSolution has been endorsed by the South African government. SIAPS will continue to capacitate identified personnel to support the installation and maintenance of RxSolution to ensure sustainability of the system.

- SIAPS encourages and supports the provinces and districts to scale up and sustain the quality improvement initiatives implemented in the PLDP. This encourages country ownership and the expansion and institutionalization of the program. SIAPS has had distinct examples of sustained interventions from the Western Cape and KZN Provinces, including the standardization of practices, institutionalization, and replication of programs, resource mobilization, and maintenance of networks for continued support and learning.
South Sudan has one of the highest maternal mortality rates in the world, estimated at 2,054/100,000 live births.\(^1\) Although close to 46.7%\(^1\) of pregnant women attend at least one antenatal clinic (ANC) visit, only 14.7% of deliveries are attended by skilled health professionals. A number of reasons have been attributed to this low turnout, including a lack of confidence in the health system, caused by chronic stock-outs of commodities, poor access due to long commutes to health facilities, inadequate human resources both in terms of skills and numbers, and poor infrastructure.

In 2012, HIV prevalence among persons aged 15-49 was estimated at 2.66%.\(^2\) Approximately 152,000 people are living with HIV (130,000 adults and 20,000 children under 15 years of age), and an estimated 16,000 new infections occur annually.\(^2\) As of December 2014, only 15,700 people living with HIV were on antiretroviral therapy (ART). There are 16 ART sites (15 supported by PEPFAR) and 19 prevention-of-mother-to-child transmission (PMTCT) sites in the country.

The uptake of malaria prevention and curative interventions remains unacceptably low—only 12% of malaria patients are treated with artemisinin-based combination therapy (ACTs) within 24 hours of fever onset. In addition, the majority of malaria cases are treated clinically without parasitological laboratory confirmation. Contributing factors to the malaria problem include weak planning and coordination mechanisms, especially at state and county levels, frequent stock-outs and changing epidemiological patterns of malaria, especially among the Internally Displaced Populations (IDP).

The long conflict in Sudan disrupted the health system leading to considerable weaknesses and gaps in all aspects of the pharmaceutical system. The primary goal of the South Sudan SIAPS program is to ensure the availability of quality pharmaceutical commodities, such as ACTs, ARVs, family planning (FP), and other essential products, and effective pharmaceutical services to achieve desired health outcomes, such as preventing maternal and child deaths, and malaria deaths and contributing to an AIDS-free generation.

\(^1\) Sudan Household Health Survey

\(^2\) SSAC; Universal Access Report 2010, Scaling Up HIV/AIDS Response, South Sudan
KEY INTERVENTIONS

Improving availability of Essential Medicines through Strengthening Governance and Stakeholder Coordination within the National Supply Chain and Pharmaceutical Sector

Following the 2010 pharmaceutical sector assessment, a number of gaps including weak medicine regulations environment, presence of poor quality medicines on the market, absence of national medicines policies, case management guidelines for diseases such as malaria, and tools for essential medicines management at health facilities were identified. In collaboration with the MOH Directorate of Pharmaceutical Services, SIAPS reviewed the current regulations for import of medicines and proposed the formation of a Food and Drugs Authority and development of guidelines for licensing private sector dispensing units.

SIAPS also conducted a mapping of all stakeholders within the South Sudan’s supply chain to ascertain the causes of frequent stock-outs and expirations of commodities, and channels of distribution used by the numerous stakeholders. The analysis found that there were several parallel and uncoordinated supply sources and distribution channels in the country, leading to duplication of efforts, and understocking and overstocking of commodities at health facilities. After engaging MOH officials; USAID partners, such as the Integrated Services Delivery Project (ISDP); other donors, such as the World Bank-funded Health Pool Fund project; NGOs; and state ministries of health management teams; SIAPS and MOH set up functional pharmaceutical technical working groups (PTWG) to provide oversight for all pharmaceutical and supply chain-related activities. The PTWG oversees and coordinates national level forecasting, quantification, and procurement of all medicines and health commodities. To address the gaps in essential medicine supply, results of national forecasting and quantification exercises are shared at the PTWG, individual distribution plans are also shared which enables stakeholders to confirm sources of funds for procurements and distribution gaps to be addressed on a continuous basis.

Because of essential medicines overstocking at several health facilities, there was a need to free up space. SIAPS lead the process of designing a checklist for dejunking such facilities and ensuring that expired products were appropriately disposed.

Addressing the Need for Data for Strengthening the Pharmaceutical Sector

As a result of tremendous instability in South Sudan, the health system information and reporting systems were all down. After attaining independence in 2011, use of data for decision making in supply chain management had been low, because of the absence of necessary data collection tools and infrequent data submission even where tools were available, causing stock-outs of HIV, malaria, and other essential medicines and commodities. The pharmaceutical sector report also highlighted the need for the MOH and Directorate of the Pharmaceuticals to improve the information management system through establishing a centralized database system to track information on commodity availability and use.

SIAPS worked with the MOH and key stakeholders to review, harmonize, and print and disseminate the Pharmaceutical Management Information Systems
(PMIS) tools to all 10 states of South Sudan. SIAPS using USAID funds and leveraging other donor funds conducted capacity building on the tool’s use in these states to ensure that all commodities were well stocked and accounted for.

To improve the quality of and increase use of data for decision making, SIAPS supported the MOH and PTWG to set up a Logistics Management unit which compiles monthly stock status reports on 22 tracer essential medicines using the tools developed and disseminated. SIAPS also worked the Juba Teaching Hospital Antiretroviral Treatment Center, the largest ART center to install the Electronic Dispensing Tool (EDT).

Improving Human Capacity Pharmaceutical Services through Trainings and Supportive Supervision

South Sudan suffers from a persistent lack of requisite number of health workers. In addition, some of these workers have demonstrated poor skills in administering supply chain management and information tools, which prevents completion, accuracy, and timely submission of reports resulting in stock-outs, overstock, or understock of medicines and commodities. The MOH requested SIAPS’ assistance to improve the human capacity of health care workers at all levels. The 2010 pharmaceutical sector assessment report highlighted the need for the establishment of a pharmacy school. While this long-term goal is being pursued, a set of in-service trainings were designed by SIAPS in collaboration with MOH and key stakeholders to start building the capacity of existing pharmaceutical sector human resources.

SIAPS developed a standard MOH-led training manual to be used by all donors in delivery trainings to pharmaceutical cadres. SIAPS conducted a number of training of trainers and supported trainings through partners like the ISDP, Health Pool Fund (HPF), and Interchurch Medical Assistance. In addition to the training of trainers TOTs, SIAPS conducted supportive supervisory visits on a quarterly basis to health facilities in the Central and Western Equatoria regions of Sudan where on-the-job training and support was given to staff to implement their post-training action plans. In addition, SIAPS, using USAID funds, embedded a technical advisor at the State Ministries of Health of Central and Western Equatoria and in the National Malaria Program to provide continuous support to new trainees for a period of time.

Scale Up of Malaria Interventions Better Coordinated and Documented

Gaps in funding have increased for key health program areas, such as malaria, leading to negative effects on services and expansion of program interventions. SIAPS has worked with the various health programs to prioritize funding and commodity needs, based on assessments and quantification exercises undertaken in collaboration with the various disease programs.

In particular, SIAPS supported the setting up of National Malaria Control Program (NMCP) and, in collaboration with MOH, recruited and trained a South Sudanese who is the current Program Manager. SIAPS supported the NMCP to set up three sites for monitoring therapeutic efficacy of antimalarial medicines. SIAPS worked with the program to develop the Malaria Indicator Survey, annual
malaria procurement supply and distribution plans, and other relevant information that were prerequisites for the successful completion of proposals for the Global Fund grants. SIAPS Malaria Technical Advisor embedded in the NMCP provides technical support in program work and took the lead in developing National Malaria Control Policy.

To address the high incidence of irrational use of antimalarial medicines, SIAPS supported the development of National Malaria Case Management guidelines and conducted capacity building for malaria personnel. The pharmaceutical sector report mentioned the current challenges with storage. An in-depth analysis of the storage situation indicated that the stores were mainly filled with expired commodities results from the push mode of distribution. To address this SIAPS embarked on a process of dejunking warehouse at all counties within the Central and Western Equatoria states to facilitate the storage of antimalarials, long lasting insecticide treated nets (LLINs), and essential medicines.

**KEY ACHIEVEMENTS**

**Improving Availability of Essential Medicines through Strengthening Stakeholder Coordination within the National Supply Chain**

Following SIAPS support with drafting the bill and collating and synthesizing stakeholder views, the South Sudan Drug and Food Control Authority Act was passed in 2012 and the authority established in 2013. This body is charged with the regulation of medicine and food. Two Mini-Labs were procured and installed at Nimule and at the Juba Airport, and five staff trained to assess quality for imported pharmaceuticals at these sites.

A Pharmaceutical Technical Working Group (PTWG) has been set up and meets at least once a month; this has effectively provided a platform for MOH and stakeholders to address the uncoordinated and parallel supply chain challenges. As a result of the PTWG work, coordination of the procurements and distribution of the World Bank, European Union, and USAID, funded antimalarials, long-lasting insecticide treated nets (LLINs) are discussed weekly through a sub-committee of the PTWG. A joint national distribution plan with stakeholder inputs for essential medicines and antimalarials is continually produced and reviewed with stakeholder input. SIAPS role as a secretariat of the PTWG is effectively being transitioned to the MOH

**Addressing the Need for Data for Decision Making in the Pharmaceutical Sector**

A logistics management unit (LMU) has been set up with a government appointee as local manager. Currently, 391 health facilities in South Sudan provide monthly stock status reports to the LMU for analysis and reporting to the PTWG. SIAPS conducted training on LMIS tool use and inventory management for 821 staff members of MOH and NGOs implementing supply chain activities at the lower levels of the health system. Several other NGOs and donors have adapted the tools and have cascaded trainings to other staff at lower levels of the health system in the states that SIAPS does not work in. SIAPS also worked in collaboration with the Venture Strategies Innovations (VSI) project to quantify misoprostol needs.
and train health care givers on the use of inventory tools to track stock status of misoprostol during its pilot use in the Central and Western Equatoria States.

The EDT has stock status data for all antiretrovirals used at Juba Teaching hospital which accounts for 60% of ART cases in South Sudan. The EDT data will improve quantification and forecasting of ARVs in South Sudan.

**Improving Human Capacity for Supply Chain and Pharmacy Services through Trainings and Supportive Supervision**

SIAPS has trained over 821 staff of the MOH and NGOs on pharmaceutical management. Follow on support supervisory visits showed that 61% of participant visited had followed up on action plans developed during trainings. Over a period of four years, ten supportive supervisions were conducted with state MOH counterparts to reinforce lessons learned through on-the-job mentoring. SIAPS had provided training for 171 sentinel sites staffs to improve malaria case detection and reporting.

**Scale-up of malaria interventions accelerated, better coordinated, and documented**

As a result of SIAPS interventions in South Sudan, the county now has a fully operational National Malaria Control Program. SIAP has successfully supported the NMCP and MOH to write Global Fund proposals to successfully raise funds through a Global Fund consolidated grant of over $97.6 million for malaria activities and commodities.

SIAPS has successful dejunked 16 out of the 17 county stores of expired antimalarial and other essential medicines to free up storage space.

**CONTRIBUTION TO USG GOALS**

All SIAPS work plans and activities have been focused on making available essential medicines such as antimalarials, oral rehydration salts, providing support to procurement and distribution of oxytocin and misoprostol to reduce maternal complications and death due to postpartum hemorrhage are guided by the overall arching goal of Ending Preventable Child and Maternal Deaths. SIAPS-supported interventions, such as assisting with condom distribution, and ensuring the availability of information for decision making on ARVs at the ART center at Juba Teaching Hospital all contribute to achieving the AIDS free generation goal. Through the scale-up of malaria interventions, SIAPS is supporting distribution of LLINs to pregnant mothers and children under five in Central and Western Equatoria states, in addition to quantities of ACTs that have been procured for distribution in FY16, contributing to the USAID goal of Protecting Communities from Infectious Diseases.

**LESSONS LEARNED**

- Involving the MOH personnel as the leaders and champions of intervention implementation improved ownership activities to the MOH at the national and state levels.
• Embedding SIAPS staff in the South Sudan State Ministry of Health and at the NMCP is a comprehensive mechanism for initiating and institutionalizing capacity improvements.

• Developing standardized tools in collaboration with development partners and in-country stakeholders facilitates the uptake and system-wide adoption of tools.

• Setting a centralized LMU unit with local leadership to provide feedback on data quality and on stock status provides the elements for sustainability post project.

**SUSTAINABILITY**

SIAPS South Sudan will use its comparative advantage of embedment within MOH programs to leverage resources of other partners and improve coordination with the MOH and its implementing partners to address the wider challenges in the above priority areas. NMCP’s program manager, who is a MOH staff member, provides day-to-day management to the program. The same holds true with LMU, which is headed by a ministry director. All partner-seconded staff members are under the leadership of the director who will continue to run the unit even after SIAPS Program is phased out.

SIAPS has encouraged country ownership and continues to leverage key multilateral organizations and other USAID partners’ resources, where possible, to ensure accelerated results and sustainability. Learning and accountability has been promoted through effective M&E of activities and results.

All the SIAPS activities are implemented within the Ministry of Health Directorate (Pharmaceuticals, and Preventive Services); the respective programs, such as National Malaria Control Program; LMU in the Pharmaceuticals Directorate; and the ART Centre in Juba Teaching Hospital are in direct leadership role; SIAPS providing only technical support to these programs.
Swaziland has the world’s highest HIV prevalence of 26% for the reproductive age group 15–49; 31% among women aged 18–49 years. The government of Swaziland adopted the decentralization strategy to HIV treatment and care services in 2010. This strategy allows rural patient’s easier access to ARVs, permits 80% of accredited public health facilities to initiate care and treatment, and has introduced the nurse ART initiation approach. The annual HIV incidence rate among 15–49 years is expected to decline from 2.9% in 2011 to 1.9% in 2015. The country has rapidly scaled-up the provision of ARVs in the past four years. The treatment guidelines for HIV have been updated twice in the past 4 years—expanding the eligibility criteria and introducing new drugs and formulations. These have placed enormous pressure on the country’s pharmaceutical services, health sector budget, supply chain system and human resources for health.

Product availability remains a key focus area for government and partners. The government is procuring 100% of the ARVs required and offering them free of charge to all Swazi citizens. The government has also introduced various technologies, such as CD4 point of care devices to improve HIV diagnosis and monitoring of treatment outcomes. However, TB/HIV co-infection has presented a more serious threat to the country’s efforts to fight HIV and also improve the quality of life of its citizens. Over 74% of TB patients are co-infected with HIV.

The goal of the SIAPS program in Swaziland is to assure 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 the governance of the pharmaceutical sector, increasing capacity for pharmaceutical supply management and services, improving use of pharmaceutical information for decision making in supply chain, improving product availability and rational use of HIV/TB commodities, and promoting patient safety. All interventions are designed and implemented as guided by

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2. Swaziland Demographic and Health Survey, SDHS 2006/7
4. The Health Sector Response to HIV/AIDS Plan 2014 - 2018
KEY INTERVENTIONS

SIAPS works closely with the Government of the Kingdom of Swaziland, local counterparts, development partners, and training institutions to implement the pharmaceutical systems strengthening strategies. The following are the main interventions implemented in the past four years of the program:

Governance

In Swaziland, the Pharmacy Act of 1929 has been the only law that governs the practice of pharmacy with few provisions on the control of medicines. This presented a gap that SIAPS has worked to address in an effort to ensure improved medicine therapeutic effectiveness of ARVs, TB commodities. SIAPS has over the year advocated for and provided TA to MOH to facilitate enactment of two bills namely: Medicines and Related Substances Control Bill no. 7 of 2015 and the Pharmacy Bill no. 8 of 2015. SIAPS worked with a diverse mix of stakeholders including community members, politicians, and health and legal professionals in the drafting the Pharmacy bill (which will repeal the Pharmacy Act of 1929), and the Medicines and Related Substances Control Bill. Inter-ministerial (Ministry of Health, Ministry of Justice, Ministry of Agriculture, and Ministry of Labor) engagements have also been carried out to ensure that all government institutions affected by the bills had an opportunity to provide input on them. The MOH Pharmaceutical Sector Strategic Plan was developed in the first year of SIAPS, and this plan served to guide the five year activities of SIAPS in Swaziland.

Pharmaceutical Pre-Service Training

SIAPS pharmaceutical human resource interventions were implemented to improve the supply and skills of health workers responsible for medicines management and pharmaceutical services. Two service training programs, a two-year certificate program in pharmacy and a three-year academic diploma program, were developed in collaboration with local universities, MOH, the Swaziland Pharmacy Association, and the Medical and Dental Council. This was the first pharmacy training program to be offered in Swaziland, and was seen as a long-term sustainable solution to increasing pharmacy personnel in Swaziland as previously all were trained in neighboring countries. The training program would assure the availability of a continuous pool of certified pharmaceutical personnel who will manage and dispense pharmaceuticals according to international standards to all patients.

Patient Safety

SIAPS interventions to improve patient safety have been designed to address challenges of adverse drug events and hence promote adherence to HIV/TB treatment. A framework to guide the implementation of active and passive surveillance was designed and approved by the National AIDS Program and the Pharmaceutical Services Department. Adverse events reporting and an electronic database for tracking adverse events were designed and providers trained on using them. The data from adverse events is used to inform decision on treatment
protocol and standard treatment guidelines.

**KEY ACHIEVEMENTS**

**Governance**

SIAPS worked with diverse stakeholders including community members, politicians, health and legal professionals in the drafting of legislative bills. The inter-ministerial (Ministry of Health, Ministry of Justice, Ministry of Agriculture, and Ministry of Labor) engagements have also assisted in ensuring that all government institutions affected by the bills had an opportunity to provide input.

The Pharmacy Bill and Medicines and Related Substances Control Bill were finalized, published on government gazette, and tabled before both Houses of Parliament in May 2014. Work on these two bills has included support to the Pharmaceutical Services Department in conducting stakeholder input hearings and workshops for parliamentary health portfolio committee members on the content and importance of these two bills. Consequently, the Pharmacy Bill no. 8 of 2015 and the Medicines Substances Control Bill no. 7 of 2015 have been approved by the Senate and are awaiting enactment into law. Once enacted, the Pharmacy bill will lead to the establishment of a Pharmacy council which will be responsible for developing and promoting pharmacy practice standards, ensuring that only appropriately qualified pharmaceutical personnel perform duties within their scope of practice. The bill will also establish standards for quality pharmaceutical service provision in line with international best practice and enable effective use of medicines, information, human resources, and finances to ensure of higher pharmaceutical service performance and improved availability and safety of medicines. The Medicines and Related substances control bill will establish a Medicines Regulatory Authority which will be responsible for control of medicines registration, importation, and use and quality assurance in the kingdom.

SIAPS has also assisted in drafting regulations to facilitate the immediate enforcement of the bills once they are enacted. SIAPS also provided technical assistance in the development of an interim medicines regulatory desk position which is currently responsible for regulating the importation and use of medicines in the country. To this end, SIAPS created a medicine importers’ database, and accompanying importation guidelines. These activities have helped the MOH to ensure that imported medicines are approved and registered, protecting PLWHIV from the marketing and sale of medicines of unproven efficacy and safety. SIAPS also supported the development of guidelines for the importation of pharmaceuticals to qualify Swaziland for the receipt of third-line pediatric ARV medicines and new TB medicines, i.e., bedaquiline.

In developing the Pharmaceutical Sector Strategic Plan, SIAPS undertook a fully consultative process to ensure that input from all local stakeholders was sought and incorporated in the plan. The plan was led by MOH, with technical assistance from SIAPS and WHO-Afro Swaziland country office. The health sector stakeholders included other government ministries, UNFPA, development and implementing partners, the private sector, civil society organizations, and members of the public. The plan was designed around the pharmaceutical systems strengthening framework and hence the implementation strategy of SIAPS.
Pharmaceutical Pre-Service Training

SIAPS collaborated with the Southern Africa Nazarene University (SANU) to establish the first preservice training program for pharmacy personnel in. The certificate in pharmacy and diploma in pharmacy curriculum were developed with participation from local stakeholders which included government and the private pharmacy sector. The curriculum was approved by the SANU council. SIAPS provided teaching material and reference books for the pharmacy program. An interim head of department and senior lecturer were engaged to run the program for the first two years. Fifteen students graduated from the pre-service Certificate in Pharmacy program in 2014. Cumulatively, 105 students have been enrolled in the pharmacy training program since inception in 2012. During the year ending September 2015, eight students (2 males, 6 females) graduated with Diploma in Pharmacy, while 6 students (2 males, 4 females) graduated with a Certificate in Pharmacy. Cumulatively, 21 students have since graduated with a Certificate in Pharmacy program and 8 have graduated with a diploma in pharmacy. A milestone toward realizing ownership and sustainability of the pharmacy diploma program during 2014 is that students started receiving government scholarships and SANU has recruited staff to replace the SIAPS supported faculty. SIAPS has also played a role in the on-boarding exercise for the new Heads of Departments and lectures for the program. Regular guidance is provided to two other universities that are interested in offering the Diploma in Pharmacy and later a Bachelor of Pharmacy degree.

Patient Safety

SIAPS supported establishing active surveillance in seven facilities providing HIV/TB treatment and care services. Health care workers at these facilities were trained on the active surveillance system and an electronic database was introduced for the capturing of all surveillance system data. A passive adverse event monitoring system was implemented at 39 SIAPS-supported ART treatment sites to monitor and manage adverse drug reactions. The information from the patient safety monitoring system (passive and active) was used to guide the country’s decision to phase out stavudine-based regimens in 2012 and review the HIV treatment guidelines in 2014. A quarterly medicines safety watch newsletter is published and distributed to all health workers in both public and private sector. Through SIAPS support, Swaziland also became a member of the WHO Uppsala Monitoring Centre (UMC) for Pharmacovigilance, providing the country access to global pharmacovigilance updates and reports.

Along with patient safety interventions, SIAPS also supports activities that seek to promote rational use of medicines. SIAPS assists MOH in monitoring implementation of the standard treatment guidelines (STG) for common public health conditions. At least 92% of health facilities in the country currently have a copy of the STGs. Improvements have also been noted in the prescribing patterns of clinicians. The STG post-implementation survey report reflected improvements on the proportion of encounters with an antibiotic prescribed (53% from a baseline of 59%) and the proportion of injections per prescription (16% from a baseline of 19%).
CONTRIBUTION TO USG GOALS

SIAPS continues to focus on investments aligned to the PEPFAR Blueprint: Creating an AIDS-free Generation. PEPFAR introduced its 3.0 policy document in 2014, which stipulates an impact driven agenda: efficiency, sustainability, partnership, and human rights. SIAPS has ensured that its interventions are aligned with strategies outlined to these documents.

SIAPS’ contributes to the various PEPFAR strategies by advocating for uninterrupted availability and rational use of safe, effective, and quality health products for HIV and TB diagnosis, treatment, and care services. SIAPS has focused on improving the procurement systems for medicines and laboratory products.

SIAPS work at ensuring availability of PMTCT commodities is aligned with the call for Ending Preventable Maternal and Childhood (EPMCD) Illnesses. Furthermore, SIAPS work on strengthening financing mechanisms is aligned with the universal health coverage (UHC) strategy with a goal to reduce out-of-pocket payment for medicines and also ensure adequate allocation and efficient use of financial resources for medicines.

LESSONS LEARNED

Governance

Lobbying is a crucial step in advocating for the bills, such as the Medicines and Related Substances Bill, and the Pharmacy Bill, to be enacted. There is a lot of ground work that needs to be done for the politicians in parliament to see the value of the bills proposed and hence prioritize them through the legislative process. The change of parliament in 2013 mid-activity implementation meant that SIAPS had to start the process from the beginning with the new parliament, though a lot of ground was covered with the previous parliament. Getting consensus on various aspects of the bill proved to be a challenge because the different legislators had varying interest in the bills, especially the component of pharmacy ownership.

SIAPS worked very closely with the officials from the Ministry of Justice, Ministry of Agriculture, and Ministry of Health to push the bills through the parliamentary processes. Creating and maintaining relationships with all key stakeholders is crucial in order to get the bills prioritized for deliberation in Parliament.

Understanding that the House of Assembly’s members have diverse backgrounds and education levels, it is crucial to understand the target audience and pitch the message in a less technical manner. Understanding legislative procedures and issues of protocol became key towards getting the bills considered by the two houses of parliament.

Pharmacy Pre-Service Training

The enthusiasm and leadership of the SANU vice-chancellor made a great difference in pushing for the establishment of the pharmacy training program.
Working as a development partner is often difficult when navigating complex government structures especially in ministries such as that for education. The vice chancellor was very helpful in facilitating all the policy issues and also getting the senate of the university to approve the curriculum within one year.

Patient Safety

The introduction of the active surveillance program was viewed as a research activity, hence many were not keen to participate and contribute. During the design of the intervention, the team at the National AIDS program was fully in support and committed to see the activity through and assure sustainability. However, staffing changes within the MOH meant that the new team was not fully aware of the activity, so the activity was not held. SIAPS managed to re-engage the new team and push for a focal person within the MOH to lead this activity. This intervention also meant that a pharmacovigilance unit could be established under the pharmaceutical services department.

SUSTAINABILITY

The advocacy work on the legislation, regulation of medicine, and pharmaceutical strategic plan implementation is already being transitioned in phases to the Pharmaceutical Services Department. Discussions are underway for WHO Swaziland office to continue providing technical assistance in this area, especially post-SIAPS. The governance interventions will endure after SIAPS because there was strong country ownership and all activities were done with the Chief Pharmacist who is currently leading this activity within the MOH. The Pharmacy Council and Medicines Regulatory Authority, once established, will need to be capacitated to perform their functions. This is expected to begin in the 2016/17 fiscal year. Support will also be required in the development of SOPs and guidelines for the functioning of the Pharmacy Council and Medicines Regulatory Authority. WHO Swaziland office could provide this support to some extent.

The certificate and diploma in pharmacy program has successfully been transitioned to Southern Africa Nazarene University (SANU), which now employs its own staff. SIAPS provided technical assistance to the newly recruited Head of Pharmacy department, and lecturers were recruited to deliver the program. Support is still required to ensure the quality of the program. There is no local capacity to provide technical assistance in this area.

Patient safety is fairly new and requires a lot of support especially the active surveillance. The passive surveillance, however, is in the process of being included in clinical care activities and supported by PEPFAR partners working on HIV/TB treatment programs.
Following the collapse of the Soviet Union, Ukraine inherited a highly centralized, nationally controlled system of health care, many aspects of which remain unreformed today. The system has traditionally been input- rather than output-based and has had little chance to operate effectively, given that the amount of resources required have been much higher than the economic capacity of the state.

Only a little over half (54.9%) of total health expenditure was from public sector sources in 2012. This has significant implications for equity in health system financing as private spending, dominated by out-of-pocket payments, makes up the rest. The existing health care financing system puts the burden of financial expenses for medicines mainly on patients and their families. Given the high cost of medicine, such a situation leads to providing little, if any, access to treatment for disadvantaged patients.

Thus, one of the key challenges of the health care system in Ukraine is access to medicines. In addition to that, health care administration at all levels has little experience in practicing a results-oriented approach to management. Obsolete legislation and an underperforming supply chain are resulting in poor patient service and high medicine prices. Paper-based systems of record keeping and reporting hinder evidence-based interventions and are vulnerable to duplication, non-efficiency, irrationalities, and corruption.

The SIAPS Program in Ukraine began in FY2013, which was the second program year for SIAPS globally. Throughout three program years (FY13, FY14, and FY15), SIAPS worked to implement three key pharmaceutical system strengthening interventions in Ukraine.

**Establishment of an Electronic TB Management Information System (e-TB Manager)**

The purpose is to help overcome many of the challenges of coordinating TB control activities by providing the required information for TB control monitoring.
and management. The e-TB Manager system, a web-based system operating as the National TB Register, is intended to provide timely and accurate data for evidence-based decision making. The utilization of the register supports better governance, influencing proper service delivery.

**Rational Medicine Use**

SIAPS supports rational medicine use (RMU) by improving prescribing practices, enhancing medicine safety monitoring, harmonizing the national pharmacovigilance (PV) guidelines with that of the European Union’s (EU), and establishing a national essential medicines list (EML) as the sole basis for public procurement of medicines and health products. This key intervention is implemented in four interconnected approaches as described below.

- Implementing a drug utilization review (DUR) as a continuous quality improvement mechanism, which allows analysis of prescription practices and medicine use and suggests further utilization of this information to improve service delivery and patient treatment outcomes.

- Developing a Pharmacovigilance Automated Information System (PAIS), a comprehensive electronic system used by the national PV authority (State Expert Center [SEC]) and Ministry of Health (MOH) for collecting and analyzing data on cases of adverse drug reactions/loss of efficacy (ADRs/LE).

- Developing national PV guidelines for harmonization of the PV system in Ukraine with EU regulations, aiming to constitute the national-level policies on monitoring the safety of medicines. Development of national PV guidelines is complimentary to implementing the PAIS, because both ensure application of international standards (e.g., E2B data format) and approaches to data collection, reporting, and analysis, as well as to decision making regarding safety of medicines.

- Establishing an EML as the sole base for public procurement with a transparent process for updating it is a corruption fighting measure that allows for transparent and accountable procurement of medicines, which enhances access to necessary pharmaceuticals, improves quality of care, and supports cost-effective use of limited resources. In addition, the EML is a necessary component to reform and improve the supply chain in Ukraine.

**Improving Supply Chain Management**

Supply chain management (SCM) is improved through building capacity, improving procurement practices at the sub-national level, and implementing the nationwide assessment of the supply chain of medicines. Two major approaches of this key intervention are as follows.

- Piloting a framework agreement mechanism in selected regions to build the capacity of local staff, giving them the opportunity to experience the process and the ability to replicate it in the future. The country has had legislation to support the framework agreement (since 2012), which is
seen as an international best practice, but it has never been utilized to procure pharmaceuticals.

- Implementing of the National Supply Chain Assessment (NSCA) [2015–2016], aiming to systematically review all existing gaps in the supply chain and prioritize them according to the impact they might have if/when addressed.

- Developing the Ukraine Medicines Price Observatory, an on-line database, to provide reliable and up-to-date information on medicine prices and availability trends to policy makers, managers, and users.

KEY ACHIEVEMENTS

National TB Registry (e-TB Manager) Transferred to Ukrainian Center for Disease Control, MOH

In 2008, the MOH requested technical support from USAID for the adaptation and implementation of e-TB Manager for the Ukrainian context. This process began as a part of the SIAPS predecessor, the Strengthening Pharmaceutical Systems (SPS) Program, implemented by MSH.

For e-TB Manager to replace the inefficient paper-based registry and reporting system, it was necessary to enter all TB cases into the new system. Piloting of the system began in April 2011 at which time there were more than 5,000 cases entered. As the number of cases in the system continued to increase each year, a data quality assurance protocol was developed to provide for error-free registry and reporting. As of August 2015, 185,760 cases were in the system, and the consistency between paper-based and electronically generated reports was approximately 99%.

The unification of the operational procedures, which is one of key features of the system, has reduced the amount of time that staff spends on paperwork, thus improving their overall performance, and the deployment of the medicines management module has allowed for more effective planning of procurement. The integration of these two achievements has improved the access to TB medicines and pharmaceutical services.

In 2015, SIAPS Ukraine officially transferred administration of e-TB Manager to the Ukrainian Center for Disease Control (UCDC). e-TB Manager is now the official information system approved by the MOH and used across the country as the National TB Registry. The transfer of e-TB Manager administration to UCDC is a testament to the strong foundations that have been built in the country to ensure the sustainability of the national TB registry and management system, as well as to advancements made in disease control on a larger scale.

Rational Medicine Use

The DUR was successfully piloted in the Kyiv Oblast TB dispensary in FY15. The DUR pilot has helped the MOH, SEC, UCDC, and other stakeholders to understand the existing challenges in building adherence of both doctors and patients to the standards of treatment. The review revealed that more regimens were in use than are stipulated by the standard treatment guidelines (STGs);
unjustified substitutions and cancellation of medicines were detected within different regimens; important laboratory tests were proven to be neglected; and about 45% of intensive-phase patients were found to have been discharged for the ambulatory phase with regimen violations. These findings highlight far-reaching organizational and technological changes required to drastically increase the adherence to STGs and enhance health outcomes. Prerequisite to these changes is a strengthened capacity of health care facilities and regional health authorities to enforce DURs as a regular practice for improving RMU.

The PAIS was successfully piloted in FY15 in four oblast AIDS centers and the National Institute of Infectious Diseases and continues to attract more users. The introduction of PAIS equips the SEC (national PV authority) and MOH with a state-of-the-art instrument for data analysis and informed decision making to ensure medicine safety and efficacy. As of October 2015, there were 210 cases entered, which is four times higher than was anticipated to declare the success of the pilot. Further roll-out of PAIS will continue, contributing to the enhancement of human and institutional capacity of the national PV system in all aspects, including management of pharmaceutical systems and services and promoting evidence-based use of medicines.

The national PV guidelines will consist of 16 modules and represent the adapted version of the Guidelines on Good Pharmacovigilance Practices (GVP) developed in 2012–2015 by the European Medicines Agency (an EU agency that evaluates medicinal products). PV activities are organized by distinct but connected processes, and each GVP module presents one major PV process. Starting in 2013, SIAPS has been supporting the adaptation of GVP and, to date, the first six modules have been adapted, with the first four modules having been approved by the MOH. The next two modules are currently in development. The national PV guidelines will apply to all medicines authorized in Ukraine and will facilitate the performance of PV activities nationwide. The implementation of the national PV guidelines will contribute to promoting RMU and preventing harm from ADRs.

Recently started, the establishment of a new EML has already achieved substantial progress. This activity builds on the Parliament Coalition Agreement, which requires the new national EML to be the sole basis for public procurement as an element of health care reform. Despite this issue being very high profile, national stakeholders expressed contradictory notions about the EML, and it took considerable efforts to make all parties come to a consensus. The SIAPS Ukraine team provided extensive technical assistance to the MOH in facilitating the initial discussions, followed by targeted advocacy, which resulted in a remarkable change in public perception of the EML concept.

Currently, SIAPS Ukraine continues to work with key stakeholders to establish the legal basis for a sustainable transparent process for the development and revision of the EML. Building this legal framework includes adoption of amendments to present legal documents and the development of new ones. To date, core documents have been developed and approved by the MOH, including regulations on the national EML and regulations on EML Expert Committee. SIAPS Ukraine will continue to provide technical assistance and expertise to ensure the bias-free selection of EML Expert Committee members and further development of the new national EML.
Improving Supply Chain Management

The introduction of framework agreements for the 2015 public health care procurements in the Poltava and Dnipropetrovsk Oblasts of Ukraine reduces the risk of stock-outs and helps employees more efficiently use their time by creating more flexible, shorter procurement procedures and decreasing the opportunity for corruption. The examples of successfully conducted tenders under framework agreements have inspired facility administrators to rethink their approach to the procurement of medicines and health commodities. These changes are even more important because of decentralization being implemented across the country, which results in the need to strengthen the procurement capacity of local health care facilities. The achieved results and stakeholder commitment show the potential for more efficient utilization of public funds through the development of a more transparent and accountable procurement system.

The USAID Mission in Ukraine and the MOH requested that SIAPS provide assistance in the assessment of Ukraine’s SCM system to produce evidence for making decisions on interventions for reform. SIAPS responded to the request and currently coordinates the implementation of the assessment of the national SCM system with the NSCA tool. This comprehensive tool is used to assess the capability and performance of national health supply chains. Its purpose is to provide the Government of Ukraine with evidence needed for decision making to strengthen the national supply chain as a part of the government’s overall health care reform initiative. The SIAPS Ukraine team is currently finalizing preparations to launch the assessment. The national stakeholders’ meeting was recently held to verify and approve essential NSCA parameters. Preparation for data collection is in progress.

SIAPS has supported the development of an online database that provides the ability to compare medicine prices on a timeline across the regions of Ukraine as well as with prices in other countries. The Price Observatory has built-in analytical tools and can accommodate as many names of medicines (international nonproprietary names), countries, manufacturers, and currencies as needed to match users’ expectations. The database will be used by NGOs, the All-Ukrainian Network of People Living with HIV, and the Anticorruption Action Center to advocate for better pricing options. Depending on the data input, the Price Observatory can be used to benchmark prices in retail versus public procurement, or procurement prices in Ukraine and other countries. This tool strengthens the capacity of civil society to advocate for open and transparent procurement practices by national and regional authorities.

**CONTRIBUTION TO USG GOALS**

According to USAID’s Vision for Health Systems Strengthening, 2015–2019, health system strengthening is a foundational and integral part of ending preventable child and maternal diseases and achieving an AIDS-free generation, as well as protecting communities against infection diseases. Meeting these goals will require high-performing health systems, ones that provide financial protection, ensure coverage of quality essential services, reach all people, and are responsive to their needs and preferences.
All SIAPS Ukraine interventions contribute to reaching priority objectives envisioned for three of the six health system functions.

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<th>Health System Function</th>
<th>Priority Objective</th>
<th>Relevant Key HSS Intervention</th>
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<td>Health Governance</td>
<td>Build civil society/private sector capacity for stronger voice, better advocacy to increase government transparency and accountability</td>
<td>Develop Ukraine Medicines Price Observatory</td>
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<td>Health Information</td>
<td>Support strategic, incremental, expansive improvement in integrated health information systems, including routine systems and evaluations vital for achievement of USAID and partner countries’ shared goals</td>
<td>Establish e-TB Manager</td>
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<td>Medical Products, Vaccines, and Technologies</td>
<td>Strengthen supply chain components to ensure the uninterrupted supply of quality-assured health commodities, including creating a supportive environment for commodity security and sustainable supply chains</td>
<td>Pilot of a framework agreement mechanism</td>
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<td>Implement NSCA</td>
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<td>Strengthen medicine regulatory capacity to protect the public from counterfeit products and pharmaceutical sector governance to promote transparency and accountability through appropriate laws, regulations, and policies</td>
<td>Establish the national EML</td>
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<td>Increase and enhance human and institutional capacity to manage pharmaceutical systems and services, including promoting evidence-based use of medications, assuring therapeutic efficacy, protecting patient safety, and slowing the emergence and spread of antimicrobial resistance</td>
<td>Implement DURs</td>
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<td>Develop PAIS</td>
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<td>Develop national PV guidelines</td>
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Furthermore, SIAPS interventions in Ukraine are in line with the development objectives and intermediate results of the Results Framework of USG/Ukraine Country Development Cooperation Strategy, 2012–2016.

**LESSONS LEARNED**

Stay focused on goals, and be flexible and ready to redesign the agenda of policy development to achieve results. In countries with an unstable political situation, rigid donor-driven action plans are often an obstacle to moving forward. Consequences of not being able to adapt to the changing political environment, although fully preventable, may include considerable loss of time and, more importantly, political support. The SIAPS Ukraine team has recognized these threats and benefited from changing its approaches to advocating for and assisting stakeholders in development of the new national EML.

Engage the regulatory bodies on the subnational level (even if at first they do not seem to be relevant stakeholders), and sensitize them on the matter of planned interventions. In an over-regulated setting, the regulatory offices were found to be likely to block initiatives about which they are not well informed and which they think might be breaking the regulations that they are charged with overseeing.
The SIAPS Ukraine team was warned about this by local partners, which made it possible to avoid altercations during the piloting of the framework agreement mechanism for procurement. A special meeting was held with local stakeholders, including regulatory bodies’ representatives, to make sure that all possible regulatory issues are cleared.

Engage and educate patients’ organizations and other civil society organizations (CSOs), while moving forward with developing and implementing new approaches, mechanisms, and tools. In highly corrupted (hence, trust-lacking) settings, such innovations may seem to watchdog CSOs to be just another form of corruption and thereby cause massive resistance. To avoid such resistance in the case of the new EML, SIAPS Ukraine team extended its educational efforts to these organizations, ensuring their awareness of the benefits the EML will bring and dispelling any myths around it.

**SUSTAINABILITY AND COUNTRY OWNERSHIP**

**e-TB Manager**

The midterm results of e-TB Manager implementation were impressive, and positive feedback from users and administrators of the system provided confidence to the Government of Ukraine, resulting in the official adoption of e-TB Manager as the National TB Registry in 2012. That same year, e-TB Manager was verified for data security issues and was certified by the State Security Service of Ukraine.

In PY4, SIAPS Ukraine implemented a year-long transition plan that resulted in smooth transfer of the National TB Registry (e-TB Manager) from SIAPS to UCDC and ensured that UCDC is able to provide sustainable operation of the system. Since September 2015, the National TB Registry is owned and sustained by UCDC.

**Drug Utilization Review**

The implementing facilities have by now acquired the experience needed to sustain and replicate DURs. Because a DUR is a cyclic process by nature, its continuous application is essential for success of the approach. It is envisioned that DURs will prove to be an effective tool for the rationalization of medicines use in Ukraine and that it will expand to include other health facilities. SIAPS will train trainers to help sustain DURs as the best practice approach to ensuring RMU.

**Pharmacovigilance Automated Information System**

PAIS, developed by SIAPS, will be handed over to the SEC as soon as the security protocol for data protection is finalized and approved. The SEC, as a state enterprise, has the capacity to fully maintain the system and to cover related costs.

**Essential Medicines List**

There may be resistance to the process of establishing an EML as the sole basis of public sector procurement because of vested commercial interests. However, a number of key stakeholders, including MOH, SEC, the National Medical University, and major NGOs have been very supportive to the development of
the new EML and its further implementation. SIAPS will continue to provide the evidence of historical medicines spending analysis to the MOH and other parties to enable them to make evidence-based decisions.

Framework Agreements

Despite the short period of being financed, the piloting of framework agreements as a mechanism for better procurement practices has been even more successful than initially planned. This approach is gaining more interest from public sector and NGOs. To respond to the rising need in capacity building, SIAPS has developed a training curriculum on framework agreements, which may be used not only at the regional level, but at the national level as well.

National Supply Chain Assessment

Country ownership is embedded in the assessment. Key stakeholders have been included in all communications and planning of the assessment. The working group on reforming the national supply chain of medicines has a subdivision responsible for shaping the assessment and recognizing its results. SIAPS will keep the process and findings of the NSCA completely open and transparent to facilitate further implementation of the recommendations derived from the assessment’s results.

Medicines Price Observatory

Developed on request from two major NGOs, the Price Observatory is now in the process of being handed over to the AllUkrainian Network of People Living with HIV. These organizations are interested in providing for the sustainable operation of the system, because it gives them powerful evidence in their advocacy work for more transparent, fair, and corruption-free pricing of medicines.
BACKGROUND

Sub-Saharan Africa is the region most globally affected by HIV and AIDS. Barriers to accessing health services remain a major constraint particularly to marginalized populations mostly due to weak health systems. In 2012, alerts of stock-out of life-saving HIV and AIDS drugs such as antiretroviral therapy (ART) and opportunistic infection drugs have been issued from a number of countries in West Africa. Countries in the region have not only reported stock-outs of critical drugs, but have also generally demonstrated a lack of capacity to identify and address underlying causes for these problems, as well as to generate accurate and reliable data for decision making, such as current stock available and projection of needs.

The root causes include poor coordination among partners, the paucity of pharmaceutical management data for quantification (forecasting and supply planning), poor inventory management and storage practices existing at pharmaceutical warehouses and dispensing points, and inadequate training and supervision of dispensary staff in health facilities.

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

KEY INTERVENTIONS

To address challenges raised above, SIAPS works closely with West Africa Health Organization (WAHO), country HIV and AIDS Control Programs, Central Medical Stores, Pharmacy and Medicines Departments, and other stakeholders at national and regional level such as Joint United Nations Regional Team on AIDS through the following interventions.

HIV and AIDS Regional Dashboard

Starting in 2014, SIAPS has developed an HIV and AIDS commodity management tool called OSPSIDA, which provides an early warning system to quickly respond to ARVs shortages and risks of overstock. OSPSIDA is a web-based program to capture, track, aggregate, and gain information about ARVs and rapid testing kits for better and faster decision making. To date, the tool has
been deployed in six focus countries where stakeholders from various entities of ministries of health involved with HIV and AIDS commodity management in each selected country have been trained on data entry and reports analysis to make evidence-based decisions. The tool has also been deployed within WAHO where a project management unit has been set to ensure the sustainability of the dashboard for management of HIV and AIDS commodities.

**Electronic Dispensing Tool**

The National AIDS Control Program of Togo (PNLS) has identified the need to improve management of patients and commodities data at antiretroviral dispensing sites to get reliable data for resupply, forecasting, and quantification. In line with SIAPS’ goal to strengthen pharmaceutical management information systems that produce data for both products and patients, SIAPS continued supporting implementation of the electronic dispensing tool (EDT) in Togo following the site readiness assessment conducted in 2014.

**Financing**

The Global Fund Country Coordinating Mechanism of Niger through the Intersectoral Coordination of Fight against STI/HIV/AIDS (CISLS) did not have the capacity to perform sound quantification and identify key activities needed to strengthen HIV and AIDS supply chain management. As part of its effort to support Niger to strengthen financing mechanisms to improve access to medicines, SIAPS supported the CISLS to perform a long-term forecast of HIV and AIDS commodities and identify key activities to support strengthening supply chain management. The SIAPS recommendations identified priorities for strengthening for August 2014 through February 2015.

**KEY ACHIEVEMENTS**

**HIV and AIDS Regional Dashboard**

Using a systemic approach to develop and implement OSPSIDA—the HIV and AIDS dashboard—in selected countries in West Africa has improved availability of pharmaceutical management information for faster decision making. Much of the success of the dashboard can be linked to SIAPS’ strong collaboration and partnership established with regional organizations, such as WAHO, international groups, including the Global Fund, and the involvement of national stakeholders (National AIDS Control Program/Commission (NACP/NACC), Central Medical Stores (CMS), Pharmacy and Medicines Departments.

Accomplishing the set-up of OSPSIDA in Togo has improved the quality of data. For example, the concordance between closing balances and opening balances of subsequent months in logistics and management information systems (LMIS) reports has increased from 55% to 100% within a year after the dashboard was deployed.

OSPSIDA has also improved Togo’s reporting rates and strengthened country coordination of management of HIV and AIDS commodities and related information system. The reporting rate went from 20% in June 2014 to 37.5%
in September 2014 to reach 100% in December 2014 and stabilized at 100% as of September 2015. The dashboard permits the country to access stock status across the peripheral to the regional to the central level, which was not doable under the old Excel® sheets system. The consumption data now used in Togo is an assessment of stock status at the national level (incorporating peripheral and regional) and calculation of stock on hand.

OSPSIDA has been able to improve early detection of ARVs stock-outs. In November 2014, reports from OSPSIDA alerted Togo to a possible stock-out of specific ARVs and the underlying causes. With SIAPS support, the reports from OSPSIDA were quickly compiled, aggregated, and shared with key donors including Global Fund and USAID/West Africa highlighting the potential stock out and quantity needed. This information was made available within a single day compared to an average of six weeks or more before the OSPSIDA was deployed. Togo used this information to make a request to PEPFAR’s emergency commodity funds (ECF) for a donation of ARVs to address the stock-out situation.

OSPSIDA enabled stakeholders at regional level to monitor ARVs and other HIV and AIDS commodities. The deployment of OSPSIDA in Niger showed that the availability of HIV and AIDS commodities is hampered by a weak LMIS. Niger was not able to keep the tool up-to-date because it could not enter paper-based LMIS data into the system because of a low reporting rate and poor data quality; this prevented Niger from detecting before it occurred. Deploying OSPSIDA in the region has helped donors coordinate needed support to local partners. Niger benefited from such intervention and avoided stock-outs by conferring with the members of the Joint United Nations Regional Team (JURTA) on HIV and AIDS/Procurement and Supply Management and Treatment Working Group. Because Togo kept OSPSIDA up-to-date, Niger was able to quickly access Togo’s HIV stock data to request a rapid transfer of ARVs from Togo to Niger.

**Electronic Dispensing Tool**

SIAPS supported the deployment of EDT in five (6.4%) antiretroviral treatment (ART) sites dispensing ARVs to 8,828 patients living with HIV and AIDS representing 26.4% of total patients on ART. While deploying EDT in Togo, SIAPS supported the PNLS to build capacity of five staff members as trainers who in turn worked with nine dispensers coming from five ART sites where the software was installed.

SIAPS supported PNLS to integrate the LMIS reports sent by ART sites each monthly into EDT. This helped improve completeness, timeliness and reliability of commodity and patients data at sites level. The five pilot sites were able to generate accurate data at any time whereas sites where EDT was not installed yet took at least five days to prepare and submit their monthly reports.

Best practices learnt from EDT implementation in five pilot sites in Togo have been used to support the development of concept note to roll out the tool nationwide which has been approved by the Global Fund. From five pilot sites in 2015, where the software is in use with support from SIAPS, Togo will reach 45 in 2016 and 75 sites with EDT in 2017 with the Global Fund money. This means that supporting implementation of EDT in one single ART site mobilized Global Fund resources to implement EDT in 14 additional sites.
Financing

Following SIAPS support to Niger’s CISLS to perform three-year forecast of ARVs and other HIV and AIDS commodities and identification of key activities to strengthen supply chain management of HIV and AIDS commodities, the Global Fund approved Niger concept note and granted an amount of USD $11,453,450 to fund procurement of HIV and AIDS products and other related system strengthening activities for three years. SIAPS has mobilized USD $32,517 to support this initiative meaning $1 from USAID provided approximately USD $352 from the Global Fund.

CONTRIBUTION OF USG GOALS

The objective of SIAPS West Africa regional is to promote and use a systems strengthening approach consistent with the Global Health Initiative that will result in a positive and sustainable health impact. Our interventions and key accomplishments described above using a systemic approach have significantly contributed to AIDS-free generation as stated in the PEPFAR Blueprint.

The development and deployment of HIV and AIDS dashboard in six focus countries in West Africa region has strengthened governance, prevented ARVs shortage, and ensured uninterrupted antiretroviral treatment for the benefit of patients living with HIV and AIDS to reach desired health outcomes.

The implementation of the EDT in Togo has improved management of patients and commodity data as well as availability of data needed for forecasting and supply planning process which are critical for proper procurement to ensure availability of life saving ARV drugs. The support to development of HIV and AIDS procurement and supply management concept note in Niger has helped to mobilize resources from the Global Fund to procure required quantity of quality assured ARVs for patients living with HIV and AIDS.

LESSONS LEARNED

HIV and AIDS Regional Dashboard

The implementation of OSPSIDA showed that countries keeping the tool up to date have experienced less risk of stock out than countries facing lot of challenges to input data into the tool. The LMIS system was so weak in Niger and Guinea that both countries faced several possible stock-outs in 2015, but the dashboard alerts helped avert stock-outs in Niger. In Togo and Benin, the strong leadership of HIV and AIDS program managers has helped both countries to use OSPSIDA as decision making tool and improve availability of ARVs. Strengthening governance in country will of course improve availability of data needed to get reliable information for faster decision making.

Electronic Dispensing Tool

In Togo, various country experiences on EDT implementation were shared with the PNLS Coordinator at an international conference. Based on that information, the PLNS officially requested that the EDT be implemented. SIAPS got country
buy-in without having to sell the tool in country and this helped to conduct the sites readiness assessment and implementation of EDT in five selected sites as pilot phase. The pilot phase has helped to develop concept note for the nationwide rollout of EDT in Togo with Global Fund monies. Sharing best practices for scaling up in country and replication in other countries need to be encouraged.

**SUSTAINABILITY**

SIAPS West Africa has ensured efforts for sustainability are embedded in all project activities. This is done largely through facilitating ownership by regional and national institutions

- At the regional level, SIAPS has involved the WAHO in the inception of the HIV and AIDS Regional Dashboard. A transition plan to hand over management of OSPSIDA to WAHO has been developed with roles and responsibilities of SIAPS and WAHO and a Project management team has been set within WAHO. WAHO has been equipped to technically lead the management of OSPSIDA as part of their Buffer Stock Initiative. A system administrator has been named. All materials for replication of the EDT in other countries are available.

- At the country level, following the deployment which was supported by SIAPS, countries are now able to input data and use reports without assistance from SIAPS except for a few technical issues whose management will be transferred to WAHO as part of handover.

- A pool of trainers for EDT implementation has been put in place in Togo and training materials are available to monitor implementation and scale up the tool nationwide. Funding has been secured with a Global Fund grant to support scaling up.
The SIAPS approach to pharmaceutical systems strengthening has been implemented in over 50 countries since the program began in 2011. While each country’s pharmaceutical system has unique characteristics; operating in distinct environments and challenges, and thus at various levels of maturity, SIAPS interventions are implemented through the dynamic relationships across the health system functions – Governance, Capacity Building, Information, Financing, and Service Delivery – with a focus to improve access and appropriate use of medical products. As such, whilst countries’ PSS interventions may seemingly have similar aims, the specifics of the activities are tailored to each country’s contextual circumstances.

This section provides a synthesis of key SIAPS country level interventions to demonstrate how the Program has applied its pharmaceutical systems strengthening approach, and their corresponding notable achievements. The syntheses emphasize the necessity of using a holistic approach to strengthen pharmaceutical systems.
## A Highlight of Key Country Level PSS Interventions

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<th>Countries of Implementation</th>
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<th>Information for Decision Making</th>
<th>Financing</th>
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<td>Strengthening Medicine Regulatory Functions</td>
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Strengthening Medicine Regulatory Functions

A key part of improving governance is the improvement of a country’s regulatory system. A functioning regulatory system will ensure that only quality, cost-effective, and safe pharmaceutical products, are allowed to enter a country, and are safely used by communities. SIAPS often provides technical support across multiple, interrelated regulatory functions in the effort of addressing a country’s regulatory system as a whole to achieve greater effectiveness and sustainability. SIAPS has worked to strengthen the regulatory systems in seven countries: Angola, Bangladesh, DRC, Ethiopia, Mozambique, Namibia, and Swaziland.

SIAPS applies a systems strengthening approach, whereby a SIAPS country implements interventions that are supported through the dynamic relationship across the health system building blocks: Governance, Capacity Building, Information, Financing, and Service Delivery. Each SIAPS country has approached the strengthening of the National Medicine Regulatory Function in a different way, with some commonality and overlap among interventions.

One of the main interventions used by many of the SIAPS countries to strengthen the Governance aspects of the medicine regulatory systems is the development or revision of key regulatory tools, including: National Essential Medicines Lists (EMLs); Standard Operating Procedures (SOPs), Guidelines, and Policies for
improving registration processes and optimizing tools and efficiencies; Tools and Guidelines for provisional marketing authorization licenses; as well as the development of Procurement Guidelines, including: Importation Guidelines, Donation Guidelines, Procurement Procedure Manuals, which also strengthens the overall supply chain management systems.

SIAPS Countries have also provided direct technical assistance to key regulatory authorities (ex. Angola’s National Directorate of Medicines and Equipment (DNME), the DRC’s Drug Regulatory Authority (DRA), and the Namibian Medicines Regulatory Council (NMRC)) to strengthen their leadership, governance, and capacity to oversee a functional medicine regulatory system. SIAPS has supported a number of countries to establish committees and technical working groups for drug registration, and has automated the drug registration system in four countries. Through the implementation of Pharmadex, a web-based tool that helps streamline and track medicines registration for a national drug regulatory authority, SIAPS countries have integrated an information system into the regulation system, thereby ensuring Information is available and used by all decision makers.

To reinforce the SIAPS interventions strengthening governance and information within the medicine regulatory systems, SIAPS is also implementing interventions that build Capacity within the institutions and individuals to sustainably strengthen the regulatory systems. SIAPS countries have accomplished this by providing direct capacity assistance, through trainings and on-the-job mentoring, to key personnel (i.e. drug registration reviewers, regulatory authority staff) to improve regulatory tools and provide guidance on data requirements for medicine registration. SIAPS has developed a number of technical training materials, including: Dossier evaluations; Good Medicine Practices (GMP) training materials; and Pharmadex Users Manuals.

Notable Achievements

A number of SIAPS-supported countries have developed or updated pharmaceutical laws and regulations to date resulting in the establishment of new regulatory authorities and systems: the first national medicines policy was developed in Haiti and the first medicine regulatory authority was established in Swaziland; Angola advocated for and helped establish a semi-autonomous institution that will play the role of national medicines regulatory authority

SIAPS support to DRC has resulted in the establishment of the national registration committee, which has resulted in an increase in the number of registered medicines, from 200 in 2010 to more than 4,000 in 2015.

SIAPS’ on-going support for quality surveillance at both central and site levels in Namibia resulted in poor quality products being removed from the market, including two batches of co-trimoxazole tablets used in the prophylaxis of opportunistic infections in AIDS and four batches of other essential medicines.

Enhancing Supply Chain Management Systems

To enhance country level supply chain management, SIAPS applies a systems strengthening approach, which focuses on strengthening the supply sub-system building blocks of improving the 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 improved service delivery. All of these components working together address the broad objective of reducing stock-outs, minimizing wastage, and ensuring the continuous availability of quality medicines and other health products.

The prevailing intervention utilized by many SIAPS countries to strengthen the supply chain management systems, is the establishment of national level coordination committees, which take on the role of Governance bodies, and strengthen the healthcare stewardship role of the Country Governments. These bodies include Quantification Coordination Committees, Pharmaceutical Logistics Management Units, Procurement and Logistics Management Cells, Supply Chain Coordination Units, and Logistics Management Units. Within these governance bodies, SIAPS has also supported many countries in setting up quantification technical working groups, and developing Terms of Reference (TOR) and Standard Operating Procedures (SOPs), to streamline forecasting and quantification systems. To enhance the capacity of the national level coordination committees, SIAPS countries have also supported the development of national supply chain management strategies, warehouse management and distribution plans, annual work plans, and budgets.

To ensure the improvements in governance within the countries, SIAPS builds the Capacity of national, provincial, and district level stakeholders through the development of quantification, forecasting, pharmaceutical management, and supply chain management training materials. SIAPS is also a strong advocate for country led supportive supervision, accompanied by coaching and on the job training. Trainings and exercises in nine SIAPS countries, for HIV/AIDS, malaria, TB, and FP/RH commodities have enabled the countries to implement their own procurements, develop financial estimates for future needs, and improve the Service Delivery of life saving commodities. To ensure the skills provided to key staff are shared and retained, SIAPS has helped many countries establish a pool of master trainers and facilitators. These trained personnel provide sustainability and institutional memory to ensure skills are improvements are retained within the key stakeholder agencies.

SIAPS supports countries in the development and use of Information management tools, to avert stock-outs of essential medicines, monitor their appropriate use, and facilitate procurement decisions. Logistics Management Units have been established in Bangladesh, Ethiopia, South Africa, and South Sudan, and web-based commodity tracking systems have been implemented in numerous SIAPS countries. Examples of these include the Supply Chain Management Portal (SCMP) in Bangladesh, the OSPSANTE commodity dashboard in Mali, and the LMIS in Swaziland. By integrating supply services through logistics management units, SIAPS also helps to leverage and maximize Financial resources across programs and partners. For example, SIAPS country teams and technical working groups use reporting data to inform concept notes when soliciting financial support from the Global Fund for national malaria programs.

Many SIAPS countries are supporting the fight against malaria under the Presidents Malaria Initiative (PMI). These countries are endeavoring to ensure an uninterrupted supply of high-quality malaria medicines and commodities.
To support the information management of malaria commodities, eight SIAPS countries, and the Latin American Region, implement PMI tools, such as end use verification (EUV) and the procurement planning and monitoring report for malaria (PPMRm), to avert stock-outs of lifesaving commodities, monitor their appropriate use, and facilitate procurement decisions. The EUV process has given MoH partners the opportunity to assess and take steps to correct and improve the availability and use of malaria commodities.

**Notable Achievements**

- SIAPS has helped establish forecasting and supply planning coordination committees, with specific terms of reference, across health programs to create more streamlined, horizontal, and reliable quantification systems in eight countries.

- In Lesotho, SIAPS has helped develop and facilitate the Supply Chain Management Leadership Development Program (SCMLDP), which is an in-service program that capacitates leadership teams in supply chain functions. The program has been successfully implemented and has been fully institutionalized within the MoH.

- In Angola, SIAPS was involved in the current efforts to establish a semi-autonomous institution that will play the role of national medicines regulatory authority.

- In Burundi, SIAPS supported the Global Fund malaria concept note approved in March 2015 for malaria commodities valued at over USD $8,000,000.

**Enhancing Information Systems for Evidence-based Decision Making**

Many countries still rely on outdated, non-standardized, tools for capturing and analyzing pharmaceutical data. While those that do have better information gathering systems, still lack the capacity to aggregate, analyze, and disseminate the information for use by key decision makers. SIAPS works with over fifteen countries to support the integration and standardization 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.

Information systems are closely linked with supply chain management systems and the rational use of medicines, as up-to-date, quality information is needed to make appropriate decisions on commodity procurement, minimizing wastage, and to ensure the continuous availability and appropriate use of quality medicines and other health products. There is a direct link between information and the availability of medicines. Pharmaceutical information is used to coordinate distributions and help avoid stock outs and expiry in countries, thus saving money. Utilization of standardized Logistics Management Information Systems (LMIS) or Pharmaceutical Management Information Systems (PMIS) supports better Governance and influences proper Service Delivery, as patient care depends on the quality and availability of medicine at the service delivery point.
The SIAPS approach to MIS spans the pharmaceutical system, and supports centralized, integrated national data systems. SIAPS countries work with key stakeholders to develop, revise, and disseminate SOPs, guidelines, and roles and responsibilities for the proper functioning of information management systems. To support these governance interventions, SIAPS builds the capacity of national, provincial, and district level stakeholders through trainings, on-the-job mentoring, and supportive supervisions. SIAPS works with countries to ensure they can implement accurate quantification and forecasting, which ensures financial efficiency.

SIAPS countries have effectively used project tools such as the electronic dispensing tool (EDT), RxSolution, eTB Manager, Quantimed, QuanTB, Pharmadex, and mobile devices for data collection. To enhance data visibility and to present aggregated and analyzed data for making decisions, many countries relied on dashboards set up by SIAPS.

e-TB Manager, a web-based platform which manages information needed by TB control programs, integrates data across major aspects of TB control, including information on suspected cases, patients, medicines, laboratory testing, diagnosis, treatment, and outcomes. Eleven countries are implementing eTB Manager, which supports the case management of over 345,000 TB and MDR-TB patients.

In Ukraine, unification of the operating procedures, which is one of the key features of the system, has significantly reduced time losses from TB facility staff, thus improving their overall performance.

RxSolution, an electronic pharmaceutical management system used to manage inventory, purchase orders, stock issues to health facilities, and dispense medication, is being implemented at over 500 sites in five countries. RxSolution has become a flagship project in South Africa with the National Department of Health endorsing RxSolution as the tool for the management of pharmaceutical inventory. Training on RxSolution has been integrated into the pre-service curricula for pharmacists and mid-level pharmacy personnel at the Nelson Mandela Metropolitan University (NMMU).

The Electronic Dispensing Tool (EDT) helps pharmaceutical providers accurately dispense medicines by collecting, managing, and generating the necessary data, including: patient profiles and medicine history; medicines inventory; and patient statistics needed for management decisions. Twelve countries are implementing EDT, covering approximately 800,000 ART patients.

**Notable Achievements**

The West Africa HIV/AIDS Regional Dashboard, OSPSIDA, is a great example of coordinating information for decision making. The Dashboard captures, tracks, aggregates, and disseminates information about ARVs, rapid test kits, and other HIV/AIDS commodities to support evidence-based decision making for six West African countries. Results from Togo and Niger have shown improvements among HIV program managers case management, as they have been utilizing stock status and patient information to predict risk associated with stock-out and over stocking.

Uzbekistan is the first former Soviet country to implement QuanTB at the regional level, utilizing the tool for electronic forecasting, quantification and early warning to support TB programs.
Improving Rational Medicine Use and Curbing the Emergence of Antimicrobial Resistance

The challenge of irrational medicine use is a global one—common to all countries and all healthcare settings. Both healthcare providers and patients contribute to irrational medicine use. Providers may prescribe too many, too few, or inappropriate medicines; they may prescribe the appropriate medicines in the wrong dose, formulation, or duration. Additionally, patients contribute to irrational medicine use through self-medication, pill sharing, or not completing a treatment regimen as prescribed. However, at a systems-level, the policy and regulatory environment in which a provider prescribes, and a patient uses medicines, heavily impacts rational use.

SIAPS is also at the forefront for the containment of antimicrobial resistance (AMR). Globally, few countries are implementing WHO’s AMR strategy, but through SIAPS, five countries: Ethiopia, Namibia, South Africa, Swaziland, and Ukraine, are supporting country and regional coalition-building efforts around AMR. SIAPS promotes a multidisciplinary, systems strengthening approach to infection control, combining diagnostic self-assessment with continuous quality improvement cycles to design, implement, monitor, readjust, and improve infection control interventions.

SIAPS works to strengthen health systems to improve access to both medicines and pharmaceutical services, and to help ensure medicines are used rationally and responsibly. Going beyond the supply chain, SIAPS aims to strengthen pharmaceutical services which make medicines information available and easy-to-understand, provide effective pharmaceutical care and counseling, and help to monitor the use of medicines and patient adherence. SIAPS supports RMU interventions in Bangladesh, Burundi, DRC, Ethiopia, Mozambique, Namibia, South Africa, South Sudan, Swaziland, Ukraine, and Central Asia.

Strengthening the rational use of medicine and containing the emergence of AMR is intrinsically linked to improving Governance of the overall health system, particularly the regulatory system. One of the main interventions implemented by SIAPS programs to improve the rational use of medicine is the development, revision, and dissemination of key regulatory tools, including: National Essential Medicines Lists (EMLs), Medicines Formularies, Standard Treatment Guidelines, and Good Prescribing Practices.

To strengthen both Governance and Service Delivery, SIAPS countries have established Drug Therapeutic Committees (DTCs) in six countries - DRC, Ethiopia, Jordan, Mozambique, South Africa, and Swaziland. In support of these DTCs, SIAPS has developed and trained on procedures and tools that govern good prescribing and dispensing practices, has promoted knowledge transfer among medical practitioners and pharmacists on rational use of medicines, and has monitored the efficient use of resources allocated to pharmaceutical procurement. SIAPS has built the Capacity of DTCs through in-service and pre-service trainings and supportive supervisions, which has improved quality and safe service delivery to patients. SIAPS has also supported the institutionalization of rational medicine use and AMR in undergraduate and post-graduate curricula at Universities in South Africa and Namibia.

SIAPS interventions increase the use of Information for decision-making, which
can be used to reduce the pharmaceutical expenditures. DTCs are now capable of identifying medical use problems, conducting ABC/VEN analyses, conducting drug use evaluations, and implementing corrective measures. Assessing how medicines are being prescribed, dispensed, administered, and used through medicine use evaluations is a critical method for health facilities to review and improve rational use. SIAPS works to build the capacity of stakeholders to design and implement medicine use studies, recently publishing a reference guide to assess antimicrobial use in hospital settings. The guide defines indicators that can be used to measure management and use of antimicrobials and provides step-by-step instructions and tools for carrying out an assessment. Additionally, SIAPS recently published guidelines to help health workers assess use of medicines to treat drug-resistant TB. SIAPS has supported medicine use studies and evaluations in eight countries including Ethiopia, Bangladesh, Jordan, Kenya, Namibia, South Africa, Swaziland, and Ukraine.

Notable Achievements

Across the SIAPS countries 51 DTC-related trainings have been given to 1,411 participants along with ongoing support, such as on-site technical assistance and supportive supervision. Over 445 DTCs have been created and 49 revitalized by the end of April 2015. The DTCs have conducted 36 medicine use studies or evaluations and 68 ABC/VEN analyses; developed or implemented 5 treatment/prophylaxis guidelines and 2 formularies; developed 5 DTC or rational medicine use-related policies; and conducted 15 in-service trainings on RMU or DTC topics.

In Ethiopia, the introduction of pharmaceutical care activities in hospitals in which pharmacy staff work with a multidisciplinary team, has resulted in better medication service provision to patients. There are now 200 pharmacy staff trained to provide clinical pharmacy services and 53 hospitals have initiated these services. Additionally, health facilities are implementing Drug Information Services (DIS), which include reference materials, patient education guidelines, and on-site training. Ethiopian DTCs that have implemented AMR advocacy or containment-related activities have increased from 29.2% to 54.2%, and facilities implementing good practices for medicine dispensing have increased from 54.2% to 91.7%.

In South Africa, the SIAPS supported hospital pharmacy model at Dr. George Mukhari Academic Hospital now serves as a center of excellence for pharmaceutical services. While, in Swaziland, based on a SIAPS supported quality improvement project at the Raleigh Fitkin Memorial Hospital DTC, the DTC led the development and implementation of hospital guidelines on prescribing antibiotics and switching from intravenous to oral antibiotic therapy.

Rational medicine use strategies enhance the effective, safe, and cost-effective use of medicines, preserve the effectiveness of antimicrobials, and contribute to good health outcomes. Through its pharmaceutical services capabilities, SIAPS helps countries build their capacity to improve rational and responsible medicine use. The tools and approaches that have been developed and used by SIAPS and its predecessor programs help pharmaceutical systems achieve positive, measurable, and sustainable health impact. SIAPS emphasizes pharmaceutical system strengthening, local capacity-building, country ownership, monitoring and measurement, and sustainability as core principles for supporting country stakeholders in their efforts to improve medicines use.
Establishing Pharmacovigilance Systems

As part of its efforts to increase access to essential medicines, SIAPS works to establish and strengthen pharmacovigilance systems to ensure medicines safety. Recognizing that even relatively rare problems associated with medicines use can have a major impact on patient safety, prescriber behavior, patient adherence, and overall health outcomes, SIAPS uses a systems-based approach to support countries in understanding and establishing both passive and, where appropriate, active approaches to the identification of medicine-related problems.

Viewing PV through a systems-strengthening lens also allows SIAPS to ensure these activities are harmonized with other components of the pharmaceutical system, including regulatory approval processes; medicines selection, procurement, and distribution; and clinical treatment guidelines. To that end, SIAPS looks for opportunities to engage in effective pharmacovigilance practices at multiple entry points—at pre-market evaluation, at the facility level, in clinics, and even in patients’ homes—and to ensure that even the most decentralized mechanisms can usefully be aggregated and feed a larger, comprehensive pharmacovigilance framework.

Using the SIAPS Integrated Pharmacovigilance Assessment Tool (IPAT), SIAPS helps countries assess their existing pharmacovigilance processes, structures, and capacity to identify strengths, weaknesses, and gaps. SIAPS then uses these assessments to recommend options and help implement selected interventions to strengthen pharmacovigilance systems. SIAPS has implemented pharmacovigilance interventions in Bangladesh, Burundi, DRC, Ethiopia, Mozambique, Namibia, Philippines, South Africa, Swaziland, and Ukraine.

To strengthen the Governance and available Information of pharmacovigilance systems, SIAPS countries have supported the establishment of pharmacovigilance and surveillance units within the Ministries of Health, including the Adverse Drug Reaction Monitoring (ADRM) Cell in Bangladesh, the Swaziland MOH Pharmacovigilance Unit, the Therapeutic information and Pharmacovigilance Center (TIPC) in the DRC, and the National Pharmacovigilance Center (NPC) in South Africa.

SIAPS has also helped countries in the development and dissemination of frameworks that guide the implementation of active and passive surveillance in health institutions, and pharmacovigilance tools, such as Adverse Events (ADE) Guidelines, ADE Reporting forms, PV SOPs for cohort event monitoring, allergy cards, and preventable adverse-event bulletins. To increase the Information available and used by decision makers, SIAPS has supported the automation of ADE reporting and consolidation of data into pharmacovigilance databases. In many countries SIAPS supports the analysis and dissemination of this data to stakeholder and health care providers to ensure appropriate regulatory decisions are made and dangerous medicines are removed from the market.

To reinforce the governance and information system strengthen interventions for the pharmacovigilance systems, SIAPS is building Capacity within institutions and health care providers by providing on-the-job trainings and mentoring, as well as incorporating pharmacovigilance training into pre-service curriculum at local universities.
Notable Achievements

Both Bangladesh and Swaziland have strengthened their medicine safety systems and ADE reporting systems significantly enough to promote the countries to full members of the WHO Uppsala Monitoring Center in Sweden. While the Philippines has become one of the first countries in the world to develop SOPs for active cohort monitoring: the National Tuberculosis Program (NTP) “SOPs for Active Pharmacovigilance Surveillance”.

In Ethiopia over 150 health facilities are reporting ADEs, nearly a 300% increase during this project year. From those facilities, 270 ADEs have been reported and entered into the national database, with the majority of health care providers who reported receiving feedback. Based on the ADE reports, two regulatory decisions were made, an investigation was carried out on a fixed-dose ARV medicine, and two product-quality defect reports were prepared and shared with the Facility Inspection Directorate.

By strengthening PV systems in parallel with our efforts to make medicines more widely available, SIAPS is working to ensure medicines safety, refine medicines selection, and support the collection of data to inform decision making at all levels of the health system. In this way, improved availability of medicines can be supported by more robust health systems and ensure delivery of better health outcomes.

Building Capacity

The SIAPS approach to building human resource capacity is cross cutting and is applied throughout all SIAPS health system strengthening interventions. In many SIAPS countries, a lack of qualified pharmaceutical professionals and associates stems from institutions not being able to produce adequate numbers of personnel. Outdated curriculums do not keep pace with rapid change in the public health system and disease burden, and results in pharmaceutical personnel with limited technical competencies. In some countries, this situation is exacerbated by lack of institutions for pharmaceutical training. In addition, there is a critical lack of tools to streamline procedures and enhance efficiency in the delivery of pharmaceutical services.

Pre-service curriculum reform is a cost-effective and sustainable intervention that leads to broader health-system strengthening. It provides students with a critical foundation of knowledge and skills and develops their competency to practice in the real world. Proper pre-service exposure to some key pharmaceutical management topics, such as rational medicine use (RMU), antimicrobial resistance (AMR), pharmacovigilance, pharmaceutical care, and supply chain, is critical for practice competency in the various health-related fields, especially pharmacy, nursing, medicine, and public health. In addition to pre-service training, SIAPS also works to improve in-service training opportunities for practicing pharmaceutical and health professionals. SIAPS aims to build technical skills among practitioners and their capacity for leadership, management, and mentoring.

SIAPS works with local universities and other training institutions to strengthen pharmaceutical curricula and programs. SIAPS has helped develop or reform a number of health professional pre-service training curricula in the areas of medicines supply management, pharmacy law ethics, rational use of medicines,
and pharmacovigilance and has worked with universities in the Dominican Republic, Ethiopia, Namibia, South Africa, and Swaziland.

Nearly all SIAPS countries provide in-service training to health practitioners. SIAPS interventions focus on strengthening existing in-service training programs to ensure the adequate and sustained availability of health workers capable of managing and providing quality services. Ethiopia demonstrates a prime example of an in-service training program aimed at building the clinical knowledge and skills of practicing hospital pharmacists. The training program has proven to be a successful initiative that has attracted much interest and has brought together universities, the Pharmaceuticals Fund and Supply Agency (PFSA) and SIAPS for a new national objective: the initiation of clinical pharmacy service in Ethiopian hospitals, which is the first of its kind in the country.

To enhance the pre-service and in-service trainings, SIAPS supports and promotes supportive supervision. Supportive supervision is a process that promotes efficient, effective, and equitable health care through a practical system of measures that foster improvement in the procedures, personal interactions, and management of primary health care facilities and pharmacies. SIAPS works with countries to help them focus on meeting staff needs for management support, logistics, training, and continuing education.

Notable Achievements

Eight health professional pre-service training curricula have been developed, four of which, have been accredited by relevant in-country governing bodies. Thirty-four in-service training curricula have been developed or revised, and more than 35,000 pharmaceutical staff in over 20 countries have been trained in various aspects of pharmaceutical management including financing, leadership, regulatory, quality assurance, pharmaceutical care, medicine safety, antimicrobial resistance, and supply chain management.

SIAPS worked with the Universidad Central del Este (UCE) in the Dominican Republic to develop a certified course (diploma) on pharmaceutical supply management. In Namibia, SIAPS helped initiate training programs for pharmacists and pharmacy assistants at the at the University of Nambia and the National Health Training Centre resulting in a four-fold increase in pharmacist assistant graduates over the last 3 years. In South Africa, SIAPS worked with the University of Western Cape (UWC) to develop the online RMU course, which is offered as a stand-alone course or as part of a Master’s in Public Health.

LESSONS LEARNED

Using six USG funding streams, SIAPS activities cover all pharmaceutical management technical areas, five health program areas and multiple non-health system components and stakeholders, (Finance, Education, Audit and Law). As diverse as these interventions, contexts, stakeholders, and resources are, SIAPS has learned some key lessons that are both consistent and cross-cutting for the implementation of systems strengthening programs. Coming into the last year of the programing, SIAPS will continue to apply these lessons to improve its programming and inform its technical leadership activities in pharmaceutical management.
Advocacy and Country Ownership

Government commitment and ownership is a prerequisite to mobilizing resources, improving legislation, policies or reforms, and establishing or improving new pharmaceutical systems. Advocacy has been critical to SIAPS’ success in securing necessary commitment to facilitate effective and sustainable improvements in pharmaceutical systems strengthening.

During the time of SIAPS, we’ve learned that:

- Advocacy and involvement of the decision makers and planners is critical. A strong political will and the cooperation of leaders from various government ministries are needed to ensure that interventions are implemented as planned.
- Institutions and governments will take ownership of interventions when they see their practical value in addressing institutional mandates and accountabilities. Matching our advocacy strategies to the host government’s needs is therefore critical for success.
- Local knowledge and credible contacts, as well as ongoing technical assistance during implementation, are essential to sustaining advancements through advocacy.

Collaboration

SIAPS uses various strategies to enlist various stakeholders, including civil society, that have an interest in or are affected by SIAPS-supported activities and to build the capacity of partners who will take over leadership and oversight of these efforts. By developing strong working relationships with government counterparts, actively engaging with other donors, implementing agencies, civil society organizations, and the private sector improves the sustainability and country ownership of SIAPS interventions.

Through these collaborative strategies, SIAPS has learned that:

- Identifying and involving stakeholders must take place from the beginning to obtain buy-in and ensure there is a common vision for the interventions. Additionally, mechanisms to clarify roles and scopes of different stakeholders should be integrated into the engagement processes.
- Collaboration among national institutions and partners affects the effectiveness of SIAPS technical assistance in systems strengthening. Good partnerships and collaboration facilitates the uptake and system-wide adoption of tools, policies, guidelines, etc.
- Including stakeholders in discussions on the progress of an intervention and developing a shared view of how to address obstacles and shortcomings will improve accountability and transparency, increase ownership, and encourage stakeholders to support continuous improvement.
- Although management and coordination of many stakeholders is challenging and may result in slower implementation, there should be
some flexibility with that since it ultimately yields returns by enabling a more successful handover of interventions to country counterparts to sustain the results achieved.

Capacity Building

A systematic approach to strengthening the capacity of local institutions significantly enhances country ownership and increases the health system’s ability to sustain the improvements in the long run. All SIAPS programs have been engaged in individual and organizational capacity building at various system levels. Some of the key lessons generated from these interventions include:

- Pre-service curriculum reform is a health system strengthening, sustainable, and cost-effective intervention that results in motivated students learning the practical aspects of public health. This has been proven through SIAPS work with universities in the Dominican Republic, Ethiopia, Namibia, South Africa, and Swaziland.

- In-service training is effective in improving the technical skills among practitioners, which directly affects access to medical products and services, improving health outcomes for patients, and can also boost the professional morale of existing health workers.

- The design of interventions aimed at improving technical capacity to manage pharmaceuticals, should be integrated within strategies aimed at strengthening governance, management, and leadership. Leadership development programs centered on a team-based approach to capacity building, as implemented in Lesotho, Philippines, and South Africa, can promote shared vision, reinforce leadership values and practices, and equip pharmacy managers to respond to challenges in their workplace.

- Interventions that include follow-up trainings, supportive supervision, and mentoring further ensure that skills and knowledge continue to be reinforced and allow for feedback, thus improving service delivery and boosting employee job satisfaction.

- The availability of relevant tools and job-aids is critical for helping newly trained workers apply their skills in the workplace and facilitate transformation from individual skills to system level practices. Capacity building activities will be ineffective if the tools for actually doing the work are not accessible.

- Seconding staff to government agencies is a comprehensive mechanism for institutionalizing target capacity improvements. This model has worked especially well in Bangladesh and South Sudan.

Data for Decision Making

With SIAPS support, countries have developed more efficient systems for collecting, collating, and processing data, through the revision and roll out of appropriate data collection tools (paper-based and electronic). In the process, we have learned:
• Even in resource-constrained settings, well-organized, dispensing-based pharmacy data can provide insight into patient uptake and prescribing patterns. This information can serve as a basis for taking timely actions to rectify deviations from treatment guidelines, as well as for program monitoring and quantification for essential medicines.

• Generating evidence using data-driven information and demonstrating how it can be used to support organizational goals can have a tremendous impact on influencing managers’ and policy makers’ behavior and on the use of information for decision making.

• Standardizing data collection and reporting tools improves data accuracy and provides confidence in using the information for effective decision making in countries and regions. However, regular participatory data quality audits are critical for assuring long-term data quality improvements and the institutionalization of a “culture of data.”

• Electronic tools are an effective mechanism for ensuring data quality, increasing efficiency, and widening access to information using mobile and/or web-based communication approaches. However, electronic tools are not appropriate for all contexts and must be implemented with due consideration to contextual determinants.

• Early warning systems (EWS) for stock-outs/overstock have proven to be efficient. Properly implemented and with follow-up, the EWS provides immediate results, such as prevention of treatment interruptions, rationalization of procurement and ordering, resulting in savings, and prevention of waste due to stock-outs. The tool also shows great potential in quantification and monitoring for phasing-in new medicines and regimens.

Response to Emerging Health System Challenges

In the past year, SIAPS country programs have been exposed to emerging challenges that have affected the ability to operate as intended and deliver planned services. A well-thought out program of technical assistance should be flexible and ready to quickly lend its expertise to other areas of priority in case of emergencies. Sometimes, this requires thinking out of the box in the development of interventions.

• Insecurity and civil unrest in Burundi affected preparation of the Global Fund grant. As travel to Burundi was not possible, the workshop was conducted in Uganda with additional assistance provided virtually to follow-up on the Uganda meeting. In addition, conducting trainings in the field due to unstable security conditions was not possible, therefore the SIAPS technical team monitored and supervised trainings remotely. SIAPS collaborated closely with the NMCP to make sure planned trainings were accomplished with the collaboration of NMCP and field-based trainers.

• In countries with security concerns, uneven technical assistance from SIAPS or other partners can have overall negative influences if data
available is only ensured for certain regions, national quantifications may be affected, thus affecting the overall availability of pharmaceutical commodities. For example, Cameroon is facing security challenges as consequence of the Boko Haram terrorist group and the refugee camps on the borders of Chad and Central Africa Republic.
## SIAPS Countries and SIAPS IRs in the Year 4 Work Plan

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